See a Social Security Number? Say Something!
Report Privacy Problems to https://public.resource.org/privacy
Or call the IRS Identity Theft Hotline at 1-800-908-4490
Return of Organization Exempt From Income Tax

Under section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except black lung benefit trust or private foundation)

The organization may have to use a copy of this return to satisfy state reporting requirements

A For the 2007 calendar year, or tax year beginning , 2007, and ending 

B Check as applicable

<table>
<thead>
<tr>
<th>Address change</th>
<th>Name change</th>
<th>Initial return</th>
<th>See Specific instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

C Name of organization

WASHINGTON LEGAL FOUNDATION

Number and street (or P O box if mail is not delivered to street address) Room/suite

2009 MASSACHUSETTS AVE., N.W. (202) 588-0302

City or town, state or country, and ZIP + 4

WASHINGTON, DC 20036

D Employer identification number

52-1071570

E Telephone number

F Accounting method

Cash

Accrual

G Website: WWW.WLF.ORG

Section 501(c)(3) organizations and 4947(a)(1) nonexempt charitable trusts must attach a completed Schedule A (Form 990 or 990-EZ).

H Yes X No

H(a) Are you a member of a group of organizations?

H(b) If "Yes," enter number of affiliates

H(c) Are all affiliates included? Yes No

H(d) Is this a separate return filed by a group covered by a group rating? Yes No

I Group Exemption Number

J Check here if the organization is not a 501(a)(3) supporting organization and its gross receipts are normally not more than $25,000. A return is not required, but if the organization chooses to file a return, be sure to file a complete set.

K Gross receipts Add lines 6b, 8b, 9b, and 20b to line 12

5,966,782

Part I Revenue, Expenses, and Changes in Net Assets or Fund Balances (See the instructions.)

<table>
<thead>
<tr>
<th>1</th>
<th>Contributions, gifts, grants, and similar amounts received</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>Contributions to donor advised funds 1a</td>
</tr>
<tr>
<td>b</td>
<td>Direct public support (not included on line 1a) 1b</td>
</tr>
<tr>
<td>c</td>
<td>Indirect public support (not included on line 1a) 1c</td>
</tr>
<tr>
<td>d</td>
<td>Government contributions (grants) (not included on line 1a) 1d</td>
</tr>
<tr>
<td>e</td>
<td>Total (add lines 1a through 1d) (cash $ 4,539,392, noncash $ 6,559) 1e 4,545,951</td>
</tr>
<tr>
<td>2</td>
<td>Program service revenue including government fees and contracts (from Part VII, line 93) 2</td>
</tr>
<tr>
<td>3</td>
<td>Membership dues and assessments 3</td>
</tr>
<tr>
<td>4</td>
<td>Interest on savings and temporary cash investments 4</td>
</tr>
<tr>
<td>5</td>
<td>Dividends and interest from securities 5</td>
</tr>
<tr>
<td>6a</td>
<td>Gross rents 6a</td>
</tr>
<tr>
<td>6b</td>
<td>Less rental expenses 6b</td>
</tr>
<tr>
<td>6c</td>
<td>Net rental income or (loss) Subtract line 6b from line 6a 6c</td>
</tr>
<tr>
<td>7</td>
<td>Other investment income (describe) 7</td>
</tr>
<tr>
<td>8a</td>
<td>Gross amount from sales of assets other than inventory 8a</td>
</tr>
<tr>
<td>8b</td>
<td>Less cost or other basis of sales expenses 8b</td>
</tr>
<tr>
<td>8c</td>
<td>Gain or (loss) (attach schedule) 8c</td>
</tr>
<tr>
<td>8d</td>
<td>Net gain or (loss) Combine line 8c, columns (A) and (B) 8d</td>
</tr>
<tr>
<td>9</td>
<td>Special events and activities (attach schedule) 9</td>
</tr>
<tr>
<td>9a</td>
<td>Gross amount from special events (attach schedule) 9a</td>
</tr>
<tr>
<td>9b</td>
<td>Less expenses other than fundraising expenses 9b</td>
</tr>
<tr>
<td>9c</td>
<td>Net income or (loss) from special events Subtract line 9b from line 9a 9c</td>
</tr>
<tr>
<td>10a</td>
<td>Gross sales of inventory, less returns and allowances 10a</td>
</tr>
<tr>
<td>10b</td>
<td>Less cost of goods sold 10b</td>
</tr>
<tr>
<td>10c</td>
<td>Gross profit or (loss) from sales of inventory (attach schedule) Subtract line 10b from line 10a 10c</td>
</tr>
<tr>
<td>11</td>
<td>Other revenue (from Part VII, line 103) 11</td>
</tr>
<tr>
<td>12</td>
<td>Total revenue, Add lines 1e, 2, 3, 4, 5, 6c, 7, 8d, 9c, 10c, and 11 12 5,315,759</td>
</tr>
<tr>
<td>13</td>
<td>Program services (from line 44, column (B)) 13</td>
</tr>
<tr>
<td>14</td>
<td>Management and general (from line 44, column (C)) 14</td>
</tr>
<tr>
<td>15</td>
<td>Fundraising (from line 44, column (D)) 15</td>
</tr>
<tr>
<td>16</td>
<td>Payments to affiliates (attach schedule) 16</td>
</tr>
<tr>
<td>17</td>
<td>Total expenses Add lines 16 and 44, column (A) 17</td>
</tr>
<tr>
<td>18</td>
<td>Excess or (deficit) for the year Subtract line 17 from line 12 18 2,030,819</td>
</tr>
<tr>
<td>19</td>
<td>Net assets or fund balances at beginning of year (from line 73, column (A)) 19</td>
</tr>
<tr>
<td>20</td>
<td>Other changes in net assets or fund balances (attach explanation) 20</td>
</tr>
<tr>
<td>21</td>
<td>Net assets or fund balances at end of year Combine lines 18, 19, and 20 21 20,501,413</td>
</tr>
</tbody>
</table>

Privacy Act and Paperwork Reduction Act Notice, see the separate instructions.

Form 990 (2007)
### Statement of Functional Expenses

All organizations must complete column (A). Columns (B), (C), and (D) are required for section 501(c)(3) and (4) organizations and section 4947(a)(1) nonexempt charitable trusts but optional for others. (See the instructions)

<table>
<thead>
<tr>
<th>Do not include amounts reported on line 6b, 8b, 9b, 10b, or 16 of Part I</th>
<th>(A) Total</th>
<th>(B) Program services</th>
<th>(C) Management and general</th>
<th>(D) Fundraising</th>
</tr>
</thead>
<tbody>
<tr>
<td>22a Grants paid from donor advised funds (attach schedule)</td>
<td>655,678</td>
<td>350,334</td>
<td>244,275</td>
<td>61,069</td>
</tr>
<tr>
<td>22b Other grants and allocations (attach schedule)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23 Specific assistance to individuals (attach schedule)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 Benefits paid to or for members (attach schedule)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25a Compensation of current officers, directors, key employees, etc listed in Part V-A</td>
<td>843,614</td>
<td>694,243</td>
<td>7,304</td>
<td>142,067</td>
</tr>
<tr>
<td>b Compensation of former officers, directors, key employees, etc listed in Part V-B</td>
<td>552,573</td>
<td>384,985</td>
<td>92,721</td>
<td>74,867</td>
</tr>
<tr>
<td>c Compensation and other distributions, not included above, to disqualified persons (as defined under section 4958(b)(1)) and persons described in section 4947(a)(3)(B)</td>
<td>58,330</td>
<td>40,640</td>
<td>9,787</td>
<td>7,903</td>
</tr>
<tr>
<td>26 Salaries and wages of employees not included on lines 25a, b, and c</td>
<td>74,572</td>
<td>51,955</td>
<td>12,513</td>
<td>10,104</td>
</tr>
<tr>
<td>27 Pension plan contributions not included on lines 25a, b, and c</td>
<td>80,286</td>
<td>80,286</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28 Employee benefits not included on lines 25a - 27</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29 Payroll taxes</td>
<td>60,455</td>
<td>42,120</td>
<td>10,144</td>
<td>8,191</td>
</tr>
<tr>
<td>30 Professional fundraising fees</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31 Accounting fees</td>
<td>5,087</td>
<td>3,052</td>
<td>1,017</td>
<td>1,018</td>
</tr>
<tr>
<td>32 Legal fees</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33 Supplies</td>
<td>99,803</td>
<td>69,534</td>
<td>16,747</td>
<td>13,522</td>
</tr>
<tr>
<td>34 Telephone</td>
<td>6,416</td>
<td>42,120</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35 Postage and shipping</td>
<td>5,087</td>
<td>3,052</td>
<td>1,017</td>
<td>1,018</td>
</tr>
<tr>
<td>36 Occupancy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37 Equipment rental and maintenance</td>
<td>602,237</td>
<td>594,542</td>
<td>7,695</td>
<td></td>
</tr>
<tr>
<td>38 Printing and publications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39 Travel</td>
<td>64,136</td>
<td>52,973</td>
<td>11,163</td>
<td></td>
</tr>
<tr>
<td>40 Conferences, conventions, and meetings</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>41 Interest</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>42 Depreciation, depletion, etc (attach schedule)</td>
<td>75,049</td>
<td>52,288</td>
<td>12,593</td>
<td>10,168</td>
</tr>
<tr>
<td>43 Other expenses not covered above (itemize)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a INSURANCE</td>
<td>15,508</td>
<td>15,508</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b OTHER PROFESSIONAL FEES</td>
<td>33,193</td>
<td>28,093</td>
<td>5,100</td>
<td></td>
</tr>
<tr>
<td>c MISCELLANEOUS</td>
<td>2,618</td>
<td>2,618</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d REPAIRS AND MAINTENANCE</td>
<td>61,801</td>
<td>43,058</td>
<td>10,370</td>
<td>8,373</td>
</tr>
<tr>
<td>44 Total functional expenses. Add lines 22a through 43g (Organizations completing columns (B)-(D), carry these totals to lines 13-15)</td>
<td>3,284,940</td>
<td>2,410,435</td>
<td>524,428</td>
<td>350,077</td>
</tr>
</tbody>
</table>

Joint Costs. Check □ if you are following SOP 98-2

Are any joint costs from a combined educational campaign and fundraising solicitation reported in (B) Program services? □ Yes □ No

If "Yes," enter (i) the aggregate amount of these joint costs $ , (ii) the amount allocated to Program services $ , (iii) the amount allocated to Management and general $ , and (iv) the amount allocated to Fundraising $.
Part III Statement of Program Service Accomplishments (See the instructions.)

Form 990 is available for public inspection and, for some people, serves as the primary or sole source of information about a particular organization. How the public perceives an organization in such cases may be determined by the information presented on its return. Therefore, please make sure the return is complete and accurate and fully describes, in Part III, the organization's programs and accomplishments.

What is the organization's primary exempt purpose?  

All organizations must describe their exempt purpose achievements in a clear and concise manner. State the number of clients served, publications issued, etc. Discuss achievements that are not measurable (Section 501(c)(3) and (4) organizations and 4947(a)(1) nonexempt charitable trusts must also enter the amount of grants and allocations to others.)

<table>
<thead>
<tr>
<th>Activity Description</th>
<th>Program Service Expenses (Required for 501(c)(3) and (4) orgs, and 4947(a)(1) trusts, but optional for others.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a LITIGATION, LEGAL PUBLIC POLICY ANALYSIS, CLINICAL LEGAL</td>
<td>1,879,165</td>
</tr>
<tr>
<td>INERN PROGRAM, BRIEFS AND RESEARCH DOCUMENTS, PUBLIC LEGAL</td>
<td></td>
</tr>
<tr>
<td>ISSUES, MONOGRAPH SERIES, EDUCATIONAL LEGAL STUDIES, SEVEN</td>
<td></td>
</tr>
<tr>
<td>DIFFERENT PUBLICATION FORMATS, MEDIA BRIEFINGS AND WEB</td>
<td></td>
</tr>
<tr>
<td>SEMINARS.</td>
<td></td>
</tr>
<tr>
<td>(Grants and allocations $) If this amount includes foreign grants, check here □</td>
<td></td>
</tr>
<tr>
<td>b EDUCATIONAL MATERIAL DISTRIBUTED THROUGHOUT THE UNITED</td>
<td>531,270</td>
</tr>
<tr>
<td>STATES AT NO CHARGE TO THE GENERAL PUBLIC; THESE</td>
<td></td>
</tr>
<tr>
<td>MATERIALS DISCUSS BROAD ISSUES OF INTEREST TO ALL AMERICANS</td>
<td></td>
</tr>
<tr>
<td>(Grants and allocations $) If this amount includes foreign grants, check here □</td>
<td></td>
</tr>
<tr>
<td>c</td>
<td></td>
</tr>
<tr>
<td>d</td>
<td></td>
</tr>
<tr>
<td>(Grants and allocations $) If this amount includes foreign grants, check here □</td>
<td></td>
</tr>
<tr>
<td>e Other program services (attach schedule)</td>
<td>2,410,435</td>
</tr>
<tr>
<td>(Grants and allocations $) If this amount includes foreign grants, check here □</td>
<td></td>
</tr>
<tr>
<td>f Total of Program Service Expenses (should equal line 44, column (B), Program services)</td>
<td></td>
</tr>
</tbody>
</table>

Form 990 (2007)
### Part IV Balance Sheets (See the instructions)

**Note:** Where required, attached schedules and amounts within the description column should be for end-of-year amounts only.

<table>
<thead>
<tr>
<th>Description</th>
<th>Beginning of year</th>
<th>End of year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>45 Cash - non-interest-bearing</td>
<td>738,984</td>
<td>668,673</td>
</tr>
<tr>
<td>46 Savings and temporary cash investments</td>
<td>13,620,893</td>
<td>16,085,271</td>
</tr>
<tr>
<td>47 Accounts receivable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a Less allowance for doubtful accounts</td>
<td>47a</td>
<td></td>
</tr>
<tr>
<td>b Pledges receivable</td>
<td>47b</td>
<td></td>
</tr>
<tr>
<td>48a Less allowance for doubtful accounts</td>
<td>47c</td>
<td></td>
</tr>
<tr>
<td>48b Less: allowance for doubtful accounts</td>
<td>150,000</td>
<td></td>
</tr>
<tr>
<td>49 Grants receivable</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>50 Receivables from current and former officers, directors, trustees, and key employees (attach schedule)</td>
<td>50a</td>
<td></td>
</tr>
<tr>
<td>50b Receivables from other disqualified persons (as defined under section 4958(f)(1)) and persons described in section 4958(c)(3)(B) (attach schedule)</td>
<td>50b</td>
<td></td>
</tr>
<tr>
<td>51a Other notes and loans receivable (attach schedule)</td>
<td>51a</td>
<td></td>
</tr>
<tr>
<td>b Less allowance for doubtful accounts</td>
<td>51b</td>
<td></td>
</tr>
<tr>
<td>52 Inventories for sale or use</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td>53 Prepaid expenses and deferred charges</td>
<td>6,741</td>
<td>18,238</td>
</tr>
<tr>
<td>54a Investments - publicly-traded securities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>54b Investments - other securities (attach schedule)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>55 Investments - land, buildings, and equipment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a Less accumulated depreciation (attach schedule)</td>
<td>55a</td>
<td></td>
</tr>
<tr>
<td>b Equipment</td>
<td>55b</td>
<td></td>
</tr>
<tr>
<td>55c Investments - land, buildings, and equipment.</td>
<td>55c</td>
<td></td>
</tr>
<tr>
<td>56 Investments - other (attach schedule)</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>57a Land, buildings, and equipment.</td>
<td>4,128,882</td>
<td></td>
</tr>
<tr>
<td>b Less accumulated depreciation (attach schedule)</td>
<td>57b</td>
<td></td>
</tr>
<tr>
<td>57c Land, buildings, and equipment.</td>
<td>1,667,732</td>
<td>2,532,904</td>
</tr>
<tr>
<td>58 Other assets, including program-related investments (describe ▶ STMT 7)</td>
<td>399,807</td>
<td>439,283</td>
</tr>
<tr>
<td>59 Total assets (must equal line 74) Add lines 45 through 58</td>
<td>20,077,066</td>
<td>22,586,274</td>
</tr>
<tr>
<td><strong>Liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60 Accounts payable and accrued expenses</td>
<td>87,812</td>
<td>69,765</td>
</tr>
<tr>
<td>61 Grants payable</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td>62 Deferred revenue</td>
<td>62</td>
<td></td>
</tr>
<tr>
<td>63 Loans from officers, directors, trustees, and key employees (attach schedule)</td>
<td>63</td>
<td></td>
</tr>
<tr>
<td>64a Tax-exempt bond liabilities (attach schedule)</td>
<td>64a</td>
<td></td>
</tr>
<tr>
<td>64b Mortgages and other notes payable (attach schedule)</td>
<td>64b</td>
<td></td>
</tr>
<tr>
<td>65 Other liabilities (describe ▶ STMT 8)</td>
<td>1,328,940</td>
<td>2,015,096</td>
</tr>
<tr>
<td>66 Total liabilities. Add lines 60 through 65</td>
<td>1,416,752</td>
<td>2,084,861</td>
</tr>
<tr>
<td><strong>Organizations that follow SFAS 117, check here X and complete lines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>67 Unrestricted</td>
<td>18,578,245</td>
<td>20,319,344</td>
</tr>
<tr>
<td>68 Temporarily restricted</td>
<td>68</td>
<td>100,000</td>
</tr>
<tr>
<td>69 Permanently restricted</td>
<td>82,069</td>
<td>82,069</td>
</tr>
<tr>
<td><strong>Net Assets or Fund Balances</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>70 Capital stock, trust principal, or current funds</td>
<td>70</td>
<td></td>
</tr>
<tr>
<td>71 Paid-in or capital surplus, or land, building, and equipment fund</td>
<td>71</td>
<td></td>
</tr>
<tr>
<td>72 Retained earnings, endowment, accumulated income, or other funds</td>
<td>72</td>
<td></td>
</tr>
<tr>
<td>73 Total net assets or fund balances. Add lines 67 through 69 or lines 70 through 72 (Column (A) must equal line 19 and column (B) must equal line 21)</td>
<td>18,660,314</td>
<td>20,501,413</td>
</tr>
<tr>
<td>74 Total liabilities and net assets/fund balances. Add lines 66 and 73</td>
<td>20,077,066</td>
<td>22,586,274</td>
</tr>
</tbody>
</table>
### Part IV-A Reconciliation of Revenue per Audited Financial Statements With Revenue per Return (See the instructions.)

| a | Total revenue, gains, and other support per audited financial statements | 5,508,769 |
| b | Amounts included on line a but not on Part I, line 12: |  |
| 1 | Net unrealized gains on investments | b1 | 193,010 |
| 2 | Donated services and use of facilities | b2 |  |
| 3 | Recoveries of prior year grants | b3 |  |
| 4 | Other (specify) | b4 |  |
| Add lines b1 through b4 | b | 193,010 |
| c | Subtract line b from line a | c | 5,315,759 |
| d | Amounts included on Part I, line 12, but not on line a: |  |
| 1 | Investment expenses not included on Part I, line 6b | d1 |  |
| 2 | Other (specify) | d2 |  |
| Add lines d1 and d2 | d |  |
| e | Total revenue (Part I, line 12). Add lines c and d | e | 5,315,759 |

### Part IV-B Reconciliation of Expenses per Audited Financial Statements With Expenses per Return

| a | Total expenses and losses per audited financial statements | 3,284,940 |
| b | Amounts included on line a but not on Part I, line 17: |  |
| 1 | Donated services and use of facilities | b1 |  |
| 2 | Prior year adjustments reported on Part I, line 20 | b2 |  |
| 3 | Losses reported on Part I, line 20 | b3 |  |
| 4 | Other (specify) | b4 |  |
| Add lines b1 through b4 | b |  |
| c | Subtract line b from line a | c | 3,284,940 |
| d | Amounts included on Part I, line 17, but not on line a: |  |
| 1 | Investment expenses not included on Part I, line 6b | d1 |  |
| 2 | Other (specify) | d2 |  |
| Add lines d1 and d2 | d |  |
| e | Total expenses (Part I, line 17). Add lines c and d | e | 3,284,940 |

### Part V-A Current Officers, Directors, Trustees, and Key Employees (List each person who was an officer, director, trustee, or key employee at any time during the year even if they were not compensated. See the instructions.)

<table>
<thead>
<tr>
<th>(A) Name and address</th>
<th>(B) Title and average hours per week devoted to position</th>
<th>(C) Compensation (If not paid, enter $)</th>
<th>(D) Contributions to employee benefit plans &amp; deferred compensation plan</th>
<th>(E) Expense account and other allowances</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEE STATEMENT 9</td>
<td></td>
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</tbody>
</table>
Part V-A  Current Officers, Directors, Trustees, and Key Employees (continued)

75a Enter the total number of officers, directors, and trustees permitted to vote on organization business at board meetings _____________________________ 3

b Are any officers, directors, trustees, or key employees listed in Form 990, Part V-A, or highest compensated employees listed in Schedule A, Part I, or highest compensated professional and other independent contractors listed in Schedule A, Part II-A or II-B, related to each other through family or business relationships? If "Yes," attach a statement that identifies the individuals and explains the relationship(s) ____________________________________________

75b x

75c

D Do any officers, directors, trustees, or key employees listed in Form 990, Part V-A, or highest compensated employees listed in Schedule A, Part I, or highest compensated professional and other independent contractors listed in Schedule A, Part II-A or II-B, receive compensation from any other organizations, whether tax exempt or taxable, that are related to the organization? See the instructions for the definition of "related organization." ____________________________________________

75d

If "Yes," attach a statement that includes the information described in the instructions

Part V-B  Former Officers, Directors, Trustees, and Key Employees That Received Compensation or Other Benefits

(If any former officer, director, trustee, or key employee received compensation or other benefits (described below) during the year, list that person below and enter the amount of compensation or other benefits in the appropriate column. See the instructions)

<table>
<thead>
<tr>
<th>(A) Name and address</th>
<th>(B) Loans and Advances</th>
<th>(C) Compensation (if not paid, enter 0)</th>
<th>(D) Contributions to employee benefit plans &amp; deferred compensation plans</th>
<th>(E) Expense account and other allowances</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

Part VI  Other Information (See the instructions.)

76 Did the organization make a change in its activities or methods of conducting activities? If "Yes," attach a detailed statement of each change ____________________________________________

76 x

77 Were any changes made in the organizing or governing documents but not reported to the IRS? ____________________________________________

77 x

78a Did the organization have unrelated business gross income of $1,000 or more during the year covered by this return? ____________________________________________

78a x

b If "Yes," has it filed a tax return on Form 990-T for this year? ____________________________________________

78b N/A

79 Was there a liquidation, dissolution, termination, or substantial contraction during the year? If "Yes," attach a statement ____________________________________________

79 x

80a Is the organization related (other than by association with a statewide or nationwide organization) through common membership, governing bodies, trustees, officers, etc., to any other exempt or nonexempt organization? ____________________________________________

80a x

b If "Yes," enter the name of the organization ____________________________________________ and check whether it is [X] exempt or [ ] nonexempt

81a

81b N/A

b Did the organization file Form 1120-POL for this year? ____________________________________________

81b N/A
Yes No
82a Did the organization receive donated services or the use of materials, equipment, or facilities at no charge or at substantially less than fair rental value? 
82b If "Yes," you may indicate the value of these items here. Do not include this amount as revenue in Part I or as an expense in Part II. (See instructions in Part III.)
83a Did the organization comply with the public inspection requirements for returns and exemption applications?
83b Did the organization comply with the disclosure requirements relating to quid pro quo contributions?
84a Did the organization solicit any contributions or gifts that were not tax deductible?
84b If "Yes," did the organization include with every solicitation an express statement that such contributions or gifts were not tax deductible?
85a Were substantially all dues non-deductible by members?
85b Did the organization make only in-house lobbying expenditures of $2,000 or less?
85c If "Yes" was answered to either 85a or 85b, do not complete 85c through 85h below unless the organization received a waiver for proxy tax owed for the prior year.
85d Dues, assessments, and similar amounts from members
85e Aggregate non-deductible amount of section 6033(e)(1)A dues notices
85f Taxable amount of lobbying and political expenditure (line 85d less 85e)
85g Does the organization elect to pay the section 6033(e) tax on the amount on line 85f? If "Yes," complete Part IX
85h If section 6033(e)(1)A dues notices were sent, does the organization agree to add the amount on line 85f to its reasonable estimate of dues allocable to non-deductible lobbying and political expenditures for the following tax year?
86 501(c)(7) orgs Enter a. Initiation fees and capital contributions included on line 12
86a Gross receipts, included on line 12, for public use of club facilities
87 501(c)(12) orgs Enter a. Gross income from members or shareholders
87b Gross income from other sources (Do not net amounts due or paid to other sources against amounts due or received from them)
88a At any time during the year, did the organization own a 50% or greater interest in a taxable corporation or partnership, or an entity disregarded as separate from the organization under Regulations sections 301.7701-2 and 301.7701-3? If "Yes," complete Part IX
88b At any time during the year, did the organization, directly or indirectly, own a controlled entity within the meaning of section 512(b)(13)? If "Yes," complete Part XI
88c Amount of tax imposed on the organization during the year under section 4911 (None), section 4912 (None), section 4955 (None)
89a 501(c)(3) organizations Enter
89b 501(c)(3) and 501(c)(4) orgs Did the organization engage in any section 4958 excess benefit transaction during the year or did it become aware of an excess benefit transaction from a prior period? If "Yes," attach a statement explaining each transaction
89c Enter Amount of tax imposed on the organization managers or disqualified persons during the year under sections 4912, 4955, and 4958
89d Enter Amount of tax on line 89c, above, reimbursed by the organization
89e All organizations At any time during the tax year, was the organization a party to a prohibited tax shelter transaction?
89f All organizations Did the organization acquire a direct or indirect interest in any applicable insurance contract?
89g For supporting organizations and sponsoring organizations maintaining donor advised funds Did the supporting organization, or a fund maintained by a sponsoring organization, have excess business holdings at any time during the year?
90a List the states with which a copy of this return is filed
90b 14 Number of employees employed in the pay period that includes March 12, 2007 (See instructions)
91a The books are in care of
91b 91a Telephone no
91c Located at
92 10 Form 990 (2007)
**Part VI** Other Information (continued)

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>92</td>
<td>Section 4947(a)(1) nonexempt charitable trusts filing Form 990 in lieu of Form 1041 - Check here and enter the amount of tax-exempt interest received or accrued during the tax year.</td>
</tr>
</tbody>
</table>

**Part VII** Analysis of Income-Producing Activities (See the instructions.)

<p>| Note: Enter gross amounts unless otherwise indicated |
| Unrelated business income |
| Excluded by section 512, 513, or 514 |
| (E) Related or exempt function income |</p>
<table>
<thead>
<tr>
<th>Business code</th>
<th>Amount</th>
<th>Exclusion code</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>93 Program service revenue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a</td>
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<td></td>
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<td>f Medicare/Medicaid payments</td>
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<tr>
<td>g Fees and contracts from government agencies</td>
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<tr>
<td>94 Membership dues and assessments</td>
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<tr>
<td>95 Interest on savings and temporary cash investments</td>
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<tr>
<td>96 Dividends and interest from securities</td>
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<tr>
<td>97 Net rental income or (loss) from real estate</td>
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<tr>
<td>a debt-financed property</td>
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<tr>
<td>b not debt-financed property</td>
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<tr>
<td>98 Net rental income or (loss) from personal property</td>
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<tr>
<td>99 Other investment income</td>
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<tr>
<td>100 Gain or (loss) from sales of assets other than inventory</td>
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<tr>
<td>101 Net income or (loss) from special events</td>
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<tr>
<td>102 Gross profit or (loss) from sales of inventory</td>
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<tr>
<td>103 Other revenue</td>
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<td>e</td>
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<tr>
<td>104 Subtotal (add columns (B), (D), and (E))</td>
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</tr>
<tr>
<td>105 Total (add line 104, columns (B), (D), and (E))</td>
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</tr>
</tbody>
</table>

**Part VIII** Relationship of Activities to the Accomplishment of Exempt Purposes (See the instructions.)

Line No. ▼ Explain how each activity for which income is reported in column (E) of Part VII contributed importantly to the accomplishment of the organization's exempt purposes (other than by providing funds for such purposes)

**Part IX** Information Regarding Taxable Subsidiaries and Disregarded Entities (See the instructions.)

| (A) Name, address, and EIN of corporation, partnership, or disregarded entity |
| (B) Percentage of ownership interest |
| (C) Nature of activities |
| (D) Total income |
| (E) End-of-year assets |

**Part X** Information Regarding Transfers Associated with Personal Benefit Contracts (See the instructions)

(a) Did the organization, during the year, receive any funds, directly or indirectly, to pay premiums on a personal benefit contract? □ Yes □ No
(b) Did the organization, during the year, pay premiums, directly or indirectly, on a personal benefit contract? □ Yes □ No

Note: If "Yes" to (b), file Form 8870 and Form 4720 (see instructions).
Part XI  Information Regarding Transfers To and From Controlled Entities. Complete only if the organization is a controlling organization as defined in section 512(b)(13).

106 Did the reporting organization make any transfers to a controlled entity as defined in section 512(b)(13) of the Code? If "Yes," complete the schedule below for each controlled entity.

<table>
<thead>
<tr>
<th>(A) Name, address, of each controlled entity</th>
<th>(B) Employer Identification Number</th>
<th>(C) Description of transfer</th>
<th>(D) Amount of transfer</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
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<tr>
<td>Totals</td>
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</tr>
</tbody>
</table>

107 Did the reporting organization receive any transfers from a controlled entity as defined in section 512(b)(13) of the Code? If "Yes," complete the schedule below for each controlled entity.

<table>
<thead>
<tr>
<th>(A) Name, address, of each controlled entity</th>
<th>(B) Employer Identification Number</th>
<th>(C) Description of transfer</th>
<th>(D) Amount of transfer</th>
</tr>
</thead>
<tbody>
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<td>a</td>
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<tr>
<td>Totals</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

108 Did the organization have a binding written contract in effect on August 17, 2006, covering the interest, rents, royalties, and annuities described in question 107 above?

Yes No  X

Please Sign Here

Signature of officer  DANIEL J. POPE  Date  11/11/08

Type or print name and title  CHAIRMAN

Preparer's signature  J. HUBBARD  Date  11/11/08

Firm's name (or your own if self-employed)  BOND, BEEBE

Address and ZIP code  4600 EAST-WEST HIGHWAY SUITE 900

BETHESDA, MD  20814-3423

Preparer's SSN or PTIN  EIN  52-1044197

Phone no  301-272-6000

Preparer's Use Only

<table>
<thead>
<tr>
<th>Preparer's signature</th>
<th>Date</th>
<th>Check if self-employed</th>
<th>Preparer's SSN or PTIN (See Gen Inst X)</th>
</tr>
</thead>
<tbody>
<tr>
<td>J. HUBBARD</td>
<td>11/11/08</td>
<td>□</td>
<td>52-1044197</td>
</tr>
</tbody>
</table>

Form 990 (2007)
<table>
<thead>
<tr>
<th>Part I</th>
<th>Compensation of the Five Highest Paid Employees Other Than Officers, Directors, and Trustees</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(See page 1 of the instructions. List each one. If there are none, enter &quot;None.&quot;)</td>
</tr>
<tr>
<td></td>
<td>(a) Name and address of each employee paid more than $50,000</td>
</tr>
<tr>
<td></td>
<td>(b) Title and average hours per week devoted to position</td>
</tr>
<tr>
<td></td>
<td>(c) Compensation</td>
</tr>
<tr>
<td></td>
<td>(d) Contributions to employee benefit plans &amp; deferred compensation</td>
</tr>
<tr>
<td></td>
<td>(e) Expense account and other allowances</td>
</tr>
<tr>
<td>BINDU BALAN</td>
<td>DIRECTOR OF ADMIN</td>
</tr>
<tr>
<td>2009 MASSACHUSETTS AVE., N.W.</td>
<td></td>
</tr>
<tr>
<td>PAUL D. KAMENAR</td>
<td>SENIOR EXEC. COUNSEL</td>
</tr>
<tr>
<td>2009 MASSACHUSETTS AVE., N.W.</td>
<td></td>
</tr>
<tr>
<td>GLENN G. LAMM</td>
<td>CHIEF CONS./LEGAL</td>
</tr>
<tr>
<td>2009 MASSACHUSETTS AVE., N.W.</td>
<td></td>
</tr>
<tr>
<td>RICHARD A. SAMP</td>
<td>CHIEF COUNSEL</td>
</tr>
<tr>
<td>2009 MASSACHUSETTS AVE., N.W.</td>
<td></td>
</tr>
<tr>
<td>MARY LEACH</td>
<td>CHIEF POLICY COUNSEL</td>
</tr>
<tr>
<td>2009 MASSACHUSETTS AVE., N.W.</td>
<td></td>
</tr>
<tr>
<td>Total number of other employees paid over $50,000</td>
<td>NONE</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part II-A</th>
<th>Compensation of the Five Highest Paid Independent Contractors for Professional Services</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(See page 2 of the instructions. List each one (whether individuals or firms). If there are none, enter &quot;None.&quot;)</td>
</tr>
<tr>
<td></td>
<td>(a) Name and address of each independent contractor paid more than $50,000</td>
</tr>
<tr>
<td></td>
<td>(b) Type of service</td>
</tr>
<tr>
<td></td>
<td>(c) Compensation</td>
</tr>
<tr>
<td>BOND BEBE, P.C.</td>
<td>ACCOUNTING</td>
</tr>
<tr>
<td>BETHESDA, MD 20814-3423</td>
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</tr>
<tr>
<td>Total number of others receiving over $50,000 for professional services</td>
<td>NONE</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part II-B</th>
<th>Compensation of the Five Highest Paid Independent Contractors for Other Services</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(List each contractor who performed services other than professional services, whether individuals or firms. If there are none, enter &quot;None. See page 2 of the instructions.)</td>
</tr>
<tr>
<td></td>
<td>(a) Name and address of each independent contractor paid more than $50,000</td>
</tr>
<tr>
<td></td>
<td>(b) Type of service</td>
</tr>
<tr>
<td></td>
<td>(c) Compensation</td>
</tr>
<tr>
<td>NONE</td>
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<tr>
<td>Total number of other contractors receiving over $50,000 for other services</td>
<td>NONE</td>
</tr>
</tbody>
</table>

* These figures are not actual contributions made, but only actuarial projections for retirement plans based upon retirement age.
Part III  Statements About Activities (See page 2 of the instructions.)

1 During the year, has the organization attempted to influence national, state, or local legislation, including any attempt to influence public opinion on a legislative matter or referendum? If "Yes," enter the total expenses paid or incurred in connection with the lobbying activities ▶ $ ____________________ (Must equal amounts on line 38, Part VI-A, or line 1 of Part VI-B).  

Organizations that made an election under section 501(h) by filing Form 5768 must complete Part VI-A. Other organizations checking "Yes" must complete Part VI-B AND attach a statement giving a detailed description of the lobbying activities

2 During the year, has the organization, either directly or indirectly, engaged in any of the following acts with any substantial contributors, trustees, directors, officers, creators, key employees, or members of their families, or with any taxable organization with which any such person is affiliated as an officer, director, trustee, majority owner, or principal beneficiary? (If the answer to any question is "Yes," attach a detailed statement explaining the transactions)

   a Sale, exchange, or leasing of property? ...........................................  
   b Lending of money or other extension of credit?  
   c Furnishing of goods, services, or facilities?  
   d Payment of compensation (or payment or reimbursement of expenses if more than $1,000)? ....................... STMT.11  
   e Transfer of any part of its income or assets?  

3a Did the organization make grants for scholarships, fellowships, student loans, etc.? (If "Yes," attach an explanation of how the organization determines that recipients qualify to receive payments)  

3b Did the organization have a section 403(b) annuity plan for its employees?  

3c Did the organization receive or hold an easement for conservation purposes, including easements to preserve open space, the environment, historic land areas or historic structures? If "Yes," attach a detailed statement  

3d Did the organization provide credit counseling, debt management, credit repair, or debt negotiation services?  

4a Did the organization maintain any donor advised funds? If "Yes," complete lines 4b through 4g. If "No," complete lines 4f and 4g.  

4b Did the organization make any taxable distributions under section 4966?  

4c Did the organization make a distribution to a donor, donor advisor, or related person?  

4d Enter the total number or donor advised funds owned at the end of the tax year.  

4e Enter the aggregate value of assets held in all donor advised funds owned at the end of the tax year.  

4f Enter the total number of separate funds or accounts owned at the end of the tax year (excluding donor advised funds included on line 4d) where donors have the rights to provide advice on the distribution or investment of amounts in such funds or accounts.  

4g Enter the aggregate value of assets held in all funds or accounts included on line 4f at the end of the tax year.  

Schedule A (Form 990 or 990-EZ) 2007
Part IV  Reason for Non-Private Foundation Status (See pages 4 through 8 of the instructions.)

I certify that the organization is not a private foundation because it is (Please check only ONE applicable box.)

5  □ A church, convention of churches, or association of churches  Section 170(b)(1)(A)(i)

6  □ A school  Section 170(b)(1)(A)(ii) (Also complete Part V)

7  □ A hospital or a cooperative hospital service organization  Section 170(b)(1)(A)(m)

8  □ A federal, state, or local government or governmental unit  Section 170(b)(1)(A)(v)

9  □ A medical research organization operated in conjunction with a hospital  Section 170(b)(1)(A)(n) Enter the hospital’s name, city, and state ▶

10 □ An organization operated for the benefit of a college or university owned or operated by a governmental unit  Section 170(b)(1)(A)(vi) (Also complete the Support Schedule in Part IV-A)

11a □ An organization that normally receives a substantial part of its support from a governmental unit or from the general public  Section 170(b)(1)(A)(vi) (Also complete the Support Schedule in Part IV-A)

11b □ A community trust  Section 170(b)(1)(A)(vi) (Also complete the Support Schedule in Part IV-A)

12 □ An organization that normally receives (1) more than 33 1/3% of its support from contributions, membership fees, and gross receipts from activities related to its charitable, etc., functions - subject to certain exceptions, and (2) no more than 33 1/3% of its support from gross investment income and unrelated business taxable income (less section 511 tax) from businesses acquired by the organization after June 30, 1975 See section 509(a)(2) (Also complete the Support Schedule in Part IV-A)

13 □ An organization that is not controlled by any disqualified persons (other than foundation managers) and otherwise meets the requirements of section 509(a)(3). Check the box that describes the type of supporting organization

□ Type I  □ Type II  □ Type III - Functionally Integrated  □ Type III - Other

Provide the following information about the supported organizations. (See page 8 of the instructions.)

<table>
<thead>
<tr>
<th>(a) Name(s) of supported organization(s)</th>
<th>(b) Employer identification number (EIN)</th>
<th>(c) Type of organization (described in lines 5 through 12 above or IRC section)</th>
<th>(d) Is the supported organization listed in the supporting organization’s governing documents?</th>
<th>(e) Amount of support</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

14 □ An organization organized and operated to test for public safety  Section 509(a)(4) (See page 8 of the instructions)
### Part IV-A: Support Schedule

**Note:** You may use the worksheet in the instructions for converting from the accrual to the cash method of accounting.

**Calendar year (or fiscal year beginning in)**  
<table>
<thead>
<tr>
<th></th>
<th>(a) 2006</th>
<th>(b) 2005</th>
<th>(c) 2004</th>
<th>(d) 2003</th>
<th>(e) Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 Gifts, grants, and contributions received. (Do not include unusual grants See line 28)</td>
<td>4,326,429</td>
<td>3,748,260</td>
<td>4,779,110</td>
<td>5,972,010</td>
<td>18,825,809</td>
</tr>
<tr>
<td>16 Membership fees received</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17 Gross receipts from admissions, merchandise sold or services performed, or furnishing of facilities in any activity that is related to the organization's charitable, etc., purpose.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 Gross income from interest, dividends, amounts received from payments on securities loans (section 512(a)(5)), rents, royalties, income from similar sources, and unrelated business taxable income (less section 511 taxes) from businesses acquired by the organization after June 30, 1975.</td>
<td>478,927.</td>
<td>364,549.</td>
<td>226,230.</td>
<td>226,231.</td>
<td>1,295,937.</td>
</tr>
<tr>
<td>19 Net income from unrelated business activities not included in line 18</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 Tax revenues levied for the organization's benefit and either paid to it or expended on its behalf.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 The value of services or facilities furnished to the organization by a governmental unit without charge Do not include the value of services or facilities generally furnished to the public without charge.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 Other income Attach a schedule Do not include gain or (loss) from sale of capital assets</td>
<td>STMT 12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23 Total of lines 15 through 22</td>
<td>4,805,356</td>
<td>4,112,809</td>
<td>5,005,340</td>
<td>6,204,230</td>
<td>20,127,735</td>
</tr>
<tr>
<td>24 Line 23 minus line 17</td>
<td>4,805,356</td>
<td>4,112,809</td>
<td>5,005,340</td>
<td>6,204,230</td>
<td>20,127,735</td>
</tr>
<tr>
<td>25 Enter 1% of line 23</td>
<td>48,054.</td>
<td>41,128.</td>
<td>50,053.</td>
<td>62,042.</td>
<td></td>
</tr>
<tr>
<td>26 Organizations described on lines 10 or 11: a Enter 2% of amount in column (e), line 24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b Prepare a list for your records to show the name of each person (other than a governmental unit or publicly supported organization) whose total gifts for 2003 through 2006 exceeded the total shown in line 26a Do not file this list with your return. Enter the total of all these excess amounts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c Total support for section 509(a)(1) test Enter line 24, column (e)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d Add Amounts from column (e) for lines 18 1,295,937 19</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 5,989 26b 1,492,225</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e Public support (line 26c minus line 26d total)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f Public support percentage (line 26e (numerator) divided by line 26c (denominator))</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27 Organizations described on line 12: a For amounts included in lines 15, 16, and 17 that were received from a &quot;disqualified person,&quot; prepare a list for your records to show the name of, and total amounts received in each year, from each &quot;disqualified person&quot; Do not file this list with your return. Enter the sum of such amounts for each year.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOT APPLICABLE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28 Unusual Grants: For an organization described in line 10, 11, or 12 that received any unusual grants during 2003 through 2006, prepare a list for your records to show, for each year, the name of the contributor, the date and amount of the grant, and a brief description of the nature of the grant. Do not file this list with your return. Do not include these grants in line 15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Part V**  
Private School Questionnaire (See page 9 of the instructions.)  

Not Applicable  
(To be completed ONLY by schools that checked the box on line 6 in Part IV)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>29 Does the organization have a racially nondiscriminatory policy toward students by statement in its charter, bylaws, or governing instrument, or in a resolution of its governing body?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 Does the organization include a statement of its racially nondiscriminatory policy toward students in all its brochures, catalogues, and other written communications with the public dealing with student admissions, programs, and scholarships?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31 Has the organization publicized its racially nondiscriminatory policy through newspaper or broadcast media during the period of solicitation for students, or during the registration period if it has no solicitation program, in a way that makes the policy known to all parts of the general community it serves?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If &quot;Yes,&quot; please describe, if &quot;No,&quot; please explain (if you need more space, attach a separate statement)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>32 Does the organization maintain the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a Records indicating the racial composition of the student body, faculty, and administrative staff?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b Records documenting that scholarships and other financial assistance are awarded on a racially nondiscriminatory basis?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c Copies of all catalogues, brochures, announcements, and other written communications to the public dealing with student admissions, programs, and scholarships?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d Copies of all material used by the organization or on its behalf to solicit contributions?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you answered &quot;No&quot; to any of the above, please explain. (If you need more space, attach a separate statement)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33 Does the organization discriminate by race in any way with respect to:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a Students' rights or privileges?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b Admissions policies?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c Employment of faculty or administrative staff?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d Scholarships or other financial assistance?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e Educational policies?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f Use of facilities?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>g Athletic programs?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>h Other extracurricular activities?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you answered &quot;Yes&quot; to any of the above, please explain. (If you need more space, attach a separate statement)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34a Does the organization receive any financial aid or assistance from a governmental agency?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b Has the organization's right to such aid ever been revoked or suspended?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you answered &quot;Yes&quot; to either 34a or b, please explain using an attached statement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35 Does the organization certify that it has complied with the applicable requirements of sections 401 through 405 of Rev Proc. 75-50, 1975-2 C.B. 587, covering racial nondiscrimination? If &quot;No,&quot; attach an explanation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Limits on Lobbying Expenditures

*The term "expenditures" means amounts paid or incurred.*

<table>
<thead>
<tr>
<th></th>
<th>Affiliated group totals</th>
<th>To be completed for all electing organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>Total lobbying expenditures to influence public opinion (grassroots lobbying)</td>
<td>36</td>
</tr>
<tr>
<td>37</td>
<td>Total lobbying expenditures to influence a legislative body (direct lobbying)</td>
<td>37</td>
</tr>
<tr>
<td>38</td>
<td>Total lobbying expenditures (add lines 36 and 37)</td>
<td>38</td>
</tr>
<tr>
<td>39</td>
<td>Other exempt purpose expenditures</td>
<td>39</td>
</tr>
<tr>
<td>40</td>
<td>Total exempt purpose expenditures (add lines 38 and 39)</td>
<td>40</td>
</tr>
<tr>
<td>41</td>
<td>Lobbying nontaxable amount Enter the amount from the following table</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If the amount on line 40 is</td>
<td>The lobbying nontaxable amount is</td>
</tr>
<tr>
<td></td>
<td>Not over $500,000</td>
<td>20% of the amount on line 40</td>
</tr>
<tr>
<td></td>
<td>Over $500,000 but not over $1,000,000</td>
<td>$100,000 plus 15% of the excess over $500,000</td>
</tr>
<tr>
<td></td>
<td>Over $1,000,000 but not over $1,500,000</td>
<td>$175,000 plus 10% of the excess over $1,000,000</td>
</tr>
<tr>
<td></td>
<td>Over $1,500,000 but not over $17,000,000</td>
<td>$225,000 plus 5% of the excess over $1,500,000</td>
</tr>
<tr>
<td></td>
<td>Over $17,000,000</td>
<td>$1,000,000</td>
</tr>
<tr>
<td>42</td>
<td>Grassroots nontaxable amount (enter 25% of line 41)</td>
<td>42</td>
</tr>
<tr>
<td>43</td>
<td>Subtract line 42 from line 36 Enter -0- if line 42 is more than line 36</td>
<td>43</td>
</tr>
<tr>
<td>44</td>
<td>Subtract line 41 from line 38 Enter -0- if line 41 is more than line 38</td>
<td>44</td>
</tr>
</tbody>
</table>

**Caution:** If there is an amount on either line 43 or line 44, you must file Form 4720.

### 4-Year Averaging Period Under Section 501(h)

(Some organizations that made a section 501(h) election do not have to complete all of the five columns below. See the instructions for lines 45 through 50 on page 13 of the instructions.)

<table>
<thead>
<tr>
<th>Calendar year (or fiscal year beginning in)</th>
<th>(a)</th>
<th>(b)</th>
<th>(c)</th>
<th>(d)</th>
<th>(e)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Lobbying Expenditures During 4-Year Averaging Period

<table>
<thead>
<tr>
<th>Lobbying nontaxable amount</th>
<th>45</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lobbying ceiling amount</td>
<td></td>
</tr>
<tr>
<td>(150% of line 45(e))</td>
<td></td>
</tr>
<tr>
<td>Total lobbying expenditures</td>
<td>47</td>
</tr>
<tr>
<td>Grassroots nontaxable amount</td>
<td>48</td>
</tr>
<tr>
<td>Grassroots ceiling amount</td>
<td></td>
</tr>
<tr>
<td>(150% of line 48(e))</td>
<td></td>
</tr>
<tr>
<td>Grassroots lobbying</td>
<td></td>
</tr>
<tr>
<td>expenditures</td>
<td>50</td>
</tr>
</tbody>
</table>

### Lobbying Activity by Nonelecting Public Charities

(For reporting only by organizations that did not complete Part VI-A) (See page 13 of the instructions.)

During the year, did the organization attempt to influence national, state or local legislation, including any attempt to influence public opinion on a legislative matter or referendum, through the use of

- a Volunteers
- b Paid staff or management (Include compensation in expenses reported on lines c through h)
- c Media advertisements
- d Mailings to members, legislators, or the public
- e Publications, or published or broadcast statements
- f Grants to other organizations for lobbying purposes
- g Direct contact with legislators, their staffs, government officials, or a legislative body
- h Rallies, demonstrations, seminars, conventions, speeches, lectures, or any other means
- i Total lobbying expenditures (Add lines c through h)

If "Yes" to any of the above, also attach a statement giving a detailed description of the lobbying activities.

**Schedule A (Form 990 or 990-EZ) 2007**
**Part VII: Information Regarding Transfers To and Transactions and Relationships With Noncharitable Exempt Organizations (See page 14 of the instructions.**

51 Did the reporting organization directly or indirectly engage in any of the following with any other organization described in section 501(c) of the Code (other than section 501(c)(3) organizations) or in section 527, relating to political organizations?

<table>
<thead>
<tr>
<th>a</th>
<th>Transfers from the reporting organization to a noncharitable exempt organization of</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) Cash</td>
<td>(51a(i)) X</td>
</tr>
<tr>
<td>(ii) Other assets</td>
<td>(a(ii)) X</td>
</tr>
</tbody>
</table>

b Other transactions:

| (i) Sales or exchanges of assets with a noncharitable exempt organization | \(b(i)\) X |
| (ii) Purchases of assets from a noncharitable exempt organization | \(b(ii)\) X |
| (iii) Rental of facilities, equipment, or other assets | \(b(iii)\) X |
| (iv) Reimbursement arrangements | \(b(iv)\) X |
| (v) Loans or loan guarantees | \(b(v)\) X |
| (vi) Performance of services or membership or fundraising solicitations | c X |

d If the answer to any of the above is "Yes," complete the following schedule. Column (b) should always show the fair market value of the goods, other assets, or services given by the reporting organization. If the organization received less than fair market value in any transaction or sharing arrangement, show in column (d) the value of the goods, other assets, or services received.

<table>
<thead>
<tr>
<th>(a) Line no</th>
<th>(b) Amount involved</th>
<th>(c) Name of noncharitable exempt organization</th>
<th>(d) Description of transfers, transactions, and sharing arrangements</th>
</tr>
</thead>
<tbody>
<tr>
<td>51C</td>
<td>BUSINESS CIVIL</td>
<td>ONE FILE DRAWER OF ADMINISTRATIVE OFFICE</td>
<td></td>
</tr>
<tr>
<td>LIBERTIES, INC.</td>
<td>(501(C)(4))</td>
<td>ADMINISTRATIVE OFFICE</td>
<td></td>
</tr>
</tbody>
</table>

52a Is the organization directly or indirectly affiliated with, or related to, one or more tax-exempt organizations described in section 501(c) of the Code (other than section 501(c)(3)) or in section 527?

- Yes [ ]
- No [ ]

b If "Yes," complete the following schedule.

<table>
<thead>
<tr>
<th>(a) Name of organization</th>
<th>(b) Type of organization</th>
<th>(c) Description of relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUSINESS CIVIL</td>
<td>ADVOCATE FOR</td>
<td>COMMON DIRECTORS</td>
</tr>
<tr>
<td>LIBERTIES, INC.</td>
<td>BUSINESS CIVIL</td>
<td></td>
</tr>
<tr>
<td>(501(C)(4))</td>
<td>LIBERTIES</td>
<td></td>
</tr>
</tbody>
</table>
ATTACHMENT
FORM 990, PART I, LINE 1

A SCHEDULE OF CONTRIBUTIONS, NOT OPEN TO PUBLIC INSPECTION, IS ATTACHED AS FORM 990, SCHEDULE B.

NO CONTRIBUTIONS WERE RAISED BY PROFESSIONAL FUNDRAISERS.
ATTACHMENT
FORM 990, PART I, LINE 8(A)

THE FOUNDATION SOLD AND REDEEMED SHARES AND UNITS OF PUBLICLY TRADED SECURITIES AND U.S. GOVERNMENT OBLIGATIONS. AS SPECIFIED IN THE INSTRUCTIONS TO FORM 990, THE GROSS PROCEEDS, COST BASIS AND NET LOSS ARE REPORTED AS LUMP-SUM FIGURES.
<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>NET UNREALIZED GAINS ON INVESTMENTS</td>
<td>193,010.</td>
</tr>
<tr>
<td>TOTAL</td>
<td>193,010.</td>
</tr>
<tr>
<td>DESCRIPTION</td>
<td>AMOUNT</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>EFFECT OF ADOPTION OF RECOGNITION AND MEASUREMENT PROVISIONS OF FASB NO. 158</td>
<td>382,730.</td>
</tr>
<tr>
<td>TOTAL</td>
<td>382,730.</td>
</tr>
<tr>
<td></td>
<td>Balance at 12/31/06</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Furniture</td>
<td>236,908</td>
</tr>
<tr>
<td>Equipment</td>
<td>488,525</td>
</tr>
<tr>
<td>Building and Land</td>
<td>3,400,155</td>
</tr>
<tr>
<td>Totals</td>
<td>4,125,588</td>
</tr>
<tr>
<td>Accum Depr - Furniture</td>
<td>273,486</td>
</tr>
<tr>
<td>Accum Depr - Equipment</td>
<td>329,395</td>
</tr>
<tr>
<td>Accum Depr - Building</td>
<td>989,801</td>
</tr>
<tr>
<td></td>
<td>1,592,682</td>
</tr>
<tr>
<td></td>
<td>2,532,906</td>
</tr>
</tbody>
</table>
FORM 990, PART III - ORGANIZATION'S PRIMARY EXEMPT PURPOSE

THE FOUNDATION SERVES THE PUBLIC INTEREST THROUGH LITIGATION AND REPRESENTATION, LEGAL PUBLIC POLICY ANALYSIS, INTERN PROGRAMS, RESEARCH AND BRIEFS, MONOGRAPHS, EDUCATIONAL MATERIALS, MEDIA BRIEFINGS AND WEB SEMINARS.
PUBLICLY TRADED SECURITIES

<table>
<thead>
<tr>
<th>Description</th>
<th>Ending Book Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORPORATE BONDS</td>
<td>101,200.</td>
</tr>
<tr>
<td>CORPORATE STOCK (&lt;5% OWNER)</td>
<td>1,546,496.</td>
</tr>
<tr>
<td>FOREIGN BONDS</td>
<td>31,042.</td>
</tr>
<tr>
<td>MUTUAL FUNDS</td>
<td>684,921.</td>
</tr>
<tr>
<td>U.S. GOVERNMENT OBLIGATIONS</td>
<td>400,000.</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td><strong>2,763,659.</strong></td>
</tr>
<tr>
<td>DESCRIPTION</td>
<td>ENDING BOOK VALUE</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>ACCRUED INTEREST RECEIVABLE</td>
<td>112,364.</td>
</tr>
<tr>
<td>CASH SURRENDER VALUE OF LIFE INSURANCE</td>
<td>326,919.</td>
</tr>
<tr>
<td></td>
<td>439,283.</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION</td>
<td>ENDING BOOK VALUE</td>
</tr>
<tr>
<td>------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>ACCRUED EMPLOYEE BENEFITS</td>
<td>461,713.</td>
</tr>
<tr>
<td>ACCRUED PENSION LIABILITY</td>
<td>1,553,383.</td>
</tr>
<tr>
<td>TOTALS</td>
<td>2,015,096.</td>
</tr>
<tr>
<td>NAME AND ADDRESS</td>
<td>TITLE AND AVERAGE HOURS PER WEEK DEVOTED TO POSITION</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------------------------------</td>
</tr>
</tbody>
</table>

SEE ATTACHED SCHEDULE
FORM 990, PART VI - NAMES OF RELATED ORGANIZATIONS

RELATED ORGANIZATION NAME: AMERICAN LEGAL FOUNDATION
EXEMPT: X NONEXEMPT:

RELATED ORGANIZATION NAME: BUSINESS CIVIL LIBERTIES
EXEMPT: X NONEXEMPT:

RELATED ORGANIZATION NAME: UNITED STATES LEGAL FOUNDATION
EXEMPT: X NONEXEMPT:
SCHEDULE A, PART III - EXPLANATION FOR LINE 2D

SEE FORM 990, PART V. THE FOUNDATION REIMBURSED FULLY-ACCOUNTED EXPENSES FOR ORDINARY AND NECESSARY OPERATIONAL PURPOSES. THE FOUNDATION DID NOT PROVIDE A NONACCOUNTABLE EXPENSE ACCOUNT OR ALLOWANCE TO ANY DISQUALIFIED PERSON.
<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>2006</th>
<th>2005</th>
<th>2004</th>
<th>2003</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTHER INCOME</td>
<td></td>
<td></td>
<td></td>
<td>5,989.</td>
<td>5,989.</td>
</tr>
<tr>
<td>TOTALS</td>
<td></td>
<td></td>
<td></td>
<td>5,989.</td>
<td>5,989.</td>
</tr>
</tbody>
</table>
ATTACHMENT
FORM 990, PART VI, LINE 82

THE FOUNDATION RECEIVED DONATED SERVICES VALUED AT HUNDREDS OF THOUSANDS OF DOLLARS.
ATTACHMENT
FORM 990, PART V-A, LINE 75B

TWO OF THE DIRECTORS LISTED UNDER PART V, DANIEL J. POPEO AND JOHN
POPEO ARE RELATED.
WASHINGTON LEGAL FOUNDATION
52-1071570

ATTACHMENT
FORM 990, PART V

<table>
<thead>
<tr>
<th>Name and address</th>
<th>Title and average hours per week devoted to position</th>
<th>Compensation</th>
<th>Contributions to employee benefit plans</th>
<th>Expense account and other allowances</th>
</tr>
</thead>
<tbody>
<tr>
<td>DANIEL J. POPEO</td>
<td>CHAIRMAN/DIRECTOR</td>
<td>350,334</td>
<td>161,954</td>
<td>NONE</td>
</tr>
<tr>
<td>2009 MASSACHUSETTS AVENUE, NW</td>
<td>45 HOURS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WASHINTON, DC 20036</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONSTANCE C LARCHER</td>
<td>PRES.-TREAS DIRECTOR</td>
<td>305,344</td>
<td>198,303</td>
<td>NONE</td>
</tr>
<tr>
<td>2009 MASSACHUSETTS AVENUE, NW</td>
<td>45 HOURS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WASHINTON, DC 20036</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JOHN POPEO</td>
<td>DIRECTOR</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
</tr>
<tr>
<td>2009 MASSACHUSETTS AVENUE, NW</td>
<td>3 HOURS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WASHINTON, DC 20036</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* THESE FIGURES ARE NOT ACTUAL CONTRIBUTIONS MADE, BUT ONLY ACTUARIAL PROJECTIONS FOR RETIREMENT PLANS BASED UPON RETIREMENT AGE

NO COMPENSATION IS PAID TO ANY DIRECTOR FOR THEIR SERVICES AS A DIRECTOR
Form 8868
(Rev April 2008)
Department of the Treasury
Internal Revenue Service
File a separate application for each return

If you are filing for an Automatic 3-Month Extension, complete only Part I and check this box
If you are filing for an Additional (Not Automatic) 3-Month Extension, complete only Part II (on page 2 of this form)

Do not complete Part II unless you have already been granted an automatic 3-month extension on a previously filed Form 8868

Part I Automatic 3-Month Extension of Time. Only submit original (no copies needed).
A corporation required to file Form 990-T and requesting an automatic 6-month extension - check this box and complete Part I only

All other corporations (including 1120-C filers), partnerships, REMICS, and trusts must use Form 7004 to request an extension of time to file income tax returns

Electronic Filing (e-file). Generally, you can electronically file Form 8868 if you want a 3-month automatic extension of time to file one of the returns noted below (6 months for a corporation required to file Form 990-T). However, you cannot file Form 8868 electronically if (1) you want the additional (not automatic) 3-month extension or (2) you file Forms 990-BL, 6069, or 8870, group returns, or a composite or consolidated Form 990-T. Instead, you must submit the fully completed and signed page 2 (Part II) of Form 8868. For more details on the electronic filing of this form, visit www.irs.gov/efile and click on e-file for Chariites & Nonprofits

Type or print
Name of Exempt Organization
WASHINGTON LEGAL FOUNDATION
Employer identification number
52-1071570

File by the due date for filing your return See instructions
Number, street, and room or suite no. If a P.O. box, see instructions
2009 MASSACHUSETTS AVE., N.W.
City, town or post office, state, and ZIP code. For a foreign address, see instructions
WASHINGTON, DC 20036

Check type of return to be filed (file a separate application for each return)

X Form 990
Form 990-BL
Form 990-EZ
Form 990-PF
Form 990-T (corporation)
Form 990-T (sec 401(a) or 408(a) trust)
Form 990-T (trust other than above)
Form 1041-A
Form 4720
Form 5227
Form 6069
Form 8870

The books are in the care of
CONSTANCE C. LARCHER

Telephone No 202 588-0302 FAX No

If the organization does not have an office or place of business in the United States, check this box
If this is for a Group Return, enter the organization's four digit Group Exemption Number (GEN) If this is for the whole group, check this box . If it is for part of the group, check this box and attach a list with the names and EINs of all members the extension will cover

1 I request an automatic 3-month (6 months for a corporation required to file Form 990-T) extension of time
until 08/15/2008 to file the exempt organization return for the organization named above. The extension is for the organization's return for

X calendar year 2007 or

tax year beginning _______ , _______ , and ending _______ .

2 If this tax year is for less than 12 months, check reason Initial return Final return Change in accounting period

3a If this application is for Form 990-BL, 990-PF, 990-T, 4720, or 6069, enter the tentative tax, less any nonrefundable credits. See instructions
3a $

3b If this application is for Form 990-PF or 990-T, enter any refundable credits and estimated tax payments made Include any prior year overpayment allowed as a credit
3b $

3c Balance Due. Subtract line 3b from line 3a. Include your payment with this form, or, if required, deposit with FTD coupon or, if required, by using EFTPS (Electronic Federal Tax Payment System) See instructions
3c $

Caution. If you are going to make an electronic fund withdrawal with this Form 8868, see Form 8453-EO and Form 8879-EO for payment instructions.

For Privacy Act and Paperwork Reduction Act Notice, see Instructions.

Form 8868 (Rev 4-2008)
Part II  Additional (Not Automatic) 3-Month Extension of Time. You must file original and one copy.

<table>
<thead>
<tr>
<th>Type or print</th>
<th>Name of Exempt Organization</th>
<th>Employer identification number</th>
</tr>
</thead>
<tbody>
<tr>
<td>File by the extended due date for filing the return. See instructions</td>
<td>WASHINGTON LEGAL FOUNDATION</td>
<td>52-1071570</td>
</tr>
<tr>
<td></td>
<td>Number, street, and room or suite no. If a P.O. box, see instructions</td>
<td>For IRS use only</td>
</tr>
<tr>
<td></td>
<td>2009 MASSACHUSETTS AVE., N.W.</td>
<td>WASHINGTON, DC 20036</td>
</tr>
<tr>
<td></td>
<td>City, town or post office, state, and zip code. For a foreign address, see instructions.</td>
<td></td>
</tr>
</tbody>
</table>

Check type of return to be filed (File a separate application for each return):

- [X] Form 990
- [ ] Form 990-PF
- [ ] Form 990-Bl
- [ ] Form 990-T (sec. 401(a) or 408(a) trust)
- [ ] Form 990-EZ
- [ ] Form 990-T (trust other than above)
- [ ] Form 1041-A
- [ ] Form 6069
- [ ] Form 4720
- [ ] Form 8870
- [ ] Form 5227

STOP! Do not complete Part II if you were not already granted an automatic 3-month extension on a previously filed Form 8868.

- The books are in the care of: CONSTANCE C. LARCHER
- Telephone No.: 202-588-0302
- FAX No.: 202-588-0302
- If the organization does not have an office or place of business in the United States, check this box SIDEBAR.
- If this is for a Group Return, enter the organization's four digit Group Exemption Number (GEN). If this is for the whole group, check this box SIDEBAR. If it is for part of the group, check this box SIDEBAR and attach a list with the names and EINs of all members the extension is for.

4 I request an additional 3-month extension of time until 11/15/2008.
5 For calendar year 2007, or other tax year beginning and ending
6 If this tax year is for less than 12 months, check reason: [ ] Initial return [ ] Final return [ ] Change in accounting period
7 State in detail why you need the extension

ADDITIONAL TIME IS REQUIRED TO ASSEMBLE THE INFORMATION IN ORDER TO FILE A COMPLETE AND ACCURATE RETURN.

8a If this application is for Form 990-Bl, 990-PF, 990-T, 4720, or 6069, enter the tentative tax, less any nonrefundable credits. See instructions. $8a
8b If this application is for Form 990-PF, 990-T, 4720, or 6069, enter any refundable credits and estimated tax payments made. Include any prior year overpayment allowed as a credit and any amount paid previously with Form 8868. $8b
8c Balance Due. Subtract line 8b from line 8a. Include your payment with this form, or, if required, deposit with FTD coupon or, if required, by using EFTPS (Electronic Federal Tax Payment System). See instructions. $8c

Signature and Verification

Under penalties of perjury, I declare that I have examined this form, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct and complete, and that I am authorized to prepare this form.

Signature: [Signature]
Title: [Title]
Date: 11/12/2008

Form 8868 (Rev. 4-2008)

BOND BEBE
4600 EAST WEST HIGHWAY SUITE 900
BETHESDA, MD 20814-3423

4817 08/11/2008 12:33:49 V07-6.1 WA7820

JSA 7F8055.2 000
“This dynamic organization is a prominent force in both judicial and regulatory arenas, promoting economic growth and allowing free enterprise to prosper. If you share my beliefs that our country's ability to compete in the world economy should not be hindered by excessive regulation and unreasonable court decisions, I encourage you to join WLF in defending free enterprise.”

The Honorable Dick Thornburgh
Kirkpatrick & Lockhart Preston Gates Ellis LLP
Chairman, Legal Policy Advisory Board
Advocate for Freedom and Justice

The Washington Legal Foundation has been defending America's free enterprise system since 1977. As WLF celebrates its 30th year, it remains more dedicated than ever to advocating for a thriving free market economy, business civil liberties, a reasonable legal system, and a strong national defense. WLF employs three persuasive tactics to achieve its mission as the nation's most effective counterweight to anti-business activist groups, and to maintain its legacy as the most prominent public interest legal organization in the country. WLF PUBLISHES and markets timely and influential legal studies; LITIGATES precedent-setting issues before the courts and regulatory agencies; and COMMUNICATES free enterprise messages to millions of Americans through public education campaigns, advertorials, and legal forums.
We continue to be amazed at the number of government officials, lawyers, and activists who just don’t like America’s free enterprise system. That’s why, after 30 years of the Washington Legal Foundation’s (WLF) continuous free enterprise legal advocacy, our work is far from over.

Unfortunately, too much of American society and government is outsourced to our judiciary. Every critical matter that can determine America’s future somehow finds its way into state and federal courtrooms. In 1977 we founded WLF to influence the law, impact public debate, and make the compelling case for free enterprise and the individual rights of all Americans whenever and wherever necessary. Thanks to you we have succeeded.

WLF’s enthusiasm and capacity for creative, high-quality work defending free enterprise in professional and unique ways is stronger than ever. Throughout 2007, WLF continued to define free enterprise public law.

Decision-makers, thought leaders, and free enterprise advocates rely and stand on the authority of WLF’s work. WLF is a nationally respected institution because of the exceptional talents and scholarship of our lawyers and distinguished authors. These professionals produce persuasive work products that carry the intellectual firepower of America’s top legal experts.

There is an enormous need for trustworthy free enterprise legal advocacy, information, insight, and analysis. WLF’s litigation, publications, and educational briefings/media campaigns have that credibility — and you make it all possible.

In 2008, we plan to significantly increase our programs and activities as we constantly race against our own institutional track record. To date, WLF has published and marketed over 1,900 timely and influential publications through our Legal Studies Division, authored by over 1,600 prestigious experts and lawyers, including federal and state judges, governors, state attorneys general, and regulatory officials. Our website, wlf.org, has received over 30 million hits. Our work products are continuously downloaded by the media, government officials, judges, students, and the public.
Through the expertise of our Litigation Division and the pro bono assistance of over 250 law firms around the country, WLF has litigated more than 1,080 court cases, participated in 745 administrative and regulatory proceedings, and has brought more than 303 civil justice reform actions and petitions.

WLF’s productivity, creativity, and leadership stand apart. The innovative, multimedia legal PR outreach of WLF’s Civic Communications Program increases our points of impact every day. Our New York Times op-ed advertorials, on-site media briefings, web seminars, and ongoing public education campaigns enhance WLF’s significant program capabilities to communicate with millions of Americans. All WLF events are webcast live, and our capacity to deliver free enterprise messages has been expanded by our online archive of WLF media briefings and web seminars.

We are humbled and grateful for the allies whose support makes WLF’s unique and valuable work possible. We remain especially grateful to the Honorable Dick Thornburgh, WLF’s Legal Policy Advisory Board Chairman, as well as our entire Board for their counsel, shared determination, and encouragement. We were honored to welcome Virginia’s Attorney General, Robert F. McDonnell, to our board in 2007. Attorney General McDonnell joins five other former and current state attorneys general who share their talents with WLF.

WLF remains independent and accepts no government, taxpayer-funded grants. We always remember that WLF’s achievements and steady momentum would not be possible without the enthusiastic and loyal tax-deductible contributions of individuals, businesses, foundations, and associations that provide us with the resources necessary to sustain the mission we share.

On behalf of everyone at WLF, we thank you for putting your faith in us over and over again. It continues to be a privilege to serve you and represent the public’s interest. Our way of saying thank you is to earn and re-earn your confidence and continued support.

Our challenges have never been greater. Unfortunately, too many judges and regulators behave as if free enterprise is a problem to be solved. Too much of America’s economy lives in a constant state of legal and regulatory anxiety. We remain committed to opposing well-organized activist groups and lawyers who use our nation’s courts to attack free enterprise and a strong national security. WLF’s mission is to ensure that our legal system works for all Americans.

WLF remains consistent and predictable. Our friends always expect more from WLF and we pledge not to disappoint them. It’s what we’ve been doing nonstop for over 30 years.

Daniel J. Popeo
Chairman and General Counsel

Constance Claflay Larcher
President and Executive Director

Daniel J. Popeo
Constance Claflay Larcher
Pro Bono Network

WLF's success is reflected in more than three decades of relationships.

"I have high regard for the work of the Washington Legal Foundation. As a member of the Legal Policy Advisory Board I would hope to be able to assist it in its efforts, particularly regarding the protection of intellectual property."

-The Honorable Gerald J. Mossinghoff
Oblon, Spivak McClelland, Maier & Neustadt PC

Alston & Bird LLP
Bancroft Associates PLLC
Borgognoni & Gutierrez
Bostock, Rogers & Donais PLLC
Bracewell & Giuliani LLP
Conner & Winters LLP
Davis & Gilbert LLP
Dechert LLP
Diaz, Reus, Rolff & Targ LLP
Dickstein Shapiro LLP
DLA Piper US LLP
Dykema
Epstein Becker & Green PC
Finnegan, Henderson, Farabow, Garret & Dunner LLP
Fish & Richardson PC
Foley & Lardner LLP
Foley, Baron & Metzger
Fried, Frank, Harris, Shriver & Jacobson LLP
Gardere Wynne Sewell LLP
Getman, Stacey, Schlthess & Steere PA
Gibson, Dunn & Crutcher LLP
Greenberg Traurig LLP
Haynsworth Sinkler Boyd PA
Hunton & Williams LLP
Jones Day
Kamlet Shepherd Reichert LLP
King & Spalding
Kirkpatrick & Lockhart Preston Gates Ellis LLP
Kutak Rock LLP
Latham & Watkins LLP
Law Offices of Joshua A. Bloom
LeBoeuf, Lamb, Greene & MacRae LLP
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Riddell Williams PS
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Sedgwick, Detert, Moran & Arnold LLP
Shook, Hardy & Bacon LLP
Sidley Austin LLP
Simpson, Thacher & Bartlett LLP
Sonnenschein Nath & Rosenthal LLP
Spriggs & Hollingsworth PC
Sterne, Kessler, Goldstein and Fox PLLC
Thorp Reed & Armstrong LLP
Professor Lawrence H. Tribe
Troutman Sanders LLP
Venable LLP
Weil, Gotshal & Manges LLP
White and Williams LLP
Wildman Harrold
Wiley Rein LLP
WilmerHale LLP
Young Conaway Stargatt & Taylor LLP
Zacks Utrecht & Leadbetter PC
Publishing

WLF's Legal Studies Division is the preeminent publisher of timely and persuasive legal analyses. These papers do more than inform the governmental, business, and legal communities and the public about issues vital to the fundamental rights of every American — they are the very essence that tips the scales in favor of those rights.

EXPLORING TIMELY LEGAL ISSUES

Our seven publishing formats target specific policy-making audiences. Each format presents single-issue advocacy on meaningful legal topics. Our authors are among the nation’s most well-versed legal professionals, including expert attorneys, business executives, judges, and senior government officials who contribute their services on a strictly pro bono basis.

PUBLICATION FORMATS

• Counsel's Advisories announce urgent legal developments that impact free enterprise.

• Legal Opinion Letters offer succinct legal analyses of recent court rulings and regulatory issues.

• Legal Backgrounders present concise discussions on selected law topics.

• Working Papers provide in-depth examination of critical legal issues.

• Contemporary Legal Notes outline basic principles and issues in a single area of law.

• "Conversations With..." — WLF’s newest format — provides a forum for leading legal experts to discuss current legal policy issues.

• Monographs provide lengthy inquiries into significant legal issues.

