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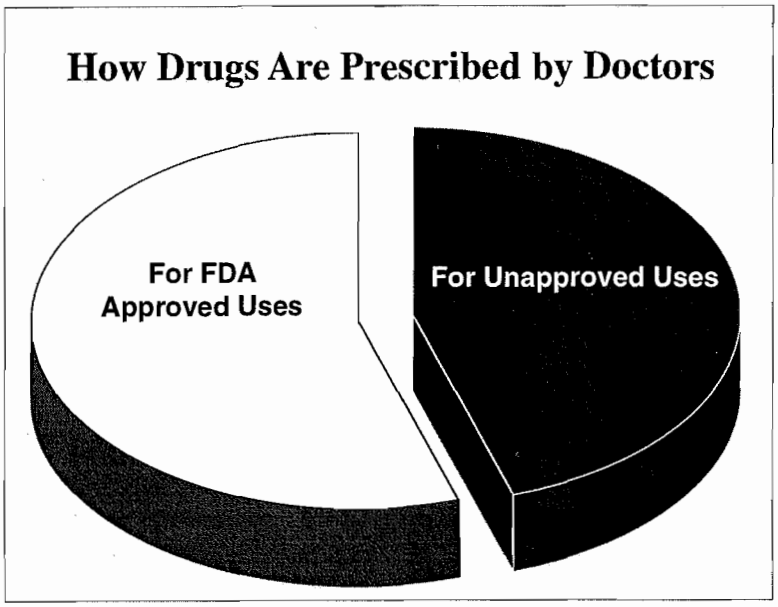
# Censorship by the FDA

For decades, doctors have published their research on the effects of various drugs in medical journals. Some years ago, pharmaceutical companies began reprinting positive reports on their drugs and sending them to doctors. The research often concerned uses for the drugs that were additional to uses already approved by the Food and Drug Administration (FDA). Reprints were commonly distributed and were helpful to busy doctors who wanted to keep abreast of the latest developments in their field.

**Division of Censorship.** But in the last few years, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) has limited the drug companies' freedom to send out reprints. The FDA "recommends" that the first time drug companies use *any* marketing materials, including reprints of medical journal articles, they "voluntarily" send two copies to the DDMAC.




The DDMAC allows drug companies to send out reprints of articles that confirm FDA-approved uses of drugs. But via a "warning letter," it routinely challenges the distribution of articles reporting positive results from "off-label" (unapproved) uses. Since the FDA has the power to confiscate the whole inventory of a drug, companies comply by recalling their mailings, writing to doctors and placing disclaimers in medical journals.

It doesn't matter to the DDMAC that in many cases the off-label use is widespread, close to the approved use or recommended by other federal agencies such as the National Institutes of Health. Further, it doesn't matter to the FDA that:

- About 40 percent to 50 percent of all drugs are prescribed for off-label uses.
- 60 percent to 70 percent of drugs in cancer treatment are used in off-label ways.
- 90 percent of drugs used in pediatrics are prescribed for off-label uses.

A government agency using its coercive power to prevent someone from communicating with someone else is censorship, and the Washington Legal Foundation is suing the FDA on the ground that its restriction of off-label promotion violates the First Amendment. The result of FDA censorship is that physicians and their patients are denied information about off-label uses of drugs.

**Permission Is Costly.** In order to list new uses of a drug on the label, a manufacturer must demonstrate its effectiveness with a so-called double-blind study. Such studies, given the large sample sizes the FDA demands, may cost as much as $26 million in addition to the cost for development and approval of a new drug (which averaged $394 million from 1981-90).

If the drug has been on the market for several years, its remaining patent life may already be less than the time it would take the drug company to realize a return on the added investment. Meanwhile, a competitor may develop a superior substitute. Thus drug companies often don't seek approval for off-label uses.

For example, a study begun in 1989 found Prozac to be effective in treating premenstrual syndrome (PMS). The drug's manufacturer, Eli Lilly, has decided against seeking FDA permission to market the drug for this use because approval would not be granted until 1998, and the patent on Prozac expires in December 2001.

