

Fact Sheet for *Side Effects: A Best-Selling Drug on Trial*:

- The use of antidepressants among children and adolescents in the U.S. tripled between 1994 and 2002, to the point where antidepressant drugs were being prescribed more frequently than acne products or eye drops for those under 18.
- In 2002 alone, nearly 11 million antidepressant prescriptions were written for children and adolescents in the U.S. and 2.7 million of those prescriptions were for children under 12. Antidepressant prescriptions continued to increase steadily in 2003 and 2004.
- By 2004, worldwide sales of antidepressants reached \$20 billion, making them among the world's best-selling drugs, according to IMS Health, a pharmaceutical and consulting company.
- Pediatric prescriptions for Paxil doubled between 1998 and 2002 even though there was no evidence the drug performed any better than sugar pills in treating depression in children and adolescents.
- Paxil became the best-selling antidepressant in the world in 2002, with sales of \$3.3 billion worldwide. Approximately 2.1 million prescriptions for Paxil were written for children and adolescents in the U.S. that year. Those pediatric prescriptions translated into \$55 million in sales for Paxil's maker, GlaxoSmithKline.
- Critics say that because of the amount of money in user fees the FDA collects from the drug industry, the nation's premier health agency is beholden to the industry it is supposed to regulate. In 1993, the pharmaceutical industry's \$8.9 million in user-fee money accounted for just 7 percent of the FDA's drug-review budget. By 2004, the industry's allocation of \$232 million in user fees represented more than 53 percent of the agency's entire drug-review budget. User fees have continued to climb: drug industry fees to the FDA are projected to be \$393 million for fiscal year 2008, an increase of \$87 million over the previous year.
- At the same time the FDA has been spending an increasing proportion of its budget on new drug reviews instead of other activities such as monitoring the safety of already approved drugs. In 1992, for example, the agency's drug center spent just over 50 percent of its budget on new drug reviews. In 2003, 79 percent of the agency's drug center budget went to new drug reviews, with the result that less resources were available for drug safety monitoring.
- According to a survey by Health and Human Services Department Inspector General in 2003, some 66 percent of FDA drug reviewers were "not at all" or only "somewhat" confident the agency adequately monitors approved drugs' safety.
- Of the 13 drugs withdrawn from the market due to health risks since 1997, at least seven are now known to have been approved over the objections of FDA safety reviewers.

- Between 1998 and 2006, the drug companies spent a total of \$1.2 billion on lobbying and political contributions in the U.S, according to the Center for Responsive Politics, a nonprofit nonpartisan research group that tracks money in politics. In 2002, the pharmaceutical industry ranked 7th in the amount of money it spent on lobbying members of Congress and others.
- Financial ties between the drug industry and medical researchers are widespread. Nine out of ten respondents in a survey of leading medical experts (who had participated in writing national guidelines for the treatment of depression and other health problems) admitted they had some type of financial relationship with a drug company. Six out of ten acknowledged they had financial ties to companies whose drugs were recommended in the guidelines they crafted, according to a University of Toronto study.
- Doctors with such financial conflicts of interest are more likely to prescribe newer and more expensive drugs than doctors who don't have such conflicts, according to recent studies.
- Researchers with financial ties to the drug industry are also 10 to 20 times **less** likely to present negative research findings than those without such financial conflicts, according to another study by the Social Policy Research Institute in Illinois.

Side Effects: A Bestselling Drug on Trial

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