Quick Study

A Policy Report Summary by the Institute for Policy Innovation

David Kessler's Legacy at the FDA

By: Dr. Robert Goldberg

"If members of our society were empowered to make their own decisions about the entire range of products for which the FDA has responsibility, however, then the whole rationale for the agency would cease to exist.…To argue that people ought to be able to choose their own risks… is to impose an unrealistic burden on people."
—Former Food and Drug Administration commissioner David Kessler

Clearly, Dr. Kessler was a man with a mission. He believed that the FDA exists (in part) to relieve people of the burden of choosing their own risks, and to prevent them from making their own decisions.

In its handling of some of the most important public health issues of this decade—the ban on silicone breast implants, the delay of a home-based AIDS test, and off-label drug use—the FDA's behavior can be explained in Kessler's belief that individuals cannot make their own decisions, or choose their own risks.

Silicone Breast Implants

The FDA ignored many of its own standards and selectively applied others to keep silicone breast implants off he market. Today, every major European nation allows access to silicone breast implants and the testing of new implants that are better than those based on older technology.

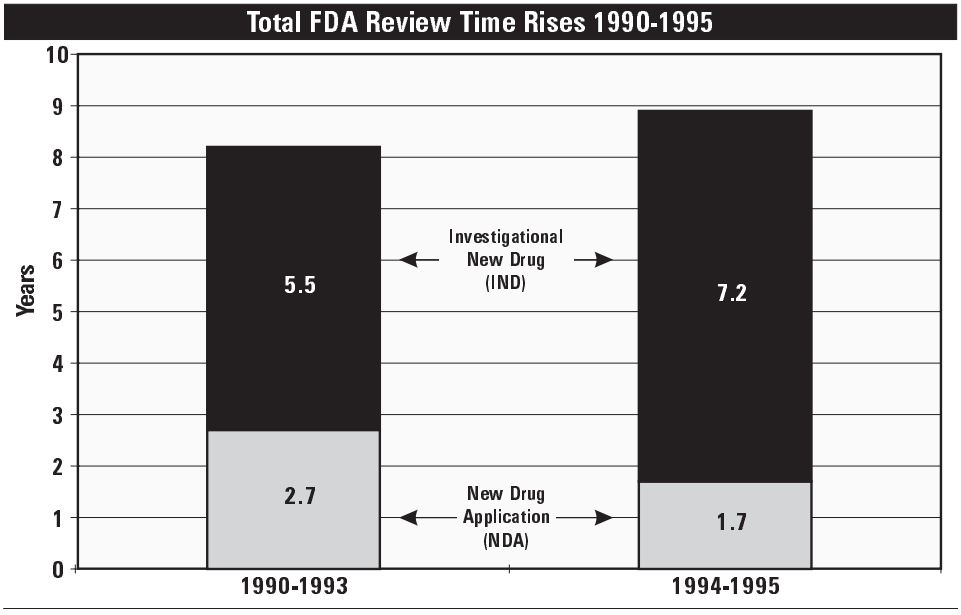
Junk Science and Kessler's Ban on Silicone Implants

What caused Kessler to ban silicone implants in the absence of any scientific proof? The trigger was a state court jury awarding a woman $7.3 million for injuries due to autoimmune disorders supposedly caused by the rupture of silicone implants, despite the fact that the plaintiff's physician testified she had autoimmune-like symptoms *before* receiving implants.

The lawsuit information, according to medical experts, did not show a relationship between the silicone gel used in the implants and autoimmune disease. But talk shows were awash with women blaming their silicone implants for a variety of health problems. Congressional hearings generated even more attention and furor. The news media failed to accurately report research on the subject of silicone breast implants. All that was left was for the FDA to review the "evidence" and ban the implants.

But over the years, several large scale epidemiological studies have been conducted. All of them have shown that there is little or no connection between silicone gel breast implants and autoimmune conditions. The most recent study, the largest of its kind, was a retrospective cohort study of 395,543 female health professionals.

Figure 1



The relative risk of *any* connective-tissue disease among those who reported having silicone breast implants was only .124 percent higher than those who did not.

Despite this evidence, the FDA has refused to alter its position. It has refused to acknowledge that the risks to silicone breast implants are relatively small compared to their benefit and that women should have the right to decide whether or not to have them.

The Home HIV Test

In 1990, a subsidiary of the Johnson and Johnson company began development of a test for HIV that would allow people to safely extract blood, place the sample on sanitary absorbent paper and send it to a lab. The test, which would allow individuals to obtain the results over the phone or at a doctors office, cost $38 dollars compared to the $300 cost at clinics. The safety of the test and its reliability in testing for HIV had been demonstrated. The FDA even acknowledged it as safe. Yet, the FDA refused to allow the test on the market for over five years.

