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## THE FIGHT TO SAFEGUARD AMERICAN DRUG SAFETY IN THE TWENTY-FIRST CENTURY

*Maurice Hinchey\**

### I. INTRODUCTION

In the autumn of 2004, the United States faced a public health crisis when Merck & Co., Inc. announced a voluntary withdrawal of Vioxx (rofecoxib), a nonsteroidal anti-inflammatory drug (“NSAID”) that had first been approved by the Food and Drug Administration in May 1999.<sup>1</sup> Over 100 million prescriptions for Vioxx had been written for 20 million consumers,<sup>2</sup> and the FDA subsequently estimated that as many as 55,000 of those consumers suffered fatal heart attacks or strokes from their ingestion of Vioxx.<sup>3</sup>

In earlier decades, incidents similar to the Vioxx revelation served as the impetus for great reform to our consumer protection standards. The modern FDA was born out of such experience, first after the dispersal of Elixir Sulfanilamide across our country in September and October 1937,<sup>4</sup> and then after Europe’s thalidomide tragedy in the early 1960s.<sup>5</sup> Through such crises, the FDA evolved over the twentieth century into an agency meant to carry out two distinct but related

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1. FDA, Vioxx (rofecoxib) Questions and Answers, <http://www.fda.gov/cder/drug/infopage/vioxx/vioxxQA.htm> (last visited Mar. 20, 2007).

2. Barnaby J. Feder, *Vioxx Recall May Bring Flood of Suits to Merck*, N.Y. TIMES, Oct. 5, 2004, at C2; see also Paul Harasim, *Concerned Patients: Drug News Has Doctors in Dilemma*, LAS VEGAS REV.-J., Jan. 2, 2005, at 1B (“In September, Vioxx, an arthritis and acute pain medication taken by an estimated 80 million people worldwide, was taken off the market when studies showed it increased the risk for heart attacks and stroke.”).

3. Gardiner Harris, *F.D.A. Official Admits ‘Lapses’ on Vioxx*, N.Y. TIMES, Mar. 2, 2005, at A15.

4. Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER, June 1981, at 18, available at <http://www.fda.gov/oc/history/elixir.html>.

5. See Herbert Burkholz, *Giving Thalidomide a Second Chance*, FDA CONSUMER, Sept.-Oct. 1997, available at [http://www.fda.gov/fdac/features/1997/697\\_thal.html](http://www.fda.gov/fdac/features/1997/697_thal.html).

healthcare goals on behalf of the American people: to approve new drugs, biologics and medical devices, and then to oversee the safe use of these products within the marketplace.

The Vioxx crisis, the resulting investigations, and the ensuing lawsuits—14,000 of which remain outstanding in state and federal courts<sup>6</sup>—strongly underscored a number of deficiencies within the FDA’s review and monitoring systems. Recent polls have shown that the agency has lost the public trust as well as the confidence of its employees.<sup>7</sup> Therefore, one certainly might have anticipated another wave of reform in the wake of the Vioxx incident.

## II. THE FDA: PROBLEMS AND A PROPOSED SOLUTION

As a member of the House Appropriations Subcommittee which has oversight of the FDA, I have come to believe that this agency is broken and must be fixed as soon as possible. That is why I introduced legislation, the FDA Improvement Act of 2005,<sup>8</sup> to address many of the regulatory and leadership problems that trouble our current drug approval and safety oversight activities.

The vast majority of these problems can be traced back to one single, undeniable issue: The pharmaceutical industry has supplanted the American people as the FDA’s primary client and number one concern. Until we are able to reestablish the consumer as the number one priority for the FDA, our nation’s public health will remain at risk and the credibility of this once great institution will continue to decline.

The instigation of much of the current failures of the FDA is the Prescription Drug User Fee Act (“PDUFA”), which was enacted and signed into law in 1992.<sup>9</sup> Called “the cornerstone of modern FDA drug review,”<sup>10</sup> the statute was created to reduce the FDA’s drug application

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6. See Alex Berenson, *Legal Stance May Pay off For Merck*, N.Y. TIMES, Aug. 4, 2006, at C1.

7. See Harris Interactive, *The FDA’s Reputation with the General Public is Under Assault* (May 26, 2006), <http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=1060>; see also Union of Concerned Scientists, *Summary of the FDA Scientist Survey*, [http://www.ucsusa.org/scientific\\_integrity/interference/fda-scientists-survey-summary.html](http://www.ucsusa.org/scientific_integrity/interference/fda-scientists-survey-summary.html) (last visited Mar. 20, 2007).

