Save Our Turnpike
Toxics-free New Jersey
Campaign For Safe Drugs
Prevent Identity Theft
Stop Exelon's Energy Takeover
Close Oyster Creek
Affordable Energy
Energy Efficient NJ
Cable Choice
Federal Scorecard
State Scorecards
Find Your Legislators
NJPIRG Student Chapters
NJ Community Water Watch
Other State PIRGs
Web Resources
Register To Vote
NJPIRG's Mission
NJPIRG Law & Policy Center
Our Staff

NJPIRG Reports

Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients At Risk

May 2006

Executive Summary | **News Release**

Download the full report. (1.53 MB, PDF)

Executive Summary

False and misleading prescription drug advertising is common and dangerous. Prescription drug marketers are inundating doctors, and to a lesser extent, the public, with marketing that misrepresents risks, promotes unproven uses, and makes unsubstantiated claims. The false and misleading messages are communicated through conventional advertising, sales representatives, doctors speaking on behalf of drug marketers, and through clinical trial suppression, manipulation and misrepresentation. Sadly, the Food and Drug Administration (FDA) is ineffective at addressing the problems. This report takes a comprehensive look at all of these facets of the prescription drug marketing problem and suggests effective solutions.

FINDINGS IN BRIEF
We looked at enforcement letters FDA sent to drug marketers from 2001-2005. Our research reveals:

Deceptive drug marketing is pervasive, dangerous, and primarily aimed at doctors.

? From 2001-2005, 85 companies received 170 notices from the FDA explaining that the marketing for 150 different drugs was false and/or misleading.

? 62% of the false or misleading messages targeted doctors, and those messages were expressed by 38 different types of advertising. By contrast, the public was exposed to 17 different types of false or misleading ads.

Newsletters

Annual Reports

? The false messages were serious: 35% misrepresented risk; 22% promoted unproven uses; and 38% made unsupported or misleading claims. For deceptive messages targeting doctors, 37% misrepresented risk; 24% promoted unproven uses; and 36% made unsupported or misleading claims.

Recidivism is rampant.

? 28 companies?approximately 1/3 of the total? received more than one letter declaring their ads false or misleading in the five years we examined. In fact, these companies accounted for two-thirds of all the letters received.

? 26 companies received more than one letter relating to advertising for the same drug that was deemed false or misleading in the same way.

Deceptive marketing includes sales representatives.

? Sales representatives, as a group, form long and deep relationships with doctors, beginning in medical school. Research suggests those early relationships increase doctors? receptiveness to sales representatives once they are in practice.

? Perhaps reflecting those relationships, other research has shown that sales representatives have a profound influence on prescribing decisions.

? Sales representative statements accounted for 30 of the 869 deceptive messages in the FDA letters, an amount that is enormous given the very small percentage chance that the FDA will detect such statements. Other research suggests that as much as 11% of sales representative statements are false and favorable to the product they pitch.

Deceptive marketing includes clinical trials.

? In the letters identifying advertising as false or misleading because it contained unsupported claims, FDA highlighted at least 82 times that the advertising cited clinical trials for propositions they did not support. In some instances, the cited trials even contradicted the claims.

? Drug marketers turn clinical trials into marketing tools by suppressing some unfavorable data; by using PR firms to write favorable reports (the PR firm does not appear as an author of the report, instead a doctor is retained to be the named author); by misrepresenting unfavorable data that is published; and, most subtly, by designing studies to get only the results they want.

Our numbers dramatically understate the problem.
The FDA letters we examined do not address anywhere near the full universe of prescription drug marketing.

? The FDA routinely reviews only ?classic? advertising and does not comprehensively monitor sales representatives, doctors acting as pitchmen, or clinical trial data manipulation. Moreover, the FDA?s review of classic advertising is not complete; not all ads are submitted to it, and of those that are, the FDA only reviews some.

? The FDA letters rarely identify how many times, or where, an ad was used. A deceptive print ad may have run in several newspapers and magazines. Each of those print runs would be another dissemination of the deceptive messages in the ads.

? The FDA reviews advertising after it has been disseminated and only requires corrective measures a quarter of the time.

? The best measure is how many people internalized the deceptive measure, an impossible figure to determine. The 869 disseminations of deceptive messages that we were able to count from 2001- 2005 included TV ads, print ads, and other mass media. How many people are deceived by a single deceptive TV ad watched by a million viewers? Similarly, a single sales representative may convey deceptive messages to hundreds or thousands of doctors in a year.

RECOMMENDATIONS
States Can Solve the Problem

? To address the scientific misconduct that is the suppression, manipulation and misrepresentation of clinical trial data, states should establish a comprehensive, searchable database of clinical trials. Drug marketers would register every clinical trial done in humans for every drug they sell in the state. To be successful, the clinical trial registry must include all the clinically significant aspects of the trial design and trial results. Such a registry would be placed in the state?s department of health, and could be financed with registration fees from the drug marketers.

