

The Feds and the Pharms, Pt. 2: The FDA

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“[A] recent study by USA Today revealed that more than half of the advisors to the Food and Drug Administration (FDA) have financial relationships with pharmaceutical companies that have an interest in FDA decisions.”

Catherine DeAngelis, “Conflict of Interest and the Public Trust,” *Journal of the American Medical Association*, 284(17), Nov 1, 2000.

“The FDA regulates products accounting for approximately 25 cents of every consumer dollar—worth more than \$1 trillion annually.”

Henry I. Miller, “The Wrong Choice for the FDA,” *The Wall St. Journal*, June 26, 1998.

No other governmental bureau under the U.S. Public Health Service has such a long and documented history of abuse and corruption as the Food and Drug Administration. And none has as intimate a relationship with the pharmaceutical industry. The FDA has absolute power to determine which drugs and medical devices can be marketed in the United States, how these products may be marketed, how they are labeled, how they may be used, and whether they are available over the counter or by prescription only. It is judge, jury, acquitter or executioner, and enforcer for every product manufactured for sale in the United States by the pharmaceutical, medical device, food and cosmetic industries.

Approval of its drug by the FDA can mean hundreds of millions of dollars in profits for a pharmaceutical company; FDA rejection of a promising drug can financially ruin a small company and deliver a multimillion-dollar hit to a big one. Given this kind of power and the huge amounts of money involved, it is not surprising that the agency has often been rocked by corruption scandals and that individuals in the agency have been found to be on the take.

“Several FDA reviewers were accepting bribes to hasten the approval of certain companies’ applications and derail those submitted by competing companies. Eventually 42 persons and 10 companies were found guilty of criminal acts.”

Robert Higgs, “An FDA Fable,” *Reason Magazine*, October 1994. This describes a generic drug scandal that climaxed in 1989. Beginning in 1990, when David Kessler was appointed head of the FDA, and for three years after that, the FDA exacted revenge on Barr Laboratories for blowing the whistle on the agency’s corruption. With or without his knowledge, Kessler’s FDA reportedly tried to put the company out of business by repeatedly inspecting its facilities and delaying approvals of its products.

“Warner-Lambert [purchased by Pfizer in 2000] played down the potentially fatal risks associated with troglitazone during the [FDA] approval process and received help from federal drug regulators in pushing the drug towards marketing approval, an article published in the Los Angeles Times has claimed.”

“The newspaper based its report on company and government documents, some secretly obtained, as well as email communications, which shows that officials from

Warner-Lambert had collaborated closely with certain senior officials in the US Food and Drug Administration (FDA) during the approval process and later, when the company was being pressured to take the drug off the market.”

Reported in *The British Medical Journal*, 322; 696, March 24, 2001. This scandal took place between 1994 and 1996, during David Kessler's reign as head of the FDA.

The agency has been investigated for corruption by the U.S. Congress and Congress has tried to “reform” the FDA. In 1997 a congressional FDA reformation effort went nowhere because it was reportedly sabotaged by Sen. Edward Kennedy (D., Mass.).

David Kessler's FDA

“A laudatory Washington Post article concluded, ‘What he cannot accomplish with ordinary regulation, Kessler hopes to accomplish with fear.’”

James Bovard, “First Step To an FDA Cure: Dump Kessler,” *The Wall St. Journal*, 12/8/94.

“Companies interested in maintaining positive relationships with the FDA usually agree to the FDA's remedy.”

David Kessler. (Quoted in Paul Rubin, “FDA Advertising Restrictions: Ignorance Is Death,” Chp. 3 of *Hazardous to Our Health? FDA Regulation of Health Care Products*, ed. By Robert Higgs, The Independent Institute, Oakland, CA: 1995, p. 31).

In 1990 David Kessler was appointed head of the FDA. The hope was that Kessler, a “dedicated activist” who was also an attorney and physician, would clean up the FDA, but what actually happened was that corruption at the FDA continued while Kessler focused on such things as food labeling, further politicized the agency, and instituted a reign of terror.

“In reality, the new commissioner quickly turned the agency into a fearsome police force. In his first two months, he ‘added a hundred new criminal investigators to the enforcement staff, many of them formerly with the Secret Service and the Drug Enforcement Agency.’ Then followed a series of armed raids on alternative health clinics, vitamin factories, and dealers in dietary supplements as well as greatly increased numbers of warning letters, product seizures, forced factory shutdowns, and criminal prosecutions in the drug and device industries.”

Robert Higgs, “An FDA Fable,” *Reason Magazine*, October 1994.

Armed with virtually unlimited power, Kessler promoted the image of the FDA “protecting” the public with the implacable sword of justice. However, Kessler's sword tended to swing at some companies and some industries more than others.

In 1991, FDA storm troopers raided a Florida orange juice producer and poured 24,000 half-gallons of Citrus Hill ‘fresh choice’ juice down the drain because the agency objected to the label. There was nothing wrong with the juice, but the FDA said the phrase ‘fresh choice’ on the label was misleading since the product was not “fresh” but was made from concentrate.

