It's Time to Track the FDA's Death Toll

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The Food and Drug Administration helped turn the coronavirus from a deadly peril into a national catastrophe. Long after foreign nations had been ravaged and many cases had been detected in America, the FDA continued blocking private testing. The FDA continued forcing the nation’s most innovative firms to submit to its command-and-control approach notwithstanding the pandemic. South Korean is in a far better situation dealing with coronavirus, because its government did not preemptively cripple private testing.

One of the clearest lessons from the current pandemic is that nothing has changed at one of the nation’s most powerful regulatory agencies. The FDA is repeating the same mistakes and showing the same arrogance that I chronicled decades ago in articles for the *Wall Street Journal*, the *American Spectator*, and other publications.

Dr. David Kessler, who became FDA commissioner in 1990, quickly sought to intimidate the companies that his agency regulates. A laudatory *Washington Post* article concluded, "What he cannot accomplish with ordinary regulation, Kessler hopes to accomplish with fear." Kenneth Feather of the FDA's drug advertising surveillance branch boasted: "We want to say to these companies that you don't know when or how we'll strike. We want to eliminate predictability."

Dr. Kessler's heavy-handed tactics battered the American medical device industry—one of the nation's export superstars. An American Electronics Association survey found that "40% [of medical device companies] reduced the number of U.S. employees because of FDA delays, 29% increased their investment in foreign operations, and 22% moved U.S. jobs overseas." The survey also found that "57% of the firms said the FDA had applied guidance instructions retroactively to some of their submissions," as Biomedical Market Newsletter reported.

The FDA's stonewalling of new medical devices was sometimes politically motivated. A 1994 report by the Medical Device Manufacturers Association noted, "It is not unusual for [FDA] reviewers to express the position that excessive requests [for additional information] are made because of a concern or fear about how a particular member or members of Congress will react" to the approval of a new device. Sacrificing lives was a small price to pay for bureaucrats to avoid bothersome interrogatories from Capitol Hill.

FDA employees also sowed fear with a deluge of official Warning Letters (up more than 300 percent since Dr. Kessler took office) to private companies. Once the FDA issues a Warning Letter, it can seize a company's products or get a court injunction to paralyze its operations. The FDA refused to establish clear guidelines or rules for issuing its letters. As a result, manufacturers could find themselves in a nightmare at the whim of a midlevel FDA employee.

Dr. Kessler did not spare the First Amendment in his grab for power, and cancer patients and other seriously ill people suffered as a result. Doctors, hospitals, and researchers often discover after FDA approval that a drug to treat one disease is also effective at treating other diseases. Drug companies have routinely publicized this news, alerting physicians to other possible ways to save lives. American Medical Association vice president Roy Schwarz estimated that "off-label" uses of drugs account for up to 60 percent of all drugs prescribed.

But in 1991 Dr. Kessler prohibited pharmaceutical companies from informing doctors of new uses for approved drugs. He announced that the FDA would enforce the ban with seizures, injunctions, and

prosecutions. Though the agency never finalized its proposed regulations, it warned companies that they would face its wrath if they violated the draft proposals. Dr. Kessler, in a speech before the Drug Information Association, said: "I would urge all members of the pharmaceutical industry to take a long and hard look at their promotional practices. I do not expect companies to wait until this guidance becomes final to put their advertising and promotional houses in order." The question of off-label treatments is becoming a key issue again as doctors search for effective treatments for the COVID-19 coronavirus.

The FDA even suppressed medical textbooks as part of its attempt to restrict what Americans learned about new treatments. In 1992, the FDA cracked down on a company for distributing, for free, portions of *Cancer, Principles and Practice of Oncology*. In 1993, the FDA stopped a pharmaceutical company from distributing free copies of *The Chemotherapy Source Book*—even though the company had already received FDA approval to give away thousands of copies. The FDA claimed that when a drug company gives doctors free textbooks that mention an off-label use of its products the drugs become subject to seizure.

Under Kessler, the FDA became far more restrictive in approving new drugs and medical devices. Stanford University professor Dale Geringer observed, "In terms of lives, it's quite possible that the FDA bureaucracy could be killing on the order of three to four times as many people as it saves." One study estimated that 150,000 heart attack victims may have lost their lives as a result of the FDA's delays in approving the emergency blood-clotting drug TPA. National Cancer Institute officials accused the FDA of being "mired in a 1960's philosophy of drug development, viewing all new agents as… poisons."

Dr. Kessler bragged that his reforms had given FDA employees "a place where, once again, the good guys could win." And how could Americans be sure that FDA enforcement agents were the good guys? Because they worked for the government.

Dr. Kessler declared in 1992: "If members of our society were empowered to make their own decisions…then the whole rationale for the [FDA] would cease to exist." Kessler derided "freedom of choice" as an illusion unless people are presented only with government-approved choices. But the FDA “liberated” people by shielding them from information, devices, and drugs that could have saved their lives.

Many Americans could die in the coming weeks and months thanks to the FDA’s blockade on coronavirus testing. Should we consider those victims as martyrs for the principle of bureaucratic supremacy? The FDA’s current commissioner, Stephen Hahn, conceded last week: “There are always opportunities to learn from situations like this one.” Perhaps the clearest lesson is that it is time to track the death toll of FDA regulatory debacles.

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