
The Case for the Food and Drug Administration as an Independent Agency

By Ralph S. Tyler*

At the Aspen Institute's Ideas Festival in June 2016, six former Commissioners of the Food and Drug Administration (FDA), who served under Presidents of both parties, voiced strong unanimous support for the idea that FDA should be an independent agency, and not, as it is now, a subordinate "operating division" of the Department of Health and Human Services (HHS). The tenure of these former commissioners spanned that of Frank Young (1984–1989) to Margaret Hamburg (2009–2015). Each had confronted different major issues, but their shared conclusion was that the present structure does not best serve the country's public health needs. Professor David Carpenter, who has extensively studied the FDA, is among those who support the agency's independence. See Daniel Carpenter, *Free the F.D.A.*, Op-Ed., NY TIMES (Dec. 14, 2011). The incoming national administration and Congress should heed this latest call and act.

HHS is a cabinet level department under which sits various operating divisions, each of substantial size. These operating divisions include, among others, FDA (regulating food, both human and animal, drugs, medical devices, biologics, dietary supplements, and tobacco), Centers for Medicare and Medicaid Services, National Institutes of Health (medical research), and Centers for Disease Control (public health research, education, and data collection).

The scale, diversity, and technical complexity of the activities undertaken by the parts of HHS are remarkable. HHS lacks staff with expertise and knowledge comparable to the expertise of the staff of the

divisions it is charged with overseeing. Nevertheless, given the structural relationship between HHS and its operating divisions, HHS exercises an aggressive gate keeper function over the FDA. By statute, the HHS Secretary holds decision making authority and thus HHS occupies the superior bureaucratic position.

With the Senate's consent, the President appoints FDA Commissioners of accomplishment and distinction, typically scientists or medical doctors. This would suggest that FDA Commissioners operate with significant autonomy. But the truth is otherwise.

The White House's Office of Management and Budget (OMB), through its Office of Information and Regulatory Affairs, exercises powerful oversight, if not literally veto authority, with respect to agency regulations and policies. This authority is set forth in Executive Order 12866 issued in 1993 by President Clinton and followed by his successors. See 58 Fed. Reg. 51735 (Oct. 4, 1993). The White House thus operates as a significant check on a FDA Commissioner's policy initiatives. The point for present purposes is that FDA's location within HHS means that a FDA Commissioner's path to the White House is impeded, not direct; absent extraordinary circumstances, the Commissioner must go through HHS. FDA matters do not, and as a practical matter cannot, reach OMB without first passing through HHS's thick filter. Before the FDA Commissioner can get to the White House with a proposed regulation, for example, the Commissioner's proposal is subjected to HHS scrutiny, review, and often extensive modification. The HHS staff exercising this review lack the technical and scientific qualifications of the Commissioner and the FDA staff who

studied, drafted, and reviewed the comments on the proposal.

The rationale for why FDA should be independent is, in part, that FDA's core mission is fundamentally different from that of other parts of HHS and, indeed, is fundamentally different from the principal activities of most agencies of the federal government. FDA's most important functions involve market access, product review, approval, and removal. Before a new drug can lawfully reach the marketplace in the United States, FDA must approve it. FDA is responsible for assuring the safety of the vast majority of the nation's food supply. For the past few years, FDA also has been our nation's tobacco regulator, charged with reducing tobacco smoking and its associated health risks and costs. Each one of these areas of responsibility—and, of course, there are many other examples—would alone be a very substantial policy and operational undertaking. The totality of FDA's areas of responsibility encompasses a wide swath of the economy and present FDA, on a daily basis, with enormous operational tasks and challenges.

In contrast to FDA, the activities of most of the domestic policy agencies of the federal government, including most of the components of HHS, involve setting and enforcing rules and policy and, in some instances, distributing funds to the states, to local governments, or others in the form of grants, direct payments, or otherwise. While FDA performs all of these functions, FDA also has direct hands-on operational responsibilities. FDA determines whether products upon which every American depends every day may enter or remain on the market. FDA's operational functions range from inspecting tons of seafood

* Partner, Venable LLP; Chief Counsel Food and Drug Administration 2010–2011.

and produce at the border to inspecting overseas and domestic pharmaceutical manufacturing facilities. Performance of these functions is not improved by layering on people in the bureaucratic chain who are not deeply informed on the underlying science, data, or operational challenges. It makes little sense for HHS, overwhelmingly a non-operational policy agency, to have oversight authority over FDA when, at its core, it is an operational agency.