Thousands of decision-makers and top legal minds across the country rely on our biweekly publications for the most insightful analysis of timely issues. Publications are marketed to expansive audiences ranging from business leaders to members of Congress and the media.
ADVOCATING ON THE FOREFRONT

WLF publications cover an expanse of legal public policy issues including:

- Antitrust and consumer protection
- Business civil liberties
- Civil justice reform
- Commercial free speech
- Corporate criminal liability
- Environmental regulation and enforcement
- Food and drug law
- Government contracting
- Health care
- Information technology and communications law
- Insurance law and regulation
- Intellectual property
- Litigation
- Managing regulatory activism
- National resources law
- National and homeland security
- Property rights
- Securities law

Since founding the Legal Studies Division, WLF has produced more than 1,900 publications. For a complete list of 2007 publications, see pages 26–31.

In addition to WLF’s own distribution network, mass communication networks (including our website, wlf.org, and the Library of Congress research system, SCORPIO) carry our publications. The full texts of all Legal Opinion Letters and Legal Backgrounders are available on the Lexis/Nexis online information system.
COUNSEL'S ADVISORY
September 7, 2007, 1 page

Two August 2007 federal and state rulings agree that alcohol advertising is not unlawfully “attractive” under state consumer protection laws.

LEGAL OPINION LETTER
February 8, 2007, 2 pages

Strategic thoughts on federal congressional investigations, including how to proactively prepare for an inquiry and manage it once Congressional staff initiate contact.
The often divergent regulatory philosophies espoused by national business competition authorities call for increased efforts among U.S. and foreign trading partners to harmonize antitrust laws and apply theories of comity to each other's enforcement actions.

Some courts have regretfully become regulators through their judicial redrafting of property insurance contracts, forcing insurers to cover losses which were explicitly excluded through an agreement between insurers and insureds.
CONVERSATIONS WITH...
Fall 2007, 8 pages

Two United States governors and one of America's top proponents of legal reform discuss the significant benefits such reforms offer to state economies and the health and well-being of all Americans.

The Issue: The Benefits of Legal Reform

The editors of Washington Legal Foundation's Conversations With Reformers in 2007 session with Governor Dick Thornburgh, Governor Haley Barbour, and Governor Joe Manchin discuss the benefits of legal reform and the positive effects it can have on state economies and the health and well-being of all Americans.

THE ALI MEDICAL MONITORING: RISKS FOR RESTATMENTS’ EMERGENCE OF A NOVEL TORT

by Sean F. Wajert
Debart LLP

CONTEMPORARY LEGAL NOTES
June 2007, 25 pages

An influential group of legal practitioners and scholars take a misguided approach toward “medical monitoring,” an emerging theory of civil liability that many state and federal courts have rejected.

SCIENCE THROUGH THE LOOKING-GLASS: THE MANIPULATION OF "ADDICTION" & ITS INFLUENCE OVER OBESITY POLICY

by Dr. John E. Cisna
The Democracy Institute

MONOGRAPH
July 2007, 73 pages

Over the past several decades, activists, government regulators, and private attorneys have manipulated the term “addiction” to support their policy and litigation goals, to the detriment of sound science and public health.
WLF Legal Policy Advisory Board

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Weil, Gotshal & Manges

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Commonwealth of Virginia

The Honorable
Rob McKenna
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State of Washington

John A. Merrigan, Esq.
DLA Piper

Professor John Norton
Moore
University of Virginia
School of Law

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Senior Vice President &
Deputy General Counsel
Viacom Inc.

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Oblon, Spivak McClelland,
Maier & Neustadt PC

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Jones Day

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Gibson, Dunn & Crutcher LLP

W. Hugh O'Riordan, Esq.
Givens, Pursley & Huntley

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White & Case

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Northwestern University
School of Law

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John M. Olin Professor of Law and Economics
Yale University

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State of Utah

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Dean, Pepperdine University
School of Law

The Honorable
Don Stenberg
Former Attorney General
State of Nebraska

The Honorable Hal Stratton
Dykema Gossett PLLC

Ambassador Robert S.
Strauss
Akin, Gump, Strauss, Hauer & Feld

The Honorable
Eugene R. Sullivan
CEO, Gavel Consulting Group

George J. Terwilliger, Esq.
White & Case

Daniel E. Troy, Esq.
Sidley Austin LLP

The Honorable
William F. Weld
McDermott Will & Emery

Joe D. Whiteley, Esq.
Alston & Bird LLP

Wayne Withers
Executive Vice President
& Special Legal Advisor
Emerson Electric Co.
Litigating

Our litigation team, together with more than 250 prestigious law firms nationwide, rigorously monitors and intervenes in any case, action, or complaint that may threaten the fundamental rights of hard-working Americans and the integrity of the country's legal system. When government agencies interfere with those rights in a manner we deem unwarranted, WLF's litigation team does not hesitate to hale those agencies into court.

WORKING TOWARD A BALANCED JUDICIARY

WLF serves as a counterweight to the voices of economic activists and the plaintiffs' bar that are heard whenever anti-free enterprise issues arise in the courts and regulatory agencies. Our legal team shapes legal policy through aggressive litigation and advocacy at all levels of the judiciary.

OUR TEAM

• Litigates original actions and files *amicus curiae* briefs.
• Files citizen petitions and position papers with government agencies.
• Testifies before congressional committees and government agencies on proposed changes in the law and its administration.
• Conducts investigations into government abuse.
• Files reform proposals with state supreme courts and bar associations to promote ethical conduct among lawyers.
• Lodges disciplinary complaints against federal or state judges in judicial misconduct cases.
• Reduces, through our Investor Protection Program (IPP), the damage done by attorneys' excessive contingency fees, punitive damages, frivolous law suits, and other litigation abuses.
• Opposes the criminalization of free enterprise by government agency enforcement.

We also work closely with the corporate legal community, developing public-interest legal strategies & trying complex cases, preparing counsel for appellate and Supreme Court oral arguments, and providing valuable briefs and reports.

Our Legal Academic Fellowship Program also enables law students to exercise the basic principles they learn in the classroom, while exposing them to pro-free-enterprise perspective on policy making.
WLF continues to define free enterprise public interest law.

SPECIAL FOCUS ON REGULATORY AGENCIES

When a federal agency begins to stand out by improperly interfering with legitimate business activities, WLF litigators have sought to highlight that interference by focusing special attention on the agency. For example, in June 2005, WLF determined that the FDA, acting through its Division of Drug Marketing, Advertising, and Communications (DDMAC), was using letters to drug companies to advance questionable legal theories and request remedial actions that the agency could not require by law. We then initiated our DDMAC Watch Program, which monitors federal regulation of prescription drug advertising. Under the DDMAC Watch Program, when DDMAC sends one of the letters to a drug company, stating theories that are legally deficient or ill-advised, WLF sends a response back to DDMAC identifying the specific ways in which this is so. The goal of this program is to alert the press and the public to the abuses occurring at DDMAC. WLF has responded to over 35 letters from DDMAC in hopes of shedding light on these questionable legal tactics.

KEEPING GOVERNMENT ACCOUNTABLE

WLF participated in more than 130 court cases and regulatory proceedings in 2007, including 29 before the U.S. Supreme Court. We have consistently maintained our commitment to holding government bureaucrats accountable in agencies such as the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Securities and Exchange Commission (SEC), the Occupational Safety and Health Administration (OSHA), and the Federal Trade Commission (FTC).

In our oversight of federal regulatory agencies, we closely monitor proposed redundant regulations that are published in the Federal Register. When proposed regulations appear to exceed an agency’s mandate, we routinely enter the administrative fray in support of free enterprise principles. We also make extensive use of the Freedom of Information Act to obtain government documents that demonstrate bureaucratic excess.
Medellin v. State of Texas
Placing Reasonable Limits on Criminal Appeals

A Mexican citizen was convicted in 1994 of brutally raping and murdering two teenage girls in Texas. Numerous courts have reviewed the case and have concluded that he was given a fair trial. He has asked the U.S. Supreme Court to overturn the conviction, claiming that he was denied certain rights under international law. Representing the parents of one of the murder victims, WLF urged the Court to reject the claim and bring the appeals process to an end. WLF argued that U.S. courts should judge criminal cases under American law, not on the basis of what activists allege is international law.

Boumediene v. Bush
Permitting the Government to Detain Suspected Terrorists

Ever since 9/11, we have been engaged in a war against militant Islamists. Suspected foreign terrorists captured by the U.S. military have been detained in Guantanamo Bay, Cuba. Activist attorneys are now asking that the suspected terrorists be afforded the same constitutional rights routinely provided to defendants in our criminal justice system. Representing a group of eight recently retired generals and admirals, WLF asked the Supreme Court to reject those claims. WLF argued that constitutional rights have never been extended during past wars to noncitizens alleged to be enemy combatants. WLF argued that the war cannot be fought effectively if soldiers must begin devoting their energies to being criminal investigators and prosecutors.
Stoneridge v. Scientific Atlanta
Opposing Unwarranted Securities Fraud Litigation

All too often, lawsuits purportedly filed to protect investors from securities fraud serve only to enrich plaintiffs' lawyers at the expense of investors. WLF's brief in this case, drafted with the pro bono assistance of former Solicitor General Kenneth Starr, argued that securities fraud suits should be limited to those who actually relied on some fraudulent statement allegedly made by the defendant.

González v. Arizona
Supporting Restrictions on Illegal Aliens

In 2004, Arizona voters adopted Proposition 200, an initiative designed to prevent illegal aliens from obtaining public benefits and voting. Activists have gone to court repeatedly since then in an effort to strike down Prop 200. Representing Protect Arizona Now, the group that spearheaded Prop 200, WLF has intervened in litigation to uphold the law. In the latest round of litigation, WLF persuaded a federal appeals court to uphold a provision that requires Arizonans to show proof of citizenship when registering to vote, and to provide an ID when voting.
No. 06-7949

IN THE
Supreme Court of the United States

BRIAN MICHAEL BALL,
Petitioner,
v
UNITED STATES OF AMERICA,
Respondent

On Writ of Certiorari to the
United States Court of Appeals
for the Eighth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION
AND ALLIED EDUCATIONAL FOUNDATION
AS AMICI CURIAE IN SUPPORT OF PETITIONER

DANIEL J. POPIO
PAUL D. KAREMBA
(Counsel of Record)
WASHINGTON LEGAL FOUNDATION
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July 26, 2007

Gall v. United States
Opposing Excessive Criminal Penalties
for Regulatory Offenses

WLF devotes considerable resources
to combating a disturbing trend among
prosecutors: bringing criminal charges against
members of the business community for what
used to be considered regulatory offenses.
WLF has been particularly concerned by the
U.S. Sentencing Guidelines, which often
mandate draconian prison sentences for such
regulatory offenses.

"WLF is a committed defender of the civil liberties of American
businesses. WLF's work ensures that special interest and activist groups do
not compromise our justice system by using the courts to implement their
anti-growth agendas. I applaud WLF for its ceaseless efforts to strengthen the
integrity of America's judicial system and to promote balance in the courts."

- Honorable Haley Barbour, Governor, State of Mississippi
SELECT LITIGATION

Abigail Alliance v. von Eschenbach
This landmark WLF lawsuit on behalf of terminally ill patients came to an end in early 2008, but not until WLF’s work brought much-needed attention to the inability of patients to get access to the drugs they need. WLF won a major victory in this case in 2006, when a three-judge panel of the federal appeals court in Washington, D.C. agreed with WLF that the U.S. Constitution protects the rights of those suffering from serious illnesses to gain access to experimental medicines when they have no other approved treatment options. However, the Food and Drug Administration appealed that decision, and in 2007 a divided appeals court sitting en banc reversed WLF’s victory.

Vidrine v. United States
WLF has become concerned in recent years by the federal government’s overly harsh enforcement of regulatory laws against members of the business community. What had once been deemed minor regulatory infractions that would have been resolved through civil or administrative proceedings, now initiate SWAT team raids by armed EPA and FBI agents and felony criminal indictments resulting in lengthy prison terms. In appropriate cases, WLF has assisted individuals who have been unfairly targeted by prosecutors. In this case, Hubert Vidrine, a refinery manager at a small Louisiana plant, was indicted for allegedly storing hazardous waste without an EPA permit. The government was forced to drop the charges four years later, after Vidrine discovered that EPA had no evidence that a hazardous substance ever existed and that the only prosecution witness was a cocaine addict who, even when hypnotized by prosecutors, could not provide any incriminating statements. WLF is helping Vidrine strike back; in 2007, represented by WLF, Vidrine filed a malicious prosecution lawsuit against the government for $5 million.

Exxon Shipping Co. v. Baker
Punitive damages awards — that is, jury awards designed not to compensate the plaintiff but to punish the defendant and deter future misconduct — continue to grow by leaps and bounds every year. WLF has been actively fighting to rein in such awards. In this case arising from the Exxon Valdez oil spill nearly 20 years ago, a federal appeals court in California upheld a $2.5 billion punitive damages award against ExxonMobil — the largest such award ever upheld by a federal appellate court. WLF’s September 2007 brief successfully urged the U.S. Supreme Court to review the case. In a December 2007 brief addressing the merits, WLF argued that the Supreme Court ought to eliminate or significantly reduce the award. Noting that to date ExxonMobil has been forced to expend $3.4 billion in connection with the spill (in clean-up costs, government fines, and payments to those who suffered economic harm from the spill), WLF argued that ExxonMobil has paid more than enough to satisfy the public’s interests in punishment and deterrence.

Presbyterian Church of Sudan v. Talisman Energy, Inc.
In recent years, activists have been making increasing use of an obscure 1789 law known as the Alien Tort Statute (ATS) as a means of attempting to enforce international law in U.S. courts. WLF has actively opposed those efforts. WLF believes that international law is enforceable in U.S. courts only to the extent that Congress has authorized such enforcement, something it has virtually never done. WLF also opposes efforts to use the ATS as a means of forcing U.S. courts to referee disputes that have no connection with the U.S. For example, in this case a Canadian oil company that does no business in the U.S. is being sued in New York under the ATS by citizens of Sudan. The company owns oil facilities in Sudan. It is accused of “aiding and abetting” international law violations by the Sudanese government — because it pays taxes to that government. WLF filed a brief in the federal appeals court in New York, urging it to dismiss the case, arguing that American courts have no business hearing disputes of this sort that have no connection to the U.S.
Allison Engine Co. v. U.S. ex rel. Sanders

WLF has litigated extensively against expanding the scope of the False Claims Act (FCA), a federal law that allows suits against those alleged to have obtained money from the federal government based on false claims. The FCA is beloved by plaintiffs’ lawyers because it includes a qui tam provision that allows private individuals to file suit under the FCA in the name of the federal government — and to keep for themselves a sizable portion of whatever is collected. This results in virtually all companies that do business with the government being constantly sued under the FCA by bounty-hunting plaintiffs. In this case, a federal appeals court ruled that a plaintiff can sue under the FCA even if the defendant never actually presented a claim to the federal government; it is enough if federal money eventually made its way into the defendant’s hands. In a brief filed in the Supreme Court in December 2007, WLF urged that that decision be overturned.

United States v. Lynne Stewart

While WLF recognizes that lawyers have an obligation to represent their clients zealously, there need to be limits. This case involves a New York attorney, Lynne Stewart, who was convicted of providing material support to an Egyptian terrorist group. While serving as the attorney for the head of that group, Sheikh Omar Abdel Rahman, Stewart funneled conspiratorial information from Rahman (being held incommunicado in a federal prison) to his followers. Stewart seeks to overturn her conviction on First Amendment grounds. In a brief filed in October 2007 in the federal appeals court in New York, WLF urged that the conviction be upheld; it argued that the First Amendment does not protect the rights of lawyers to assist a criminal conspiracy.

United States v. Rayburn HOB,
Room 2113

This case came about in connection with the bribery investigation of U.S. Rep. William Jefferson of Louisiana, who is under indictment for accepting a $100,000 bribe from Nigerian officials. In connection with their investigation, prosecutors sought to search Jefferson’s congressional office. Jefferson argued that the search violated his rights under the Speech or Debate Clause of the Constitution. WLF disagreed, arguing (in a brief filed in the federal appeals court in Washington) that the Speech or Debate Clause only protects legislative materials and should not be used to thwart legitimate criminal investigations. The appeals court’s August 2007 decision sided with Jefferson. If the U.S. Supreme Court agrees to hear the prosecutors appeal, WLF has pledged to file a new brief in that court in 2008.
WLF Clients

ORGANIZATIONS
Abigail Alliance for Better Access to Developmental Drugs
Allied Educational Foundation
Kansas Grain and Feed Association
Kidney Cancer Association
Lorenzen Cancer Foundation
National Association of Manufacturers
National Defense Committee
Project Arizona NOW
60 Plus Association

MEMBERS OF CONGRESS
U.S. Senator James M. Inhofe
U.S. Representative Trent Franks

INDIVIDUALS
Brigette Brennan (MO)
Thomas J. and Zan Brennan (MO)
Trent England (WA)
Sandra and Randy Erman (TX)
Rebecca Fox (PA)
Edward and Mary Samp (MA)
Joan Taragan (FL)
Hubert and Tammy Vidrine (LA)
Todd Wayne (TX)

"The Washington Legal Foundation is truly an advocate for freedom and justice. We are grateful for WLF’s legal representation and tireless work for the Abigail Alliance to give every cancer patient and other patients with life-threatening illnesses every chance they deserve to fight for their lives."

- Frank Burroughs, Founder, Abigail Alliance for Better Access to Developmental Drugs
Communicating

WLF's Civic Communications Program ensures that champions of free enterprise are equipped with the scholarly, timely, and pertinent information they need to become effective advocates. We believe that knowledge empowers citizens nationwide to recognize threats to their individual liberties.

Our targeted, broad-based communications programs — featuring webcast Media Briefings and Web Seminars on current legal issues, educational seminars, advocacy ads in national journals and newspapers, legal PR, and op-ed features published in The New York Times — provide exposure to important knowledge and help ensure the preservation of freedom and justice.

INFORMING THE PEOPLE

WLF fosters the free and open exchange of ideas among today's thought leaders, policymakers, and the general public. As an autonomous, nonprofit, public interest communications and public affairs organization, we are positioned to arrange and lead these debates.

"The Washington Legal Foundation plays an exceptionally important role in cases involving free competition, business, and other matters before the Supreme Court and provides an extraordinary forum for discussing these issues."

- Thomas C. Goldstein, Akin, Gump, Strauss, Hauer & Feld LLP
Our Civic Communications Program educates Americans about critical legal issues affecting their rights, while supporting WLF’s litigation and publication initiatives. This multifaceted public education program includes:

- A comprehensive website, wlf.org, to help visitors stay abreast of WLF’s advancements in strengthening America’s free enterprise system.

- A Media Briefing series to highlight timely legal issues, featuring top legal experts including federal judges, executive branch officials, U.S. senators and representatives, key congressional staff members, and corporate general counsel.

- Advocacy ads in national newspapers and periodicals to focus the public’s attention on important legal issues.

- “In All Fairness,” an advertorial published in the national edition of The New York Times that covers a wide range of timely issues, from overzealous government regulation to judicial abuse. The advertorial has appeared more than 172 times since its first run in 1998, reaching the top 75 population markets and 100 percent of major newspaper editors.

- A Web Seminar series, which presents viewers with live webcast analysis and commentary by noted legal experts on timely developments in law and public policy.

- A webcasting system that allows viewers to watch WLF’s Media Briefings and Web Seminars broadcast live on their computers or access the archived webcasts at their convenience.

MAKING THE MESSAGE CLEAR

Unless legal cases are plainly and thoroughly explained to the general public and other involved parties, complex doctrines and legalese often confound the issues. Our attorneys and pro bono legal experts engage in extensive efforts to shape the public’s understanding and opinion of high-profile cases and legal matters.

Over 30 million people have visited wlf.org.
INFORMING THE MEDIA

Targeted and broad based, our Civic Communications Program hosts Media Briefings on current legal issues to educate key decision-makers and opinion leaders. As an essential element of our outreach strategy, these briefings are often moderated by the Honorable Dick Thornburgh and feature leading legal authorities addressing a wide variety of timely topics. Participating speakers donate their time and expertise to discuss legal reform, clean air regulation, national security, white collar crime, judicial selection, the Supreme Court, drug regulation, bio-terrorism, and criminalization of free enterprise.
FRAMING THE ISSUES

WLF's educational message reaches far beyond Washington, thanks to our webcasting capabilities. Decision-makers and thought leaders around America and the world can either tune in live to our briefings and seminars, or visit WLF's website, wlf.org, where each program is conveniently archived. Additionally, each archived program is individually indexed, so viewers can choose to watch particular speakers or just the question-and-answer session.
IN ALL FAIRNESS

Class Action Crimes

News of notorious class action lawyer Bill Lerach's decision to plead guilty to conspiracy is a watershed moment for those concerned with the dysfunctional civil justice system. Lerach has exploited frail enterprise for decades, transforming millions from shareholder's nest eggs to his own pocket. Last year his former firm, Milberg Weiss, and several of its partners were indicted for manipulating stock prices in defrauds and were ordered to repay $500 million. Though their motives have earned them the most attention, Lerach and Milberg Weiss are certainly not alone in a growing gallery of rogue class-action lawyers.

A federal judge recently fined and incarcerated a prominent Mississippi trial lawyer and two state judges for bribery and racketeering. Yet another federal judge ordered three Kentucky lawyers jailed pending their trial for allegedly withholding settlement funds to defraud their clients of their drug class action. "Not only have these gentlemen acted on the trail, the whole legal profession is on trial," the judge stated. In addition, an Illinois judge has ordered two prominent law firms, Dickie Scruggs and with criminal contempt for not fully disclosing attorney-client statements and documents obtained from whistleblowers in an insurance class action.

Such abuse of consumer and disinformation of the legal system should provoke cries of outrage from public officials, the media, the legal community, and politicians. Instead what we hear is deafening silence. The justice industry is a threat to the concept of a legal protection society that all should be too busy lining up new lawsuits to be concerned about holding rogue lawyers accountable.

Who can we count on to protect us from litigation's bad apples? Civil enforcement may sometimes be acceptable, but it is far too delayed and cumbersome. An approach to effectively control lawyer abuses is to set standards. Consumers and regulators either can't or won't safeguard class-action class members. The system is being robbed at pen point by certain class-action lawyers if any. Industry charges a nationally uniform defendant fee, or peddled their services through aggressively misleading ads, they would be investigated or prosecuted.

The FTC and state attorneys general don't seem to be troubled when plaintiffs' lawyers do it. Instead, government regulators regularly defer to the preverbal fox - lawyers through bar associations - to guard the hen house. But when lawyers are being criminally prosecuted, and their defective clients are forced to risk their own careers against them, the status quo simply can't go on. The litigation industry has grown too powerful, and the financial incentives for abuse too great, to trust lawyers to regulate themselves.

All who have fallen prey to Big Law and its subsidiaries have no idea that even these legal predators can be stopped. The most effective, more profit-seeking lawyers, with more money and clout, will get independent oversight and accountability of their activities. They continue to run roughshod over our entire economy. Isn't it time we get started?

The Best of Intentions

As Americans ponder their year-end gifts, they should consider the charitable giving of some famous philanthropists like Henry Ford, Andrew Carnegie, John D. Rockefeller, and John D. MacArthur. All made fortunes in the free enterprise system and were passionate believers in market capitalism and self-reliance. Yet the philanthropic remains of their riches have been hijacked by special interests to fund social engineering and legal assaults on economic freedom.

One of the most fundamental principles of trust and estate law is that the assets of the deceased must be distributed in full to those who have a legal claim. With charitable contributions, institutions often ignore the clear intent of their donors. Unfortunately, many of these institutions fail to recognize their beneficiaries' financial legacy to bar nonprofit professional activities that destroy free enterprise. Literally hundreds of foundations across the country have been turned into cash cows for radical causes.

These foundations fund a cadre of activist groups that expose causes contrary to the values of the benefactors whose intentions are to free themselves from the restrictions that restrict rights to private property, sizable businesses, civil liberties, and general government control over everyday life. Often beneficiaries of free enterprise money have justified literacy legate an ever-expanding list of "rights" for criminals, illegal aliens, and even terrorists. These "charities" bear little resemblance to their founders' visions.

In addition, other special interest group activism is funded by corporations and individuals who simply do not pay enough attention to the activities of the organizations they subsidize. Many anti-business organizations are run by well-meaning donors who are deluding themselves that they are used to bolster free market principles.

A case in point: corporate alumni of the University of California who are members of the American Bar Association. Essentially trained camp for the most active members of the insurance industry, these lawyers are on the front lines supporting laws to hamper free enterprise with newly concocted radical theories of legal liability. When they are not undermining small businesses with frivolous lawsuits, they are busy filing endless appeals and petitions on behalf of import-competing industries. Many who contribute to the academic movement that hinders the growth of new jobs would oppose such activities — just as many scientists would. They're the graying of the foundation of American government.

Whatever one's philosophical stripe, donors have a right to expect that the dignity of their ideas will be respected as they come through the charitable distribution of their assets. Sadly, the more often the case. Unless they do their homework, Americans can expect that the money they charity earmarks today may well up pay for the causes they find unacceptable.

Too frequently, the wafflers of donors are given little more than lip service by the beneficiaries of their largesse. Before writing that next check to charity, be very cautious. America — philanthropy has too little respect for donor intent.

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Advocate for freedom and justice*
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Speakers

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Powell Goldstein LLP

John F. Olson
Gibson, Dunn & Crutcher LLP

Professor Antonio F. Perez
Catholic University of America’s
Columbus School of Law

Andrew J. Pincus
Mayer Brown LLP

Victor E. Schwartz
Shook, Hardy & Bacon LLP

The Honorable Dick Thornburgh
Kirkpatrick & Lockhart Preston Gates
Ellis LLP

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George Mason University School of Law

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The “McNulty Memo”: A Missed Opportunity To Reverse Erosion Of Attorney-Client Privilege
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Second Circuit Provides Clearer Picture On Its False Advertising Doctrine
By Marc J. Rachman, Joseph J. Lewczak, and Christopher Poindexter, Davis & Gilbert LLP

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By Donald B. Ayer, Jones Day

“Attractive Advertising” Suits Held Judicially Unappealing
By David W. Ichel and Bryce L. Friedman Simpson, Thacher & Bartlett LLP

Bill Denying Tax Deduction For Drug Ads Unconstitutional
By Arnold I. Friede, McDermott Will & Emery LLP and John F. Kamp, Wiley Rein LLP

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Three Federal Courts Reject Public Nuisance As Climate Change Control Tool
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By Donald W. Fowler and Eric G. Lasker
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By Joseph P. McGill and E. Jason Blankenship
Foley, Baron & Metzger

ENVIRONMENTAL REGULATION
Globalizing Serious Environmental Offenses: Now It’s A Crime Too
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By Harry Edward Grant and David C. Weber
Riddell Williams PS

FALSE CLAIMS ACT
The Deficit Reduction Act Of 2005: Eliminating Fraud, Waste And Abuse In Medicaid?
By Rebecca C. Fayad
Sonnenschein Nath & Rosenthal LLP

The False Claims Correction Act: What Would It Correct?
By Stuart M Gerson, Epstein Becker & Green PC
FOOD, DRUG, AND MEDICAL DEVICE REGULATION

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By Dr. John C. Luik and Professor Patrick Basham
The Democracy Institute

By Dr. John C. Luik. Foreword by Daniel J. Popeo, Washington Legal Foundation

Court Rejects Activists’ Attempt To Judicially Manage Restaurant’s Menu
By James Flanagan
Catholic University Columbus School of Law

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Dickstein Shapiro LLP

Greater Transparency Needed In Reprocessing Of Medical Devices
By The Honorable Bob Franks
HealthCare Institute of New Jersey

Surgeon-Owned Device Companies: A Risky Proposition
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IMMIGRATION LAW

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INSURANCE LAW

Weiss v. First Unum Life: Treating Insurers Like Racketeers
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Deliberative Process Needed To Reform Insurance Guaranty Funds
By Roger H. Schmelzer and Mark D. Steckbeck
National Conference of Insurance Guaranty Funds

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Congress, Once Again, Debates Insurers’ Antitrust Exemption Under McCarran-Ferguson Act
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By Gregorry Heidrich
Property Casualty Insurers Association of America

INTELLECTUAL PROPERTY

In Re Seagate: We Have Met The Enemy, And He Is Us
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Congress Should Not Tread On Courts’ Resolution Of Trademark Disputes
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Compulsory Licensing Of Intellectual Property: The Exception That Ate The Rule?
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Canadian Court Decision Places Broad Class Of Patents In Jeopardy
By Charles E. Lipsey
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Force Licensing Of Drug Patents Reflects "IP Counterfeiting" Efforts on World Stage
By Lawrence A. Kogan, Institute for Trade, Standards and Sustainable Development Inc.

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No Sea Change In Patent Law
By The Honorable Gerald J. Mossinghoff
Oblon, Spivak, McClelland, Maier & Neustadt PC

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By Richard L. Frank and Kenneth D. Ackerman
Olsson, Frank and Weeda PC

JUDICIARY AND COURTS

CONVERSATIONS WITH: U.S. Supreme Court Practice & Jurisprudence
The Honorable Dick Thornburgh, Kirkpatrick & Lockhart Preston Gates Ellis LLP; Maureen E. Mahoney, Latham & Watkins LLP; and Thomas C. Goldstein, Akin Gump Strauss Hauer & Feld LLP

LAWYERS

Trial Lawyer Misconduct Alleged In Katrina-Related Lawsuits
By Adam Botzenhart, Washington Legal Foundation

Inflated Fen-Phen Fees: Plaintiffs' Lawyers Face Federal Criminal Probe
By Paul D. Kamenar, Washington Legal Foundation

A Reasoned Approach To Sanctions Under The Securities Act Of 1933
By Dorothy Fernandez, Morrison & Foerster LLP and Tammy Albarran, Esq.

Federal Appeals Court Scrutinizes Lawyers' Conduct In Asbestos Lawsuit
By John S. Stadler, Nixon Peabody LLP

LITIGATION

Anti-Suit Injunctions: Protecting U.S. Businesses In Overseas Markets
By Michael Diaz, Jr. and Carlos F. Gonzalez
Diaz, Reus, Rolff & Targ LLP

NewSpeak In Court Rules: "Restyled" Civil Procedure Rules Need Further Review
By Professor Jeffrey S. Parker
George Mason University School of Law

National Australia Bank And The Threat Of Global Class Action Securities Suits
By Joshua Rohrscheib and Niki Carelli, DLA Piper US LLP

Judges Impose Reality Check On Public Nuisance Litigation
By John S. Gray and Richard O. Faulk
Gardere Wynne Sewell LLP

Looking For Lead In All The Wrong Places: Alternative Sources Of Exposure In Lead Paint Litigation
By Richard O. Faulk, John S. Gray, and Diana P. Larson
Gardere Wynne Sewell LLP

The Mouse That Roared?: Novel Public Nuisance Theory Runs Amok In Rhode Island
By Richard O. Faulk and John S. Gray
Gardere Wynne Sewell LLP

NATIONAL SECURITY

El-Masri v. USA: Constitutional Foundation Of State Secrets Doctrine Upheld
By Thomas R. McCarthy and Sarah M. Isgur
Wiley Rein LLP

New Federal Rules Dictating Anti-Terrorism Standards For Chemical Facilities
By Joe Whitley, Alston & Bird LLP and Ava Harter
The Dow Chemical Company

Federal Judge Intrudes Upon Executive Authority To Designate Terrorist Organizations
By Andrew C. McCarthy
Foundation for the Defense of Democracies
PREEMPTION
Parting The Watters: Tort Law Preemption Signals From High Court’s Banking Opinion
By Eric Lasker and Rosemary Stewart Spriggs & Hollingsworth PC

Federal Preemption: Another Form Of State Tort Reform?
By James M. Wooton, Esq.

Courts’ Misapplication Of FDA Preemption Policy Creates Quandary For Drug Producers
By Linda Pissott Reig and John T. Chester Porzio, Bromberg & Newman PC

Courts Give Mixed Reviews To Preemption Policy In 2006 FDA Labeling Rule
By James M. Wood, Reed Smith LLP and Claire A. Hass, Esq.

SECURITIES REGULATION & CORPORATE GOVERNANCE
Delaware High Court Empowered To Answer Formal Questions From SEC
By Rolin P. Bissell Young Conaway Stargatt & Taylor LLP

Early Inferences From The Supreme Court’s Tellabs Ruling
By Kenneth A. Kuwayti and Olga A. Tkachenko Morrison & Foerster LLP

Stoneridge v. Scientific-Atlanta: “Scheme Liability” In The High Court
By Andrew M. Edison, Bracewell & Giuliani LLP

PRODUCT LIABILITY
Competing Rulings Test Limits Of Design Defect Liability Under New York Law
By Steven L. Vollins Patterson Belknap Webb & Tyler LLP

PUNITIVE DAMAGES
Philip Morris USA v. Williams: Another Brick In The Punitive Damages Wall
By Evan M. Tager, Mayer Brown LLP

Bell Atlantic Corp. v. Twombly: A Tectonic Shift In Pleading Standards (Or Just A Tremor)?
By Thomas P. Brown and Christine C. Wilson O’Melveny & Meyers LLP

Tellabs, Inc. v. Makor: Will It Make A Difference?
By Susan E. Hurd, John A. Jordak, and Kelly C. Wilcove Alston & Bird LLP

Lessons From Record Penalty Under Federal Anti-Corruption Law
By Claudius O. Sokenu, Mayer Brown LLP

SCIENTIFIC EVIDENCE
Texas High Court Heightens Scientific Evidence Standards
By Richard O. Faulk and Joy E. Palazzo Gardere Wynne Sewell LLP

Methodology Is The Key To Exclusion Of Expert Testimony: Allgood v. General Motors
By Margaret A. Costello and Krista L. Lenart, Dykema

Court Should Dismiss Junk Science-Based Proposition 65 Suit
By Dr. Andrea D. Tiglio, McGuire Woods LLP

More Intrusive Federal Rules For Executive Compensation Unjustified
By Professor Stephen Bainbridge, University of California at Los Angeles Law School

High Court To Examine Scienteer Pleading Standard In Securities Suits
By D. Anthony Rodriguez, Morrison & Foerster LLP
TORT LIABILITY

Courts Reject Two Nationwide Consumer-Fraud Class Actions
By John T. Chester and C. Michael Rowan Porzio Bromberg & Newman PC

CONVERSATIONS WITH: The Benefits Of Legal Reform
The Honorable Dick Thornburgh, Kirkpatrick & Lockhart Preston Gates Ellis LLP; Governor Joe Manchin, West Virginia; Governor Haley Barbour, Mississippi; and Steven Hantler, American Justice Partnership

The ALI & Medical Monitoring: Risks For Restatements’ Embrace Of A Novel Tort
By Sean P. Wajert, Dechert LLP

Executive Order Bars Agencies From Hiring Contingent Fee Counsel
By John S. Stadler, Nixon Peabody LLP

Contingent Fee Lawyers’ Representation Of County Rejected By State Court
By John S. Stadler, Nixon Peabody LLP

Illinois High Court Refines State Class Action Jurisprudence
By Anthony J. Anscombe and C. Kinnier Lastimosa Sedgwick, Detert, Moran & Arnold LLP

Liggett Group v. Engle: Florida High Court’s Imperfect Response To Class Action Abuse
By Professor Michael I. Krauss
George Mason University School of Law

Mississippi Supreme Court Rejects Medical Monitoring
By Mark A. Behrens and Christopher E. Appel Shook, Hardy & Bacon LLP

TOXIC TORTS

Manufacturer’s Lawsuit Spotlights Substance Listings Under Proposition 65
By Ann G. Grimaldi, McKenna Long & Aldridge LLP

California’s Attorney General Acknowledges Prop 65 Abuse
By Lisa L. Halko, Greenberg Traurig LLP

State Regulators Impose Sanction For Unlawful Silicosis Screenings
By Nathan A. Schachtman, McCarter & English LLP

Judicial Leadership Emerging In Asbestos And Silica Mass Torts
By The Honorable Griffin B. Bell, King & Spalding

WORKPLACE AND EMPLOYMENT LAW

Employee-Protected Activity Under Sarbanes-Oxley § 806: Is Fraud Against Shareholders Essential?
By Donn C. Meindertsma and Melinda L. Kirk Conner & Winters LLP

Sarbanes-Oxley Whistleblower Risks: Still Real, Still Hazy
By Donn C. Meindertsma and Melinda L. Kirk Conner & Winters LLP
Litigation and Regulatory Reform

The Washington Legal Foundation litigates at every level of the judicial system, from local courts to the U.S. Supreme Court. WLF also regularly initiates or intervenes in administrative proceedings to promote regulatory reform. WLF participated in over 130 court cases and regulatory proceedings in 2007. Briefs and regulatory comments filed by WLF are available on its website at wlf.org.

Abdullahi v. Pfizer
U.S. Court of Appeals for the 2nd Circuit
Opposing tort suit against company whose doctors provided medical aid to children in Nigeria

Abigail Alliance v. von Eschenbach
U.S. Supreme Court and U.S. Court of Appeals for the District of Columbia Circuit
Supporting terminally-ill patients seeking access to lifesaving experimental drugs

ACLU v. National Security Agency
U.S. Court of Appeals for the 6th Circuit
Opposing ACLU’s efforts to shut down NSA electronic surveillance of al Qaeda and other terrorist international communications

Aguilar v. ExxonMobil Corp. (Lockheed Litigation Cases)
California Supreme Court
Opposing improper expert witness testimony

Allison Engine Co. v. United States ex rel. Sanders
U.S. Supreme Court
Opposing suits under False Claims Act where defendant never presented claim to U.S.

Al Odah v. United States
U.S. Court of Appeals for the District of Columbia Circuit
Opposing challenges to detention of enemy combatants at Guantanamo Bay

Bell Atlantic v. Twombly
U.S. Supreme Court
Opposing frivolous antitrust lawsuits

Biotechnology Industry Organization v. District of Columbia
U.S. Court of Appeals for the Federal Circuit
Opposing local price controls on prescription drugs

Boumediene v. Bush
U.S. Supreme Court
Opposing challenges to detention of enemy combatant at Guantanamo Bay

Center for Constitutional Rights v. Bush
U.S. District Court for the Southern District of New York
Opposing CCR’s efforts to shut down NSA electronic surveillance of al Qaeda and other terrorist international communications

Chance v. United States Tobacco
District Court of Seward County, Kansas
Opposing excessive attorneys’ fees in class action case

City of Hope Medical Center v. Genentech, Inc.
California Supreme Court
Opposing excessive punitive damages award in licensing lawsuit

Claiborne v. U.S.; Rita v. U.S.
U.S. Supreme Court
Opposing excessive sentences under sentencing guidelines for minor regulatory infractions

Connecticut v. American Electric Power Company
U.S. Court of Appeals for the 2nd Circuit
Opposing lawsuit seeking to hold power companies responsible for global warming

Credit Suisse Securities (USA) LLC v. Billing
U.S. Supreme Court
Opposing use of antitrust law to regulate market for initial public offerings (IPOs)

Crawford v. Marion County Election Bd.
U.S. Supreme Court
Supporting requirement that voters show IDs when voting
Daniel Measurement Services, Inc. v. Eagle Research Corp.
U.S. Supreme Court
Supporting right of civil defendants to obtain meaningful appellate review of jury verdicts

Day v. Bond
U.S. Court of Appeals for the 10th Circuit
Opposing college tuition statute that discriminates in favor of illegal aliens

Doe v. Wal-Mart Stores, Inc.
U.S. District Court for the Southern District of California
Supporting First Amendment right of company to refute charges critical of company's labor practices overseas

Dukes v. Wal-Mart Stores, Inc.
U.S. Court of Appeals for the 9th Circuit
Opposing certification of nationwide class in employment discrimination suit

U.S. Supreme Court
Opposing EPA effort to greatly increase costs of modifying power plants

Everest Properties II, LLC v. Prometheus Development Co.
California Supreme Court
Opposing expansion of a general partner's potential liability to the partnership

Exxon Shipping Co. v. Baker
U.S. Supreme Court
Opposing excessive punitive damages under federal maritime law

Free Enterprise Fund v. Public Company Accounting Oversight Board
U.S. Court of Appeals for the District of Columbia Circuit
Challenging constitutionality of accounting board established by Sarbanes-Oxley

Fresco v. Automotive Directions, Inc.
U.S. District Court for the Southern District of Florida
Objecting to excessive fee request in class action where plaintiffs received little benefit

Gall v. United States
U.S. Supreme Court
Opposing excessive sentences under federal sentencing guidelines

Gonzalez v. State of Arizona
U.S. Court of Appeals for the 9th Circuit
Opposing attempt by activists to strike down immigration control measure

Grisham v. Philip Morris USA, Inc.
California Supreme Court
Opposing efforts to allow tort lawsuits to be filed after limitations period expires

Humanitarian Law Project v. Gonzales
U.S. Court of Appeals for the 9th Circuit
Supporting PATRIOT Act provision forbidding material support to terrorist groups

IMS Health Inc. v. Ayotte
U.S. Court of Appeals for the 1st Circuit
Supporting First Amendment right to disclose critical health care information

Johnson v. Tampa Sports Authority
U.S. Court of Appeals for the 11th Circuit
Supporting NFL policy that requires brief search of patrons attending NFL football games to deter terrorist attacks

Lorillard Tobacco Co. v. Engida
U.S. Supreme Court
Supporting efforts to prevent sale of counterfeit goods bearing fake trademarks

Massachusetts v. EPA
U.S. Supreme Court
Opposing attempts to require EPA to regulate carbon dioxide emissions

Matar v. Dichter
U.S. Court of Appeals for the 2nd Circuit
Opposing use of Alien Tort Statute to enforce human rights law in U.S. courts
Medellin v. Texas
U.S. Supreme Court
Opposing effort to overturn death sentence based on international law

Merck & Co. v. Apotex Corp.
U.S. Court of Appeals for the Federal Circuit
Supporting limitations on standing to bring lawsuits challenging validity of patents

Morrison v. National Australia Bank Ltd.
U.S. Court of Appeals for the 2nd Circuit
Opposing extraterritorial application of U.S. securities laws to foreign corporations

Mother Doe v. Sheikh Mohammed
U.S. District Court for the Southern District of Florida
Opposing use of U.S. courts to assert international law claims unconnected to U.S.

Nat'l Assoc. of Home Builders v. Defenders of Wildlife
U.S. Supreme Court
Supporting efforts to limit scope of Endangered Species Act

Neer v. Pelino
U.S. Court of Appeals for the 3rd Circuit
Opposing Sarbanes-Oxley suits seeking disgorgement from company officials

New Jersey v. EPA
U.S. Court of Appeals for the District of Columbia Circuit
Opposing unjustified regulation of mercury emissions from power plants

New York State Board of Elections v. Lopez
U.S. Supreme Court
Supporting right of party members to play meaningful role in candidate selection

Omari v. Kindred Healthcare Operating, Inc.
California Supreme Court
Opposing award of punitive damages for breach of contract

Paramount Citrus v. Superior Court
California Court of Appeal
Opposing tort award to illegal alien based on assumption alien would remain in U.S.

Perez v. Asurion Corporation
U.S. District Court for the Southern District of Florida
Opposing attorney fee award based on "coupon" settlement of class action suit

Pfizer Inc. v. Apotex Corp.
U.S. Supreme Court
Supporting limits on claims that a patent is invalid on "obviousness" grounds

Philip Morris USA v. Williams
U.S. Supreme Court
Opposing excessive punitive damages

Physicians Committee for Responsible Medicine v. General Mills
U.S. Court of Appeals for the 4th Circuit
Opposing efforts by animal rights activists to stop milk industry advertising

Presbyterian Church of Sudan v. Talisman Energy, Inc.
U.S. Court of Appeals for the 2nd Circuit
Opposing use of Alien Tort Statute to sue foreign corporations with few U.S. contacts

Raytheon Aircraft Co. v. United States
U.S. District Court for the District of Kansas
Supporting challenge to EPA environmental cleanup order

Raytheon Technical Services Co. v. Hyland
Virginia Supreme Court
Opposing employee libel suit over statements in annual performance evaluation

Rehm v. Navistar
Kentucky Supreme Court
Opposing extending workers’ compensation liability for claims by subcontractor

Riegel v. Medtronic, Inc.
U.S. Supreme Court
Supporting preemption of tort suits against maker of medical device approved by FDA

R.J. Reynolds Tobacco Co. v. Engle
U.S. Supreme Court
Opposing class action certification where individualized issues predominate over issues common to the class
Rockwell Int’l Corp. v. United States ex rel. Stone
U.S. Supreme Court
Opposing abuse of the qui tam provision of the False Claims Act

Safeco Insurance Co. of America v. Burr
U.S. Supreme Court
Opposing misuse of Fair Credit Reporting Act in suits against insurance industry

Schering Corp. v. First DataBank, Inc.
U.S. Court of Appeals for the 9th Circuit
Opposing use of California anti-SLAPP statute to unnecessarily delay lawsuits

SmithKline Beecham Corp. v. PTO
U.S. District Court for the Eastern District of Virginia
Opposing government rule that restricts number of “continuation patents” one may file

Tellabs, Inc. v. Makor Issues & Rights, Ltd.
U.S. Supreme Court
Supporting limits on fraud suits under securities laws

United States v. Caputo
U.S. Court of Appeals for the 7th Circuit
Supporting First Amendment claims of executives charged with improperly promoting medical devices

United States v. Hagerman
U.S. District Court for the Southern District of Indiana
Opposing excessive sentence for businessman convicted of minor regulatory infraction

United States v. Nacchio
U.S. Court of Appeals for the 10th Circuit
Opposing “insider trading” conviction of executive who lacked material information

United States v. Philip Morris USA, Inc.
U.S. Court of Appeals for the District of Columbia Circuit
Supporting First Amendment right of corporations to speak out on public issues

United States v. Ramos and Compean
U.S. Court of Appeals for the 5th Circuit
Opposing conviction of border patrol agents for use of excessive force

United States v. Rayburn House Office Building, Rm 2113
U.S. Court of Appeals for the District of Columbia Circuit
Supporting right of FBI to search congressional office for evidence of crime

United States v. Lynne Stewart
U.S. Court of Appeals for the 2nd Circuit
Supporting conviction of radical attorney for providing material support to terrorists

United States v. Stringer
U.S. Court of Appeals for the 2nd Circuit
Opposing unwarranted criminal prosecution for alleged violations of securities law

Vidrime v. United States
U.S. District Court for the Eastern District of Louisiana
Representing businessman suing environmental officials for malicious prosecution

Vietnam Assoc. for Victims of Agent Orange v. Dow Chemical Co.
U.S. Court of Appeals for the Second Circuit
Opposing class action by Viet Cong fighters against American companies

Warner-Lambert Co. v. Kent
U.S. Supreme Court
Supporting preemption of state tort suits alleging that defendant defrauded FDA

Washington Legal Foundation v. Leavitt
U.S. District Court for the District of Columbia
Supporting First Amendment right of companies to inform senior citizens of coverage options under Medicare

Watson v. Philip Morris Companies
U.S. Supreme Court
Supporting right of defendants to remove lawsuits from state court to federal court

Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.
U.S. Supreme Court
Opposing novel antitrust liability for so-called “predatory buying”
In re: Centers for Medicare and Medicaid Services
Urging CMS to tighten regulations regarding documentation of citizenship status of Medicaid applicants

In re: Centers for Medicare and Medicaid Services
Opposing exclusion of anti-cancer drug from new prescription drug benefit

In re: Centers for Medicare and Medicaid Services
Opposing proposal to tie coverage of some new treatments to the patient's participation in a clinical trial

In re: Centers for Medicare and Medicaid Services
Opposing proposal to deny insurance coverage for many uses of Erythropoiesis Stimulating Agents (ESAs)

In re: Chemical Safety and Hazard Investigation Board
Opposing proposed regulation requiring unnecessary retention of records

In re: Congoleum Corp.
U.S. District Court for the District of New Jersey
Supporting massive sanction against law firm for unethical conduct in bankruptcy case

In re: Department of Homeland Security
Challenging college tuition programs discriminating in favor of illegal aliens

In re: Department of Justice
Supporting prosecution of class action attorneys allegedly involved in illegal secret kickbacks of attorneys’ fees

In re: Department of Justice
Petitioning for revision of criminal enforcement policy to ensure use of non-criminal penalties for regulatory offenses in lieu of criminal prosecution

In re: Department of Justice
Petitioning DOJ to undertake proper oversight of FDA criminal cases

In re: Department of Justice–Drug Enforcement Administration
Supporting measured regulation of prescription pain medication that maintains the ability of physicians to treat bona fide pain patients

In re: Department of State
Requesting action, possibly economic sanctions, where foreign governments refuse to cooperate with U.S. deportations of their nationals

In re: Department of Transportation–National Highway Trans. Safety Admin.
Supporting preemption of state tort suits on roof safety where they would conflict with and frustrate NHTSA's goals of reducing rollover crashes

In re: Department of Treasury–Alcohol and Tobacco Tax and Trade Bureau
Seeking revocation of rules against showing basic serving facts on alcohol beverage labels

In re: Dynex Capital Securities Litigation
U.S. Court of Appeals for the Second Circuit
Opposing corporate securities law liability based on collective knowledge of employees

In re: Environmental Protection Agency
Petitioning for assessment of carcinogenicity based on sound science

In re: Environmental Protection Agency
Petitioning for revision of criminal enforcement policy to ensure use of civil or administrative remedies where appropriate in lieu of criminal prosecution

In re: Federal Trade Commission
Supporting continuation of current rules on parental consent to children’s online activities

In re: Federal Trade Commission
Opposing revision of guidelines regarding use of endorsements in advertising

In re: Food and Drug Administration–Division of Drug Marketing, Advertising, and Communications
Requesting, on 18 occasions, withdrawal of ill-considered DDMAC enforcement letters sent to drug manufacturers alleging violation of advertising restrictions

In re: Food and Drug Administration
Petitioning FDA to curtail unwarranted effort to enforce its “medical device” regulations against clinical labs that offer m-house tests to physicians
In re: Food and Drug Administration
Supporting FDA proposal regarding use of word “lean” in labeling

In re: Food and Drug Administration
Opposing expansion of user fee program to cover FDA costs not directly related to review of applications

In re: Food and Drug Administration
Opposing petition from activist group seeking new warnings on soda cans and bottles

In re: Food and Drug Administration
Supporting direct-to-consumer drug ads where the ads are truthful and non-misleading

In re: Food and Drug Administration
Opposing activist petition against approval of silicone gel breast implants

In re: Food and Drug Administration
Supporting proposal for emergency approval of medical products to respond to high risk of biological, chemical, radiological, or nuclear attack

In re: Food and Drug Administration
Opposing activist group’s efforts to censor advertising for arthritis drug Celebrex

In re: Food and Drug Administration
Opposing FDA proposal to impose additional regulations on manufacturers of analyte specific reagents (ASRs)

In re: Michigan Supreme Court
Submitting comments supporting inactive asbestos litigation docket

In re: National Cancer Institute
Requesting agency to review the legality of grants made in support of political activity

In re: National Institute for Occupational Safety and Health
Petitioning NIOSH to discipline x-ray readers for wrongfully detecting asbestos disease

In re: New York Office of Court Administration
Supporting regulations to prevent deceptive attorney advertising

In re: Ohio Department of Health
Opposing proposed rules that would ban indoor smoking

In re: Securities and Exchange Commission
Supporting exempting smaller public companies from burdensome compliance with certain provisions of Sarbanes-Oxley

In re: Securities and Exchange Commission
Petitioning SEC to amend its plan for distributing recovered funds to investors

In re: Securities and Exchange Commission
Complaint to investigate relationship between short-selling and class action case

In re: Tobacco Cases II
California Supreme Court
Opposing private tort claims based on truthful, federally-regulated ads

In re: U.S. Sentencing Commission
Supporting protection of attorney-client privilege and work product privilege
Resources and Support

HOW TO SUPPORT THE WASHINGTON LEGAL FOUNDATION'S WORK

The Washington Legal Foundation has an annual budget of over $4 million.

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WLF is an independent corporation and is neither associated nor affiliated with any other organization. WLF does not accept government (taxpayer-financed) grants. It does not employ professional fundraisers.

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Leveraging our pragmatic perspective as a public interest advocate, WLF advances free enterprise principles with a broad-based communications program that provides timely information and legal opinions from leading experts. Our outreach program disseminates WLF’s message to major print and electronic media, judges, Congress, government decision-makers, business leaders, law students, and professors.

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ACTIVITIES REPORT

to the

WASHINGTON LEGAL FOUNDATION
BOARD OF TRUSTEES

SUPPORTING
PATIENTS' RIGHTS AND
IMPROVED HEALTH CARE

July 11, 2007
TABLE OF CONTENTS

INTRODUCTION ................................................................. 1

I. LITIGATION AND ADMINISTRATIVE PROCEEDINGS .................. 1
   A. Protecting the First Amendment ..................................... 2
   B. Excessive FDA Caution .................................................. 10
   C. Opposing Interference with the Free Market ...................... 14
   D. Exposing FDA Misconduct .............................................. 18
   E. Opposing Unwarranted Tort Suits ................................... 20
   F. Preemption of Medical Device Suits ................................. 26
   G. Protecting Patent Rights ............................................... 29
   H. Misuse of Antitrust Law ............................................... 32

II. CIVIC COMMUNICATION .................................................... 33
    A. Media Briefings ...................................................... 33
    B. Web Seminars ......................................................... 36
    C. Advocacy Ads ......................................................... 37
    D. Public Appearances .................................................. 38

III. PUBLICATIONS ............................................................. 43
JULY 11, 2007

ACTIVITIES REPORT TO THE
WASHINGTON LEGAL FOUNDATION
BOARD OF TRUSTEES

SUPPORTING PATIENTS’
RIGHTS AND IMPROVED HEALTH CARE

The ideals upon which America was founded – individual freedom, limited government, a free-market economy, and national security – are the same principles that the Washington Legal Foundation (WLF) defends in the public interest arena. Adherence to those principles is essential to maintaining America’s position as the possessor of the finest health care system in the world.

Throughout its 30 years, WLF has devoted a significant portion of its resources to improving the health care available to all Americans. WLF believes that goal can best be achieved through free market solutions: providing consumers with the widest range of choices in health care, assisting them in making those choices by giving them access to all relevant information, providing private industry with the incentives to engage in vigorous research and development, and ensuring that health care is not stifled by excessive litigation.

WLF has worked to achieve these objectives through precedent-setting litigation, involvement in government regulatory proceedings, publication of timely articles on health-related issues, and tireless advocacy for free-market solutions in the news media and other public forums. This report highlights some of the more significant WLF health-related activities over the past 12 years.

I. LITIGATION AND REGULATORY PROCEEDINGS

Litigation is the backbone of WLF’s public interest programs. The Foundation litigates across the country before state and federal courts and administrative agencies. WLF represents only those who are otherwise unable to retain counsel on their own. Its clients have included numerous patients and patient-advocacy groups who have turned to WLF for assistance when government bureaucrats denied them adequate health care and access to health care information.
A. Protecting the First Amendment

Some bureaucrats argue that health care decisions should be dictated by providers and
government officials because most consumers cannot begin to understand treatment issues. WLF
takes the opposite approach. It believes that providing consumers with unlimited access to
accurate medical information vastly improves health care delivery. Accordingly, WLF has worked
tirelessly over the past decade to eliminate government restrictions on dissemination of truthful
medical information. WLF has worked to lift advertising restrictions, regulations that prevent
dissemination of information on off-label uses of FDA-approved products, overly strict rules
governing product labeling, and rules that limit discussions at Continuing Medical Education
(CME) events.

District Court for the District of Columbia against federal Medicare officials at CMS (the federal
Centers for Medicare and Medicaid Services), alleging that CMS is trampling on First Amendment
rights in seeking to suppress truthful speech regarding insurance coverage available to senior
citizens under Medicare Part D. Part D is the recently enacted Medicare program that offers
insurance for the cost of prescription drugs. WLF filed suit on behalf of senior citizens who, as
a result of CMS's actions, are unable to obtain accurate information about competing insurance
providers. The suit seeks an injunction against continuation of CMS's policy. Ironically, the
groups that CMS bars from providing truthful information — including nursing homes and
pharmacies — are often the very groups that have the most knowledge regarding the health care
needs of Medicare recipients. The case is in the discovery phase; WLF is in the midst of taking
the sworn deposition testimony of various CMS officials. WLF expects to go to the district judge
this fall and ask for a permanent injunction against CMS speech restrictions.

Washington Legal Foundation v. Henney. On February 11, 2000, the U.S. Court of
Appeals for the District of Columbia Circuit dismissed FDA's appeal from a district court decision
that struck down FDA regulations that severely restricted the flow of truthful information
regarding off-label uses of FDA-approved drugs and medical devices. The decision was a major
victory for WLF in its long-running battle against FDA speech restrictions; WLF had filed suit
against FDA in 1994, after FDA rejected a 1993 WLF Citizen Petition that asked that the
regulations be lifted. In 1998 and 1999, the district court ruled that the regulations violated the
First Amendment rights of consumers who wished to learn truthful information about off-label
product uses that are widely accepted within the medical community as safe and effective. As a
result of WLF's victory, FDA has not initiated enforcement actions against any of the
manufacturers who have exercised their First Amendment rights by distributing peer-reviewed
journal articles that discuss off-label uses of their products.

"DDMAC Watch." In June 2005, WLF inaugurated its "DDMAC Watch" program,
designed to monitor federal regulation of prescription drug advertising. WLF has determined that
FDA, acting through its Division of Drug Marketing, Advertising, and Communications
(DDMAC), has been using letters to industry to advance questionable legal theories and request
remedial actions that the agency could not require under law. Under the DDMAC Watch program,
when DDMAC sends a letter to a drug company employing theories that are legally deficient or
ill-advised, WLF will immediately send back a response letter to DDMAC identifying the specific
ways in which this is so. The goal of the program is to alert the press and public to abuses occurring at DDMAC. As of June 2007, WLF has responded to 47 letters from DDMAC and related agencies. Those letters were sent to Eli Lilly, Endo Pharmaceuticals, MedImmune Vaccines, Dutch Ophthalmic USA, Hoffman LaRoche, Abbott Laboratories, Pfizer, Pharmaceuticals US, SuperGen, Allergan, Alcon Research, Nephrix, ISTA Pharmaceuticals, GenTrac, Medicis Pharmaceuticals, Sanky Pharma, Duramed Pharmaceuticals, Biogen Idec, Mayne Pharma (USA), ZLB Behring, Palatin Technologies, InterMune, VaxGen, Bioniche Pharma Group, Sandoz, BIPI, Wyeth Pharmaceuticals, PrimaPharm, GlaxoSmithKline, Eli Lilly, Astellas Pharma US, Reliant Pharmaceuticals, Mallinckrodt, Alcon, 3M Pharmaceuticals, DSI, WellSpring Pharmaceutical, MGI Pharma, Cephalon, Takeda Pharmaceuticals, Alcon Laboratories, DUSA Pharmaceuticals, Schering, GlaxoSmithKline, KV Pharmaceutical, Enzon Pharmaceuticals, and Allergan. On August 7, 2006, WLF issued its first annual DDMAC Watch report, in which it outlined trends regarding DDMAC abuses; the report asserted that the repeat nature of some DDMAC enforcement activities establishes that DDMAC has adopted de facto regulatory policies by means of its letters.

**IMS Health v. Ayotte.** On April 30, 2007, the U.S. District Court for the District of New Hampshire broadly protected First Amendment rights by striking down a New Hampshire law that blocked access to critical health care information. The law criminalized the collection and disclosure of information about the prescribing practices of physicians. The decision was a victory for WLF, which filed a brief in the case. WLF argued that the New Hampshire law violated the First Amendment by prohibiting disclosures of truthful information, even disclosures arising outside the context of advertising. The district court agreed with WLF that such prohibitions are impermissible where, as here, they do not directly advance any substantial government interest and/or are broader than necessary to advance such interests. New Hampshire has appealed the decision. WLF has pledged to continue its support to the challenge to the law.

**Physician Comm. for Responsible Medicine v. General Mills.** On April 4, 2007, WLF filed a brief in the U.S. Court of Appeals for the Fourth Circuit in Richmond, urging the court to uphold the dismissal of a lawsuit by animal rights activists who are seeking to stop advertisements being run by the milk industry. WLF argued that the suit threatens to undermine manufacturers’ commercial speech rights. WLF argued that if a manufacturer can be subjected to expensive lawsuits filed by activists who do not like statements the manufacturer makes on issues of public importance, then significant amounts of truthful speech will be chilled as manufacturers become increasingly unwilling to comment on such issues. The suit targets a recent milk industry advertising campaign that advocates increased consumption of dairy products as a method of losing weight. The Physicians Committee for Responsible Medicine (PCRM) challenges the validity of the scientific studies that form the basis for the industry’s advertising. PCRM argues that the weight-loss claim is false and violates Virginia’s consumer protection and false advertising laws. Their principal request is that the court issue an injunction against any further promotion of the weight-loss claims. WLF argued that Virginia law does not permit individuals to obtain injunctions against speech. WLF also argued that such suits raise serious First Amendment issues because of their potential to chill truthful speech on issues of public importance, such as whether increases in consumption of dairy products are good for one’s health. WLF also filed a brief in the district court in 2005, urging dismissal; WLF earned a major victory in November 2006 when the district court dismissed the case.
Preserving Direct-to-Consumer Advertising of Prescription Drugs. On November 2, 2005, WLF Chief Counsel Richard Samp testified before an FDA panel in support of expanding the rights of pharmaceutical companies to engage in direct-to-consumer (DTC) advertising. Samp asserted that FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC) needs to rein in its efforts to suppress advertising, and step in only when advertisements are likely to mislead consumers. When FDA announced that it would be holding hearings on November 1 and 2, 2005, its announcement suggested that FDA is considering moving in the other direction and imposing additional restrictions on advertising. Many hearing witnesses called for severely limiting drug ads, calling them inherently biased and misleading. WLF’s Samp countered that DTC advertising has played a vital public health role in recent years by increasing consumer awareness of treatment options.

Legislation Proposing 2-Year Moratorium on Direct-to-Consumer Advertising of Prescription Drugs. On April 20, 2007, at the request of U.S. Senator Richard Burr, WLF submitted to the Senate a legal analysis of the constitutionality of proposed legislation that would prohibit direct-to-consumer advertising of prescription drugs within the first two years after a drug first receives FDA approval. WLF’s analysis concluded that the legislation violates the First Amendment because Congress cannot demonstrate that the ad ban would achieve the goal of protecting public health and safety or that it would do so in a narrowly tailored manner. Thanks in part to WLF’s arguments, the Senate ultimately deleted the ad ban from its FDA legislation.

United States v. Caputo. On January 16, 2007, WLF filed a brief in the U.S. Court of Appeals for the Seventh Circuit in Chicago, urging it to overturn the criminal convictions of business executives alleged to have promoted an FDA-approved medical device for an off-label use (that is, a use not strictly conforming to the uses specified on the FDA-approved labeling). WLF argued that the First Amendment broadly protects the rights of individuals to speak truthfully about off-label uses of FDA-approved products. The government has alleged that some statements made by the defendants were false. But WLF argued that because the jury returned a general verdict against the defendants and thus might have voted to convict on the basis of their truthful statements, the conviction cannot not be allowed to stand. WLF also argued that by prosecuting those engaged in such speech, the federal government is significantly hindering health care delivery in this country, because off-label use is often standard-of-care medical practice.

Fullerton v. Florida Medical Association. On July 11, 2006, the Florida District Court of Appeal reinstated a defamation lawsuit filed by a doctor against the Florida Medical Association (FMA) and several other doctors, based on the defendants having instigated professional peer review of the plaintiff’s expert testimony in a medical malpractice suit. The defendants had begun their investigation because they did not believe that the opinions expressed by the plaintiff’s doctor in his expert testimony demonstrated professional competence. The decision was a setback for WLF, which filed a brief in the case, urging that the trial court’s dismissal of the case be upheld. WLF argued that both Florida law and a federal statute (the Health Care Quality Improvement Act of 1986) provide immunity from money damages to doctors who criticize their peers in connection with peer review proceedings. In reinstating the defamation lawsuit, the appeals court ruled that immunity extends only to complaints regarding a doctor’s competence in treating an actual patient, not to competence in expert testimony. The physician who brought the case, Dr. John Fullerton, had testified in an earlier, unsuccessful medical malpractice action. After the conclusion of that
action, the doctors against whom Dr. Fullerton had testified wrote a letter of complaint to the FMA in 2003, alleging that his testimony was false and financially motivated. They further requested an investigation of Dr. Fullerton’s testimony. That letter is the basis of the present lawsuit.

Oversight of Criminal Investigations into Improper Drug Promotion. On March 24, 2005, WLF filed a petition with the U.S. Department of Justice (DOJ), urging DOJ to remove the Office of Consumer Litigation (“OCL,” a branch of DOJ located within the Civil Division) from its oversight and supervisory role in criminal cases arising under the Food, Drug, and Cosmetics Act (FDCA) involving alleged improper promotion of pharmaceuticals and medical devices. WLF charged that OCL has failed in that role and has done little to develop a coherent federal government policy regarding when such criminal investigations are warranted. WLF said that OCL has simply rubber-stamped whatever criminal investigation local U.S. Attorney Offices have sought to initiate. WLF asked that the coordination role be reassigned to an office within DOJ’s Criminal Division, which has far more expertise and experience in addressing the issues inherent in any criminal investigation. WLF said that it is particularly concerned about the need for effective DOJ coordination in this area because criminal investigations of promotional activities have the potential to adversely affect the nation’s health care delivery system.

In re: ACCME Restrictions on Continuing Medical Education. On January 29, 2003, WLF filed comments with the Accreditation Council for Continuing Medical Education (ACCME), severely criticizing the ACCME for its proposal to impose draconian restrictions on who may speak at CME activities. WLF argued that the proposed restrictions are an unwarranted infringement on free speech rights. Current ACCME standards are designed to ensure unbiased CME presentations by, among other things, requiring speakers to disclose whether they have received any funding from the manufacturer of any of the drugs being discussed. The proposed standards go considerably further: they would altogether prohibit doctors who have been compensated by a pharmaceutical company from speaking at a CME activity. WLF noted in its comments that most of the top medical authorities in the country are employed in some capacity by one or more of the country’s drug companies and thus would no longer be permitted to participate in CME events. Without the participation of top doctors, CME would no longer be the important source of new medical information that it is today, WLF argued. WLF attorneys repeated their criticisms of the proposed restrictions at several well-attended ACCME-related forums in 2003. The revised ACCME rules became final and took effect in late 2004. While not as objectionable as earlier drafts, the final rules continue to be a significant obstacle to the open dissemination of truthful speech. WLF continues to speak out against the rules.

Challenge to Celebrex Advertising. On April 17, 2007, WLF filed comments with FDA, urging the agency to reject a challenge – filed by Public Citizen Health Research Group – to a direct-to-consumer television advertisement being run by Pfizer, Inc. regarding safe use of the drug Celebrex. Public Citizen charged that the ad was dangerous and misleading because (according to Public Citizen) the ad downplayed health risks associated with use of Celebrex. WLF responded that Public Citizen’s letter was inaccurate and amounted to a dangerous affront to speech rights protected by the First Amendment. WLF stated that the ad provides detailed descriptions of Celebrex’s risks and benefits and thus is precisely the type of commercial speech in which FDA should be encouraging all pharmaceutical companies to engage. WLF noted that the advertisement went out of its way to describe in detail the cardiovascular risks posed by
Celebrex; no consumer seeing the advertisement would fail to understand that such risks are significant. Moreover, rather than suggesting that patients should decide on their own whether the risks of Celebrex outweigh the benefits, WLF noted, the advertisement stated explicitly that the risk/benefit calculation should only be made in consultation with one’s doctor.

"Lean" Labeling. On February 8, 2006, WLF filed comments with FDA supporting the agency’s proposal to expand the allowable nutrition information of certain small-package foods so that manufacturers can label those foods with the word “lean.” WLF argued that the proposed change would assist consumers by providing them with accurate and relevant information and would also expand the market for lean foods.

In re: FDA Request for Comments on First Amendment Issues. FDA has lost several major First Amendment lawsuits in recent years, including WLF v. Henney. FDA responded in 2002 by requesting public input on whether any current FDA policies violate the First Amendment. On September 13, 2002, WLF filed extensive comments, citing a broad array of FDA regulatory activities that violate the First Amendment rights of those seeking to speak truthfully about pharmaceutical products. On October 28, 2002, WLF filed a second round of comments, responding to arguments (made by several U.S. Senators in connection with the initial round of comments) that public health concerns justify exempting FDA from First Amendment constraints applicable to other government entities. WLF criticized the contention of those Senators that consumers are likely to misuse truthful information. FDA has pledged to address these First Amendment concerns but, to date, has established no timetable for doing so.

Citizen Petition Regarding Restrictions on Truthful Speech. Following WLF’s victory in WLF v. Henney (see above), FDA began to suggest that it was not bound by the court's decision in WLF’s favor. FDA issued statements to manufacturers, suggesting that they might be sanctioned for engaging in the types of off-label speech that WLF v. Henney had held to be constitutionally protected. Accordingly, on May 23, 2001, WLF filed a Citizen Petition with FDA, urging the agency to repudiate those statements and to announce that it had lifted restrictions on manufacturers’ rights to disseminate non-misleading information concerning off-label uses of FDA-approved products. WLF argued that by raising the threat of enforcement action against manufacturers that exercise their free-speech rights, FDA was violating the First Amendment rights of manufacturers who wish to speak in a non-misleading manner about off-label uses of their products, and of those who wish to hear such speech. WLF noted that WLF v. Henney had resulted in a ruling that the First Amendment prohibits FDA from restricting manufacturer dissemination of “enduring materials” (medical texts and reprints of peer-reviewed medical journal articles) that discuss off-label uses of FDA-approved products. WLF charged that FDA was flouting that ruling by threatening enforcement action against manufacturers who disseminate enduring materials. FDA’s response to the petition amounted to another WLF victory. Although continuing to argue that the ruling in WLF v. Henney was not as broad as WLF asserted, FDA pledged that in the future (in light of its limited resources) it would not bring enforcement actions based on the types of manufacturer speech described by WLF.

Nike, Inc. v. Kasky. On June 26, 2003, the U.S. Supreme Court decided not to review a California decision that threatens to impose severe restrictions on the right of corporations to speak freely on matters of public importance— including drug companies seeking to speak truthfully
about off-label uses of their products. The Court in January 2003 agreed to review the case but five months later changed its mind and dismissed as “improvidently granted” its original order granting review. In two separate briefs filed in the case, WLF argued that the California court effectively held that all corporate speech – even speech on matters of great public importance – is entitled to reduced levels of First Amendment protection. WLF argued that the decision is contrary to a long line of Supreme Court decisions and threatens to chill significant amounts of speech by corporations.

**Investigating Efforts to Evade WLF Courtroom Victory.** Although WLF established in *WLF v. Henney* (see above) that the First Amendment protects the right of drug manufacturers, in certain instances, to disseminate truthful information about off-label uses of their products, WLF has become increasingly concerned that various federal officials are seeking to evade that decision. In particular, the United States Attorney’s office in Boston has threatened criminal prosecution of companies that disseminate truthful off-label information, while other federal officials have indicated that such conduct may violate the federal False Claims Act or the anti-kickback statute. WLF in December 2003 began an investigation into whether such federal officials are violating the terms of the injunction entered in *WLF v. Henney*. That investigation includes a series of document requests (pursuant to the Freedom of Information Act) directed to (among others) FDA and the Office of Inspector General of the U.S. Department of Health and Human Services. WLF has also asked a number of pharmaceutical companies to share with WLF their experiences in such investigations. WLF hopes that it can gather enough information to determine whether actions by federal officials are sufficient to constitute a policy of suppressing constitutionally protected speech.

**WLF Petition Regarding Direct-to-Consumer Advertising of Prescription Drugs.** In 1997, FDA adopted substantial revisions to its direct-to-consumer advertising policy. FDA’s action was in direct response to WLF’s July 20, 1995 Citizen Petition that sought relaxation of FDA restrictions on prescription drug advertising. The petition argued that those restrictions violated the First Amendment rights of drug manufacturers to convey truthful information to consumers, as well as the rights of consumers to receive such information. In particular, WLF asked FDA to eliminate: (1) the “brief summary” requirement, which often renders advertising non-cost-effective by requiring hundreds of words to be added to advertising; (2) the “fair balance” requirement, a totally subjective requirement that permits FDA to reject any advertisement it does not like; and (3) the requirement that advertisements be submitted to FDA for preclearance before being published. FDA’s new policy substantially relaxed the “brief summary” requirements with respect to broadcast advertising. The result of that change is that television advertising of prescription drugs has increased substantially over the past eight years, and consumers have received significantly more information about these products. In November 2005, FDA conducted hearings to investigate the pros and cons of direct-to-consumer advertising; testimony from WLF attorneys pointed out the tremendous benefits that such advertising provides for consumers.

**Labeling of Soda Containers.** On December 16, 2005, WLF filed comments with FDA, urging the agency to reject a petition filed by the Center for Science in the Public Interest (CSPI), a Washington, D.C. based activist group founded by Ralph Nader, that would require warning labels on non-diet soda cans and bottles advising consumers, among other things, that “drinking too much soft drinks may contribute to weight gain.” WLF argued that such warning labels are
not mandated by law and, as a matter of public policy, are unnecessary since current labels on all beverages provide caloric content, sugar content, and other nutritional information to help consumers make informed choices.

