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Speak No Good:

The Tragedy of FDA Gag Rules

Sharing information about new drugs and new uses for old drugs is an essential part of physicians' quest to cure disease and save lives. Unfortunately, the federal government often stands in the way.

When the U.S. Food and Drug Administration (FDA) approves a drug, it prohibits drug companies from providing doctors and patients with verbal or written information about medical research demonstrating how a drug approved for one medical problem might help solve another. FDA Commissioner David Kessler defends these "gag rules" and argues that it is illegal to allow pharmaceutical firms to distribute scientific information on "unapproved" drug uses because it would put patients' health at risk.

By contrast, when physicians have reason to believe that a new drug could have wider application — for example, that a cancer drug approved for adults could help children — they may test it and publish their findings in the medical literature, such as the peer-reviewed *Journal of the American Medical Association* or *New England Journal of Medicine*. However, drug companies are prohibited from even handing out reprints of such articles.

An analysis of unapproved drug use suggests that the vast majority of such applications are not only safe and effective but essential to patient health. Furthermore, it appears that in cases where the FDA has aggressively sought to limit the spread of information about "off-label," i.e., unapproved, uses, it has undermined the public health in the process.

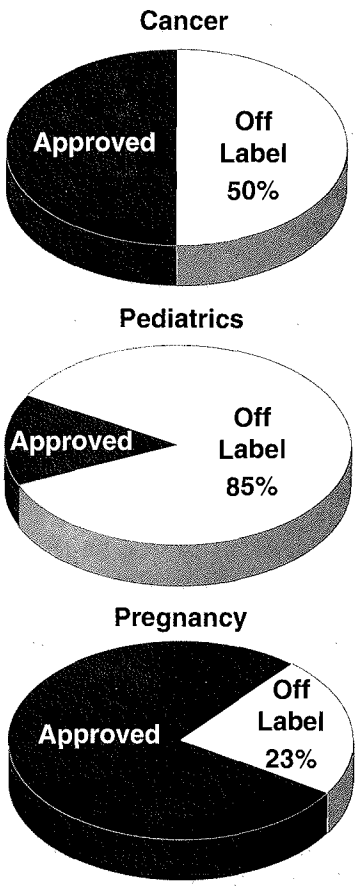
"Off-Label" Use Is Common. Doctors frequently prescribe drugs for purposes other than those for which they are approved. For example:

- An American Medical Association (AMA) survey of its members revealed that an average of 40 percent of all prescriptions are used in off-label ways.
- The Drug Information Division of the United States Pharmacopoeia Convention (USP) — a private-sector organization that confirms and catalogs off-label uses after they are generally accepted in clinical practice — found that about 20 percent of all accepted medical indications are off-label.

Apparently, as the figure shows, specialists rely on off-label usage even more than do general practitioners.

- In specialties such as oncology (cancer treatment), more than 50 percent of the medically accepted indications are for off-label uses.
- One pediatric working group estimates that up to 85 percent of all drugs used in pediatrics in the United States are off-label.

Off-Label* Uses of Drugs in Medical Practice



* Not approved by the Federal Food and Drug Administration (FDA).

Sources: American Society of Clinical Oncologists; American Medical Association; and W.F. Rayburn, G.L. Tumbull, "Off-Label Drug Prescribing in a State University Service," *Journal of Reproductive Medicine*, Vol. 40, No. 3.

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- Recent estimates for dermatologists indicate about 35 percent of all medically accepted indications for drugs used in dermatology are off-label.
- About 73 percent of dosing of an anti-nausea drug in children undergoing cancer treatment is off-label.
- Some surveys show that 23 percent of all drug use during (mostly the third trimester) and after pregnancy is off-label.

The primary reason obstetricians turn to off-label uses is to preclude premature labor and delivery, for which no approved drug is as effective as off-label uses of other drugs.

Are FDA Regulations Killing People? It is ironic, considering the FDA's mandate to advance and protect the public health, that the agency's restrictions on information actually endanger lives. Just consider:

(1) tPA — Prior to FDA approval, research on the use of the drug tPA, which dissolves blood clots, found that a change in the recommended dosage increased the survival rate of patients experiencing heart failure. Proper dosing was also found to alleviate adverse side effects. Nevertheless, the new dosing guidelines were deemed an off-label use of tPA and the company's developer, Genentech, was barred by the FDA from distributing information about alternative dosing.

(2) Taxol — Taxol was approved by the FDA in 1992 for use on metastatic ovarian cancer. However, despite strong evidence that a lower dosage of Taxol was less toxic than the approved dosage and would allow patients to get the drug outside of the hospital, the FDA took more than a year to approve the safer schedule. In addition, Bristol-Myers, the developer of Taxol, is prohibited from distributing medical textbooks that contain information about off-label uses and from providing oncologists with information on treatment breakthroughs.

(3) Aspirin — Despite overwhelming evidence from the Physician's Health Study that taking aspirin daily reduces by a third the risk of heart attacks and strokes in men over age 50, the FDA refuses to let aspirin manufacturers promote these benefits. In fact, the agency only recently relented on promotions dealing with the use of aspirin in avoiding second heart attacks.

(4) Zoloft and Prozac — Though research has documented that giving antidepressant drugs such as Zoloft and Prozac improves the quality of life of people who have suffered heart attacks, the FDA has challenged drug companies that have attempted to use this information to promote their products. As a result, according to Fred Goodwin, former director of the National Institutes of Mental Health, "less than 25 percent of all heart attack patients are receiving any medication at all for underlying depression."

(5) Neurontin — For people suffering from Lou Gehrig's disease, using neurontin, a drug approved for the treatment of Parkinson's disease, can offer some relief. Yet the FDA doesn't agree.

The FDA won't allow aspirin producers to say aspirin helps prevent heart attacks.

The FDA's Defense. In response to claims that people are being harmed by FDA gag rules, the agency contends that off-label usage can be harmful. For example, the agency points out that certain heart medicines known as antiarrythmia drugs — which are intended to control irregular heart beats — were used on patients who had suffered cardiac arrest. Instead of helping patients, this unapproved application actually led to an increase in deaths. However, the adverse effect of these drugs was discovered and their use curtailed by medical researchers and pharmaceutical firms — without FDA involvement. Indeed, the primary source of information on the safest use of these medications was not the FDA but private companies and the scientific community.

Conclusion. The FDA's prohibition on distribution of medical information limits the ability of patients to gain access to medications that might diminish their pain and even save their lives. Although researchers look for different drugs and different combinations of drugs that will cure disease, reduce pain and enhance quality of life, they are prohibited from communicating the results of their research to the medical community.

Access to information is the key to good medicine. It is also the essence of free speech. FDA gag rules limiting information harm the quality of medicine and undermine the foundation of a free society.

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