A persistent concern about FDA by companies and industries subject to FDA's regulatory jurisdiction is that FDA takes too long to make decisions. Industry rightly complains, for example, that it takes too long for FDA to issue guidance documents and regulations. There are many causes for this delay and FDA is not entirely without fault. FDA should improve its internal review process to make it less cumbersome and multi-layered. What is certain, however, is that eliminating the HHS review layer would be a step in the right direction. Again, every FDA policy proposal of any significance must be reviewed and cleared by HHS before the proposal can be forwarded to OMB where the review process then repeats itself.

Another persistent complaint about FDA, both from industry and from consumer advocacy groups, is the lack of transparency of FDA's decision making process. This, too, is an area in which the agency could improve; it should be both more timely and forthcoming in its decisions and reasoning. The goal of greater FDA transparency argues for removing the mostly hidden hand of HHS in directing or shaping FDA's decisions.

The question is whether HHS review sufficiently improves the regulatory product to warrant the associated costs. The bipartisan group of former Commissioners unanimously recommended making FDA an independent agency. Their recommendation reflects their shared view that the HHS layer adds delay, at times injects politics, and does not add value. If the HHS layer were

eliminated, ample checks on the FDA would still remain. Among other things, OMB would retain its authority to review proposed and final regulations and final FDA decisions would remain subject to judicial review.

In matters of public policy involving science, health, and safety, the goal is for governmental decisions to be determined by reasoned scientific judgment based upon the best

*“There is a persuasive case
for change to establish an
independent FDA”*

understanding of the known facts, uninfluenced by politics or other extraneous considerations. Because no governmental structure is absolutely immune from politics, that lofty goal will not always be met. Still, the government can be structured in ways to better further that goal. The current FDA/HHS structure, by contrast, tilts in the opposite direction. The present structure separates those with the specialized knowledge necessary to make the proper scientific decision (FDA) from those with the power to make the decision or, at least, to impact the decision (HHS). This structure facilitates politicization by granting a large degree of decision making authority to people whose primary policy perspective is non-scientific.

The most prominent recent case where the Secretary of HHS injected herself to overrule the FDA Commissioner on a matter of science involves the so-called Plan B “morning after” oral contraceptive pill. FDA had concluded that the pill was safe and effective and should be available without a prescription for young women/girls below the age of 17. The HHS Secretary, who was not

qualified to second guess this judgment as a matter of science, despite her claims to the contrary, responded to the social, political, and public relations sensitivities of the issue and overruled that FDA decision. The current structure allowed this outcome because the HHS Secretary, not the FDA Commissioner, held (and holds today) the ultimate power to decide.

As the former FDA Commissioners discussed when they met at the Aspen Institute, there are a number of possible models for an “independent FDA.” These models range from the Federal Reserve degree of independence to a cabinet level agency that is not part of a cabinet department (such as the Environmental Protection Agency). The irreducible minimum feature of independence requires unburdening FDA from having HHS sit atop FDA.

Achieving any reorganization of the federal government, even a relatively modest one, is not a task for the timid. The forces of inertia and self-justification are powerful and never easily overcome. In the end, though, there is a persuasive case for change to establish an independent FDA. Doing so would strengthen FDA and enable it to better serve the American people. The need for change plainly exists and is arguably growing as FDA's responsibilities continue to expand. The issue is not whether there is a need, but whether there is the will to change. FDA's former Commissioners have extended their records of service to the agency they each headed by urging that we and Congress find that will. ○

E-Cigarettes: Prevention Is Not Enough

By Craig Oren*

Two years ago, I argued in these pages that regulation of e-cigarettes ought to be preventive—that the Food & Drug Administration (FDA) should regulate under the Tobacco Control Act of 2009 even if it is not certain that e-cigarettes present a risk to public health. See Oren, *E-Cigarettes: The Importance of a Preventative Approach*, ADMINISTRATIVE & REGULATORY LAW NEWS, at pp. 4-6 (Fall 2014). The FDA has since promulgated a finding that “deems” e-cigarettes and miscellaneous tobacco goods (such as cigars) to be “tobacco products,” and has established rules (such as a ban on sales to minors and a requirement for a warning label) controlling the making and marketing of these products in many of the same ways that cigarettes are regulated. See 81 Fed. Reg. 28974 (May 10, 2016).