**Opposing Regulation of Internet.** On November 10, 2001, FDA responded to an April 12, 2001 WLF Citizen Petition that urged the agency to adopt a rule or policy that would make it clear that health claims and other consumer information that appear on a company's website do not constitute "labeling" of that company's product, and thus, are not subject to FDA's stringent and detailed food and drug labeling requirements. Rather, any such promotional information should be regarded, at best, as advertising, and thus subject in certain circumstances to review by the Federal Trade Commission (FTC) under its "false and misleading" advertising standard. The FTC standard is more consistent with First Amendment protections of commercial speech than FDA labeling requirements. WLF's filing was prompted by an alarming FDA Warning Letter sent to Ocean Spray Cranberries, Inc. on January 19, 2001, the last day of the Clinton Administration. FDA claimed that Ocean Spray's cranberry and grapefruit juices were "misbranded" and subject to seizure simply because of certain health claims and other information that appeared on the company's website and related links. In its response to WLF's petition, FDA indicated that it would not be issuing an across-the-board regulation at this time, but that it would not generally regard a company's website content as labeling if the company does not sell products online.

**Petition Regarding Disclosure of Clinical Trial Results.** On December 28, 1995, WLF filed a joint petition for rulemaking with FDA and the Securities and Exchange Commission (SEC), urging FDA to exempt from FDA regulation the public disclosure of clinical test results of Investigational New Drugs (INDs). Such information is required by SEC rules to be disclosed to the investment community. Current FDA rules and policies prohibit drug companies from "promoting" or "commercializing" an IND until the drug obtains final approval. Yet the SEC requires that drug companies file reports with that agency and inform the investment community of major product developments. FDA has interpreted its rule against "promoting" an IND to include press releases and other communications made by companies regarding the results of clinical tests of INDs. FDA has not taken any decisive action on this issue, and WLF continues to press for relaxation of speech restrictions in this area. WLF argues that investors need to receive truthful information about drugs in "the pipeline" if they are to measure accurately the value of a pharmaceutical company's stock.

**Proposal Regarding Trans Fatty Acid Nutrition Labeling.** On March 27, 2003, WLF filed comments with FDA, objecting to its proposal to require all food containing trans fatty acids (trans fat) to include on its label the following statement: "Intake of trans fat should be as low as possible." WLF argued that requiring that statement would violate the First Amendment protection against compelled speech. WLF argued that although the First Amendment permits the government to compel commercial speech when necessary to prevent consumers from being confused or deceived, there is no serious argument that the proposed statement is necessary to prevent food labels from being confusing or deceptive. WLF stated that FDA may do no more than mandate disclosure of the quantity of trans fat contained in each serving of the food being sold. While the proposed statement may contain sound health information, it may unnecessarily alarm consumers; and WLF argued that it is not the role of the government to commandeer the property of others for the purpose of spreading information that may promote public health.
a victory for WLF, FDA announced on July 11, 2003 that it would not require food labels to include the controversial statement.

Defending Corporate Speech on Food Irradiation. On August 7, 2003, WLF filed comments with the Federal Trade Commission, objecting to efforts by activists to censure speech about food irradiation. Two activist groups, Public Citizen and the Center for Food Safety, petitioned the FTC to take enforcement action against Giant Food based on statements Giant made regarding the irradiation of its food products. Giant issued a pamphlet that, in an effort to add to consumers’ understanding of irradiation, compared the irradiation process to milk pasteurization. The activist groups asserted that the law prohibits food sellers from representing irradiated food as “pasteurized.” WLF’s response argued that the comparison of irradiation and pasteurization is not misleading and assists American consumers in understanding that irradiation is a process designed to enhance food safety and cleanliness. WLF argued that the First Amendment protects Giant’s right to make truthful statements regarding the irradiation process.

FDA Proposals to Regulate Food Labeling. WLF has long been at the forefront of efforts to ease FDA regulation of food labeling. For example, in a series of submissions to FDA in the early 1990s, WLF urged FDA to lift the ban on health-related information and certain types of pictures on food labels. The ban on health-related information eventually was lifted by Congress, and WLF has worked to ensure that the new legislation is being fairly administered.

Novartis Corp. v. Federal Trade Commission. On August 18, 2000, the U.S. Court of Appeals for the D.C. Circuit upheld an Federal Trade Commission order requiring Novartis Corp., a pharmaceutical company, to include a governmentally-dictated message in its advertising. The court ruled that the First Amendment posed no bar to the FTC’s so-called corrective advertising order. The decision was a setback for WLF, which on October 29, 1999, filed a brief urging the court to set aside the FTC’s order. The case involved an order from the FTC -- which had determined that Novartis’s advertisements for Doan’s Pills had been misleading in suggesting that Doan’s offers more effective relief for back pain than other pain relievers -- directing Novartis to include the following statement in all Doan’s advertising: “Although Doan’s is an effective pain reliever, there is no evidence that Doan’s is more effective than other pain relievers for back pain.” In its brief filed with the court, WLF argued that the FTC’s corrective advertising order ought to be set aside because it violated Novartis’s right not to speak. WLF said that the FTC order was particularly troublesome because the result was that Novartis had refrained from advertising at all rather than conveying the FTC’s “corrective” message.

Draft Compliance Policy Guide on Labeling. On July 23, 1999, WLF filed comments with FDA, opposing its efforts to expand the definition of “labeling” under federal food and drug law. Under FDA’s proposed definition, “labeling” of a drug would have included books and other publications that merely discuss a particular drug, even though that material does not “accompany” the drug as that term is commonly understood and as Congress intended. FDA ultimately abandoned its effort to expand the definition of what constitutes “labeling” of a drug or medical device.

Labeling of Genetically Engineered Products. On March 19, 2001, WLF filed comments with FDA, generally supporting the agency’s proposed guidelines for the labeling of food with
respect to whether it has been developed using biotechnology. WLF strongly supported FDA's tentative decision to continue its policy against mandatory labeling on the subject; WLF noted that such labeling does not provide any nutritionally meaningful information. WLF asserted, however, that industry should be afforded broad leeway when it comes to voluntary labeling with regard to bioengineering, because any effort to restrict industry choice significantly would raise major First Amendment issues. WLF asserted that the one area in which FDA restrictions are warranted is the area of health claims; WLF argued that labeling should not be permitted if it suggests that the labeled food is safer based on the presence/absence of genetically engineered ingredients – because there is no sound scientific basis for such claims. FDA ultimately adopted guidelines that closely tracked WLF's suggestions.

Citizen Petition on Pharmacy Compounding. On March 6, 1992, WLF filed a Citizen Petition with FDA, alleging that the agency’s efforts to control advertising by pharmacies regarding their drug compounding capabilities violated the First Amendment, and urging the agency to utilize notice-and-comment rulemaking before adopting new regulations on that subject. FDA failed to heed WLF's warnings; the result was the U.S. Supreme Court's 2002 decision in Thompson v. Western States, which struck down on First Amendment grounds FDA’s efforts to regulate advertising regarding pharmacy compounding of drugs.

FDA Draft Guidance on Medical Product Promotion. On April 6, 1998, WLF filed comments expressing its deep reservations regarding FDA's Draft Guidance regarding “medical product promotion by health care organizations or pharmacy benefits management companies.” WLF argued that FDA failed to demonstrate any need for the guidance and that it would have an adverse impact on health care. WLF also argued that FDA lacked statutory authority to issue the guidance and that it infringed the First Amendment rights of drug companies, doctors, and consumers. WLF requested that FDA withdraw the Draft Guidance and not issue it in final form. In light of intense opposition, FDA placed the proposal on hold in July 1998 and has taken no further action.

B. Excessive FDA Caution

FDA often has exhibited excessive caution when it comes to the review and approval of new life-saving therapies. The source of that excess caution is easy to understand: government bureaucrats are fearful that they will be held responsible if they approve a product that later turns out to have adverse health effects. But as WLF has repeatedly pointed out, excessive caution by government regulators often leads to thousands of needless deaths; patients who could have been saved by a new therapy end up dying while they wait years for the new therapy to win FDA approval. WLF has worked tirelessly to ensure that FDA officials do not unnecessarily delay their review of products for safety and effectiveness. WLF recently won a major lawsuit against FDA for failing to permit the marketing of promising (but as-yet not-fully-approved) drugs to terminally ill patients who lack effective alternative treatments.

Abigail Alliance for Better Access to Investigational Drugs v. von Eschenbach. In a major victory for WLF, the U.S. Court of Appeals for the District of Columbia Circuit ruled on May 2, 2006 that terminally ill patients have a “fundamental right” – protected by the U.S. Constitution
– to have access to experimental drugs that have not yet been fully approved by the Food and Drug Administration. The decision is the culmination of a three-year WLF effort to overturn FDA policies that deny such access. WLF filed suit against FDA in 2003 on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a patients’ rights group. The district court dismissed the suit, ruling that the Constitution imposes no barriers to FDA efforts to regulate the treatment decisions of terminally ill patients and their doctors. WLF appealed from that decision. The appeals court reversed, ruling 2-1 that once FDA has determined, after Phase I trials, that a potentially life-saving investigational new drug is sufficiently safe for expanded human trials, terminally ill patients have a constitutional right to seek treatment with the drug if there are no other FDA-approved drugs available to the patient. The court held that the Fifth Amendment’s Due Process Clause encompasses a right, recognized throughout American history, of all individuals facing terminal illnesses to make fundamental decisions regarding whether or not to seek medical treatment. The court said that if FDA wishes to prevent such patients from gaining access to investigational drugs that have completed Phase I trials, it bears the burden of demonstrating that its restrictions are “narrowly tailored” to serve a compelling governmental interest. In November 2006, the court agreed to rehear the case in front of all 10 judges who sit on the court. Oral arguments on the rehearing were held on March 1, 2007; WLF is awaiting a decision.

**In re Tier 1 Initial Approval.** In light of the continuing failure of FDA to allow terminally ill patients to obtain promising new drugs in a timely manner, WLF filed a Citizen Petition with FDA on June 11, 2003, seeking faster drug availability for these patients. As in its lawsuit, WLF is representing the Abigail Alliance for Better Access to Developmental Drugs, a Virginia-based group of terminally ill patients and parents of terminally ill patients who have tried and failed to obtain access to drugs that are tied up in FDA’s approval process (see above). WLF’s petition urges the adoption of a preliminary approval program, “Tier 1 Initial Approval,” that would make promising new drugs available to patients with life-threatening illnesses while clinical trials and FDA reviews are underway. The petition shows in detail that such a program is within FDA’s statutory authority and does not require new legislation – contrary to past contentions by FDA staff. WLF wrote to the new acting FDA commissioner on April 16, 2004, to urge prompt action on the issue.

**Washington Legal Foundation v. Shalala.** In the early 1990s, FDA adopted a policy that imposed virtually insurmountable roadblocks in the path of cardiac patients who sought human-tissue heart valve transplant surgery. Although human-tissue heart valve surgery had been widely performed since the early 1960s, FDA suddenly decided for the first time that such valves were subject to FDA regulation, and a multi-year review process was imposed before FDA would consider approving use of what FDA now deemed a “medical device.” The effect of that decision was to render such surgery unavailable to all but the wealthiest Americans. Infant children were most directly affected by the policy, because they did not have available to them any equally effective, alternative procedures. On May 20, 1992, WLF filed a Citizen Petition with FDA, asking that its new policy be rescinded. WLF filed the petition on behalf of itself, two patients in need of heart valve implant surgery, and three of the nation’s leading heart surgeons – Dr. Robert B. Karp of the University of Chicago, Dr. Richard A. Hopkins of Georgetown University, and Dr. A.D. Pacifico of the University of Alabama at Birmingham. After FDA denied WLF’s petition in 1993, WLF filed suit on behalf of its clients in federal court in the District of Columbia,
challenging FDA’s new policy as a violation of federal law. WLF won a huge victory in the case in 1994 when FDA abandoned its controversial policy. FDA’s sudden policy shift was prompted by WLF’s suit and a related suit in Chicago; FDA acted only after it realized, based on preliminary rulings, that it faced near-certain defeat in court.

**Petition to Stop FDA Regulation of Clinical Labs.** On September 28, 2006, WLF filed a Citizen Petition with FDA, calling on the agency to cease its efforts to enforce its “medical device” regulations against clinical laboratories that provide physicians with in-house developed and validated tests used to assist in making diagnoses and in developing treatment regimens. WLF’s Citizen Petition asserted that FDA lacks statutory authority to regulate tests developed by laboratories for their own use and offered only to health care professionals. WLF noted that clinical labs have long been subject to regulation by another federal agency – the Centers for Medicare and Medicaid Services (CMS) and its predecessors – pursuant to the Clinical Laboratory Improvement Amendments (CLIA). WLF argued that FDA enforcement efforts could undermine effective health care by crippling these labs’ ability to quickly develop tests – e.g., for new or rapidly mutating infectious diseases. On February 8, 2007, WLF’s Richard Samp testified at an FDA hearing looking into this issue. WLF filed follow-up comments with FDA on March 5, 2007. FDA has not yet determined how closely, if at all, it intends to regulate clinical labs.

**FDA Regulation of ASRs.** On March 5, 2007, WLF filed formal comments with FDA, calling on the agency to withdraw a draft guidance document that seeks to impose additional layers of regulation on manufacturers of analyte specific reagents (ASRs). WLF argued that FDA’s proposed regulatory activity violates FDA’s statutory mandate, the Administrative Procedure Act (APA), and the First Amendment. FDA’s guidance document, issued in September 2006, would impose significant new burdens on manufacturers who supply ASRs to clinical labs. FDA asserted that the draft guidance document merely clarified existing regulations. WLF disputed that assertion and argued that FDA may not adopt such major changes without complying with the APA’s rulemaking requirements.

**Approval of Silicone Gel-Filled Breast Implants.** On March 28, 2005, WLF filed comments with FDA’s Medical Devices Advisory Committee, charging that FDA denial of premarket applications (PMAs) submitted by two companies seeking permission to market silicone gel-filled breast implants would violate clearly established rules governing administrative procedure. WLF stated that the Administrative Procedure Act (APA) prohibits FDA from imposing (as it has contemplated doing) far stricter approval requirements on silicone breast implants than it has imposed on similar medical devices. FDA indicated that it wanted Mentor and Inamed (the two manufacturers) to provide ten years of data regarding the health consequences of breast implant failure (particularly rupture). Both PMAs include at least three years of post-implant data on the large number of women included in Mentor’s and Inamed’s studies. Were FDA to require long-term post-implant follow-up data, Mentor and Inamed would not be able to gain approval of their PMAs for many years to come. WLF charged that the APA prohibits FDA from imposing long-term pre-approval data requirements on the silicone breast implant PMAs, given that FDA has never previously imposed such requirements on similar medical devices. WLF Chief Counsel Richard Samp later elaborated on WLF’s charges during testimony given to an FDA panel on April 11. On October 11, 2005, WLF reiterated those same arguments in a brief to FDA that responded to a petition from Public Citizen and others that urged rejection of the
PMAs. In November 2006, FDA gave final approval to both PMAs.

*Emergency Approval of Medical Products.* On September 6, 2005, WLF filed comments in support of FDA’s issuance of guidance on emergency approval of medical products. Congress has given FDA authority to allow the use of unapproved medical products, or to authorize unapproved uses of an approved product, in response to a heightened risk of attack from biological, chemical, radiological, or nuclear weapons. While expressing its support, WLF expressed concerns regarding the preemption aspects of the proposal. WLF argued that those provisions should be clarified to establish that the preemptive effect of an emergency authorization covers labeling matters and tort liability. WLF’s comments noted that the emergency powers created by Congress to protect the public health would be frustrated by assertions of state or local authority in either of these areas - either to establish contrary or supplemental labeling requirements or to impose tort liability where a manufacturer is acting in compliance with an emergency use authorization.

*Restriction on Lung Cancer Drug.* On July 25, 2005, WLF filed comments with the Food and Drug Administration asking the agency to withdraw or modify its order for the restrictive labeling of the lung cancer drug Iressa. FDA’s action effectively limits the use of Iressa in the United States to the approximately 4,000 patients already being treated with it. WLF’s comments argued that this limitation on the availability of Iressa is unjustified and will harm lung cancer patients in the future who have no other approved treatment options and who may benefit from this medicine. WLF previously filed comments on April 20, 2005 with FDA opposing a petition from Public Citizen, Inc., in which Public Citizen sought the immediate withdrawal of Iressa.

*Regulation of Pain Medication.* On March 21, 2005, WLF filed formal comments with the Drug Enforcement Administration (DEA), urging that DEA regulation of pain medication not create a risk of denying needed pain medicines to terminally ill patients and chronic pain patients. In response to DEA’s plan to issue new guidance regarding dispensing of controlled substances, WLF emphasized the importance of granting physicians leeway in treating bona fide pain patients, and stated that physicians should not be at risk of prosecution unless they distribute or prescribe controlled substances to a person outside the scope of legitimate practice. In separate comments filed the same day, WLF also expressed concern that DEA’s new mandate to withhold approval for procurement of controlled substances used in the production of pain medicines not be used by DEA to second-guess FDA approval decisions. WLF argued that DEA’s role in this regard is advisory and that Congress has vested drug approval authority with FDA.

*WLF Advertising Campaigns.* In combating excessive FDA caution, WLF has not confined its efforts to litigation and publishing. WLF has also undertaken numerous advertising campaigns designed to focus public attention on FDA’s shortcomings. When 1994 studies showed that FDA’s delays had led to a record backlog of products awaiting approval, WLF sought to publicize those delays by launching a major public relations campaign that featured six different advertisements in the national editions of the *Wall Street Journal, USA Today, The Washington Post, The New York Times,* and *National Journal.* The advertisements were widely praised for their effectiveness, each winning a prestigious Addy Award in 1995. WLF’s work was widely credited with forcing FDA to streamline its product approval process and also brought the issue to the attention of major decision makers in government. Congress subsequently adopted major reform
legislation in 1997.

**Financial Disclosures by Investigators Conducting Clinical Studies.** On December 21, 1994, WLF filed with FDA its opposition to FDA’s proposal to require detailed disclosure of financial interests that could potentially bias the outcome of clinical trials. WLF argued that this proposal would needlessly complicate and slow the product-approval process, because there was no evidence of such bias in any clinical trials, yet the burdensome nature of these disclosure and reporting requirements would force some leading doctors simply to forgo participation in clinical trials. Despite WLF’s strong opposition, FDA adopted this proposal on February 2, 1998. WLF continues to agitate for repeal of this unnecessary and counter-productive regulatory requirement.

**CFC-Containing Inhalers.** On May 5, 1997, WLF filed comments with the FDA opposing any effort to ban the use of Chlorofluorocarbon (CFC) propellants in self-pressuring containers that are used by asthmatics. FDA had proposed such a ban because it feared that the propellants might be damaging the earth’s ozone layer and believed that such propellants were no longer essential. WLF supported the position taken by the Allergy and Asthma Network and Mothers of Asthmatics organizations that such inhalers should not be banned in the absence of an effective alternative, especially in light of EPA’s current proposal to limit ozone levels in the name of asthmatics. FDA delayed making its proposal final; when it eventually issued a new proposed rule on July 24, 2002, the proposal was far less objectionable to asthmatics.

**Waiver of FDA Regulations for Operation Desert Storm.** On January 22, 1991, WLF petitioned FDA to permit the waiver – in connection with military operations in the Persian Gulf – of regulations prohibiting the administration of certain drugs without the informed consent of the recipient. WLF argued that military necessity required granting the waiver; WLF argued that the effectiveness of military units could not be assured unless all soldiers in those units were inoculated against possible biological attack. WLF noted that the drugs in question had been determined to be safe. FDA ultimately granted the waiver.

**C. Opposing Interference with the Free Market**

WLF believes that the best way to ensure an adequate supply of medical products and services is to allow the free market to decide how to price such products and services. The experience in Canada (where widespread government intervention in the market has led to product shortages, long waiting lists for surgery, and patients crossing into the United States in search of high-quality health care) well demonstrates the folly of price controls. Nonetheless, a number of States in recent years have reacted to increases in health care costs by seeking to impose price controls, particularly with respect to prescription drugs. WLF has gone to court repeatedly to challenge such efforts. WLF has filed its court papers on behalf of a broad coalition of patients'-rights groups that have seen first-hand the damage caused by price-control efforts: the Kidney Cancer Association, the Allied Educational Foundation, the Seniors Coalition, the International Patient Advocacy Association, and the 60 Plus Association. WLF has also opposed proposed federal initiatives — designed to cut costs — whereby the federal government would deny Medicare patients coverage for expensive but life-saving drugs which their doctors have prescribed for them, and would divert funds raised through “user fees” (ostensibly imposed to cover costs associated
with product approval reviews) to cover routine FDA expenditures.

**Biotechnology Industry Organization v. District of Columbia.** On December 29, 2006, WLF filed a brief in the U.S. Court of Appeals for the Federal Circuit, urging it to protect critical drug research by striking down a District of Columbia law that imposes strict price controls on prescription drugs still covered by a patent. WLF argued that the law is preempted by federal patent laws because it interferes with the objective Congress sought to achieve in adopting the patent laws – namely, to encourage innovation by rewarding those who expend the resources necessary to develop new products. WLF also argued that the law would have devastating long-term adverse effects on health care. WLF argued that price controls on drugs stifle research, with the inevitable result that fewer life-saving drugs will be developed. Drug companies will be unwilling to invest the massive sums necessary to develop new drugs if price controls deprive them of any assurance that they can recover those costs under the patent system, WLF argued. The case involves D.C.’s Prescription Drug Pricing Act of 2005, which prohibits sales of patented prescription drugs at an “excessive price.” The D.C. Act provides that a prima facie case of excessive pricing can be established “where the wholesale price of a patented prescription drug” sold in D.C. is “30% higher than the comparable price” in either the United Kingdom, Germany, Canada, or Australia. It permits any citizen who feels aggrieved by the price charged for drugs to file suit against the drug manufacturer as a private attorney general. A federal district judge struck down the Act on preemption grounds; WLF urged that that decision be affirmed. The D.C. Circuit heard oral arguments in the case on April 4, 2007.

**Pharmaceutical Research and Manufacturers of America [“PhRMA’”] v. Walsh.** On May 19, 2003, the U.S. Supreme Court declined to strike down a Maine law that imposes strict controls on the price of all prescription drugs sold there. The decision was a setback for WLF, which filed a brief arguing that the price control scheme is void because it conflicts with federal laws regulating the sale of drugs. The Court held that the challenge to the Maine law was premature, because the program has not been operating long enough to allow a determination whether (as alleged by WLF) the price controls are reducing Medicaid recipients’ access to life-saving drugs. The Court also stated that it was reluctant to strike down the Maine law in the absence of a ruling by federal officials that the Maine law conflicts with federal law. Such a ruling is a distinct possibility, because the federal government filed a brief with the Supreme Court asking that the Maine law be struck down. The Court remanded the case to the trial court and indicated that, on remand, the law should be struck down unless Maine can demonstrate that its program in some way serves the Medicaid law’s purposes.

**Regulation of Pain Medication Prescriptions.** On November 6, 2006, WLF filed formal comments with the Drug Enforcement Administration (DEA), urging DEA to make final its proposed rule regarding issuance of multiple prescriptions for Schedule II Controlled Substances. WLF stated that the proposed rule was an important first step in addressing a serious health care problem in this country: the underutilization of pain medication. WLF said that it understood the need for DEA to provide careful controls over potentially dangerous and addictive medications. At the same time, WLF argued, unless the need for controls is balanced with the need to provide ready access to those with a genuine medical need, health care will suffer. WLF argued that the proposed rule – by permitting prescriptions of pain medications to be refilled under some circumstances without the need for the patient to make a separate visit to his or her doctor, thereby
cutting down on medical costs – takes a significant step toward bringing those competing interests into a proper balance.

**PhRMA v. Thompson.** On December 23, 2002, the U.S. Court of Appeals for the District of Columbia Circuit struck down a separate Maine law (not the one at issue in Walsh) that also imposed strict controls on the price of many prescription drugs sold in the State. The decision was a victory for WLF, which filed a brief urging that the law be struck down. The court agreed with WLF that the Maine price control scheme was invalid because it conflicted with federal laws regulating the sale of prescription drugs. The court further agreed that the U.S. Department of Health and Human Services (HHS) acted improperly in approving the Maine program. WLF had noted that although Maine purported to adopt the program pursuant to its authority under the Medicaid law, those covered under the Maine program are moderate income individuals who are too wealthy to qualify for Medicaid.

**PhRMA v. Thompson II.** On April 2, 2004, the U.S. Court of Appeals for the District of Columbia Circuit upheld a Michigan statute that imposes price controls on pharmaceuticals sold to Medicaid recipients in the State. The decision was a setback for WLF, which filed a brief challenging the statute. The appeals court rejected WLF’s argument that the Michigan program is invalid because it conflicts with the federal Medicaid law. While agreeing with WLF that the Medicaid statutes in question could reasonably be interpreted as prohibiting the type of price control scheme imposed by Michigan, the court held that Medicaid officials’ contrary interpretation was also plausible and that it was required to defer to those officials’ interpretation of the law. WLF also argued that the program will result in substandard care for Michigan’s poorest citizens, because it will result in their being denied access to essential drugs that the State has deemed too expensive.

**Opposing Unwarranted User Fees.** On December 14, 2005, WLF filed comments with the FDA on the reauthorization of the prescription drug user fee program. WLF warned against abuse of the program. Under the Prescription Drug User Fee Act (PDUFA), sponsors of new drug applications pay user fees to allow FDA to hire more scientific review staff and improve its information technology for the purpose of expediting the new drug review process. In its comments, WLF argued that because PDUFA’s purpose is to accelerate the availability of safe and effective new medicines, PDUFA fees should be expended only on direct application-related costs – not on unrelated costs as FDA officials have suggested. WLF argued that the prescription drug user fee program must not evolve into an industry-specific tax to finance FDA’s normal regulatory and law enforcement activities.

**CMS Proposal On Tying Coverage To Clinical Trial Participation.** WLF filed comments on June 6, 2005, with the Centers for Medicare & Medicaid Services (CMS), the agency of the U.S. Department of Health and Human Services that operates the Medicare program, asking the agency to withdraw its proposal to tie reimbursement for selected new treatments to the patient’s participation in a clinical trial or a similar evidence-gathering process. WLF argued that such requirements may restrict patients’ access to needed care and that CMS has numerous alternative tools with which to spur research. WLF further argued that CMS has not justified such requirements under the Medicare statute’s “reasonable and necessary” provision governing reimbursement.
**Oral Cancer Drug Demonstration Project.** On June 25, 2004, WLF filed comments with the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, regarding the agency's proposed exclusions from a congressionally-mandated Medicare demonstration project known as the “Section 641” demonstration. CMS subsequently announced that it was reversing its decision to exclude all off-label prescriptions from the demonstration, and that it would cover a narrow class of off-label uses – those for which the indication “is being reviewed by the FDA” and for which the FDA has stated that “no filing issues remain.” As an interim measure prior to the implementation of the newly enacted prescription drug benefit in 2006, the demonstration project was to give 50,000 patients access to oral substitutes for drugs that would otherwise have been administered in a doctor’s office. WLF argued that the agency should abandon its proposal to exclude off-label uses of drugs from the project because that exclusion would harm patients’ health and violate congressional intent.

**CMS Guidance on “Part D” Drug Formularies.** On August 19, 2005, WLF filed comments with the Centers for Medicare & Medicaid Services, asking the agency to withdraw its plan to allow the exclusion of the lung cancer drug Iressa from drug plans under the new “Part D” prescription drug benefit. WLF’s comments are in response to a CMS decision to exclude Iressa from a requirement that carriers offering coverage under the new benefit program must include in their formularies “all or substantially all” cancer drugs. WLF noted that Iressa is believed to represent the best available care for many lung cancer patients in the Medicare population for whom other therapies have failed.

**Coverage of Cancer Drugs.** On February 10, 2004, WLF filed a petition with CMS, asking the agency not to terminate coverage of “off-label” uses of certain cancer drugs. The petition was in response to national coverage reviews in which CMS is considering whether to end those reimbursemens. In the petition, WLF noted that off-label prescribing – that is, a physician’s use of a drug for conditions other than the specific ones for which the FDA has given marketing approval – is common and important to medical practice in obstetrics, pediatrics, and AIDS treatment, as well as cancer treatment. WLF was concerned that a denial of reimbursement for cancer drugs would not only deny the treatments of choice to thousands of dying cancer patients, but would set a precedent for denying proper treatment to other patients.

**PhRMA v. Medows.** On May 27, 2003, the U.S. Supreme Court declined to review a decision that upheld a Florida statute that imposes strict price controls on prescription drugs sold to Medicaid recipients in the State. WLF had urged the Court to review the case, arguing that the Florida price control scheme is invalid because it conflicts with federal Medicaid law. WLF also argued that the Florida statute will result in substandard medical care for the State’s poorest citizens, because it will result in their being denied access to essential drugs that the State has deemed too expensive. WLF also filed a brief in the case when it was before the U.S. Court of Appeals for the Eleventh Circuit in Atlanta, which upheld the statute in a September 6, 2003 decision.

**PhRMA v. Michigan Dept of Community Health.** This was a state-court challenge to Michigan’s price control scheme for prescription drugs. On June 27, 2003, the Michigan Supreme Court declined to review a decision that upheld a program that imposes strict price controls on pharmaceuticals sold to Medicaid recipients in the State. The decision was a setback for WLF,
which filed a brief on February 5, 2003, urging that review be granted. WLF argued that the program was invalid because it conflicted with Michigan law and violated separation-of-powers principles of the Michigan Constitution. WLF also argued that the program would result in substandard care for the State’s poorest citizens, because it would result in their being denied access to essential drugs that the State has deemed too expensive. WLF argued that the price control statute was inconsistent with the Michigan Constitution because the Michigan legislature purported to retain a “legislative veto” over any price controls adopted by the Executive Branch – a retention of power that WLF contended violates separation-of-powers principles. WLF also filed a brief in the case when it was before the Michigan Court of Appeals, which issued a decision on December 13, 2002 upholding the program.

Proposal That Prescription Allergy Medications Be Switched to OTC Status. On May 11, 2001, WLF filed comments with FDA, objecting to a proposal that three popular prescription allergy drugs – Allegra, Claritin, and Zyrtec – be switched to over-the-counter (OTC) status over the objections of their manufacturers. WLF renewed its objections in petitions submitted to FDA Commissioner Mark McClellan (on May 13, 2003) and HHS Secretary Tommy Thompson (on October 8, 2003). WLF argued that the proposed switch would undermine the intellectual property rights of the manufacturers of the drugs in question and would have significant adverse effects on health care in this country. WLF noted that FDA to date has never approved a switch to OTC status over the manufacturer's objection. WLF argued that if the switch is approved here, the lesson to be learned by manufacturers is that the financial rewards they heretofore have hoped to gain from the successful development of pioneer drugs can no longer be counted on. The inevitable results will be a reduction in research and development expenditures by major pharmaceutical companies. Such a reduction will have long-term adverse effects on health care, WLF argued.

United Seniors Association, Inc. v. Shalala. In July 1999, the U.S. Court of Appeals for the District of Columbia Circuit ruled that Medicare laws that restrict the right of senior citizens to contract with their physicians do not violate the Constitution. The decision was a setback for WLF, which filed a brief in support of the senior citizens who were challenging the law. WLF argued that Section 4507 of the Medicare laws effectively prohibits seniors from entering into private contracts with their physicians, by requiring physicians entering into such contracts to forgo participation in the Medicare program for two years. WLF argued that the Constitution recognizes an individual’s right to autonomy in pursuit of health, and that that right encompasses selection of a physician and a course of treatment.

D. Exposing FDA Misconduct

The great majority of FDA employees are hard-working and dedicated individuals who act in good faith to improve health care. However, a handful of FDA employees has from time-to-time undermined FDA’s goals by surreptitiously working with plaintiffs’ attorneys whose focus is to earn millions in fee awards by bringing tort suits (usually unwarranted) against the pharmaceutical industry. WLF has worked throughout the past decade to expose such misconduct.

WLF Investigation of Abusive Federal Inspections and Enforcement Actions. In September 2003, WLF launched an investigation of abusive federal agency inspection and
enforcement actions against businesses and individuals. In a series of Freedom of Information Act requests filed with FDA and five other regulatory agencies, WLF demanded that the agencies disclose copies of complaints filed against any enforcement agent, as well as the result of any investigation by the agencies’ Inspector General or similar official. WLF also asked that the agencies disclose any training manuals that disclose enforcement policies. WLF’s probe into agency misconduct was spurred by a number of instances in which enforcement agents harassed and threatened company managers, their employees, and others in the course of investigating suspected violations of agency regulations.

**Improper Contacts with Plaintiffs’ Bar.** Through a series of requests filed under the Freedom of Information Act in the mid 1990s, WLF slowly uncovered a pattern of improper contacts between senior FDA officials and members of the plaintiffs’ bar. The attorneys were seeking to delay FDA-approval of certain medical devices, in hopes of gaining an advantage in pending litigation against several device manufacturers. Documents WLF uncovered led to a formal investigation (by FDA’s Office of Internal Affairs) of Mitch Zeller, a Special Assistant to then-FDA Commissioner David Kessler. Documents uncovered by WLF in July 1997 revealed that Zeller had met with John J. Cummings, the lead plaintiffs’ attorney in pending multi-district product liability litigation against pedicure screw manufacturers. WLF also discovered that Zeller took handwritten notes of that meeting. FDA officials at first denied the existence of those notes, then refused to release all but one page of the notes. In July 1997, WLF appealed FDA’s decision not to release the notes. On April 23, 1998, FDA finally released those notes to WLF.

**Violations of FDA Regulations by Senior FDA Personnel.** After uncovering a meeting between FDA’s Mitch Zeller and senior members of the plaintiffs’ bar (see above), WLF discovered that Zeller never filed an official report of the meeting – as is required by FDA regulations. WLF thereafter filed a complaint against Zeller with FDA’s Office of Internal Affairs (OIA), complaining of Zeller’s misconduct. After conducting a complete investigation, OIA sustained WLF’s charges.

**Petition RegardingLeaks of Confidential Information.** On February 6, 1995, WLF filed a Citizen Petition with FDA, asking the agency to begin cracking down on widespread leaks of confidential information in its possession. WLF asked FDA to establish procedures whereby it would be required to investigate significant unauthorized document disclosures and to punish those found responsible. WLF also asked FDA to establish an office whose purpose it would be to receive complaints regarding unauthorized releases and to track the frequency and patterns of such releases. WLF cited “adverse reaction reports” – reports voluntarily submitted by a manufacturer to FDA in which the manufacturer discloses health problems experienced by a user of its product – as a particular problem area. Much of the information in such reports is supposed to be kept confidential, but such information was regularly finding its way into the hands of plaintiffs’ attorneys. FDA responded to WLF in August 1995, stating that it was taking unspecified steps to address the issue. The problem appeared to abate somewhat in following years, particularly after HHS’s Office of the Inspector General (at WLF’s request) began an investigation of the issue.

**Sofamor Danek Group, Inc. v. Gaus.** On August 4, 1995, the U.S. Court of Appeals for the District of Columbia Circuit ruled that expert panels convened by the Department of Health
and Human Services (HHS) to develop clinical practice guidelines for medical providers did not violate the Federal Advisory Committee Act (FACA) by meeting in secret. The decision was a setback for WLF, which filed a brief arguing that the secret meetings violated FACA. WLF argued that the courts were creating a “giant loophole” in FACA by ruling that a panel of private citizens convened by HHS is not an “advisory committee” (as defined by FACA) when its advice is directed primarily to the private sector rather than to government officials. WLF argued that FACA was intended by Congress to require openness among all advisory groups that are utilized by government officials, regardless whether a group’s advice is also directed to the private sector.

E. Opposing Unwarranted Tort Suits

It has become a mantra of plaintiffs’ lawyers: anyone who suffers any injury deserves to be compensated by one or more deep-pocketed corporations. WLF strongly disagrees and works to ensure that our tort system permits recovery only against the blameworthy. Unfortunately, our health care system is being undermined because the huge liability verdicts being rendered against health care providers and drug manufacturers are discouraging the level of investment – both of money and human resources – necessary to maintain public health. Throughout the past decade, WLF has participated in numerous proceedings in an effort to counteract that trend.

Abdullahi v. Pfizer, Inc. On May 24, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit, urging the court to dismiss claims that a pharmaceutical company violated international law when a team of its doctors provided emergency medical aid to children in Nigeria suffering from meningitis. WLF argued that federal law does not permit private parties to file tort suits in federal court asserting that doctors violated international law by allegedly treating patients without first obtaining the patients’ informed consent. WLF urged the court to reject claims that such suits are authorized by the Alien Tort Statute (ATS), a 1789 law that lay dormant for nearly 200 years before activists began seeking to invoke it in the past several decades. WLF argued that the ATS was adopted in 1789 to allow the federal courts to hear cases involving piracy and assaults on ambassadors. WLF charged that the ATS has been transformed by activist attorneys into a tool for second-guessing American foreign policy and for attacking the overseas conduct of corporations. The appeals court was scheduled to hear oral arguments in the case on July 12, 2007.

Zito v. Zabarsky. On May 16, 2006, the Appellate Division of the New York Supreme Court issued an order declining to reconsider a decision that permits questionable expert testimony to be introduced in a medical malpractice case. The decision was a setback for WLF, which filed a brief urging reconsideration. WLF’s brief argued that expert medical testimony must be excluded from court proceedings when it is based on “junk science.” WLF argued that the testimony in this case should have been excluded because the medical conclusions reached by the “experts” lacked support in the medical literature. The American Medical Association also urged the appeals court to reconsider its decision. WLF argued that allowing the “expert” testimony in this case was particularly inappropriate because it consisted of a claim that an FDA-drug had caused the plaintiff’s disease, yet the drug in question has been marketed for decades without any indication in the medical literature that the drug can trigger that disease.
City of Hope Medical Center v. Genentech, Inc. On January 26, 2006, WLF filed a brief in the California Supreme Court urging it to reverse a court of appeal ruling that upheld a compensatory damages award of $300 million along with an unprecedented $200 million punitive damages award against Genentech, a biotech company. The company was involved in a contract dispute over royalties with City of Hope Medical Center which developed synthesized DNA material. WLF argued that if the massive award is not overturned on appeal, businesses involved in typical contract disputes risk debilitating lawsuits by plaintiffs' attorneys not only for normal contract damages, but also for multimillion dollar punitive damages awards. WLF also argued that the excessive award was not justified and should not have been imposed simply because the company could afford to pay the amount without going bankrupt. WLF also filed a brief in this case in 2004, urging the California Supreme Court to agree to hear Genentech's appeal; the court's January 2005 decision to grant review was a significant victory for WLF. The court has not yet heard oral arguments in the case.

United States v. Rx Depot, Inc. On February 22, 2006, the U.S. Court of Appeals for the Tenth Circuit in Denver declined an opportunity to prevent FDA from exercising enforcement powers that the evidence suggests were never delegated to it by Congress. The court's decision, affirming FDA's authority to seek a massive damage award against an internet pharmaceutical distributor, was a setback for WLF, which had filed a brief urging the court to deny FDA that authority. In its brief, WLF argued that FDA has no power to seek disgorgement or restitution from companies alleged to have violated federal drug laws. WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that disgorgement and restitution are not among them. WLF argued that FDA, throughout most of its history, never asserted a right to seek disgorgement; WLF charged that FDA only recently began asserting that power, to have a big club with which to intimidate manufacturers who might otherwise seek to challenge FDA. The Tenth Circuit disagreed; it upheld FDA's authority to seek restitution, finding that the FDCA's grant of authority to "restrain" violations of the Act should be read broadly to include all forms of injunctive relief. On May 23, 2006, the defendant petitioned the U.S. Supreme Court to review the case.

United States v. Lane Labs-USA, Inc. On October 21, 2005, the U.S. Court of Appeals for the Third Circuit in Philadelphia declined an opportunity to prevent the Food and Drug Administration (FDA) from exercising enforcement powers that the evidence suggests were never delegated to it by Congress. The court's decision, upholding a massive $109 million restitution award against a dietary supplement manufacturer, was a setback for WLF, which had filed a brief urging the court to overturn the award. WLF had argued that FDA has no power to seek restitution from manufacturers alleged to have violated the Federal Food, Drug, and Cosmetics Act (FDCA). WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that restitution is not among them. The Third Circuit disagreed; it upheld FDA's authority to seek restitution, finding that the FDCA's grant of authority to "restrain" violations of the Act should be read broadly to include all forms of injunctive relief. The case involves a dietary supplement manufacturer accused by FDA of improperly promoting its products as a treatment for cancer; it was ordered to refund to consumers all money used to buy its products.

Howland v. Purdue Pharma, L.P. On December 15, 2004, the Ohio Supreme Court overturned a lower court's decision to certify as a state-wide class action a product liability suit
brought by three individuals who claim they were injured due to their use of the defendant’s pain-relief medication. The decision was a victory for WLF, which filed a brief urging that the class be decertified. WLF argued that personal injury product liability suits are virtually never appropriate for class action treatment because the claims of each class member are unique— for example, each plaintiff must separately establish such elements of his/her tort claim as inadequacy of warning, reliance, causation, and damages. The court agreed with WLF that when, as was true here, individual issues of fact and law predominate over common issues, class action treatment is rarely appropriate, and that the trial court had given inadequate consideration to the “predominance” issue when it certified the class.

*American Home Products, Inc. v. Collins.* On April 18, 2005, the U.S. Supreme Court issued an order declining to review an appeals court decision that makes it much more difficult for out-of-state defendants to move their lawsuits from state court to federal court. The decision was a setback for WLF, which had filed a brief urging the Court to review (and ultimately overturn) the lower court decision. The suit at issue is one filed against all the major childhood vaccine manufacturers, and threatens to drive even more manufacturers out of the market. WLF argued that the lower court defined “fraudulent joinder” in an unnecessarily narrow manner. WLF argued that plaintiffs’ lawyers regularly join fraudulent defendants to their lawsuits in an effort to prevent out-of-state corporations from moving lawsuits to federal court, which are generally considered less hostile to out-of-state corporations than are state courts. WLF argued that the appeals court decision frustrates the will of Congress that cases of this sort be removable to federal court as a means of ensuring that out-of-state defendants can have their cases heard in an impartial forum.

*Legal Advice Regarding National Uniformity for Food Act.* On November 29, 2005, at the request of U.S. Representative Edolphus Towns, WLF attorneys provided him with legal counsel regarding the propriety of the proposed National Uniformity for Food Act of 2005 (NUFA), which would require national uniformity in food safety and warning requirements. WLF’s legal memorandum concluded that Congress would be acting appropriately were it to adopt the legislation. WLF concluded that NUFA is consistent with the federal government’s traditional role in the regulation of interstate commerce and an appropriate response to the disruptions in interstate commerce caused by tort suits filed pursuant to California’s Proposition 65. WLF praised NUFA as “a carefully designed effort to balance the respective roles of the federal and State governments in food safety issues.” WLF said that NUFA would have a significant impact only in those few States—such as California—in which excessive imposition of food warning requirements (requirements often imposed by means of lawsuits filed by private citizens) is having a negative effect on interstate commerce.

*Dura Pharmaceuticals v. Broudo.* On April 18, 2005, the Supreme Court unanimously reversed an appeals court ruling that had established a highly relaxed pleading standard for attorneys filing securities class action cases against publicly-held companies. Instead, the Supreme Court agreed with WLF that a plaintiff in such suits must establish “loss causation”—that is, that the stock price was inflated due to the company’s misstatements and that a later drop in the stock price was causally related to the disclosure of the truth about the misstatements. The Court noted that there may be many reasons, unrelated to alleged wrongdoing, why the price of the stock dropped. The Court agreed with WLF that Congress had enacted the Private Securities Litigation Reform Act (PSLRA) in 1995 to prevent class action attorneys from filing securities fraud cases
based on nothing more than a drop in stock price. The decision could go a long way in reducing the number of abusive lawsuits filed against pharmaceutical companies.

*Baxter International Inc. v. Asher.* On March 21, 2005, the U.S. Supreme Court declined to review this case, thereby passing on an opportunity to give real meaning to a 1996 federal law that was intended to limit the liability of corporations that make projections ("forward-looking statements") regarding future sales and earnings. The decision was a setback for WLF, which had filed a brief urging that review be granted. The Private Securities Litigation Reform Act creates a "safe harbor" for forward-looking statements; provided that such statements are accompanied by "meaningful" cautionary statements, the safe harbor provides that the statements cannot be used to hold a publicly held corporation liable to its shareholders for making false statements, regardless how inaccurate the statements turn out to be. In this case, the appeals court held that the PSLRA safe harbor cannot be invoked to win dismissal of a securities law class action at the pleadings stage because the issue of whether the accompanying cautionary statements are sufficiently "meaningful" can never be determined until after all pre-trial discovery is complete and the facts of the case have been fully fleshed out. In urging that the Court review (and ultimately overturn) the appeals court decision, WLF argued that the PSLRA was intended to permit defendants to invoke the "safe harbor" provision to win dismissal of suits at the pleadings stage. WLF argued that by precluding all possibility of early dismissal, the appeals court essentially wrote the safe harbor out of the law, because the principal purpose of the provision was to allow corporations to win dismissal of "forward-looking statement" lawsuits without having to incur the huge drain on resources that the litigation discovery process generally entails.

*Stetser v. TAP Pharmaceutical Products, Inc.* On July 6, 2004, the North Carolina Court of Appeals issued an opinion that imposes strict limits on nationwide class action suits against drug manufacturers. The decision was a victory for WLF, which had filed a brief urging that the lower court’s class certification order be overturned. WLF’s brief argued that plaintiffs’ lawyers often bring such nationwide class actions as a means of coercing a settlement, without regard to the merits of the suit. Such suits tend to be totally unmanageable, because class members often have widely varying damage claims, and different sets of laws often apply to class members from different states. In this case, the trial judge certified a nationwide class of consumers allegedly injured by the pricing policies of several drug companies. He attempted to avoid unmanageability problems by decreeing that all claims would be judged under North Carolina law, the state in which the suit was filed. The court of appeals agreed with WLF that applying North Carolina law violated the due process rights of the vast majority of litigants who had no connection with North Carolina, and that even the defendants (which are headquartered in other states) had no more than minimal contacts with North Carolina. The court of appeals remanded the case to the trial court for reconsideration; its opinion indicates that if the trial court chooses to certify any plaintiff class at all, the class must be limited to North Carolina residents.

*PaciﬁCare Health Systems, Inc. v. Book.* On April 7, 2003, the U.S. Supreme Court mandated the enforcement of agreements to arbitrate commercial disputes, regardless whether the remedies available in an arbitration proceeding are less broad than those available in a lawsuit. The decision was a victory for WLF, which filed a brief urging that the enforceability of arbitration agreements be upheld. The decision (involving a dispute between HMOs and a group of doctors) likely will lead to reduced health care costs. The court of appeals refused to enforce an arbitration
agreement between the HMO and the doctors because the arbitrator likely would not have been permitted to award punitive damages, a remedy that the plaintiffs could seek in a federal court action. WLF argued that a party that decides in advance that it will arbitrate all disputes – a very rational decision given arbitration's speed and efficiency advantages over litigation – should not be permitted to wriggle out from that agreement simply because it later concludes that litigation offers it tactical advantages.

In re Vitamin Cases/Philion v. Lonza. The California Supreme Court on June 11, 2003 let stand a class action settlement in which the plaintiffs' lawyers are to receive millions in fees, while consumers – their purported clients – will receive nothing. WLF had filed a brief on May 9, 2003 in support of the objecting class members, arguing that the settlement violated California law and urging the High Court to grant review. The suit raised price-fixing charges against various vitamin manufacturers. As a result of the settlement to which WLF objected, the consumers will have no opportunity to seek compensation of any kind. Instead, the so-called cy pres settlement of $38 million will be paid to governmental and nonprofit organizations; the plaintiffs' attorneys will receive an award of $16 million in fees. WLF argued that the case was a classic example of abuse of the litigation process by plaintiffs' attorneys.

Taylor v. SmithKline Beecham Corp. On March 24, 2003, the Michigan Supreme Court upheld a Michigan statute that precludes design-defect tort actions against the manufacturer of any drug that has been approved for sale by FDA. The decision was a victory for WLF, which filed a brief in the case, urging that the statute be upheld. The court agreed with WLF that the Michigan legislature acted properly in adopting the statute and that it did not violate a state constitutional provision that prohibits the legislature from delegating its powers to a federal administrative agency. WLF has argued repeatedly that such measures are necessary to hold down health care costs and to ensure that low-income Americans continue to have access to quality health care.

Pegram v. Herdrich. On June 12, 2000, the U.S. Supreme Court issued a decision that is likely to rein in the continuing expansion of civil lawsuits brought under ERISA, the federal pension law. The decision was a victory for WLF, which had argued in a November 12, 1999 brief that the lower court's decision threatened to undermine health care in this nation by allowing a patient to sue his health care provider under ERISA anytime the provider takes into account cost considerations when deciding how to treat the patient. The Court noted that patients are already permitted to sue their doctors for malpractice under state tort law. The Court agreed with WLF's argument that a patient should not also be permitted to file an ERISA suit against his HMOs and doctors (based on a claim that they allegedly violated a fiduciary duty under ERISA to act in the patient's best interests). WLF had argued that allowing such suits would lead to dramatically increased health care costs by preventing doctors and HMOs from trying to control costs. WLF filed an earlier brief in the case on July 28, 1999, successfully urging the Court to grant review.

Dow Chemical Company v. Mahlum. On December 31, 1998, the Nevada Supreme Court upheld the imposition of compensatory damages against Dow Chemical Co. for breast implants manufactured by Dow Corning, but struck down the imposition of punitive damages against the company. The decision was a partial victory for WLF, which in August 1996 had filed a brief urging the court to reverse a trial court ruling that imposed a $14 million judgment upon Dow Chemical for the manufacture and sale of silicone breast implants by another company, Dow
Corning. The plaintiffs sued Dow Chemical for injuries allegedly suffered in 1985 by silicone breast implants that were tested, manufactured, and sold by Dow Corning, a legally distinct company from Dow Chemical. The plaintiffs' attorneys argued that Dow Chemical should be held liable for not disclosing studies done in 1948, 1956, and 1970 regarding the industrial uses of certain silicones. But those studies had nothing to do with the different type of gel silicone developed and tested many years later by Dow Corning.

Artiglio v. Corning, Inc. On July 20, 1998, WLF scored a major victory when the California Supreme Court affirmed a lower court ruling that Dow Chemical Co. was not liable for any damages allegedly caused by breast implants manufactured by another company, Dow Corning Corp. WLF filed a brief in the case in June 1997, urging the court to affirm the lower court ruling. The plaintiffs sued Dow Chemical, Corning, and Dow Corning for injuries allegedly caused by silicone breast implants tested, manufactured, and sold only by Dow Corning. Because Dow Corning later declared bankruptcy, the plaintiffs' attorneys pursued Dow Chemical on the novel theory that it should be held liable for not disclosing studies done in 1948, 1956, and 1970 regarding the industrial uses of certain silicones.

Daubert v. Merrell Dow Pharmaceuticals. In June 1993, the U.S. Supreme Court struck a blow against use of "junk science" in the courtroom, ruling that judges must exclude expert scientific testimony from reaching a jury unless that evidence is generally accepted within the scientific community. The result of the decision was to throw out the thousands of suits that alleged that the drug Bendectin causes birth defects; lower courts have agreed that the evidence used to establish such a link was nothing more than "junk science." The decision was a victory for WLF, which filed a brief in the case arguing that allowing juries to consider scientific evidence that is rejected by the majority of scientists undermines the role of the courts as truth-finding institutions.

Petition Urging Balanced Study of Silicone Implants. On January 20, 1992, WLF filed a petition with Secretary of Health and Human Services Louis Sullivan, urging him to convene an unbiased panel of health experts to review the data on silicone breast implants. WLF argued that FDA had mishandled the issue, noting that FDA's unwarranted restrictions on silicone implants had provided the impetus for an unprecedented wave of product liability suits against implant manufacturers. WLF argued that FDA Commissioner David Kessler acted without statutory authority and used biased, "junk" science in making decisions on the issue. WLF was ultimately vindicated when later studies showed that FDA's concerns were totally unfounded.

In re Dow Corning Corp. On November 22, 2000, WLF scored a victory when the U.S. District Court for the Eastern District of Michigan overturned a ruling by a bankruptcy court invalidating a third-party release of liability in a bankruptcy settlement. Under the settlement, which reorganized Dow Corning Corporation in the face of numerous product-liability claims for silicone breast implants, Dow Corning's parent companies, Dow Chemical Company and Corning, Inc., were released from future tort claims. Instead, claimants would receive compensation out of the settlement fund. WLF maintained in its brief filed in March 2000 that such a release is permissible under the bankruptcy code and would put an end to the quagmire of litigation surrounding this case. Moreover, WLF noted, the vast majority of tort claimants, along with Dow Corning, Dow Chemical, and Corning, supported the plan, which the bankruptcy court’s decision
threatened to unravel.

F. Preemption of Drug/Medical Device Suits

Federal law provides certain special protections to medical device manufacturers. In particular, once FDA has determined that a medical device is safe and effective for its intended use, a state court may not reach a contrary conclusion in connection with a tort suit alleging that the device is defectively designed. Furthermore, although federal law includes no comparable preemption statute applicable to drugs, FDA has taken the position that failure-to-warn claims against a drug manufacturer are impliedly preempted by federal law, because FDA (at the time it approves a drug for marketing) specifies the precise warnings that are to be included on the product label. Thus, if FDA determines that a suggested warning is inappropriate because not medically substantiated, states may not override that determination by imposing tort liability on a drug company for failing to include the warning. WLF has gone to court repeatedly to support a broad interpretation of the federal rules that require preemption of contrary state laws and court judgments. The Supreme Court significantly cut back on the extent of preemption in Medtronic, Inc. v. Lohr, but its later decision in Buckman Co. v. Plaintiffs’ Legal Committee restored a fair degree of the protection previously afforded to device manufacturers. WLF continues to litigate against plaintiffs’ efforts to circumvent the Buckman decision.

Warner-Lambert Co. v. Kent. WLF is scheduled to file a brief on July 13, 2007 in the U.S. Supreme Court, urging the court to review (and ultimately overturn) a federal appeals court decision that held that Michigan law permits courts to base the tort liability of a drug manufacturer in part on whether the manufacturer had defrauded the FDA in the course of obtaining approval to market its drug. Michigan law provides that consumers may not sue drug manufacturers for injuries incurred as a result of taking an FDA-approved drug that has been manufactured in accordance with FDA specifications. However, Michigan creates an exception from that immunity if the plaintiff can demonstrate that the manufacturer obtained approval by means of defrauding the FDA. WLF argues that that exception should be stricken from Michigan law because, under the Buckman decision (see below), federal law preempts all state efforts to second-guess the FDA approval process. WLF argues that so long as FDA continues to conclude that a drug is sufficiently safe and effective to be marketed, states should not be permitted to challenge FDA’s initial decision to approve the product for marketing.

Medtronic, Inc. v. Lohr. On June 26, 1995, the U.S. Supreme Court ruled 5-4 against WLF in this important product liability case when it found that state tort claims against medical device manufacturers are not preempted by federal law. A federal statute provides that if a medical device is subject to regulation by FDA, it may not also be subjected to state law “requirements.” The lower courts had been split on whether tort claims qualify as “requirements” imposed by state law; the Supreme Court held that they generally do not so qualify, albeit the Court left the door open to preempting tort claims in some limited contexts. WLF had argued in its brief that federal regulation of the design, manufacture, and marketing of medical devices is sufficient to ensure that medical devices are safe, and that additional regulation at the state level discourages development of new and useful medical devices.
**Buckman Co. v. Plaintiffs' Legal Committee.** On February 21, 2001, the U.S. Supreme Court ruled that plaintiffs' lawyers may not second-guess FDA product approval decisions by filing state-law suits against the product manufacturer. The decision was a victory for WLF, which had filed a brief with the Court arguing that federal law does not permit such challenges because they would undermine FDA's authority to regulate the pharmaceutical industry. The suits here were product liability claims against the manufacturers of orthopedic screws used in spinal surgery; the plaintiffs asserted that the screws never should have been permitted on the market and that FDA approved marketing only because manufacturers defrauded the FDA in connection with their product-approval applications. The Court agreed with WLF that because FDA has stood by its decision to permit marketing of the screws, federal law prohibits plaintiffs from filing state-law tort actions that, in essence, second-guess FDA's approval.

**U.S. ex rel. Gilligan v. Medtronic, Inc.** On April 6, 2005, the U.S. Court of Appeals for the Sixth Circuit in Cincinnati dismissed a lawsuit that sought to second-guess decisions of FDA authorizing the sale of drugs or medical devices. The decision was a victory for WLF, which filed a brief in support of the manufacturer whose product was being challenged. WLF argued that permitting such suits to go forward would undermine the integrity of FDA's product-approval system and could result in patients being denied access to life-saving medical products. Although it dismissed the lawsuit, the Sixth Circuit did so on narrower grounds than WLF had argued. The plaintiffs were suing under the False Claims Act (FCA), a federal law that permits bounty-hunting private citizens to file a suit in the name of the federal government against anyone who makes a "false claim" to the government. They alleged that the defendant, a medical device manufacturer, induced health care providers to falsely claim that the manufacturer's products had been properly approved by FDA. The Sixth Circuit held that the information on which the plaintiffs based their lawsuit was publicly available before they filed suit. The appeals court held that under those circumstances, the FCA suit was barred by the "public disclosure" bar, which eliminates federal court jurisdiction over an FCA claim where the plaintiff is not the original source of the allegations. On January 9, 2006, the U.S. Supreme Court denied a petition to review the Sixth Circuit's decision, thereby sealing WLF's victory.

**Reeves v. Acromed.** On February 10, 1995, the U.S. Court of Appeals for the Fifth Circuit in New Orleans ruled that state-law suits claiming injuries caused by alleged defects in FDA-approved medical devices are impermissible because they are preempted by federal law, at least when the suits are premised on a failure-to-warn claim. The decision was a victory for WLF, which had filed a brief in the case in 1994 urging that the tort claims be dismissed on preemption grounds. WLF argued that federal regulation of medical device design and marketing is sufficient to ensure that medical devices are safe, and that additional regulation at the state level discourages development of new and useful medical devices.

**Smith & Nephew Dyonics, Inc. v. Violette.** On August 1, 1995, the U.S. Court of Appeals for the First Circuit affirmed a tort judgment for a plaintiff who claimed he was not warned about the dangers of a medical device despite the manufacturer's compliance with FDA's strict labeling requirements. WLF had urged the court to rule that state-law suits claiming injuries caused by alleged defects in FDA-approved medical devices are impermissible because they are preempted by federal law. The device at issue was the ECTRA System, used by physicians in performing wrist surgery. The court declined to rule on WLF's preemption argument; it held that the
manufacturer had waived that argument by failing to raise it in the trial court.

_Feldt v. Mentor._ On August 21, 1995, the U.S. Court of Appeals for the Fifth Circuit ruled that most state-law product liability claims brought against a medical device manufacturer are preempted by federal law. The court held that because FDA already closely regulates medical devices, additional state regulation in the form of tort liability is unwarranted -- except for claims that the device is defectively designed. The decision was a victory for WLF, which had filed a brief urging dismissal of the claims. WLF successfully argued that preemption occurs even when, as here, the medical device in question is being marketed pursuant to an FDA § 510(k) "substantial equivalence" finding, rather than pursuant to the more rigorous pre-market approval process. WLF argued that in the absence of such preemption, development of new and useful medical devices would be stifled.

_English v. Mentor._ On September 29, 1995, the U.S. Court of Appeals for the Third Circuit ruled that most state-law claims against a medical device manufacturer are preempted by federal law. The decision was a victory for WLF, which had filed a brief supporting the district court’s dismissal of the plaintiffs’ product liability claims. The plaintiffs sought damages under theories of strict liability, negligent design, and breach of express and implied warranties of merchantability because the plaintiffs’ prosthesis began malfunctioning. The only claim that the appeals court held was not preempted was that the manufacturer breached express warranties regarding the performance of its product.

_Rosci v. Acromed._ On December 19, 1995, a Pennsylvania court handed WLF a partial victory in a products liability action. The court ruled that some, but not all, state tort claims against medical device manufacturers are preempted by federal law. WLF had filed a brief in the case, urging the Superior Court of Pennsylvania to affirm a lower court's dismissal of the plaintiff's claim that a device manufacturer violated express and implied warranties when its bone plates and screws, which were inserted into the plaintiff's back, did not produce the results desired by the plaintiff. WLF argued that federal law preempted the plaintiff's state-law claims. The court ruled that federal law preempts breach of warranty claims where the warranty is one implied by state law, but does not preempt claims that the manufacturer breached a warranty it expressly made at the time of sale.

_Guidance Document on Medical Devices Preemption._ WLF achieved a major victory in July 1998, when FDA agreed to withdraw a proposed guidance document regarding when federal law preempts state tort lawsuits against medical device manufacturers. In February 1998, WLF had filed comments urging that the proposed guidance be withdrawn. In _Medtronic, Inc. v. Lohr_, the Supreme Court ruled that federal law operates to preempt at least some state tort suits against device manufacturers. Despite that decision, FDA’s proposed guidance declared that state tort suits are virtually never preempted by the relevant federal statutes. WLF argued that the FDA guidance document was directly contrary to the plain language of the federal statutes and flouted the _Medtronic_ decision.
G. Protecting Patent Rights

If advances in health care are to continue, it is vital that research-based pharmaceutical companies that develop new drugs and medical devices be afforded a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. When it adopted the Hatch-Waxman Act in 1984, Congress carefully balanced the need, on the one hand, for a strong patent system that rewards companies that develop new therapies and, on the other hand, for the competition among manufacturers that provides lower prices for consumers. Numerous politicians have been pushing the courts to upset that balance by abridging patent rights created by Hatch-Waxman. WLF has vigorously opposed such efforts, going to court repeatedly to support those rights.

_Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc._ On February 1, 2006, the U.S. Court of Appeals for the Federal Circuit reversed its earlier decision to invalidate a multi-billion dollar pharmaceutical patent, and remanded the case to the district court to consider the invalidity issue anew. The decision was a major victory for WLF, which filed a brief in June 2005, urging the three-judge appeals court panel to reverse its prior decision. Particularly gratifying to WLF was that the panel reversed itself based on the precise arguments raised by WLF in its brief. The case then returned to the U.S. District Court for the Southern District of New York for reconsideration of the patent invalidity issue; based on guidance provided by the appeals court regarding how the issue should be resolved, it was likely that the district court ultimately would have upheld the patent. However, the parties entered into a settlement before the district court could rule. The patent at issue covers OxyContin, a powerful pain relief medication. A federal district court ruled in 2004 (and the appeals court panel affirmed in June 2005) that the patent should be invalidated as a penalty for alleged “inequitable conduct” committed by the drug’s manufacturer when applying to the Patent and Trademark Office (PTO) for the patent. A patent can be invalidated on those grounds only upon a showing that the applicant omitted “material” information from its patent application and did so intending to deceive the PTO. WLF argued (and the latest appeals court decision largely agreed) that the district court improperly lowered the bar for demonstrating inequitable conduct by applying far too lax standards for intent. WLF argued that any information withheld in this case was trivial and that there was no evidence that the manufacturer intended to deceive the PTO.

_Ferring B.V. and Aventis Pharmaceuticals v. Barr Laboratories._ On October 30, 2006, the U.S. Supreme Court declined to review an appeals court decision that invalidated an immensely valuable pharmaceutical patent on the ground that, when applying for the patent 15-20 years ago, the applicant failed to disclose to patent examiners all past relationships between the applicant and its expert witnesses. The Court’s one-sentence order declining review was a setback for WLF, which filed a brief urging that review of the case be granted. WLF argued that the appeals court decision invalidating the patent had the potential to undermine public confidence in our nation’s patent system. The patent at issue covered a new, more efficient method of administering a drug used to treat diabetes insipidus. A three-judge panel of the U.S. Court of Appeals for the Federal Circuit ruled 2-1 that the patent should be invalidated as a penalty for alleged “inequitable conduct” committed by the patent applicant when applying to the Patent and Trademark Office (PTO) for the patent. WLF urged the Supreme Court to grant review in order to make clear that a patent should not be struck down on inequitable conduct grounds except in the most extreme circumstances. WLF argued that any omission by a patent applicant in his
presentation to the PTO should not be deemed sufficiently “material” to warrant invocation of the inequitable conduct defense unless the defendant demonstrates that there is a reasonable likelihood that the patent would not have been issued had there been no omission. WLF argued that the defendants could not make such a showing in this case and that any flaws in the patent application process were trivial.

Mylan Pharmaceuticals, Inc. v. Thompson. On October 12, 2001, the U.S. Court of Appeals for the Federal Circuit ruled that those challenging patents held by pharmaceutical companies are not permitted to circumvent the procedural protections that Congress granted to patent holders when it adopted the Hatch-Waxman Act in 1984. The ruling was a victory for WLF, which on April 20, 2001, had filed a brief urging that the procedural rights of patent holders be upheld. The court agreed with WLF that those challenging patents should be required to raise their claims in connection with the normal procedures established for such challenges; they should not be permitted to circumvent those procedures with novel legal claims, such as suits challenging a drug company’s decision to list a patent in the “Orange Book” maintained by FDA. WLF also argued that undermining the patent rights of drug manufacturers inevitably will slow development of new, life-saving therapies by reducing financial incentives for research spending.

SmithKline Beecham Corp. v. Apotex Corp. On June 19, 2006, the U.S. Supreme Court issued an order declining to review an appeals court decision that invalidated a significant pharmaceutical patent based on a finding that the drug was not “novel” when the patent application was filed in 1986 – even though it is undisputed that if the drug existed before then, it was in such minute quantities as to be undetectable. The order, issued without comment, was a setback for WLF, which filed a brief urging that review be granted. WLF argued that if allowed to stand, the decision of the U.S. Court of Appeals for the Federal Circuit would undermine confidence in the nation’s patent system as an effective means of protecting intellectual property rights. WLF argued that under the doctrine of “accidental prior use,” an invention should not be deemed to have been “anticipated” by the prior art if the prior art’s disclosure of the claimed invention is accidental or unwitting and no one – not even experts in the field – would have recognized the existence of the disclosure. WLF argued that the challenged patent should have been upheld under the “accidental prior use” doctrine. WLF also filed briefs in the case – supporting the validity of the underlying patent – in the Federal Circuit in 2004 and 2005.

Allergan, Inc. v. Alcon Laboratories. On December 1, 2003, the U.S. Supreme Court declined to review an appeals court decision that barred a pharmaceutical company from seeking recourse in the courts as soon as one of its patents is threatened by a generic drug company’s announced plan to market a generic version of the drug covered by the patent. The decision was a setback for WLF, which on October 24, 2003 had filed a brief urging the Court to grant review. WLF also filed two briefs in 2002/2003 when the case was in the appeals court. The Court’s order provided no explanation for its decision to deny review. In its brief urging Supreme Court review, WLF argued that permitting early resolution of patent disputes between pioneer and generic drug companies was one of Congress’s principal purposes in adopting the Hatch-Waxman Act in 1984. WLF argued that the lower court’s decision dismissing the pioneer company’s claim on ripeness grounds undermined congressional intent and ought to be reversed.

Pfizer, Inc. v. Dr. Reddy’s Laboratories, Inc. On February 27, 2004, the U.S. Court of
Appeals for the Federal Circuit (in a victory for WLF) overturned a district court decision that threatened to cut short patent rights granted to pharmaceutical companies under the Hatch-Waxman Act. The appeals court rejected the district court’s rationale, under which generic companies would have had little difficulty avoiding patent infringement actions by merely altering one of the inactive ingredients of the patented product. The appeals court agreed with WLF’s argument that by assigning too restrictive a definition of what constitutes the chemical substance protected by a patent, the district court undermined patent rights and thereby significantly reduced the economic incentives for companies to invest the vast sums necessary to develop new life-saving products. The district court had held that a generic drug does not infringe a product whose patent term has been extended under the Hatch-Waxman Act, so long as it is combined with an “addition salt” different from the one used in the patented drug— even if the generic drug includes the same active ingredient as the patented product.

Opposition to Activist Petition Threatening Patent Rights. The National Institute of Health (NIH) announced on September 17, 2004, that it would not grant a “march-in” petition from an activist group seeking to abrogate the exclusivity of patent rights held by a pharmaceutical company. The petition, filed by a group called Essential Inventions, argued that federal law gives federal agencies the authority to regulate the prices of products that are based on technology wholly or partly funded by federal grants and licensed to the private sector. NIH’s decision was a victory for WLF, which had filed comments on August 9, 2004, urging NIH to deny the petition. The Essential Inventions petition claimed that Pfizer had set excessive prices for its glaucoma drug Xalatan by charging more for the drug in the U.S. than overseas. The petition argued that the march-in provision of the Bayh-Dole Act could be invoked based on a licensee’s decision to set “unreasonable” prices for a product. WLF’s response analyzed the Act and its legislative history to show that the Act was never intended to serve as a price-control law.

Revision of Hatch-Waxman Act Regulations. On December 23, 2002, WLF wrote to FDA, generally supporting the agency’s proposed revision of rules implementing the Hatch-Waxman Act’s procedures for resolving patent disputes between pioneer and generic drug manufacturers. WLF agreed with FDA that, in order to prevent pioneer manufacturers from abusing Hatch-Waxman procedures in an effort to delay entry of generic competition, they should be allowed to invoke the Act’s 30-month stay provision only once in connection with a single Abbreviated New Drug Application (ANDA). However, WLF contended that FDA’s proposed rule goes too far in this regard. FDA proposes that a pioneer manufacturer’s sole opportunity to invoke the 30-month stay should arise only in the period immediately following the first occasion on which a generic company has filed a “Paragraph IV Certification” in connection with its ANDA. WLF argued that FDA’s proposal is based on a misreading of the relevant statute; pioneer manufacturers should not be deemed to have waived the stay if they do not deem it necessary to file an infringement suit in response to the generic company’s first Paragraph IV Certification. Rather, WLF argued, the 30-month stay should not be triggered until the pioneer manufacturer has filed a patent infringement lawsuit. On June 18, 2003, FDA adopted final regulations in substantially the same form as it had proposed in December 2002.

Proposed Rulemaking to Implement Pediatric Exclusivity Laws. On January 28, 2002, WLF petitioned FDA to initiate a rulemaking proceeding to implement the pediatric exclusivity provisions of the newly enacted Best Pharmaceuticals for Children Act (BPCA). The BPCA
authorizes FDA to approve a marketing application from a generic drug manufacturer even when the brand-name manufacturer still holds exclusive rights to market the drug to children. WLF argued that allowing generic drugs to be marketed without any sort of pediatric labeling raises serious health concerns. WLF argued that, in general, generic manufacturers should be required to purchase a license from the brand-name manufacturer that would allow them to include pediatric labeling on their products.

H. Misuse of Antitrust Law

When the government grants a limited-time patent to the inventor of a product, it recognizes that the antitrust laws (which normally operate to prohibit all "restraints of trade") are generally inapplicable to the actions of the patent holder. Nonetheless, plaintiffs' lawyers with increasing frequency have been filing antitrust claims against patent holders and those who enter into marketing agreements with patent holders — thereby threatening the viability of the patent system. WLF has regularly litigated in the federal courts against those who would use the antitrust laws to limit the rights of patent holders — rights that are essential if research and development are to be encouraged.

Schering-Plough Corp. v. FTC. On March 8, 2005, the U.S. Court of Appeals for the Eleventh Circuit overturned an FTC decision that would have imposed antitrust liability on two drug companies based on the settlement of a patent dispute. WLF had filed a brief on June 9, 2004, encouraging the court to overturn the FTC's ruling. The settlement agreements (between Schering-Plough Corp., Upshur-Smith, and American Home Products) settled a dispute involving generic drug companies who wished to manufacture a drug for which Schering-Plough claimed patent rights. The FTC held that the settlement unreasonably restrained trade because the generic companies agreed to delay their entry into the market. In its brief, WLF argued that the FTC's view of patent settlements between drug companies is commercially unrealistic and counter to federal antitrust law. WLF further argued that the FTC's position would deter settlement of patent disputes. WLF also filed a brief when the matter was before the FTC. In August 2005, the FTC filed a petition for certiorari with the Supreme Court seeking review of the Eleventh Circuit decision. Interestingly, the U.S. Department of Justice has filed a brief urging that the Court reject the FTC's petition. WLF's victory became final on June 26, 2006, when the Supreme Court declined to review the case.

Valley Drug Co. v. Geneva Pharmaceuticals. On September 15, 2003, the U.S. Court of Appeals for the Eleventh Circuit in Atlanta rejected claims that agreements to settle patent disputes can amount to per se violations of the antitrust laws. The decision was a victory for WLF, which filed a brief in the case urging against blanket condemnation of such agreements. The appeals court explained that patents are intended to provide holders with the power to exclude competition; the court agreed with WLF that agreements that settle patent disputes by simply confirming patent holders' power to exclude do not violate the antitrust laws. The appeals court reversed a district court decision that had condemned a patent settlement as a per se antitrust violation. The case involves the settlement of a patent dispute between Abbott Laboratories (which held a patent to manufacture the drug Hytrin) and several companies that wished to manufacture generic equivalents of Hytrin. Under the settlement, the generic manufacturers agreed to delay their entry into the field. The court agreed with WLF that the antitrust analysis was unchanged by the fact that Abbott paid money to the generic companies in connection with the settlement. In October
2004, the U.S. Supreme Court declined a petition to review the Eleventh Circuit’s decision.

