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Vioxx Scandal Sparks Criticism of the FDA

The Food and Drug Administration (“FDA”) is supposed to protect consumers from pharmaceutical companies that might otherwise be tempted to market unsafe drugs. But it was Merck & Co. (“Merck”), and not the FDA, who took Vioxx, its blockbuster arthritis medication,¹⁰³ off the market on September 30th after studies showed that the drug was linked to between 88,000 and 139,000 heart attacks, of which up to forty percent were fatal.¹⁰⁴

A Merck memo uncovered in November showed that Merck scientists were aware in 1996 that the drug might contribute to heart problems.¹⁰⁵ Then in 2000, a Merck study found that patients taking Vioxx were twice as likely to suffer heart attacks as patients taking older painkillers.¹⁰⁶ Meanwhile, mid-level FDA officials who warned of these dangers were shunned by the agency.¹⁰⁷ In FDA parlance, those with a “point of view” on Vioxx were unwelcome in certain meetings concerning the drug.¹⁰⁸

Dr. David Graham, an FDA scientist, testified before a Senate Finance Committee on November 18th, that his superiors pressured him to change his negative findings about the drug.¹⁰⁹ Graham, a 20-year FDA employee, described the FDA as incapable of keeping unsafe drugs off the market because of its cozy relationship with the

¹⁰³ John Carey, Amy Barrett, & Carol Marie Cropper, *Lessons from the Vioxx Fiasco*, BUSINESSWEEK, Nov. 29, 2004, at 42 (“How could a drug get to \$2.5 billion in annual sales despite evidence that it caused heart problems?”).

¹⁰⁴ *An Ailing, Failing FDA*, L.A. TIMES, Nov. 23, 2004, at B10.

¹⁰⁵ *Id.*

¹⁰⁶ Carey, *supra* note 103. Sadly, Vioxx’s primary benefit over older medicines was realized by only the small percentage of patients who would have experienced stomach bleeding on the older medicines. *Id.*

¹⁰⁷ *An Ailing, Failing FDA*, L.A. TIMES, Nov. 23, 2004, at B10.

¹⁰⁸ *Id.* At least one commentator compares the situation to that of the CIA officials who questioned evidence that Iraq possessed weapons of mass destruction were shunned during the run-up to the Iraq war. *Id.*

¹⁰⁹ Ricardo Alonso-Zaldivar, *FDA Scientist Says He Faces Retaliation*, L.A. TIMES, Nov. 25, 2004, at 26.

pharmaceutical industry.¹¹⁰ “The scientific standards [the FDA] applies to drug safety guarantee that unsafe and deadly drugs will remain on the U.S. market.”¹¹¹ According to Graham’s testimony, the FDA considers a drug safe until its reviewers conclude otherwise with ninety-five percent certainty.¹¹² The FDA, he added, “overvalues the benefits of the drugs it approves and seriously undervalues, disregards and disrespects drug safety”¹¹³

Graham specifically expressed concern about the safety of five other drugs currently on the market—namely, Accutane, Bextra, Crestor, Meridia, and Serevent.¹¹⁴ Predictably, the FDA responded that Graham’s views do not “reflect the views of the agency.”¹¹⁵ However, the FDA did announce that the agency is taking steps to reduce risks associated with Accutane and Bextra.¹¹⁶ Meanwhile, Public Citizen’s Health Research Group has written to the FDA twice this year calling for the removal of Crestor (an aggressively marketed cholesterol reducer) from the market because of a high-risk of kidney problems associated with the drug.¹¹⁷ European regulators have also expressed concern with Crestor.¹¹⁸

Graham also criticized the FDA’s organizational structure as

¹¹⁰ *Id.* Specifically, Graham described the FDA as “feckless and far too likely to surrender to demands of drug makers.” *Politics & Policy Vioxx: FDA Official Says Agency Cannot Protect U.S. Residents*, American Political Network, Nov. 19, 2004.

¹¹¹ *Politics & Policy Vioxx: FDA Official Says Agency Cannot Protect U.S. Residents*, American Political Network, Nov. 19, 2004.

¹¹² *Id.*

¹¹³ *Id.* It will be interesting to see if the FDA’s perceived inability to monitor drugs in the U.S. market will undermine arguments against the importation of less expensive Canadian drugs on safety grounds. See Debra Rosenberg, Health for Life, *NEWSWEEK*, Dec. 6, 2004, at 72 (observing that the White House has relied on the need for the FDA to ensure drug safety as its justification for resisting the importation Canadian drugs).

¹¹⁴ Ricardo Alonso-Zaldivar, *FDA, Drug Companies Deny Oversight Flaws*, *L.A. TIMES*, Nov. 20, 2004, at A1.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*; see also Press Release, Public Citizen, *FDA Knew of Crestor Dangers but Approved Drug Anyway*, (June 24, 2004) available at <http://www.citizen.org/pressroom> (last visited Dec. 13, 2004).