8. FDA Improvement Act of 2005, H.R. 2090, 109th Cong. (1998).

9. Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (codified as amended at 21 U.S.C. § 379g note (2000)).

10. See FOOD & DRUG ADMIN., WHITE PAPER PRESCRIPTION DRUG USER FEE ACT (PDUFA): ADDING RESOURCES AND IMPROVING PERFORMANCE IN FDA REVIEW OF NEW DRUG APPLICATIONS 1, available at <http://www.fda.gov/oc/pdufa/PDUFAWhitePaper.pdf> (last visited Mar. 20, 2007).

review times by charging petitioners application, marketing, and establishment fees in return for an expedited review and approval process. Unfortunately, over the fifteen years of its existence, PDUFA has become one of the main sources of the hostile takeover of the FDA by the drug companies.

The conditions of the expedited drug approval process under PDUFA have become more onerous with each reauthorization of this legislation.<sup>11</sup> At the same time, since fiscal year 2004, the agency has relied upon these fees to cover about fifty-three percent of all funds expended on the review of human drug applications.<sup>12</sup> This percentage has been steadily increasing since the first enactment of PDUFA in 1992, creating a strong financial dependency of the FDA on the companies it is supposed to oversee and regulate.

This financial dependency, along with the FDA's constant negotiations with companies over how to spend the fees, became the foundation for the cozy relationship that exists today between the FDA and the pharmaceutical industry. PDUFA's 2007 reauthorization should include substantive reforms to sever the inappropriate behavior engendered by this statute. My FDA Improvement Act cuts the direct financial link between the FDA and the drug industry by prohibiting the FDA from collecting fees directly from companies. Instead, the bill redirects those fees to the general fund of the U.S. Treasury and creates mandatory funding levels to cover the cost of the FDA functions now paid by drug companies. It also prohibits the FDA from negotiating with drug companies over the agency's budget and ends such previous agreements between the FDA and those companies.

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11. PDUFA I (in effect from 1992-1997) required the FDA to use fees to turn around drug applications quickly, completing priority reviews in six months and standard reviews in twelve months. The legislation also required the FDA to complete manufacturing supplement reviews and resubmitted applications within six months. PDUFA II (in effect from 1997-2002) upgraded the timeline for the FDA to complete standard drug reviews to ten months, manufacturing supplement reviews to four months, and certain resubmitted applications to two months. PDUFA II also instituted new standards for responses to industry requests for meetings and resolutions of disputes appealed by industry, among other items. PDUFA III (in effect from 2002-2007) continues all of the standards outlined in PDUFA I and upgraded in PDUFA II, and adds requirements that the FDA will issue discipline review letters, report substantive deficiencies in New Drug Applications, and complete reviews of efficacy supplements within certain periods of time, while also enhancing electronic applications receipts and reviews by the end of fiscal year 2007. *See* FOOD & DRUG ADMIN., PDUFA III FIVE-YEAR PLAN (July 2003), available at <http://www.fda.gov/oc/pdufa3/2003plan/default.htm>. *See also* Notice of Public Meeting, Prescription Drug User Fee Act, 72 Fed. Reg. 1743, 1743-45 (Jan. 16, 2007).

12. *See* FOOD & DRUG ADMIN., FY 2004 PDUFA FINANCIAL REPORT, available at <http://www.fda.gov/oc/pdufa/finreport2004/report.html> (last visited Mar. 20, 2007).

My legislation also takes significant steps to strengthen the FDA's efforts to protect consumers once approved drugs have reached the market. Unfortunately, while the agency currently spends the vast majority of its PDUFA funds on pre-market activities, and has great authority to oversee these approval efforts, the agency has only spent about five percent of its PDUFA fees on postmarket initiatives.<sup>13</sup>

Furthermore, the agency has minimal authority to conduct follow-up activities on drugs once they have been approved. Unlike its abilities on the drug approval front, the FDA's options on the drug safety front are reduced to pleading for small changes—such as trying to convince pharmaceutical companies to behave correctly regarding required postmarket studies, drug labeling, and safety warnings—and is only able to enforce one major change: declaring a drug misbranded and yanking it from the market—an action that is rarely used.