**Andrx Pharmaceuticals, Inc. v. Kroger Co.** On October 12, 2004, the U.S. Supreme Court declined to review a lower-court ruling that agreements to settle patent disputes can amount to *per se* violations of the antitrust laws. The decision not to hear the case was a setback for WLF, which filed a brief in the case, urging that review be granted. WLF argued that parties ought to be encouraged to settle their patent disputes. By raising the possibility that settlements will be subjected to *per se* condemnation under the antitrust laws, the federal appeals court in Cincinnati is unnecessarily discouraging settlements, WLF argued. The case involves the settlement of a patent dispute between Hoechst Marion Roussel (which held a patent to manufacture the drug Cardizem CD) and a generic drug manufacturer, Andrx Pharmaceuticals, which had announced plans to market a generic version of Cardizem CD. Under the settlement, Andrx agreed to delay its entry into the field. The plaintiffs, purchasers of Cardizem CD, allege that the settlement constituted an unreasonable restraint of trade in violation of antitrust laws. WLF argued that litigation settlements often have significant procompetitive effects and thus that they ought to be judged under the “rule of reason” rather than being condemned as *per se* illegal in all cases.

**II. CIVIC COMMUNICATION**

WLF recognizes that its litigation and regulatory activities cannot alone suffice if it is to have a significant impact in shaping the nation’s health care policy. WLF has also sought to influence public debate and provide information through its Civic Communications Program. This targeted and broad-based program features WLF’s sponsorship of frequent, well-attended media briefings featuring experts on a wide range of health-related topics, web seminars featuring analysis and commentary by noted legal experts on timely developments in law and public policy, the publication of advocacy advertisements in national journals and newspapers, and participation in countless healthcare symposia. WLF supplements these efforts by making its attorneys available on a regular basis to members of the news media – from reporters for general-circulation newspapers to writers for specialized FDA journals.

**A. Media Briefings**

The centerpiece of WLF’s Civic Communications Program is its media briefings, which bring news reporters from the print and electronic media together with leading experts on a wide variety of legal topics. WLF sponsors more than a dozen such breakfast briefings each year, often focusing on health-related topics. Recent media briefings (dubbed media “noshes”) on health-related issues have included the following:

**Targeting “Off-Label” Speech: Are Civil & Criminal Actions Contrary to Law and Effective Patient Care?,** February 22, 2007

- **Dr. Paul E. Kalb**, Partner, Sidley Austin LLP
- **Professor Ralph F. Hall**, Univ. of Minnesota Law School, Counsel, Baker & Daniels
- **James M. Beck**, Counsel, Dechert LLP

**Self-Regulation of Advertising: Promoting Responsibility and Maintaining Commercial Speech,**
December 5, 2006
• Lynne J. Omlie, Distilled Spirits Council of the United States
• Joan Z. Bernstein, Bryan Cave LLP
• Lee E. Peeler, National Advertising Review Council
• Diane E. Bieri, Pharmaceutical Research and Manufacturers of America

KSR Int'l Co. v. Teleflex Inc.: The Supreme Court Examines the Patent "Obviousness"
Standard, November 21, 2006
• The Hon. Gerald J. Mossinghoff, Oblon, Spivak, McClellan, Maier & Neustadt, P.C.
• Thomas C. Goldstein, Akim, Gump, Hauer, Strauss & Feld LLP
• James W. Dabney, Fried, Frank, Harris, Shiver & Jacobson LLP

WLF v. Leavitt: How CMS Speech Restriction Policy Harms Medicare Drug Beneficiaries,
August 29, 2006
• V. Thomas DeVille, DeVille Pharmacies, Inc.
• Richard A. Samp, Washington Legal Foundation

• Michael S. Wroblewski, Federal Trade Commission
• David A. Balto, Robins, Kaplan, Miller & Ciresi L.L.P.
• Christopher J. Kelly, Mayer, Brown, Rowe & Maw LLP

FDA's Federal Preemption Policy: Implications for Drug Labeling and Product Liability
Litigation, March 8, 2006
• Daniel E. Troy, Sidley Austin LLP
• Mark S. Brown, King & Spalding LLP

Scrutiny of Medical Education Grants: A Chilling Wind for Doctors and Patients?, February 9, 2006
• Jeffrey N. Gibbs, Hyman, Phelps & McNamara, P.C.
• Steven E. Irizarry, ML Strategies
• Laura Frick Laemmle, Patton Boggs LLP

Regulating Drug Promotion: Assessing a Tumultuous 2005 and Prospects for the New Year,
December 13, 2005
• David Bloch, Reed Smith
• Adonis Hoffman, American Association of Advertising Agencies
• Richard A. Samp, Washington Legal Foundation

Hospital-Physician "Gainsharing": Legal and Healthcare Implications for Patients, Providers,
and Product Producers, May 25, 2005
• David Nexon, AdvaMed
• D. McCarty Thornton, Sonnenschein Nath & Rosenthal LLP
• William T. Mathias, Ober Kaler
Cold Medicines and Meth: What is the Right Approach to Curbing Illegal Use of OTC Drugs?, May 18, 2005
• The Honorable Dennis C. Vacco, Crane & Vacco
• James R. Phelps, Hyman, Phelps & McNamara, P.C.

• David M. McIntosh, Mayer, Brown, Rowe & Maw LLP
• Thomas J. McGinnis, R.Ph., Food & Drug Administration
• Jayson S. Slotnik, Biotechnology Industry Organization

“Off Label” Communications At Risk: Promoting Prescription Drugs in an Uncertain Legal Environment, February 3, 2004
• John F. Kamp, Wiley, Rein & Fielding
• Stephen Paul Mahinka, Morgan Lewis LLP
• Richard A. Samp, Washington Legal Foundation

From Prescription to “OTC”: The Legal and Policy Issues FDA Would Face on Forcing a Switch, June 17, 2003
• Andrew S. Krulwich, Wiley, Rein & Fielding
• Linda F. Golodner, National Consumers League
• Nathan A. Beaver, McDermott, Will & Emery

Defending Against Bio-Terrorism: Legal Policy Challenges For Government And Private Industry, April 22, 2003
• Dr. Ken Alibek, George Mason University
• Christine Grant, Aventis Pasteur
• Frank M. Rapoport, McKenna Long & Aldridge LLP

• John E. Calfee, American Enterprise Institute
• Richard L. Frank, Olsson, Frank & Weeda
• Sandra J. P. Dennis, Morgan Lewis LLP

Drug Patent and Pricing Litigation: Will it Help or Hinder Health Care?, March 13, 2002
• James M. Spears, Ropes & Gray
• Daniel A. Small, Cohen, Millstein, Hausfeld & Toll
• Elizabeth A. Leff, Rothwell, Figg, Ernst & Manbeck
• Jeffrey D. Pariser, Common Good

Priorities for the New FDA Commissioner, October 3, 2001
• Alan Slobodin, House Energy and Commerce Committee
• John W. Bode, Olsson, Frank & Weeda
• Larry R. Pilot, McKenna Long & Aldridge

Drug Pricing and Intellectual Property: Will Government Intervention Help or Hinder Health
Care?, May 2, 2001
  • Willard K. Tom, Morgan, Morgan & Lewis
  • Robert Goldbergh, Ph.D., National Center for Policy Analysis
  • Frank M. Rapoport, McKenna Long & Aldridge
  • Michie I. Hunt, Ph.D., Michie I. Hunt & Associates

  • Dr. Lester M. Crawford, Georgetown University Center for Food and Nutrition Policy
  • Gregory Conko, Competitive Enterprise Institute
  • Edward L. Korwek, Hogan & Hartson L.L.P.

  • Bert W. Rein, Wiley, Rein & Fielding
  • Robert A. Dormer, Hyman, Phelps & McNamara
  • Richard A. Samp, Washington Legal Foundation

WLF v. Henney: What’s Next And What Impact on FDA and Off-label Promotion?, August 18, 1999
  • Daniel E. Troy, Food & Drug Administration
  • George S. Burditt, Bell, Boyd & Lloyd
  • Howard Cohen, Greenberg Traurig

Regulating Off-label Drug Promotion: Impact of WLF v. Friedman and FDAMA, March 3, 1999
  • Richard A. Samp, Washington Legal Foundation
  • James W. Hawkins, III, Bergner Bockorny, Inc.
  • Alan R. Bennett, Ropes & Gray

B. Web Seminars

WLF inaugurated its Web Seminar Series in 2005. Web Seminars present viewers with live webcast analysis and commentary by noted legal experts on timely developments in law and public policy. These hour-long presentations are also conveniently archived and available on WLF’s website. The speakers for the programs, who provide their insights on a pro bono basis, are leading experts in the field of law to be discussed. Recent web seminars on health-related issues have included the following:

  • Hon. Gerald J. Mossinghoff, Senior Counsel, Oblon Spivak McClelland Maier & Neustadt P.C.
  • Robert P. Parker, Partner, Paul, Weiss, Rifkind, Wharton & Garrison LLP

Fighting “Serial” Product Liability Litigation: Parlodel® as a Defense Case Study, October 16,
2006

• Joe G. Hollingsworth, Partner, Spriggs & Hollingsworth
• Katharine R. Latimer, Partner, Spriggs & Hollingsworth

Incentivizing Whistleblower Litigation: Ramifications for Health Care Contractors as False Claims Laws Spread in the States, April 27, 2006

• John T. Boese, Fried Frank Harris Shriver & Jacobson LLP
• Beth C. McClain, Fried Frank Harris Shriver & Jacobson LLP

Abigail Alliance v. Crawford: Litigating Access Rights to Lifesaving Medicine, October 24, 2005

• J. Scott Ballenger, Latham & Watkins LLP
• David Price, Washington Legal Foundation

Reuse of Medical Devices: Issues in Federal Policy, October 18, 2005

• James D. Miller, King & Spalding LLP
• Pamela J. Furman, Olsson, Frank and Weeda, P.C.

C. Advocacy Ads

In 1998, WLF began running a series of opinion editorials on the op-ed page of the national edition of The New York Times called “In All Fairness.” The op-ed has appeared over 100 times, reaching over five million readers in 70 major markets and 90 percent of major newspaper editors. Health care policy and FDA regulation has been the focus of a number of “In All Fairness” columns:

• Stolen Property, Stolen Future, May 21, 2007 (Foreign countries’ disrespect for U.S. companies’ intellectual property rights will lead to less innovation in key areas such as health care treatments.)

• Bureaucrats Practicing Medicine, April 24, 2004 (Government efforts to limit and regulate health care causes substandard medical care for patients and can even be life-threatening.)

• Why We’re Suing HHS, October 14, 2003 (Two agencies within HHS are keeping gravely ill Americans from getting lifesaving medicines, and unfortunately litigation is required to fight for their rights.)

• Who’s Tampering with Your Medicines?, June 30, 2003 (Development of new medicines is harmed by trial lawyers who file novel lawsuits against drug companies and by government preferences of generic and over-the-counter drugs.)

• A New FDA?, December 16, 2002 (FDA should expedite its drug approval procedures to improve public health and stop micromanaging drug advertising.)

• Bring Accountability to FDA, August 6, 2001 (Excessive FDA enforcement and
misguided regulatory policies harm the health of Americans.)

• **Phony Food Safety Scares**, November 20, 2000 (Professional activists whip up public hysteria with phony allegations aimed at genetically modified food, pesticides, and food irradiation, when in fact these technological tools hold the potential for cheaper, safer, more abundant food.)

• **Bad Medicine for Consumers**, June 21, 2000 (Price controls should not be placed on drugs because the free market, not a new bureaucracy, is most suited to determining how much drugs ought to cost and because price controls stifle innovation.)

• **The World According to FDA**, September 27, 1999 (FDA’s policy to regulate the dissemination of publications describing off-label use of FDA-approved drugs harms the health of Americans and violates the First Amendment.)

• **Pound-Foolish Public Policy**, June 21, 1999 (Price controls on products such as prescription drugs are counterproductive and undermine the free market system.)

These and other “In All Fairness” columns can be accessed from WLF’s comprehensive website, [www.wlf.org](http://www.wlf.org).

In addition to its high-profile “In All Fairness” series, WLF also creates and places advocacy ads in national newspapers and periodicals to focus the public’s attention on important legal issues.

When 1994 studies showed that FDA’s delays had led to a record backlog of products awaiting approval, WLF sought to publicize those delays by launching a major public relations campaign that featured six different advertisements in the national editions of the *Wall Street Journal*, *USA Today*, *Washington Post*, *The New York Times*, and *National Journal*. The advertisements were widely praised for their effectiveness, each winning a prestigious Addy Award in 1995. WLF’s work was widely credited with forcing FDA to streamline its product approval process and also brought the issue to the attention of major decision makers in government. Congress subsequently adopted major reform legislation in 1997.

**D. Public Appearances**

WLF attorneys have appeared as featured panelists and speakers on health care issues before such groups as the Food and Drug Administration, the Federal Trade Commission, the Food and Drug Law Institute, the American Medical Association, the North American Spine Society, the Regulatory Affairs Professional Society, the Federalist Society, the Heritage Foundation, the American Bar Association, the Pharmaceutical Research and Manufacturers of America, and Medical Alley. What follows are highlights of the numerous public appearances that WLF attorneys have made in the past 12 years, to address health-related issues:

March 22, 2007, WLF Chief Counsel Richard Samp was a featured speaker at the National Coalition for Cancer Survivorship’s annual Industry Roundtable in Washington, DC. Samp spoke
about *Abigail Alliance v. von Eschenbach*, a WLF case that seeks to establish a constitutional right for terminally ill patients, with the concurrence of their doctors, to receive experimental medicines when they have no other available treatment options.

February 8, 2007, Samp testified at a hearing conducted by the Food and Drug Administration, in opposition to FDA plans to begin regulating tests performed by clinical laboratories. FDA recently announced that it now deems such tests to be "medical devices" and thus subject to FDA regulation.

June 6, 2006, Samp was a featured speaker on a teleconference sponsored by Mealey's Publications, regarding FDA's recently announced policy regarding federal preemption of state-law failure-to-warn tort suits against pharmaceutical manufacturers and health practitioners.

May 16, 2006, Samp was a featured speaker at the annual conference of the ALS Association, a patient advocacy group that promotes improved treatment and medical research for those suffering from ALS. Samp discussed WLF's recent victory in *Abigail Alliance v. von Eschenbach*.

March 30, 2006, Samp was a featured panelist at the Medical Device Regulatory and Compliance Congress, held at Harvard University. Samp discussed manufacturers' First Amendment rights to speak truthfully about FDA-approved medical products.

December 14, 2005, Samp was the keynote speaker at a breakfast symposium in Minneapolis sponsored by Medical Alley and MNBIO. Samp's speech focused on recent federal government enforcement actions under the False Claims Act and the anti-kickback statute.

December 6, 2005, Samp was a featured panelist at the Food and Drug Law Institute's Fourth Annual Enforcement and Litigation Conference in Washington, D.C. Samp spoke on the federal government's efforts to obtain restitution/disgorgement as a remedy for violations of the Federal Food, Drug, and Cosmetic Act.

November 2, 2005, Samp testified before an FDA panel in support of expanding the rights of pharmaceutical companies to engage in direct-to-consumer advertising.

May 11, 2005, Samp was a featured speaker at a seminar in New York City sponsored by Harvard Business School Publishing. Samp spoke on the corporate community's First Amendment rights to speak out on issues of public importance, particularly on health care issues.

January 27, 2005, Samp was a featured speaker at a conference organized by the Food & Drug Law Institute in Washington, D.C. entitled, "Product Liability for FDA Regulated Products: In What Kind of World Are We Living?" Samp addressed potential pitfalls to manufacturers created by the federal False Claims Act.

June 10, 2004, WLF Senior Vice President David Price was a panelist at a forum sponsored by the Cato Institute, together with volunteers from WLF's client, the Abigail Alliance for Better Access to Developmental Drugs. Price discussed WLF's lawsuit on behalf of itself and the Abigail Alliance against the FDA seeking earlier availability of investigational drugs for the terminally ill.
January 23, 2004, Samp was a featured speaker at the annual meeting in Atlanta of NAAMECC (a trade group for companies that produce continuing medical education symposia), warning against government restrictions on the First Amendment right to speak truthfully regarding medical issues.

November 20, 2003, Samp addressed the American Bar Association’s annual pharmaceutical conference in Philadelphia, arguing that expanded use of the False Claims Act as a vehicle for suing drug companies is jeopardizing free speech rights and the ability of drug company’s to continue to develop new, life-saving therapies.

November 8, 2003, Samp addressed the annual meeting of the Society for Academic Continuing Medical Education in Washington, arguing that proposed restrictions on who may speak at Continuing Medical Education events are far too restrictive.

September 25, 2003, Samp spoke in Washington, DC at a symposium organized by Pharmaceutical Education Associates, on the right to enforce drug patents that cover off-label uses of FDA-approved drugs.

September 9, 2003, Samp addressed the American Medical Association’s National Task Force on Continuing Medical Education (CME) in Chicago; Samp argued that proposed restrictions on who can speak at CME gatherings violate First Amendment norms.

May 13, 2003, WLF Chairman and General Counsel Daniel J. Popeo was the keynote speaker at the Ventura County Medical Society's membership meeting in Oxnard, California. Popeo’s speech was titled, “What You Can Do About Lawyers: The Future of Tort Reform and the Role that Doctors Must Play.”

April 23 and June 26, 2003, Samp appeared on CNBC to discuss Nike v. Kasky, the Supreme Court case that addressed the First Amendment right of corporations to freely discuss matters of public interest.

October 25, 2002, Samp was a featured panelist at a symposium organized by the Federalist Society, entitled, “FDA and the First Amendment.”

October 7, 2002, Samp was a panelist at the annual conference of the Regulatory Affairs Professional Society in Washington, D.C., speaking on “The First Amendment and FDA Regulation.”

September 11, 2002, Samp spoke at the Food and Drug Law Institute’s (FDLI) annual conference in Washington, regarding First Amendment constraints on FDA regulation of speech by pharmaceutical companies.

September 10, 2002, Samp testified before the Federal Trade Commission in connection with the FTC’s hearings on “Health Care and Competition.”

September 10, 2002, Samp spoke at the annual conference of the National Task Force on CME Provider/Industry Collaboration in Baltimore, on the topic of whether CME (Continuing Medical
Education) should be subject to FDA regulation.

August 1, 2002, Samp was a featured panelist in an audio conference sponsored by FDLI on "First Amendment Issues Facing the Food and Drug Administration."

May 22, 2002, Popeo was the featured speaker at the Annual Meeting of the Medical Device Manufacturers Association (MDMA). At the MDMA Chairman's Luncheon, Popeo discussed the crucial work of WLF in promoting open markets, free enterprise, and competition, and WLF's legal activities challenging excessive regulation by FDA.

October 10, 2001, Samp appeared on a program sponsored by Maine Public Radio regarding the propriety of States' efforts to impose price controls on prescription drugs.

May 18, 2001, Samp spoke at a luncheon of the Philadelphia chapter of the Federalist Society, regarding FDA regulation of manufacturer speech.

April 20, 2000, Samp was a featured panelist at a New York City symposium sponsored by the Federalist Society, entitled, "The Future of Commercial Speech."

April 6, 2000, Samp addressed a symposium in Washington, D.C. sponsored by the Drug Information Association, regarding "Promoting, Prescribing, and Paying for Off-Label Indications."

September 28, 1999, Samp was interviewed on ABC Radio regarding Pegram v. Herdich, a Supreme Court case in which a patient sought to sue her HMO under ERISA (the federal pension law) because the HMO took steps to reduce medical treatment costs.

September 13, 1999, Samp was a panelist at the FDLI's annual conference, discussing First Amendment restrictions on FDA regulation.

August 25, 1999, Samp was the keynote speaker at the annual meeting of the Indiana Medical Device Manufacturers Association in Indianapolis, where he discussed WLF's successful challenge to FDA speech restrictions.

June 29, 1999, Samp addressed an FDLI conference regarding manufacturer dissemination of peer-reviewed journal articles that discuss off-label uses of FDA-approved products.

May 20, 1999, Samp addressed an FDLI conference regarding WLF's First Amendment victory over the FDA in WLF v. Henney.


January 13, 1999, WLF Legal Studies Division Chief Glenn Lammi provided educational commentary on the WLF v. Henney case to a group of pharmaceutical marketers at a Center for Business Intelligence seminar.
September 10, 1998, Samp addressed a FDLI symposium, to discuss WLF’s court victories over FDA on First Amendment issues.

August 19, 1997, WLF Executive Legal Director Paul Kamenar was featured on FOX 24 Hour News discussing the tort reform implications of a large silicone breast implant verdict by a Louisiana jury against Dow Chemical Company.

June 13, 1997, Kamenar was a featured speaker at the 6th Annual Conference on Biologics and Pharmaceuticals sponsored by International Business Communications, discussing WLF’s First Amendment lawsuit against FDA.

April 9, 1997, Samp addressed a conference sponsored by the Drug Information Association in New Orleans, regarding efforts by FDA to suppress speech regarding off-label uses of approved drugs and medical devices.

November 25, 1996, Samp appeared on National Public Radio to discuss the resignation of FDA Commissioner David Kessler.

August 6, 1996, Samp spoke at the American Bar Association’s annual convention in Orlando, Florida on the topic, “Is the FDA Really Reforming Itself?”

March 20, 1996, Popeo was a keynote speaker at a conference of the Healthcare Marketing & Communications Council in New York City discussing reform of FDA, WLF’s litigation against FDA, and other related programs promoting commercial free speech.

December 7, 1995, Samp spoke to a group of pharmaceutical executives at a Rockville, Maryland forum sponsored by International Business Conferences, regarding WLF’s continuing efforts to prevent FDA abuse of First Amendment rights.

December 7, 1995, Samp was a featured speaker (along with U.S. Representative Joe Barton) at a forum sponsored by the Heritage Foundation entitled, “Is the FDA Killing America?”

November 16, 1995, Samp spoke in Philadelphia at a legal forum sponsored by Mealey’s Publications regarding federal preemption of state tort claims against medical device manufacturers.

October 20, 1995, Samp addressed (along with U.S. Senator Bill Frist of Tennessee) a gathering of orthopedic surgeons at a symposium of the North American Spine Society on the need to streamline FDA.

October 18, 1995, Samp testified before an FDA panel, urging FDA to lift restrictions on direct-to-consumer advertising of prescription drugs.

September 20, 1995, Lammi spoke at a meeting of the Ad Hoc In-House Counsels Working Group, a group of attorneys for pharmaceutical companies, on FDA’s restrictions on advertising and promotion.
September 19, 1995, Popeo served on the faculty at the American Medical Association’s Sixth National Conference on Continuing Medical Education. Popeo discussed WLF’s lawsuit against FDA regarding the suppression of medical literature discussing off-label uses of FDA-approved drugs and devices.

June 27, 1995, Kamenar was a featured speaker at an FDLI conference in Washington, D.C. He discussed WLF’s FDA-reform project and its lawsuit against FDA for prohibiting the dissemination of information about off-label uses of approved drugs and devices.

June 16, 1995, Lammi appeared on National Empowerment Television to discuss FDA reform.

May 22, 1995, Kamenar debated U.S. Representative Don Wyden (D-Ore.) and Bruce Silverglade of the Center for Science in the Public Interest on “America’s Talking” cable television network, regarding FDA reform.

March 13, 1995, Samp addressed the annual meeting of the Pharmaceutical Research and Manufacturers of America (PhRMA) on the need for reform of FDA.

January 31, 1995, Samp was a featured guest on the Diane Rehm Show (syndicated by WAMU-Radio in Washington, D.C.), debating the need for reform of FDA with Dr. Sidney Wolfe of the Public Citizen Health Research Group.

III. PUBLICATIONS

WLF’s Legal Studies Division is the preeminent publisher of persuasive, expertly researched, and highly respected legal papers. They do more than inform the legal community and the public about issues vital to the fundamental rights of every American – they are the very substance that tips the scales in favor of those rights. WLF publishes in seven different formats, which range in length from concise LEGAL BACKGROUNDLERS covering current developments affecting the American legal system, to comprehensive MONOGRAPHS providing law-review-length inquiries into significant legal issues.

A large percentage of WLF publications have focused on health-related topics. WLF’s recent health-related publications include the following:

**Forced Licensing Of Drug Patents Reflects “IP Counterfeiting” Efforts on World Stage**
By Lawrence A. Kogan, CEO of the Institute for Trade, Standards and Sustainable Development Inc.
LEGAL BACKGROUNDER, June 22, 2007, 4 pages

**KSR v. Teleflex: High Court’s “Obviousness” Ruling No Sea Change in Patent Law**
By The Honorable Gerald J. Mossinghoff, Senior Counsel at the Alexandria, Virginia law firm Oblon, Spivak, McClelland, Maier & Neustadt, P.C.
LEGAL BACKGROUNDER, June 8, 2007, 4 pages

43
Greater Transparency Needed In Reprocessing Of Medical Devices
By The Honorable Bob Franks, President of the HealthCare Institute of New Jersey. Previously, Mr. Franks served four consecutive terms representing the Seventh District of New Jersey in the U. S. House of Representatives.
LEGAL OPINION LETTER, March 23, 2007, 2 pages

Courts’ Misapplication Of FDA Preemption Policy Creates Quandary For Drug Producers
By Linda Pissott Reig and John T. Chester, attorneys in the Morristown, New Jersey office of the law firm Porzio, Bromberg & Newman, P.C.
LEGAL BACKGROUNDER, March 9, 2007, 4 pages

Regulatory Pathway For “Biosimilar” Products Debated
By Donald E. Segal, Sharon D. Brooks, Marc J. Scheineson, and Julie K. Tibbets, attorneys in the Washington, D.C. office of the law firm Alston & Bird LLP.
LEGAL BACKGROUNDER, February 23, 2007, 4 pages

Pharmaceutical Advertising: “May You Live In Interesting Times”
By Arnold I. Friede, an attorney who previously served in the FDA’s Chief Counsel's Office, and is currently Senior Corporate Counsel at Pfizer Inc.
WORKING PAPER, February 2007, 18 pages

Surgeon-Owned Device Companies: A Risky Proposition
By Eugene E. Elder, a partner in the law firm Akin Gump Strauss Hauer & Feld LLP in its Washington, D.C. office.
LEGAL BACKGROUNDER, January 26, 2007, 4 pages

Mandated Research Database Would Impair Copyrights and Health
By Richard L. Frank, a founder of and Senior Principal Attorney with Olsson, Frank and Weeda P.C. and Kenneth D. Ackerman, Of Counsel to the firm.
LEGAL BACKGROUNDER, January 12, 2007, 4 pages

A Priority For The FDA: Fix The “Warning Letter” Process
By Larry R. Pilot, a partner with the law firm McKenna Long & Aldridge LLP in its Washington, D.C. office.
LEGAL BACKGROUNDER, October 20, 2006, 4 pages

Beyond The “Yuck Factor”: Product Liability Implications Of Medical Device Reprocessing
By Peter J. Goss, a partner in the Minneapolis office of the law firm Faegre & Benson LLP.
WORKING PAPER, September 2006, 15 pages

Drug Price Control Fails Constitutional Test
By Grant P. Bagley and Rosemary Maxwell, members of the healthcare and pharmaceutical regulatory practice in the Washington D.C. office of the law firm Arnold and Porter LLP.
LEGAL BACKGROUNDER, August 4, 2006, 4 pages
CMS Information Policy Under Medicare “Part D” Creates 1st Amendment Problems
By Ronald D. Rotunda, a professor of law at the George Mason University School of Law.
LEGAL BACKGROUNDER, July 7, 2006, 4 pages

New False Claims Law Incentives Pose Risks To Contractors And States
By John T. Boese and Beth C. McClain, a partner and a special counsel, respectively, to the law firm Fried, Frank, Harris, Shriver & Jacobson LLP in its Washington, D.C. office.
WORKING PAPER, June 2006, 16 pages

Multiple Sclerosis Patients v. FDA Overcaution
By Lauren Roberts, a multiple sclerosis patient living in California.
LEGAL OPINION LETTER, May 19, 2006, 2 pages

Health And Speech Rights At Risk from Attacks On Medical Education
By Jeffrey N. Gibbs, a principal with the law firm Hyman, Phelps & McNamara, P.C. in its Washington, D.C. office.
LEGAL BACKGROUNDER, April 7, 2006, 4 pages

Advertising And Preemption Under FDA's New Drug Labeling Rule
By Tish E. Pahl, a principal with Olsson, Frank and Weeda, P.C.
LEGAL OPINION LETTER, March 24, 2006, 2 pages

Quietly Expanding Qui Tam: Federal Law Encourages New State False Claims Acts
By John T. Boese, a partner in the Washington, D.C. office of the law firm Fried, Frank, Harris, Shriver & Jacobson LLP.
LEGAL OPINION LETTER, March 10, 2006, 2 pages

European Commission Paper On “Healthy Diets” Has Implications For Food Industry
By Sarah A. Key, an associate in the Washington D.C. office of Foley & Lardner LLP. She is a member of the Regulatory Department, its General Regulatory Practice Group, and the Food Industry and International Business Teams.
COUNSEL’S ADVISORY, March 10, 2006, 1 page

Don’t Dilute Drug Approval Process With Non-Scientific Criteria
By Gilbert L. Ross, M.D., the Executive Director and Medical Director of the American Council on Science and Health (ACSH), a consumer education-public health organization; and Elizabeth M. Whelan, MPH, ScD, President and founder of the American Council on Science and Health.
LEGAL OPINION LETTER, March 10, 2006, 2 pages

“Off-Label” Speech: Uncertainty Reigns For Device & Drug Makers
By Ralph F. Hall, Visiting Associate Professor of Law at the University of Minnesota Law School and Counsel to the law firm Baker & Daniels, Indianapolis, Indiana, and Washington D.C.
LEGAL BACKGROUNDER, December 2, 2005, 4 pages
Streamlining Appeals At FDA: A Modest Proposal
By Donald E. Segal, a partner in the Food, Drug and Device Group of the law firm Alston & Bird LLP, and Sharon D. Brooks, an associate in the firm’s Washington, D.C. office.
LEGAL BACKGROUNDER, November 4, 2005, 4 pages

Courts Scrutinize FDA “Disgorgement” Demands
By Christine P. Bump, an associate with the law firm Hyman, Phelps & McNamara, P.C.
LEGAL BACKGROUNDER, November 4, 2005, 4 pages

DOJ Prosecution Guidance Impacts Health Care Businesses
By Karen Owen Dunlop, a partner in the Chicago office of the law firm Sidley Austin Brown & Wood LLP.
LEGAL OPINION LETTER, August 26, 2005, 2 pages

FDA's Unauthorized User Fee Money Grab
By Robert A. Dormer, a director, and Kurt R. Karst, an associate, at the Washington, D.C. law firm Hyman, Phelps & McNamara, P.C.
LEGAL BACKGROUNDER, August 12, 2005, 4 pages

Impact On Patient Care Must Be Factor When Assessing “Gainsharing” Arrangements
By Bradley Merrill Thompson, a partner in the law firm of Baker & Daniels in its Indianapolis office.
LEGAL BACKGROUNDER, July 15, 2005, 4 pages

Conditioning FDA Approval On Agreement Not To Advertise Violates Law And Constitution
LEGAL BACKGROUNDER, July 15, 2005, 4 pages

“Gainsharing” Arrangements Present Challenging Issues For Policymakers & Participants
By Sanford V. Teplitzky, a principal and Chairman of the Health Law Department of the law firm Ober, Kaler, Grimes & Shriver in its Baltimore office; and William T. Mathias, a principal in the Health Law Department of Ober, Kaler, Grimes & Shriver.
LEGAL BACKGROUNDER, July 1, 2005, 4 pages

Proposal Limiting Distribution Of Health Care Information Infringes Free Speech Rights
By Glenn G. Lammi, Chief Counsel to Washington Legal Foundation’s Legal Studies Division.
LEGAL OPINION LETTER, June 17, 2005, 2 pages

Measured, Uniform Approach Needed To Battle “Meth” Makers’ Abuse Of OTC Medicines
By John A. Gilbert, Jr., a partner with the law firm Hyman, Phelps & McNamara, P.C. He was previously an attorney in the Drug Enforcement Administration’s Office of Chief Counsel, Diversion/Regulatory Section.
LEGAL BACKGROUNDER, June 3, 2005, 4 pages

46
Linking Medicare Coverage to Research Participation: Reasonable and Necessary?
By Grant P. Bagley, M.D., J.D., a partner in Arnold & Porter LLP’s Washington, D.C., office, where his practice focuses on the representation of drug and device manufacturers for regulatory and reimbursement matters before public and private agencies; and Rosemary Maxwell, Counsel to the law firm Arnold & Porter LLP in its Washington, D.C. office. Ms. Maxwell focuses on healthcare compliance and public policy issues.
WORKING PAPER, May 2005, 23 pages

Petition Seeks Transfer Of Oversight For Drug Promotion Investigations
By Richard Samp, Chief Counsel of the Washington Legal Foundation.
COUNSEL’S ADVISORY, May 6, 2005, 1 page

State Drug Ad “Rebate” Proposal Treads On Commercial Speech Rights
By Rosemary C. Harold, a partner, and Mark A. McAndrew, an associate in the Washington, D.C. law firm Wiley, Rein & Fielding LLP.
LEGAL OPINION LETTER, March 25, 2005, 2 pages

DEA’s Review Of Drug Approvals Could Limit Access To Vital Medicines
By James R. Phelps, a founding partner of the law firm Hyman, Phelps & McNamara, P.C. and John A. Gilbert, Jr., also a partner with the firm.
LEGAL BACKGROUND, March 11, 2005, 4 pages

Making FDA Work For Patients
By Steven Walker, Regulatory Advisor to the Abigail Alliance for Better Access to Developmental Drugs, an Arlington, Virginia-based patient group dedicated to helping cancer patients and others with life-threatening and serious diseases.
LEGAL BACKGROUND, February 25, 2005, 4 pages

Conversations With: Prescription Drug Abuse
Features The Honorable Dick Thornburgh, Counsel to the law firm Kirkpatrick & Lockhart Nicholson Graham LLP leading a discussion with The Honorable Rudolph W. Giuliani, Chairman and Chief Executive Officer, Giuliani Partners LLC.
CONVERSATIONS WITH, Winter 2005, 6 pages

What Businesses Need To Know About FDA’s Plan To Combat Obesity
By Sarah A. Key, an attorney in the Washington, D.C. office of the law firm Morgan Lewis LLP.
LEGAL OPINION LETTER, January 28, 2005, 2 pages

FDA Must Reform Its Arbitrary Drug Name Review Process
By Jeffrey N. Gibbs, a director at the Washington, D.C. law firm Hyman, Phelps & McNamara.
LEGAL BACKGROUND, January 28, 2005, 4 pages
Drug Price Regulation By Lawsuit Hazardous To American’s Health
By Kevin E. Grady, an antitrust partner in the Atlanta office of the law firm Alston & Bird LLP; Marc J. Scheineson, a food and drug partner in the firm’s Washington, D.C. office and a former FDA Associate Commissioner; and Stewart F. Alford IV, an associate in the trial practice and antitrust groups of the firm’s Atlanta office.
LEGAL BACKGROUNDER, December 3, 2004, 4 pages

CMS Advises On Reimbursement For Off-Label Use Of Drugs
By David Price, Senior Vice President for Legal Affairs of the Washington Legal Foundation.
COUNSEL’S ADVISORY, October 15, 2004, 1 page

State Fraud Suits Over Drug Clinical Trial Results Tread On Free Speech Rights
By Mark E. Nagle, a partner in the Washington, D.C. office of the law firm Sheppard, Mullin, Richter & Hampton LLP, who, immediately prior to joining the firm, served as Chief of the Civil Division in the United States Attorney’s office for the District of Columbia.
LEGAL BACKGROUNDER, September 17, 2004, 4 pages

Medicare Drug Reimbursement Reform Presents Challenges And Opportunities
By Glenn G. Lammi, Chief Counsel of the Washington Legal Foundation’s Legal Studies Division.
LEGAL OPINION LETTER, August 20, 2004, 2 pages

Senate Proposal On Drug Importation Treads On Constitutional Rights
By Burt Neuborne, John Norton Pomeroy Professor of Law at New York University Law School, where he has taught Constitutional Law, Federal Courts, Civil Procedure and Evidence for more than thirty years.
LEGAL BACKGROUNDER, July 9, 2004, 4 pages

NIH Invites Public Comment On Petition Seeking Drug Price Controls
By David Price, Senior Vice President for Legal Affairs of the Washington Legal Foundation.
COUNSEL’S ADVISORY, June 25, 2004, 1 page

Drug Importation: A Prescription To Put Biotech On Life Support
By David M. McIntosh, a former Congressman from Indiana, and currently a partner in the Washington office of the Washington law firm Mayer, Brown, Rowe & Maw LLP.
LEGAL BACKGROUNDER, June 11, 2004, 4 pages

Debate Over “Generic Biologics” Poses Unique Challenges For Policy Makers
By Alvin J. Lorman, a partner in the Washington, D.C. office of the global law firm of Mayer, Brown, Rowe & Maw LLP.
LEGAL BACKGROUNDER, May 14, 2004, 4 pages

Unique California Laws Imperil Speech On “Off-Label” Use Of Drugs
By Lisa M. Baird and Michael K. Brown, partners in the international law firm of Reed Smith LLP who specialize in litigation involving the pharmaceutical and medical device industries.
LEGAL BACKGROUNDER, May 14, 2004, 4 pages

48
Altering Patent Suit Proof Burden Would Chill Innovation
By Michael J. Shuster, co-chair of the law firm Fenwick & West’s Bioscience Industries Group, Dan Flam, an intern with the firm, and Sasha Blaug, an analyst with the firm.
LEGAL BACKGROUNDER, April 16, 2004, 4 pages

Better Late Than Sorry: Medicare Reform Ushers In New Rules On Generic Drugs
By Alan R. Bennett, a partner with the law firm of Ropes & Gray LLP in the firm’s Washington, D.C. office and X. Joanna Wu, Ph.D., an associate with the law firm in the Boston office.
LEGAL BACKGROUNDER, March 19, 2004, 4 pages

Appeals Court Opens Door To Suits On Medicare Agency Decisions
By David Price, Senior Vice President, Legal Affairs, of the Washington Legal Foundation.
COUNSEL’S ADVISORY, March 5, 2004, 1 page

Does Reprocessing Of Medical Devices Tread On Trademark Rights?
By James Dabney Miller, a partner with the law firm King & Spalding LLP.
LEGAL BACKGROUNDER, March 5, 2004, 4 pages

FDA Guidance for “DTC” Ads Strives To Advance Consumer Understanding
By Rosemary C. Harold, a partner with the Washington, D.C. law firm Wiley Rein & Fielding LLP, and John F. Kamp, of counsel to the firm.
LEGAL OPINION LETTER, February 20, 2004, 2 pages

Patent Harmonization Through The UN: International Progress Or Deadlock?
By The Honorable Gerald J. Mossinghoff, Senior Counsel, Oblon, Spivak, McClellan, Maier & Neustadt; Cifelli Professorial Lecturer, The George Washington University Law School; and former Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.
LEGAL BACKGROUNDER, December 19, 2003, 4 pages

Avoiding Collisions At The Intersection Of Antitrust And Intellectual Property Laws
By Scott P. Perlman and Lily Fu Swenson, partners in the Washington, D.C. office of the law firm Mayer, Brown, Rowe & Maw LLP.
CONTEMPORARY LEGAL NOTE, December 2003, 38 pages

European Court Issues Encouraging Ruling On Intellectual Property
By Howard Fogt, a partner in the Washington, D.C. office of the law firm Foley & Lardner and Sophie Lignier, of counsel in the firm’s Brussels office.
LEGAL OPINION LETTER, October 31, 2003, 2 pages

Accurate Drug Price Reporting: A Modest Proposal
LEGAL BACKGROUNDER, October 17, 2003, 4 pages
FDA Lacks Authority To Impose Civil Monetary Fines
By Marc J. Scheineson, a partner in the law firm of Reed Smith, LLP and Robert J. Kaufman, a third year law student at Harvard Law School.
LEGAL BACKGROUNDER, October 17, 2003, 4 pages

FDA Should Propose Rule On Federal Preemption Of Failure To Warn Lawsuits
By James Dabney Miller, a partner with the law firm King & Spalding LLP in its Washington, D.C. office.
LEGAL BACKGROUNDER, September 19, 2003, 4 pages

Research Grants And Fraud Laws: The Need To Separate Sales And Science
By David Hoffmeister, a partner with the law firm Wilson Sonsini Goodrich & Rosati.
LEGAL BACKGROUNDER, July 18, 2003, 23 pages

Compliance Planning For “Voluntary” Guidelines On Drug Marketing Practices
CONTEMPORARY LEGAL NOTE, July, 2003, 4 pages

FDA Lacks Authority To Force Over-The-Counter Drug Switch
By Andrew S. Krulwich, a partner in the Washington, D.C. law firm Wiley Rein & Fielding LLP.
LEGAL BACKGROUNDER, June 27, 2003, 4 pages

States’ Use Of Lawsuits To Regulate Drug Pricing Threatens Patients’ Health
By James M. Spears and Terry S. Coleman, partners in the Washington office of Ropes & Gray.
LEGAL BACKGROUNDER, June 27, 2003, 4 pages

The High Cost Of Low Cost Drugs: Why The “Canadian Model” Is No Panacea For Pricing
By Monte Solberg, the Canadian Alliance Member of Parliament for Medicine Hat Alberta currently serves as Vice Chair of the House of Commons Standing Committee on Human Resources Development.
LEGAL OPINION LETTER, June 6, 2003, 2 pages

FDA “Trans Fat” Labeling Proposal Treads On Commercial Free Speech
By Christopher A. Brown, an associate with the law firm of Sonnenschein Nath & Rosenthal in its Washington, D.C. office.
LEGAL OPINION LETTER, June 6, 2003, 2 pages

New CME Bias Standards Will Reduce Quality Of Medical Education
By Alan R. Bennett and Dr. Gregory J. Glover, partners with the law firm Ropes & Gray in its Washington, D.C. office.
LEGAL OPINION LETTER, June 6, 2003, 2 pages
HHS Expanded Use Of Fraud Law's "Corporate Death Sentence" Is Legally Suspect
By Ronald H. Clark, a Member of Arent Fox Kintner Plotkin & Kahn, PLLC in its Washington, D.C. office; Gabriel L. Imperato, the Managing Partner of Broad and Cassel's Fort Lauderdale office and head of the firm's White Collar/Health Care Criminal and Civil Fraud Practice; and Robert Salcido, a partner at Akin Gump Strauss Hauer & Feld, L.L.P., in its Washington, D.C. office.
LEGAL BACKGROUNDER, June 6, 2003, 4 pages

Commercial Speech And The Limits Of Federal Anti-Kickback Laws
By Rosemary Maxwell, a member of the health care and pharmaceutical regulatory practice in the Washington, D.C. office of the law firm Arnold & Porter.
WORKING PAPER, May 2003, 27 pages

FDA Limits On Dual Trademarks Tread On Patient Safety And Law
By Marc J. Scheineson, a partner in the law firm of Reed Smith, LLP in Washington, D.C. where he heads the firm's food and drug practice.
LEGAL BACKGROUNDER, April 25, 2003, 4 pages

Michigan High Court Upholds Drug Product Liability Reform
By Thomas J. Foley, a founder of the Detroit area law firm of Foley, Baron & Metzger, PLLC.
COUNSEL'S ADVISORY, April 25, 2003, 1 page

FDA Must Clarify Drug Makers' Ability To Publicly Defend Products
By Kathleen M. Sanzo and Stephen Paul Mahinka, partners in the Washington, D.C. office of the law firm of Morgan Lewis, LLP.
LEGAL OPINION LETTER, February 28, 2003, 2 pages

Dramatic Changes To CME Accreditation Process Compel Scrutiny And Comment
By Richard Samp, Chief Counsel of the Washington Legal Foundation.
COUNSEL'S ADVISORY, February 14, 2003, 1 page

Pharmacist's Crime Shouldn't Expose Businesses To Liability
By Thomas P. Redick, a partner in the St. Louis law firm Gallop, Johnson & Neuman, L.C.
LEGAL OPINION LETTER, January 31, 2003, 2 pages

Mixed Results For Free Speech In FDA Health Claims Guidance
By George W. Evans, Associate General Counsel to Pfizer, Inc., and Arnold I. Friede, Senior Corporate Counsel to Pfizer.
LEGAL OPINION LETTER, January 17, 2003, 2 pages

Vaccine Liability Law Clarification Protects Lives And Resources
By Victor E. Schwartz, chairman of the Public Policy Group at the law firm Shook, Hardy & Bacon L.L.P., and Leah Lorber, of counsel to the firm.
LEGAL BACKGROUNDER, January 10, 2003, 4 pages
Biting The Hand That Feeds?: Generic Drugs And Abuse Of The Hatch-Waxman Law
LEGAL BACKGROUND, December 6, 2002, 4 pages

Federal Court Ruling Impacts FDA Suppression Of Medical Speech
By George W. Evans, an Associate General Counsel, Pfizer Inc., and General Counsel–Pfizer Pharmaceuticals Group, and Arnold I. Friede, a Senior Corporate Counsel at Pfizer Inc., who formerly served in the FDA Chief Counsel’s Office.
LEGAL OPINION LETTER, November 15, 2002, 2 pages

FDA Limits On Print Drug Ads Violate First Amendment
By Richard L. Frank, a principal at the Washington, D.C. law firm Olsson, Frank and Weeda, P.C., and Tish Eggelston Pahl, a senior associate at Olsson, Frank and Weeda, P.C.
LEGAL BACKGROUND, October 4, 2002, 4 pages

FTC Administrative Judge Rejects Commission’s View Of Drug Patent Settlements
By Geraldine M. Alexis and Zorah Braithwaite, a partner and an associate, respectively, with the law firm Bingham McCutchen LLP in its San Francisco office.
LEGAL BACKGROUND, October 4, 2002, 4 pages

In The Eye Of The Storm: Tips For Managing An FDA Recall
By David M. Hoffmeister, a partner with the law firm Wilson Sonsini Goodrich & Rosati, and Wayne L. Pines, President of Regulatory Services and Healthcare at APCO Worldwide.
LEGAL BACKGROUND, September 6, 2002, 4 pages

FTC, Not FDA, Should Regulate Online Food Information
By Lawrence S. Ganslaw, an associate, and Kathleen M. Sanzo, a partner, in the Washington, D.C. office of the law firm Morgan, Lewis & Bockius LLP.
LEGAL BACKGROUND, September 6, 2002, 4 pages

An FDA Q&A: How Does The First Amendment Limit Its Regulatory Power
LEGAL BACKGROUND, August 23, 2002, 4 pages

Proposed Limits On Prescription Drug Ads: A Constitutional Analysis
WORKING PAPER, July 2002, 40 pages

Drug Ads Enhance Health By Empowering Patients
By Richard L. Manning, PhD, Director of Economic Policy Analysis at Pfizer Inc.
LEGAL OPINION LETTER, May 10, 2002, 2 pages
Recent Patent Ruling Intrudes On Key Antitrust Immunity Doctrine
By Christopher Sipes and James R. Atwood, partners in the Washington, D.C. office of the law firm Covington & Burling.
LEGAL BACKGROUND, April 26, 2002, 4 pages

New FDA Policy On Warning Letters A Sensible Move Towards Due Process
By Larry R. Pilot, a partner in the Washington, D.C. office of the law firm McKenna Long & Aldridge.
LEGAL OPINION LETTER, January 25, 2002, 2 pages

Forcing Drugs To “OTC” Status Treads On Law And Patient Safety
By Richard F. Kingham, a partner with the Washington, D.C. law firm Covington & Burling practicing for nearly thirty years in the areas of food and drug law and regulation.
LEGAL BACKGROUND, November 2, 2001, 4 pages

New Commissioner Must Adapt FDA To A New Security Role
By Alan Slobodin, Senior Oversight Counsel at the House Energy and Commerce Committee.
LEGAL BACKGROUND, October 19, 2001, 4 pages

Priorities For A New FDA Commissioner
By John W. Bode, a partner with the Washington, D.C. law firm Olsson, Frank and Weeda, P.C. and a former Assistant Secretary of Agriculture.
LEGAL BACKGROUND, October 5, 2001, 4 pages

Innovative Reforms Could Reduce Time And Cost Of Drug Approvals
By Henry I. Miller, a fellow at the Hoover Institution and the Competitive Enterprise Institute.
LEGAL OPINION LETTER, June 15, 2001, 2 pages

Excessive FDA Scrutiny Of DTC Ads Undermines Speech Rights
By Sandra J. P. Dennis, a partner, and Lawrence S. Ganslaw, an associate, in the Washington D.C. office of Morgan Lewis LLP in the FDA/Product Regulation Practice Group.
LEGAL BACKGROUND, May 18, 2001, 4 pages

Activists Use Mad Cow Scare To Advance Ideological Agendas
By David Martosko, Director of Research for The Guest Choice Network.
LEGAL BACKGROUND, May 4, 2001, 4 pages

Does Junk Science Influence FDA Decisions On Drug Recalls?
By Carl W. Hampe, a partner with the international law firm Baker & McKenzie.
LEGAL BACKGROUND, February 9, 2001, 4 pages

Federal Court Blocks Maine Drug Price Control Law
By Richard A. Samp, Chief Counsel to the Washington Legal Foundation.
COUNSEL’S ADVISORY, November 17, 2000, 1 page

Proposal To Deny Tax Deduction For Drug Ad Expenses Unconstitutional
LEGAL OPINION LETTER, October 23, 2000, 2 pages
FDA's Restitution "Authority" Relies Upon Flawed Court Ruling
By Jeffrey N. Gibbs, a partner with the Washington, D.C. law firm Hyman, Phelps & McNamara.
LEGAL OPINION LETTER, October 6, 2000, 2 pages

Maine Drug Price Control Act Vulnerable To Legal Challenge
By Glenn G. Lammi, Chief Counsel to Washington Legal Foundation's Legal Studies Division.
LEGAL OPINION LETTER, July 14, 2000, 2 pages

FDA And DTC Advertising: Changes, Challenges & Constitutional Scrutiny
By Sandra J. P. Dennis, a partner in the Washington D.C. office of Morgan Lewis LLP
CONTEMPORARY LEGAL NOTE, October 1999, 28 pages

Court Again Nullifies FDA Policies Restricting Health Care Information
By George M. Burditt, a partner with the Chicago law firm Bell, Boyd & Lloyd.
LEGAL OPINION LETTER, September 17, 1999, 2 pages

Court Ruling Frustrates Access To Off-label Drug Information
By Mark Boulding, General Counsel and Vice President, Regulatory Affairs for Medscape Inc.
LEGAL OPINION LETTER, April 30, 1999, 2 pages

Court Suppresses FDA Censorship Of Health Product Information
By George M. Burditt, a partner with the Chicago law firm Bell, Boyd & Lloyd.
LEGAL OPINION LETTER, November 4, 1998, 2 pages

FDA "Draft Guidance" Suppresses Critical Health Care Information
By Marc J. Scheineson, head of the food and drug practice at the law firm Reed Smith from its
Washington, D.C. office, and a former FDA Associate Commissioner for Legislative Affairs, and
Katherine Chen, a food and drug associate at the firm.
LEGAL BACKGROUNDER, April 3, 1998, 4 pages

Public Comment Can Shape FDA Guidance On TV Advertising
By Mark E. Boulding, General Counsel & Vice President, Regulatory Affairs for Medscape Inc.
LEGAL OPINION LETTER, September 12, 1997, 2 pages

Ten Questions For The Next FDA Commissioner
By Daniel J. Popeo, Chairman and General Counsel to the Washington Legal Foundation.
LEGAL BACKGROUNDER, April 4, 1997, 4 pages

Federal Appeals Court Finds State Food Labeling Law Unconstitutional
By Steven J. Rosenbaum, a partner and Sarah E. Taylor, Of Counsel, in the Washington, D.C.
offices of Covington & Burling.
LEGAL OPINION LETTER, December 6, 1996, 2 pages.

Federal Court Must Strike Down FDA Censorship Of Advertising
By David S. Versfelt, a partner with the New York office of the law firm Kirkpatrick & Lockhart
LLP.
LEGAL BACKGROUNDER, November 1, 1996, 4 pages
FDA Regulation May Inhibit Positive Uses Of The Internet
By Daniel A. Kracov, a partner with the Washington, D.C. law firm Patton Boggs LLP, and
David J. Bloch, a partner in the Washington, D.C. office of the law firm Reed Smith.
LEGAL BACKGROUNDER, October 4, 1996, 4 pages

Era Of Big Government Continues With Scrutiny Of Menus
By Elizabeth Toni Guarino, an attorney with the Washington, D.C. law firm Vorys, Sater,
Seymour and Pease LLP.
LEGAL BACKGROUNDER, September 6, 1996, 4 pages

Comment On Potential Revisions To FDA Regulations
By Alan R. Bennett, a partner in the Washington, D.C. office of the law firm Ropes & Gray.
COUNSEL'S ADVISORY, August 23, 1996, 1 page

FDA Prevents Doctors And Consumers From Receiving Health Care Information
By William G. Castagnoli, former Chairman of Medicus Communications, and Harry A.
Sweeney, Jr., President of Dorland Sweeney Jones, agencies specializing in pharmaceutical
advertising and health care communications.
LEGAL BACKGROUNDER, December 15, 1995, 4 pages

The Pedicle Screw And FDA: Another Example Of Politicized Science
By Neil Kahanovitz, M.D., a practicing orthopedic surgeon and founder and President of Center
for Patient Advocacy.
COUNSEL'S ADVISORY, October 18, 1995, 1 page

FDA Suppression Of Advertising To Consumers Violates The First Amendment
By William C. MacLeod, a partner with the Washington, D.C. law firm of Collier Shannon Scott.
LEGAL BACKGROUNDER, September 15, 1995, 4 pages

FDA Inhibits Free Flow Of Information On Medical Products
By Alan R. Bennett, a partner in the Washington, D.C. office of the law firm Ropes & Gray, and
Mark E. Boulding, General Counsel and Vice President, Regulatory Affairs for Medscape.
LEGAL BACKGROUNDER, September 1, 1995, 4 pages

FDA Criminal Enforcement: Punish Intent — Not Relationships
By John F. Lemker, a partner with the Chicago law firm Bell, Boyd & Lloyd.
LEGAL BACKGROUNDER, June 30, 1995, 4 pages

FDA Financial Disclosure Proposal Should Be Withdrawn
By Jeffrey N. Gibbs, a partner with the Washington, D.C. law firm Hyman, Phelps & McNamara.
LEGAL BACKGROUNDER, April 14, 1995, 4 pages

FDA Reform Will Improve Nation's Health Care And Competitiveness
By Alan H. Magazine, former President of the Health Industry Manufacturers Association.
LEGAL BACKGROUNDER, March 3, 1995, 4 pages
Oversight Of FDA Should Focus On Agency’s Abuse Of Power And Misuse Of Science
By James R. Phelps, a partner with the Washington, D.C. law firm Hyman, Phelps & McNamara.
LEGAL BACKGROUNDER, March 3, 1995, 4 pages

FDA Direct-To-Consumer Advertising Regulation Raises Constitutional And Policy Concerns
By James M. Johnstone, a Washington, D.C. lawyer.
LEGAL BACKGROUNDER, January 20, 1995, 4 pages

Weigh In Against FDA Suppression
By Richard A. Samp, Washington Legal Foundation Chief Counsel.
COUNSEL’S ADVISORY, December 16, 1994, 1 page

FDA’s Legally Suspect Actions Invite Challenge
By Glean G. Lammi, Chief Counsel of WLF’s Legal Studies Division.
LEGAL BACKGROUNDER, November 28, 1994, 4 pages

FDA Paralysis Raises Health Care Costs
By Alan M. Slobodin, Senior Counsel to the House Energy & Commerce Committee, and Roman P. Storzer, a former WLF Fellow.
LEGAL BACKGROUNDER, November 14, 1994, 4 pages

The Real Problem With Health Care In America: While FDA Fiddles, Medical Approvals Lag And Americans Die
By Alan M. Slobodin, Senior Counsel to the House Energy & Commerce Committee.
LEGAL BACKGROUNDER, October 28, 1994, 4 pages

What The FDA Doesn’t Want You To Know Could Kill You
By Richard A. Samp, Chief Counsel to the Washington Legal Foundation.
LEGAL BACKGROUNDER, October 28, 1994, 4 pages

Let’s Stop Playing Culinary Roulette And Get On With Irradiating Food
By Paul B. Jacoby, a Washington, D.C. attorney, and James Baller, a partner with the Washington, D.C. law firm of Baller Hammett, P.C.
LEGAL OPINION LETTER, May 20, 1994, 2 pages

Regulate To Eliminate: The Real Goal Of The Neo-Prohibitionist Movement
By Dr. James T. Bennett, a Professor of Economics at George Mason University.
LEGAL BACKGROUNDER, February 28, 1994, 4 pages

The Delaney Clause Should Not Block A More Balanced Food Safety Policy
By Richard A. Merrill, Dean of the University of Virginia School of Law and Special Counsel to the Washington, D.C. law firm of Covington & Burling.
LEGAL BACKGROUNDER, March 19, 1993, 4 pages

FDA Should Stay Bound By Its Advisory Opinions
By Jeffrey N. Gibbs, a partner with the Washington, D.C. law firm Hyman, Phelps & McNamara.
LEGAL OPINION LETTER, March 5, 1993, 2 pages
FDA Criminal Enforcement: How To Prevent And Defend Against Liability
By Steven M. Kowal, a partner with the Chicago law firm Bell, Boyd & Lloyd. Foreword by C. Manly Molpus, President and CEO, Grocery Manufacturers of America, Inc.
MONOGRAPH, January 1993, 72 pages

Zero-Risk Standards For Pesticides In Foods Should Be Reversed
LEGAL OPINION LETTER, September 25, 1992, 2 pages

Public Health Advances Impeded As Anti-Science Activists Thwart Food Safety Program
By Robert G. Hibbert, a partner with the law firm of McDermott, Will & Emery, Washington, D.C.
LEGAL BACKGROUNDER, August 14, 1992, 4 pages

FDA’s Enforcement Agenda — What’s Next?
By Stuart M. Pape, a partner in the Washington, D.C. law firm of Patton Boggs specializing in food and drug law.
LEGAL BACKGROUNDER, June 5, 1992, 4 pages

Pesticide Tolerances And Food Safety: Two Hot Topics In Congress And The Courtroom In 1992
LEGAL OPINION LETTER, April 10, 1992, 2 pages

There They Go Again: Activists Use Junk Science To Block Food Irradiation Technology
By Glenn G. Lammi, Chief Counsel to WLF’s Legal Studies Division.
LEGAL OPINION LETTER, February 21, 1992, 2 pages

Proposed FDA Advertising And Promotion Guidelines Would Inhibit Free Exchange Of Ideas
By Melinda L. Sidak, an attorney with the Washington, D.C. office of Covington & Burling.
LEGAL BACKGROUNDER, February 21, 1992, 4 pages

FDA Food Agenda Overlooks The Basics
By Gary Jay Kushner, a partner in the Washington, D.C. office of Hogan & Hartson.
LEGAL BACKGROUNDER, February 21, 1992, 4 pages

Targeting Of Brand Names By FDA And USDA Raises First And Fifth Amendment Issues
By Hugh Latimer, a partner in the Washington, D.C. office of Wiley, Rein & Fielding.
LEGAL BACKGROUNDER, January 24, 1992, 4 pages

MSG “Junk Science”: A Folly That Does Not Warrant FDA Regulation
By Glenn G. Lammi, Chief Counsel to WLF’s Legal Studies Division.
LEGAL BACKGROUNDER, January 10, 1992, 4 pages
Proposed Legislation To Enhance FDA Enforcement Powers Raises Constitutional Concerns
By Edward Dunkelberger, formerly a partner in the Washington, D.C. office of Covington & Burling.
LEGAL BACKGROUND, September 6, 1991, 4 pages
April 15, 2008

QUARTERLY ACTIVITIES REPORT TO THE WASHINGTON LEGAL FOUNDATION BOARD OF TRUSTEES

The ideals upon which America was founded -- individual freedom, limited government, free market economy, and a strong national security and defense -- are the same principles that the Washington Legal Foundation (WLF) defends in the public interest arena. WLF's overriding mission is to defend and promote freedom and justice.

WLF engaged in the following activities in support of its public interest mission during the first quarter of 2008:

TIMELINE AND SPECIAL REPORT: FEDERAL EROSION OF BUSINESS CIVIL LIBERTIES

In February 2008, WLF published a useful reference guide and resource, TIMELINE: FEDERAL EROSION OF BUSINESS CIVIL LIBERTIES, that presents, in summary form, the key legal, judicial, and regulatory developments in the growing trend to criminalize normal business activities. The unique format of WLF's timeline is a convenient, fold-out, color chart that contains over 130 entries covering six related subject-matter categories over a time period from 1900 to 2007. Ideal for corporate counsel, white-collar defense attorneys, and the general legal and public policy community, WLF's timeline traces the chronological development of the law in the following areas, with an emphasis on environmental law: (1) Mens Rea, Public Welfare Offenses, and the Responsible Corporate Officer Doctrine; (2) EPA Criminal Enforcement Policies; (3) DOJ Criminal Prosecution Policies; (4) Attorney-Client and Work Product Privileges; (5) Deferred Prosecution and Non-Prosecution Agreements; and (6) Criminal Sentencing.

In April 2008, WLF is publishing the companion SPECIAL REPORT: FEDERAL EROSION OF BUSINESS CIVIL LIBERTIES, a 125-page report that discusses in greater detail the topics outlined in the timeline. With an Introduction by Former Attorney General Dick Thornburgh, the report reveals how the EPA and DOJ have often resorted to criminal prosecution of minor regulatory offenses when administrative and civil remedies would be more appropriate. In that regard, the report presents several alarming case studies that illustrate EPA's and DOJ's abusive prosecutorial practices.

WLF's timeline and report are being produced as part of WLF's CRIMINALIZATION OF FREE ENTERPRISE-BUSINESS CIVIL LIBERTIES PROGRAM, which, as discussed in this activities report, includes precedent-setting litigation activities and timely publications by WLF's Legal Studies Division opposing the increasing criminalization of legitimate business activities.
FEDERAL PREEMPTION -- MEDICAL DEVICES. *Riegel v. Medtronic, Inc.* On February 19, 2008, the U.S. Supreme Court ruled that federal law preempts state-law product liability suits challenging the design or labeling of medical devices that have been determined to be safe and effective by the Food and Drug Administration (FDA). The 8-1 decision was a victory for WLF, which filed a brief urging the Court to find in favor of preemption. The Court agreed with WLF that Congress mandated such preemption when it adopted the Medical Device Amendments of 1976 (MDA), which established a rigorous Premarket Approval process (PMA) for all new medical devices. The Court held that allowing state court judgments against a device manufacturer that are based on a determination that the device is either defectively designed or deficiently labeled would undermine the PMA process by calling into question FDA’s decisions mandating specific product designs and labels. The plaintiff claimed that he suffered an injury during heart surgery because a catheter used by his surgeon was defectively designed and inadequately labeled. Noting that FDA continues to stand behind the design and labeling of the catheter, the Court held that Congress has directed courts not to second-guess such FDA decisions.

Status: Victory.

SECURITIES LAW -- INVESTOR PROTECTION. *Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc.* On January 15, 2008, the U.S. Supreme Court issued a decision that protects investors by imposing restraints on the ability of plaintiffs’ attorneys to bring unwarranted securities fraud lawsuits that, although nominally filed for the purpose of protecting investors, actually harm investors by transferring wealth from stockholders to the pockets of lawyers. The decision was a victory for WLF, which filed a brief opposing such lawsuits. WLF argued that a company should not be subject to a securities fraud lawsuit based solely on having entered into an arm’s-length, non-financial transaction with another company alleged to have engaged in fraud. WLF’s brief was written with the *pro bono* assistance of Kenneth Starr, the Dean of Pepperdine University School of Law and a former federal judge, U.S. Solicitor General, and Independent Counsel. Assisting Starr were other attorneys associated with the law firm of Kirkland & Ellis LLP, including Robert R. Gasaway, Ashley C. Parrish, Derek S. Bentsen, and Angela M. Butcher. The Supreme Court agreed with WLF that securities law claims are improper unless the plaintiff can demonstrate that, when buying or selling a security, (s)he relied on the defendant’s allegedly deceptive practice or conduct. The Court stated that there was no evidence of reliance in this case; the defendants had had no contact with the plaintiffs but were simply merchants who had done business with the company that had issued fraudulent earnings statements. The Court stated that suits filed under the securities law ought to focus on conduct directly related to the purchase and sale of securities and should not be used to justify suits over every-day commercial activity unrelated to stock sales.

Status: Victory.
ILLEGAL IMMIGRATION -- TORT REFORM. *Paramount Citrus Association v. Garcia.* On March 26, 2008, the California Court of Appeal overturned a multi-million dollar tort judgment awarded to an illegal alien injured in a traffic accident. The decision was a victory for WLF, which filed a brief urging that the judgment be overturned. WLF's brief argued that plaintiffs in personal injury lawsuits should be barred from recovering anticipated future costs when those costs are dependent on the plaintiffs remaining illegally in the United States. WLF urged the court to overturn a $850,000 judgment awarded to an illegal alien based on the cost of receiving medical care here in the United States for the remainder of his life. The same care would cost only $200,000 if the illegal alien were to return to his native Mexico, as is required by law. The appeals court decision went even further than WLF had requested. It overturned the entire tort award, finding that the defendant landowner should not be held liable because it owed no duty of care whatsoever to the illegal alien plaintiff. Garcia, the plaintiff, is an illegal alien who was injured in a two-car collision. The owner of a private road was found negligent for having failed to post a stop sign. WLF argued that damage awards in tort actions should be based on an assumption that the plaintiff will obey the law. Because Garcia is required by federal immigration law to leave the U.S., WLF argued, any award for future damages should be calculated based on the cost of caring for Garcia in Mexico. WLF argued that an award that is based on an assumption that Garcia will remain in the U.S. is preempted by federal law because it would provide illegal aliens with a financial incentive to remain in the U.S. in violation of the immigration laws.

**Status:** Victory.

INTERNATIONAL LAW -- CAPITAL PUNISHMENT. *Medellin v. Texas.* On March 25, 2008, the U.S. Supreme Court determined that a criminal defendant, properly convicted of murder and sentenced to death, was not permitted to invoke international law as a basis for overturning his conviction. The Court's decision was a victory for WLF, which filed a brief urging the Court to reject the appeal. WLF argued that a Mexican citizen convicted of raping and murdering two teenage girls in 1993 has received more than a fair review of his sentence and that it is time now to bring his appeal rights to a close. WLF filed its brief on behalf of Randy and Sandy Ertman, the parents of one of the murder victims: 14-year-old Jenny Ertman. WLF also filed on behalf of the Allied Educational Foundation. The Supreme Court held that neither the International Court of Justice (ICJ) nor President Bush have the authority to order Texas courts to reconsider the conviction and death sentence. The defendant asserted that the conviction was invalid because at the time of his arrest police did not tell him of his rights under the Vienna Convention, a 1969 international treaty, to meet with Mexican officials -- even though he has lived in this country since he was three. The Supreme Court agreed with WLF that President Bush acted in excess of his authority when he issued an order directing Texas to comply with a decision of the ICJ by rehearing Medellin's claims. It also held that ICJ decisions are not enforceable in U.S. courts. WLF also filed a brief in this case when it was last before the Supreme Court in 2005.

**Status:** Victory.
NATIONAL SECURITY -- SEARCHES AND SEIZURES. Johnston v. Tampa Sports Authority. On June 26, 2007, the U.S. Court of Appeals for the Eleventh Circuit in Atlanta overturned an injunction issued by a trial court against a National Football League (NFL) policy that entails brief searches of all patrons entering NFL stadiums. The decision was a victory for WLF, which filed a brief in the case, urging the appeals court to reject a challenge to the search policy. WLF argued that the searches are "reasonable" within the meaning of the Fourth Amendment and in any event are not subject to the Fourth Amendment because they are being carried out at the direction of private entities. The decision arose in connection with an appeal from a federal district court, which issued a preliminary injunction against such searches at games being played by the Tampa Bay Buccaneers, an NFL team. The appeals court held that because the plaintiff, a Buccaneers season ticket holder, consented to being searched (in order to gain admittance to Buccaneers games), the searches must be deemed "reasonable." In light of that ruling, the appeals court never reached the question of whether the searches were reasonable. WLF argued that the searches are minimally intrusive and are more than justified by the very real possibility that terrorist groups will attempt to kill large numbers of civilians by planting a bomb in a football stadium.

Status: Victory. Plaintiff's motion for rehearing is pending.

NATIONAL SECURITY -- INTERCEPTING ELECTRONIC COMMUNICATIONS. ACLU v. National Security Agency. On February 19, 2008, the Supreme Court denied review of this important case in the war on terrorism. On June 29, 2007, the U.S. Court of Appeals for the Sixth Circuit reversed an unprecedented ruling by a lower court striking down the Terrorist Surveillance Program (TSP) initiated by the National Security Agency (NSA), ruling in a 2-1 decision that the plaintiffs lacked legal standing to bring the case. The decision was a victory for WLF, which had filed briefs in both the district court and court of appeals, arguing that the President had the legal authority to conduct the surveillance without prior court approval. Under TSP, certain international electronic communications where one of the parties to the communication is a suspected al Qaeda agent or affiliate could be intercepted without a court order. On June 6, 2006, WLF filed a similar brief in New York federal court in a related case filed by the Center for Constitutional Rights (CCR), CCR v. Bush. In both cases, the activist groups claim that the recently revealed NSA surveillance program where international calls and emails are monitored violates the Foreign Intelligence Surveillance Act of 1978 (FISA), which requires approval by a special FISA court confirming that there is probable cause to believe that the person targeted for electronic surveillance is an agent of a foreign power. WLF argued forcefully in its briefs that it is FISA that violates the separation of powers to the extent it impairs the President's ability to carry out his constitutional responsibilities to defend the country from further attack and to collect foreign intelligence. WLF's briefs were drafted with the pro bono assistance of Bryan Cunningham of Morgan & Cunningham in Denver, CO.

Status: Victory. Petition for review in Supreme Court denied.
ABUSIVE SECURITIES ENFORCEMENT -- LACK OF CRIMINAL INTENT.  *United States v. Nacchio.* On March 17, 2008, the U.S. Court of Appeals for the Tenth Circuit in Denver, Colorado reversed the conviction of Joseph P. Nacchio, former CEO of Qwest Communications, for insider trading and took the rare step of ordering the case to be retried before a different federal judge. The decision yesterday was a victory for business civil liberties and WLF, which filed a brief in the case urging the court to reverse the conviction and the six-year prison sentence. At his trial last year, Nacchio was acquitted on 23 counts of securities fraud but convicted on 19 other counts for trading on inside information. The trial judge sentenced Mr. Nacchio to six years’ imprisonment and fined him $19 million. On appeal, Nacchio’s attorneys argued that the evidence was insufficient to convict him, that the jury was improperly instructed, and that the judge improperly excluded expert testimony relevant to Qwest’s business prospects and Nacchio’s trading patterns. In the 2-1 decision, Circuit Judge Michael McConnell ruled that the district court improperly excluded the key defense expert witness at trial, who would have provided an economic analysis showing that Nacchio’s sales were inconsistent with trading on inside information. He would have also testified that, in any event, Qwest stock was not significantly affected when the alleged non-public information was released. WLF filed a brief supporting Mr. Nacchio on October 17, 2007.

**Status:** Victory.

CRIMINALIZATION OF FREE ENTERPRISE -- U.S. SENTENCING GUIDELINES. *Thurston v. United States.* On January 7, 2008, the Supreme Court granted review, vacated the lower court decision, and remanded the case to be reconsidered in light of the Court’s recent decision in *Gall v. United States.* On July 26, 2006, the U.S. Court of Appeals for the First Circuit in Boston reversed a three-month prison sentence that was imposed by two different district court judges on two separate occasions, and ordered that the defendant be resentenced for a third time to a sentence of at least three years. On March 20, 2006, WLF filed a brief in the court of appeals opposing an appeal by the Justice Department seeking to have a businessman resentenced to five years in prison despite the fact that prosecutors plea bargained with a more culpable co-defendant to receive only probation for pleading *nolo contendere.* In effect, the Justice Department took the extreme position that even though the Sentencing Guidelines were ruled unconstitutional by the U.S. Supreme Court in early 2005 and are no longer mandatory, the trial court should have treated the voluntary guidelines as if they were mandatory, and that Mr. Thurston should have received the maximum statutory sentence. Thurston filed a petition for writ of *certiorari* to the Supreme Court in September 2006, which was held in abeyance pending the Court’s decision in the related case, *Gall v. U.S.*

**Status:** Victory; case remanded to First Circuit.

TORT REFORM -- ALIEN TORT STATUTE. *Vietnam Assoc. for Victims of Agent Orange v. Dow Chemical Co.* On February 22, 2008, the U.S. Court of Appeals for the Second Circuit dismissed a class action lawsuit brought on behalf of Vietnamese nationals,
including former North Vietnamese and Viet Cong fighters, against a group of American chemical companies for their role in producing Agent Orange during the Vietnam War. The decision was a victory for WLF, which filed a brief urging that the claims be dismissed. The lawsuit arose out of the U.S. military’s use of Agent Orange and other herbicides in Vietnam beginning in 1961. These operations, approved personally by President Kennedy, were intended to clear vegetation from transit routes of U.S. troops to curb anti-U.S. ambushes and to destroy crops grown by Viet Cong forces. The State Department determined at the time that the operations were consistent with international law. The plaintiffs filed suit against the chemical companies under the Alien Tort Statute, which provides federal court jurisdiction over cases alleging violations of international law. In dismissing the claims, the court of appeals agreed with WLF that international law has never been understood to prohibit use of herbicides in waging war. While a 1925 treaty prohibits use of “poisoned weapons,” the court held that that treaty was only intended to prevent the poisoning of enemy soldiers, not to prohibit use of herbicides to kill vegetation.

Status: Victory.