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**Kessler's Power Grab.** Beginning with the 1962 Amendments to the Food, Drug and Cosmetics Act, the FDA has had the power to regulate drug promotion and advertising. And it has taken a broader and broader view of what constitutes advertising and promotion. Prior to becoming head of the FDA, David Kessler warned that:

- Brochures, calendars, mailing pieces, sound and film recordings, letters to formularies, exhibits, detailing pieces, references in published works like the *Physicians' Desk Reference* and even books used to promote the sale of a product are considered labeling by the FDA.
- Arranging with a university or third party to run a symposium (funded by a drug company) does not automatically ensure its safety from FDA scrutiny.

As FDA Commissioner, Kessler has intensified the crackdown on off-label uses of drugs. He has expanded the staff of the DDMAC from fewer than 10 employees to about 25, allowing the FDA to broaden its targets. Kessler instituted the preview process, inducing drug companies to submit marketing materials before disseminating them. The FDA does not "require" that drug companies presubmit their marketing materials, but it *strongly* suggests that they do so.

**Misleading Consumers.** The FDA also explicitly requires drug companies to *mislead* doctors and patients:

- If an advertisement stresses a drug's benefits, it must stress the risks with equal weight, even if the risks are minimal.
- While there is no requirement to explicitly name and fully describe alternative therapies (maybe a competitor's) in advertising, the DDMAC believes explicit mention of alternative treatments is essential — even if they are not as effective or safe.

**The FDA Bans Meaningful Cost Comparisons.** Many doctors depend on cost comparisons of drugs, which show costs for given levels of effectiveness. Drug companies are an obvious source of cost-effectiveness data. However, the FDA prevents drug companies from making these comparisons.

- Any cost comparisons must be made with drugs used as specified in the package insert, which is closely regulated by the FDA, regardless of how the drugs are used in practice.
- The FDA now requires a drug company that claims its drug is more cost-effective in a given use to fund an additional study, typically costing several million dollars more.

**Reining in the FDA.** By delaying the introduction of new drugs, the FDA allows thousands of people to die or to suffer needlessly. For example:

- In the 9.5 months the FDA took to approve Mioprostol after the new drug application had been filed, 8,000 to 15,000 people died from gastric ulcer bleeding.
- By holding up approval for Interleukin-2 for 3.5 years, the FDA allowed 3,500 people to die from kidney cancer.

Behind the suppression of both new drugs and information is the fear that someone might take the wrong drug. That does not justify giving the FDA the power to make people's risk decisions for them, preventing too many people from taking the right drug at the right time.

A simple solution is to take the FDA out of the business of regulating what drug companies may say in their advertising and return that role to the Federal Trade Commission, where it resided before 1962. Drug companies should be subject to the same restrictions against false and misleading advertising as firms in other industries, with one additional regulation: any drug not approved by the FDA should be clearly labeled as such.

**Ending the FDA Monopoly.** As long as the FDA has monopoly power over what drugs can be produced, it will have inordinate say over what information can be disseminated. The solution is to have the FDA serve solely as an information agency that could approve drugs, but could not suppress them. Drug companies should be free to sell unapproved drugs to consumers under two conditions: first, that their unapproved status be clearly labeled and, second, that they be sold only by medical prescription.

Drug developers who wanted the FDA's seal of approval could obtain it, along with the seals of approval of other certifiers. One potential certifier that recently began operating in Europe is the European Medicines Evaluation Agency. Private agencies — whose certification is now worth little due to the FDA monopoly — might arise. After all, despite the fact that many electrical appliances pose even greater hazards than many prescription drugs, a private organization, Underwriters Laboratory, certifies them.

*This Brief Analysis is condensed from David R. Henderson, "FDA Censorship Can Be Hazardous to Your Health," Center for the Study of American Business, Policy Brief 158 September 1995, and is published with permission.*