Clearly, the home HIV test was considered a threat and a nuisance to various entities including HIV activists, a powerful alliance who emphasized treatment over prevention, and HIV clinics that conducted the more expensive tests. Even more disturbing, a memo from the Centers for Disease Control (CDC) to the FDA demonstrates that CDC lobbied against approval of the test because it would lead to "HIV positive individuals flooding public health clinics."

In short, the FDA simply ignored science and gave a set of interest groups and agencies what they wanted. It is estimated that because of the embargo, 10,000 more people—nearly 10 percent of all HIV cases—contracted AIDS because of a lack of knowledge. Even worse, this happened while the FDA approved condoms as safe and effective when such "devices" fail to protect in nearly 10 percent of all cases. Widespread testing and knowledge of who has HIV is surely a sturdier prophylactic than condoms.

Squelching "Off-Label" Uses

Increasingly, the FDA is getting into the business of telling people and doctors what drugs to take and for what purposes. In other words, the FDA would prefer that doctors only prescribe drugs for the purposes specifically listed on the label that are approved by the FDA, and avoid prescribing drugs for purposes not approved by the FDA. Such use is commonly known as "off-label" use. Kessler wanted each particular use of a drug to go through the Investigational New Drug (IND) process before information about a particular use was to circulate. This caused serious delays for several effective treatments [see Figure 1].

The FDA claims that off-label drug use is inherently unsafe and unproven because it doesn't go through the same testing as newly developed products. This claim flies in the face of years of clinical experience and careful research in real world settings.

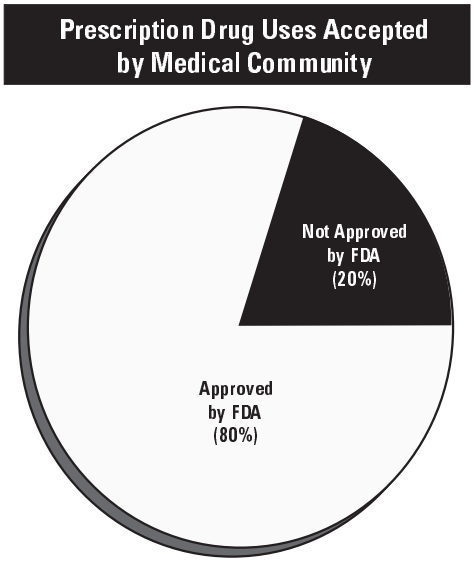
For instance, if people do not know that aspirin can prevent heart attacks, they may thank the FDA and David Kessler. In 1988, after scientists discovered the connection, aspirin makers wanted to publicize the discovery. In 1989, the FDA called them in and told them they couldn't advertise the good news because the agency hadn't approved aspirin as a preventive heart medicine.

As a result, the deaths and suffering of many Americans can be laid directly on Kessler's doorstep. The British Journal of Medicine estimates that 10,000 Americans die each year because they don't know about aspirin's value in reducing the incidence of heart attacks.

Off-Label Risk vs. Public Risk

The United States Pharmacopoeia Convention (USP) examined how much of what is considered to be good medical practice is off-label. It found that about *20 percent of all accepted medical indications are not approved by the FDA* [see Figure 2]. "In some specialties, oncology for instance, more than 50 percent of the [medically accepted] indications are for off-label uses. Our pediatric working group feels that up to 85 percent of all drugs used in pediatrics in the United States are off label. Our latest figures for dermatologists indicate about 35 percent of all medically-accepted indications in the USP

Figure 2



Drug Indications database for drugs used in dermatology are off-label [see Figure 3]."

Dr. Kessler used the examples of the cardiac arrhythmia suppression trial (CAST), calcium channel blockers and Botox to "demonstrate" the dangers of off-label drug use and promotion. Under close examination, none of these cases are examples of either off-label drug promotion or the negative effects they have on public health.

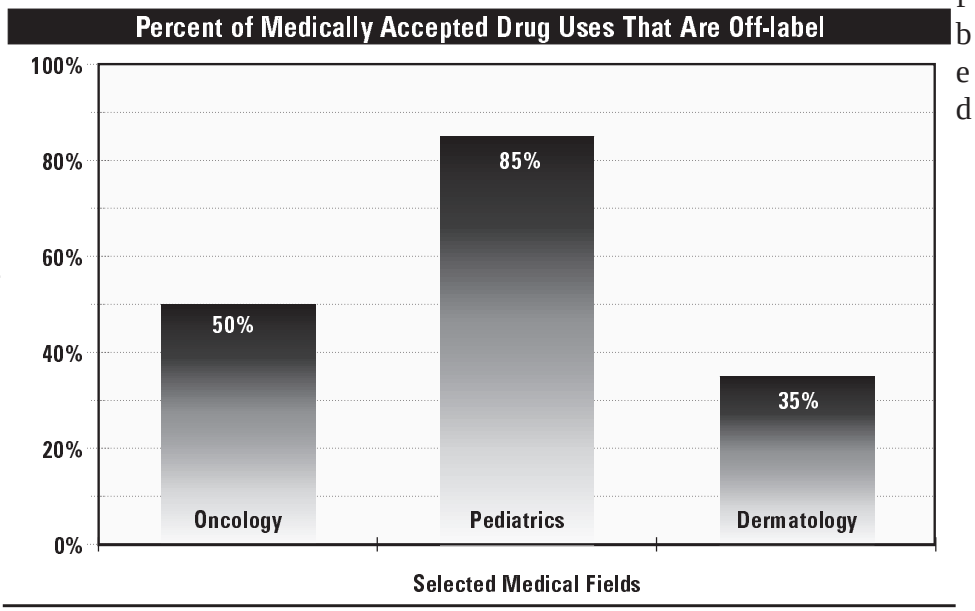
The Cardiac Arrhythmia Suppression Trial (CAST) Study