TORT REFORM -- FIRST AMENDMENT. In re Tobacco Cases II. On August 2, 2007, the California Supreme Court upheld the dismissal of tort claims filed against tobacco companies for having run truthful advertising that allegedly overglamorized smoking. The decision was a victory for WLF, which had filed a brief urging that the tort claims be dismissed. WLF argued that such claims are barred both by the First Amendment and by federal law -- regardless of the plaintiffs’ claim that glamorous advertisements induce minors to buy cigarettes in violation of California law. The court agreed with WLF that the Federal Cigarette Labeling and Advertising Act, adopted by Congress in 1969, imposes significant federal oversight of cigarette advertising, and that Congress made clear that it did not want additional regulations in the form of state-law tort suits. The court noted that its decision still leaves significant regulatory authority in place: the Federal Trade Commission closely monitors cigarette advertising, as do state regulators. WLF argued that there was no reason to permit an additional level of advertising regulation, in the form of tort suits filed under State law. WLF also noted that the plaintiffs seeking recovery are all admitted lawbreakers (they purchased cigarettes while under age 18) and argued that they should not be rewarded for their misconduct.


TORT REFORM -- FAIR CREDIT REPORTING ACT. Radian Guaranty, Inc. v. Whitfield. On January 28, 2008, WLF filed a brief in the U.S. Supreme Court, urging it to crack down on frivolous lawsuits filed by plaintiffs’ attorneys against the insurance industry, alleging technical violations of the Fair Credit Reporting Act (FCRA) but seeking billions of dollars in damages. WLF argued that attorneys for plaintiffs in FCRA suits rarely claim that their clients suffered any real damages for alleged violations of FCRA disclosure provisions, and are simply trying to extort settlements from deep-pocketed defendants. WLF argued that the plaintiffs in this case cannot show that any alleged violations were committed "willfully"
and that the suit must be dismissed in the absence of such a showing. WLF also argued that
the issue of willfulness is an issue of law to be determined by judges, not (as the appeals
court held) as an issue of fact to be determined by juries. In its 2007 Safeco decision, the
Supreme Court made clear that whether a FCRA defendant acted "willfully" in violating the
FCRA (thereby opening itself up to punitive damages and potentially crippling statutory
damages) is an issue of law that generally can be determined by the courts. Just three
months later, the U.S. Court of Appeals for the Third Circuit issued a decision in this case
that directly conflicts with Safeco, holding that willfulness is an issue of fact to be
determined by the jury. Rather than granting plenary review, WLF urged the Supreme Court
to summarily reverse the appeals court decision. WLF filed its brief on behalf of itself and
three insurance industry trade organizations: the American Insurance Association, the
National Association of Mutual Insurance Companies, and the Property and Casualty Insurers
Association of America.

Status: Awaiting decision.

TORT REFORM -- QUALIFIED IMMUNITY. Ashcroft v. Iqbal. On March 7, 2008,
WLF filed a brief in the U.S. Supreme Court, urging it to review (and ultimately overturn)
an appeals court decision that permitted a damages action raising sensitive national security
issues to proceed through discovery against former Attorney General John Ashcroft and
current FBI Director Robert Mueller. WLF filed the brief on behalf of former Attorneys
General William P. Barr, Edwin Meese III, and Richard Thornburgh; and former FBI
Directors William S. Sessions and William H. Webster. WLF argued that allowing the case
-- which is essentially a political challenge to Bush Administration anti-terrorism policies --
to proceed through discovery threatens to interfere with the ability of high-level government
officials to carry out their jobs effectively. WLF argued that by allowing the case to proceed
based on the barest of conclusory allegations, the appeals court is eviscerating the qualified
immunity doctrine, which is designed to protect public officials from the burdens of
litigation. The plaintiff, a Pakistani citizen, alleges that he received harsh treatment while
incarcerated on fraud charges, and that the harsh treatment was imposed due solely to his
religion (Islam) and nationality. Although the only allegations against Ashcroft and Mueller
were conclusory in nature and did not cite any facts suggesting that they had any involvement
in his detention, the lower courts denied their motions to dismiss the case based on qualified
immunity and allowed the case to proceed to discovery. The brief filed by WLF asks the
Supreme Court to review that decision.

Status: Awaiting decision.

ILLEGAL IMMIGRANTS -- LOCAL LAW ENFORCEMENT. Lozano v. City of
Hazleton. On February 19, 2008, WLF filed a brief in the U.S. Court of Appeals for the
Third Circuit in Philadelphia, urging it to uphold efforts by the City of Hazleton,
Pennsylvania to prevent illegal aliens from renting housing within the city. WLF argued that
local governments have an important role to play in enforcing our immigration laws and that
Congress has never indicated that it seeks to confine immigration enforcement to federal
officials only. WLF argued that in the absence of any such indication, the court should reject the plaintiffs' claim that the Hazleton ordinances are preempted by federal law. WLF also argued that the plaintiffs did not even have standing to challenge the ordinances. Noting that the new laws have not yet taken effect, WLF argued that the plaintiffs failed to demonstrate that they suffered any injury and thus should not be permitted to continue with the suit. The case involves immigration enforcement ordinances passed by Hazleton, which has experienced a marked influx of illegal aliens within the past decade. The ordinances require those seeking rental housing in the city to provide evidence of their legal status and impose sanctions on landlords who knowingly rent to illegal aliens. Hazleton does not on its own determine the immigration status of aliens; rather, it relies on federal officials to make that determination. WLF filed its brief on behalf of itself and the Allied Educational Foundation.

**Status:** Awaiting oral argument.

**TORT REFORM -- RICO. Bridge v. Phoenix Bond & Indemnity Co.** On February 21, 2008, WLF filed a brief in the U.S. Supreme Court, urging it to halt the seemingly endless expansion of civil lawsuits brought under RICO (the acronym for the federal Racketeer Influenced and Corrupt Organizations Act). WLF argued that plaintiffs should not be able to recover in a civil RICO action unless they can demonstrate that they "reasonably relied" on the defendant's allegedly fraudulent misrepresentations. WLF argued that reliance has always been an element of common-law fraud actions and should be required in RICO actions as well. In this case, the plaintiffs claim they were injured when someone else relied on the defendant's allegedly fraudulent statements. WLF argued that eliminating the reliance requirement in RICO suits would allow plaintiffs to transform garden-variet commercial disputes into RICO cases in which plaintiffs seek treble damages for alleged racketeering. WLF argued that when (as here) a RICO claim is predicated on alleged violations of the federal mail fraud or wire fraud statutes, proof of reliance is a necessary element of the plaintiffs' burden of establishing that the defendant's misrepresentation was the "proximate cause" of the plaintiff's injuries.

**Status:** Awaiting oral argument on April 14, 2008.

**BUSINESS CIVIL LIBERTIES -- RIGHT TO COUNSEL AND DUE PROCESS. United States v. Stein.** On January 23, 2008, WLF filed a brief with the United States Court of Appeals for the Second Circuit urging it to uphold the dismissal of indictments against certain employees of KPMG, a major accounting firm, accuse of promoting unregistered tax shelters to clients. Last year, U.S. District Court Judge Lewis Kaplan dismissed the indictments because KPMG was pressured by the Justice Department to stop advancing legal defense fees to the targeted employees. As Judge Kaplan described it, "KPMG refused to pay [the employees' defense fees] because the government had the proverbial gun to its head," when it offered the company to a deferred prosecution agreement (DPA) to settle charges against the company. KPMG officers were mindful of the fact that just a few years ago, DOJ prosecuted Arthur Andersen on charges relating to Enron, which forced the
company to fold and lose some 28,000 jobs, even though its conviction was overturned in 2005 by the Supreme Court. In its brief, WLF argued that the appellate court could uphold the dismissal of the indictments without having to rule on whether or not the employees' rights were violated. The district court's supervisory power constitutes sufficient authority to remedy the prosecutorial misconduct that occurred in this case.

Status: Case on appeal.

CLASS ACTION ABUSE -- EXCESSIVE ATTORNEYS' FEES. In Re Currency Conversion Antitrust Litigation. On February 14, 2008, WLF filed formal objections with the United States District Court for the Southern District of New York, urging it to slash the $86 million requested for attorneys' fees in a proposed class action settlement for being excessive, especially since most class members will receive $25 or less. WLF also asked the Court to reject or reduce the payment of so-called incentive awards of $350,000 to the 20 lead plaintiffs. These consolidated class actions were brought under the Sherman Act and Truth in Lending Act, challenging the setting and disclosure of markups and fees imposed on transactions made in a foreign currency or foreign country on MasterCard, Visa, and Diners Club credit and debit cards between February 1, 1996 and November 8, 2006. According to the lawsuits, the card companies did not fully disclose that they were charging up to three percent of the amount charged for the currency conversion service. The proposed settlement provides for a common fund of $336 million for the class, from which class counsel are seeking attorneys' fees of $86 million plus $4 million for expenses. WLF submitted the objections on behalf of its client who traveled extensively abroad. Besides objecting to the fee request, WLF complained that the procedures for objecting to the settlement was overly burdensome, requiring class members to serve their objections on class counsel by hand, overnight mail, or certified mail, unlike typical the procedure in other class action cases where mailing by first-class mail will suffice.


NATIONAL SECURITY -- DETENTION OF ENEMY COMBATANTS. Boumediene v. Bush. On October 9, 2007, WLF filed a brief in the U.S. Supreme Court, urging it to dismiss challenges to the American military's detention of enemy combatants at Guantanamo Bay, Cuba. WLF filed its brief on behalf of a group of recently retired generals and admirals experienced in detention issues: John Altenburg, James J. Carey, Steven B. Kantrowitz, Michael J. Marchand, Michael J. Nardotti, William L. Schachte, Jr., and Thomas L. Hemingway. WLF argued that Congress and the President were acting well within their rights in limiting the ability of nonresident aliens (such as the Guantanamo detainees) to seek habeas corpus rights in federal court. WLF noted that a statute passed by Congress still permits detainees to obtain federal court review of their detention, but first they must challenge their detention in front of administrative bodies known as CSRTs. WLF argued that in any appeals from those administrative proceedings, the detainees may challenge the fairness of proceedings but may not raise constitutional claims. WLF previously filed briefs in this case when it was before the federal appeals court; in a victory
for WLF, that court dismissed the detainees' claims in February 2007. The Supreme Court is reviewing that decision. Other WLF clients in the case include the Allied Educational Foundation and the National Defense Committee.

**Status:** Oral argument held December 5, 2007. Awaiting decision.

**ANTI-TERRORISM LAWS -- ATTORNEY MISCONDUCT. United States v. Lynne Stewart.** On October 12, 2007, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit in New York, urging the court to uphold the criminal conviction of Lynne Stewart, a well-known radical New York attorney found guilty of providing support to an Egypt-based terrorist organization. WLF argued that the statute under which Stewart was convicted is not impermissibly vague and does not violate the First Amendment rights of individuals who wish to advocate in support of terrorist groups. WLF argued that the First Amendment does not prevent Congress from barring actions taken to aid terrorist groups simply because the actions may have an expressive component. Stewart was found by a jury to have provided material support to an Egypt-based group designated by the U.S. government in 1997 as a "foreign terrorist organization" and headed by Sheikh Omar Abdel Rahman, the "blind Sheikh" who is serving a life sentence for his role in the 1993 World Trade Center bombing. Because of Abdel Rahman's continuing leadership role, federal authorities have prohibited him from communicating with those outside the prison system. An exception to that prohibition are his lawyers; he is permitted to communicate with them on legal issues relating to his efforts to win release from prison. Stewart served as one of his lawyers. In violation of the limitations on outside communications, Stewart knowingly served as a vital communication link between Abdel Rahman and his followers.

**Status:** Oral argument held January 29, 2008. Awaiting decision.

**TORT REFORM -- PUNITIVE DAMAGES. Exxon Shipping Co. v. Baker.** On December 26, 2007, WLF filed a brief in the U.S. Supreme Court, urging it to overturn a federal appeals court decision that upheld a $2.5 billion punitive damages award against ExxonMobil, by far the largest punitive damages award ever upheld by a federal appeals court. The award was made in a case arising from the 1989 Exxon Valdez oil spill in Alaska. WLF argued that federal maritime law traditionally has barred punitive damages awards in cases, as here, in which there was no finding that the defendant's wrongful act was either intentional or reckless. WLF further argued that even if a punitive damages award is not completely barred, the $2.5 billion award should be substantially reduced based on common law principles. WLF argued that punitive damages awards have only two permissible purposes: to punish wrongdoing and to deter future misconduct. WLF argued that by any rational measure, the $3.4 billion that Exxon has been forced to expend to date (in clean-up costs, government fines, and reimbursement of those caused economic harm by the spill) adequately serves both of those goals. The Court's October 2007 decision to review the case was a victory for WLF, which had filed a brief in September urging the Court to grant review.
HEALTH CARE -- FIRST AMENDMENT. IMS Health Inc. v. Ayotte. On October 18, 2007, WLF filed a brief in the U.S. Court of Appeals for the First Circuit in Boston, urging it to protect First Amendment rights by striking down a New Hampshire law that blocks access to critical healthcare information. The law, which is unique to New Hampshire, criminalizes the collection and disclosure of information about the prescribing practices of physicians. WLF argued that the law violates the First Amendment by prohibiting disclosures of truthful information, even disclosures arising outside the context of advertising. WLF argued that such prohibitions are only rarely permissible and only then when based on showings of the most compelling of government needs. WLF argued that the information that New Hampshire is trying to ban plays a vital healthcare role; it is used to monitor the safety of medications, implement drug recalls, and rapidly communicate information to doctors about innovative new treatments. WLF also filed a brief in 2006 in the case when it was before the federal district court; in a victory for WLF, that court struck down the law on First Amendment grounds in April 2007.


BUSINESS CIVIL LIBERTIES -- MALICIOUS PROSECUTION BY DOJ & EPA. Vidrine v. United States. On July 23, 2007, WLF filed a federal lawsuit in U.S. District Court for the Western District of Louisiana in Lafayette against the United States for maliciously prosecuting Hubert P. Vidrine, Jr. of Opelousas, LA, for allegedly storing a hazardous substance without a permit from the Environmental Protection Agency (EPA). In 1996, a "SWAT Team" -- consisting of almost two dozen, armed EPA Special Agents from EPA's Criminal Investigation Division (CID), FBI, and other law enforcement officers -- raided Canal Refining with M-16 rifles and police dogs; falsely accused Mr. Vidrine of storing hazardous waste and lying about it; prevented employees from using the reused for several hours; prevented those same employees from calling their homes and daycare centers to make plans to have children picked up; falsely told the employees that Mr. Vidrine had been poisoning them and giving them cancer; and threatened them with imprisonment if they did not provide damaging evidence against Mr. Vidrine. After being indicted in 1999, and after four years of prosecution, felony charges were suddenly dropped on the eve of trial in September 2003 after Vidrine had discovered that the key witness for the government was addicted to cocaine which causes hallucinations. Even after putting its witness under hypnosis in vain, the EPA could not produce the allegedly hazardous substance or any test results. The suit, filed under the Federal Tort Claims Act (FTCA), seeks a total of $5 million in damages. On December 19, 2007, the court issued an order allowing access to the grand jury transcripts. In February 2008, the United States filed a motion for partial dismissal of some of the claims, which is pending. WLF is providing legal assistance to Mr. Vidrine and his attorney, Gary Cornwell of Beaumont, Texas.

Status: Case pending; pre-trial discovery underway.
PATENT RIGHTS -- UNFULLY RESTRICTION ON PATENT APPLICATIONS. *SmithKline Beecham Corp. v. PTO.* On December 27, 2007, WLF filed a brief in the U.S. District Court for the Eastern District of Virginia urging the court to strike down new regulations issued by the U.S. Patent and Trademark Office (PTO) that would severely restrict the number of "continuation" applications a company may file based on its original patent application. In its brief, WLF argued that such unlawful restrictions would deprive patent applicants of substantial property rights and constitute an unconstitutional "taking" of intellectual property rights without just compensation. In *SmithKline Beecham Corp. v. PTO*, the PTO issued new rules essentially limiting an inventor to no more than two "continuation" applications based on its original filing, that is, additional information and data supporting the original patent application. In its brief, WLF explained how patent applications are a valuable asset, even though the patent has not been granted. Indeed, pending applications are routinely made available for licensing long before any patents issue. Accordingly, the PTO failed to conduct the required analysis under Executive Order 12630 for new rules that affect property rights; instead, it summarily concluded that the new rule "will not effect a taking of private property." WLF’s brief was filed with the *pro bono* assistance of Alan Charles Raul, David L. Fitzgerald, Ann M. Mace, and Kevin H. Henry of the Washington, D.C. law firm of Sidley Austin LLP.

**Status:** Hearing held on February 8, 2008. Awaiting decision.

BUSINESS CIVIL LIBERTIES -- SECURITIES LAW. *United States v. Stringer.* Oral argument was held on September 26, 2007 in this important case dealing with abusive civil and criminal parallel prosecutions. On January 29, 2007, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit urging it to uphold the dismissal of criminal charges against three officers of a company for securities law violations. The district court had dismissed the charges because the U.S. Attorney’s Office used attorneys from the Securities and Exchange Commission (SEC) in a civil investigation as a secret "stalking horse" to develop criminal charges against the company officials. Accordingly, the businessmen's Due Process and Fifth Amendment rights were violated. The outcome of this appeal will have far-reaching effects on every employee who works for a company that is subject to regulation by any federal agency, such as the SEC, the Environmental Protection Agency (EPA), or the Food & Drug Administration (FDA). At issue is the abuse of "parallel prosecutions" whereby suspected violations of a regulation are investigated by the agency, and at the same time, prosecutors are building a criminal case against the same targets. While *bona fide* parallel prosecutions are generally lawful, Chief Judge Ancer Haggerty of Oregon ruled in *Stringer* that the civil investigation by the SEC was essentially being run by criminal prosecutors to lull company employees into foregoing their constitutional rights.

**Status:** Awaiting decision.

VOTING FRAUD -- ID REQUIREMENTS. *Crawford v. Marion County Election Board.* On December 10, 2007, WLF filed a brief in the U.S. Supreme Court, urging the Court to reject a challenge to an Indiana law that requires voters to present photo IDs when they come
to vote and that is designed to prevent improper voting by aliens and others not permitted to vote. WLF argued that Indiana legislators were well within their rights in adopting measures designed to prevent election fraud. WLF argued that these measures do not violate the U.S. Constitution by (as the plaintiffs allege) imposing an undue burden on the right to vote. WLF noted that virtually all Indiana residents possess a driver’s license or some other photo ID, and that those without an ID can get one for no cost and with relatively little effort. WLF argued that in light of the relatively minor documentation burden imposed on prospective voters and Indiana’s significant interest in preventing election fraud, the Indiana law does not infringe on anyone’s constitutional right to vote. WLF’s brief was drafted with the pro bono assistance of Thomas R. McCarthy, Bert Rein, Suzette Rodriguez Hurley, and Brendan Morrissey, attorneys with the Washington, D.C. law firm of Wiley Rein LLP.

**Status:** Oral argument held on January 9, 2008. Awaiting decision.

FALSE CLAIMS ACT -- EXPANDING LIABILITY. *Allison Engine Co. v. U.S. ex rel. Sanders.* On December 20, 2007, WLF filed a brief in the United States Supreme Court urging it to reverse a court of appeals’ ruling that, if left intact, would greatly expand a company’s liability under the False Claims Act (FCA) to cases where it has not been shown that the U.S. Treasury suffered any financial loss due to the alleged false claim. In *Allison Engine Co. v. United States ex rel. Sanders,* a government sub-contractor submitted an allegedly false claim for payment not to the government, but to the private contractor that had hired the sub-contractor. The U.S. Court of Appeals for the Sixth Circuit ruled that even though there was no showing of "presentment" to the government of the claim by the sub-contractor and no showing of financial loss to the Government, liability can nevertheless be imposed. WLF’s brief presented an exhaustive historical analysis of the FCA, demonstrating that Congress intended a showing of financial loss to the Treasury and a causal link between the alleged fraud and the loss. Otherwise, any company doing business with a government contractor runs the risk of being sued under the FCA for seeking payment for work from that contractor, even though no claim was ever presented to the government for payment.

**Status:** Oral argument held on March 26, 2008. Awaiting decision.

PARTNERSHIP LIABILITY -- "INHERENT FAIRNESS" DOCTRINE MISAPPLIED. *Everest Properties II, LLC v. Prometheus Development Co.* On December 20, 2007, WLF filed a brief in the California Supreme Court urging it to review and reverse a court of appeal’s ruling that, for the first time, expanded legal liability of a general partner when proposing transactions involving the partnership property to ensure that the proposed transactions were "inherently fair" to the limited partners, despite those partners’ approval of the transaction and California law, which allows a general partner to make a profit in dealing with partnership property. WLF argued in its brief that the lower court ruling stands in stark contrast to the holding of another California court of appeal and two U.S. District Court rulings interpreting California law, one of which involves the very same dispute as the *Everest* case, including the same the plaintiffs’ attorneys who brought the federal suit with
different plaintiffs. On January 16, 2008, the Court denied review.

**Status:** Loss.

**CLEAN WATER ACT -- ABUSIVE PROSECUTION AND SENTENCING. United States v. Hagerman.** On October 15, 2007, WLF filed a brief in the United States District Court for the Southern District of Indiana in Indianapolis urging the judge to reject a recommendation by the U.S. Attorney to sentence a small business owner to prison for over six years. WLF recommended that the court impose probation instead for this first offender found guilty of minor discharge reporting offenses where there was no showing of any real environmental harm. In *United States v. Hagerman*, Derrik Hagerman was charged with filing false monitoring reports for a few discharges in 2004 from Wabash Environmental Technologies, a wastewater treatment facility owned by Mr. Hagerman, in violation of the Clean Water Act. Instead of handling this infraction by using more reasonable and effective administrative or civil remedies, the U.S. Attorney filed felony criminal charges. Before trial, the U.S. Attorney filed a motion to prevent Mr. Hagerman from introducing any evidence that there was no environmental damage from the alleged violations, which the court granted. Mr. Hagerman and his company were found guilty of the minor regulatory offenses. At the sentencing hearing held on November 15, 2007, the district court ignored pleas for probation and community service for Mr. Hagerman, the father of two small children and pillar of his community. Using the flawed U.S. Sentencing Guidelines, and urged by the prosecutors, the judge instead sentenced Mr. Hagerman to a harsh five-year prison term.

**Status:** Loss. Case on appeal.

**SEPARATION OF POWERS -- CONSTITUTIONALITY OF SARBANES-OXLEY. Free Enterprise Fund v. PCAOB.** On December 31, 2007, WLF filed its brief in the U.S. Court of Appeals for the District of Columbia Circuit urging it to reverse a lower court ruling that dismissed a lawsuit seeking to strike down as unconstitutional the Public Company Accounting Oversight Board (PCAOB) established by Congress under the Sarbanes-Oxley Act of 2002. Congress gave the PCAOB massive and unchecked powers to regulate the auditing of publicly traded companies by public accounting firms, including the power to tax the firms and establish criminal penalties. Congress established the PCAOB as a private organization whose members are appointed by the Securities and Exchange Commission (SEC) rather than by the President as required by the Appointments Clause of Article II, and who are otherwise immune from control or removal by the President in violation of the separation of powers. WLF's brief presented a historical analysis of the President's removal power as well as describing the negative economic consequences of the Sarbanes-Oxley law. WLF had also filed a brief in the case when it was before the district court. WLF's appellate brief was drafted with the *pro bono* assistance of Helgi C. Walker, Thomas R. McCarthy, and Brendan T. Carr of the Washington, D.C. office of Wiley Rein LLP.

**Status:** Oral argument in appeals court scheduled for April 15, 2008.
PRODUCT DISPARAGEMENT -- ANTI-SLAPP STATUTES. \textit{Schering Corp. v. First DataBank, Inc.} In February 2008, the parties settled their product disparagement suit before the U.S. Court of Appeals for the Ninth Circuit had a chance to issue a decision. In November 2007, WLF had filed a brief urging the appeals court to rein in use of California's anti-SLAPP statute, a device often used by attorneys to prevent litigants from obtaining a fair and prompt hearing on their legal claims. WLF argued that the interests of justice are not served when defendants are permitted to disrupt the normal litigation process by filing an anti-SLAPP motion. WLF argued that other procedures provide a more appropriate means of winning dismissal of frivolous litigation. SLAPP is an acronym for "strategic lawsuits against public participation." The term was coined in the 1980s by activist law professors who viewed SLAPP suits as an illegitimate tool used by powerful business interests to silence individuals who publicly voiced criticism of those interests. Activists contend that businesses bring such suits in the hopes that their critics will stop speaking rather than incur the costs of defending the lawsuits. In response to these alleged abuses, a number of states (including California) adopted anti-SLAPP statutes; the statutes allow defendants in alleged SLAPP suits to win expedited dismissal and an award of attorney fees. WLF's brief argued that many attorneys have been abusing the anti-SLAPP statute by invoking it in an effort to obtain expedited dismissal of suits that are far afield of the statute's intended purpose -- one instance of such abuse being the dispute here, which is between two large corporations.

\textbf{Status: } Case settled.

FOREIGN AFFAIRS -- ALIEN TORT STATUTE. \textit{Matar v. Dichter.} On November 16, 2007, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit in New York, urging the court to rein in activists' use of the Alien Tort Statute (ATS) as a means of attempting to enforce international human rights law in federal courts. WLF argued that when it adopted the ATS in 1789, Congress never intended to assign federal courts the role of policing alleged human rights violations throughout the world. WLF argued that federal court intervention in overseas activities is particularly inappropriate when, as here, adjudication of the case could have negative foreign policy ramifications. Noting that the defendant (Avraham Dichter) is a cabinet member in the Israeli government being sued for actions taken in his official government capacity, WLF argued that the case ought to be dismissed as a nonjusticiable political question. WLF filed its brief on behalf of itself and the Allied Educational Foundation. The plaintiffs, Palestinians who live in the Gaza Strip, are close relatives of individuals who were killed or wounded in the Israeli bombing of a Gaza City building in 2002. The attack was carried out by Israel in order to kill a Hamas terrorist leader who was staying in the building. The attack was successful in killing the terrorist leader, but it also killed or wounded a number of civilians living nearby. The plaintiffs allege that the Israel attack amounted to an "extrajudicial killing" and a war crime, in violation of customary international law. They filed suit against Dichter under the ATS, which provides jurisdiction to federal courts over tort suits brought by aliens for violations of "the law of nations."
Status: Awaiting oral argument.

FDA REFORM -- ACCESS TO LIFESAVING MEDICINES. Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach. On January 14, 2008, the U.S. Supreme Court issued a one-sentence order declining to hear WLF’s ground-breaking case in which it sought to establish a constitutionally-based right for terminally ill patients to gain access to experimental drugs that have not yet been fully approved by the Food and Drug Administration (FDA). In a petition filed with the Court in September 2007, WLF had argued that throughout American history the judiciary has recognized the right of individuals to engage in self-defense -- regardless whether the attacker is another person, an animal, or a disease. WLF argued that, based on that traditional self-defense right, the Supreme Court should recognize a constitutional right of terminally ill patients who lack effective treatment options to take experimental drugs, without interference from FDA. WLF argued that the decision to take such drugs should be left up to the patient, his or her doctor, and the drug’s manufacturer. In a historic decision in May 2006, a three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit ruled in WLF’s favor on the issue. However, in August 2007 the D.C. Circuit (sitting en banc) reversed that decision by an 8-2 vote and dismissed WLF’s suit. The Supreme Court’s January 2008 order declined to review the appeals court decision. WLF filed suit against FDA in 2003 on behalf of itself and the Abigail Alliance for Better Access to Developmental Drugs, a patients-rights group. At the appellate level, WLF received invaluable pro bono legal assistance from Scott Ballenger, a partner in the Washington office of Latham & Watkins.

Status: Supreme Court review denied.

EXTRATERRITORIAL JURISDICTION -- SECURITIES LAW. Morrison v. National Australia Bank Ltd. On July 15, 2007, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit urging it to affirm a ruling by the district court that United States securities laws do not have extraterritorial application to a foreign corporation. A decision in this case will have an impact on foreign corporations, especially those that have invested in U.S. businesses. In Morrison v. National Australia Bank Ltd (NAB), plaintiff attorneys filed a securities-fraud class action lawsuit against an Australian company on behalf of foreign investors in U.S. federal court. They claim that just because NAB allegedly made misstatements relating to its U.S. business activities, federal securities laws are applicable to the foreign company. The U.S. District Court for the Southern District of New York dismissed the lawsuit, ruling that U.S. securities laws are not applicable to foreign corporations for conduct occurring outside the United States, and the plaintiffs appealed. WLF argued as a matter of law and policy that unless otherwise made expressly clear, Congress does not intend for U.S. laws to apply to actions outside the territory of the United States. A ruling in favor of the plaintiffs would greatly discourage foreign investment in U.S. businesses, making the foreign companies ripe targets for abusive securities class action lawsuits. WLF’s brief was filed with the pro bono assistance of Louis R. Cohen, Ali M. Stoeppelwerth, and Justin S. Rubin of the law firm Wilmer Cutler Pickering Hale & Dorr, LLP.
Status: Awaiting oral argument.

COMMERCIAL FREE SPEECH -- PUBLIC STATEMENTS. United States v. Philip Morris USA, Inc. On August 17, 2007, WLF filed a brief in the U.S. Court of Appeals for the District of Columbia Circuit on behalf of itself and the National Association of Manufacturers urging the court to reverse a district court ruling against the tobacco companies that would greatly infringe on the First Amendment rights of companies to engage in public debate about controversial topics, such as product safety or even global warming. In this case, the district court ruled against the companies for making public statements and testifying before Congress in response to public criticism and proposed regulation of tobacco products. WLF argued in its brief that these statements were core First Amendment speech and thus enjoyed broader constitutional protections than mere commercial speech. WLF's brief was filed with the pro bono assistance of Andrew G. McBride, William S. Consovoy, Thomas R. McCarthy, and Sean C. Day of the Washington, D.C. law firm of Wiley Rein LLP.

Status: Awaiting oral argument.

FIRST AMENDMENT -- ELECTION LAW. New York State Board of Elections v. Lopez Torres. On January 16, 2008, the U.S. Supreme Court issued a decision upholding a New York State election scheme that, in practice, has placed control over the selection of judges in the hands of the leader of the political party that is dominant within each of the state's judicial districts. The decision was a setback for WLF, which filed a brief urging the Court to strike down the election scheme. The Court rejected WLF's argument that New York's electoral scheme for Supreme Court Justices violates the First Amendment rights of rank-and-file party members by denying them any effective access to the candidate selection process. The Court overturned a decision of the U.S. Court of Appeals for the Second Circuit, which last year struck down the New York electoral scheme on First Amendment grounds. WLF's brief stressed that it supports the right of political parties to establish their own rules for nominating candidates. WLF argued, however, that the lower court decision striking down New York's judicial electoral system did not in any way interfere with the rights of political parties to associate as they see fit.

Status: Loss.

CLASS ACTION ABUSE -- EXCESSIVE ATTORNEYS' FEES. Fresco v. Automotive Directions, Inc. On September 25, 2007, WLF filed formal objections in the United States District Court in Miami, Florida on behalf of two class members opposing a proposed class action settlement that provides for $25 million in attorneys' fees to class counsel, $15,000 for each of their named clients, but no monetary compensation for the estimated 200 million persons who are class members. WLF strongly urged the court to disapprove the settlement, but that at a minimum, to cut the excessive fee request by at least two-thirds the requested amount, and as much as 80 percent. In Fresco v. Automotive Directions, Inc., a class action was filed in 2003 on behalf of Florida residents alleging that the defendants, who are
engaged in marketing services, violated the federal Driver’s Privacy Protection Act (DPPA).
That law generally prohibits the disclosure and use of personal information on file with
the state’s department of motor vehicles with regard to drivers’ licenses and motor vehicle
registration information, without the express written consent of the individual. Plaintiffs
allege, and the defendants admit, that private information was obtained and used for
marketing purposes without the person’s permission as required by the DPPA, but the
defendants deny they were liable under the DPPA because they were unaware that Florida
did not get the consent of the individuals.

Status: Hearing held on October 24, 2007. Awaiting decision.

TORT REFORM -- FEDERAL PREEMPTION. Warner-Lambert Co. v. Kent. On March
3, 2008, the U.S. Supreme Court announced that it was evenly divided on whether to
overturn an appeals court decision that permits plaintiffs’ lawyers to bring state-law tort suits
against drug companies, even when those suits have the effect of second-guessing decisions
of the Food and Drug Administration (FDA) to approve the marketing of a new drug. The
result of the 4-4 decision is that the appeals court decision is affirmed; but the decision has
no precedential value, and the Supreme Court issued no opinion. The decision was a
disappointment for WLF, which filed a brief urging that the appeals court decision be
overturned. WLF argued that any product liability suit that requires a court to litigate claims
that a manufacturer obtained marketing approval by defrauding the FDA is preempted by
federal law. WLF argued that Congress intended to prohibit such suits because they interfere
with FDA’s ability to regulate the marketing of drugs and to police fraud on the agency.
WLF filed its brief with the pro bono assistance of Eric G. Lasker and James M. Sullivan,
attorneys with the Washington, D.C. office of Spriggs & Hollingsworth. WLF scored an
earlier victory in the case when in September 2007 the Court agreed to review the case;
WLF had filed a brief in July 2007, urging the Court to grant review.

Status: Decision below affirmed by equally divided (4-4) Court.

PATENT LAW -- GENERIC DRUGS. Merck & Co. v. Apotex Corp. On September 20,
2007, WLF filed a brief in the U.S. Court of Appeals for the Federal Circuit, urging it not
to permit a generic drug maker to challenge the validity of drug patents when the owner has
made clear that it does not believe that the generic manufacturer is violating its patents.
WLF argued that federal courts lack jurisdiction over such suits because there does not exist
a controversy between parties having adverse interests. WLF argued that exercising
jurisdiction in such cases would expand jurisdiction well beyond limits imposed by the
Constitution and would put courts in the business of rendering advisory opinions. WLF
argued that federal courts lack jurisdiction to hear a suit seeking a declaration that a patent is
invalid unless the plaintiff establishes: (1) a reasonable apprehension that it will be sued for
violating the patent; or (2) it is forgoing activity that it would otherwise engage in but for the
likelihood of a potentially ruinous patent infringement suit.

ALIEN TORT STATUTE -- INTERNATIONAL COMITY. *Presbyterian Church of Sudan v. Talisman Energy, Inc.* On May 8, 2007, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit in New York, urging it to rein in activists’ use of the Alien Tort Statute (ATS) as a means of attempting to enforce international human rights law in federal courts. WLF argued that when it adopted the ATS in 1789, Congress never intended to assign federal courts the role of policing alleged human rights violations throughout the world. WLF argued that federal court intervention in overseas activities is particularly inappropriate when, as here, neither the parties nor the controversy have any connection to the United States. Noting that the defendant (Talisman) is a major Canadian oil company and that the government of Canada has strenuously objected to continuation of this lawsuit, WLF argued that -- under the doctrine of international comity -- the plaintiffs ought to be required to file their claims in Canada. The plaintiffs, a group of Sudanese citizens, allege that the government of Sudan violated their human rights in the course of fighting a civil war in the southern portions of Sudan. They allege that Talisman, which until 2002 conducted oil operations in Sudan, unlawfully "aided and abetted" the government’s human rights violations by providing material support to the government.

**Status:** Awaiting oral argument.

CONGRESSIONAL ACCOUNTABILITY -- SPEECH OR DEBATE CLAUSE IMMUNITY. *United States v. Rayburn HOB, Rm 2113.* On August 3, 2007, the U.S. Court of Appeals for the District of Columbia Circuit ruled that Congressman William Jefferson had a right under the Speech or Debate Clause of the constitution to review legislative documents before they were seized by the FBI in executing a search warrant of his congressional evidence seeking evidence of bribery and other crimes. A lawful search of Rep. Jefferson’s home in August 2005 turned up $90,000 in cash in his freezer that was part of the $100,000 that was allegedly earmarked for bribing Nigerian officials to obtain contracts for a business venture. In its brief filed in the case, WLF argued that the Speech or Debate Clause should be narrowly construed to bar any use of legitimate legislative materials as opposed to the mere incidental discovery of such documents. Otherwise, the privilege can be abused by Members of Congress to thwart legitimate criminal investigations and prosecutions by the Executive Branch. WLF’s brief was filed with the *pro bono* support of Viet D. Dinh, professor of law at Georgetown University Law Center and principal of Bancroft Associates, PLLC; attorneys Perry O. Barber and Lizette D. Benedi with the firm; and Wendy J. Keefer, formerly with Bancroft and of counsel to Haynsworth Sinkler Boyd in Charleston, SC.

**Status:** Loss. Petition for review in the Supreme Court denied March 31, 2008.

PROTECTING U.S./MEXICO BORDER -- UNFAIR PROSECUTION OF BORDER AGENTS. *United States v. Compean; United States v. Ramos.* On December 3, 2007, oral argument was heard by the U.S. Court of Appeals for the Fifth Circuit in this important case concerning the legality of certain border enforcement measures. On June 5, 2007, WLF
filed a brief with the court, urging it to reverse the convictions and lengthy prison terms imposed on two U.S. Border Patrol Agents for chasing down and wounding a drug smuggler from Mexico. The smuggler was transporting almost 750 pounds of marijuana in a van across the Mexico/Texas border. Both Agents testified that they fired shots after seeing a gun in his hand. The smuggler suffered only a minor injury after one bullet hit his left buttock as he turned to run back across the Rio Grande River. The smuggler was later located and given immunity by the Department of Justice to testify against the two agents. Agent Ignacio Ramos received 11 years in prison and Agent Jose Compean received 12 years for depriving the drug smuggler of his civil rights. The prosecutors invoked a mandatory 10-year prison term law, which Congress intended to apply only against gun-wielding criminals and drug dealers. This case has received nationwide criticism, including a recent oversight hearing by the Senate Judiciary Committee led by Senator Diane Feinstein who demanded that the U.S. Attorney Jeffrey Sutton explain why the drug smuggler was given immunity, medical care, and not questioned about suspected plans by drug dealers to seek retribution and kill border agents. The drug smuggler is also suing the U.S. for $5 million in damages. Last year, the Justice Department also prosecuted Texas Deputy Sheriff Gilmer Hernandez who shot at the rear tires of van smuggling illegal aliens as the driver of the van tried to run him over. WLF filed a brief in March 2007 urging a sentence of probation for Deputy Hernandez.

**Status:** Awaiting decision.

ENVIRONMENTAL LAW -- MERCURY EMISSIONS LEVELS. *New Jersey v. EPA.* On February 8, 2008, the U.S. Court of Appeals for the District of Columbia Circuit upheld a legal challenge by New Jersey and other states to the Environmental Protection Agency’s (EPA) decision not to regulate mercury emissions from power plants under Section 112 of the Clean Air Act (CAA). In its brief filed on May 17, 2007, WLF agreed with the EPA that mercury emissions from utilities do not pose a hazard to public health, and that in any event, any risks to health are adequately addressed by other CAA programs. If anything, EPA’s reference-dose for the safe level of mercury is highly conservative and overly protective of human health. This case is important not only to utilities, but also to other companies regulated by government agencies charged with protecting the public’s health, including the EPA and the Food and Drug Administration (FDA), to ensure that sound science, rather than junk science, controls regulatory decisionmaking. News reports that mercury levels found in fish are at dangerous levels have prompted calls to cut mercury emissions by utilities. But as WLF pointed out in its brief, utility mercury emissions have been substantially reduced by 40 percent over the last 10 years, and that mercury emissions from utilities are not harmful. Nevertheless, the Court ruled that EPA did not have the discretion not to regulate the mercury emissions since the statutory language was clear.

**Status:** Loss.

FIRST AMENDMENT -- COMMERCIAL SPEECH. *United States v. Caputo.* On February 27, 2008, the U.S. Court of Appeals for the Seventh Circuit in Chicago upheld the
criminal convictions of business executives alleged to have promoted an FDA-approved medical device for an off-label use (that is, a use not strictly conforming to the uses specified on the FDA-approved labeling). The decision was a partial setback for WLF, which had filed a brief expressing concern that the convictions could be viewed as upholding restrictions on the right of manufacturers to speak truthfully regarding off-label uses for their FDA-approved product. WLF was gratified that although the appeals court upheld the conviction, it went out of its way to make clear that it was not condoning government efforts to suppress truthful off-label speech. Rather, the court held, it did not need to reach the First Amendment issue because the trial court had made clear to the jury that it could not convict the defendants unless the jury found both that the defendants had lied to the FDA and that their medical device had never been approved by FDA. WLF’s brief had argued that the First Amendment broadly protects the right of individuals to speak truthfully about off-label uses of FDA-approved products, even in a commercial context. WLF argued that if there was any chance at all that the jury might have convicted the defendants based solely on their having made constitutionally protected statements, the First Amendment required that the convictions be overturned. WLF filed its brief with the pro bono assistance of James M. Beck, Arnon D. Siegal, Sean P. Wajert, and Michael E. Planell, attorneys with the law firm of Dechert LLP. WLF argued that the First Amendment broadly protects the rights of individuals to speak truthfully about off-label uses of FDA-approved products.

**Status:** Loss.

**TORT REFORM -- FIRST AMENDMENT.** *Physicians Committee for Responsible Medicine v. General Mills.* On April 4, 2007, WLF filed a brief in the U.S. Court of Appeals for the Fourth Circuit in Richmond, urging the Court to uphold the dismissal of a lawsuit by animal rights activists who are seeking to stop advertisements being run by the milk industry. WLF argued that Virginia law does not permit private citizens to seek injunctions against advertisements with which they disagree. WLF also argued that the suit threatened to undermine manufacturers’ commercial speech rights. WLF argued that if a manufacturer can be subjected to expensive lawsuits filed by activists who do not like statements the manufacturer makes on issues of public importance, then significant amounts of truthful speech will be chilled. WLF argued that the plaintiffs’ real objection was not to the ads, but to what they view as inhumane treatment of cows. WLF argued that the courts should not allow the judicial process to be abused in this manner. WLF also filed a brief in the case when it was before the district court.

**Status:** Oral argument held March 19, 2008. Awaiting decision.

**CLASS ACTIONS -- EMPLOYMENT DISCRIMINATION.** *Dukes v. Wal-Mart Stores.* On January 18, 2008, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit, urging it to grant rehearing en banc in a case in which a three-judge panel of the appeals court upheld a lower-court decision that certified a massive class action against retailer Wal-Mart. The suit was filed by a small number of female Wal-Mart employees who claimed that the company denied them equal pay and opportunities for promotion. But the trial court
has certified them as representatives of a class of 1.6 million current and former female employees. WLF argued that the plaintiffs have failed to demonstrate that the case could manageably be tried as a class action. WLF argued that the plaintiffs failed to demonstrate that common issues of fact and law predominate over individual issues. WLF was particularly critical of the trial court's reliance on testimony from the plaintiffs' "expert" sociology witness; WLF argued that the testimony was inadmissible "junk" science. WLF's brief was prepared with the pro bono assistance of Jennifer L. Brown of Shook, Hardy & Bacon, L.L.P. WLF also filed a brief with the three-judge Ninth Circuit panel that initially heard the case; that panel ruled 2-1 against Wal-Mart in February 2007. In March 2007, WLF filed a brief urging the panel to reconsider. In response, the panel issued a slightly revised decision in December 2007. At that point, WLF filed its brief urging rehearing en banc.

Status: Awaiting decision.

BUSINESS CIVIL LIBERTIES -- SECURITIES LAW. In re: Dynex Capital Inc. Securities Litigation On January 17, 2007, WLF filed a brief with the U.S. Court of Appeals for the Second Circuit urging it to reverse a lower court ruling that found that a corporation can be held liable in a securities class action case based on the collective knowledge of corporate employees, regardless of their position or role in making any alleged misstatements about the company’s financial matters. If the lower court opinion is upheld, it will expose many businesses to abusive class action lawsuits and be contrary to the pleading requirements that Congress intended to apply in securities litigation. In its brief, WLF argued that this "collective scienter" theory is contrary to the common law and decisions of other courts which require specific allegations of intent or scienter in a complaint against individuals because a corporation, by definition, is a fictional entity and cannot be personified. In addition, WLF argued that this broad theory of corporate liability conflicts with the pleading requirements of the Private Securities Litigation Reform Act (PSLRA) enacted by Congress in 1995.


FIRST AMENDMENT -- HEALTH CARE DELIVERY. Washington Legal Found. v. Leavitt. On October 15, 2007, WLF filed a brief asking the federal district court in Washington, D.C. to grant it summary judgment in its legal challenge to speech restrictions imposed by federal Medicare officials. WLF filed suit against CMS (the federal Centers for Medicare and Medicaid Services) in August 2006, alleging that CMS is trampling on First Amendment rights in seeking to suppress truthful speech regarding insurance coverage available to senior citizens under Medicare Part D. Part D is the recently enacted Medicare program that offers insurance for the cost of prescription drugs. WLF filed suit on behalf of members who, as a result of CMS's actions, are unable to obtain accurate information about competing insurance providers. The suit seeks an injunction against continuation of CMS's policy. Ironically, the groups that CMS bars from providing truthful information – including nursing homes and pharmacies – are often the very groups that have the most knowledge
regarding the health-care needs of Medicare recipients, WLF charged. WLF’s October 15, 2007 motion argues that the court should enter judgment in WLF’s favor without the necessity of conducting a full trial because CMS has failed to provide an adequate rationale for its decision to suppress speech. CMS has also filed a summary judgment motion. The court is expected to rule on the motions by mid-2008.

**Status:** Awaiting decision.

**NATIONAL SECURITY -- SUPPORT FOR TERRORIST GROUPS.** *Humanitarian Law Project v. Gonzales.* On December 10, 2007, the U.S. Court of Appeals for the Ninth Circuit struck down a portion of the USA PATRIOT Act that makes it a crime to provide "material support" to any group that has been designated by the Attorney General as a "foreign terrorist organization." The decision was a setback for WLF, which filed a brief urging the court to uphold the law. The appeals court ruled that the statute that makes it a crime to provide "material support" to designated terrorist organizations is unconstitutionally vague because it is not sufficiently clear regarding what it means to provide such support. WLF had argued that the statute was sufficiently clear: it banned virtually all support for terrorist organizations. In a partial victory for WLF, the appeals court agreed with WLF that the ban on providing "material support" does not violate the First Amendment rights of those who wish to support humanitarian work conducted by terrorist groups. The court agreed with WLF that the First Amendment does not prevent Congress from barring actions taken to aid terrorist groups simply because the actions may have an expressive component. WLF filed its brief on behalf of itself and the Allied Educational Foundation.

**Status:** Loss. Petition for rehearing pending.

**TORT REFORM -- ALIEN TORT STATUTE.** *Abdullahi v. Pfizer.* On May 24, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit, urging it to dismiss claims that a drug company violated international law when a team of its doctors provided emergency medical aid to children in Nigeria suffering from meningitis. WLF argued that federal law does not permit private parties to file tort suits asserting that doctors violated international law by allegedly treating patients without first obtaining the patients’ informed consent. WLF urged the court to reject claims that such suits are authorized by the Alien Tort Statute (ATS), a law that lay dormant for nearly 200 years before activists recently began seeking to invoke it. WLF argued that the ATS was adopted in 1789 to allow the federal courts to hear cases involving piracy and assaults on ambassadors. WLF argued that it has been transformed by activist attorneys into a tool for second-guessing American foreign policy and for attacking the overseas conduct of corporations.

**Status:** Oral argument held on July 12, 2007. Awaiting decision.

**GLOBAL WARMING -- ENVIRONMENTAL REGULATION.** *Connecticut v. American Electric Power Company.* On June 7, 2006, oral argument was held in this important global warming case. On March 2, 2006, WLF filed a brief in the U.S. Court of Appeals for the
Second Circuit in New York on behalf of itself and its client, U.S. Senator James M. Inhofe, Chairman of the Senate Environment and Public Works Committee, urging the court to reject an appeal filed by several states and environmental groups claiming that global warming is a public nuisance, and that the courts should order the major power companies to restrict their carbon dioxide emissions. The States of Connecticut, New York, California, Iowa, New Jersey, Rhode Island, Vermont, and Wisconsin sued American Electric Power Company, Southern Company, Xcel Energy, Inc., Cinergy Corp., and the Tennessee Valley Authority (TVA) in federal court in New York City claiming that global warming constitutes a legal and actionable public nuisance under federal common law. A related lawsuit was filed against the same power companies by the Open Space Institute, the Open Space Conservancy, and the Audubon Society of New Hampshire. WLF argued in its brief that the district court was correct in dismissing the case on political question grounds because the policy issues involved in the case should be resolved by the political branches rather than by a federal court. WLF argued that the Congress has repeatedly rejected proposed legislation and the Kyoto Treaty that would impose unfair mandatory caps on carbon dioxide emissions on U.S. power companies while leaving countries such as China and India free from any constraints.

Status: Awaiting decision.

ILLEGAL ALIENS -- COLLEGE TUITION RATES. Day v. Bond. On August 30, 2007, the U.S. Court of Appeals for the Tenth Circuit in Denver upheld the dismissal of a challenge to a Kansas law that offers preferential in-state college tuition rates to illegal aliens. The decision was a setback for WLF, which urged the court to reinstate the case on behalf of WLF’s client, a Missouri resident who attends the University of Kansas. The statute grants illegal aliens the right to attend Kansas universities at in-state rates but denies that same right to U.S. citizens who live outside of Kansas. WLF argued that the Kansas law violates a 1996 federal statute, 11 U.S.C. § 1623, that prohibits states from granting more favorable tuition rates to illegal aliens than they grant to citizens. The appeals court did not dispute WLF’s interpretation of the statute but held that Congress did not intend to permit individuals to sue for violations of the law. Instead, any enforcement must be at the hands of the federal government, the court ruled. The court also ruled that the plaintiffs lack standing to argue that its preferential tuition-rate scheme violates the Constitution’s Equal Protection Clause. In light of the court’s ruling, WLF wrote to officials at the U.S. Department of Homeland Security, demanding that they begin enforcing § 1623 against States that are flouting the law. WLF filed its brief on behalf of Brigette Brennan, who attended and graduated from a Kansas high school and has been living for the past five years in Kansas while attending the University of Kansas. But Kansas has refused to offer her in-state tuition rates because she lived in Kansas City, Missouri while attending high school. The result is that she is paying considerably higher tuition than do illegal aliens who lived in Kansas illegally while attending high school and whose presence in this country continues to be illegal. WLF also filed its brief on behalf of itself and the Allied Educational Foundation.

Status: Loss. WLF to file brief seeking Supreme Court review on April 16, 2008.
LEGAL REFORM -- PUNITIVE DAMAGES. *City of Hope Medical Center v. Genentech, Inc.* On January 26, 2006, WLF filed a brief the California Supreme Court urging it to reverse a court of appeal ruling that upheld a compensatory damages award of $300 million along with an unprecedented $200 million punitive damages award against Genentech, a biotech company. The company was involved in a contract dispute over royalties with City of Hope Medical Center which developed synthesized DNA material. If not overturned on appeal, businesses involved in typical contract disputes risk debilitating lawsuits by plaintiffs’ attorneys not only for normal contract damages, but also for multimillion dollar punitive damages awards. The $200 million award was in addition to the $300 million compensatory damages award, bringing the total to $500 million. WLF argued in its brief that if the decision were left intact, all businesses involved in typical contract disputes are at risk for lawsuits by plaintiffs’ attorneys not only for normal contract damages, but also for multimillion dollar punitive damages awards. WLF also argued that the excessive award was not justified and should not have been imposed simply because the company could afford to pay the amount without going bankrupt.

**Status:** Oral argument held on February 5, 2008. Awaiting decision.

**REGULATORY PROCEEDINGS**

DEPARTMENT OF TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU

*Labeling of Wines, Distilled Spirits, and Malt Beverages.* On January 25, 2008, WLF filed comments with the Alcohol and Tobacco Tax and Trade Bureau (TTB), objecting to TTB’s proposed regulation that would prohibit various types of truthful information from appearing on labels for alcoholic beverages, including information about the beverage’s alcohol content (expressed as fluid ounces of alcohol per serving). WLF argued that such a prohibition violates the First Amendment’s protection of commercial speech. WLF argued that TTB may not ban such truthful speech entirely, but rather is limited to requiring manufacturers to include reasonable disclaimers to ensure that consumers are not misled. WLF further argued that information regarding alcohol content is of significant benefit to consumers and, indeed, is widely disseminated by the government itself. WLF’s comments were a follow-up to comments WLF filed in 2005 requesting the TTB to revoke its ban on truthful alcohol labeling.

DEPARTMENT OF TREASURY
COMMITTEE ON FOREIGN INVESTMENT IN THE UNITED STATES

*Proposed Acquisition of 3Com Corp.* On January 24, 2008, WLF filed formal comments with the Committee on Foreign Investment in the United States (CFIUS), expressing its
"extreme concern" over the proposed acquisition of 3Com Corp. by a group that includes a Chinese company, Huawei Technologies. WLF stated that while it strongly supports the free flow of capital as a vital component of U.S. economic strength, it believed that the proposed 3Com Corp. acquisition raised grave national security concerns. WLF noted that a 3Com division, TippingPoint, provides top secret technology to the Department of Defense (DoD); the technology is designed to prevent intrusion into military computer systems by foreign governments. WLF further noted that Huawei Technologies has close ties to the Chinese military and that the Chinese military is suspected of having launched a cyber attack in June 2007 against DoD. WLF argued that allowing the 3Com Corp. acquisition to go through would likely result in TippingPoint's intrusion prevention technology falling into the hands of the Chinese military. In a victory for WLF, the group attempting to arrange the 3Com Corp. acquisition announced in March 2008 that it was abandoning its plans because it determined that it would be unable to obtain CFIUS approval of the deal.

HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Proposed Exclusion of Executives from Pharmaceutical Industry. On January 31, 2008, WLF filed formal comments with HHS's Office of Inspector General (OIG), expressing its "grave concern" with OIG's pursuit of "permissive exclusion" actions against three pharmaceutical executives who pleaded guilty to misdemeanor violations of federal food and drug laws. WLF noted that the executives were never charged with any knowing violations of the law; rather, they were convicted of the misdemeanor charges based on evidence that sales personnel working for their company -- and acting without their knowledge -- had improperly promoted one of the company's drugs. WLF argued that under those circumstances, federal law does not permit OIG to end their careers by excluding them from working in the pharmaceutical industry. WLF also charged that OIG is violating the three executive's due process rights by proposing to issue an exclusion order without first providing them with a hearing on the charges.

Proposed Restrictions on Medicare/Medicaid Coverage for ESAs. On June 11, 2007, WLF filed formal comments with CMS, objecting to CMS's proposal to deny Medicare/Medicaid coverage for many uses of Erythropoiesis Stimulating Agents (ESAs), even uses that are FDA-approved. ESAs are a class of drugs approved by FDA for treating numerous types of cancer. Although ESAs are widely used, FDA has required them to be labeled with "black box" warnings that remind doctors of health concerns associated with their use. WLF's comments argued that so long as FDA continues to conclude that the benefits of ESAs outweigh the risks, the Social Security Act prohibits CMS from second-guessing that conclusion by denying Medicare/Medicaid coverage for FDA-approved uses. WLF also argued that CMS's decision to deny coverage is bad for public health because it denies many patients access to the drugs their physicians believe are medically necessary.

HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
Proof of Citizenship for Medicaid Applicants. On July 11, 2006, WLF filed comments with CMS, urging the agency to tighten its requirements regarding the documentation that Medicaid applicants must provide to demonstrate that they are U.S. citizens (and thus eligible to receive Medicaid benefits). WLF argued that some of the guidelines adopted by CMS in this area are not as strict as Congress mandated in 2005 legislation. WLF argued that in the absence of stricter documentation requirements, Medicaid administrators could have little assurance that Medicaid program participants are actually eligible to receive benefits. WLF requested that CMS not permit administrators to waive documentation requirements for those claiming that it would be too burdensome to obtain proof-of-citizenship documents; it argued that if documentation exists that would verify whether an applicant is a citizen, then the applicant should be required to provide the documentation.

Restrictions on Speech About Part D Plans. On April 4, 2006, WLF petitioned CMS to lift restrictions on commercial speech imposed by CMS’s marketing guidelines for carriers offering Medicare prescription drug benefit plans. The guidelines prohibit carriers from making truthful and non-misleading statements comparing their plans to other plans. WLF’s petition asserted that the speech restrictions are beyond the scope of CMS’s authorizing regulations and violate the First Amendment rights of carriers and consumers.

CMS Guidance on “Part D” Drug Formularies. On August 19, 2005, WLF filed comments with the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, asking the agency to withdraw its plan to allow the exclusion of the lung cancer drug Iressa from drug plans under the new “Part D” prescription drug benefit. WLF’s comments are in response to a CMS decision to exclude Iressa from a requirement that carriers offering coverage under the new benefit program must include in their formularies “all or substantially all” cancer drugs. WLF noted that Iressa is believed to represent the best available care for many lung cancer patients in the Medicare population for whom other therapies have failed. WLF filed the comments on behalf of itself, the Abigail Alliance for Better Access to Developmental Drugs, the Lorenzen Cancer Foundation, and the Lung Cancer Alliance.

CMS Proposal On Tying Coverage To Clinical Trial Participation. WLF filed comments on June 6, 2005, with the Centers for Medicare & Medicaid Services (CMS), the agency of the U.S. Department of Health and Human Services (HHS) that operates the Medicare program, asking the agency to withdraw its proposal to tie reimbursement for selected new treatments to the patient’s participation in a clinical trial or a similar evidence-gathering process. WLF argued that such requirements may restrict patients’ access to needed care and that CMS has numerous alternative tools with which to spur research. WLF further argued that CMS has not justified such requirements under the Medicare statute’s “reasonable and necessary” provision governing reimbursement.
HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Response to Public Citizen Petition to Restrict Advertising for Celebrex. On April 17, 2007, WLF filed with FDA a formal response to a petition filed by Public Citizen’s Health Research Group regarding the arthritis drug Celebrex. The petition from Public Citizen (a Ralph Nader activist group) urged FDA to bar an ongoing advertising campaign for Celebrex. Public Citizen charged that the advertisement is "dangerous" and "misleading" because, Public Citizen alleged, the ad improperly downplays cardiovascular risks associated with Celebrex. WLF responded that the ad is accurate and well-balanced and that any effort to restrict the ad would violate the First Amendment. WLF argued that the ad - which runs 2 1/2 minutes and provides detailed descriptions of Celebrex’s risks and benefits - is precisely the type of commercial speech in which FDA should be encouraging all pharmaceutical companies to engage. The ad accurately summarizes the FDA-approved labeling for Celebrex (including potential health risks in taking the drug), and repeatedly advises consumers that the choice of a prescription medication is one that should only be made in consultation with one’s doctor. WLF charged that Public Citizen provided no evidence for its claim that viewers of the ad would draw the inaccurate inferences.

Improper Regulation of ASRs. On March 5, 2007, WLF filed formal comments with the Food and Drug Administration (FDA), urging FDA to withdraw a draft guidance document that seeks to impose additional layers of regulation on manufacturers of analyte specific reagents (ASRs). WLF argued that FDA’s proposed regulatory activity violates FDA’s statutory mandate, the Administrative Procedure Act (APA), and the First Amendment. FDA’s proposed guidance document, issued on September 9, 2006, would impose significant new burdens on manufacturers who supply ASRs to clinical labs. (ASRs are complex chemicals -- such as antibodies and nucleic acid sequences -- that are used by laboratories as the "building blocks" for tests developed and validated by those labs (often referred to as "laboratory-developed tests" or LDTs)). In response to FDA’s draft guidance, WLF argued: (1) the document changes the definition of ASRs, with the result that the definition is ambiguous and purports to preclude the sale of ASRs that are lawful under existing regulations; (2) the proposed changes violate the APA, which requires any changes in substantive regulations to be undertaken only in connection with notice-and-comment rulemaking; and (3) the proposed changes violate the First Amendment because they seek to limit dissemination of truthful information about ASRs.

Petition to Stop FDA Regulation of Clinical Labs. On September 28, 2006, WLF filed a Citizen Petition with the Food and Drug Administration, calling on FDA to cease its efforts to enforce its “medical device” regulations against clinical laboratories that provide physicians with in-house developed and validated tests used to assist in making diagnoses and in developing treatment regimens. WLF’s Citizen Petition asserted that FDA lacks statutory authority to regulate tests developed by laboratories for their own use and offered only to health care professionals. WLF noted that clinical labs have long been subject to regulation by another federal agency - the Centers for Medicare and Medicaid Services (CMS) and its
predecessors - pursuant to the Clinical Laboratory Improvement Amendments (CLIA). WLF argued that FDA enforcement efforts could undermine effective health care by crippling these labs' ability to quickly develop tests – e.g., for new or rapidly mutating infectious diseases. The FDA has not responded to WLF's petition. But it has gone ahead with plans to issue a guidance document that would have the effect of regulating most clinical laboratory tests as "medical devices." WLF testified at a February 8, 2007 FDA hearing in opposition to the proposed guidance document, and also filed formal comments in opposition in March and August 2007.

"Lean" Labeling. On February 8, 2006, WLF filed comments with the FDA supporting the agency's proposal to expand the allowable nutrition information of certain small-package foods so that manufacturers can label those foods with the word "lean." WLF argued that the proposed change would assist consumers by providing them with accurate and relevant information and would also expand the market for lean foods.

User Fees. On December 14, 2005, WLF filed comments with the FDA on the reauthorization of the prescription drug user fee program. Under the Prescription Drug User Fee Act (PDUFA), sponsors of new drug applications pay user fees to allow FDA to hire more scientific review staff and improve its information technology for the purpose of expediting the new drug review process. In its comments, WLF argued that because PDUFA's purpose is to accelerate the availability of safe and effective new medicines, PDUFA fees should be expended only on direct application-related costs – not on unrelated costs as FDA officials have suggested. WLF emphasized that the prescription drug user fee program must not evolve into an industry-specific tax to finance FDA's normal regulatory and law enforcement activities.

Labeling of Soda Containers. On December 16, 2005, WLF filed comments with the FDA urging the agency to reject a petition filed by the Center for Science in the Public Interest (CSPI), a Washington, D.C.-based activist group founded by Ralph Nader, that would require warning labels on non-diet soda cans and bottles advising consumers, among other things, that "drinking too much soft drinks may contribute to weight gain." WLF argued that such warning labels are not mandated by law and, as a matter of public policy, are unnecessary since current labels on all beverages provide caloric content, sugar content, and other nutritional information to help consumers make informed choices.

Denial of Public Citizen's Petition on Silicone Breast Implants. On October 11, 2005, WLF filed formal comments with FDA, urging it to deny a Citizen Petition, filed by Public Citizen and others, seeking to block FDA approval of PMAs (premarket applications) for silicone gel-filled breast implants. WLF argued that the Citizen Petition is based on a misreading of the Administrative Procedure Act (APA) and the Federal Food, Drug, and Cosmetic Act (FDCA). WLF argued that Mentor Corp. and Inamed Corp., the manufacturers seeking PMAs, have provided adequate assurances that their products are safe and effective and that (contrary to Public Citizen's contention) a demonstration of absolute safety is neither possible nor required under federal law. An FDA Advisory Panel heard
extensive public testimony in April regarding the PMAs, including testimony from WLF urging approval. FDA issued an "approvable" letter to Mentor in July and an "approvable" letter to Inamed in September. Public Citizen’s petition is a last-ditch effort to block final marketing approval for silicone breast implants manufactured by the two companies. Public Citizen has indicated that it may file suit if FDA grants final approval. Although FDA has not acted on the Citizen Petition, it granted final marketing approval to both Mentor and Inamed in November 2006. Public Citizen has subsequently threatened efforts to block marketing, by taking the issue either to Congress or the courts.

Emergency Approval of Medical Products. On September 6, 2005, WLF filed comments in support of FDA’s issuance of guidance on emergency approval of medical products. Congress has given FDA authority to allow the use of unapproved medical products, or to authorize unapproved uses of an approved product, in response to a heightened risk of attack from biological, chemical, radiological, or nuclear weapons. While expressing its support, WLF expressed concerns regarding the preemption aspects of the proposal. WLF argued that those provisions should be clarified to establish that the preemptive effect of an emergency authorization covers labeling matters and tort liability. WLF’s comments noted that the emergency powers created by Congress to protect the public health would be frustrated by assertions of state or local authority in either of these areas - either to establish contrary or supplemental labeling requirements or to impose tort liability where a manufacturer is acting in compliance with an emergency use authorization.

Restriction on Lung Cancer Drug. On July 25, 2005, WLF filed comments with the Food and Drug Administration asking the agency to withdraw or modify its order for the restrictive labeling of the lung cancer drug Iressa. WLF’s comments were joined by three patient groups, the Abigail Alliance for Better Access to Developmental Drugs, the Lorenzen Cancer Foundation, and the Lung Cancer Alliance. FDA’s action effectively limits the use of Iressa in the United States to the approximately 4,000 patients already being treated with it. WLF’s comments argued that this limitation on the availability of Iressa is unjustified and will harm lung cancer patients in the future who have no other approved treatment options and who may benefit from this medicine. WLF previously filed comments on April 20, 2005, with the FDA opposing a petition from the Nader group Public Citizen, Inc., in which Public Citizen sought the immediate withdrawal of Iressa.

Approval of Silicone Gel-Filled Breast Implants. On March 28, 2005, WLF filed comments with FDA’s Medical Devices Advisory Committee, charging that FDA is violating clearly established rules governing administrative procedure in its handling of premarket applications (PMAs) submitted by two companies seeking permission to market silicone gel-filled breast implants. WLF stated that the Administrative Procedure Act (APA) prohibits FDA from imposing far stricter approval requirements on silicone breast implants than it has imposed on similar medical devices. FDA has indicated that it wants Mentor and Inamed (the two manufacturers) to provide long-term data regarding the health consequences of breast implant failure (particularly rupture). Both PMAs include at least three years of post-implant data on the large number of women included in Mentor’s and Inamed’s studies. But because only a
tiny fraction of breast implants rupture within seven years, gathering the breast implant failure information requested by FDA would require at least 10 years of post-implant clinical testing. Thus, if FDA stands by its request for long-term post-implant follow-up data, Mentor and Inamed would not be able to gain approval of their PMAs for many years to come. WLF charged that the APA prohibits FDA from imposing long-term pre-approval data requirements on the silicone breast implant PMAs, given that FDA has never previously imposed such requirements on similar medical devices. WLF Chief Counsel Richard Samp later elaborated on WLF’s charges during testimony given to an FDA panel on April 11, 2005.

DEPARTMENT OF JUSTICE

Curbing Prosecutorial Abuse. On July 12, 2007, WLF filed a petition calling upon the Department of Justice (DOJ) to revise its policy for prosecuting violations of environmental laws and regulations. The 23-page filing, addressed to the Attorney General, requests that DOJ and U.S. Attorneys establish effective procedures to screen referrals from EPA and other agencies to curtail prosecutorial abuses. Moreover, WLF urged DOJ to decline criminal prosecution when more reasonable administrative and civil remedies are available, as Congress intended. WLF’s petition recounts examples over recent years of abusive criminal enforcement prosecutions discussed in this report, including cases where armed EPA Special Agents raided small businesses in a manner that one federal judge aptly described as a "virtual SWAT Team," for trivial infractions where there was little or no environmental harm or criminal intent.

Criminal Prosecution of Class Action Attorneys. On December 12, 2005, WLF called upon then-U.S. Attorney General Alberto Gonzales and the Justice Department to vigorously prosecute class action attorneys who may be involved in paying illegal secret kickbacks of attorneys’ fees in some two dozen class action cases from 1984 to 2001, as alleged in a federal criminal indictment. WLF requested that the Justice Department establish a task force similar to the Corporate Fraud Task Force established in 2002 to investigate other cases of possible plaintiff attorney misconduct. The Milberg Weiss firm and Bill Lerach have been identified as the attorneys in question but denied any wrongdoing; they claim the payments were not kickbacks but legitimate "referral fees" to their client’s local attorney. In 2004, the Milberg Weiss firm split in two, with the New York law firm renamed Milberg Weiss Bershad & Schulman and the San Diego, California, firm of Lerach Coughlin Stoia Geller Rudman & Robbins, headed by Bill Lerach who was lead attorney in some of the cases. On May 18, 2006, the Milberg Weiss law firm was indicted as well as two of its partner partners, one of whom pled guilty. In September 2007, both Melvyn Weiss and Bill Lerach were also indicted. Bill Lerach has agreed to plead guilty and serve up to two years in prison and forfeit millions of dollars. In March 2008, Melvyn Weiss also pled guilty and will be sentenced up to two years in prison.

Oversight of Criminal Investigations into Improper Drug Promotion. On March 24, 2005, WLF filed a petition with the U.S. Department of Justice (DOJ), urging DOJ to remove the
Office of Consumer Litigation ("OCL," a branch of DOJ located within the Civil Division) from its oversight and supervisory role in criminal cases arising under the Food, Drug, and Cosmetics Act (FDCA) involving allegedly improper promotion of pharmaceuticals and medical devices. WLF charged that OCL has failed in that role and has done little to develop a coherent federal government policy regarding when such criminal investigations are warranted. WLF said that OCL has simply rubber-stamped whatever criminal investigation local U.S. Attorney Offices have sought to initiate. WLF asked that the coordination role be reassigned to an office within DOJ's Criminal Division, which has far more expertise and experience in addressing the issues inherent in any criminal investigation. WLF said that it is particularly concerned about the need for effective DOJ coordination in this area because criminal investigations of promotional activities have the potential to adversely affect the nation's health care delivery system. In March 2008, DOJ indicted Dr. W. Scott Harkonen, for CEO for Intermune, for off-label promotion of Actimmune, even though the drug was helpful to those suffering from serious diseases.

 Prosecutions Based on Communications about Off-Label Uses of Medicines. On October 5, 2004, the Assistant Attorney General in charge of the Justice Department's Civil Division responded to WLF's request for clarification of the Department's policies regarding off-label prescribing. Off-label uses of medicines – that is, prescribing of FDA-approved medicines for conditions that the FDA has not specifically approved – is standard medical practice and is heavily relied upon in areas such as cancer treatment, AIDS treatment, and pediatrics. WLF wrote to the Department on April 16 and June 15, 2004, to express concern about federal criminal and civil investigations of communications by pharmaceutical companies regarding off-label uses, which appear to violate speech rights and harm the interests of patients and doctors. The Department's response to WLF argued that its investigations and prosecutions are consistent with free speech rights. WLF's response to the Justice Department was published in the March-April 2005 issue of FDLI Update, a leading industry trade journal. WLF is continuing to monitor DOJ enforcement policy in this area.

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

 Regulation of Pain Medication Prescriptions. On November 6, 2006, WLF filed formal comments with the Drug Enforcement Administration (DEA), urging DEA to make final its proposed rule regarding issuance of multiple prescriptions for Schedule II Controlled Substances. WLF stated that the proposed rule was an important first step in addressing a serious health care problem in this country: the underutilization of pain medication. WLF said that it understood the need for DEA to provide careful controls over potentially dangerous and addictive medications. At the same time, WLF argued, unless the need for controls is balanced with the need to provide ready access to those with a genuine medical need, health care will suffer. WLF argued that the proposed rule -- by permitting prescriptions of pain medications to be refilled under some circumstances without the need for the patient to make a separate visit to his or her doctor, thereby cutting down on medical costs -- takes a significant step toward bringing those competing interests into a proper
balance.

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Proposed Regulations Requiring Preservation of Physical Evidence. On March 6, 2006, WLF submitted formal comments to the Chemical Safety and Hazard Investigation Board opposing proposed regulations that would require owners and operators of chemical and other companies to preserve certain physical evidence, including computer records and other information, following an accidental release of a toxic chemical or other hazardous substance into the ambient air. In addition, the proposed rule would trigger civil or criminal referral by the CSB if there is a "knowing failure to comply" with the proposed regulations. WLF argued that the CSB does not have the statutory authority to promulgate the proposed preservation of evidence rule, that the Board had failed to demonstrate that there was any need for the rule, and that the rule would allow the Board to make criminal referrals even if there was no criminal intent on the part of the company or its employees for not complying with the rule.

DEPARTMENT OF HOMELAND SECURITY

In-State Tuition for Illegal Aliens. August 9, 2005, WLF filed a formal complaint with the U.S. Department of Homeland Security (DHS) against the State of Texas, charging that Texas is violating the civil rights of U.S. citizens who live outside the State. WLF filed a similar complaint against New York State on September 7, 2005. WLF charged that Texas and New York are violating federal law by offering in-state college tuition rates to illegal aliens who live in those states, while denying those same rates to U.S. citizens who do not live in those states. WLF called on DHS to bring appropriate enforcement action against Texas and New York, including ordering them to make refunds to students who have been charged excessive tuition. The federal statute at issue, 8 U.S.C. § 1623, was adopted in 1996 and is designed to ensure that any state that offers discounted, in-state tuition rates to illegal aliens on the basis of their residence in the state must offer the same discounted rates to all U.S. citizens. In 2001-02, Texas and New York adopted laws that allow illegal aliens to attend public universities at in-state rates, but they have refused to extend that same opportunity to U.S. citizens living outside the states. Similar laws have since been adopted in seven other states: California, Utah, Illinois, Washington, Oklahoma, Kansas, and New Mexico. WLF periodically has followed up on the two complaints, writing to DHS in late 2007 to demand that the agency take action.