In 1992, the FDA headed a guns-drawn raid on a Tahoma, Washington medical clinic because the physician in charge of the clinic had promoted nutrition and vitamins as an alternative to some traditional medical treatments.

In 1993, the FDA fined start-up company Lexicor \$1,580,000 (twice the company's total 1993 revenues) for promoting its electroencephalographs which measure brain waves, even though the company had received FDA approval for the device, which it was selling under a different brand name.

On the other hand, Summit Technologies, a Massachusetts manufacturer of laser eye surgery devices, was supported by the FDA in selling a \$40,000 device for \$400,000. The FDA was aware that Summit may have been violating federal law by pre-selling an unapproved device along with an already-approved device, but the company's political connections apparently influenced the FDA decision not to prosecute. The company had collected nearly \$500,000 in campaign contributions for Sen. Edward Kennedy, and according to a whistle-blower the chairman of Summit discussed a potential payment of more than \$1 million to Kennedy's reelection campaign.

“An FDA memo dated Jan 1, 1995...shows how the FDA went about helping Summit and Senator Kennedy. ‘Summit has apparently complained a lot in the past to Ted Kennedy regarding the lack of timeliness in FDA’s responses to issues regarding [Summit’s application for approval]’ the memo states. It then goes on to state that the FDA will not seek criminal charges against Summit, and to assert that Summit will eventually get approval.”

Robert Goldberg, “The Ethical Mess at the FDA,” *The Wall St. Journal*, 1/16/97.

Then there is the case of Ethicon and the contaminated sutures. Ethicon, a subsidiary of Johnson & Johnson, manufactures 80 percent of all medical sutures used in operations. The company accidentally distributed at least 3.6 million packages of contaminated sutures to medical supply distributors, hospitals and physicians between December 1993 and September 1994. According to class-action attorney Wendy York, the contaminated sutures were unknowingly used by surgeons and physicians all over the country, and their use resulted in raging infections, disfigurement and even death in patients who had been stitched with the medical sutures [Geoff Metcalf, *worldnetdaily* Sunday Q & A, Interview with Wendy York].

Did the FDA conduct an armed raid or levy a multimillion-dollar fine on Ethicon? No. According to attorney York, the FDA did issue a stern warning letter to Ethicon in 1994, but the company assured the FDA it would take care of the problem, and no further action has been pursued by the government agency.

One would gather that Ethicon and Summit “maintained positive relationships” with Kessler's FDA, while other food companies, drug companies, and medical clinics did not.

During Kessler's reign at the FDA, the agency initiated at least two new policies which would result in increased profits for at least the major pharmaceutical companies.

In May 1995, the FDA ruled that a new federal law extended drug patents for up to an additional three years. This news was welcomed enthusiastically by the big drug companies. Glaxo Wellcome's Nancy Pekarek said, "This is very good news, not just for Glaxo but for upholding the patent rights of innovative companies" (Miami Herald, 5/26/95). But consumer advocates said this windfall for the pharmaceutical companies could cost U.S. consumers as much as \$6 billion.

Then in 1997 the FDA relaxed the restrictions on TV ads for prescription drugs. This gave the big pharmaceutical companies a big new marketing tool because they could promote their prescription drugs directly to the consumer. Obviously the smaller companies are without the means to pay for glossy professional television spots, but the big drug companies were quick to take advantage of television marketing for prescription drugs. Sales of these drugs soared as people began pressuring their physicians for prescriptions for the products they had heard so glowingly described in primetime TV ads.

And, of course, David Kessler also gave a big boost to the sales of the big pharmaceuticals' "nicotine replacement" products for smoking cessation when he went after the tobacco companies.

Kessler's FDA and Tobacco

"If members of our society were empowered to make their own decisions...then the whole rationale for the [FDA] would cease to exist."

David Kessler. Quoted in James Bovard, "First Step To an FDA Cure: Dump Kessler," *The Wall St. Journal*, 12/8/94.

"[A] strict application of these provisions could mean, ultimately, removal from the market of tobacco products containing nicotine at levels that cause or satisfy addiction."

David Kessler in a letter to an anti-smoking group in 1994. Quoted in Jerry Taylor, "Clinton's Tobacco War: How High the Constitutional Price?" *The Cato Institute*, 8/30/96.

"Cigarettes in America should be produced and sold only by a single, congressionally chartered, tightly regulated company, with no profits, former Food and Drug Administration commissioner David Kessler says."

Joe Ward, "Should single firm make cigarettes?" *The Louisville Courier-Journal*, 3/25/01.

In 1991, Kessler's FDA approved the Nicotrol and Nicoderm patches as prescription drugs for smoking cessation (Nicorette gum had been approved for such use in 1984). In 1992, the patch was introduced to the American public. In 1993, the FDA prohibited the sale of existing over-the-counter smoking-cessation products because the agency said they had not been demonstrated to be effective. This, of course, had the effect of eliminating all competition to Johnson & Johnson's Nicotrol patch and SmithKline Beecham's Nicoderm patch and Nicorette gum. Then in 1996 the FDA approved the gum and the two patches for over-the-counter sale. It all worked out extremely well for Johnson & Johnson and SmithKline Beecham.

