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New CPR Report: Vioxx Disaster a Product of Hollowing Out of FDA

Steinzor: 'Tens of thousands of Americans suffered heart attacks or strokes not just because Merck hid data, but because FDA's structure severely compromises the kinds of post-approval monitoring that would have identified the problem much earlier.'

Washington, DC – A new report from the Center for Progressive Reform blames the FDA's failure to prevent tens of thousands of Vioxx-induced strokes and heart attacks on the agency's inability to monitor the safety of drugs after they are on the market. Report authors Rena Steinzor and Margaret Clune write that the agency's priorities have been dangerously slanted toward fast-tracking new drugs at the expense of ongoing monitoring of newly approved drugs. The result, according to an FDA official quoted in the report, is that "FDA, as currently configured, is incapable of protecting Americans against another Vioxx. We are virtually defenseless."

"When it comes to monitoring the safety of the drugs it has approved for sale," Steinzor said in releasing the report, "FDA is a hollow shell. Americans rightly expect FDA to protect them from drugs with deadly side effects, and that requires pre-approval screening and post-approval monitoring. But in its eagerness to help drug companies get products to market, FDA is paying far too little attention to the critical task of monitoring drugs in widespread use. That's why Merck got away with hiding the dangers of Vioxx for so long, and why an estimated 88,000 to 139,000 Americans suffered heart attacks or strokes from taking the drug."

The report, "The Hidden Lesson of the Vioxx Fiasco: Reviving a Hollow FDA," available on CPR's website (http://www.progressivereform.org/articles/Vioxx_514.pdf), was released on the eve of jury deliberations in the second of thousands of lawsuits against Merck. It cites two critical factors in FDA's under-emphasis on post-approval monitoring – a 1992 law intended to speed approval drugs, and budget shortfalls. The authors write that the Prescription Drug User Fee Act of 1992 (PDUFA), which was intended to speed the approval of new drugs, created a new funding stream for FDA – a user fee on pharmaceutical companies applying for drug approvals. By law, FDA could only use those funds to research new approvals.

But as Congress cut the agency's budget in the years since, those fees became a larger share of the relevant FDA budget; to the point that post-approval monitoring is now an afterthought. Steinzor and Clune write,

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> These PDUFA restrictions, combined with lagging congressional appropriations, meant that in the years that followed, FDA was forced to cut appropriated funds from other uses in order to keep its budget of appropriated funds for new drug reviews high enough to be able to spend the user fees. Activities that supported post-market drug safety monitoring were among those sacrificed to keep enough money flowing into new drug reviews.
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> Specifically, in 1992, the year the law was passed, FDA's Center for Drug Evaluation and Research spent about 53 percent of its budget on new drug reviews. By 2002, the amount of CDER's budget devoted to reviewing new drug applications had increased by nearly half -- to 74 percent. In that same year the Office of Drug Safety, which is part of CDER and responsible for monitoring the safety of drugs once they are on the market, comprised only six percent of CDER's budget.

As a result, the agency is increasingly reliant on drug companies to detect and report safety risks for their products on the market – a system that failed famously and disastrously in the case of Vioxx. But the systemic problem goes beyond Vioxx, the authors write. "As of 2005," the report says, "FDA reported that of the nearly 1,200 post-market safety studies that drug companies committed to perform, nearly 70 percent have not yet begun. Moreover, companies' financial stakes in the continued sale of approved drugs pose a serious conflict of interest in decisions of whether and when to withdraw products that prove dangerous once on the market."

The authors call on Congress to take a number of steps to fix FDA's problems, including:

- Reforming current FDA performance goals that skew the agency's focus toward pre-market approval at the expense of post-approval monitoring;
- Authorizing FDA to impose substantial civil monetary penalties on companies that fail to follow through on commitments to conduct post-market safety studies;
- Authorizing FDA to demand, not negotiate, revised product labeling when new safety risks emerge after a drug is on the market; and
- Providing FDA with the funds and the mandate to evaluate whether warnings concerning drug safety risks are achieving their intended effect.

Rena Steinzor is a board member of the Center for Progressive Reform and a professor at the University of Maryland School of Law. Margaret Clune is a lawyer and Policy Analyst for CPR. The Center for Progressive Reform is a nonprofit research and educational organization dedicated to protecting health, safety, and the environment through analysis and commentary. For more information, contact Matthew Freeman at 301-762-8980 or at mfreeman@progressivereform.org. Visit CPR on the web at www.progressiverform.org.

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