ENVIRONMENTAL PROTECTION AGENCY

Reforming EPA’s Criminal Prosecution Policy. On June 11, 2007, WLF petitioned the Environmental Protection Agency (EPA) to revise its criminal enforcement policy and practices to ensure that more reasonable, non-criminal remedies -- including administrative and civil remedies -- are utilized as Congress intended to address alleged violations of the myriad of complex environmental laws and regulations. In its 13-page filing with the
agency, WLF called upon EPA Administrator Steve Johnson and Peter Murtha, EPA’s Director of Criminal Enforcement, to discontinue abusive and unjust criminal investigations and prosecutions against honest businesses, managers, and employees who face stiff fines and substantial prison terms for even minor regulatory infractions.

Improper Assessment of Cancer Risks. On September 5, 2006, the Environmental Protection Agency (EPA) declined WLF’s request that it reconsider its February 2006 decision to decline to hear a WLF petition to eliminate “junk science” from the process by which EPA determines whether a substance is likely to cause cancer in humans. In a petition filed pursuant to the Information Quality Act (IQA) in August 2005, WLF had argued that EPA guidelines for determining human carcinogenicity violate the IQA because they are not based on sound science but rather on an EPA policy judgment that extreme caution should be adopted in connection with substances that pose any possible cancer risk. EPA’s response asserted that because its guidelines constitute a “policy” document, they are not subject to the IQA. WLF’s March 21 reconsideration petition explained why EPA policy documents are not exempt from the IQA. WLF filed its initial petition and its reconsideration request on behalf of itself and the American Council on Science and Health (“ACSH”). ACSH recently published a study, America’s War on “Carcinogens,” that is extremely critical of EPA’s guidelines for determining cancer risks.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Disciplinary Action Against "B Readers" Who Engage in Misconduct. On April 10, 2006, WLF filed a petition with NIOSH, urging it to take disciplinary action against "B Readers" who have acted inappropriately in connection with their analysis of x-rays of those being screened from asbestos-related disease. NIOSH is the licensing agency for all such B Readers. WLF charged that evidence being developed in pending asbestos litigation suggests that a small number of B Readers has been involved in a massive fraud in which thousands of healthy individuals have been diagnosed as suffering from asbestos and silica-related illnesses. WLF urged NIOSH to establish a program to look into these misconduct charges and to take appropriate disciplinary action. NIOSH responded in a lengthy letter dated May 30, 2006, assuring WLF that it intends to make an appropriate response and inviting WLF’s continued participation in the issue.

DEPARTMENT OF TRANSPORTATION
NATIONAL HIGHWAY TRANSPORTATION SAFETY ADMINISTRATION

Federal Roof Strength Safety Standards Preempt State Law. On November 21, 2005, WLF filed comments with NHTSA that would extend roof safety rules to include vehicles with a gross weight of 10,000 pounds, increase the applied force for testing roof resistance to 2.5 times the weight of the unloaded vehicle from the current 1.5 factor, and replace the current headroom limit with a new requirement. WLF supported NHTSA’s conclusion that its proposed safety rule would preempt state common law because such state tort rules would conflict with and frustrate’s NHTSA’s goals of reducing rollover crashes and the consequent
injuries to the vehicles' occupants.

FEDERAL TRADE COMMISSION

In re: FTC Regulation of Endorsements and Testimonials. On June 18, 2007, WLF filed formal comments with the Federal Trade Commission (FTC), urging it not to revise its guidelines regarding the use of endorsements and testimonials in advertising. WLF is opposing efforts by Commercial Alert and other activist groups, which seek tighter control on the use of endorsements and consumer testimonials in advertising, no matter how truthful. WLF argued that truthful speech is fully protected by the First Amendment and is not subject to government prohibition simply because some consumers might give greater credence to the endorsements or testimonials than activists might deem appropriate. WLF argued that simple disclaimers (such as that "the results reported may not be typical of all users") are sufficient to prevent consumer testimonials (e.g., "I lost 38 pounds using this weight-loss plan") from being misleading.

Verifying Parental Consent for Online Activity. On June 27, 2005, WLF filed comments with the FTC, urging the agency to retain its "sliding scale" approach in mandating verifiable parental consent to their children's online activities. Under the Children's Online Privacy Protection Act (COPPA), the FTC is charged with ensuring that companies not collect, use, or disclose information about children under 13 who use their internet sites, unless the children's parents consent to such activities. In 1999, the FTC adopted its "sliding scale" rule, pursuant to which the level of required verification depends on the uses the company plans to make of information it collects. If a website operator collects personal information for its internal use only, an email signed by the parent is sufficient to establish consent; but much more elaborate verification of consent is required if the operator intends to disclose information about a child to outsiders. In its comments, WLF argued that the "sliding scale" approach has been working well and thus there is no need to impose harsher verification requirements, as some groups have urged.

SECURITIES AND EXCHANGE COMMISSION

In re: Reports on Internal Control over Financial Reporting Under Sarbanes-Oxley. The SEC announced in February 2008 that it will postpone external auditing requirements for smaller companies until 2009 under the Sarbanes-Oxley Act (SOX), but will require those companies to make internal assessments under SOX. WLF had filed comments with the SEC on February 27, 2007, on its proposed interpretive guidance urging the SEC to exempt smaller public companies from the burdensome reporting requirements on the company's internal control over financial reporting (ICFR) under Section 404 of the Sarbanes-Oxley Act. WLF further urged the Commission to develop clearer and more flexible guidance for management regarding its evaluation and assessment of ICFR, and to adopt relevant recommendations of the Commission's Advisory Committee on Smaller Public Companies. WLF requested that the Commission reduce, as much as possible, the regulatory burden of Sarbanes-Oxley on all public companies, both large and small. WLF
particularly supported those recommendations which include partial or complete exemptions for specified types of smaller public companies until satisfactory guidance has been issued by the Commission and the PCAOB. WLF filed similar comments at an earlier stage of these proceedings last year.

In re: SEC Fair Funds Distributions. On January 26, 2006, WLF filed formal comments with the Securities and Exchange Commission (SEC), urging it to amend its plan for distribution of funds collected from companies that engaged in unfair stock trading practices, to ensure that all such funds are distributed only to those who were injured by such practices. WLF argued that the proposed plan was deficient under the Sarbanes-Oxley Act (which established the Fair Funds for Investors program) because it did not provide for the distribution of $50-70 million of collected funds. WLF said it feared that unless such a provision is adopted, the SEC may decide to deposit those funds into the U.S. Treasury. The SEC has amassed a $250 million fund as a result of settlements with NYSE specialist firms accused of using improper trading practices. WLF argued that the SEC should retain left-over funds to allow interest to be paid on losses and to ensure that any late-filed claims for damages can be covered.

SPECIAL PROJECTS

DDMAC Watch

In June 2005, WLF inaugurated its "DDMAC Watch" program, designed to monitor federal regulation of prescription drug advertising. WLF has determined that the Food and Drug Administration (FDA), acting through its Division of Drug Marketing, Advertising, and Communications (DDMAC), has been using letters to the pharmaceutical industry to advance questionable legal theories and request remedial actions that the agency could not require under law. Under the DDMAC Watch program, when DDMAC sends a letter to a drug company employing theories that are legally deficient or ill-advised, WLF will immediately send back a response letter to DDMAC identifying the specific ways in which this is so. The goal of the program is to alert the press and public to abuses occurring at DDMAC.


On August 7, 2006, WLF issued "The Year in Review," a comprehensive report on WLF’s analysis of all DDMAC letters in the preceding 12 months. The report concluded that three DDMAC "policies" discernable from DDMAC’s letters violate the First Amendment and various federal statutes. WLF submitted its report to FDA as a Citizen Petition, asking that DA abandon those policies. WLF issued its second analysis of recent DDMAC letters on January 30, 2008.

**Investor Protection Program**

On January 21, 2003, WLF launched its new INVESTOR PROTECTION PROGRAM (IPP) by filing a complaint with the Securities and Exchange Commission (SEC). WLF’s complaint is the first in a series of legal actions, expert legal studies, and public educational/advertising campaigns that the Foundation will undertake.

The goals of WLF’s IPP are comprehensive: to protect the stock markets from manipulation by trial attorneys; to protect employees, consumers, pensioners, and investors from stock losses caused by abusive class action litigation practices; to encourage congressional and regulatory oversight of the conduct of the plaintiffs’ bar with members of the securities industry; and to restore investor confidence in the financial markets through regulatory and judicial reform measures.

WLF engaged in a wide variety of litigation and regulatory activities under this program, which are described in greater detail throughout this report. Among other activities, WLF (1) filed three formal complaints with the SEC and the Department of Justice, urging an investigation into the questionable circumstances of short-selling in J.C. Penney Co. stock just before a major class action lawsuit was filed involving the company; requesting an investigation into the class action lawsuit against Terayon Communication Systems, Inc. by two short-sellers of the stock; and requesting an investigation into the class action lawsuit against Bayer Company; (2) filed Freedom of Information Act (FOIA) requests seeking SEC documents regarding enforcement actions involving possible violations of insider trading regulations or other SEC rules involving trial attorneys and related SEC policies, followed up by a FOIA lawsuit against the SEC; (3) filed a formal Petition for Rulemaking requiring disclosure of contacts made by trial attorneys with stock analysts and short-sellers; (4) testified before Congress on short-selling and class actions; (5) filed comments with the SEC on hedge fund regulation and the Sarbanes-Oxley Act; (6) filed formal objections and briefs in several class action cases, and (7) filed a brief challenging the
constitutionality of the Public Company Accounting Oversight Board (PCAOB) established by Sarbanes-Oxley. In addition, WLF published several op-eds and Legal Studies publications on the topic. Further details of these and related IPP activities can be found throughout this report under the Litigation, Regulatory, Civic Communications Program, and Legal Studies Division sections.

**Civic Communications Program**

WLF’s highly acclaimed Civic Communications Program consists of a broad-based outreach program which disseminates our free enterprise message through print and electronic media, public education advertising campaigns, and on-site seminars and briefings. WLF attorneys and *pro bono* legal experts also engage in extensive "Litigation PR" efforts in high profile cases and legal matters.

WLF continued to be active during the first quarter of 2008 with its publication of hard-hitting public policy op-eds in the editorial pages of the *New York Times*. The op-eds, inaugurated in 1998 and published under the headline "In All Fairness," address a variety of topics of interest to the business community and appear regularly in the national edition of the *New York Times*, which reaches over five million readers in 70 major markets, as well as a diverse group of thought leaders, decision makers, and the public. WLF’s op-eds have been well received and have generated substantial public discussion on the particular topics selected.

Titles and summaries of the op-eds published during the first quarter of 2008 include:

*Manipulating the Public’s Interest*
(Activist groups, along with plaintiffs’ lawyers and state and federal prosecutors, use the media and scare tactics to target companies and force settlements of baseless lawsuits)

*The Real "Special Interests"?*
(Activists and lawyers who attack businesses to advance their ideological agenda harm our economic system and destroy confidence in free enterprise)

**Media Briefings & Educational Programs**

Reaching out to journalists in the national media is critical to communicating WLF’s free enterprise message. WLF uses its in-house facilities to host media briefings, which are often moderated by former U.S. Attorney General and WLF Legal Policy Advisory Board Chairman Dick Thornburgh. WLF’s "Media Nosh" press conferences focus on a different, timely legal policy topic each week.

This component of the Civic Communications Program enables WLF to influence
journalistic analyses of the issues and court cases and prevent activists from monopolizing the media by default. The briefings attract top reporters from high-profile electronic and print media such as USA Today, National Law Journal, Wall Street Journal, New York Times, Washington Post, Business Week, CNN, NBC News, ABC News, Voice of America, National Public Radio, C-SPAN, the major wire services, and syndicated legal reporters in the Washington, D.C. bureaus of national newspaper chains. These briefings are also webcast live and conveniently archived on WLF’s website at www.wlf.org.

WLF media briefings during the first quarter of 2008 included the following:

**Media Briefings**

- Richard L. Frank, Olsson Frank Weeda
- Scott M. Lassman, WilmerHale LLP
- Marc J. Scheineson, Alston & Bird LLP

**Web Seminars**

WLF also continued its *Web Seminar Series* this quarter. Web Seminars present viewers with live webcast analysis and commentary by noted legal experts on timely developments in law and public policy. These hour-long presentations are also conveniently archived and available on WLF’s website. The speakers for the programs, who provide their insights on a *pro bono* basis, are leading experts in the field of law to be discussed.

- Professor Michael I. Krauss, George Mason University School of Law
- Damon W.D. Wright, Venable LLP

**State Attorneys General Suits: Courtroom & Legal Policy Strategies for Defeating the AG-Trial Lawyer Alliance**, March 20, 2008
- Brian Anderson, O'Melveny & Myers LLP
- Amber Taylor, O'Melveny & Myers LLP

**Sowing the Seeds of Litigation: Securities Class Action Lawyers and Their Quiet Efforts to Tilt the Scales of Justice**, March 13, 2008
- Mark Tapscott, *The Washington Examiner*

**Sovereign Wealth Funds: Issues and Legal Policy Implications of Their Investments in American Institutions**, March 5, 2008
- Steven W. Preston, WilmerHale LLP
Robert P. O'Quinn, U.S. Congress Joint Economic Committee

The Foreign Corrupt Practices Act: SEC & DOJ Enforcement Breathes New Life and Risks into the 30 Year-Old Law, February 27, 2008
• Homer E. Moyer, Jr., Miller & Chevalier, Chartered
• Kathryn Cameron Atkinson, Miller & Chevalier, Chartered

• Mark Fox Evens, Sterne, Kessler, Goldstein & Fox P.L.L.C.
• Professor Christopher Cotropia, University of Richmond School of Law

Criminalization of Free Enterprise - Business Civil Liberties Program

There continues to be a growing and dangerous trend by federal and state authorities to trample on business civil liberties and criminalize honest business activities when more appropriate administrative and civil remedies are available. WLF aggressively fights for economic and commercial free speech rights, and vigorously opposes wrongful criminal prosecution of businesses.

WLF continued throughout 2007 to fight for business civil liberties via litigation, administrative proceedings, and publications. WLF also has vigorously opposed the Department of Justice prosecutorial guidelines that would unfairly intrude on the attorney-client privilege between counsel and corporations. WLF has been working closely with the American Bar Association's Working Group on Attorney-Client Privilege Waiver and other business groups on criminal law reform as it affects business interests. WLF has been critical of the U.S. Sentencing Commission's guidelines that coerce attorney-client waiver, which were revoked by the Commission in April 2006. WLF was also the only pro-free enterprise public interest organization to file briefs in the U.S. Sentencing Guidelines cases before the U.S. Supreme Court and lower courts attacking the misuse of the Sentencing Guidelines by federal prosecutors.

Court Watch Project

WLF's Court Watch Project involves the investigation of judges who may have acted unethically or improperly in either civil or criminal cases. When appropriate, WLF not only brings these cases to public attention, but also files complaints with judicial misconduct commissions so as to make the civil and criminal justice system more responsive to the needs of everyday citizens. To date, WLF has investigated and/or filed complaints against more than 135 state and federal judges.
SAVE Program

WLF continues to spread its pro-free enterprise message to the nation's youth through its Salvatori American Values Education (SAVE) Program. WLF's SAVE Program is designed to help educate the thousands of high school and college students who travel to Washington, D.C., every year -- in organized educational programs, as interns, and on class trips -- by stressing the values of liberty, freedom, free enterprise, and limited government espoused by the Founding Fathers.

The SAVE Program's approach is twofold. First, WLF attorneys make personal appearances at SAVE seminars to speak directly to students regarding the Founding Fathers' values and engage in question and answer sessions with the students. Second, WLF's Legal Studies Division publishes SAVE Program literature. SAVE Program appearances to date include presentations to students at events sponsored by the following groups:

* Institute for Jewish Leadership and Values
* Marquette University
* Washington Workshops Foundation
* The Washington Center for Politics and Journalism
* Smithsonian Institution's Campus on the Mall
* The American University Washington Semester Program
* The Luther Institute
* The Close-Up Foundation
* The University of Kansas
* The D.C. School of Law - Federalist Society
* The American University, Washington College of Law
* Georgetown University Law Center - Federalist Society
* Catholic University Law School
* National Youth Leadership Forum
* United States Naval Academy
* Gallaudet University
* University of Baltimore Law School - Federalist Society
* Hofstra University Law School
* Tulane University School of Law
* Oklahoma City University Law School - Federalist Society
* Texas Tech Law School - Federalist Society
* Duke University Law School - Federalist Society
* Quinnipiac Law School - Federalist Society
* George Washington University Law School - Federalist Society
* George Mason University School of Law
* Panim el Panim
* Cazenovia College
* Boston University
Outreach Project

WLF continues to expand its nationwide network of attorneys to encourage them to engage in pro bono litigation activity on behalf of free enterprise and to give them an opportunity to write legal policy papers for national distribution through WLF's Legal Studies Division. During 2007, WLF received pro bono assistance from a number of law professors, lawyers, and law firms listed throughout this report.

Legal Studies Division Publications

WLF’s Legal Studies Division published the following, Counsel’s Advisories, Legal Opinion Letters, Legal Backgrounders, Working Papers, Contemporary Legal Notes, Conversations Withs, and Monographs in the first quarter of 2008.

Counsel’s Advisories

Proposal On Deferred Prosecution Merits Close Monitoring
By Stephanie A. Martz, Director of the National Association of Criminal Defense Lawyers’ (NACDL) White Collar Crime Project.

Wisconsin Court Continues Trend Against “Attractive Advertising” Suits
By Rebecca J. Schwartz, a senior associate in the Class Action and Complex Litigation Practice Group of Shook, Hardy & Bacon, L.L.P.

Legal Opinion Letters

Twombly Ruling Compels Dismissal Of Antitrust Class Action
By William Kolasky, Christopher Lipsett & Andrew Ewalt, attorneys in the Washington, D.C. office of the law firm WilmerHale LLP.

Time To End Unconstitutional Linkage Of Judges’ And Legislators’ Pay
By The Honorable Robert F. Julian, who until February 5, 2008, is a member of the New York State Supreme Court. Judge Julian will after that date be practicing law with the Utica, New York based law firms of Brindisi, Murad, Brindisi and Pearlman, L.L.P, and Julian and Pertz, P.C.

Judges Take Harder Line Against Lawyer Misconduct
By Glenn G. Lammi, Chief Counsel of Washington Legal Foundation’s Legal Studies Division.
Legal Backgrounders

Arming Government Contractors With A Statutory Defense Against Speculative *Qui Tam* Actions
By Todd J. Canni, a government contracts attorney with the law firm of McKenna Long & Aldridge LLP in Washington, D.C.

How Market-Based Policies Could Spur Biotechnology Growth In Russia
By Yelena M. Bakulina, an attorney at the Office of the Lieutenant Governor of the Kirov Region of the Russian Federation, and Lawrence A. Kogan, an international business, trade, and regulatory attorney and President and CEO of the Princeton, NJ-based nonprofit Institute for Trade, Standards and Sustainable Development, Inc.

Riverboat Poker And Paradoxes: The Vioxx Mass Tort Settlement
By Theodore H. Frank, Resident Fellow, American Enterprise Institute for Public Policy Research and Director, AEI Legal Center for the Public Interest.

*Stoneridge* Ruling Shuts Down Creative Securities Fraud Claims
By Susan E. Hurd, a partner in the Securities Litigation Group of Alston & Bird LLP.

*Stolt-Nielsen* Ruling Offers Lessons On Negotiating Corporate Amnesty Agreements
By F. Joseph Warin, chair of the Litigation Department in the Washington, D.C. office of the law firm Gibson, Dunn & Crutcher LLP, and Peter E. Jaffe, Of Counsel to the firm.

*Riegel v. Medtronic*: What Does It Portend For Device & Drug Suit Preemption?
By Eric Lasker, a partner in the Washington, D.C. law firm, Spriggs & Hollingsworth, P.C.

Florida Court Reaffirms Outdated *Frye* Test For Scientific Evidence
By Lewis F. Collins, Jr., a partner, and Barbara M. Cowherd, an associate, with the law firm Butler Pappas Weihmuller Katz Craig, LLP in Tampa, Florida.

Probate Battle Illustrates Value Of Constitution's Full Faith & Credit Clause
By Janice R. Brenman, an attorney with the Los Angeles law firm Fleming, Greenwald & Associates.

*Exxon Shipping* Provides Court Welcome Opportunity On Excessive Punitive Damages
By Evan M. Tager, a partner in the Washington, D.C. office of Mayer Brown LLP.

Chill Wind On Free Speech Blows In From The Hill
By Arnold I. Friede, Counsel to the law firm McDermott, Will & Emery, and Robert B. Nicholas, a Partner and Chair of the FDA practice at the firm.

Ohio High Court Upholds Law Limiting Tort Damages
By Kurtis A. Tunnell and Anne Marie Sferra, partners, and Miranda Creviston Motter,
an associate, at the law firm of Bricker & Eckler LLP in Columbus, Ohio.

Earmarks: Are They Constitutional?
By Philip C. Olsson, a founder and a senior principal of Olsson Frank Weeda Terman Bode Matz PC.

High Court Continues Patent Law Examination With Quanta Computer Case
By David M. Young, a partner in the Washington, D.C. office of the law firm Goodwin Procter LLP.

Collective Litigation In Europe: Policy Considerations From The U.S. Class Action Experience
By Gary A. Rubin, an attorney in the Washington, D.C. office of the law firm Skadden, Arps, Slate, Meagher & Flom LLP.

Contemporary Legal Notes

CAFA Case Study: Settlement Rejection Reveals Mixed Impact Of Class Action Law
By Brian Anderson, a partner, and Mel Schwing, a counsel, respectively, with the law firm O’Melveny & Myers LLP.

Working Papers

Technical Standards Setting Organizations And Competition: A Case For Deference To Markets
By Raymond T. Nimmer, Dean and Leonard Childs Professor of Law at the University of Houston Law Center.

Conversations With

CONVERSATIONS WITH: Free Enterprise – Left Behind After Sarbanes-Oxley
Features The Honorable Dick Thornburgh, Of Counsel to the law firm Kirkpatrick & Lockhart Preston Gates Ellis LLP, leading a discussion with Professor Craig Lerner, George Mason University School of Law and Professor Moin A. Yahya of the Faculty of Law at the University of Alberta.

PUBLIC APPEARANCES

While WLF attorneys are regularly quoted or featured by the print media in numerous news and trade publications, highlights of public appearances made by WLF attorneys during the first quarter of 2008 include:
January 8, WLF Chief Counsel Richard Samp was interviewed on CNN Radio regarding *Crawford v. Marion County*, a Supreme Court case in which activists are challenging an Indiana law that requires Indiana voters to present picture IDs before being permitted to vote.

February 10, Samp was interviewed on BBC Radio regarding the U.S. detention of enemy combatants at Guantanamo Bay, Cuba.

March 25, Samp was interviewed on CBS Radio regarding the Supreme Court’s decision in *Medellin v. Texas*, in which the Court ruled that criminal defendants may not invoke international law as a basis for overturning their convictions.
ACTIVITIES REPORT

to the

WASHINGTON LEGAL FOUNDATION
BOARD OF TRUSTEES

PROTECTING
COMMERCIAL SPEECH RIGHTS

August 1, 2007
TABLE OF CONTENTS

INTRODUCTION .................................................................................................................. 1

I. LITIGATION AND REGULATORY PROCEEDINGS .................................................. 1
   A. Print and Broadcast Advertising and Promotion ................................................. 2
   B. Product Labeling ................................................................................................. 9
   C. Discriminatory Treatment of Commercial Speakers ........................................ 12
   D. Private Tort Actions Against Commercial Speakers ....................................... 14
   E. Government Enforcement Actions Against Commercial Speakers .............. 17
   F. Outdoor Advertising ........................................................................................... 21
   G. Compelled Speech ............................................................................................. 23

II. CIVIC COMMUNICATIONS PROGRAM ................................................................. 25
   A. Media Briefings .................................................................................................. 25
   B. Web Seminars .................................................................................................... 27
   C. Advocacy Ads .................................................................................................. 28
   D. Public Appearances .......................................................................................... 29

III. PUBLICATIONS ..................................................................................................... 32
August 1, 2007

ACTIVITIES REPORT TO THE
WASHINGTON LEGAL FOUNDATION
BOARD OF TRUSTEES

PROTECTING
COMMERCIAL SPEECH RIGHTS

The ideals upon which America was established — individual freedom, limited government, a free-market economy, and national security — are the same principles that the Washington Legal Foundation (WLF) defends in the public interest arena. Adherence to those principles is essential to maintaining Americans’ high standard of living, and, more important, is essential to maintaining America’s position as the freest nation in the world.

Since its founding in 1977, the Washington Legal Foundation (WLF) has labored to protect the right of all Americans to speak freely. That right has come under increasing attack in recent years, particularly when the speaker is a company in a moment of crisis or in a politically vulnerable industry. All too often, members of the business community have found their right to speak freely being challenged by opportunistic politicians.

Regulators and activists often believe that they can make the world a better place by silencing companies they dislike, or by forcing those companies to disseminate government-mandated messages. WLF believes that freedom of speech is for everyone — as does the U.S. Supreme Court. Accordingly, WLF has been at the forefront of fighting for the right of business enterprises to engage in truthful and non-misleading speech.

WLF has worked to achieve those objectives through precedent-setting litigation, involvement in government regulatory proceedings, publication of timely articles on speech-related issues, and tireless advocacy for free-market solutions in the news media and other public forums. This report highlights many of WLF’s significant commercial speech-related activities.

I. LITIGATION AND REGULATORY PROCEEDINGS

Litigation is the backbone of WLF’s public interest programs. WLF litigates across the country before state and federal courts and administrative agencies. WLF represents only those who are otherwise unable to retain counsel on their own. Its clients have included numerous individuals who have been denied the right to speak freely on business-related issues, as well as other individuals who have been denied access to truthful information that a government bureaucrat does not want them to hear.
A. Print and Broadcast Advertising and Promotion

Government officials often view advertising and product promotion as a waste of resources that serves only to encourage unwarranted consumer demand for products. WLF strongly disagrees; it believes that truthful advertising has numerous public benefits — particularly increasing public awareness about the types of products available to meet consumer needs. In the medical arena, government officials may become upset when increased consumer awareness leads to increased consumer demand (and thereby may drive up the cost of some government programs), but WLF opposes government efforts to keep consumers in the dark merely to assist in budget-balancing efforts. Accordingly, WLF has battled in the courts and before administrative agencies to lift advertising restrictions, regulations that prevent dissemination of truthful information (such as information on off-label uses of FDA-approved products), and rules that limit discussions at professional gatherings (such as Continuing Medical Education events).

"DDMAC Watch." WLF has concluded that the FDA office that regulates prescription drug advertising, DDMAC (an acronym for the Division of Drug Marketing, Advertising, and Communications), routinely has failed to respect the First Amendment rights of pharmaceutical companies whose activities it is monitoring. In response, WLF in 2005 launched its “DDMAC Watch” program, designed to monitor DDMAC’s activities. Under the program, when DDMAC sends a regulatory letter to a drug company employing theories that are legally deficient or ill-advised, WLF will immediately send back a response letter to DDMAC identifying the ways in which this is so. The goal of the program is to alert the press and public to abuses occurring at DDMAC. As of July 2007, WLF has responded to 47 letters from DDMAC and related agencies; those letters were sent to Eli Lilly, Endo Pharmaceuticals, MedImmune Vaccines, Dutch Ophthalmic USA, Hoffman LaRoche, Abbott Laboratories, Pfizer, Actelion Pharmaceuticals US, SuperGen, Allergan, Alcon Research, Nephryx, ISTA Pharmaceuticals, Gen Trac, Medicis Pharmaceuticals, Sankyo Pharma, Duramed Pharmaceuticals, Biogen Idec, Mayne Pharma (USA), ZLB Behring, Palatin Technologies, InterMune, VaxGen, Bioniche Pharma Group, Sandoz, BIPI, Wyeth Pharmaceuticals, PrimPharm, GlaxoSmithKline, Eli Lilly, Astellas Pharma US, Reliant Pharmaceuticals, Mallinkrodt, Alcon, 3M Pharmaceuticals, Daiichi Sankyo, Wellspring Pharmaceutical, MGI Pharma, Cephalon, Takeda Pharmaceuticals North America, Alcon Laboratories, DUSA Pharmaceuticals, Schering, GlaxoSmithKline, KV Pharmaceutical, Enzon Pharmaceuticals, and Allergan.

On August 7, 2006, WLF issued “The Year in Review,” a comprehensive report on WLF’s analysis of all DDMAC letters in the preceding 12 months. The report concluded that three DDMAC “policies” discernable from DDMAC’s letters violate the First Amendment and various federal statutes. WLF submitted its report to FDA as a Citizen Petition, asking that FDA abandon those policies. FDA’s response is due in August 2007.

Opposition to Ban on Direct-to-Consumer Drug Advertising. On April 20, 2007, WLF submitted to Congress a detailed legal analysis of proposed legislation to ban direct-to-consumer (DTC) prescription drug advertising during the first two years following FDA approval of a drug.
WLF concluded that the advertising ban would violate the First Amendment to the U.S. Constitution. WLF reached that conclusion because, it determined, any such across-the-board ban could not be deemed "narrowly tailored" to serve any of the legitimate interests sought to be served by such a ban. WLF submitted its analysis at the request of U.S. Senator Richard Burr of North Carolina. The FDA legislation ultimately adopted by the Senate and House of Representatives in 2007 did not include the ban on DTC advertising.

**Washington Legal Foundation v. Henney.** On February 11, 2000, the U.S. Court of Appeals for the District of Columbia Circuit dismissed FDA’s appeal from a district court decision that struck down FDA regulations that severely restricted the flow of truthful information regarding off-label uses of FDA-approved drugs and medical devices. The decision was a major victory for WLF in its long-running battle against FDA speech restrictions; WLF had filed suit against FDA in 1994, after FDA rejected a 1993 WLF Citizen Petition asking that the regulations be lifted. In 1998 and 1999, the district court ruled that the regulations violated the First Amendment rights of consumers who wished to learn truthful information about off-label product uses that are widely accepted within the medical community as safe and effective. As a result of WLF’s victory, FDA has not initiated enforcement actions against any of the manufacturers who have exercised their First Amendment rights by distributing peer-reviewed journal articles that discuss off-label uses of their products.

**FDA Testimony Regarding Direct-to-Consumer Pharmaceutical Advertising.** On November 2, 2005, WLF Chief Counsel Richard Samp testified before an FDA panel in support of expanding the rights of pharmaceutical companies to engage in direct-to-consumer (DTC) advertising. Samp asserted that DDMAC, the FDA division that oversees drug promotion, needs to rein in its efforts to suppress advertising, and step in only when advertisements are likely to mislead consumers. When FDA announced that it would be holding hearings in November 2005, its announcement suggested that FDA was considering moving in the other direction and imposing additional restrictions on advertising. Many hearing witnesses called for severely limiting drug ads, branding them as inherently biased and misleading. WLF’s Samp countered that DTC advertising has played a vital public health role in recent years by increasing consumer awareness of treatment options.

**In re: ACCME Restrictions on Continuing Medical Education.** On January 29, 2003, WLF filed comments with the Accreditation Council for Continuing Medical Education (ACCME), severely criticizing the Council for its proposal to impose draconian restrictions on who may speak at CME activities. WLF argued that the proposed restrictions are an unwarranted infringement on free speech rights. Pre-2003 ACCME standards were designed to ensure unbiased CME presentations by, among other things, requiring speakers to disclose whether they have received any funding from the manufacturer of any of the drugs being discussed. The proposed standards went considerably further; they would have altogether prohibited doctors who had been compensated by a pharmaceutical company from speaking at a CME activity. WLF noted in its comments that most of the top medical authorities in the country are employed in some capacity by one or more of the country’s drug companies and thus would no longer be permitted to participate in CME events.
WLF argued that without the participation of top doctors, CME would no longer be the important source of new medical information that it is today. WLF attorneys repeatedly voiced their criticisms of the proposed restrictions at several well-attended ACCME-related forums in 2003. The ACCME board of directors approved new rules on April 1, 2004, and they took effect in early 2005. However, in response to criticisms from WLF and others, the ACCME somewhat modified the restrictions such that they are considerably less objectionable than earlier versions had been.

In re: FDA Request for Comments on First Amendment Issues. FDA has lost several major First Amendment lawsuits in recent years, including WLF v. Henney (see above). FDA responded in 2002 by requesting public input on whether any current FDA policies violate the First Amendment. On September 13, 2002, WLF filed extensive comments, citing a broad array of FDA regulatory activities that violate the First Amendment rights of those seeking to speak truthfully about pharmaceutical products. On October 28, 2002, WLF filed a second round of comments, responding to arguments (made by several U.S. Senators in connection with the initial round of comments) that public health concerns justify exempting FDA from First Amendment constraints applicable to other government entities. WLF criticized the contention of those Senators that consumers are likely to misuse truthful information. FDA has pledged to address these First Amendment concerns, but it has yet to do so in a systematic manner.

Citizen Petition Regarding Restrictions on Truthful Speech. Following WLF’s victory in WLF v. Henney (see above), FDA began to suggest that it was not bound by the court’s decision in WLF’s favor. FDA issued statements to manufacturers, suggesting that they might be sanctioned for engaging in the types of off-label speech that WLF v. Henney had held to be constitutionally protected. Accordingly, on May 23, 2001, WLF filed a Citizen Petition with FDA, urging the agency to repudiate those statements and to announce that it had lifted restrictions on manufacturers’ rights to disseminate non-misleading information concerning off-label uses of FDA-approved products. WLF argued that by threatening enforcement action against manufacturers who exercise their free-speech rights, FDA was violating the First Amendment rights of manufacturers who wish to speak in a non-misleading manner about off-label uses of their products, and of those who wish to hear such speech. WLF noted that WLF v. Henney had resulted in a ruling that the First Amendment prohibits FDA from restricting manufacturer dissemination of “enduring materials” (medical texts and reprints of peer-reviewed medical journal articles) that discuss off-label uses of FDA-approved products. WLF charged that FDA was flouting that ruling by threatening enforcement action against manufacturers who disseminate enduring materials. FDA’s response to the petition amounted to another WLF victory. Although continuing to argue that the ruling in WLF v. Henney was not as broad as WLF asserted, FDA pledged that in the future (in light of its limited resources) it would not bring enforcement actions based on the types of manufacturer speech described by WLF.

Investigating Efforts to Evade WLF Courtroom Victory. Although WLF established in WLF v. Henney (see above) that the First Amendment protects the right of drug manufacturers, in certain instances, to disseminate truthful information about off-label uses of their products, WLF has become increasingly concerned that various federal officials are seeking to evade that decision. In particular, the United States Attorney’s office in Boston has threatened criminal prosecution of
companies that disseminate truthful off-label information, while other federal officials have indicated that such conduct may violate the federal False Claims Act or the anti-kickback statute. In the past two years, WLF has been investigating whether such federal officials are violating the terms of the injunction entered in WLF v. Henney. That investigation includes a series of document requests (pursuant to the Freedom of Information Act) directed to (among others) FDA and the Office of Inspector General of the U.S. Department of Health and Human Services.

Oversight of Criminal Probes Into Allegedly Improper Drug Promotion. In connection with the investigation described above, WLF quickly concluded that criminal probes into allegedly improper drug promotion are not being supervised effectively by officials from the U.S. Department of Justice (DOJ) in Washington. On March 24, 2005, WLF filed a petition with the DOJ, urging it to remove the Office of Consumer Litigation ("OCL," a branch of DOJ located within the Civil Division) from its oversight and supervisory role in criminal cases arising under the Food, Drug, and Cosmetic Act (FDCA) involving alleged improper promotion of pharmaceuticals and medical devices. WLF charged that OCL has failed in that role and has done little to develop a coherent federal government policy regarding when such criminal probes are warranted. WLF said that OCL has simply rubber-stamped whatever criminal probe local U.S. Attorney Offices have sought to initiate. WLF asked that the coordination role be reassigned to an office within DOJ's Criminal Division, which has far more expertise and experience in addressing the issues inherent in any criminal probe. WLF said that it is particularly concerned about the need for effective DOJ coordination in this area because criminal probes of promotional activities have the potential to adversely affect the nation's health care delivery system. FDA has not yet responded to WLF's petition.

Proposed Restrictions on Alcohol Advertising and Marketing. On November 1, 2005, WLF wrote to the Utah Attorney General, who also serves as head of the National Association of Attorneys General Task Force on Youth Access to Alcohol, to object to certain initiatives being undertaken by the Task Force. WLF argued that some of the Task Force's efforts to restrict alcohol advertising violate the First Amendment rights of product manufacturers. WLF argued that the Task Force had no basis for attempting to ban advertising in publications with more than a negligible youth readership; WLF cited Supreme Court decisions that prohibit government from barring truthful commercial speech aimed at adults simply because some children might see the advertisements. WLF also argued that the Task Force's proposed regulations of Flavored Malt Beverages are unwarranted and based on a misunderstanding of the manner in which these products have been marketed.

Tax Deductibility of Drug Advertising. After a U.S. Senator introduced legislation that would deny tax deductibility for pharmaceutical advertising for any drug company that sought to block reimportation of its drugs to the United States, WLF was asked by Capitol Hill officials to provide an analysis of the legislation's constitutionality. In an October 20, 2004 legal memorandum to Senator Charles Grassley and others, WLF concluded that the legislation would violate First Amendment rights. WLF noted that the bill threatened to deny speech-related tax deductions to a small group of companies in a single industry, while it would continue to grant tax deductions to
similarly situated companies in other industries. WLF pointed out that the bill’s sponsor admitted that the bill’s sole purpose was to coerce pharmaceutical companies not to take actions designed to prevent importation of price-controlled prescription drugs. WLF argued that, under those circumstances, the bill could only be deemed speech regulation (not a mere denial of a speech subsidy) and thus could not pass muster under established First Amendment case law. Since WLF submitted its analysis, the bill has not advanced out of committee.

**WLF Petition Regarding Direct-to-Consumer Advertising of Prescription Drugs.** In 1997, FDA adopted substantial revisions to its direct-to-consumer advertising policy. FDA’s action was in direct response to WLF’s July 20, 1995 Citizen Petition that sought relaxation of FDA restrictions on prescription drug advertising. The petition argued that those restrictions violated the First Amendment rights of drug manufacturers to convey truthful information to consumers, as well as the rights of consumers to receive such information. In particular, WLF asked FDA to eliminate: (1) the “brief summary” requirement, which often renders advertising non-cost-effective by requiring hundreds of words to be added to advertising; (2) the “fair balance” requirement, a totally subjective requirement that permits FDA to reject any advertisement it does not like; and (3) the requirement that advertisements be submitted to FDA for preclearance before being published. FDA’s new policy substantially relaxed the “brief summary” requirements with respect to broadcast advertising. As a result of this change, television advertising of prescription drugs has increased substantially over the past eight years, and consumers have received significantly more information about these products.

**In re: Television Product Placement.** The Federal Trade Commission issued an opinion letter on February 10, 2005, rejecting a petition from an activist group urging greater regulation of product placement on television. The pro-regulatory petition had been filed by Commercial Alert, an activist group co-founded by Ralph Nader. Commercial Alert petitioned the FTC and the FCC in September, 2003, to adopt new regulations that would mandate a warning for all instances of product placement on television. WLF had filed a response arguing that product placements are not harmful or deceptive. WLF further argued that even if Commercial Alert could show some harm from product placements, the proposed regulations would violate freedom of speech as defined in U.S. Supreme Court cases. Coverage of WLF’s response in *The Hollywood Reporter* and elsewhere raised awareness of the threat to commercial speech rights. The FTC agreed with WLF’s position that paid product placement does not mislead or confuse consumers. WLF was the only public interest organization to file comments in opposition to the Commercial Alert proposal.

**Greater New Orleans Broadcasting Ass’n v. United States.** On June 14, 1999, the U.S. Supreme Court struck down a federal law prohibiting broadcast advertising within Louisiana for gambling casinos that legally operated within the State. The decision was a victory for WLF, which filed a brief urging that the law be struck down. The Court agreed with WLF that the advertising ban served no significant government interest, in light of the fact that casino gambling is legal in all areas where the plaintiffs were seeking to run advertisements. The Court held that the First Amendment virtually never permits a ban on non-misleading advertising for a lawful activity.
44 Liquormart, Inc. v. Rhode Island. On May 13, 1996, the U.S. Supreme Court unanimously struck down Rhode Island's ban on retailer advertising of alcoholic beverage prices as a violation of the First Amendment. The decision was a victory for WLF, which had filed a brief urging the Court to over turn the ban. The Court agreed with WLF that only rarely can truthful commercial speech be banned. The Court held that Rhode Island failed to demonstrate that a ban on truthful price information served any important state interest.

Jakanna Woodworks, Inc. v. Montgomery County. On February 14, 1997, the Maryland Court of Appeals (Maryland's highest court) unanimously struck down on First Amendment grounds a county ordinance that required merchants to obtain a license before advertising a "closing-out" sale. The decision was a victory for WLF, which had filed a brief in the case arguing that the license requirement imposed an unwarranted burden on commercial speech rights. The court agreed with WLF that the ordinance was unconstitutional as applied to truthful advertising; the court held that the county's interest in preventing deceptive advertising could be protected without requiring businesses to get licenses before being allowed to advertise.

Opposing Regulation of Internet. On November 10, 2001, FDA responded to an April 12, 2001 WLF Citizen Petition urging the agency to adopt a rule or policy explaining that health claims and other consumer information that appear on a company's website do not constitute "labeling" of that company's product, and thus are not subject to FDA's stringent and detailed food and drug labeling requirements. Rather, any such promotional information should be regarded, at best, as advertising, and thus subject in certain circumstances to review by the Federal Trade Commission (FTC) under its "false and misleading" advertising standard. The FTC standard is more consistent with First Amendment protections of commercial speech than FDA labeling requirements. WLF's filing was prompted by an alarming FDA Warning Letter sent to Ocean Spray Cranberries, Inc. on January 19, 2001, the final day of the Clinton Administration. FDA claimed that Ocean Spray's cranberry and grapefruit juices were "misbranded" and subject to seizure simply because of certain health claims and other information that appeared on the company's website and related links. In its response to WLF's petition, FDA indicated that it would not be issuing an across-the-board regulation at this time, but that it would not generally regard a company's website content as labeling if the company does not sell products online.

Petition Regarding Disclosure of Clinical Trial Results. On December 28, 1995, WLF filed a joint petition for rulemaking with FDA and the Securities and Exchange Commission (SEC), urging FDA to exempt from FDA regulation the public disclosure of clinical test results of Investigational New Drugs (INDs). Such information is required by SEC rules to be disclosed to the investment community. Current FDA rules and policies prohibit drug companies from "promoting" or "commercializing" an IND until the drug obtains final approval. Yet the SEC requires that drug companies file reports with that agency and inform the investment community of major product developments. FDA has interpreted its rule against "promoting" an IND to include press releases and other communications made by companies regarding the results of clinical tests of INDs. FDA has not taken any decisive action on this issue, and WLF continues to press for relaxation of speech restrictions in this area. WLF argues that investors need to receive truthful information about drugs
in “the pipeline” if they are to measure accurately the value of a pharmaceutical company’s stock.

**Citizen Petition on Pharmacy Compounding.** On March 6, 1992, WLF filed a Citizen Petition with FDA, alleging that the agency’s efforts to control advertising by pharmacies regarding their drug compounding capabilities violated the First Amendment, and urging the agency to utilize notice-and-comment rulemaking before adopting new regulations on that subject. FDA failed to heed WLF’s warnings, resulting in the U.S. Supreme Court’s 2002 decision in *Thompson v. Western States*, which found that FDA’s efforts to regulate advertising regarding pharmacy compounding of drugs violated the First Amendment.

**FDA Draft Guidance on Medical Product Promotion.** On April 6, 1998, WLF filed comments expressing its deep reservations regarding FDA’s Draft Guidance regarding “medical product promotion by health care organizations or pharmacy benefits management companies.” WLF argued that FDA failed to demonstrate any need for the guidance and that it would have an adverse impact on health care. WLF also argued that FDA lacked statutory authority to issue the guidance and that it infringed the First Amendment rights of drug companies, doctors, and consumers. WLF requested that FDA withdraw the Draft Guidance and not issue it in final form. In light of intense opposition, FDA placed the proposal on hold in July 1998 and has taken no further action.

**Opposing Proposed Controls on Tobacco Advertising.** On September 24, 2003, WLF submitted to U.S. Senator Jeff Sessions its analysis of proposed legislation that would impose severe federal controls on tobacco advertising and marketing. WLF completed the analysis at Senator Sessions’s request. WLF concluded that the bill violates the First Amendment because it would prohibit vast amounts of truthful advertising, yet it is not narrowly tailored to achieve its stated goals — reduction of tobacco use by youth and adults. The bill would write into law 1995 FDA tobacco restrictions that were never enforced because the courts determined that FDA was not authorized to issue them. WLF noted that a 2001 Supreme Court decision that struck down Massachusetts tobacco advertising restrictions on First Amendment grounds made clear that many provisions in the 1995 FDA regulations — provisions that are incorporated into the pending legislation — are unconstitutional. WLF was particularly critical of provisions in the proposed legislation that would greatly restrict any comparative health claims by tobacco manufacturers. WLF argued that the First Amendment bars restrictions on such claims as long as manufacturers can demonstrate that the claims are truthful.

**Opposing Restrictions on Alcohol Advertisements.** WLF filed a petition with the FCC in October 1996, urging it not to take any action limiting the advertising of distilled spirits on television. WLF argued that the Supreme Court’s recent decisions in this area made it absolutely clear that restrictions on truthful commercial speech are rarely, if ever, an effective or appropriate way for the government to achieve a public policy goal. WLF argued that this strict standard cannot be met with respect to liquor ads. There is little or no evidence that prohibiting television advertising of liquor will have a significant effect on underage drinking. Moreover, any restriction on the advertising of distilled liquor would primarily affect adults and would be far broader than necessary
to reduce underage drinking. WLF made clear that the legitimate problem of underage drinking should be attacked through greater enforcement of existing laws, not through restrictions on the free speech rights of adults. Although FCC Chairman Reed Hundt had been advocating new limitations on television advertising, the FCC dropped the matter in June 1997 by voting not to issue a Notice of Inquiry regarding alcohol advertising.

**Relaxing Restrictions on Speech about Securities.** On December 20, 1995, WLF filed a petition for rulemaking with the Securities and Exchange Commission (SEC), asking the agency to revise its rules on the contents of securities prospectuses and advertisements to allow any truthful and nonmisleading information to be included. The permissible contents of an advertisement or prospectus within the SEC’s jurisdiction are limited to certain information enumerated by statute and regulation. WLF argued that present regulations are inordinately restrictive and violate the First Amendment. WLF argued that although the SEC can compel disclosures in advertising and prospectuses to protect the public from fraud and abuse, it should not impose limitations on advertising content and on the content of prospectuses except to require that all information be truthful and nondeceptive.

**B. Product Labeling**

Some bureaucrats argue that consumer decisions (particularly decisions related to food consumption and health care) should be dictated by government officials because, they claim, most consumers cannot begin to understand the issues involved. Such paternalism is particularly prevalent with respect to the information that manufacturers are permitted to place on their product labels; bureaucrats regularly adopt rules that tightly restrict the information that may be included on a label, without regard to its truthfulness. WLF takes the opposite approach; it believes that providing consumers with access to accurate information vastly improves the quality of their choices, and including that information on a product label is often the best way to ensure that consumers have access to it. Accordingly, WLF has worked tirelessly over the past decade – both in the courts and before administrative agencies – to eliminate overly strict rules governing product labeling.

**Rubin v. Coors Brewing Co.** On April 19, 1995, WLF scored a decisive free-speech victory in the U.S. Supreme Court when the Court struck down a federal law that prohibited beer manufacturers from including the alcoholic content of their products on their labels. WLF’s brief challenging the law was written with the assistance of former U.S. Solicitor General Charles Fried. The Court agreed with WLF that the First Amendment does not permit the government to bar inclusion of truthful information on product labels merely because it believes that some consumers might abuse that information. The Court held that denying consumers truthful information about a product whose sale is wholly lawful serves no legitimate government interest.

**Legal Advice Regarding National Uniformity for Food Act.** On November 29, 2005, at the request of U.S. Representative Edolphus Towns, WLF attorneys provided him with legal counsel regarding the propriety of the proposed National Uniformity for Food Act of 2005 (“NUFA”), which
would require national uniformity in food safety and warning requirements. The bill would achieve uniformity by preventing States from imposing their own food labeling requirements once the federal government has established labeling requirements for a particular type of product. WLF's legal memorandum concluded that Congress would be acting appropriately were it to adopt the legislation. WLF concluded that NUFA is consistent with the federal government's traditional role in the regulation of interstate commerce and an appropriate response to the disruptions in interstate commerce caused by California's Proposition 65. WLF praised NUFA as "a carefully designed effort to balance the respective roles of the federal and State governments in food safety issues." WLF said that NUFA would have a significant impact only in those few States—such as California—in which excessive imposition of food warning requirements is having a negative effect on interstate commerce.

**Alcohol Labeling Restrictions.** On September 26, 2005, WLF filed formal comments with the Alcohol and Tobacco Tax and Trade Bureau (TTB) requesting that TTB revoke its ban on truthful alcohol labeling that would disclose basic "Serving Facts" information to consumers. WLF argued that consumers benefit when alcoholic beverage labeling lists the serving size, the number of servings per container, and the amount of alcohol per serving. WLF argued that such labeling is in the public interest, is truthful and not misleading, and is protected against unwarranted government regulations by the First Amendment. WLF argued that TTB is acting illogically by permitting manufacturers to convey this type of information in their advertisements but preventing the same information from being displayed on containers of beer, wine, or distilled spirits.

**Association of National Advertisers v. Lungren.** Manufacturers often seek to include on product labels information indicating that their products do not cause environmental harm. Some state and local governments have sought to restrict (or even ban) such labeling without regard to truthfulness. WLF has regularly gone to court to oppose such restrictions on First Amendment grounds. For example, California has a law that prohibits a manufacturer from labeling its product "recyclable" in most instances, regardless whether the product is, in fact, recyclable. After WLF's challenge to the law proved unsuccessful in the lower courts, WLF asked the U.S. Supreme Court to hear the case. WLF argued that the restrictions on truthful labeling regarding environmental issues violated the First Amendment. On October 2, 1995, the Supreme Court declined to hear the case.

**"Lean" Labeling.** On February 8, 2006, WLF filed comments with FDA supporting the agency's proposal to expand the allowable nutrition information of certain small-package foods so that manufacturers can label those foods with the word "lean." WLF argued that the proposed change would assist consumers by providing them with accurate and relevant information and would also expand the market for lean foods.

**Opposing Warning Labels on Soft Drinks.** On December 16, 2005, WLF submitted comments to FDA, urging FDA to reject a petition filed by the Center for Science in the Public Interest (CSPI), a Washington-based consumer activist group. The petition would require labels on non-diet soft drinks to bear a warning that "drinking too much soft drinks may contribute to weight
gain.” WLF argued that such warning labels are unwarranted because labels on all beverages currently provide caloric content, sugar content, and other nutritional information to help consumers make informed choices. WLF argued that it is well known to all consumers that maintaining a healthy diet requires avoiding over-consumption of food containing sugar and fat. WLF argued that the First Amendment protects manufacturers from being forced to display warning statements under such circumstances. WLF also cited studies indicating that lack of exercise plays a far greater role in juvenile obesity than does overconsumption of sugar and fat.

**Proposed Labeling for Flavored Malt Beverages.** On October 21, 2003, WLF filed comments with the Alcohol and Tobacco Tax and Trade Bureau (a branch of the U.S. Treasury Department), opposing proposed regulations that would impose excessive and unjustified restrictions on truthful labeling and advertising by brewers of flavored malt beverages. The proposed regulations would ban a range of legitimate, non-misleading statements that brewers might wish to make about their products’ taste, aroma, production process, flavoring, and the like. For example, it would prohibit brewers from truthfully informing consumers that a particular beer was aged in bourbon barrels. Citing the *Coors* decision (see above), WLF noted that the Supreme Court has specifically held that information on beer labels is commercial speech protected by the First Amendment and that the government must look to less restrictive alternatives before banning truthful statements.

**Proposal Regarding Trans Fatty Acid Nutrition Labeling.** On March 27, 2003, WLF filed comments with FDA, objecting to FDA’s proposal to require all food containing trans fatty acids (trans fat) to include on its label the following statement: “Intake of trans fat should be as low as possible.” WLF argued that requiring that statement would violate the First Amendment protection against compelled speech. WLF argued that while the First Amendment permits the government to compel commercial speech when necessary to prevent consumers from being confused or deceived, there is no serious argument that the proposed statement is necessary to prevent food labels from being confusing or deceptive. WLF stated that FDA may do no more than mandate disclosure of the quantity of trans fat contained in each serving of the food being sold. While the proposed statement might contain sound health information, it might also unnecessarily alarm consumers; and WLF argued that it is not the role of the government to commandeer the property of others for the purpose of spreading information that may promote public health. In a victory for WLF, FDA announced on July 11, 2003 that it would not require food labels to include the controversial statement.

**FDA Proposals to Regulate Food Labeling.** WLF has long been at the forefront of efforts to ease FDA regulation of food labeling. For example, in a series of submissions to FDA in the early 1990s, WLF urged FDA to lift the ban on health-related information and certain types of pictures on food labels. The ban on health-related information eventually was lifted by Congress, and WLF has continuously worked to ensure that the new legislation is being fairly administered.

**Draft Compliance Policy Guide on Labeling.** On July 23, 1999, WLF filed comments with FDA, opposing its efforts to expand the definition of “labeling” under federal food and drug law. Under FDA’s proposed definition, “labeling” of a drug would have included books and other publications that merely discuss a particular drug, even though that material does not “accompany”
the drug as that term is commonly understood and as Congress intended. FDA ultimately abandoned its effort to expand the definition of what constitutes "labeling" of a drug or medical device.

**Labeling of Genetically Engineered Products.** On March 19, 2001, WLF filed comments with FDA, generally supporting the agency's proposed guidelines for the labeling of food with respect to whether it has been developed using biotechnology. WLF strongly supported FDA's tentative decision to continue its policy against mandatory labeling on the subject; WLF noted that such labeling does not provide any nutritionally meaningful information. WLF asserted, however, that industry should be afforded broad leeway when it comes to voluntary labeling with regard to bioengineering, because any effort to significantly restrict industry choice would raise major First Amendment issues. WLF asserted that the one area in which FDA restrictions are warranted is the area of health claims; WLF argued that labeling should not be permitted if it suggests that the labeled food is safer based on the presence or absence of genetically engineered ingredients — because there is no sound scientific basis for such claims. FDA ultimately adopted guidelines that closely tracked WLF’s suggestions.

**Comments on Labeling of “Alcopops.”** On July 23, 2001, WLF filed comments with the Bureau of Alcohol, Tobacco, and Firearms (BATF), expressing strong opposition to a request from the Center for Science in the Public Interest (CSPI) that BATF revoke existing labels for sweet-tasting malt-based alcoholic beverages (referred to by CSPI as "alcopops"). WLF argued that CSPI failed to identify any portion of such labeling that is in any way misleading to consumers or is otherwise in violation of BATF regulations. WLF also argued that any effort to prohibit "alcopop" manufacturers from disseminating non-misleading product labeling would violate their First Amendment rights to engage in truthful commercial speech.

**C. Discriminatory Treatment of Commercial Speakers**

Often, governments discriminate against commercial speakers by treating differently two speakers who act and speak in an identical manner, based solely on the fact that one speaker is speaking in a commercial context and one is not. WLF views such discrimination as a blatant violation of the First Amendment and has regularly gone to court to ensure that commercial speakers are not treated as second-class citizens.

**Washington Legal Found. v. Leavitt.** On August 24, 2006, WLF filed suit in U.S. District Court for the District of Columbia against CMS (the federal Centers for Medicare and Medicaid Services), alleging that CMS is trampling on First Amendment rights in seeking to suppress truthful speech regarding insurance coverage available to senior citizens under Medicare Part D. Part D is the recently enacted Medicare program that offers insurance for the cost of prescription drugs. WLF filed suit on behalf of members who, as a result of CMS’s actions, are unable to obtain accurate information about competing insurance providers. The suit seeks an injunction against continuation of CMS’s policy. Ironically, the groups that CMS bars from providing truthful information—including nursing homes and pharmacies—are often the very groups that have the most knowledge
regarding the health-care needs of Medicare recipients, WLF charged. WLF charged that CMS’s rationales for its speech-suppression policies—including a concern that health care providers might accept kick-backs in return for recommending a particular insurance plan—do not justify its infringement on free speech rights. WLF noted that CMS may enforce anti-kickback statutes without suppressing speech. WLF asked the Court to enjoin CMS from continuing to bar providers from providing truthful information. WLF has been taking the depositions of senior CMS officials, and the case is nearing the end of the discovery phase. Both sides are expected to file motions for summary judgment in the fall of 2007.

**IMS Health Inc. v. Ayotte.** On April 30, 2007, the U.S. District Court for the District of New Hampshire broadly protected First Amendment rights by striking down a New Hampshire law that blocked access to critical health care information. The decision was a victory for WLF, which filed a brief urging the court to strike down the law, which is unique to New Hampshire but which has been considered by other States. It criminalizes the collection and disclosure of information about the prescribing practices of physicians. The court agreed with WLF that the law violates the First Amendment by prohibiting disclosures of truthful information, even disclosures arising outside the context of advertising. The court also agreed with WLF that such prohibitions are only rarely permissible and only then when based on showings of the most compelling of government needs. WLF argued that the information that New Hampshire is trying to ban plays a vital health care role; it is used to monitor the safety of medications, implement drug recalls, and rapidly communicate information to doctors about innovative new treatments. New Hampshire has appealed from the decision; WLF has pledged to file a brief in the appeals court, once again urging that the New Hampshire law be ruled unconstitutional.

**Petition Regarding Restrictions on Speech About Part D Plans.** On April 4, 2006, WLF petitioned the federal Centers for Medicare and Medicaid Services (CMS) to lift restrictions on commercial speech imposed by CMS’s marketing guidelines for carriers offering Medicare prescription drug benefit plans. The guidelines prohibit carriers from making truthful and non-misleading statements comparing their plans to other plans. WLF’s petition asserted that the speech restrictions are beyond the scope of CMS’s authorizing regulations and violate the First Amendment rights of carriers and consumers.

**Los Angeles Police Dep’t v. United Reporting Publishing Corp.** On December 7, 1999, the U.S. Supreme Court refused to overturn a California law that permits localities to withhold from the public at large (including commercial users) the names and addresses of those arrested, while simultaneously releasing that information to select noncommercial groups. The 7-2 decision was a setback for WLF, which had filed a brief urging that the statute be struck down. In its brief, WLF had argued that the Los Angeles Police Department was violating the First Amendment by favoring noncommercial users over commercial users. The Court said that the plaintiffs could not bring a facial First Amendment challenge to the law (that is, a suit asserting that the law is unconstitutional in all possible situations) because they were not being prohibited from conveying information in their possession; rather, their only complaint was that they were being denied access to government information. But the Court said that on remand the plaintiffs (commercial users of the names) could
argue that the statute is unconstitutional as applied to them in particular, because it treats them less favorably than it treats other groups (such as newspapers) seeking the arrestee information.

**City of Cincinnati v. Discovery Network.** On March 24, 1993, the U.S. Supreme Court struck down a Cincinnati ordinance prohibiting the distribution of commercial publications (such as real estate listings) by means of news racks placed on city streets, while simultaneously allowing newsrack distribution of general-circulation newspapers. The decision was a victory for WLF, which filed a brief urging that the ordinance be struck down on First Amendment grounds. WLF argued that the First Amendment prohibits such government content-based discrimination against commercial speakers, particularly where (as in this case) the potential harm created by news rack distribution of commercial circulars (litter on the streets) is no greater than the harm created by news rack distribution of general-circulation newspapers.

**Austin v. Michigan State Chamber of Commerce.** On March 27, 1990, the U.S. Supreme Court held that the First Amendment does not protect the right of corporations to make independent political expenditures in support of a candidate for public office — even though individuals do have a constitutional right to make such expenditures. The decision was a setback for WLF, which filed a brief urging the Court to strike down a Michigan law prohibiting such corporate expenditures. WLF argued that there is no reason to afford corporations less protection than individuals under the First Amendment. WLF argued that the danger of corruption is no greater when the independent expenditures are made by a corporation than when they are made by individuals.

**D. Private Tort Actions Against Commercial Speakers**

It is not just government agencies that bring enforcement actions against companies based on what they say or do not say. Such actions also take the form of tort actions filed by private parties. WLF has been particularly vigilant in opposing lawsuits by private parties who do not claim to have been hurt by the speech; they sue simply because they do not like what the company has said. For example, WLF has also gone to court in an effort to curb abuse of state statutes (e.g., California’s 17200 “unfair competition” statute) that allow trial lawyers and other uninjured individuals to seek court sanctions against commercial speakers by purporting to act on behalf of the state government.

**Doe v. Wal-Mart Stores, Inc.** On April 2, 2007, the U.S. District Court for the Central District of California dismissed a lawsuit brought against Wal-Mart by activists who are critical of Wal-Mart’s overseas labor practices. In response to such criticisms, Wal-Mart issued statements denying that it purchases products manufactured overseas under “sweat shop” conditions. The activists responded by filing suit against Wal-Mart under California’s infamous § 17200 “unfair competition” law, claiming that Wal-Mart’s denials were false and constituted unfair competition. The decision to dismiss the suit was a victory for WLF, which filed a brief urging dismissal. The court agreed with WLF that dismissal was warranted on the ground that the First Amendment fully protects Wal-Mart’s right to speak out on issues of public importance, such as international labor conditions. The court also agreed with WLF that the plaintiffs’ human rights claims (they likened
the labor practices used by Wal-Mart’s overseas suppliers to slavery) were not actionable under the Alien Tort Statute. The plaintiffs are appealing from the dismissal; WLF has pledged to continue its support of Wal-Mart’s speech rights, by filing an appeals court brief urging affirmance of the district court’s dismissal.

**Nike, Inc. v. Kasky.** On June 26, 2003, the U.S. Supreme Court declined review of a California Supreme Court decision threatening to impose severe restrictions on the right of corporations to speak freely on matters of public importance — including manufacturers seeking to respond to critics of their overseas labor practices. In January 2003, the Court agreed to review the case but five months later changed its mind and dismissed as “improvidently granted” its original order granting review. In two separate briefs filed in the case, WLF argued that the California court effectively held that all corporate speech — even speech on matters of great public importance — is entitled to reduced levels of First Amendment protection. WLF argued that the decision is contrary to a long line of Supreme Court decisions and threatens to chill significant amounts of speech by corporations.

**Physicians Comm. for Responsible Medicine v. General Mills.** On April 4, 2007, WLF filed a brief in the U.S. Court of Appeals for the Fourth Circuit in Richmond, urging the court to uphold the dismissal of a lawsuit by animal rights activists who are seeking to stop advertisements being run by the milk industry. WLF argued that Virginia law does not permit private citizens to seek injunctions against advertisements with which they disagree. WLF also argued that the suit threatened to undermine manufacturers’ commercial speech rights. WLF argued that if a manufacturer can be subjected to expensive lawsuits filed by activists who do not like statements the manufacturer makes on issues of public importance, then significant amounts of truthful speech will be chilled. The Physicians Committee for Responsible Medicine challenges the validity of the scientific studies that form the basis for the industry’s advertising. WLF responded that the plaintiffs’ real objection was not to the ads, but to what they view as inhumane treatment of cows. WLF argued that the courts should not allow the judicial process to be abused in this manner. WLF also filed a brief in the case when it was before the district court; the district court dismissed the case on November 30, 2006.

**Raytheon Technical Services Co. v. Hyland.** On March 2, 2007, the Virginia Supreme Court struck a blow for First Amendment rights by imposing limits on the ability of disgruntled employees to file defamation actions against their employers based on unhappiness over statements made in performance evaluations. The decision was a victory for WLF, which filed a brief urging the court to overturn a massive judgment awarded to a former employee. The Court agreed with WLF that most of the statements of which the plaintiff complained were statements of opinion, which (under the First Amendment) are not actionable. WLF argued that allowing employees to sue every time they disagree with a performance evaluation would cause corporations — wary of the prospect of large jury verdicts — to cease providing candid evaluations. WLF argued that by its very nature, a performance evaluation constitutes a supervisor’s subjective judgment regarding how well an employee is performing and as such constitutes a non-actionable statement of opinion.
In re Tobacco Cases II. On September 14, 2005, WLF filed a brief in the California Supreme Court, urging the court to uphold the dismissal of tort claims filed against tobacco companies for having run truthful advertising that allegedly overglamorized smoking. WLF argued that such claims are barred both by the First Amendment and by federal law—regardless of the plaintiffs' claim that glamorous advertisements induce minors to buy cigarettes in violation of California law. WLF argued that cigarette advertising is already heavily regulated at the federal level (by the Federal Cigarette Labeling and Advertising Act and by oversight conducted by the Federal Trade Commission), and at the State level by State regulators (by virtue of the Master Settlement Agreement entered into between tobacco companies and State attorneys general). WLF argued that there is no reason to permit an additional level of advertising regulation, in the form of tort suits filed under State law. WLF also noted that the plaintiffs seeking recovery are all admitted lawbreakers (they purchased cigarettes while under age 18) and argued that they should not be rewarded for their misconduct. The California Supreme Court heard oral arguments in the case on June 16, 2007.

Baxter International Inc. v. Asher. On March 21, 2005, the U.S. Supreme Court issued an order declining to review (and ultimately overturn) an appeals court decision that eviscerates a 1996 federal law intended to limit the liability of corporations that make projections ("forward-looking statements") regarding future sales and earnings. The decision was a setback for WLF, which had filed a brief urging the court to review (and ultimately overturn) the appeals court decision. The 1996 law creates a "safe harbor" for forward-looking statements; provided such statements are accompanied by "meaningful" cautions, the safe harbor mandates that the statements cannot be used to hold a publicly held corporation liable to its shareholders for subsequent drops in stock prices, regardless how inaccurate the statements turn out to be. The appeals court interpreted the safe harbor so narrowly that it provides virtually no protection to corporations. WLF argued that Congress intended to provide broad protection for forward-looking statements in order to encourage companies to provide such information. WLF is looking for other cases raising the same issue, with a goal of bringing the issue to the Supreme Court's attention once again.

Philip Morris USA v. Boeken. On March 20, 2006, the U.S. Supreme Court declined to review a California court decision that imposed a massive liability award against the manufacturer of a "light" cigarette on the ground that the public believes that "light" cigarettes pose less of a health risk than they actually do. The order, issued without comment, was a setback for WLF, which filed a brief urging the Court to review the case. WLF argued that such tort claims are preempted by federal law because cigarette manufacturers already display all the health and safety warnings mandated by the federal government. WLF argued that Congress determined, when it adopted the Federal Cigarette Labeling and Advertising Act, the health warnings that manufacturers must include in advertising and on their labeling. WLF argued that states should not be permitted to second-guess that congressional determination by allowing tort suits that would require manufacturers to impose additional warning requirements. WLF argued that Congress has passed a series of laws designed to allow companies in a wide variety of industries to advertise nationwide by imposing a uniform advertising standard and barring States from adopting conflicting standards. WLF argued that the California court decision could have the effect of undermining all such laws.
Metro-Goldwyn-Mayer Studios v. Grokster. On June 27, 2005, the U.S. Supreme Court issued a decision that provided appropriate protection for copyrights without unduly interfering with commercial speech rights or otherwise interfering with computer software development. The Court held that a company whose file-sharing software allows others to illegally copy and disseminate copyrighted music and films on the Internet also itself violates the copyright law. The decision addressed several important and previously undecided copyright issues. WLF had filed a brief in November 2004, urging the Court to address those issues. Copyright laws protect owners of the copyrighted work from having their music or films downloaded without paying the owner a royalty fee. Grokster software enabled computer users to share music and film files between each other utilizing so-called “peer-to-peer services,” usually violating the copyright laws. Consequently, major motion picture studios and record companies sued Grokster on the theory that it was guilty of contributory infringement. The Court ruled against Grokster, but in a manner unlikely to infringe speech rights or to inhibit development of innovative software products.

National Cable & Telecomm. Ass’n v. Brand X Internet Services. On June 27, 2005, the U.S. Supreme Court ruled that the Federal Communications Commission (FCC) could properly decide not to infringe the speech rights of cable and DSL companies by imposing burdensome regulatory requirements on the delivery of broadband Internet access. The decision was a victory for WLF, which filed a brief with the Court supporting the FCC’s position. The case arose from a decision by the FCC to treat cable modem service as an “information service” rather than a “telecommunications service.” The decision meant that cable modem providers (local cable television providers) would not be required to share their lines with other providers of Internet. The Supreme Court agreed with WLF that the FCC’s decision was sound policy because intense competition in the broadband market – among cable companies, local telephone companies (which provide DSL service), and companies in the process of developing new technologies for broadband service – ensures that consumers will be well served without the need for exacting FCC regulation of what these companies do and say.

E. Government Enforcement Actions Against Commercial Speakers

When a government agency goes to court to bring an enforcement action against companies based on statements they have made (or on their failure to include the government’s preferred warnings along with their statements), WLF has joined the fray in opposing sanctions against entities that have done nothing more than speak the truth.

United States v. Caputo. On January 16, 2007, WLF filed a brief in the U.S. Court of Appeals for the Seventh Circuit in Chicago, urging it to overturn the criminal convictions of business executives alleged to have promoted an FDA-approved medical device for an off-label use (that is, a use not strictly conforming to the uses specified on the FDA-approved labeling). WLF argued that the First Amendment broadly protects the rights of individuals to speak truthfully about off-label uses of FDA-approved products. The government has alleged that some statements made by the defendants were false. But WLF argued that because the jury returned a general verdict against the
defendants and thus might have voted to convict on the basis of their truthful statements, the conviction cannot not be allowed to stand. WLF also argued that by prosecuting those engaged in such speech, the federal government is significantly hindering health care delivery in this country, because off-label use is often standard-of-care medical practice. Oral argument in the case is scheduled for September 10, 2007.

**California v. R.J. Reynolds Tobacco Co.** On June 9, 2004, the California Supreme Court declined to review a lower court decision that imposed significant sanctions on a company for engaging in nonmisleading commercial speech. The decision was a setback for WLF, which filed a brief urging the Court to grant review. WLF argued that the First Amendment protects a company's right to engage in such advertising and that tobacco companies have never agreed to waive such rights. California sued R.J. Reynolds Tobacco Co. for allegedly “targeting” youth with its advertising, based on evidence that Reynolds places advertising in magazines (such as *Sports Illustrated*) with up to 25% youth readership. WLF argued that Reynolds may not be sanctioned for its advertising in the absence of evidence that it purposely intended to target youth; mere knowledge that a youth would see its ads is not sufficient to sanction non-misleading speech.

**Trans Union LLC v. Federal Trade Comm'n.** On June 10, 2002, the U.S. Supreme Court declined to review a lower-court decision that denied full First Amendment protection to truthful speech deemed by the court not to “relate to matters of public concern.” In its brief urging review, WLF argued that all truthful, noncommercial speech should be entitled to full First Amendment protection, and that a court should not get into the business of determining which speech involves topics that are insufficiently weighty and thus are less worthy of protection. In this case, the lower court upheld an FTC order prohibiting companies from transmitting truthful, noncommercial lists of names and addresses of consumers, and imposing sanctions on a company that had done so. WLF argued that the decision was inconsistent with numerous Supreme Court First Amendment decisions.

**FTC Regulation of Endorsements and Testimonials.** On June 18, 2007, WLF filed formal comments with the Federal Trade Commission (FTC), urging it not to revise its guidelines regarding the use of endorsements and testimonials in advertising. WLF is opposing efforts by Commercial Alert and other activist groups, which seek tighter control on the use of endorsements and consumer testimonials in advertising, no matter how truthful. WLF argued that truthful speech is fully protected by the First Amendment and is not subject to government prohibition simply because some consumers might give greater credence to the endorsements or testimonials than activists might deem appropriate. WLF argued that simple disclaimers (such as that “the results reported may not be typical of all users”) are sufficient to prevent consumer testimonials (e.g., “I lost 38 pounds using this weight-loss plan”) from being misleading.

**Word-of-Mouth Marketing.** On February 2, 2006, WLF filed with the FTC a response in opposition to a petition seeking an investigation of word-of-mouth, or “buzz,” marketing programs. The petition had been filed by Commercial Alert, an activist group co-founded by Ralph Nader. Commercial Alert claimed in its petition that programs inviting consumers (without compensation) to tell their peers about new products are deceptive if the consumers do not also disclose that they
are participating in a marketing program. WLF argued in its response that such communications are not deceptive and that there is no basis for requiring the disclosures sought by Commercial Alert.

**Novartis Corp. v. Federal Trade Commission.** On August 18, 2000, the U.S. Court of Appeals for the D.C. Circuit upheld a Federal Trade Commission (FTC) order requiring Novartis Corp., a pharmaceutical company, to include a government-dictated message in its advertising. The court ruled that the First Amendment posed no bar to the FTC’s so-called corrective advertising order. The decision was a setback for WLF, which had filed a brief urging the court to set aside the FTC’s order. The case involved an order from the FTC—which had determined that Novartis’s advertisements for Doan’s Pills had been misleading in suggesting that Doan’s offers more effective relief for back pain than other pain relievers—directing Novartis to include the following statement in all Doan’s advertising: “Although Doan’s is an effective pain reliever, there is no evidence that Doan’s is more effective than other pain relievers for back pain.” In its brief, WLF argued that the FTC’s corrective advertising order violated Novartis’s right to remain silent. WLF said that the FTC order was particularly troublesome because it resulted in Novartis refraining from advertising at all rather than conveying the FTC’s “corrective” message.