The results make clear that, while a preventive philosophy is necessary to sound regulation, it is not sufficient. Rather, considerable judgment is required to decide what precisely to prevent and what restrictions should be imposed in the name of prevention.

The process of promulgating the finding and the requirements is typical of modern rulemaking on important topics. It took the FDA two years to get from proposal to promulgation. See 79 Fed. Reg. 23142 (Apr. 25, 2014). This is not surprising; the FDA was faced with 135,000 comments. In response, the agency classified the comments into a little more than 300 categories, indicating the complexity of the issues. The FDA’s explanation of its final rule covers over a hundred pages in the Federal Register. And of course this is not the end of the process. Judicial challenges claim that the rules violate the Tobacco Control Act, the Constitution, and are arbitrary and capricious under the Administrative Procedure Act. See,

e.g., *Right to be Smoke-Free v. FDA*, No. 1:16-cv-01210 (D.D.C. June 20, 2016). In addition, the e-cigarette industry has been lobbying Congress to intervene. See Eric Lipton, *Tobacco Industry Works to Block Rules on E-Cigarettes*, N.Y. TIMES (Sept. 3, 2016).

The key questions are twofold: First, was the FDA appropriately protective? Second, did the FDA adopt the right strategies in seeking to be protective? The first difficulty is to gauge how serious the e-cigarette problem is. There are signs that the e-cigarette boom discussed in my last article is ending. Many smokers apparently do not get the same satisfaction from “vaping” e-cigarettes that they do from using traditional tobacco products. See Susan Adams, *Can E-Cigarettes Survive the War Against Vaping*, FORBES (May 5, 2016). Reports that e-cigarettes sometimes explode have hardly helped. See 81 Fed. Reg. at 29035. Retail sales of e-cigarettes have dropped over the past year, and one e-cigarette manufacturer reported flat revenue. See Adams, *supra*. On the other hand, e-cigarette use among high school students jumped 800%—a nine-fold increase—between 2011 and 2014 to the point where one out of eight students use the product. See 81 Fed. Reg. at 28984.

Current evidence indicates that vaping e-cigarettes poses a lesser risk to health than using other tobacco products. See *Id.* at 28981. Britain’s public health department believes that e-cigarettes are 95% less harmful than traditional cigarettes. See <https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review>. That is because e-cigarettes do not contain the tar that “combusted” products do, and thus do not cause cancer. Still, e-cigarettes contain nicotine, which is a threat to fetuses in gestation. See 81 Fed. Reg. at 28981. And nicotine

is addictive, creating the possibility that e-cigarettes may be a gateway to the use of riskier products. See *id.* at 28986. This is particularly a problem with young people, who are more susceptible than adults to nicotine addiction. See *id.* at 29024. Moreover, the vapor exhaled by e-cigarette users contains trace amounts of toxic products, although in amounts smaller than found in tobacco smoke. In sum, to quote a recent headline in the New York Times, “E-Cigarettes Are Safer, But Not Exactly Safe.” Aaron Carrol, NY TIMES (May 10, 2016). Yet there is considerable evidence that users and potential users, particularly the young, do not understand that e-cigarettes pose risks. See 81 Fed. Reg. at 28981.

We do not know what further research will show about e-cigarettes’ effects. Thus a policy of prevention seems appropriate. But not all agree that the FDA carried prevention far enough. Public health groups are distressed by the FDA’s refusal to restrict the use of flavoring (such as chocolate or bubble gum flavoring) in e-cigarettes and other products covered by the new rules. These groups note that flavoring tobacco products makes their use more attractive to adolescents.