? To address the problem of deceptive classic advertising, deceptive sales representative statements and deceptive doctor-to-doctor marketing, states can create a new type of citizen lawsuit. This would allow citizens to sue for injunctive relief?stopping the false advertising and conducting corrective advertising?reasonable attorney?s fees, and, at the judge?s discretion depending on the circumstances of the case, civil penalties payable only to the state. Suits could only be won if the deceptive advertising created a public health risk; deceptive advertising that misleadingly, but not dangerously, hypes a drug?s properties would not qualify. Doctors, their patients, attorneys general, and in certain instances, the public, would have standing to sue, depending on the type of marketing.

Examples of sufficiently dangerous advertising might include promoting a drug for illnesses for which the company knows it?s not effective, or denying or consistently minimizing serious risks. The

advantage of this approach is it enables the recipients of deceptive advertising?the people who can most easily detect it?a way to address the problem but it avoids creating financial incentives that would distort enforcement.

Increasing Enforcement at FDA
To make the FDA a potent regulator able to prevent and correct deceptive advertising, it needs more power and financial resources to:

? Review all advertising submitted to it before it is disseminated, in a commercially relevant timeframe, so that deceptive classic advertising is not used;

? Review sales representative training materials and make unannounced inspections of training sessions;

? Review the presentation materials for talks given by doctors on behalf of drug marketers and make unannounced visits to the talks;

? Require and oversee corrective advertising in every situation where deceptive marketing occurs;

? Require drug marketers to get the FDA?s approval before citing any study as support for any claim; and finally,

? Levy significant fines against drug marketers, fines that escalate to truly punitive levels, to serve as a deterrent and eliminate today?s rampant recidivism.

The Medical Profession?s Role: Improve Prescriber Education and Information Resources
Th e medical profession and the independent organizations and academic institutions that service it can help.

? Doctors need better access to independent, accurate, digested information about drugs. The information produced by the clinical trial registry should be packaged by an independent group or agency into a form easily useable by prescribers who want information about treatment options. The information provided should include not only the clinically important information about each drug, but also how the drug compares to other treatments in terms of safety, efficacy, and cost. The Drug Effectiveness Review Project (DERP) generates this information, but it is aimed more at policy makers than prescribers. Similarly, Consumers Union takes DERP?s data and packages it for patients, as part of its BestBuyDrugs project. To the extent that the information is already accessible (for example, The Medical Letter), the profession must find a way to ensure that doctors use it. Only by breaking their reliance on sales representatives and other sources of promotional information can doctors ensure they are getting unbiased information.

? Medical schools and teaching hospitals should heavily invest in

training students and residents to be skeptical of pharmaceutical sales representatives and to rely on independent sources of information.

REPORT ROADMAP

After introducing the problem and laying out the regulatory context, the report presents the results of our analysis of the most comprehensive database on false and misleading advertising available: FDA?s enforcement letters to pharmaceutical companies engaging in deceptive marketing practices. We look at five years of letters to see what kinds of false messages pharmaceutical companies are directing toward whom and how. We also explain why those numbers are grotesque understatements of the problem. One reason they are understatements is that they mostly address conventional advertising, such as ads in professional journals or on TV; they rarely address sales representative statements or the presentations made by doctors consulting for the drug marketer. The latter activities are currently beyond the FDA?s resources to monitor.

Then we look at the ways the FDA currently fails to address even the classic advertising slice of the false marketing problem, the one it monitors as closely as it can. As part of our evidence of the FDA?s failure, we describe the high rates of ?general recidivism,? that is, drug marketers that have received multiple letters from the FDA about their false or misleading marketing, and ?specific recidivism,? that is, drug marketers who have received multiple letters about their advertisements for a single drug, advertisements that are all false or misleading in the same way.

We complete our analysis of the deceptive marketing problem by focusing on the marketing outside of the FDA?s routine review. Specifically, we focus on prescription drug sales representatives and clinical trials. Sales representatives are powerful marketing forces because they have many opportunities to interact with physicians, and the evidence shows that they give false and misleading information far too often. As disturbing as our findings in this area are, they may be mitigated to some extent, given that doctors may expect sales representatives to present misleading information. After all, their job is to sell drugs, not educate physicians. Clinical trials, however, are the cornerstone of prescription drug science, and few physicians let alone patients would anticipate the extent to which drug marketers shape and control them.

We conclude with concrete solutions that states can take now and off er recommendations for addressing FDA?s problems. Fortunately, steps the states can take are powerful enough to rein in the drug marketers to the point where the public can again be confident that they and their doctors are consistently receiving accurate information. Best of all, the state steps are inexpensive.

THE APPENDIX?CASE STUDIES

To fill in the big picture of deceptive marketing we sketch, we

present six case studies of deceptive marketing of prescription drugs in the appendix, located in the center spread. Four?Vioxx, OxyContin, Paxil, and Neurontin?are offered primarily to illustrate different features of the problem and to convey how deceptive messages can permeate drug marketing. Two other case studies, Accutane and Tindamax, are included to highlight the FDA?s inability to police drug marketers.

THE NEW JERSEY PUBLIC INTEREST RESEARCH GROUP
Citizen Lobby and Law & Policy Center
143 East State Street, Suite 6 • Trenton, NJ 08608 • 609-394-8155