**Defending Corporate Speech on Food Irradiation.** On August 7, 2003, WLF filed comments with the Federal Trade Commission, objecting to efforts by activists to censure speech about food irradiation. Two activist groups, Public Citizen and the Center for Food Safety, petitioned the FTC to take enforcement action against Giant Food based on statements Giant made regarding the irradiation of its food products. Giant issued a pamphlet that, in an effort to add to consumers’ understanding of irradiation, compared the irradiation process to milk pasteurization. The activist groups asserted that the law prohibits food sellers from representing irradiated food as “pasteurized.” WLF countered that the comparison of irradiation and pasteurization is not misleading and assists American consumers in understanding that irradiation is a process designed to enhance food safety and cleanliness. WLF argued that the First Amendment protects Giant’s right to make truthful statements regarding the irradiation process.

**PCRM Petition Regarding “Milk Mustache” Advertisements.** On March 13, 2000, WLF filed comments with the FTC, opposing a petition filed by the Physicians Committee for Responsible Medicine (PCRM), which charged that the famous “Milk Mustache” advertisements are false or misleading. The PCRM argued that the advertisements are misleading because they provide consumers with the allegedly false impression that milk consumption is good for everyone’s health. WLF argued that the First Amendment protected the Milk Mustache ads from any government control. WLF argued that there is not only an overwhelming consensus in the medical community that milk consumption promotes good health among everyone except those with specific allergies, but also that the FTC and the courts have no authority to second-guess Congress’s determination that milk consumption should be promoted. The FTC ultimately decided not to address the petition.

**CSPI Petition Regarding Olestra Advertisements.** On September 28, 1998, WLF filed comments with the FTC, urging the agency to reject “false advertising” claims raised by a self-appointed consumer watchdog group. The Center for Science in the Public Interest (CSPI) has been
waging a quixotic campaign for years in an effort to prevent marketing of Olestra, a fat substitute used in potato chips and other snacks. The Food and Drug Administration rejected CSPI's claims that Olestra is not safe for human consumption, so CSPI then brought its campaign to the FTC arguing that advertising claims that Olestra is safe are false. In its comments, WLF argued that advertisements being run by makers of chips containing Olestra have been accurate. WLF argued that CSPI's hysterical campaign is merely an attempt to scare consumers away from Olestra-containing products. It also noted that health experts (as well as CSPI) have been stressing for years that Americans need to reduce fat consumption, and that substituting Olestra-containing chips for regular snack foods (which invariably are high in saturated fats) is one effective way to improve overall nutrition. The FTC subsequently adopted WLF's position and rejected CSPI's petition. In late 2005, CSPI announced that it plans to sue manufacturers of products containing Olestra, asserting that manufacturers include inadequate warnings on their labels. WLF intends to participate in that litigation, in opposition to CSPI.

**Action Against Alcoholic Beverage Advertisers.** On October 13, 1998, WLF filed comments with the FTC, urging it to reconsider proposed consent agreements against two companies regarding the advertising of their products. The FTC claimed that an advertisement for Beck's Beer was false and deceptive merely because it pictured actors standing on a sailboat and holding the product. The FTC claimed that such advertisements convey the false image that it is safe to drink beer while boating, and that viewers would so the same. The FTC also objected to an advertisement claiming that the Kahlua White Russian pre-mixed cocktail was "low alcohol" because beer has less alcohol. WLF argued that the advertisements were not false or misleading and that the FTC's interpretation of its authority was mistaken.

**Kraft, Inc. v. Federal Trade Comm'n.** On February 22, 1993, the U.S. Supreme Court denied review in this case involving suppression of Kraft's television and print advertisements by the FTC. The FTC contended that certain advertisements for "Kraft Singles" constituted false advertisement by implying untrue claims. The Supreme Court's decision was a setback for WLF, which filed a brief urging the Court to hear the case. WLF argued that federal agencies should not be permitted to censor an advertisement where, as in this case, every claim in the ad is literally true and the FTC has conducted no studies to substantiate its assertion that some consumers might nonetheless be misled by those truthful claims. WLF argued that the First Amendment does not permit the government to restrict advertisements without some substantial basis for asserting that the ads are misleading.

**Peel v. Attorney Registration and Disciplinary Comm'n.** On June 4, 1990, the U.S. Supreme Court ruled that the First Amendment bars states from prohibiting lawyers from publicizing their certification as "specialists" by bona fide private organizations. The decision was a victory for WLF, which filed a brief in the case in support of an Illinois lawyer who was sanctioned by state authorities for listing on his letterhead the truthful statement that he had been certified as a civil trial specialist. The Court agreed with WLF that the First Amendment protects the right of professionals to make truthful statements about their qualifications.
F. Outdoor Advertising

State and local governments continue to impose unwarranted restrictions on billboards and other types of outdoor advertising. Sometimes these restrictions are based on an antipathy to all types of outdoor signs; WLF believes that while governments should be permitted to impose reasonable zoning restrictions on signage, many of these restrictions go much too far and significantly interfere with individuals’ ability to exercise their First Amendment rights on their own property. On other occasions, the restrictions prohibit only certain types of signs, based on their content. WLF has repeatedly gone to court to oppose such content-based speech restrictions. The Supreme Court’s Lorillard decision, in which WLF won a resounding First Amendment victory, may have put such content-based restrictions to rest for the immediate future.

Lorillard Tobacco Co. v. Reilly. On June 28, 2001, the U.S. Supreme Court overturned Massachusetts regulations that banned outdoor advertising of tobacco products while imposing virtually no restrictions on other products’ advertising. The decision was a victory for WLF, which had filed a brief arguing that the regulations were unconstitutional. The Supreme Court agreed with WLF that the regulations could not be upheld in the face of a First Amendment challenge, as a measure reasonably designed to reduce underage smoking. The Court held that states could achieve that same objective by stepping up enforcement against merchants who violate the ban on sales to minors without interfering with speech. The Court also agreed with WLF that the Massachusetts regulations were preempted by a federal statute that severely limits states’ power to regulate cigarette advertising.

Federation of Advertising Industry Representatives v. Chicago. On October 6, 2003, the U.S. Supreme Court without comment denied WLF’s petition for review in this commercial speech case. WLF’s July 2003 petition had urged the Court to reinstate a challenge to commercial speech restrictions imposed by the City of Chicago. WLF represented a group of advertisers that had been fighting in federal court since 1997 against a Chicago ordinance that prohibited outdoor advertising of alcoholic beverages. In April 2003, a federal appeals court dismissed the case as moot simply because Chicago repealed the ordinance after it became apparent that WLF would win the case. In its petition asking the Supreme Court to review that decision, WLF argued that a suit is never rendered moot simply because a defendant voluntarily ceases its objectionable conduct, except in very rare cases when it is absolutely clear that the conduct will not recur. WLF argued that to dismiss a suit as moot under these circumstances would leave a government free to re-impose its speech restrictions at any time.

City of Ladue v. Gilleo. On June 13, 1994, the U.S. Supreme Court unanimously struck down a city ordinance that prohibited homeowners from placing virtually all types of signs on their property. The Court’s decision was a victory for WLF, which filed a brief arguing that the First Amendment protects the right of homeowners to express themselves by posting signs. WLF argued that the First Amendment prohibits a municipality from deciding which signs are acceptable and which are not, based solely on their content.
**Lindsey v. Tacoma-Pierce County Health Department.** On November 19, 1999, the U.S. Court of Appeals for the Ninth Circuit handed WLF a major victory in this important commercial speech rights case. The appeals court struck down a Tacoma, Washington ordinance that banned outdoor advertising of tobacco products while imposing virtually no restrictions on other products' advertising. The court agreed with WLF’s argument that when Congress adopted the Federal Cigarette Labeling and Advertising Act, it intended to prohibit any attempts by state and local governments to regulate cigarette advertising. WLF had also argued that the First Amendment prohibits government from deciding what advertising is acceptable based solely on the message conveyed by the advertisement. WLF argued that Tacoma’s ostensible purpose in adopting the ordinance — to reduce underage smoking — could be achieved without infringing on speech rights if Tacoma intensified efforts to enforce the ban on sales to minors.

**Greater New York Metropolitan Food Council v. Giuliani.** On April 17, 2000, the U.S. Supreme Court issued an order declining to review this critical commercial speech case. WLF had filed a brief in the Court, urging it to hear a challenge to a New York City ordinance that banned virtually all outdoor advertising of tobacco products. The U.S. Court of Appeals for the Second Circuit had upheld the ordinance, holding (contrary to WLF’s arguments) that the ordinance was not preempted by the Federal Cigarette Labeling and Advertising Act (FCLAA), which bars state and local government regulation of cigarette advertising that is “based on smoking and health.” While the parties awaited a Supreme Court decision on whether to review the Second Circuit’s FCLAA ruling, the plaintiffs pressed ahead in the district court with an alternative argument that the advertising ban violated their First Amendment rights. Adopting arguments raised by WLF regarding the First Amendment issue, the district court in January 2000 issued a preliminary injunction against enforcement of the ordinance. New York dropped its appeal from that decision after the Supreme Court issued its decision in the *Lorillard* case (see above).

**Anheuser-Busch v. Baltimore.** On April 28, 1997, the U.S. Supreme Court denied WLF’s request to hear this commercial speech case, bringing to an end a challenge to Baltimore’s stringent restrictions on billboards advertising liquor products. The case went up and down the federal courts several times, with WLF filing briefs opposing the billboard restrictions at every level of the judiciary. WLF scored a victory in 1996, when the Supreme Court vacated an appeals court decision upholding the ban, and remanded the case to the appeals court for reconsideration. The court of appeals, however, again upheld the speech restrictions; the Supreme Court declined to review that second decision. In its four briefs filed in the case, WLF argued that the plaintiffs should have been given the opportunity to present evidence that Baltimore’s ordinance had no effect on underage drinking. Baltimore was later obliged to repeal its ordinance, following the Supreme Court’s *Lorillard* decision (see above).

**Penn Advertising of Baltimore, Inc. v. Baltimore.** The U.S. Supreme Court on April 28, 1997 declined WLF’s invitation to hear this case, which challenged Baltimore’s near-total ban on billboards advertising tobacco products. In November 1996, the U.S. Court of Appeals for the Fourth Circuit upheld the ban. The 2-1 decision was a setback for WLF, which filed several briefs urging the Fourth Circuit to strike down the ordinance on First Amendment grounds. Baltimore was
later obliged to repeal its tobacco ordinance, following the Supreme Court’s *Lorillard* decision (see above).

**G. Compelled Speech**

The First Amendment protects not only the right to speak but also the right *not* to speak. All too often, governments attempt to compel companies to speak against their will, either by forcing them to say things they do not wish to say or by forcing them to provide financial support for speech with which they disagree. WLF repeatedly has litigated in support of companies and individuals whose First Amendment right not to speak is being infringed upon.

*Johanns v. Livestock Marketing Ass’n.* On May 23, 2005, the U.S. Supreme Court ruled that the federal government may force beef producers to provide financial support for advertising with which they disagree, because the government at least nominally supervises the advertising. The 6-3 decision was a setback for WLF, which filed a brief urging the Court to strike down the advertising program. WLF argued that the First Amendment protects not only the right to speak but also the right not to speak, and that forcing someone to provide financial support for private speech with which he disagrees violates his First Amendment rights. The Court held that so long as the speech in question originates with the government, the First Amendment does not prohibit the government from forcing small groups of people to fund the speech against their will. The Court left open the possibility that the plaintiffs could still establish, in later proceedings, that the government was not exercising any control over the speech – in which case they could prevail on their First Amendment claims.

*R.J. Reynolds Tobacco Co. v. Shewry.* On February 21, 2006, the U.S. Supreme Court declined to review an appeals court decision that rejected a First Amendment challenge to an advertising campaign conducted by the State of California. The Court’s action, made without comment, was a setback for WLF, which filed a brief urging the Court to review the appeals court ruling. WLF argued that the First Amendment prohibits a State from forcing a company to pay for advertisements that vilify the company. California imposes a special fee on the tobacco industry and then uses it to finance a $25 million per-year ad campaign that repeatedly portrays tobacco companies as liars and “public enemies.” WLF argued that the First Amendment protection against compelled financial support of speech to which one objects has been recognized repeatedly by the courts and applies just as strongly when the speaker is the government as it does when the speaker is a private party. WLF argued that the vilification campaign is unconstitutional because the government may not use funds obtained from a small group of citizens to finance ideological speech to which those citizens object. WLF also filed briefs in the case when it was before the appeals court.

*Gerawan Farming, Inc. v. Kawamura.* On June 3, 2004, the California Supreme Court issued a decision that sets strict free-speech standards for reviewing a California law that compels farmers to pay for advertisements generically promoting plums. The court did not strike down the
law; rather, it remanded the case for a trial, during which the California Supreme Court's new standards were to be applied. The decision was a partial victory for WLF, which filed a brief arguing that forcing individuals to fund advertising with which they disagree violates their free-speech rights. WLF had asked the court to strike down the law without ordering a trial. The advertising in question conveys the message that all California plums are of uniformly good quality. Gerawan objects to being forced to pay for those ads, because it has invested heavily in developing a distinctive, high-quality plum.

_United States v. United Foods, Inc._ On June 25, 2001, the U.S. Supreme Court handed WLF a victory by striking down a federal program forcing farmers to contribute to generic advertising with which they disagree. The Court agreed with WLF that compelled _commercial_ speech deserves no less constitutional protection than other forms of compelled speech. This case arose from a constitutional challenge brought to overturn certain provisions of a federal law that requires mushroom growers to fund generic advertising. In its brief filed with the Supreme Court, WLF had urged the Court to adopt the most searching standard of judicial review — strict scrutiny — in cases where a governmentally mandated subsidy program is challenged on free speech grounds. WLF concluded that the mandatory subsidy in this case cannot survive the strict scrutiny test.

_Board of Regents of the Univ. of Wisconsin v. Southworth._ On March 20, 2000, the U.S. Supreme Court overturned a court of appeals ruling and held that compelling objections to pay "student fees" to subsidize the political activities of activist campus groups does not violate the students' First Amendment rights because the funding scheme was viewpoint neutral. The University of Wisconsin at Madison distributes approximately $1 million a year in student fees to private organizations on campus, including Ralph Nader's Public Interest Research Group (PIRG); the Internationalist Socialist Organization; and the Militant Student Union. Other universities across the United States have similar funding schemes, although some of them allow objections to opt out of the system. WLF argued that compelling college students to subsidize the political speech and lobbying activities of activist groups violates the objecting students' fundamental First Amendment rights not to be forced to subsidize the speech of others.

_Glickman v. Wileman Bros. & Elliott, Inc._ On June 25, 1997, the U.S. Supreme Court upheld a federal program that requires California fruit growers and distributors to fund generic fruit advertising even though they disagree with the message being conveyed by the advertisements. The 5-4 decision was a setback for WLF, which had filed a brief arguing that the program violated First Amendment protections against compelled speech. WLF's brief argued that the First Amendment protects not only the right to speak but also the right not to speak, and that the latter includes the right not to be forced to provide financial support for others' speech. WLF also argued that the protection against compelled speech is not lessened simply because the speech one is forced to support is commercial in nature.

_Hollingsworth v. Lane Community College._ On March 24, 1999, the U.S. Court of Appeals for the Ninth Circuit upheld a lower court decision that rejected a challenge by a group of students who were forced to fund Oregon Student Public Interest Research Group (OSPIRG) at Lane
Community College. The decision was a setback for WLF, which filed a brief urging the appeals court to overturn a lower court decision dismissing a challenge to the funding scheme. WLF argued that compelling the students to subsidize a political and ideological group with which they disagreed violated their First Amendment rights. OSPIRG is just one of many Naderite PIRG groups that operate on campuses across the country and lobby state legislatures on behalf of liberal causes. All students at these schools are forced to pay a portion of their student fees to these campus PIRG groups, although a few universities refund students the portion of fees earmarked for PIRG if they so request through a cumbersome procedure.

Smith v. Regents of University of California. In February 1993, WLF scored a victory when the California Supreme Court ruled that state universities are prohibited by the state constitution as well as the First Amendment from using a student’s mandatory fees to fund campus organizations whose political activities the student finds objectionable. The court agreed with WLF that requiring students to financially support political and ideological organizations through mandatory student fees violates the students’ rights to freedom of speech and association. The case arose at the University of California at Berkeley, where student fees were used to subsidize a number of environmental, anti-business, and radical organizations.

Keller v. State Bar of California. On June 4, 1990, the U.S. Supreme Court unanimously held that attorneys cannot be compelled to support the political and ideological campaigns of state bar associations as a condition of practicing law. The decision was a victory for WLF, which filed a brief in support of the objecting attorneys. WLF argued that because California requires individuals wishing to practice law to join the state bar, the use of mandatory bar dues to support political and ideological causes violates the First Amendment rights of attorneys not to be forced to fund speech with which they disagree.

II. CIVIC COMMUNICATIONS PROGRAM

WLF recognizes that its litigation and administrative agency advocacy is not enough to bring about a long-term effect in opposing the efforts of activists and policymakers hostile to commercial speech. WLF has also sought to influence public debate and provide information through its Civic Communications Program. This targeted and broad-based program features WLF’s sponsorship of frequent, well-attended media briefings featuring experts on a range of commercial speech-related topics, the publication of advocacy advertisements in national journals and newspapers, and participation in countless advertising and commercial speech symposia. WLF supplements these efforts by making its attorneys available on a regular basis to members of the news media — from reporters for general-circulation newspapers to writers for specialized legal journals.

A. Media Briefings

The centerpiece of WLF’s Civic Communications Program is its media briefings, which bring news reporters from the print and electronic media together with leading experts on a wide
variety of legal topics. WLF sponsors more than a dozen such breakfast briefings each year, often focusing on health-related topics. Recent media briefings on commercial speech-related issues have included the following:

**Targeting “Off-Label” Speech: Are Civil & Criminal Actions Contrary to Law and Effective Patient Care?**

- Dr. Paul E. Kalb, Partner, Sidley Austin LLP
- Professor Ralph F. Hall, University of Minnesota Law School; Counsel, Baker & Daniels LLP
- James M. Beck, Counsel, Dechert LLP

**Self-Regulation of Advertising: Promoting Responsibility and Maintaining Commercial Speech**

- Lynne J. Omlie, Distilled Spirits Council of the United States
- Joan Z. Bernstein, Bryan Cave LLP
- Lee E. Peeler, National Advertising Review Council
- Diane E. Bieri, Pharmaceutical Research and Manufacturers of America

**WLF v. Leavitt: How CMS Speech Restriction Policy Harms Medicare Drug Beneficiaries**

- V. Thomas DeVille, DeVille Pharmacies, Inc.
- Richard A. Samp, Washington Legal Foundation

**Scrutiny of Medical Education Grants: A Chilling Wind for Doctors and Patients?**

- Jeffrey N. Gibbs, Hyman, Phelps & McNamara, P.C.
- Steven E. Irizarry, ML Strategies
- Laura Frick Laemmle, Patton Boggs LLP

**Regulating Drug Promotion: Assessing a Tumultuous 2005 and Prospects for the New Year**

- David Bloch, Reed Smith
- Adonis Hoffman, American Association of Advertising Agencies
- Richard A. Samp, Washington Legal Foundation

**Veneman v. Livestock Marketing: Compelled Commercial Speech Pays Another Visit to the Supreme Court**

- Philip C. Olsson, Olsson, Frank and Weeda, P.C.
- Gregory G. Garre, Hogan & Hartson L.L.P.
- Thomas C. Goldstein, Goldstein & Howe, P.C.

**Alcohol Use and Promotion: The Next Target for “Regulation by Litigation”?**

- John A. Calfee, American Enterprise Institute
- Jonathan Turley, George Washington University
- John J. Walsh, Carter, Ledyard & Milburn LLP
“Off Label” Communications At Risk: Promoting Prescription Drugs in an Uncertain Legal Environment
- John F. Kamp, Wiley, Rein & Fielding
- Stephen Paul Mahinka, Morgan Lewis LLP
- Richard A. Samp, Washington Legal Foundation

Free Speech & Public Health: FDA, Congress, and the Future of Food and Drug Promotion
- John E. Calfee, American Enterprise Institute
- Richard L. Frank, Olsson, Frank & Weeda
- Sandra J. P. Dennis, Morgan Lewis LLP

Washington Legal Foundation v. Henney: The Appeals Court’s Ruling and FDA’s Curious Response on Off-label Promotion
- Bert W. Rein, Wiley, Rein & Fielding
- Robert A. Dormer, Hyman, Phelps & McNamara
- Richard A. Samp, Washington Legal Foundation

Does FCC’s “Public Interest Mandate” Inhibit Our Freedom to Communicate?
- The Honorable Harold Furchtgott-Roth, Federal Communications Commission
- Richard E. Wiley, Wiley, Rein & Fielding
- Robert L. Corn-Revere, Hogan & Hartson LLP
- Randolph J. May, The Progress and Freedom Foundation

Tobacco Legislation: A Constitutional Tragedy in the Making?
- Solange E. Bitol, American Civil Liberties Union
- Robert A. Levy, The Cato Institute

FCC and the First Amendment: An “Elastic” Public Interest Mandate?
- The Honorable James H. Quello, former Commissioner of the Federal Communications Commission

B. Web Seminars

WLF Web Seminars, initiated in March 2005, present viewers with live webcast analysis and commentary by noted legal experts on timely developments in law and public policy. These hour-long presentations are also conveniently archived and available on WLF’s website. The speakers for the programs, who provide their insights on a pro bono basis, are leading experts in the field of law to be discussed. Recent web seminars on commercial speech-related issues have included the following:

An Unattractive Legal Theory: Lessons from the Successful Defense of Anti-Alcohol Advertising Class Actions
- J. Russell Jackson, Skadden, Arps, Slate, Meagher & Flom LLP
Serono and DOJ's False Claims Settlement: Implications for Medical Product Marketing
- Laura Frick Laemmle, Patton Boggs LLP
- Richard A. Samp, Washington Legal Foundation

Got Lawyers?: Why Court Should Dismiss Activists’ Anti-Milk “Consumer Protection” Suit
- Richard A. Samp, Washington Legal Foundation

C. Advocacy Ads

Since 1998, the Washington Legal Foundation has published a series of opinion editorials titled “In All Fairness” on the op-ed page of the national edition of The New York Times. The op-ed series has appeared over 100 times, reaching over five million readers in 70 major markets as well as 90 percent of major newspaper editors. Excessive government regulation of commercial speech has been the focus of many “In All Fairness” columns:

Exploiting Beer, Liquor & Food
(Activists’ attacks on advertising of disfavored products in the name of protecting children and health are actually a tactic to promote their special interest agenda)

Will Ronald McDonald Survive the Millennium?
(Consumer and regulatory activism against disfavored products poses threat to consumer choice)

A Constitutional Tragedy in the Making
(Legislation regulating tobacco advertising raises serious First Amendment concerns for all businesses)

Gagging Free Enterprise
(Courts and regulators should demonstrate more sensitivity to the constitutional implications of restricting businesses’ speech)

Eating Away at Our Freedoms
(Attacks by consumer activists against certain food products harm consumer choice and result in costly regulations and taxes)

A New FDA?
(FDA should expedite its drug approval procedures to improve public health and stop micromanaging drug advertising)

Bring Accountability to FDA
(Excessive FDA enforcement and misguided regulatory policies harm the health of Americans)

The World According to FDA
(FDA’s policy to regulate the dissemination of publications describing off-label use of FDA-approved drugs harms the health of Americans and violates the First Amendment)
These and other "In All Fairness" columns are available at WLF’s web site, www.wlf.org.

D. Public Appearances

WLF attorneys regularly address policymakers and thought leaders on commercial speech issues. WLF attorneys have appeared as featured panelists and speakers on commercial speech issues before such institutions as the Federal Trade Commission, the Food and Drug Law Institute, the American Medical Association, the Federalist Society, the Heritage Foundation, the American Bar Association, the Pharmaceutical Research and Manufacturers of America, and MedicalAlley. What follows are highlights of the numerous public appearances that WLF attorneys have made in the past decade to address commercial speech issues:

March 30, 2006, WLF Chief Counsel Richard Samp was a featured panelist at the Medical Device Regulatory and Compliance Congress, held at Harvard University; Samp discussed manufacturers’ First Amendment rights to speak truthfully about FDA-approved medical products.

December 14, 2005, Samp was the keynote speaker at a breakfast symposium in Minneapolis sponsored by MedicalAlley and MNBIO. Samp’s speech focused on recent federal government enforcement actions – directed against advertising and promotional activities of the pharmaceutical and medical device industries – under the False Claims Act and the anti-kickback statute.

May 11, 2005, Samp was a featured speaker at a seminar in New York City sponsored by Harvard Business School Publishing. Samp spoke on the corporate community’s First Amendment rights to speak out on issues of public importance.

January 27, 2005, Samp was a featured speaker at a conference organized by the Food & Drug Law Institute in Washington, D.C. entitled, “Product Liability for FDA Regulated Products: In What Kind of World Are We Living?” Samp addressed tort liability faced by drug manufacturers for speaking truthfully about their products.

January 23, 2004, Samp was a featured speaker at the annual meeting in Atlanta of NAAMECC (a trade group for companies that produce continuing medical education symposia), warning against government restrictions on the First Amendment right to speak truthfully regarding medical issues.

November 20, 2003, Samp addressed the American Bar Association’s annual pharmaceutical conference in Philadelphia, arguing that expanded use of the False Claims Act as a vehicle for suing drug companies is jeopardizing free speech rights and the ability of drug company’s to continue to develop new, life-saving therapies.

November 8, 2003, Samp addressed the annual meeting of the Society for Academic Continuing Medical Education in Washington, arguing that proposed restrictions on who may speak at Continuing Medical Education events are far too restrictive.

September 9, 2003, Samp addressed the American Medical Association’s National Task Force on Continuing Medical Education (CME) in Chicago; Samp argued that proposed restrictions on who can speak at CME gatherings violate First Amendment norms.
April 23 and again June 26, 2003, Samp appeared on CNBC to discuss *Nike v. Kasky*, the Supreme Court case that addressed the First Amendment right of corporations to freely discuss matters of public interest.

October 25, 2002, Samp was a featured panelist at a symposium organized by the Federalist Society, entitled, “FDA and the First Amendment.”

October 7, 2002, Samp was a panelist at the annual conference of the Regulatory Affairs Professional Society in Washington, D.C., speaking on “The First Amendment and FDA Regulation.”

September 11, 2002, Samp spoke at the Food and Drug Law Institute’s (FDLI)” annual conference in Washington, regarding First Amendment constraints on FDA regulation of speech by pharmaceutical companies.

August 1, 2002, Samp was a featured panelist in an audio conference sponsored by FDLI on “First Amendment Issues Facing the Food and Drug Administration.”

May 22, 2002, WLF Chairman Daniel Popeo was the featured speaker at the Annual Meeting of the Medical Device Manufacturers Association (MDMA). At the MDMA Chairman’s Luncheon, Popeo discussed the crucial work of WLF in promoting open markets, free enterprise, and competition, and WLF’s legal activities challenging excessive regulation by FDA.

May 18, 2001, Samp spoke at a luncheon of the Philadelphia chapter of the Federalist Society, regarding FDA regulation of manufacturer speech.

April 20, 2000, Samp was a featured panelist at a New York City symposium sponsored by the Federalist Society, entitled, “The Future of Commercial Speech.”

April 6, 2000, Samp addressed a symposium in Washington, D.C. sponsored by the Drug Information Association, regarding “Promoting, Prescribing, and Paying for Off-Label Indications.”

September 13, 1999, Samp was a panelist at the FDLI’s annual conference, discussing First Amendment restrictions on FDA regulation.

August 25, 1999, Samp was the keynote speaker at the annual meeting of the Indiana Medical Device Manufacturers Association in Indianapolis, where he discussed WLF’s successful challenge to FDA speech restrictions.

June 29, 1999, Samp addressed an FDLI conference regarding manufacturer dissemination of peer-reviewed journal articles that discuss off-label uses of FDA-approved products.

May 20, 1999, Samp addressed an FDLI conference regarding WLF’s First Amendment victory over the FDA in *WLF v. Henney*.

January 13, 1999, WLF Legal Studies Division Chief Glenn Lammi provided educational commentary on the *WLF v. Henney* case to a group of pharmaceutical marketers at a Center for Business Intelligence seminar.

October 26, 1998, Samp was the keynote luncheon speaker at the annual meeting of the Outdoor Advertising Association of America; Samp spoke about First Amendment limitations on the power of government to prohibit billboards.

September 10, 1998, Samp addressed a FDLI symposium, to discuss WLF’s court victories over FDA on First Amendment issues.

June 13, 1997, WLF Senior Executive Counsel Paul Kamenar was a featured speaker at the 6th Annual Conference on Biologics and Pharmaceuticals sponsored by International Business Communications, discussing WLF’s First Amendment lawsuit against FDA.

April 9, 1997, Samp addressed a conference sponsored by the Drug Information Association in New Orleans, regarding efforts by FDA to suppress speech regarding off-label uses of approved drugs and medical devices.

March 20, 1996, Popeo was a keynote speaker at a conference of the Healthcare Marketing & Communications Council in New York City discussing reform of FDA, WLF’s litigation against FDA, and other related programs promoting commercial free speech.

December 7, 1995, Samp spoke to a group of pharmaceutical executives at a Rockville, Maryland forum sponsored by International Business Conferences regarding WLF’s continuing efforts to prevent FDA abuse of First Amendment rights.

December 7, 1995, Samp was a featured speaker (along with Rep. Joe Barton) at a forum sponsored by the Heritage Foundation entitled, “Is the FDA Killing America?”

October 20, 1995, Samp addressed (along with U.S. Senator Bill Frist of Tennessee) a gathering of orthopedic surgeons at a symposium of the North American Spine Society on the need to streamline FDA.

October 18, 1995, Samp testified before an FDA panel, urging FDA to lift restrictions on direct-to-consumer advertising of prescription drugs.

September 20, 1995, Lammi spoke at a meeting of the Ad Hoc In-House Counsels Working Group, a group of attorneys for pharmaceutical companies, on FDA’s restrictions on advertising and promotion.

September 19, 1995, Popeo served on the faculty at the American Medical Association’s Sixth National Conference on Continuing Medical Education. Popeo discussed WLF’s lawsuit against FDA regarding the suppression of medical literature discussing off-label uses of FDA-approved drugs and devices.
June 27, 1995, Kamenar was a featured speaker at an FDLI conference in Washington, D.C. He discussed WLF’s FDA-reform project and its lawsuit against FDA for prohibiting the dissemination of information about off-label uses of approved drugs and devices.

June 16, 1995, Lammi appeared on National Empowerment Television to discuss FDA reform.

May 22, 1995, Kamenar debated U.S. Representative Don Wyden (D-Ore.) and Bruce Silverglade of the Center for Science in the Public Interest on “America’s Talking” cable television network, regarding FDA reform.

March 13, 1995, Samp addressed the annual meeting of the Pharmaceutical Research and Manufacturers of America (PhRMA) on the need for reform of FDA.

January 31, 1995, Samp was a featured guest on the Diane Rehm Show (syndicated by WAMU-Radio in Washington, D.C.), debating the need for reform of FDA with Dr. Sidney Wolfe of the Public Citizen Health Research Group.

III. PUBLICATIONS

WLF’s Legal Studies Division is the preeminent publisher of persuasive, expertly researched, and highly respected legal policy papers. WLF publishes in seven different formats, which range in length from concise LEGAL BACKGROUNDERS covering current developments affecting the American legal system, to comprehensive Monographs providing law-review-length inquiries into significant legal issues.

Since its inception fifteen years ago, WLF’s Legal Studies Division has produced a voluminous library of publications regarding commercial speech rights. The areas on which these papers have focused range from substantive explanations of key court decisions to analyses of federal and state regulations and legislation for their impact on commercial speech rights. Authoring these papers pro bono for WLF are America’s leading commercial speech experts from business, government, the judiciary, private law firms, and academia. Notable authors include: New York University law professor Burt Neuborne; U.S. Court of Appeals for the Ninth Circuit Judge Alex Kozinski; former FDA Chief Counsel Daniel Troy; and former Federal Appeals Court Judge Robert Bork.

WLF commercial speech publications have been cited in influential court rulings, law review articles, legal briefs, and congressional debates; have provided intellectual firepower to those who are fighting against advertising restrictions at the federal and state levels; are relied upon by constitutional and advertising issue reporters; and are frequently reprinted in widely read trade journals and newsletters.

UK To Impose New Restrictions On Food Advertisements To Children
By Sarah A. Key, an associate in the Washington, D.C. office of the law firm Foley & Lardner LLP. COUNSEL’S ADVISORY, February 23, 2007, 1 page
Pharmaceutical Advertising: "May You Live In Interesting Times"
By Arnold I. Friede, an attorney who previously served in the FDA’s Chief Counsel’s Office, and is currently Senior Corporate Counsel at Pfizer Inc.
WORKING PAPER, February 2007, 18 pages

The First Amendment And Lawyer Blogs
By Larry E. Ribstein, who authors the blog Ideoblog and is the Mildred Van Voorhis Jones Chair in Law at the University of Illinois College of Law.
LEGAL OPINION LETTER, December 8, 2006, 2 pages

Alcohol Advertising: Federal And State Regulators Should Tread Lightly
By David Versfelt, a partner with the law firm Kirkpatrick & Lockhart Nicholson Graham LLP and Adonis Hoffman, Senior Vice President and Counsel with the American Association of Advertising Agencies.
LEGAL BACKGROUNDER, October 6, 2006, 4 pages

Fresh Bagels And A Schmear: A Sign Of The Times Ruling On Commercial Free Speech
By Arnold I. Friede, Senior Corporate Counsel with Pfizer, Inc.
COUNSEL’S ADVISORY, October 6, 2006, 1 page

Judicial Chorus Against "Attractive Advertising" Suits Grows Louder With Ruling
By J. Russell Jackson, a partner at Skadden, Arps, Slate, Meagher, & Flom LLP and an adjunct professor of law at Brooklyn Law School.
LEGAL OPINION LETTER, June 16, 2006, 2 pages

D.C. Court Dismisses “Attractive Advertising” Class Action Lawsuit
By J. Russell Jackson, a partner in the Complex Mass Torts Group of New York’s Skadden, Arps, Slate, Meagher & Flom LLP and an adjunct associate professor of law at Brooklyn Law School.
COUNSEL’S ADVISORY, May 5, 2006, 1 page

Health And Speech Rights At Risk from Attacks On Medical Education
By Jeffrey N. Gibbs, a principal with the law firm Hyman, Phelps & McNamara, P.C. in its Washington, D.C. office.
LEGAL BACKGROUNDER, April 7, 2006, 4 pages

Advertising And Preemption Under FDA’s New Drug Labeling Rule
By Tish E. Pahl, a principal with Olsson, Frank and Weeda, P.C.
LEGAL OPINION LETTER, March 24, 2006, 2 pages

Federal And State Courts Reject “Attractive Advertising” Claims
By J. Russell Jackson, a partner in the Complex Mass Torts Group of New York’s Skadden, Arps, Slate, Meagher & Flom LLP and an adjunct associate professor of law at Brooklyn Law School.
LEGAL BACKGROUNDER, March 10, 2006, 4 pages
Court Properly Dismisses Anti-Alcohol Class Action Suit
By Carl K. Dawson, a partner, and Tiffany L. Powers, an associate, with the law firm of Alston & Bird LLP.
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"Off-Label" Speech: Uncertainty Reigns For Device & Drug Makers
By Ralph F. Hall, Visiting Associate Professor of Law at the University of Minnesota Law School and Counsel to the law firm Baker & Daniels, Indianapolis, Indiana, and Washington D.C.
LEGAL BACKGROUNDER, December 2, 2005, 4 pages

Beware: Warning Labels On Soft Drinks
By Michael J. O’Flaherty, a principal at the law firm Olsson, Frank and Weeda, P.C., who concentrates his practice in food and dietary supplement regulatory matters.
LEGAL BACKGROUNDER, November 4, 2005, 4 pages

Conversations With: Commercial Free Speech
Features The Honorable Dick Thornburgh, Counsel to the law firm Kirkpatrick & Lockhart Nicholson Graham LLP moderating a discussion with leading First Amendment experts Floyd Abrams of the New York City law firm Cahill Gordon & Reindel LLP; and Eric S. Sarner, Senior Assistant General Counsel of Praxair, Inc., and a former counsel with the law firm Skadden, Arps, Slate, Meagher & Flom LLP in its New York City office.
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Proposal Limiting Distribution Of Health Care Information Infringes Free Speech Rights
By Glenn G. Lammi, Chief Counsel to Washington Legal Foundation’s Legal Studies Division.
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State Attorney General Issues Opinion On Commercial Speech Rights
By Glenn G. Lammi, Chief Counsel to Washington Legal Foundation’s Legal Studies Division.
COUNSEL’S ADVISORY, May 3, 2005, 1 page

State Drug Ad “Rebate” Proposal Treads On Commercial Speech Rights
By Rosemary C. Harold, formerly a partner with the Washington, D.C. law firm Wiley Rein & Fielding LLP and currently Deputy Director of the Mass Media Bureau at the Federal Communications Commission, and Mark A. McAndrew, an associate in the Washington, D.C. law firm Wiley, Rein & Fielding LLP.
LEGAL OPINION LETTER, March 25, 2005, 2 pages
Commercial Speech: Essential For Health Of Consumers And Free Enterprise
By Timothy J. Muris, Of Counsel to O'Melveny & Myers LLP, where he co-chairs the firm's antitrust and competition practice. Mr. Muris is also a George Mason University Foundation Professor of Law, and from 2001-04 he was Chairman of the Federal Trade Commission.
LEGAL BACKGROUNDER, March 25, 2005, 4 pages

Recent Court Rulings Undermine Suits Against Alcohol Advertising
By Lisa Jose Fales, a partner at Venable LLP in Washington, D.C., specializing in consumer protection and antitrust law; and Ronald M. Jacobs, an associate at Venable LLP in Washington, D.C., also specializing in consumer protection and antitrust law.
LEGAL BACKGROUNDER, February 11, 2005, 4 pages

Lawsuits Targeting Alcohol Ads Tread On Free Speech Rights
By John J. Walsh, Senior Counsel to the New York City law firm Carter Ledyard & Milburn LLP.
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Federal Appeals Court Rules Alcohol Ad Ban Unconstitutional
By Eric S. Sarner, Senior Assistant General Counsel of Praxair, Inc., and a former counsel with the law firm Skadden, Arps, Slate, Meagher & Flom LLP in its New York City office.
LEGAL OPINION LETTER, October 1, 2004, 2 pages

State Fraud Suits Over Drug Clinical Trial Results Tread On Free Speech Rights
By Mark E. Nagle, a partner in the Washington, D.C. office of the law firm Troutman Sanders LLP, who, prior to joining the firm, served as Chief of the Civil Division in the United States Attorney's office for the District of Columbia.
LEGAL BACKGROUNDER, September 17, 2004, 4 pages

Senate Proposal On Drug Importation Treads On Constitutional Rights
By Burt Neuborne, John Norton Pomeroy Professor of Law at New York University Law School, where he has taught Constitutional Law, Federal Courts, Civil Procedure and Evidence for more than 30 years, and former National Legal Director of the ACLU.
LEGAL BACKGROUNDER, July 9, 2004, 4 pages

Activists' Product Placement Proposal Threatens Commercial Free Speech
By Douglas J. Wood, a partner at Reed Smith, LLP, a top 25 international law firm, and head of Reed Smith Hall Dickler, the firm's advertising and marketing practice.
LEGAL BACKGROUNDER June 11, 2004, 4 pages

Unique California Laws Imperil Speech On “Off-Label” Use Of Drugs
By Lisa M. Baird and Michael K. Brown, partners in the international law firm of Reed Smith LLP who specialize in litigation involving the pharmaceutical and medical device industries.
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Investigations Of Drug Promotion Threaten First Amendment Rights
By Richard A. Samp, Chief Counsel to the Washington Legal Foundation.
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FDA Guidance for “DTC” Ads Strives To Advance Consumer Understanding
By Rosemary C. Harold, formerly a partner with the Washington, D.C. law firm Wiley Rein & Fielding LLP and currently Deputy Director of the Mass Media Bureau at the FCC, and John F. Kamp, of counsel to the law firm.
LEGAL OPINION LETTER, February 20, 2004, 2 pages

Compelled “Counter Advertising” For Alcohol Products Would Tread On Free Speech
By Marc Sorini, a partner with McDermott, Will & Emery’s Alcohol Beverages & Products Group, and Cary Greene, a J.D. candidate at Emory Law School.
LEGAL BACKGROUNDER, September 5, 2003, 4 pages

Should Media Outlets Be Held Liable For Deceptive Advertising?
By Randal M. Shaheen, Special Counsel with the Washington, D.C. law firm Arnold & Porter.
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CONTEMPORARY LEGAL NOTE, July, 2003, 23 pages

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By Christopher A. Brown, an associate with the law firm Sonnenschein Nath & Rosenthal in its Washington, D.C. office.
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New CME Bias Standards Will Reduce Quality Of Medical Education
By Alan R. Bennett and Dr. Gregory J. Glover, partners with the law firm Ropes & Gray in its Washington, D.C. office.
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Free Speech Rights Trump Goals Of Anti-Alcohol Activists
By John J. Walsh, senior counsel to the New York City law firm Carter Ledyard & Milburn LLP.
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FDA Must Clarify Drug Makers’ Ability To Publicly Defend Products
By Kathleen M. Sanzo and Stephen Paul Mahinka, partners in the Washington, D.C. office of the law firm of Morgan Lewis, LLP.
LEGAL OPINION LETTER, February 28, 2003, 2 pages

High Court Cases May Shape First Amendment’s Application To Federal Securities Laws
By Larry E. Ribstein, Richard W. and Marie L. Corman Professor of Law at the University of Illinois College of Law.
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Dramatic Changes To CME Accreditation Process Compel Scrutiny And Comment
By Richard Samp, Chief Counsel of the Washington Legal Foundation.
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By George W. Evans, an Associate General Counsel, Pfizer Inc., and General Counsel–Pfizer Pharmaceuticals Group, and Arnold I. Friede, a Senior Corporate Counsel at Pfizer Inc., who formerly served in the FDA Chief Counsel’s Office.
LEGAL OPINION LETTER, November 15, 2002, 2 pages

FDA Limits On Print Drug Ads Violate First Amendment
By Richard L. Frank, a principal at the Washington, D.C. law firm Olsson, Frank and Weeda, P.C., and Tish Eggelston Pahl, a senior associate at Olsson, Frank and Weeda, P.C.
LEGAL BACKGROUNDER, October 4, 2002, 4 pages

Kasky v. Nike: U.S. Supreme Court Review Can Protect Free Public Debate
By Clark S. Judge, the Managing Director of White House Writers Group, a communications and policy consulting firm based in Washington, D.C.
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An FDA Q&A: How Does The First Amendment Limit Its Regulatory Power
LEGAL BACKGROUNDER, August 23, 2002, 4 pages

Proposed Limits On Prescription Drug Ads: A Constitutional Analysis
By Bert W. Rein and Rosemary C. Harold, respectively a partner and former partner at the Washington, D.C. firm Wiley, Rein & Fielding, and John F. Kamp, of counsel to the firm.
WORKING PAPER, July 2002, 40 pages

Drug Ads Enhance Health By Empowering Patients
By Richard L. Manning, PhD, Director of Economic Policy Analysis at Pfizer Inc.
LEGAL OPINION LETTER, May 10, 2002, 2 pages

DOJ Tobacco Suit Threatens Commercial Speech Rights
By Elizabeth Vella Moeller, an attorney with the Washington, D.C. law firm Patton Boggs LLP.
LEGAL OPINION LETTER, April 26, 2002, 2 pages

New Judicial Precedents Expand Commercial Speech Protection
By Steven G. Brody, a partner in the New York City office of the law firm King & Spalding.
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Excessive FDA Scrutiny Of DTC Ads Undermines Speech Rights
By Sandra J. P. Dennis, a partner, and Lawrence S. Ganslaw, an associate, in the Washington, D.C. office of Morgan Lewis LLP in the FDA/Product Regulation Practice Group.
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Supreme Court Should Expand Commercial Speech Protection
By John J. Walsh, senior counsel to the New York law firm Carter, Ledyard & Milburn.
LEGAL BACKGROUND, September 8, 2000, 4 pages

California High Court Should Protect Commercial Speech
By Steven G. Brody, a partner with the New York law firm King & Spaulding; and Christine P. Jackson, an associate with the New York law firm Cadwalader, Wickersham & Taft.
LEGAL OPINION LETTER, June 9, 2000, 2 pages

Proposal To Regulate Cigar Ads And Sales Sets Dangerous Precedent
By William H. Lash, III, former Assistant Secretary for Market Access and Compliance at the U.S. Department of Commerce and professor at George Mason School of Law.
LEGAL OPINION LETTER, January 21, 2000, 2 pages

Proposed Regulation Of Cigar Ads Unconstitutional
By William C. MacLeod and John E. Villafranco, partners with the Washington, D.C. law firm Collier Shannon Scott.
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Constitutional Implications Of Display Advertising Restrictions
By John F. Fithian, Chairman of the National Association of Theater Owners and formerly a partner with the Washington, D.C. law firm Patton Boggs LLP.
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FDA And DTC Advertising: Changes, Challenges & Constitutional Scrutiny
By Sandra J. P. Dennis, a partner in the Washington D.C. office of Morgan Lewis LLP in the FDA/Product Regulation Practice Group.
CONTEMPORARY LEGAL NOTE, October 1999, 28 pages

Court Again Nullifies FDA Policies Restricting Health Care Information
By George M. Burditt, a partner with the Chicago law firm Bell, Boyd & Lloyd.
LEGAL OPINION LETTER, September 17, 1999, 2 pages

Free Flow Of Commercial Speech Essential To World Market
By Richard M. Corner, the Executive Director of the International Advertising Association (IAA) in New York City.
LEGAL BACKGROUND, August 20, 1999, 4 pages
FTC Treads On Free Speech Rights With Corrective Advertising Order
LEGAL BACKGROUNDER, July 23, 1999, 4 pages

Court Ruling Frustrates Access To Off-label Drug Information
By Mark Boulding, General Counsel and Vice President, Regulatory Affairs for Medscape Inc.
LEGAL OPINION LETTER, April 30, 1999, 2 pages

Supreme Court Should Strengthen Commercial Free Speech Rights
By John J. Walsh, senior counsel to the New York law firm Carter Ledyard & Milburn LLP, and
Steven G. Brody, a partner in the New York office of the law firm King & Spalding.
LEGAL OPINION LETTER, April 16, 1999, 2 pages

FTC’s Expansion Of “Unfairness” Jurisdiction Imperils Speech Rights
By D. John Hendrickson, a partner in the Los Angeles office of the law firm Hall Dickler Kent
Goldstein & Wood LLP.
LEGAL BACKGROUNDER, January 22, 1999, 4 pages

Court Suppresses FDA Censorship Of Health Product Information
By George M. Burditt, a partner in the Chicago law firm Bell, Boyd & Lloyd.
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Commercial Speech Restrictions Failing Federal Court Tests
By Glenn G. Lammi, Chief Counsel of WLF’s Legal Studies Division.
COUNSEL’S ADVISORY, October 16, 1998, 1 page

Marketing Restrictions In Tobacco Legislation Are Unconstitutional
By Solange E. Bitol, former Legislative Counsel to the American Civil Liberties Union.
LEGAL BACKGROUNDER, May 1, 1998, 4 pages

FDA “Draft Guidance” Suppresses Critical Health Care Information
By Marc J. Scheineson, a partner with the law firm Alston & Bird in its Washington, D.C. office
and a former FDA Associate Commissioner for Legislative Affairs, and Katherine Chen, a food and
drug associate with the law firm Reed Smith in Washington, D.C.
LEGAL BACKGROUNDER, April 3, 1998, 4 pages

European Union Should Resist French-Style Alcohol Ad Restrictions
By Marc E. Sorini, a partner with McDermott, Will & Emery’s Alcohol Beverages & Products
Group.
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Tobacco Settlement Speech Limits Unconstitutional If Imposed By Law
By Burt Neuborne, the John Norton Pomeroy Professor of Law at New York University School of
Law.
LEGAL OPINION LETTER, November 7, 1997, 2 pages
FCC Lacks Authority Over Alcohol Advertising
By Glenn G. Lamm, Chief Counsel to Washington Legal Foundation’s Legal Studies Division.
LEGAL OPINION LETTER, November 21, 1997, 2 pages

Federal Agencies’ Attacks On Ads Offend Commercial Speech Rights
By Robert A. Levy, a senior fellow in constitutional studies at the Cato Institute.
LEGAL OPINION LETTER, September 26, 1997, 2 pages

Public Comment Can Shape FDA Guidance On TV Advertising
By Mark E. Boulding, General Counsel and Vice President, Regulatory Affairs for Medscape
LEGAL OPINION LETTER, September 12, 1997, 2 pages

The Supreme Court’s Puzzling Silence On Billboard Advertising Ban
By Felix H. Kent, a partner in the New York law firm Reed Smith LLP.
LEGAL BACKGROUND, July 11, 1997, 4 pages

Actions Against Alcohol Ads Blow Chilling Winds On Commercial Speech
By William C. MacLeod, a partner with the Washington, D.C. law firm Collier Shannon Scott.
LEGAL OPINION LETTER, May 2, 1997, 2 pages

FTC Should Continue Careful Approach On “Unfair” Alcohol Advertising Charges
By Deborah Owen, General Counsel of Armstrong World Industries and a former Commissioner of the Federal Trade Commission.
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A Constitutional Analysis Of FDA’s Restrictions On Advertising
By Jerome L. Wilson, counsel to the New York law firm Clifford Chance Rogers & Wells LLP.
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Attempts To Restrict Alcohol Ads Face Serious Constitutional Hurdles
By Nell Kilburn Shapiro, former President for Litigation Affairs for WLF.
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Federal Court Must Strike Down FDA Censorship Of Advertising
By David S. Versfelt, a partner with the New York office of the law firm Kirkpatrick & Lockhart.
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Supreme Court’s Decision Requires FDA To Reconsider Free Speech Issues
By Daniel A. Kracov, a partner with the law firm Arnold & Porter, and David J. Bloch, a partner with the law firm Reed Smith LLP.
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Supreme Court Should Strike Down Compelled Commercial Speech
By Richard A. Samp, Chief Counsel for the Washington Legal Foundation.
LEGAL OPINION LETTER, June 21, 1996, 2 pages
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By Jeffrey S. Edelstein, a partner, and Joel L. Goldberg, an associate, with the New York City office of the law firm Reed Smith LLP.
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By Jeffrey R. Chanin, a partner, and Ragesh K. Tangri and Daralyn J. Durie, associates, with the San Francisco law firm Keker & Van Nester.
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Activist FDA Threatens Constitutional Speech Rights
By The Honorable Robert H. Bork, who served as Circuit Judge, United States Court of Appeals for the District of Columbia Circuit, from 1982 to 1988, and as Solicitor General of the United States, Department of Justice, from 1973 to 1977.
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Canadian Commercial Speech Decision Sends Message To U.S. Policymakers
By Glenn G. Lamm, Chief Counsel of WLF's Legal Studies Division.
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FDA Regulation May Inhibit Positive Uses Of The Internet
By Daniel A. Kracov, a partner with the law firm Arnold & Porter, and David J. Bloch, a partner with the law firm Reed Smith LLP.
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FDA Suppression Of Advertising To Consumers Violates The First Amendment
By William C. MacLeod, a partner with the Washington, D.C. law firm of Collier Shannon Scott.
LEGAL BACKGROUNDER, September 15, 1995, 4 pages

Comment On FTC Green Advertising Guidelines
By Elhanan C. Stone, counsel to the New York-based law firm Reed Smith LLP.
COUNSEL'S ADVISORY, September 15, 1995, 1 page

FDA Inhibits Free Flow Of Information On Medical Products
By Alan R. Bennett, a partner with the law firm Ropes & Gray in its Washington, D.C. office, and Mark E. Boulding, General Counsel and Vice President, Regulatory Affairs for Medscape.
LEGAL BACKGROUNDER, September 1, 1995, 4 pages

Guidelines To Keep Advertisers Out Of Court
By Lawrence Savell, an attorney specializing in products liability defense and counseling in the New York City office of the law firm Chadbourne & Parke.
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Federal Court Blocks Consumer Activists' Attempts To Bring False Advertising Suits
By Robert D. Paul, a partner in the Washington, D.C. office of White & Case and former General Counsel of the FTC, and Jay L. Levine, an associate with the law firm Shaw Pittman.
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Courts Must Delicately Balance Privacy And Commercial Free Speech Rights
By Robert C. Cumbow, an associate with the Seattle law firm Perkins Coie.
LEGAL BACKGROUNDER, August 11, 1995, 4 pages

Rubin v. Coors: Supreme Court Rejects Prohibitionism
By Burt Neuborne, John Norton Pomeroy Professor of Law at New York University Law School, where he has taught for more than 30 years, and former National Legal Director of the ACLU.
LEGAL OPINION LETTER, June 9, 1995, 2 pages

Federal Court Decision: A Roadblock To Advertising On Information Highway?
By Daniel Brenner, Vice President for Law and Regulatory Policy at the National Cable Television Association.
LEGAL OPINION LETTER, June 9, 1995, 2 pages

Advertising Bans Vulnerable To Constitutional And Statutory Challenges
By Ralph D. Davis, former Lecturer of Law and Marketing at Illinois Institute of Technology, Stuart School of Business, currently an attorney and consultant in Chicago.
LEGAL BACKGROUNDER, June 9, 1995, 4 pages

Appeals Court Should Protect Commercial Speech In Green Advertising Case
By John J. Walsh, senior partner with the law firm Carter, Ledyard & Milburn, and Steven G. Brody, a partner with the law firm King & Spalding.
LEGAL OPINION LETTER, February 17, 1995, 2 pages

FDA Direct-To-Consumer Advertising Regulation Raises Constitutional And Policy Concerns
By James M. Johnstone, a Washington, D.C. lawyer.
LEGAL BACKGROUNDER, January 20, 1995, 4 pages

Weigh In Against FDA Suppression
By Richard A. Samp, Washington Legal Foundation’s Chief Counsel.
COUNSEL’S ADVISORY, December 16, 1994, 1 page

FTC’s New Authority Over “Unfair” Advertising Is A Mixed Blessing For Commercial Speech
By Richard E. Wiley, Senior Partner, and Hugh Latimer, a partner, with the Washington, D.C. law firm of Wiley, Rein & Fielding.
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What The FDA Doesn’t Want You To Know Could Kill You
By Richard A. Samp, Washington Legal Foundation’s Chief Counsel.
LEGAL BACKGROUNDER, October 7, 1994, 4 pages

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By Richard Mendelson, an attorney with the law firm of Dickenson, Peatman & Fogarty in Napa, California.
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Ibanez v. Florida Dept. Of Business And Professional Regulation: The Supreme Court Strengthens Commercial Speech Protection
By Peter Nichols, a New York attorney specializing in commercial litigation, and a former Manhattan Assistant District Attorney.
LEGAL BACKGROUNDER, August 12, 1994, 4 pages

City Ordinances Banning Tobacco And Alcohol Advertising Are Unconstitutional
By Daniel E. Troy, partner with the Washington, D.C. office of the law firm Sidley, Austin, Brown & Wood LLP and former Chief Counsel to the Food & Drug Administration.
LEGAL OPINION LETTER, July 29, 1994, 2 pages

Can Government, Private Interests Preserve Advertising As A Tool Of Competition In The Global Marketplace?
By Barry J. Cutler, an attorney with the Washington, D.C. office of the law firm Baker & Hostetler.
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Customs Rule On Country Of Origin Marks On Front Panels Of Frozen Produce Packages Lacks Legal Basis
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The New Prohibition Has No Place In FTC Food Advertising Policy
By Susan E. Chamberlin, an attorney with the Washington, D.C. law firm of Wiley, Rein & Fielding.
LEGAL OPINION LETTER, May 6, 1994, 2 pages

New Prohibitionism On Trial: Judicial Approval Of Baltimore's Ad Ban Should Be Reversed
By Ralph D. Davis, an Adjunct Lecturer of Marketing and Law, Illinois Institute of Technology, Stewart School of Business and an attorney and consultant on marketing and business strategy in Chicago.
LEGAL BACKGROUNDER, April 29, 1994, 4 pages

New Prohibitionism And The First Amendment
By Robert S. Peck, former Legislative Counsel for the ACLU.
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Speakeasies In A New Age Of Prohibition
By Sandy Shaw and Durk Pearson, best-selling authors on health issues and commercial speech.
LEGAL BACKGROUNDER, April 22, 1994, 4 pages
A Structural Approach To Increasing Commercial Speech Protection
By Robert A. Destro, an Associate Professor at Columbus School of Law, Catholic University of America, Washington, D.C.
LEGAL OPINION LETTER, April 22, 1994, 2 pages

1993 Supreme Court Decisions Signal Opportunities To Challenge Commercial Speech Restrictions
By Raymond L. Friedlob, a partner with the Denver law firm Friedlob Sanderson Raskin Paulson & Tourtillott, and George D. Kreye, a partner with the Denver law firm Brenman Bromberg & Tenenbaum.
LEGAL OPINION LETTER, October 1, 1993, 2 pages

Supreme Court Decisions Reaffirm Need To Provide Commercial Speech Full Constitutional Protection
By Bernard H. Siegan, Distinguished Professor of Law at University of San Diego School of Law.
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Recent Commercial Speech Decision Casts Doubt On Bans Of Advertising Names Or Images
By Alan M. Slobodin, former President of WLF's Legal Studies Division.
LEGAL OPINION LETTER, May 14, 1993, 2 pages

Proposed Alcohol Ad Warings Are Contrary To Free Speech Values And Consumer Interests
By John E. Calfee, a resident scholar with the American Enterprise Institute.
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California Proposal To Ban Cartoon Advertising For “Inherently Unsafe” Products Is Unconstitutional
LEGAL OPINION LETTER, April 2, 1993, 2 pages

Proposal To Eliminate Tax Deduction For Advertising Expenses Is Unconstitutional
By Robert S. Peck, former Legislative Counsel for the ACLU.
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Anti-Industry Propaganda Is Constitutionally Suspect
By Alan M. Slobodin, former President of WLF's Legal Studies Division.
LEGAL OPINION LETTER, March 5, 1993, 2 pages

Will FTC Win Battle Against Kraft But Lose War In Its Effort To Limit Commercial Speech?
By Hugh Latimer, a partner with the Washington, D.C. law firm Wiley, Rein & Fielding.
LEGAL OPINION LETTER, February 5, 1993, 2 pages

Constitutionally Suspect Ad Ban Enacted In Seattle
By P. Cameron DeVore, a partner with the Seattle office of the law firm of Davis Wright Tremaine.
LEGAL OPINION LETTER, February 4, 1993, 2 pages

44
Product Placement In Movies Cannot Be Regulated As Commercial Speech Under The First Amendment
By Jeffrey R. Chanin, a partner with the San Francisco law firm Keker & Van Nest, and James E. Boasberg, a Washington, D.C. attorney.
LEGAL BACKGROUNDER, January 22, 1993, 4 pages

Open Season On Commercial Speech
By Stephen R. Bergerson, an attorney with the Minneapolis firm of Fredrikson & Byron.
LEGAL BACKGROUNDER, December 4, 1992, 4 pages

Proposal Forcing Preclearance Of Drug Advertising Would Violate First Amendment
By Alan R. Bennett, a partner with the law firm Ropes & Gray in its Washington, D.C. office.
LEGAL BACKGROUNDER, November 20, 1992, 4 pages

Pepsico And Other Corporate Boycotts, 1990s Style: First Amendment Issues And Response
By Elliot M. Minnberg, the Legal Director of People For the American Way.
LEGAL OPINION LETTER, November 6, 1992, 2 pages

BATF Censorship Is Hazardous To Health Of Alcohol Market And Free Speech
By John E. Calfee, a resident scholar with the American Enterprise Institute.
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BATF Restriction On Truthful Health Claims In Wine Advertising Violates First Amendment
By John A. Hinman, a partner in the San Francisco law firm of Hinman & Carmichael, which specializes in alcoholic beverage law.
LEGAL BACKGROUNDER, September 11, 1992, 4 pages

Project “ASSIST” : Federal Funds For Speech And Behavior Control
By Jonathan W. Emord, a Washington, D.C. attorney.
LEGAL BACKGROUNDER, July 10, 1992, 4 pages

California Proposal To Ban Cartoon Figures In Advertising Violates First Amendment
LEGAL OPINION LETTER, June 19, 1992, 2 pages

Supreme Court Should Affirm Strong Protection For Commercial Speech
By Robert S. Peck, former Legislative Counsel for the ACLU.
LEGAL OPINION LETTER, April 10, 1992, 2 pages

California’s Environmental Advertising Law — An Unconstitutional Restraint On Free Speech?
By Rex S. Heinke, a partner with the Beverly Hills law firm Greines Martin Stein & Richland, and Kelli L. Sager, a partner attorney with the Los Angeles office of the law firm Davis Wright Tremaine.
LEGAL OPINION LETTER, March 27, 1992, 2 pages
New York City’s Attempt To Limit Tobacco Ads Is Constitutionally Suspect
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Advisory Council’s Ad Ban Recommendation Has No Place In Health Care Debate
By Alan M. Slobodin, former President of WLF’s Legal Studies Division.
LEGAL OPINION LETTER, January 31, 1992, 2 pages

Congressional Confusion On Labeling And Advertising Could Deny Consumer Information And Free Speech
LEGAL OPINION LETTER, October 25, 1991, 2 pages

Overturning Of Canada’s Advertising Ban Is A Lesson For America’s Judges
By Alan M. Slobodin, former President of WLF’s Legal Studies Division.
LEGAL OPINION LETTER, August 23, 1991, 2 pages

A Case Of Official Political Correctness: Anti-Industry Propaganda
By Daniel D. Polsby, Professor of Law at George Mason University.
LEGAL BACKGROUNDER, August 23, 1991, 4 pages

Making The World Safe From Kiddie-Food: Is AAP’s Food Advertising Ban Idea Constitutional?
By Alan M. Slobodin, former President of WLF’s Legal Studies Division.
LEGAL OPINION LETTER, August 9, 1991, 2 pages

States’ Proposed Recycling Regulations Are Constitutionally Suspect
By Richard A. Samp, Chief Counsel to WLF.
LEGAL OPINION LETTER, July 19, 1991, 2 pages

Canadian Advertising Case Could Bolster Constitutional Arguments Against Restrictions On Commercial Speech In U.S.
By Alan M. Slobodin, former President of WLF’s Legal Studies Division.
LEGAL OPINION LETTER, April 5, 1991, 2 pages
ACTIVITIES REPORT

to the

WASHINGTON LEGAL FOUNDATION
BOARD OF TRUSTEES

SUPPORTING
NATIONAL AND HOMELAND SECURITY

May 29, 2007
# TABLE OF CONTENTS

INTRODUCTION .................................................. 1

I. LITIGATION AND REGULATORY PROCEEDINGS .... 1
   A. Detaining and Prosecuting Enemy Combatants .... 1
   B. Detaining Alien Felons Pending Deportation .... 5
   C. Protecting Our Nation’s Borders ................. 8
   D. Opposing Application of Foreign Law in U.S. Courts .......... 14
   E. Enhancing Homeland Security ..................... 17
   F. Assisting Victims of Terror ....................... 19
   G. Protecting National Security Information ......... 20
   H. Protecting Military Activities from Environmental Restrictions .......... 22

II. CIVIC COMMUNICATIONS ................................. 23
   A. Media Briefings .................................... 23
   B. Advocacy Ads ..................................... 25
   C. Public Appearances ............................... 26

III. PUBLICATIONS ........................................... 32
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SUPPORTING
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The ideals upon which America was founded – individual freedom, limited
government, a free market economy, and a strong national security and defense – are the same
principles that the Washington Legal Foundation (WLF) defends in the public interest arena.
WLF’s overriding mission is to defend and promote the principles of freedom and justice.

Over the last 30 years, WLF has been the only public interest law and policy center on
the forefront of legal battles to defend our national security and oppose terrorism, including
filing legal briefs opposing the terrorists who bombed the World Trade Center in 1993. Since
the attacks on America on September 11, 2001, WLF has redoubled its efforts in the courts,
agencies, and public arena to promote its belief that the clearest path to peace and prosperity is
through military strength and zero tolerance for those who seek to do us harm. This report
highlights some of the more significant WLF national security/anti-terrorism activities over the
past six years:

I. LITIGATION AND REGULATORY PROCEEDINGS

Litigation is the backbone of WLF’s public interest programs. WLF litigates across the
country before courts and administrative agencies in support of maintaining national security,
both by providing our armed forces and law enforcement personnel with the tools to carry out
their missions and by securing our nation’s borders.

A. Detaining and Prosecuting Enemy Combatants

Before 9/11, the United States generally responded to terrorism by bringing traditional
criminal prosecutions. One of the lessons of 9/11 was that the war on terrorism cannot be
fought effectively if we continue to provide every terrorist with a full-blown criminal trial
rather than doing as we have done in past wars: locking up enemy combatants without trial for
the duration of hostilities. WLF has repeatedly gone to court to support the federal government
when it is challenged by anti-war groups whose actions, if successful, would cripple our ability
to prevent another major attack within this country. In many cases, hundreds of groups have
lined up against the Bush Administration, while WLF is the Administration’s only courtroom
supporter.
**Boumediene v. Bush.** On February 20, 2007, the U.S. Court of Appeals for the District of Columbia Circuit dismissed challenges to the American military’s detention of enemy combatants at Guantanamo Bay, Cuba, ruling that federal law bars such challenges when filed in the form of *habeas corpus* petitions. On April 2, 2007, the U.S. Supreme Court declined to review that dismissal. The decisions were victories for WLF, which filed a series of briefs in the cases. The appeals court agreed with WLF that recent congressional legislation deprives federal courts of jurisdiction to hear such *habeas corpus* claims and that Congress acted within its powers in adopting that legislation. WLF also argued that the U.S. Constitution does not extend protections to aliens not living in the United States, and thus that the detainees’ claims based on the U.S. Constitution should be dismissed for failure to state a claim. In light of its jurisdictional ruling, the appeals court did not need to reach that alternative argument. The appeals court ruling still permits detainees to obtain federal court review of their detention; first they must challenge their detention in front of administrative bodies known as CSRTs, and then their appeals are limited to challenging the fairness of the CSRT proceedings. This case is a follow-on to *Rasul v. Bush* (see below), in which the Supreme Court held that a statute grants federal courts jurisdiction to hear claims of nonresident aliens who are challenging their detention; Congress responded by amending the statute, and the appeals court decision upholds that action.

**Hamdi v. Rumsfeld.** On June 28, 2004, the U.S. Supreme Court upheld the federal government’s right to detain Yaser Hamdi, a Saudi-American accused of serving as a Taliban soldier in Afghanistan, without initiating criminal proceedings. The decision was a partial victory for WLF, which filed a brief in the case in support of the military. The Court agreed with WLF that the government’s right to detain Hamdi as an enemy combatant is not diminished simply because of his claim to citizenship – he was born in Louisiana to Saudi parents and moved with his family to Saudi Arabia as an infant. The Court also agreed with WLF that the courts should deferentially treat the military’s factual determination that Hamdi was in Afghanistan to fight for the Taliban, not (as Hamdi claims) to undertake humanitarian work. The Court remanded the case to the lower courts, however, finding that Hamdi should have been given a greater opportunity to prove his innocence than he was initially afforded by the federal appeals court. Hamdi was later released from custody after he agreed to abandon his U.S. citizenship and the military determined that he no longer posed a threat to national security.

**Padilla v. Hanft.** On April 3, 2006, the U.S. Supreme Court declined to review a lower court decision upholding the federal government’s detention of Jose Padilla, the “dirty bomber” accused of being an al Qaeda operative. The decision was a victory for WLF, which filed a brief urging the Court not to hear the case. The Supreme Court neither declared the case moot nor vacated the lower court decision on mootness grounds, even though Padilla, a U.S. citizen, is no longer being held as an “enemy combatant” – Padilla was recently released from military custody and turned over to civilian authorities to face trial in connection with largely unrelated charges that he conspired to aid overseas terrorist organizations. As a result of the
Supreme Court not taking any action to declare the case moot, the September 2005 appeals court decision in the government’s favor remains standing and can serve as a precedent in future enemy combatant cases. WLF filed a total of four briefs in support of the government as Padilla’s case wended its way through the federal courts over the past four years. On September 9, 2005, the U.S. Court of Appeals for the Fourth Circuit in Richmond upheld the federal government’s detention of Padilla. As a result of decisions in this case, the courts have now clearly established that the government is entitled to detain without trial American citizens discovered fighting for enemy forces, just as it is entitled to detain any enemy soldier captured in time of war. The courts also agreed with WLF that the right to detain Padilla was not diminished simply because he was captured in Chicago rather than on some overseas battlefield. The government alleges that Padilla fought with al Qaeda/Taliban forces in Afghanistan against the United States. Padilla is currently imprisoned in Miami, awaiting trial on criminal charges alleging conspiracy to promote terrorism.

*Hamdan v. Rumsfeld.* On June 29, 2006, the U.S. Supreme Court struck down the Bush Administration’s plan to convene military commissions to conduct trials of al Qaeda leaders accused of war crimes. The 5-3 decision was a setback for WLF, which filed a brief in the case urging that the plan be upheld. The Court held that while the President has the authority to convene military commissions, the commissions that he established were improper because they did not provide defendants with all of the procedural rights required under the Uniform Code of Military Justice (UCMJ). The Court said that if the Administration wishes to employ its proposed procedures, it will have to go to Congress and ask it to amend the UCMJ. Alternatively, the Court ruled, the Administration could conduct trials before military commissions but must use the same procedural rules commonly employed in courts martial. WLF’s brief argued that Congress has explicitly endorsed the creation of such commissions, which have been used throughout American history. WLF also filed briefs in the case when it was before the district court and the court of appeals. Despite the Court’s ruling, the petitioner — who served as Osama bin Laden’s personal driver and is accused of conspiring to murder Americans — remains in custody at Guantanamo Bay, Cuba; the ruling affects only the government’s right to proceed with a trial, not its right to detain Hamdan.

*Rasul v. Bush.* On June 28, 2004, the U.S. Supreme Court held that the federal courts have jurisdiction to hear a challenge to the U.S. military’s decision to detain captured Taliban and al Qaeda fighters at the Naval Base in Guantanamo Bay, Cuba. The decision was a setback for WLF, which filed a brief urging a finding of no jurisdiction. The detained fighters filed petitions for writs of habeas corpus, alleging that their detention without trial violates their rights under the Fifth Amendment’s Due Process Clause as well as their rights under international law. Ignoring a 1950 precedent to the contrary, the Court ruled 6-3 that the habeas corpus statute adopted by Congress grants federal courts jurisdiction to hear claims filed by nonresident aliens who are challenging their detention. The Court did not address the merits of the detainees’ claims, nor did it indicate how such claims are to proceed (e.g., whether detainees should have access to counsel). In urging the Court to deny jurisdiction, WLF had argued that allowing America’s enemies to use our courts to challenge military
detention is one of the surest ways to hamper our military effectiveness.

**Coalition of Clergy, Lawyers, and Professors v. Bush.** On November 18, 2002, the U.S. Court of Appeals for the Ninth Circuit dismissed a habeas corpus petition filed by a group of activists on behalf of the detainees at Guantanamo Bay, Cuba. The court agreed with WLF that the plaintiffs lacked standing to bring the case. The activists had filed a petition for a writ of habeas corpus in federal district court in California, seeking judicial review of the conditions of confinement of the detainees, who include Taliban and al Qaeda fighters captured by U.S. forces in Afghanistan. The so-called “Coalition of Clergy, Lawyers, and Professors” included such activists as Ramsey Clark, a former Attorney General who has represented radicals and terrorists (including the PLO and one person who was convicted in the 1993 World Trade Center bombing), and activist law professor Erwin Chemerinsky.

**Opposing ABA’s Resolution on Torture.** On August 9, 2004, the American Bar Association’s (ABA) governing body, the House of Delegates, adopted a resolution at the ABA’s annual meeting in Atlanta, Georgia, that condemned “degrading” or “cruel” treatment of any terrorist suspect who is in the physical control of the U.S. government – but it failed to define those terms. Because the ABA resolution could easily be read to prohibit the military from using effective and well-recognized interrogation techniques, WLF actively opposed the resolution. WLF argued before the House of Delegates that the ABA’s extreme position was wrong both as a matter of law and on public policy grounds. WLF’s views were presented by David B. Rivkin, Jr., a partner in the Washington, D.C. office of Baker & Hostetler, who represented WLF pro bono at the ABA meeting.

**Opposing ABA’s Resolution Condemning Designation of Enemy Combatants.** On February 10, 2003, WLF presented testimony before the ABA’s winter meeting in Seattle, Washington, opposing a Board of Governor’s Resolution that condemned the Bush Administration’s designation of certain terrorists and their supporters as “enemy combatants.” WLF argued that the President has the constitutional authority to make such designations, regardless whether the terrorist is a United States citizen. Although the resolution was passed with modifications, WLF’s legal arguments were ultimately vindicated in lawsuits involving U.S. citizens, and enemy combatants, Yaser Hamdi and Jose Padilla.

**Jurisdiction of Military Tribunals over Terrorists.** On March 7, 2003, WLF filed comments with the Department of Defense urging it to expand the categories of offenses committed by terrorists that could be subject to trial before military tribunals. WLF’s comments related to crimes involving the use of poisonous gases, the improper use of a flag of truce, and aiding the enemy. WLF also recommended expanding acts of terrorism to include solicitation, conspiracy, and attempted offenses. The Defense Department agreed, and ultimately revised its rules to expand the jurisdiction of military tribunals.