The study found that though antiarrhythmic drugs suppressed ventricular contractions after myocardial infarction, they also led to a higher rate of death among patients. But under Kessler's off-label use policy, it would have been an illegal act of off-label promotion for the innovators of these drugs to talk about their adverse effects, thus warning clinicians and saving patients lives.

Calcium Channel Blockers (CCBs)

A study conducted by Dr. Bruce Psaty suggested that some patients receiving CCBs have a higher risk of dying compared with patients receiving beta-blockers and diuretics. The FDA Advisory Committee voted against a total ban because it determined that most appropriate course of action was to alert doctors who continued to prescribe acute-release CCBs to treat high blood pressure despite ample evidence that they should not. But by deciding to recommend that doctors be warned of the risk of using a particular drug in a specific way by disseminating existing off-label information more widely, *the FDA acknowledged that off-label drug information has a safety value.*

Figure 3



How the Ban on Off-Label Promotion Undermines Safety

It has become apparent that rather than protecting the public health from unsafe drug use, the "current proscription on off-label promotion may actually facilitate rather than limit such [unsafe] practices." Note the following examples which support this claim.

Etoposide for Non-Hodgkin's Lymphoma (NHL) in the Elderly

Studies conducted at the National Cancer Institute found that the off-label use of another cancer drug—etoposide—was very effective in treating NHL in the elderly in combination with other agents. Ideally, the pharmaceutical firm that makes etoposide would be able to work with oncologists to actively promote the safest dosage and drug combination possible. However, such dissemination was barred by the FDA under Dr. Kessler.

Desipramine for Bed Wetting in Children

Desipramine is one of the tricyclics used to treat depression in adults. It has been employed in the treatment of bedwetting in children since the early 1970s. A substantial body of literature, including randomized trials, has demonstrated that the drug effectively controls bedwetting in children, and that specific steps should be taken to ensure safe treatment. Despite the widespread use of tricyclics in treating children, companies are prohibited from disseminating information on safe and appropriate off-label treatments.

tPA For Myocardial Infarction

Prior to its FDA approval, research on the use of the clot-breaking drug tPA found that a change in dosing strategy increased the survival rate of patients undergoing myocardial infarction. Proper dosing was also found to alleviate complications due to excessive bleeding as a result of using the drug. But the new dosing regimen was deemed an off-label use of tPA and the company's developer, Genentech, was barred from distributing information about the new approach by the FDA.

Is Off-Label Promotion Necessary for Good Medical Practice?

Research suggests that if patients and doctors were to wait to apply off-label uses until the FDA got around to reviewing and approving them, Americans would be waiting years to obtain new medical information. Because active dissemination is critical to educating doctors on appropriate clinical practice, the FDA's ban on off-label promotion creates "orphan information"—valuable medical knowledge that has no home due to FDA limits on its free distribution.

Conclusion

The FDA's misuse or abuse of regulatory authority has been a constant complaint of drug and device companies and its critics for 30 years. Why then focus on David Kessler's actions? Because under Kessler the FDA became the only legitimate arbiter of what is regarded as a threat to public health. Second, Kessler demanded that only the FDA has the legal and ethical right to define what that threat is. Third, because Kessler's particular justification of FDA's power demanded that the agency be accountable to no one and that neither he nor the agency accept responsibility for the consequences of its decisions and behavior. And fourth, because Kessler more skillfully and aggressively exploited FDA's control over product approval and market access—the means of production—in order to leverage its power.

It would be a mistake to assume that it is possible to reinvent the FDA by simply appointing a new commissioner. Kessler's use of power not only set a standard that the media and reformers will use to judge future commissioners, but he also transformed the way the FDA operates, politicizing its decisions and decision-making apparatus to an unprecedented degree and making it less accountable to political oversight than at any other time in recent history. In doing so he created a new FDA in his own image, at the expense of individual choice, the public's health, and the public's well-being.

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This study is a summary of IPI Policy Report # 143, *David Kessler's Legacy at the FDA*

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