But by far the biggest boost for the pharmaceuticals in the nicotine war was David Kessler's attempt to regulate tobacco products as "nicotine delivery devices" under FDA jurisdiction.

Kessler first publicly expressed his interest in regulating tobacco when he went before Congress in 1994 and asked for "guidance" and "direction" before his agency took any action to regulate tobacco. Prior to Kessler, the FDA had never expressed an interest in extending its regulatory empire to tobacco. Tobacco products were not considered to be food, cosmetics, drugs or medical devices, which meant they did not fall under the scope of the FDA's regulatory apparatus.

However, the anti-regulatory mood of the Republican-led Congress meant there was no legislative enthusiasm for giving the FDA authority to regulate tobacco products.

Kessler then by-passed Congress altogether. In 1995 he declared tobacco to be a "pediatric disease" and submitted to the very receptive Clinton White House a list of proposed FDA tobacco regulations ostensibly intended to protect the children from tobacco.

Meanwhile, the Robert Wood Johnson Foundation was funding policy studies to support FDA regulation of tobacco products. In 1994 the RWJF awarded a \$142,600 contract to Mathematica Policy Research for a "National Tobacco Survey" which would assess public attitudes "toward various government policy measures designed to limit youth access to tobacco products and make those products less attractive." David Kessler later said the findings from the survey "played a critical role in winning the necessary support for the FDA's tobacco control policy."

Joseph DiFranza was given a \$99,999 RWJF grant for "Investigating the Scientific and Legal Basis for Regulations Requiring the Generic Packaging of Tobacco Products," and Alan Morrison and David Vladeck of the Public Citizen Foundation were awarded a \$50,608 RWJF grant for a legal analysis of the proposed FDA regulations on tobacco.

By August 1996, the Clinton administration was set to approve new FDA regulation of tobacco products. Tobacco products would be considered "drug delivery devices," and thus would be subject to FDA regulation with regard to advertising, marketing, and packaging. Cigarette vending machines would be outlawed, tobacco advertising would be banned from magazines with high youth readership, advertising on billboards would be limited to black and white text and prohibited within 1,000 feet of schools. Furthermore, the tobacco companies would be forced to fund a \$150 million annual anti-smoking education campaign. And if all these measures did not cut underage smoking in half within seven years, the FDA would be empowered to employ even harsher measures, including the banning of cigarettes as a "nicotine delivery system."

The newly formed, RWJF-funded Campaign for Tobacco-Free Kids beat the drum for the proposed FDA rules. "This is the first national policy in history that will stop tobacco

companies from marketing to kids,” said TFK’s Brian Ruberry (quoted in Brian McGrory, “New FDA rules would declare nicotine a drug,” *The Boston Globe*, 8/22/96).

Not only would the proposed FDA regulation of tobacco products expand the agency’s already wide scope of regulatory power, but it would increase its budget by 30 percent or more since the agency would get considerable extra funding to cover the cost of implementing and enforcing these regulations.

The tobacco companies immediately filed suit against the FDA to stop the new regulations. After a protracted legal battle, the case reached the U.S. Supreme Court. In March 2000, nearly three years after David Kessler resigned as head of the FDA, the Supreme Court ruled that the FDA lacked congressional authority to regulate tobacco.

But the battle over FDA regulation of tobacco products isn’t over. The Robert Wood Johnson Foundation and organizations it funds are still working to convince Congress to empower the FDA to regulate tobacco products as nicotine delivery devices and shift the market advantage to the pharmaceuticals’ own nicotine delivery devices. And David Kessler is touring the world to promote his new book, “A Question of Intent: A Great American Battle With a Deadly Industry,” about his “heroic” battle to destroy demon tobacco.

KESSLER REFUSES TO TESTIFY UNDER OATH

On Thursday, March 5, 1998, former FDA commissioner David Kessler, along with former Surgeon General C. Everett Koop, was scheduled to testify before a Congressional committee regarding legislation to regulate tobacco.

However, upon learning that they would be put under oath (required to tell the truth), Kessler and Koop abruptly canceled their testimony.

In a letter to the chairman of the subcommittee on health of the House Commerce Committee, Kessler and Koop wrote, among other things, that “it is extremely unusual for private citizens to be sworn in before a Congressional committee unless they themselves are being investigated. We can only assume that this is being done in our case to put us on some sort of parity or equal footing with the tobacco executives, who were sworn in. We decline to be put in that position.”

According to the *New York Times*, Kessler said he did not know until Tuesday that he would be required to take an oath, and “he left no doubt that this was the reason he would not be appearing.”

Source: *New York Times*, “2 Antismoking Witnesses Cancel Testimony,” by David E. Rosenbaum, March 5, 1998, p. A15.