**Revisions to Sentencing Guidelines for Terrorism.** On March 19, 2002, WLF submitted comments to the U.S. Sentencing Commission supporting certain proposed revisions
to its guidelines, policy statements, and commentary in response to adoption of the USA PATRIOT Act of 2001. WLF urged the Commission to adopt changes to its guidelines that would allow federal courts to impose the maximum punishment permitted by law for those who commit terrorist acts and for those who aid and conspire with them. The Sentencing Commission ultimately adopted the revisions.

**Regulation Providing for Monitoring of Detainee-Lawyer Communications.**
On December 28, 2001, WLF filed comments with the U.S. Department of Justice (DOJ) supporting its interim regulations that allow DOJ to monitor conversations between certain suspected terrorists who are being detained and their attorneys. WLF argued that the regulations are clearly constitutional inasmuch as the attorney-client privilege does not extend to communications to an attorney that involve the commission of further crimes. WLF also noted that the DOJ regulations include constitutional safeguards, such as notification to both the detainee and the attorney that their conversations may be monitored and use of a special “taint team” that ensures that information obtained from monitoring is not given to prosecutors for use in any criminal trial. DOJ ultimately adopted the regulations on a permanent basis.

**B. Detaining Alien Felons Pending Deportation**

Federal law requires the deportation of all aliens convicted of supporting terrorism or other felonies. However, effecting those deportations often takes years. WLF has repeatedly gone to court to ensure that convicted felons remain in detention while they are fighting deportation. Even after a deportation order has been entered, deportation can be delayed for years while immigration authorities seek a country willing to accept the convicted felon; many countries are slow in taking back their own citizens, while others (e.g., Cuba) will not take anyone back. WLF also litigates in support of detention of convicted felons who are subject to final deportation orders; WLF argues that indefinite detention is appropriate, even when an alien felon subject to a final deportation order has no realistic short-term prospect of finding a country willing to accept him, if the convicted felon is deemed to pose a serious public safety risk.

**Clark v. Martinez.** On January 12, 2005, the U.S. Supreme Court held that the federal government may not indefinitely detain excludable aliens while they await deportation to their native countries, even if the aliens are dangerous felons. The decision was a setback for WLF, which filed a brief urging the Court to permit such detentions. The decision has resulted in the release from detention of more than 1,100 illegal aliens convicted of violent crimes. WLF had argued that society’s interest in being protected from violent criminals and terrorists far outweighs any interest that illegal aliens may have in being free from detention during the time it takes to arrange their deportation. The two cases before the Court involved Cubans who came to this country illegally in 1980 as part of the Mariel boatlift. Although at least one of them had been convicted of armed robbery in Cuba, they were released “temporarily” into U.S. society until Cuba could be persuaded to take them back. In the ensuing years, both Cubans
were repeatedly convicted of violent crimes. WLF argued that the U.S. government need not give them yet another chance at freedom while they await deportation. The Court disagreed, holding that a 1996 federal statute bars indefinite detention of aliens with no prospect of being returned to their native countries. The Court made clear, however, that Congress was free to amend the law to provide for such detentions.

**Snyder v. Rosales-Garcia.** On June 23, 2003, the U.S. Supreme Court declined to review a lower-court decision that raised the same issue (detention of excludable aliens pending deportation to Cuba) that was later decided in *Clark v. Martinez* (see above). The decision was a setback for WLF, which on May 23, 2003 filed a brief urging that review be granted. The case involved two Cubans who sought to sneak into the country illegally in 1980 and were later convicted of numerous violent felonies. When their prison terms were completed, the INS sought to detain them indefinitely until their deportation could be arranged. The U.S. Court of Appeals for the Sixth Circuit (in conflict with other appeals courts) ruled that indefinite detention violated the alien felons' rights to liberty.

**Al Najjar v. Ashcroft.** On August 30, 2002, the Immigration and Naturalization Service (INS) deported Mazen Al Najjar, a suspected fundraiser for Palestinian terrorists, to Lebanon. Despite efforts by the ACLU and other civil libertarian groups, the INS was allowed to continue to detain Al Najjar up until the date of his departure. The continued detention of the suspected terrorist was a victory for WLF, which on two occasions filed briefs in the U.S. Court of Appeals for the Eleventh Circuit in Atlanta in support of Al Najjar's detention. His deportation brought to an end Al Najjar's final court challenge to his detention; the appeals court several weeks later dismissed the challenge as moot. In its most recent brief supporting Al Najjar's detention, filed on May 28, 2002, WLF argued that the INS does not violate the First Amendment rights of illegal aliens by detaining those it believes have engaged in fundraising for terrorist groups. WLF argued that such detention does not interfere with rights of political association, because fundraising goes beyond mere association and is not protected by the First Amendment.

**Kiareledeen v. Ashcraft.** On December 5, 2001, the U.S. Court of Appeals for the Third Circuit in Philadelphia reversed a district court's finding that the INS was not "substantially justified" in detaining a suspected alien terrorist pending deportation. Based on that finding, the lower court had ordered taxpayers to pay the suspected terrorist, Hany Kiareledeen, $110,000 to cover his attorney fees. In reversing, the Third Circuit held that the district court's decision was "an abuse of discretion." The decision was a victory for WLF, which on October 25, 2001 had filed a brief in the case, arguing that the government is always justified in detaining an illegal alien when it has reason to suspect that the illegal alien is a terrorist. The appeals court agreed with WLF that the government was justified in relying on classified evidence (i.e., evidence shown to the defendant in summary form only) in deciding to detain him.

**Demore v. Kim.** On April 29, 2003, the U.S. Supreme Court upheld the authority of the
federal government to detain, pending completion of deportation proceedings, all aliens (including permanent resident aliens) subject to deportation because they have been convicted of aggravated felonies. The decision was a victory for WLF, which had filed a brief with the Court arguing that alien felons have no constitutional right to be free from detention during the time it takes to complete deportation proceedings. A federal law mandates detention of all such felons; the U.S. Court of Appeals for the Ninth Circuit struck down the law as a violation of felons’ due process rights. The Court agreed with WLF that the statute is based on the reasonable assumption that any felon facing deportation will flee if released from detention after he has completed his criminal sentence. WLF also argued that Congress has explicitly prohibited courts from second-guessing such detention decisions.

**Riley v. Radonic.** On May 5, 2003, the U.S. Supreme Court overturned a decision that challenged the authority of the federal government to detain, pending completion of deportation proceedings, those illegal aliens subject to deportation because they have been convicted of aggravated felonies. The decision was a victory for WLF, which had filed a brief urging the Court to uphold the authority of the federal government to detain such aliens. WLF argued that alien felons who admittedly are in this country illegally have no constitutional right to be free from detention during the time it takes to complete deportation proceedings. A federal law mandates detention in all such cases; the U.S. Court of Appeals for the Third Circuit struck down the law as a violation of illegal aliens’ due process rights. In successfully urging the Supreme Court to overturn that decision, WLF argued that illegal aliens should be afforded extremely limited due process rights and that the federal statute mandating detention is based on the reasonable assumption that illegal alien felons will flee if released from detention after they have completed their criminal sentences. The case involved Sabrija Radonic, a citizen of Yugoslavia who sneaked into the U.S. in 1991 and thereafter earned his livelihood smuggling other illegal aliens into the country.

**Rule Denying Permanent Residency to Refugees Who Commit Major Crimes.** On September 9, 2002, WLF filed comments with the Immigration and Naturalization Service (INS), supporting an INS proposal (ultimately adopted) that tightened immigration rules for refugees who commit major crimes and urging the INS to adopt rules that would absolutely prohibit granting permanent resident alien status to refugees who commit major crimes after arriving in this country. WLF argued that Congress has made clear that even permanent resident aliens who commit felonies should be deported as soon as possible, so there can be no justification for granting more leniency to refugees (who have a lower immigration status than do resident aliens) who engage in criminal activity. The INS’s rule provided that refugees who commit violent crimes should be granted permanent resident alien status only in the most extraordinary circumstances. While applauding that proposal as a step in the right direction, WLF argued that the rule should be amended to eliminate all exceptions.

**Proposed Rule Regarding Detention of Aliens Subject to Final Deportation.** On January 15, 2002, WLF filed comments with INS, strongly supporting the INS’s proposed changes (ultimately adopted) to its custody review process governing the detention of aliens
who are subject to a final order of removal. A June 2001 Supreme Court decision barred the INS in most cases from holding such aliens in custody indefinitely if the INS cannot locate a country willing to accept them. WLF applauded INS for coming up with new rules that comply with the Supreme Court’s mandate without unnecessarily endangering public safety. WLF urged INS to change its policy in one significant respect: WLF urged that all aliens who have been convicted of an aggravated felony and are subject to a final order of removal be detained, regardless whether the INS can prove that they pose a threat to public safety.

Proposal for Procedural Reforms for Case Management of Board of Immigration Appeals. On March 21, 2002, WLF submitted comments in support of DOJ’s proposed procedural reforms to improve case management at the Board of Immigration Appeals (BIA). The proposed rule (ultimately adopted) revised the structure and procedures of the BIA, provided for an enhanced case management procedure, and expanded the number of cases referred to a single BIA member for disposition. These changes have been a major factor in BIA’s ability in subsequent years to significantly reduce its notoriously long backlog of cases.

Proposed Interim Rule Regarding Temporary Detention of Aliens. On November 19, 2001, WLF submitted comments in support of the interim rule amending the INS’s rules on “Custody Procedures.” The interim rule was a modest but needed measure that allowed the INS up to 48 hours, rather than the previous 24-hour period, within which to make a determination whether an arrested alien will continue to be held in custody or released on bond or recognizance. Adoption of this measure on a permanent basis has decreased the danger that suspected terrorists will be released before their identity can be uncovered.

Stays Pending Appeal in Immigration Detention Cases. On December 28, 2001, WLF filed comments with the Department of Justice supporting DOJ’s proposal to provide an automatic stay pending appeal in any case in which an Immigration Judge orders the release of an alien previously ordered detained by the INS. WLF argued that in light of the enhanced risk of terrorist attacks, it is crucial that the INS take all steps to ensure that aliens who it believes pose a threat to public safety not be released while the issue of whether they pose a threat is still being litigated. WLF argued that aliens objecting to being detained while they fight deportation will still be entitled to rapid adjudication of their objections, because the DOJ proposal requires that any appeals from an Immigration Judge to the Board of Immigration Appeals must be handled expeditiously.

C. Protecting Our Nation’s Borders

Preventing terrorist attacks within the United States requires the federal government to increase efforts to protect the nation’s border, in order to prevent terrorists and weapons from being smuggled into the country. WLF has regularly litigated in support of allowing increased law enforcement activity along the border, making it more difficult for terrorists and criminals to obtain false identification documents (such as driver licenses) and public benefits, and
deporting aliens engaged in terrorism or other criminal behavior as quickly as possible. WLF also works to reduce the incentives for illegal aliens to sneak into this country; such efforts include reducing awards available to illegal aliens in lawsuits, reducing their ability to obtain public benefits, and making it more difficult for them to register to vote.

**Gonzalez v. State of Arizona.** On April 20, 2007, the U.S. Court of Appeals for the Ninth Circuit in San Francisco rejected a challenge to Proposition 200, an initiative adopted in November 2004 by Arizona voters. The initiative was designed to prevent aliens from voting. The decision was a victory for WLF, which filed a brief urging that Prop 200 be upheld. The appeals court agreed with WLF that Arizona voters were within their rights in adopting measures designed to prevent election fraud – including a requirement that those seeking to register to vote must provide documentary proof of citizenship. The court also agreed that these measures violated neither the U.S. Constitution nor the National Voting Rights Act of 1993 (NVRA), which requires all States to permit mail-in voter registration. The appeals court affirmed a federal district court’s decision to deny the plaintiffs a preliminary injunction pending trial. WLF represented Protect Arizona NOW (PAN), the group that spearheaded adoption of Proposition 200. WLF also represented PAN when the case was in the district court and in prior litigation challenging other portions of Proposition 200 that seek to prevent illegal aliens from collecting welfare benefits. WLF prevailed in the prior litigation *(see below)*, and the welfare-related provisions were not at issue in the latest round of lawsuits.

**Lopez v. Gonzales.** On December 5, 2006, the U.S. Supreme Court ruled that the federal government is not required to deport all aliens convicted of drug-related felonies. Rather, the Court held, a state-court drug-related felony conviction should not lead to automatic deportation unless the crime for which the alien was convicted would also have been deemed a felony under federal drug laws. The decision was a setback for WLF, which had filed a brief urging the Court to permit the U.S. government to deport all aliens who commit felonies that are drug-related. WLF urged the Court to rule that such crimes are “aggravated felonies,” which bar the alien from pleading extenuating circumstances as a reason to avoid deportation. Because his deportation is no longer deemed automatic, the alien is now permitted to apply for “cancellation of removal” and plead that extenuating circumstances should permit him to avoid deportation. The case before the Court involved Jose Lopez, a Mexican citizen who sneaked into the country illegally in the 1980’s. Lopez was later convicted on felony cocaine charges and sentenced to five years imprisonment, but he is seeking to avoid deportation on the grounds that he has developed strong ties to this country and has only one felony conviction.

**Day v. Bond.** On October 25, 2005, WLF filed a brief in the U.S. Court of Appeals for the Tenth Circuit in Denver, urging the court to reinstate a challenge to a Kansas statute that, WLF charges, violates the civil rights of U.S. citizens who live outside the State. The statute grants illegal aliens the right to attend Kansas universities at in-state rates but denies that same right to U.S. citizens who live outside of Kansas. WLF argued that the Kansas law violates a 1996 federal statute that prohibits States from granting more favorable tuition rates to illegal
aliens than they grant to citizens. A federal district court dismissed the suit in 2005 on procedural grounds; WLF urged the appeals court to overturn that dismissal. WLF filed its brief on behalf of Brigette Brennan, who attended and graduated from a Kansas high school and has been living for the past four years in Kansas while attending the University of Kansas. But Kansas has refused to offer her in-state tuition rates because she lived in Kansas City, Missouri while attending high school. The result is that she is paying considerably higher tuition than do illegal aliens who lived in Kansas illegally while attending high school and whose presence in this country continues to be illegal. The appeals court heard oral arguments in the case on September 26, 2006, and a decision is expected by mid-2007.

*Cubas v. Martinez.* On July 6, 2006, the Appellate Division of the New York Supreme Court upheld new regulations adopted by the State of New York that make it extremely difficult for illegal aliens to obtain driver’s licenses. The decision was a victory for WLF, which filed a brief urging the court to uphold the regulations. WLF argued that the restrictions are needed to ensure that terrorists and criminals do not obtain fake identification documents that can facilitate their activities. The Appellate Division agreed and held that those interests outweigh any interests that illegal aliens may have in obtaining driver’s licenses. The appeals court overturned a trial court’s preliminary injunction against the new regulations. Among other changes, the new Department of Motor Vehicles (DMV) regulations prohibit use of foreign-source documents (such as foreign passports) to establish identity, because their authenticity cannot easily be verified. The result is that illegal aliens rarely qualify to obtain new or renewed driver’s licenses, because they rarely possess verifiable U.S.-source documents (e.g., birth certificates or immigration papers) that establish their identity. The appeals court agreed with WLF’s argument that DMV’s authority to demand proof of “identity” includes the right to adopt any reasonable rule designed to ensure that the driver’s license applicant is who he says he is. The regulations are not rendered invalid simply because they have the effect of preventing illegal aliens from obtaining licenses, the appeals court agreed.

*United States v. Hernandez.* On March 16, 2007, WLF filed a brief in federal district court in Texas, urging the judge to impose only probation or home detention on a Texas deputy sheriff who was convicted of violating the civil rights of an illegal alien while being smuggled into this country. Although the U.S. Sentencing Guidelines provided for a sentence of up to seven years in prison, the court sentenced the deputy sheriff to federal prison for one year and a day. The illegal alien was slightly injured after the deputy shot at the tires of a van smuggling a group of illegal aliens from Mexico. The van had tried to run over the deputy after he stopped the vehicle for running a stop sign. The judge also imposed a three-year period of supervised release and ordered the deputy to pay a fine of $5,000 and victim compensation to the illegal alien of another $5,000. In its brief, WLF argued that the deputy sheriff did not intend to injure anyone, but was only trying to stop the vehicle from fleeing. Accordingly, the deputy should not have been prosecuted in the first place.

*Balbuena v. IDR Realty LLC.* On February 21, 2006, the New York Court of Appeals
declined to bar illegal aliens who are plaintiffs in personal injury lawsuits from recovering wages lost as a result of their injuries. The decision was a setback for WLF, which filed a brief in the case, urging that such damages be barred. WLF argued that awarding illegal aliens the "lost" wages they would have earned if they had not been injured would be inequitable because it would have been illegal for them to have actually earned those wages by taking a job in this country. WLF argued that such awards are preempted by federal law because they undermine federal immigration policy by encouraging more illegal aliens to enter the country and to seek employment. The Court of Appeals rejected WLF's argument, contending that denying damages for lost wages would encourage employers to reap the economic benefits of hiring illegal aliens. This personal injury tort suit was filed by Gorgonio Balbuena, an illegal alien who was severely injured while performing construction work. Balbuena alleged that his injuries were caused by his employer's negligence. Balbuena's right to recover for his injuries and medical expenses was not challenged; but WLF challenged Balbuena's claim that he was entitled to recover the wages he could have earned in this country had he not been injured.

_**Paramount Citrus v. Superior Court.**_ On January 5, 2006, the California Supreme Court declined to review a trial court decision that allows illegal aliens who file tort actions to seek recovery for damages not yet incurred and to base those damage claims on an assumption that they will remain in the United States for the remainder of their lives. The decision was a setback for WLF, which filed a brief urging the court to grant review. WLF argued that, because illegal aliens have no right to remain in this country, such damage claims should be limited to the amount of damages that would be incurred if the illegal alien returned to his native country. The case involves an illegal alien who was permanently disabled in a car accident. He seeks recovery of the cost of providing him "life care" for the next 50 years. The present value of such care is $5.3 million if he remains in the United States, but only $1.8 million if he returns to his native Mexico. WLF argued that because the plaintiff has no right to remain in this country, he has no right to recover damages computed based on an assumption that he will remain here. WLF also argued that granting the plaintiffs' damage claims would undermine federal immigration policy. In 2006, a California trial court entered a massive verdict in favor of the illegal alien, including damages based on the cost of medical care within the U.S. WLF plans to file another brief in the case in the summer of 2007, urging that the damage award be overturned.

_**Ambros-Marcial v. U.S.**_ On July 13, 2005, a federal district court in Arizona held that immigrants rights groups should not be permitted to undermine border security measures by suing the federal government for failing to establish water stations in the Arizona desert. The decision was a victory for WLF, which filed a brief in the case arguing that although 100 or more aliens die in the Arizona desert from dehydration every year while attempting to cross the border illegally, making such crossing easier by establishing water stations would serve only to encourage more illegal immigration. The issue arose in connection with a lawsuit for damages filed by relatives of Mexicans who died in the desert. The district court agreed with WLF that the Federal Tort Claims Act does not grant the federal courts jurisdiction over tort claims based on "discretionary functions" of the federal government – such as a decision whether to install
water stations.

_Foreign Cooperation with U.S. Deportation of Aliens._ On March 25, 2005, WLF petitioned Secretary of State Condoleezza Rice, asking that the State Department take significant steps – including, where necessary, the imposition of economic sanctions – with regard to foreign governments that refuse to cooperate with U.S. deportations of their nationals. WLF noted that the absence of cooperation has rendered the U.S. incapable of removing thousands of aliens ordered to be deported because they have been convicted of violent crimes. WLF urged the Department to make explicit demands upon the governments involved. Where that does not bring cooperation, WLF urged the Department to impose sanctions, including sanctions under the power granted by the Immigration and Nationality Act to discontinue granting visas to countries that refuse to cooperate in the issuance of travel documents for purposes of repatriation of excluded aliens; and under the Immigration Act of 1990, which authorizes the Secretary of State to exclude aliens from designated countries for policy purposes.

_Friendly House v. Napolitano._ On August 9, 2005, the U.S. Court of Appeals for the Ninth Circuit upheld Proposition 200, an initiative adopted in November 2004 by Arizona voters and designed to deter illegal aliens from collecting welfare benefits. The decision was a victory for WLF, which represented PAN, the group that sponsored Proposition 200; that group intervened in the case as a defendant, to ensure that a vigorous defense was mounted. The group intervened because the Arizona Attorney General (along with virtually every other senior Arizona official) opposed Proposition 200, so there was some reason to suspect that he might mount a less-than-vigorous defense of the new law. The appeals court threw out the plaintiffs’ challenge entirely; it agreed with WLF that the plaintiffs (mostly illegal aliens seeking welfare benefits) lacked “standing” to challenge the law. WLF’s brief also argued that Arizona voters were well within their rights in adopting such measures. WLF argued that because federal law prohibits states from providing welfare benefits to illegal aliens, there can be no objection to taking steps to ensure that the prohibition is enforced. WLF argued that Proposition 200 is neither preempted by federal immigration law nor a violation of the due process rights of state employees or welfare applicants. WLF also represented PAN in the district court. WLF won a major victory in December 2004, when the district court denied the plaintiffs’ request for a preliminary injunction against Proposition 200; the appeals court affirmed that victory.

_Jama v. Immigration and Naturalization Service._ On January 12, 2005, the U.S. Supreme Court held that the U.S. government is permitted to deport alien felons to Somalia. The decision was a victory for WLF, which filed a brief urging the Court to reject a lower court decision that prohibited deporting _anyone_ to Somalia because that country lacks a functioning central government. The Court agreed with WLF that although the U.S. usually does not deport an alien when his native country objects to taking him back, federal law does _not_ prohibit deportations to countries that lack a functioning government capable of formally accepting (or rejecting) its returning citizens. The issue is of critical importance in connection
with alien felons from Somalia because Somalia has not had a functioning central government since 1991. There are now more than 10,000 aliens in this country awaiting deportation to Somalia, but a federal appeals court had issued an injunction blocking all such deportations. Most of those awaiting deportation, including several thousand convicted of serious crimes, are not in detention but rather are freely roaming the streets – because courts do not permit indefinite detention pending deportation. The Supreme Court agreed with WLF that deportation of these alien felons should be allowed to proceed.

_U.S. v. Flores-Montano_. On March 30, 2004, the U.S. Supreme Court held that customs officials are permitted to conduct thorough inspections of all vehicles crossing the border into the United States, regardless whether they suspect that the vehicle contains contraband. The decision was a victory for WLF, which filed a brief in the case, arguing that such searches are essential to national security. The case involved the search of a car being driven into California by a Mexican citizen. Although they lacked solid evidence that the driver was engaged in smuggling, customs officials decided to remove and inspect the gas tank (a process that took less than an hour). The search turned up 37 kilograms of marijuana. The appeals court threw out the evidence, ruling that the search was “unreasonable” in violation of the Fourth Amendment. In reversing, the Supreme Court agreed with WLF’s argument that the government should have far broader rights to conduct suspicionless searches at the border than elsewhere. WLF argued that terrorists, drug cartels, and immigrant smugglers cannot effectively be thwarted unless the government is permitted to conduct random searches of all entering vehicles.

_United States v. Drayton_. On June 17, 2002, the U.S. Supreme Court upheld the power of police to question and search bus passengers who voluntarily consent to be searched. The decision was a victory for WLF, which had filed a brief in the case in support of the police officers. The Court agreed with WLF that consensual questioning of citizens by police is an important law enforcement tool and should not be deemed to violate the Fourth Amendment’s ban on unreasonable searches and seizures simply because some bus passengers might feel uncomfortable in refusing a police request to search baggage. WLF argued that in light of terrorism threats, it is particularly important that police have all the tools necessary to ensure that public transportation systems remain safe. The case involved a police search of bus passengers in Florida who were found to be carrying nearly a kilogram of cocaine. The lower court had held that the search could not be deemed consensual in the absence of a _Miranda_-like warning that passengers had the right to refuse to consent to the search.

_Proof of Citizenship for Medicaid Applicants_. On July 11, 2006, WLF filed comments with the federal Centers for Medicare and Medicaid Services (CMS), urging the agency to tighten its requirements regarding the documentation that Medicaid applicants must provide to demonstrate that they are U.S. citizens, and thus eligible to receive Medicaid benefits. WLF argued that some of the guidelines adopted by CMS in this area are not as strict as Congress mandated in 2005 legislation. WLF argued that in the absence of stricter documentation requirements, Medicaid administrators could have little assurance that Medicaid program
participants are actually eligible to receive benefits. WLF requested that CMS not permit administrators to waive documentation requirements for those claiming that it would be too burdensome to obtain proof-of-citizenship documents; it argued that if documentation exists that would verify whether an applicant is a citizen, then the applicant should be required to provide the documentation.

**In-State Tuition for Illegal Aliens.** On August 9, 2005, WLF filed a formal complaint with the U.S. Department of Homeland Security (DHS) against the State of Texas, charging that Texas is violating the civil rights of U.S. citizens who live outside the State. WLF filed a similar complaint against New York State on September 7, 2005. WLF charged that Texas and New York are violating federal law by offering in-state college tuition rates to illegal aliens who live in those states, while denying those same rates to U.S. citizens who do not live in those states. WLF called on DHS to bring appropriate enforcement action against Texas and New York, including ordering them to make refunds to students who have been charged excessive tuition. The federal statute at issue, 8 U.S.C. § 1623, was adopted in 1996 and is designed to ensure that any State that offers discounted, in-state tuition rates to illegal aliens on the basis of their residence in the State must offer the same discounted rates to all U.S. citizens. In 2001-02, Texas and New York adopted laws that allow illegal aliens to attend public universities at in-state rates, but they have refused to extend that same opportunity to U.S. citizens living outside the states. Similar laws have since been adopted in seven other States: California, Utah, Illinois, Washington, Oklahoma, Kansas, and New Mexico. DHS has not yet formally responded to WLF’s petitions.

**D. Opposing Application of Foreign Law in U.S. Courts**

The U.S. Constitution mandates that U.S. courts are to look for guidance to U.S. law, not foreign law. Nonetheless, activists are with increasing frequency urging courts to decide cases on the basis of foreign or international law, and some judges are agreeing to do so. WLF strongly opposes this trend as an affront to American sovereignty and a threat to national security. It regularly litigates in opposition to efforts to have cases decided on the basis of foreign/international law. Activists have sought to invoke international law in each of the “enemy combatant” cases listed above. Other cases in which WLF has opposed this trend are listed here.

**Presbyterian Church of Sudan v. Talisman Energy Inc.** On May 8, 2007, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit, urging it to rein activists’ use of the Alien Tort Statute (ATS) as a means of attempting to enforce international human rights law in federal courts. WLF argued that when it adopted the ATS in 1789, Congress never intended to assign federal courts the role of policing alleged human rights violations throughout the world. WLF argued that federal court intervention in overseas activities is particularly inappropriate when, as in this case, neither the parties nor the controversy have any connection to the United States. Noting that the defendant (Talisman Energy Inc.) is a major
Canadian oil company and that the government of Canada has strenuously objected to continuation of this lawsuit. WLF argued that the plaintiffs ought to be required to file their claims in Canada. The plaintiffs, a group of Sudanese citizens, complain that their human rights have been violated by the government of Sudan. From 1998 to 2003, a corporate affiliate of Talisman conducted oil production operations in the southern Sudan and provided logistical support to the Sudanese government in that region. The plaintiffs allege, based on that support, that Talisman unlawfully “aided and abetted” the government’s violation of their rights under international law. They filed suit against Talisman under the ATS, which provides jurisdiction to federal courts over tort suits brought by aliens for violations of “the law of nations.”

**Mother Doe v. Sheikh Mohammed.** On April 5, 2007, WLF filed a brief in federal district court in Miami, urging it not to permit human rights activists to use U.S. courts as a platform for asserting international law claims that bear no relation to the United States. WLF argued that when it adopted the Alien Tort Statute (ATS) in 1789, Congress never intended to assign federal courts the role of policing alleged human rights violations throughout the world. WLF urged the court to dismiss this case, which alleges that the Middle Eastern defendants violated the “law of nations” based on conduct in their own countries. WLF argued that federal court intervention in overseas activities is particularly inappropriate when, as here, the case raises sensitive foreign policy considerations. Noting that the defendants in the suit include senior officials in the government of the United Arab Emirates (UAE), WLF argued that the issues raised by the suit ought to be handled within the UAE – given that no Americans are involved in the suit and all the events described took place overseas.

**Abdollahi v. Pfizer.** On May 24, 2006, WLF filed a brief in the U.S. Court of Appeals for the Second Circuit, urging the court to dismiss claims that a pharmaceutical company violated international law when a team of its doctors provided emergency medical aid to children in Nigeria suffering from meningitis. WLF argued that federal law does not permit private parties to file tort suits in federal court asserting that doctors violated international law by allegedly treating patients without first obtaining the patients’ informed consent. WLF urged the court to reject claims that such suits are authorized by the Alien Tort Statute (ATS), a 1789 law that lay dormant for nearly 200 years before activists began seeking to invoke it in the past several decades. WLF argued that the ATS was adopted in 1789 to allow the federal courts to hear cases involving piracy and assaults on ambassadors. WLF charged that it has been transformed by activist attorneys into a tool for second-guessing American foreign policy and for attacking the overseas conduct of corporations. In this case, Pfizer sent a team of doctors to Kano, Nigeria in 1996 to provide *pro bono* medical care to assist in dealing with a severe outbreak of meningitis in children. The doctors treated their patients with Trovan, a Pfizer-manufactured antibiotic that had not yet been approved by FDA for treating pediatric meningitis in the United States. The children treated by the Pfizer doctors had a survival rate superior to that of other Nigerian children receiving treatment. Nonetheless, lawyers from Milberg Weiss (a well-known New York plaintiffs’ law firm) filed suit against Pfizer on behalf of some of the patients and their parents, alleging that Pfizer had failed to inform them, prior to
commencing treatment, that Trovan was not yet fully approved by FDA. The plaintiffs claim that Pfizer’s alleged failure to obtain informed consent violated international law and is actionable in U.S. federal courts under the ATS. The appeals court is expected to conduct oral arguments in the case in late 2007.

**Medellin v. Dretke.** This case, involving a Mexican citizen convicted of murdering two Texas teenagers in 1993, raises important international law issues and is heading back to the U.S. Supreme Court for a second time in late 2007. WLF is actively involved in the case, representing the family of one of the murder victims. On May 23, 2005, the U.S. Supreme Court dismissed as improvidently granted a case in which a criminal defendant, properly convicted of murder and sentenced to death, was attempting to invoke international law as a basis for overturning his conviction. The decision was a victory for WLF, which filed a brief on behalf of the parents of one of the murder victims, 14-year-old Jenny Ertman. WLF argued that Jose Medellin, a Mexican citizen convicted of the rapes and murders, has received more than a fair review of his sentence and that it is time now to bring his appeal rights to a close. Medellin, who has lived in Houston most of his life, argues that his conviction should be overturned because Texas erred when, at the time of his arrest, it failed to advise him of his rights under international law to meet with a Mexican consular official. In its 2005 brief filed in support of Texas, WLF argued that only American law, not international law, is enforceable in U.S. courts. Following the Supreme Court’s dismissal of his case, Medellin (with the support of the Bush Administration) asked that a Texas state court consider his international law claim. The Texas court refused to do so, holding that the President lacks the power to order Texas courts to ignore Texas law for the purpose of considering stale appeals. The Supreme Court in April 2007 agreed to hear Medellin appeal from that decision. WLF will file a brief with the Supreme Court in July 2007, arguing (on behalf of the Ertman family) that further delay in carrying out the sentence is unwarranted.

**Doe v. Wal-Mart Stores, Inc.** On May 5, 2006, WLF filed a brief in U.S. District Court in Los Angeles, urging the Court to dismiss a lawsuit brought against Wal-Mart by activists who are critical of Wal-Mart’s overseas labor practices. The activists allege that Wal-Mart purchases products manufactured overseas by others under “sweat shop” conditions. They allege that Wal-Mart should be held liable for violations of international human rights laws because its purchasing activities amount to “aiding and abetting” working conditions that amount to slavery. WLF argued that the plaintiffs’ “slavery” allegations are far-fetched. WLF also argued that there is no international law that prohibits such “aiding and abetting” activity; and even if there were such a law, it is not enforceable in American courts – which only enforce American law, not international law. On December 5, 2006, the court heard oral arguments on the motion to dismiss.

**Sosa v. Alvarez-Machain.** On June 29, 2004, the U.S. Supreme Court unanimously overturned a lower-court ruling that allowed aliens to second-guess American law enforcement policy by filing suits for money damages under the Alien Tort Statute (ATS), alleging violations of international law. The decision was a major victory for WLF, which filed a brief
in the case. The lower court had affirmed an award of damages imposed against Sosa, a former Mexican policeman, because, at the request of the U.S. government, he assisted the U.S. in apprehending a Mexican doctor indicted for torturing and murdering an American drug enforcement agent. In response to the doctor’s civil suit, the appeals court ordered Sosa to pay $25,000 in damages for a supposed violation of international law. The appeals court held that the ATS, a 1789 statute designed to deal with piracy issues, permits foreigners to sue in U.S. courts for alleged violations of international law. The Supreme Court agreed with WLF not only that Sosa’s conduct did not violate international law, but also that the ATS does not authorize suits in the federal courts to enforce international law.

**Doe v. Unocal Corporation.** On April 22, 2003, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit, seeking to overturn a lower court ruling that greatly expanded the reach of the Alien Tort Statute (ATS). The ATS provides for jurisdiction in U.S. courts by aliens for torts “committed in violation of the law of nations or a treaty of the United States.” Although the law originally was intended to govern relations between nation states when enacted in 1789, human rights activists are now invoking the law to hold U.S. corporations operating abroad liable for human rights abuses allegedly suffered by citizens of the host country. In this case, the aliens claimed that injuries they suffered at the hands of the Myanmar military should be attributed to Unocal Corp. because the military was protecting an oil pipeline being built by Unocal. Following the Supreme Court’s Sosa decision (see above), which greatly cut back on liability under the ATS, the parties settled this case before the appeals court could issue a decision.

**E. Enhancing Homeland Security**

Ever since September 11, 2001, governments at all levels have been implementing new programs to enhance homeland security by tracking and deterring potential terrorists. Unfortunately, a wide variety of activist groups have gone to court repeatedly in an effort to block virtually all such programs. WLF has responded by joining the judicial battle in support of these vital security measures.

**MacWade v. Kelly.** On August 11, 2006, WLF scored a major victory when the U.S. Court of Appeals for the Second Circuit upheld a trial court ruling that rejected a constitutional challenge by the New York Civil Liberties Union (NYCLU) to New York City’s subway bag inspection program designed to detect and deter terrorist attacks. WLF filed a brief in the case in April 2006 on behalf of numerous public officials, as well as several groups representing the families of terror victims. The appeals court agreed with WLF that the bag inspection program did not violate the Fourth Amendment’s prohibition against unreasonable searches and seizures. The program was implemented shortly after the London terrorist subway bombings in the summer of 2005. WLF also filed two briefs when the case was before the trial court – the second brief was filed at the specific invitation of the trial judge.
**ACLU v. National Security Agency; Center for Constitutional Rights v. Bush.** On October 24, 2006, WLF filed a brief in the U.S. Court of Appeals for the Sixth Circuit in Cincinnati, seeking to overturn a lower court ruling that struck down the National Security Agency’s (NSA) electronic Terrorist Surveillance Program (TSP). Under the TSP, certain international electronic communications involving at least one party who is a suspected al Qaeda agent or affiliate may be intercepted without a court order. A federal district judge in Detroit ruled in July 2006 – at the urging of the ACLU – that the TSP is illegal; that ruling has been stayed pending appeal. WLF also filed briefs in support of the TSP in the Detroit district court and in a separate case in federal court in New York that raised identical claims, *Center for Constitutional Rights v. Bush.* In both cases, the plaintiffs claim that the NSA surveillance program violates the Foreign Intelligence Surveillance Act of 1978 (FISA), which requires advance approval by a special FISA court of all monitoring activity. FISA provides that the court should approve the surveillance request if it finds probable cause to believe that the person targeted for electronic surveillance is an agent of a foreign power. In its most recent appeals court brief, WLF argued that FISA’s limitations on surveillance powers are themselves unconstitutional: they violate separation-of-powers principles by impairing the President’s ability to carry out his constitutional responsibilities to collect foreign intelligence as a means of defending the country from further attack. The Sixth Circuit heard oral arguments in the case on January 31, 2007. The Bush Administration recently began seeking approval from the FISA court for all electronic surveillance, a move that may render this case moot.

**Johnston v. Tampa Sports Authority.** On November 17, 2006, WLF filed a brief in the U.S. Court of Appeals for the Eleventh Circuit, urging it to reject a challenge to an NFL policy that entails brief searches of all patrons entering NFL stadiums. WLF argued that the searches are “reasonable” within the meaning of the Fourth Amendment and in any event are not subject to the Fourth Amendment because they are being carried out at the direction of private entities. The case is on appeal from a district court injunction against such searches at home games being played by the Tampa Bay Buccaneers, an NFL team. Pursuant to a league-wide policy, the Buccaneers required that all patrons entering their stadium submit to a brief, non-intrusive pat-down search to determine whether they are carrying explosives. WLF argued that the searches are minimally intrusive and are more than justified by the very real possibility that terrorist groups will attempt to kill large numbers of civilians by planting a bomb in a football stadium. The appeals court heard oral arguments in the case on April 17, 2007.

**Humanitarian Law Project v. Gonzales.** On April 13, 2006, WLF filed a brief in the U.S. Court of Appeals for the Ninth Circuit in San Francisco, urging the court to uphold a portion of the USA PATRIOT Act that makes it a crime to provide “material support” to any group that has been designated by the Attorney General as a “foreign terrorist organization.” WLF argued that the statute is not impermissibly vague and does not violate the First Amendment rights of individuals who wish to support humanitarian work conducted by terrorist groups. WLF also argued that the First Amendment does not prevent Congress from barring actions taken to aid terrorist groups simply because the actions may have an expressive component. The law in question, 18 U.S.C. § 2339B, was adopted in 1996 and was
strengthened by the USA Patriot Act in 2001 and by other legislation in 2004. WLF argued that § 2339B is not impermissibly vague (in violation of the Fifth Amendment’s Due Process Clause) because it provides people of ordinary intelligence with a reasonable opportunity to understand what conduct it prohibits. WLF argued that Congress’s intent was clear: to bar virtually all significant direct support of designated terrorist groups. WLF argued that the plaintiffs’ real objection is that they disagree with Congress’s decision, not that Congress has failed to specify what actions are prohibited. The appeals court heard oral arguments in the case on May 1, 2007.

F. Assisting Victims of Terror

When Americans are killed or injured by terrorists, WLF supports their right to obtain compensation from the perpetrators. Most American terrorism victims do not bother to sue, because the potential defendants either lack financial resources or are not amenable to suit in American courts. But when a foreign government is shown to have assisted the terrorists, WLF regularly goes into court to assist Americans seeking compensation from those foreign governments—which often have substantial assets that plaintiffs can seize to satisfy judgments.

Jacobsen v. Oliver. On September 12, 2006, the U.S. District Court for the District of Columbia ruled that victims of Middle East terrorism are not permitted to seek punitive damages against MOIS (the Iranian foreign intelligence agency) based on MOIS’s active involvement in Hezbollah’s terrorist activities. The decision was a setback for WLF, which filed a brief urging the court to rule that MOIS could be forced to pay punitive damages. WLF argued that allowing punitive damage awards against government sponsors of terrorism will make it less likely that governments will be willing to provide such support in the future. WLF filed its brief in conjunction with the Jewish Institute for National Security Affairs (JINSA). The case involved David Jacobsen, an American who was kidnapped by the terrorist organization Hezbollah and held hostage for several years in the 1980s in Lebanon. The issue before the district court was whether MOIS, as an arm of the government of Iran, was entitled to sovereign immunity. WLF’s brief argued that MOIS was not entitled to immunity from suit to the extent that it engaged in the kidnapping and torture of Americans. Although Iran has been designated as a state sponsor of terrorism, federal law imposes strict limits on the ability of an individual to seek damages in federal court against a foreign state. WLF argued that MOIS is not synonymous with the Islamic Republic of Iran but, rather, should be deemed an “agent or instrumentality” of Iran and thus liable for punitive damage awards; but the court disagreed. The court rejected WLF’s argument that providing support for terrorists around the world is not a legitimate, core government function and thus does not warrant special protection from damage awards.

Acree v. Iraq. On April 25, 2005, the Supreme Court declined to review this important case seeking damages against Iraq and Saddam Hussein for torturing American Prisoners of War (POWs) during the 1991 Gulf War. The decision was a setback for WLF, which had filed
a brief urging Supreme Court review. WLF also filed a brief in support of the former POWs when the case was before a federal appeals court; that court dismissed the case in 2004. It ruled that while the district court had jurisdiction in the case, federal law does not provide a cause of action for the POWs. The plaintiffs, Colonel Clifford Acree and 16 other American servicemen, filed suit against the Republic of Iraq in early 2002, seeking damages for injuries they suffered when they were physically and psychologically tortured after being captured by Iraqi forces during the 1991 Gulf War. The district court entered a large judgment in their favor, but the appeals court reversed. WLF filed its briefs on behalf of a bipartisan congressional group that included U.S. Senators George Allen, Tom Harkin, Patty Murray, and Harry Reid, and 17 Members of the U.S. House of Representatives.

_Ungar v. Palestine Liberation Organization._ On March 31, 2005, the U.S. Court of Appeals for the First Circuit in Boston required the Palestine Liberation Organization (PLO) and the Palestinian Authority (PA) to be answerable in court to claims that they are complicit in the deaths of Americans killed by Middle East terrorists. Because the PLO and PA refused to raise a merits-based defense in the trial court but instead chose to rely solely on their alleged sovereign immunity, that court entered a $116 million default judgment against them in 2004. The First Circuit’s decision upheld that massive judgment. The decision was a victory for WLF, which filed a brief in the case in support of the plaintiffs. The appeals court agreed with WLF that because there is not now a sovereign state of Palestine, neither the PLO nor the PA should be granted sovereign immunity from suit in U.S. courts, a privilege normally granted by the U.S. to other nations. The case arose in the aftermath of the murders of Yaron Ungar (an American citizen) and his wife Efrat at the hands of Hamas terrorists. Their survivors filed suit under the Antiterrorism Act against (among others) the PLO and the PA, claiming that those groups aided and abetted the murders. WLF’s victory in the case became complete on November 28, 2005 when the Supreme Court declined to review the First Circuit’s decision.

**G. Protecting National Security Information**

In this information age, the federal government needs to be careful not to make sensitive government information too readily accessible to potential terrorists. WLF regularly takes steps to ensure that government agencies are not inadvertently disclosing sensitive information and has gone into court to oppose activists’ efforts to require disclosure of information that could endanger national security.

_Center for National Security Studies v. Dep’t of Justice._ On June 17, 2003, WLF scored a major victory when the United States Court of Appeals for the District of Columbia Circuit upheld the decision by the Department of Justice (DOJ) to withhold the public release of the names and certain other information about those aliens detained in the United States following the September 11, 2001 terrorist attacks on America. The court agreed with WLF that releasing the information could interfere with law enforcement efforts, and that the government was not required by law to disclose the information. WLF filed briefs in the case
in both the district court and court of appeals. The suit against the government was filed under the Freedom of Information Act (FOIA) by a group of activists, led by the ACLU. The suit sought the names of all aliens who were arrested or detained in connection with DOJ’s investigation of the 9/11 terrorist attacks, as well as the names of any of their attorneys. The Supreme Court later denied the ACLU’s request to review the case.

**Interim Rule to Keep Detainee Information Confidential.** On June 26, 2002, WLF filed formal comments with the INS supporting an interim rule (ultimately made permanent) that prohibited state and local governments from releasing any identifying information about alien detainees that are held in non-federal facilities under contract with the INS. Due to limited space availability in federal detention facilities, many of the aliens detained following the 9/11 terrorist attacks were held in state and local facilities. The effect of this rule was to pre-empt state and local disclosure laws that would otherwise have allowed the information to be released. The interim rule was issued in response to a ruling in a lawsuit brought by the American Civil Liberties Union of New Jersey, seeking the release of the names of alien detainees held in New Jersey’s county jails under New Jersey’s Right-to-Know law. WLF argued that releasing the names of all detainees would endanger national security.

**Closing Public Reading Rooms Containing Sensitive Information About Dangerous Chemicals.** Citing the risk of foreign and domestic acts of terrorism, WLF petitioned the EPA on December 8, 2001, to close all of its public reading rooms where sensitive information and data on the chemical industry can be easily obtained. WLF also petitioned the EPA to refrain from posting sensitive information on its website. Following the terrorist attacks on America on September 11, 2001, the EPA only “temporarily” shut down that part of its website which provided information to the public about the Risk Management Plans (RMP) submitted by companies regarding the specific location, use, storage, and production of dangerous chemicals. EPA nonetheless continued to make this sensitive information readily available for inspection by anyone who visited EPA reading rooms across the country. In response to WLF’s petition, EPA revised its policies by imposing additional restrictions on access to sensitive information.

**Deleting Sensitive Materials from Government Websites.** On December 31, 2001, WLF filed petitions with three separate government agencies, urging them to review their policies regarding posting sensitive information on their Internet sites. The three agencies were the National Nuclear Security Administration (NNSA), the Department of Transportation’s Office of Pipeline Safety (OPS), and the Nuclear Regulatory Commission (NRC). The NNSA’s responsibilities include the manufacture and maintenance of nuclear weapons materials for the Department of Defense. The OPS’s activities include the National Pipeline Mapping System, which provides detailed mapping information about utility pipelines located in the U.S., including data on “sensitive” areas through which pipelines pass (e.g., areas that are sources of drinking water or are otherwise ecologically sensitive). The NRC’s responsibilities include the regulation of all nuclear power plants in this country. WLF argued that NNSA, OPS, and NRC had all failed to remove sensitive information from their websites.
that might prove useful to terrorists. In response to WLF's petitions, each of the three agencies revised its Internet posting policies to take greater account of national security concerns. A similar petition filed with the Federal Energy Regulatory Commission (FERC) on March 25, 2005 led to similar changes in FERC policies regarding public access to documents.

H. Protecting Military Activities from Environmental Restrictions

The nation's military preparedness is regularly being undermined by court decisions that expansively apply federal environmental laws in ways – never intended by Congress – that prevent the military from engaging in routine training exercises. WLF recognizes that environmental laws apply to everyone, including the government; but federal courts should not be permitted to invoke environmental laws in a manner that second-guesses the military's considered judgments regarding military needs. WLF regularly litigates against activists who seek to use environmental laws to hamstring the military.

National Audubon Society v. Dep't of the Navy. On September 7, 2005, the U.S. Court of Appeals for the Fourth Circuit in Richmond ruled that the Navy should be permitted to go forward with planning for construction of a new North Carolina airfield, even as it prepares a new environmental impact statement (EIS) for the airfield. The decision was a victory for WLF, which had filed a brief urging the court to lift a district-court injunction against all site-preparation and planning work. The airfield, desperately needed for pilots being trained to land planes on aircraft carriers, has been blocked by questions over the adequacy of the initial EIS. The appeals court held that a new EIS was required. But it agreed with WLF that the district court erred in blocking all work on the airfield while the new EIS is being prepared. The appeals court agreed with WLF that the district judge acted improperly in second-guessing the Navy's determination that building the base is vital for national security.

Center for Biological Diversity v. England. On January 24, 2003, the U.S. Court of Appeals for the D.C. Circuit overturned a lower court decision that had blocked Navy military training exercises. The decision was a victory for WLF, which had filed a brief seeking to overturn a dangerous district court decision. The Center for Biological Diversity (CBD) sued the Department of the Navy to halt all live-fire training exercises on the small uninhabited Pacific island of Farallon de Medinilla (FDM). CBD claimed that the bombing of the island resulted in the unintentional killing of a several endangered migratory sea birds listed under the Migratory Bird Treaty Act (MBTA). The district judge issued, in effect, a "cease-fire" order against the Navy, halting the training exercises even though the Navy had taken costly measures to mitigate any environmental harm. WLF argued in its brief that the CBD lacked legal standing to challenge the military exercises because the alleged injury to its members' bird-watching activity was too speculative. WLF also argued that if the MBTA were applied to the facts in this case, it would unconstitutionally encroach on the President's Commander in Chief power under Article II of the Constitution. While the case was on appeal, Congress enacted a law that exempted military training exercises from the MBTA, whereupon the case
was dismissed as moot.

_**Application of Environmental Rules to Combat Training Exercises.**_ On August 2, 2004, WLF filed comments with the U.S. Fish & Wildlife Service (F&WS) regarding a proposed rule that purports to govern any Department of Defense combat training exercises that may have an adverse effect on migratory birds. WLF supported a provision in the proposed rule that would allow DoD, rather than F&WS, to determine whether proposed military activity is likely to have a “significant adverse effect” on migratory birds. However, WLF objected to the proposed rules on suspension and withdrawal of a DoD’s “take” authorization (i.e., authorization to engage in activity that could harm migratory birds) because the proposed rules state that F&WS may _unilaterally_ suspend DoD’s authorization. WLF argued that Congress (in adopting the 2003 National Defense Authorization Act) mandated that “take” authorizations not be suspended or withdrawn over DoD’s objections, and also argued that such unilateral action would infringe on the President’s Commander-in-Chief powers under Article II of the Constitution.

## II. CIVIC COMMUNICATIONS PROGRAM

WLF recognizes that its litigation and regulatory activities cannot alone suffice if it is to have a significant impact in opposing the efforts of activists and in educating the public and policy makers regarding threats to national security. WLF has also sought to influence public debate and provide information through its Civic Communications Program. This targeted and broad-based program includes WLF’s sponsorship of frequent, well-attended media briefings featuring experts on a wide range of national security-related topics; the publication of advocacy advertisements in national journals and newspapers; and participation in countless national security-related symposia. WLF supplements these efforts by making its attorneys available on a regular basis to members of the news media – from reporters for general-circulation newspapers to writers for specialized legal journals.

### A. Media Briefings

The centerpiece of WLF’s Civic Communications Program is its media briefings, which bring news reporters from the print and electronic media together with leading experts on a wide variety of legal topics. WLF sponsors more than a dozen such breakfast briefings each year, often focusing on national security topics. Recent media briefings (dubbed media “noshesse”) on national and homeland security-related issues have included the following:

  * **John A. Merrigan**, Partner, DLA Piper US LLP
  * **Kevin O’Scanlan**, Of Counsel, DLA Piper US LLP
Terrorism Risk Insurance: Assessing Public & Private Roles as TRIA Nears its Sunset, September 15, 2005

• Warren W. Heck, Greater New York Mutual Insurance Company
• Travis B. Plunkett, Consumer Federation of America
• Commissioner Lawrence H. Mirel, Dept. Of Insurance, Banking & Securities

The PATRIOT Act and Beyond: Is America’s War On Terrorism Compromising Civil Liberties?, September 25, 2003

• Hon. Daniel J. Bryant, Acting Assistant Attorney General
• Stuart Taylor, Jr., National Journal
• Timothy Edgar, American Civil Liberties Union

Assault on Terror or Liberties?: Assessing the Administration’s Legal Strategy, One Year Later, September 19, 2002

• Professor Ruth Wedgwood, Yale Law School
• Professor Jonathan Turley, George Washington University Law School
• Lee A. Casey, Baker & Hostetler


• The Honorable Dick Thornburgh, Kirkpatrick & Lockhart, LLP (moderator)
• The Honorable Ed Bethune, Bracewell & Patterson, L.L.P.
• Thomas F. Cullen, Jones, Day, Reavis & Pogue
• Joseph E. diGenova, diGenova & Toensing
• Richard S. Levick, Esq., Levick Strategic Communications, Inc.


• The Honorable Viet D. Dinh, Assistant Attorney General of the United States
• George J. Terwilliger III, White & Case
• Victoria Toensing, diGenova & Toensing
• Ronald Weich, Zuckerman Spaeder LLP

The War on Terrorism: Risks and Rewards of Relying upon Criminal and International Law Principles, October 19, 2001

• The Honorable Dick Thornburgh, Kirkpatrick & Lockhart, LLP (moderator)
• Philip Allen Lacovara, Mayer, Brown & Platt
• Professor Ruth Wedgwood, Yale Law School
• Michael J. O’Neill, Preston Gates & Ellis
B. Advocacy Ads

In 1998, WLF began running a series of opinion editorials on the op-ed page of the national edition of The New York Times called “In All Fairness.” The op-ed has appeared well over 100 times, reaching over five million readers in 70 major markets and 90 percent of major newspaper editors. Titles and summaries of the op-eds published since September 11, 2001, relating to terrorism issues, include:

Defending Our Own Civil Liberties
The September 11, 2001 attack on America was caused in large measure by the restrictions placed on our domestic and foreign intelligence gathering capabilities.

Wanted: Public Interest Reality
Lawsuits by activists to block military training exercises, energy development, and economic growth, sacrifice national interests in favor of their narrow ideological agendas.

Holiday Wishes
Attacks on the Administration’s efforts to combat terrorism by so-called “civil libertarians” are misguided.

Tampering With Our Lives
Activist groups opposing homeland security efforts and the war on terrorism threaten the safety of all Americans.

Hijacking Liberties
Activists who attack law enforcement efforts to gather intelligence and instead seek to provide civil liberties protections to terrorists and their supporters harm our national security.

Mirandize Our Foreign Enemies?
Efforts to extend civil liberties protections to suspected terrorists hamper our ability to combat terrorism and threaten our safety.

No Blood For Oil
United States security requires less dependence on foreign oil and more development of domestic energy resources.

Unwittingly Aiding Al-Qaeda
Activists who seek repeal of USA PATRIOT Act’s anti-terrorism provisions and tough enforcement are ill-informed and help our enemies.

The State of Our Union
Efforts to combat terrorism are under constant attack by misguided activists who use the courts to undermine our national security.
“Civil Liberties” for Terrorists?
Activists are harming American interests by opposing major military activities overseas and domestic law enforcement efforts to fight the war on terrorism.

Fueling National Insecurity
Energy development in America has been unnecessarily limited by activists and overly restrictive regulations.

National Security and Energy
American dependence on foreign oil is the result of activists’ efforts to prohibit domestic exploration and production.

C. Public Appearances

WLF attorneys have appeared as featured panelists and speakers on national security issues before a wide variety of groups, and are frequently sought out by the electronic news media for interviews on national security issues coming before the courts. Public appearances made by WLF attorneys relating to national security issues, dating back to September 11, 2001, include:

2007

* March 26, WLF Chief Counsel Richard Samp participated in an on-air debate on National Public Radio’s “To the Point” program, on Bush Administration policy regarding detention of enemy combatants at Guantanamo Bay, Cuba.

* March 7, Samp was interviewed on Australian TV (by the Australian Broadcasting Corp.) regarding U.S. detention of Australian citizen David Hicks as an enemy combatant at Guantanamo Bay, Cuba.

2006

* October 5, Samp was interviewed on the Lou Dobbs Show in CNN regarding enactment by cities across the country (including Hazleton, Pennsylvania) of laws designed to crack down on illegal immigrants.

* October 3, WLF Chief Counsel Richard Samp participated in an on-air debate on National Public Radio’s “To the Point” program, on Bush Administration policy regarding detention of enemy combatants at Guantanamo Bay, Cuba.

* July 5, Samp was interviewed on Voice of America regarding the Supreme Court’s
decision in *Hamdan v. Rumsfeld* (which struck down the Bush Administration's plan to try alleged al Qaeda war criminals before military tribunals).

* June 29, Samp was interviewed regarding the Supreme Court's decision in *Hamdan v. Rumsfeld* by Fox News, ABC-Radio, CBS-Radio, NPR's "To the Point," Voice of America, and Court TV.

* June 21, Samp was interviewed on National Public Radio's nationally syndicated "Fresh Air" program, regarding the propriety of continued detention of "enemy combatants" at Guantanamo Bay, Cuba.

* April 4, Samp was interviewed on WBGQ-Radio in Newark, New Jersey regarding a recent court decision that held that illegal immigrants who are injured on the job are entitled to recover damages for lost wages – even though they would have had no right to continue to work in this country if they had not been injured.

* March 27, Samp participated in a debate, sponsored by the Cato Institute, against Charles Swift, the military attorney for Salim Hamdan, who faces a war crimes trial for his work as an aide to Osama bin Laden. Hamdan's challenge to the military tribunal process was being argued before the Supreme Court the next day. The debate, which was broadcast on C-SPAN, addressed whether the President has the authority to establish military tribunals to try war crimes suspects.

* March 2, Samp was interviewed on Radio Free Europe regarding U.S. immigration policy.

**2005**

* September 19, Samp was interviewed on KFI-Radio in Los Angeles regarding New York State's policy of granting in-state tuition rates to illegal aliens attending New York colleges, while denying those same rates to U.S. citizens living outside the State. Samp was interviewed on that same topic on Bloomberg Radio on October 21.

* September 19, Samp was a guest on the Kojo Nnamde Show on WAMU-Radio in Washington, D.C., discussing the U.S. military's detention of al Qaeda suspects at Guantanamo Bay, Cuba. Samp debated David Remes, a lawyer representing some of those detainees.

* August 24, Samp was interviewed on WBAL-Radio in Baltimore regarding Texas's policy of granting in-state tuition rates to illegal aliens attending Texas colleges, while denying those same rates to U.S. citizens living outside the State. WLF was interviewed on the same subject on KLBJ-Radio in Austin (Aug. 24), KTSA-Radio in
San Antonio (Aug. 24), and KLIF-Radio in Dallas (Aug. 25).

* August 12, WLF Senior Executive Counsel Paul Kamenar was interviewed on KVT National Public Radio in Austin, Texas discussing WLF's petition challenging Texas's policy of granting in-state tuition to illegal aliens attending Texas colleges while denying those same lower rates to U.S. citizens living outside of the State.

* August 9, Samp was interviewed on National Public Radio regarding a lawsuit filed against top Bush Administration officials by a suspected al Qaeda terrorist; the suspect contends that he has been tortured while in U.S. custody.

* July 18, Samp was interviewed on the Chris Core Show on WMAL-Radio in Washington, D.C. regarding the military's decision to detain Jose Padilla, an American citizen accused of plotting with al Qaeda to blow up an American city; and regarding a recent court decision upholding his detention.

* May 23, Samp was interviewed on CBS Radio regarding the Supreme Court's decision in Medellin v. Dretke, a case in which a Texas prisoner is attempting to invoke international law to overturn his death sentence.

* May 16, Samp participated in a debate in Philadelphia, broadcast nationally on National Public Radio, regarding the U.S. military's detention of enemy combatants at Guantanamo Bay, Cuba. Samp debated against Thomas Wilner, an attorney representing many of the detainees.

* April 26, Kamenar was a featured guest on the FOX News "Big Story," hosted by Judge Andrew Napolitano. Kamenar discussed Acree v. Iraq, in which WLF is representing Senator George Allen and a bipartisan group of congressmen supporting a lawsuit by ex-POWs from the Gulf War suing Iraq and Saddam Hussein for torture.

* March 28, Samp was interviewed on CNN regarding Medellin v. Dretke, a Supreme Court case in which a convicted murderer is invoking international law in an effort to avoid execution.

* March 23, Samp was interviewed by Voice of America on the case of Jose Padilla, the alleged "dirty bomber" being held by the government as an enemy combatant.

* March 3, Samp was interviewed on NBC-TV Nightly News regarding Clark v. Martinez, the case in which the Supreme Court ordered the release of Mariel Cubans who have been convicted of violent crimes but cannot be deported back to Cuba.

* January 31, Samp was interviewed on CNN regarding lawsuits filed by foreigners being held at Guantanamo Bay, Cuba as "enemy combatants." Samp was also interviewed on
January 31 by KLIF-Radio in Houston and on February 7 by KPCC-Radio in Denver on the same topic.

2004

* November 9, 2004, Samp was interviewed on Voice of America regarding Hamdan v. Rumsfeld, a challenge to the Administration’s plan to try alleged al Qaeda war criminals before military commissions.

* October 19, Samp was interviewed on KPCC-Radio in Los Angeles regarding anti-terrorism measures enacted as part of the USA PATRIOT Act.

* June 3, Samp was interviewed by Azteca America, a Spanish-language television network, regarding detention of American citizens as “enemy combatants.”

* May 25, Glenn Lammi, Chief Counsel of WLF’s Legal Studies Division, discussed energy policy and the war on terrorism on the Pat Whitely Show, WRKO, Boston.

* May 17, Samp was interviewed on Fox News regarding pending lawsuits designed to force the U.S. government to build water stations in the Arizona desert to assist illegal aliens attempting to sneak into the country. Samp was interviewed on the same subject on Fox News’ “The O’Reilly Factor” on June 9, and on WSBA-Radio in York, Pennsylvania on May 18.

* May 14, Samp was interviewed by Medill News Service (whose broadcasts are carried by numerous cable television companies) regarding the propriety of the federal government’s detention of enemy combatants.

* April 29, WLF co-sponsored a briefing in Boston with Kirkpatrick & Lockhart LLP on “Homeland Security-Venture Capital Investment and Business Opportunities.”

* April 12, Samp was interviewed on ABC-Radio regarding national security cases pending in the U.S. Supreme Court.

* March 3, Kamenar was the moderator at a seminar co-hosted by WLF, Kirkpatrick & Lockhart, and the Bureau of National Affairs (BNA) on legal and business issues involving Homeland Security. Other speakers included Joseph Whitley, General Counsel of the Department of Homeland Security; and U.S. Senator Pat Roberts, Chairman of the Senate Select Committee on Intelligence.

* February 24, Samp was interviewed on CBS Radio regarding U.S. v. Flores-Montano, a Supreme Court case that addressed constitutional limitations on the federal
government's power to inspect vehicles entering the country.

* January 26, Samp was interviewed on CBS Radio regarding *Sosa v. Alvarez-Machain*, a Supreme Court case that addressed whether individuals may sue in federal court for alleged violations of international law.

* January 7, Kamenar was interviewed by Voice of America regarding capital punishment for terrorists and the refusal to extradite suspects by European countries which oppose the death penalty.

2003

* December 18-22, Samp was interviewed on NBC-TV, ABC-Radio, NPR, and Democracy Now Radio Network on the court of appeals's decision in *Padilla v. Rumsfeld* regarding the detention of a suspected terrorist.

* September 12, Samp debated ACLU's Nadine Stroessen on CNBC on the USA PATRIOT Act and its enforcement.

* April 30, Samp appeared on CNBC's Buchanan & Press Show to discuss *Demore v. Kim*, a case that addressed the government's authority to detain alien felons pending completion of deportation proceedings.

* April 11, Samp was interviewed on CBC (Canadian television) on the *Rasul v. Bush* case involving detainees at Guantanamo Bay, Cuba.

* April 7, Kamenar debated Art Spitzer, Director of the ACLU's Washington, D.C. office, on "National Security and Civil Liberties" at a conference in Washington, D.C., sponsored by Panim el Panim for Jewish students from around the country.


2002

* December 6, Kamenar was the featured luncheon speaker before a group of 40 editorial page editors of major newspapers. The editors were attending a conference sponsored by the University of Maryland's Knight Journalism Center. The topic of the conference and Kamenar's remarks was "Civil Liberties in the Age of Terrorism."

* November 17, Samp spoke to the annual meeting of the Jewish Institute for National Security Affairs regarding WLF's efforts in the courts to defend the Bush
Administration’s war on terrorism.

* October 8, Samp spoke to a group of senior citizens visiting Washington under the auspices of the Close-Up Foundation, on legal challenges faced by the federal government in connection with the war on terrorism.

* September 12, Kamenar was a featured panelist at the Annual Symposium of the American Society of Access Professionals, an organization composed of government officials in charge of handling Freedom of Information Act requests. Kamenar discussed pending litigation involving the disclosure of the identities of aliens detained since the terrorist attack of September 11.

* August 15, Kamenar was a featured guest commentator on National Public Radio’s “All Things Considered,” discussing the ACLU lawsuit demanding the release of the names of aliens detained since September 11, 2001.

* January 16, Samp was interviewed by ABC Radio on the upcoming trial of John Walker Lindh, the accused American Taliban.

2001

* December 31, Samp was interviewed on WLAC-Radio in Nashville on the Justice Department’s plans to monitor conversations between suspected terrorists and their attorneys.

* December 21, Kamenar was a guest on CNBC television along with Newsweek reporter Michael Isakoff discussing the legal ramifications of prosecuting John Walker Lindh, the U.S. citizen captured for fighting with the Taliban.

* December 19, Kamenar was a guest on CNN television discussing the legality of military tribunals and alien detention proceedings.

* December 18, Kamenar was the featured guest on the award-winning Northern Virginia cable show “Law Weekly” hosted by noted attorney Glenn Lewis. The topic was the legality of military tribunals.

* December 17, Kamenar was the featured guest on the hour-long Tom Clark show aired by Wisconsin National Public Radio discussing the legality of anti-terrorism measures.

* December 7, Lammi discussed civil liberties and national securities issues on the “Ray Flynn Show” on WROL-Radio in Boston.
December 6, Samp appeared on C-SPAN’s “Washington Journal,” to discuss the Bush Administration’s anti-terrorism measures, as well as on National Public Radio and Fox News Channel with a leading critic of Administration policy.

November 16, Kamenar was a guest on National Public Radio along with ACLU President Nadine Stroessner and Dean Doug Kmiec of Catholic University Law School discussing the legality of military tribunals.

November 9, Samp appeared on CNN to discuss federal government plans to monitor conversations between imprisoned terrorism suspects and their attorneys. Samp was interviewed on the same subject on Talk-Radio News Service.

November 8, Samp was interviewed on WFM-Radio in Tampa regarding government detention of illegal aliens suspected of terrorism.

September 25, Lammi debated Harvard Law School’s Alan Dershowitz on civil liberties and national security on CNN’s “Talkback Live.”

III. PUBLICATIONS

WLF’s Legal Studies Division is the preeminent publisher of persuasive, expertly researched, and highly respected legal papers. WLF publishes in seven different formats, which range in length from concise LEGAL BACKGROUNDERS covering current developments affecting the American legal system, to comprehensive Monographs providing law-review-length inquiries into significant legal issues.

Since its inception fifteen years ago, WLF’s Legal Studies Division has produced a library of publications of considerable size and depth. The publications explore a wide-variety of legal topics. Since the 9/11 terrorist attacks, a significant number of WLF’s publications have focused on national security issues. Notable WLF authors on national security issues include: former Attorney General Richard Thornburgh, University of Virginia Law Professor John Norton Moore, and former Deputy Solicitor General Philip Lacovara.

Federal Judge Intrudes Upon Executive Authority To Designate Terrorist Organizations
By Andrew C. McCarthy, head of the Center for Law and Counterterrorism at the Foundation for the Defense of Democracies
LEGAL BACKGROUNDER, May 11, 2007, 4 pages

The SAFETY Act: A Vital Tool In The Fight Against Terrorism
By Joe Whitley and George Koenig, members of Alston & Bird LLP’s Global Security & Enforcement Practice Team, and Parney Albright, Managing Director with the Civitas Group.
CONTEMPORARY LEGAL NOTE, November 2006, 14 pages
By Andrew C. McCarthy, head of the Center for Law and Counterterrorism at the Foundation for The Defense Of Democracies.
LEGAL OPINION LETTER, November 3, 2006, 2 pages

Court Upholds Government’s Illegal Alien Detention Authority
By George M. Kraw, a partner in the San Jose, California law firm Kraw & Kraw.
LEGAL OPINION LETTER, August 18, 2006, 2 pages

Activist Suits Challenging Terrorist Surveillance Should Be Dismissed
By Andrew C. McCarthy, head of the Center for Law and Counterterrorism at the Foundation for the Defense of Democracies.
LEGAL BACKGROUNDER, June 2, 2006, 4 pages

Congress Enacts Substantial Liability Protections For Public Health Emergencies
By John M. Clerici, a partner with the law firm McKenna Long & Aldridge LLP in its government contracts practice and government affairs group; Frank M. Rapoport, also a partner and focuses on government contracts, information technology, federal litigation and public health law; and Douglas B. Farry, a Managing Director in the firm’s Government Affairs practice.
LEGAL OPINION LETTER, February 10, 2006, 2 pages

Hamdan v. Rumsfeld: High Court Should Uphold Executive Wartime Powers
By Andrew C. McCarthy, a Senior Fellow at the Foundation for Defense of Democracies.
LEGAL OPINION LETTER, December 16, 2005, 2 pages

Federal Role Essential For Terrorism Risk Insurance
By John T. Leonard, President and CEO of Maine Employers’ Mutual Insurance Company (MEMIC) and MEMIC Indemnity Company of New Hampshire.
LEGAL BACKGROUNDER, October 7, 2005, 4 pages

Ruling Expands Judiciary’s Role In Transfer of Terror Detainees
By Robert Chesney, Associate Professor of Law at Wake Forest University School of Law.
LEGAL BACKGROUNDER, August 26, 2005, 4 pages

Military Commissions For Terrorists On Solid Constitutional Grounds
By Bradford A. Berenson, who served as Associate Counsel to President George W. Bush from January 2001 through January 2003 and is currently a partner with the law firm Sidley Austin Brown & Wood LLP; and Christian M.L. Bonat, an associate at the firm.
LEGAL BACKGROUNDER, September 17, 2004, 4 pages
Deciding The Rules For Detainees: Wars Are Not Criminal Prosecutions
By George M. Kraw, a partner in the San Jose, California law firm Kraw & Kraw.
LEGAL OPINION LETTER, March 19, 2004, 2 pages

Foreign “War Crimes” Lawsuits Against American Soldiers Threaten National Security
By Margaret D. Stock, Assistant Professor, Department of Law, United States Military
Academy, West Point, New York.
LEGAL BACKGROUNDER, August 22, 2003, 4 pages

Courts, Military Detainees, And The War On 21st Century Terrorism
By George M. Kraw, a partner in the San Jose, California law firm Kraw & Kraw.
LEGAL OPINION LETTER, May 9, 2003, 2 pages

President Has Clear Authority To Designate Detainees As “Enemy Combatants”
By Robert L. Siriani, Jr., a Fall 2002 student in the Washington Legal Foundation’s Economic
Freedom Clinic at the George Mason University School of Law.
LEGAL BACKGROUNDER, March 2003, 4 pages

No Absolute Right To Open Deportation Hearings
By John Williams, a Fall 2002 student in the Washington Legal Foundation’s Economic
Freedom Clinic at the George Mason University School of Law.
LEGAL BACKGROUNDER, March 2003, 4 pages

Court Should Uphold Citizenship Requirement For Airport Security Screeners
By S. Alexander Fiske, a Fall 2002 student in the Washington Legal Foundation’s Economic
Freedom Clinic at the George Mason University School of Law.
LEGAL BACKGROUNDER, March 2003, 4 pages

Vaccine Liability Law Clarification Protects Lives And Resources
By Victor E. Schwartz, chairman of the Public Policy Group at the law firm Shook, Hardy &
Bacon L.L.P., and Leah Lorber, of counsel to the firm.
LEGAL BACKGROUNDER, January 10, 2003, 4 pages

Courts Must Respect President’s Authority In Times Of War
By George M. Kraw, a partner in the San Jose, California law firm Kraw & Kraw.
LEGAL OPINION LETTER, September 6, 2002, 2 pages

Chemical Risk Data Remains Dangerously Available To The Public
By Emily Cochran, Institute for Human Studies Fellow at the Washington Legal Foundation.
LEGAL BACKGROUNDER, August 23, 2002, 4 pages

Courts Must Not Meddle In Military Detainment Decisions
By George M. Kraw, a partner in the San Jose, California law firm Kraw & Kraw.
LEGAL OPINION LETTER, June 7, 2002, 2 pages
Flaws Undermine Use Of Alien Terrorist Removal Court
By Steven R. Valentine, a partner in the law firm Preston Gates Ellis & Rouvelas Meeds LLP, Washington, D.C.
LEGAL BACKGROUNDER, February 22, 2002, 4 pages

Securing Personal Information Key To Anti-Terror Efforts
By Barnaby Zall, Of Counsel to the law firm of Weinberg & Jacobs, LLP, in Rockville, Maryland.
LEGAL BACKGROUNDER, January 11, 2002, 4 pages

“Anticipatory” Self-Defense Against Terrorism Is Legal
By Lee A. Casey and David B. Rivkin, Jr., partners in the Washington, D.C. office of the law firm Baker & Hostetler.
LEGAL OPINION LETTER, December 14, 2001, 2 pages

Court Should Dismiss Activists’ Misguided Missile Defense Suit
LEGAL OPINION LETTER, December 14, 2001, 2 pages

What Role For The United Nations In Responding To Terrorism?
By The Honorable Richard Thornburgh, Counsel to the law firm Kirkpatrick & Lockhart LLP, who previously served as Under-Secretary-General of the United Nations, U.S. Attorney General, and Governor of Pennsylvania.
LEGAL BACKGROUNDER, November 6, 2001, 4 pages

Courts Should Uphold Detention Of Aliens Accused Of Terrorist Acts
By Richard A. Samp, Washington Legal Foundation’s Chief Counsel.
LEGAL OPINION LETTER, October 19, 2001, 2 pages

U.S. And International Laws Support Our War On Terrorism
By Professor John Norton Moore, Director of the Center for National Security Law at the University of Virginia and former Counselor on International Law to the Department of State.
LEGAL OPINION LETTER, October 19, 2001, 2 pages

Criminal Or Military Justice For Captured Terrorists?
By Philip Allen Lacovara, a partner with the law firm Mayer, Brown, Rowe & Maw, LLP in New York City and a former Deputy Solicitor General of the United States.
LEGAL BACKGROUNDER, October 5, 2001, 4 pages