As is required by executive order, the FDA sent its final rules for final review to the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget. According to the Campaign for Tobacco-Free Kids, the FDA rules, as sent to OIRA, sharply regulated flavors in the products covered by the rule, and contained seventeen pages of preamble language justifying its action. But OIRA objected, and the restrictive regulations were removed from the final rule. See http://www.tobaccofreekids.org/press_releases/post/2016_05_31_whitehouse. OIRA, as is customary,

* Professor of Law, Rutgers Law School.

has not made its objections public. The FDA explained the removal of the ban on the grounds that there is evidence—very limited, the FDA agreed—that flavors in e-cigarettes help cigarette users to quit smoking. See 81 Fed. Reg. at 28977.

This explanation, evidently forced by OIRA, creates a contradiction in the FDA's rule because it is in tension with the FDA's refusal to treat e-cigarettes as smoking cessation aids. See *id.* at 29028. Some scientists believe that e-cigarettes are useful in helping smokers quit. Yet, it is not clear whether this is the case. One study showed that e-cigarettes are 60% more effective than a nicotine patch or gum in helping smokers to stop; on the other hand, using e-cigarettes is only 20% effective in ending smoking. See <http://www.webmd.com/smoking-cessation/news/20140520/can-e-cigarettes-help-you-quit-smoking>.

The FDA finds the evidence on e-cigarettes' capacity to help smokers quit is very mixed and uncertain. One study shows that e-cigarette use actually hinders smokers in quitting because it does not wean them from nicotine. See <http://www.cbsnews.com/news/e-cigarettes-dont-help-smokers-quit-study>. The FDA therefore refuses to classify e-cigarettes as smoking cessation devices, unlike, say, the nicotine patch. This path, I suggested in my 2014 article, was appropriate; as with the nicotine patch and gum, the burden ought to be on the e-cigarette industry to show that its product really does reduce smoking. At the same time, the current crop of smoking-cessation products is not effective for the vast majority of those who try them, see <http://www.tobaccofree.org/quitlinks.htm>, and so, perhaps, a more relaxed approach to e-cigarettes would be appropriate to aid smoking cessation. The FDA's rules, though, seem to treat e-cigarettes as smoking cessation devices for one purpose but not for another.

The FDA also needed to address the key issue of what constitutes prevention. While the use of e-cigarettes

has increased dramatically among adolescents, the rate of smoking in this group has decreased—perhaps indicating that e-cigarettes are not the gateway to smoking that the FDA fears. See <http://www.cdc.gov/media/releases/2014/p0612-yrbs.html>. Indeed, some have suggested that discouraging the use of e-cigarettes would only serve to increase the smoking rate among nicotine-craving adolescents, and so regulation is counterproductive because e-cigarettes pose a lesser risk. See http://www.irvinetimes.com/news/14345934.E-cigarettes_face_restrictions_for_public_use_from_Welsh_Assembly_vote/?ref=mr&lp=16.

The “gateway” controversy illustrates another important issue in administering a policy of prevention. As noted in my previous article, society tends to put the burden of proof for showing safety on the advocates for a new product, like e-cigarettes, even when the new product is alleged to actually increase safety. In effect, we prefer the risk we know to the one we do not. Yet it is not obvious exactly how high the burden should be. In assessing arguments that e-cigarettes add to safety, the FDA must decide how much evidence is needed to rebut its preventive assumptions.

This has long been an issue at the Environmental Protection Agency (EPA), which must decide how much of a risk is posed by a cancer-causing substance. EPA has long used protective “default” assumptions in the absence of contrary data. For instance, if there is no information to the contrary, EPA assumes that a substance that causes cancer in rodents also does so in humans. In this way, EPA gives a margin of protection, which is appropriate where public health is concerned. But how much evidence should be required to rebut the default assumption when EPA is assessing the risk from a specific substance? The agency has not been able to come up with a general approach to this question, and instead takes a largely ad hoc approach. See

National Research Council, Science and Decisions, 190–91 (2009).

The FDA is faced with the same kind of problem. In the absence of evidence to the contrary, the FDA assumes that, because e-cigarettes contain nicotine, discouraging their use helps protect public health. But how much of a showing should be needed to convince the agency to depart from this assumption? There is no precise formula to gauge this; the agency must exercise discretion.