¹¹⁸ Alonso-Zaldivar, *supra* note 109.

part of the problem.¹¹⁹ Oddly, it is the FDA's Office of New Drugs which was responsible for monitoring the safety of Vioxx, the same office that was responsible for approving the drug in the first place.¹²⁰ In the wake of so many thousands of deaths, consumers are left wondering why the FDA would build-in such a conflict of interest into its organizational structure.¹²¹ Finance Committee Chair Chuck Grassley (R-Iowa) suggested that he would introduce legislation to correct this situation.¹²² "It doesn't make any sense from an accountability standpoint to have the office that reviews the safety of drugs that are already on the market to be under the thumb of the office that put the drugs on the market in the first place."¹²³ Since Graham's testimony, the editors of the Journal of the American Medical Association have called for a new board, independent of the FDA, to monitor the safety of drugs after they are in the market.¹²⁴

While there is a necessary balancing that must take place between getting drugs to patients in a timely manner and testing the drugs long enough to ensure safety, there is simply no justification for lax post-marketing oversight of approved drugs.¹²⁵ The FDA

¹¹⁹ *Politics & Policy Vioxx: FDA Official Says Agency Cannot Protect U.S. Residents*, American Political Network Nov. 19, 2004. In the wake of Graham's testimony reports have begun to surface that the FDA is pressuring him to transfer to another department within the FDA, one where he would not be doing drug research at all. Ricardo Alonso-Zaldivar, *FDA Scientist Says He Faces Retaliation*, L.A. TIMES, Nov. 25, 2004, at A26. Graham characterized the move as "a reprisal." *Id.* Graham's trouble with his superiors at that FDA appears to go back to this summer when he attempted to present his findings that there were potential problems with Vioxx. *Id.* The FDA blamed Graham for the conflict saying that he failed to follow agency procedure in submitting his findings for publication. *Id.* Graham's former co-worker, Dr. Paul Stolley, says of Graham, "[W]hen there are attempts to intimidate him, he resists. But he is not a bomb thrower. He is a good citizen and a steady guy." *Id.*

¹²⁰ *Politics & Policy Vioxx: FDA Official Says Agency Cannot Protect U.S. Residents*, American Political Network, Nov. 19, 2004.

¹²¹ *An Ailing, Failing FDA*, L.A. TIMES, Nov. 23, 2004, at B10.

¹²² *Politics & Policy Vioxx: FDA Official Says Agency Cannot Protect U.S. Residents*, American Political Network, Nov. 19, 2004.

¹²³ *Id.*

¹²⁴ Ricardo Alonso-Zaldivar, *When New Drugs Go Wrong: Role of the FDA Debated*, L.A. TIMES, Nov. 26, 2006, at A38.

¹²⁵ See John Carey, *How to Prevent Another Vioxx*, BUSINESSWEEK, Dec. 13, 2004, at 42 (noting that "it is very difficult to pick up infrequent effects" during pre-approval testing).

could require doctors' reports whenever patients appear to have been harmed by a drug. Presently, doctors' reports are "voluntary and haphazard" making comprehensive analysis of a drug's effects virtually impossible.¹²⁶ One wonders if the drug industry's tolerance for incomplete data is reflective of an industry preference for marketing drugs based profitability rather than effects.¹²⁷ Surely, drug companies would not be so tolerant of incomplete financial data on their drugs. Furthermore, incomplete data on harmful drugs would seem to make it more difficult for plaintiffs to prevail against drug makers in court.

While the examination of the FDA continues, consumers of new drugs will have no choice but to depend on the agency and the drug companies themselves (and their fear of litigation) to monitor drugs on the U.S. market. "To a real degree, the people who get the drug in the first few years after its approval are being experimented on," according to Dr. Brian L. Strom, a professor of biostatistics and epidemiology at the University of Pennsylvania.¹²⁸ Consequently, some doctors recommend that consumers avoid taking newer drugs in favor of older, cheaper medicines.¹²⁹ At the very least, consumers should seek out doctors who actively keep up with the latest drug research.¹³⁰ Studies show that even when the FDA does issue adequate warnings about negative effects of a particular drug many doctors fail to pay attention.¹³¹ Finally, consumers must keep in mind that drugs are always a double-edged sword.¹³² Even after extensive use all the side effects of drugs are not known.¹³³

¹²⁶ Carey, *supra* note 125, at 42.

¹²⁷ See *Regulators Protect Dollars, Not People*, L.A. TIMES, Nov. 26, 2004 ("The Vioxx scandal further underscores the imbalance of corporate power in our society . . . Unrelentingly a friend of big business, President Bush sneers when he says the words 'trial lawyer.' But given the cronyism and impotence of our government agencies, who is safeguarding the public? If Bush wants to put trial lawyers out of work, he should encourage regulatory agencies to protect us instead of the bottom line.").

¹²⁸ Alonso-Zaldiver, *supra* note 124.

¹²⁹ Carey, *supra* note 125.

¹³⁰ *Id.*

¹³¹ *Id.* (observing that in the 1990's the FDA repeatedly warned of doctors of potentially fatal liver problems associated with Rezulin, yet doctors tested fewer than five percent of patients as instructed).

¹³² *Id.*

¹³³ *Id.*