Here is one example of the FDA's impotence on the post-market front: As of September 30, 2005, there were 1231 incomplete postmarketing studies that had been requested by the FDA upon drug approval. Sixty-five percent of those studies had not been started yet, and were thus classified as pending.<sup>14</sup> Aside from those matters focusing on drugs whose approval processes have been accelerated, while it may request as much postmarket analysis as it deems appropriate, the FDA has no authority to force these studies to completion. The significant amount of direct financial support that the agency receives from the companies it is trying to monitor also interferes with this process.

To make matters worse, responsibility for postmarket drug safety is managed by the Center for Drug Evaluation and Research ("CDER"), the same Center that carries out the initial approval of new drugs. Earlier this year CDER reorganized its drug safety activities for the fifth time in a decade, creating an Associate Director for Safety Policy and Communications, in an alleged attempt to strengthen the postmarket position within the FDA. This effort seems to have little or no value, especially since under this arrangement, the well-documented<sup>15</sup> friction

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13. See U.S. GOV'T ACCOUNTABILITY OFFICE, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 7-8 (2006) (explaining that while "[i]n fiscal year 2005, more than half of OND's expenditures, or \$57.2 million, came from PDUFA funds," only "\$7.6 million of ODS's expenditures were from PDUFA funds").

14. Notice of Availability, Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies, 71 Fed. Reg. 10,978, 10,979 (Mar. 3, 2006).

15. See U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 13, at 4-6, 18-24; see also COMM. ON THE ASSESSMENT OF THE U.S. DRUG SAFETY SYS. AND BD. ON POPULATION HEALTH & PUB. HEALTH PRACTICE, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC, at 3-2 (Alina Baciu et al. eds., 2006).

between staff responsible for new drugs and those responsible for postmarket drug safety continues to scrape together. This friction appears to be a long-standing internal problem borne out of the aforementioned discrepancies in funding and authority.

The FDA Improvement Act would create an independent Center for Drug Safety and Effectiveness. The Center would be within the FDA, but the Secretary of the Department of Health and Human Services would appoint its director. Different doctors and scientists than the ones who approve a drug would monitor its safety once it hit the market. The Center would also be given increased funding and authority to strengthen the FDA's post-market regulatory functions. Additionally, the FDA Improvement Act would empower the FDA and the new Center with the authority to force companies to actually carry out post-marketing studies of FDA-approved drugs, mandate changes to drug labels, impose civil penalties, require patient and doctor education programs, and release to the public critical information about drug safety and effectiveness.

While the FDA Improvement Act would do much to address the structural problems that have been plaguing the FDA's efforts to guarantee drug safety, it is important to note that even this solution will be imperfect absent true executive reform at the agency. There has been no permanent commissioner at the FDA during much of the Bush Administration. Meanwhile, many of those in appointed leadership positions at the agency appear to be twisting its efforts for their professional—and even personal—gain. A prime example of this travesty can be found in the efforts of Daniel Troy, the FDA's Chief Counsel from 2001 to 2004.

During his time at the agency, Mr. Troy wasted taxpayer money on ideological pursuits that undermined the FDA's basic missions. For the first time in history, the FDA's Chief Counsel actively sought out private industrial company lawyers to bring him cases in which the FDA could intervene in support of drug and medical device manufacturers.<sup>16</sup> The cases he pursued were private state civil litigation cases. These are cases in which the court did not ask for FDA opinion, involving drug and medical device manufacturers who were being sued by people

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16. Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 589 n.5 (2005).

harmful by their products.<sup>17</sup> During his time at the FDA, Mr. Troy set a new and terrible precedent that is still being pursued, albeit not as actively, by the agency.

### III. CONCLUSION

The FDA Improvement Act would allow the public to hold drug companies accountable by reversing the preemption policy employed by the FDA since 2001 and restoring the policy used by the FDA for the previous quarter-century. This would ensure that individual state consumer protections, and other methods through which states hold companies legally liable, are not preempted by FDA regulations unless there is a clear and direct conflict between an FDA regulation and a state regulation.

For the purposes of public protection, the FDA is one of the most important agencies of the federal government. Unfortunately, the agency's struggles with regulatory and statutory obstacles are keeping it from effectively executing its mandate. The FDA Improvement Act would do much to address these difficulties, and restore the FDA to its rightful position as defender of the public health.

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17. Richard C. Ausness, "After You, My Dear Alphonse!": Should the Courts Defer to the FDA's New Interpretation of § 360k(a) of the Medical Device Amendments?, 80 TUL. L. REV. 727, 755-58 (2006).