Consumers Union
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Consumers Union PRESCRIPTION FOR CHANGE

STATE-BASED MANDATES REQUIRING REGISTRY AND REPORTING OF CLINICAL TRIALS AND RESULTS

Overview:

Currently, drug companies conduct clinical trials but may not release the final results to physicians and the public if the results do not reflect favorably on their product. The widely-reported problems of Vioxx and antidepressants in children are just two of several examples of this problem. Physicians and consumers deserve full and complete information about prescription drugs.

The Problem:

Drug companies now sponsor more clinical trials than the government but are free to publicize only the positive findings in medical journals. [1] "Six months after the drug industry vowed to make its clinical trials more transparent, and three months after launching a common website to give the public "unprecedented access" to studies both good and bad, drug companies have posted unpublished trial results on the site for just five drugs."[2]

Non-Steroidal Anti-Inflammatory Drugs (NSAIDS): In 2004, Vioxx was withdrawn from the market based on a study showing that Vioxx increased heart attack risk. It appears that Merck was aware of the cardiovascular risk as early as 2000.[3] While Merck has posted some previously unpublished clinical trial data Merck did not publish results from a significant Vioxx trial from 2000 indicating these risks because PhRMA voluntary guidelines only call for posting data completed after October 2002.[4]

Since 1999, when it was approved, until it was withdrawn in 2004, Vioxx had been taken more than 80 million people worldwide. In the US, it is estimated that between 88,000 and 140,000 more cases of "serious coronary heart disease" have resulted from the use of Vioxx.[5]

Antidepressants: Pfizer conducted two clinical trials from 1999-2001 to test Zoloft on depressed children. Zoloft did not perform well and the FDA did not approve Zoloft for treating

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[1] Deardorf, Julie. "Medication should be cheaper, sure—but it also should work." Chicago Tribune. September 5, 2004.
[2] Rowland, Christopher. "Drug firms lagging on openness despite vow, few studies publicized." Boston Globe. January 9, 2005.
[3] Horton, Richard. 'Vioxx, the implosion of Merck, and aftershocks at the FDA." The Lancet. November 5, 2004.
[4] Rowland, Christopher. January 9, 2005.
[5] Maxwell, Simon and David J. Webb. "COX-2 selective inhibitors – important lessons learned." The Lancet, January 25, 2004.

depression in children. Yet Pfizer did not disclose the results from these tests. The FDA also did not disclose its conclusion deeming the studies "proprietary."[6]

In June 2004, the New York State Attorney General filed suit against GlaxoSmithKline alleging fraudulent marketing. GSK had studied the effects of Paxil in adolescents and learned that children and adolescents taking Paxil were "twice as likely to show behaviors that may be associated with suicide than children on sugar pills." At the same time GSK's detailers were telling doctors and health care professionals that Paxil worked well in children. Since the studies were unpublished, there was no way for health care providers to learn the truth. The FDA knew, but again, it did not act because the data it had from GSK was considered proprietary.[7]

Diabetes medication: In early trials of Rezulin, Parke-Davis learned of "important liver damage" but did not disclose that information to FDA prior to approval. Subsequent to approval, Parke-Davis provided FDA with more details about those prior trials, but since it had already been approved, the information was not widely distributed. Rezulin stayed on the market and despite continued reports of post-marketing adverse effects, Rezulin continued to be sold in the US until 2000.[8]

After just three years on the market in the US, Rezulin was withdrawn from sale in the US in March 2000. The UK withdrew the drug in December 1997, after being on the market for just three months. Unfortunately, it was withdrawn too late in the US for the more than 66 individuals who died as a result of acute liver failure.[9]

The solution:

States can and should require that the results from clinical trials be available to the public, physicians, and researchers. States spend billions of dollars every year to provide prescription drugs for their residents – and have a responsibility to be sure those drugs are safe and that the state is spending its money wisely. The state of Maine recently adopted a requirement that drug companies post information from their clinical trials, and other states should follow suit.

We propose state legislation, based on the Maine model. The bill would require that drug companies provide information about their clinical trials and make it available on a publicly accessible web site, like the federal government's public registry (http://www.clinicaltrials.gov/). Such a bill would be a big step forward in making clinical trial results available to physicians and consumers.

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[6] Prakash, Snigdha. "Lawmakers grill drug companies and find many are not disclosing enough information on anti-depressants." NPR's Morning Edition. September 10, 2004.
[7] Prakash, Snigdha. "Drug giant GlaxoSmithKline being sued by New York for suppressing studies showing their drug may not be effective in children and might increase their risk of suicide." National Public Radio, June 11, 2004.
[8] Avorn, Jerry, MD. Excerpt of "Chapter 4: Too Sweet To Be True." Powerful Medicines. 2004.
[9] Avorn, Jerry, MD. 2004.