Thus, we can see that a preventive policy toward e-cigarettes necessitates important judgments by FDA. The concept of prevention may be a good guide to what the agency should do. But it is not determinative of the issues. More than philosophy is needed. Rather, careful study of the scientific record and good judgment about how to handle uncertainties are needed.

There is an additional difficulty that cannot be answered just by invoking the concept of prevention: It is not easy to decide what steps should be taken to prevent a public health problem. Small e-cigarette manufacturers and vape shops (specialty stores that sell e-cigarettes and accessories) have filed suit to have the new rules set aside. The challengers agree that steps to try to stop use by minors are appropriate. But they assert that the FDA used a “one-size-fits-all” approach that equates e-cigarettes with more dangerous products, and that the FDA rules actually put a disproportionate burden on e-cigarettes as compared to cigarettes.

The Tobacco Control Act requires that cigarettes not on the market in 2007 go through a pre-market review process to show that marketing the product would be beneficial to public health. The FDA rules apply this requirement to e-cigarettes, giving their manufacturers two years to submit the necessary applications, and another year to obtain approval. While there is an exemption for products substantially equivalent to those on the market in 2007, e-cigarette makers say these products are so new that this path is of limited use.

Instead, many current e-cigarette manufacturers will have to go through a lengthy and expensive process of generating an application for each product. This would require much information (including, the industry fears, submission of clinical studies about each new product, even though such studies about e-cigarettes are practically nonexistent). Moreover, each vape shop is defined as a “manufacturer,” meaning that shops that mix and bottle their own products will have to go through pre-marketing review for those products or cease mixing and bottling, thus destroying much of the point of vape shops. While the FDA rules do contain some relief for small manufacturers, and promise guidance on how e-cigarette makers may satisfy pre-marketing review, *see* 81 Fed. Reg. at 28997, the e-cigarette industry believes this is not enough to prevent its products from being driven from the market.

The FDA defends the pre-marketing review requirement as necessary to protect legitimate manufacturers from unfair competition, and to protect public health from dangerous products. These concerns are of course reasonable. In fact, some health and medical organizations, joined by some Democratic members of Congress, believe the FDA did not go far enough. But, unless the FDA shows considerable flexibility, the result of the requirements could be a boon for the big tobacco companies and large players in the e-cigarette industry—which can afford to go through the pre-marketing process and could therefore come to dominate the e-cigarette market. Indeed, the big tobacco companies favored treating e-cigarettes like other tobacco products, even though e-cigarettes appear less dangerous. According to the authors of one recent article, this illustrates what is called the

“Bootlegger and Baptist” theory (named for those who combined to seek Sunday closings of liquor stores) under which public interest groups, such as anti-smoking advocates, often find themselves in coalition with major players in the regulated industry who desire to stifle innovation and competition. *See* Jonathan Adler, Andrew Morriss, Roger Meiners, & Bruce Yandle, *Baptists, Bootleggers and Electronic Cigarettes*, 33 YALE J. REG 313 (2016).

Thus, there remains substantial dispute over the FDA’s regulations. Calls for prevention, while important, leave open substantial questions about how much evidence of a problem is needed and about what the appropriate response is to that problem. These issues are agonizingly difficult for any agency. The future of e-cigarettes and their regulation remains to be seen. ○

Administrative Law Conference

December 8–9, 2016

Walter E. Washington Convention Center • Washington, DC



PROGRAM TOPICS

- ★ Beyond OIRA
- ★ Judicial Deference
- ★ China Crackdown
- ★ Future of Cost-Benefit State
- ★ Justiciability
- ★ Mind the Gap—Digital World
- ★ Presidential Transition
- ★ Rulemaking Capture
- ★ International Investor Arbitration
- ★ Ethics & Prof Resp. in Presidential Transition
- ★ Decline of Administrative Law Exceptionalism
- ★ Administrative Adjudication
- ★ Developments Part 1
- ★ Developments Part 2
- ★ Ethics for Government Attorneys
- ★ State Securities Regulation
- ★ Public-Private Partnerships
- ★ Top Ten on the FDA Agenda
- ★ George Washington University Panel
- ★ Diversity at Federal Agencies

<http://shop.americanbar.org/ebus/ABAEventsCalendar/EventDetails.aspx?productId=256081222>