POLICY FORUM

SCIENCE AND REGULATION

When science and politics collide: Enhancing the FDA

Science-based decisions on drug safety are threatened by political interference

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For the better part of a century, the U.S. Food and Drug Administration (FDA) preserved public health by rigorously applying the scientific method. The central tenet of the *Food, Drug, and Cosmetic Act of 1938* which created the FDA calls for "experts qualified by scientific training and experience to investigate the safety of drugs." In recent times, however, partisan political interposition has grown increasingly worrisome. As the sole arbiter standing between a new drug application and a potential public health calamity, the FDA can hardly afford to be buffeted by undue political interference. In a recent salvo in this decades-long tug-of-war over politics and independence, seven former FDA commissioners, hailing from both sides of the political aisle and spanning many administrations, recently recommended that the "FDA should be an independent federal agency reporting to the President" (*1*, *2*). It is against this backdrop that we explore the utility, desirability, and feasibility of restructuring the FDA charter with political insulation and administrative streamlining in mind. Amid uncertainty over leadership and direction at the FDA since the commissioner stepped down in April, it is a particularly critical time to reflect on how to enhance the independence of the FDA in keeping with its enabling statute.

INDEPENDENCE CURTAILED

Practiced wisely, politics is the lifeblood of a representative pluralist democracy.

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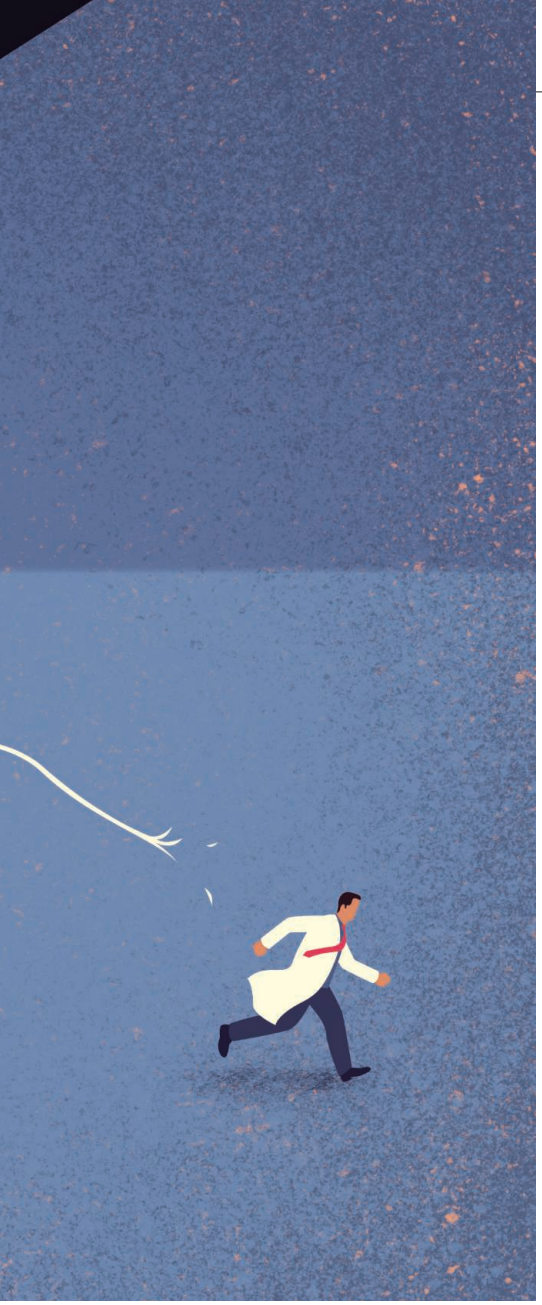

Tethered to a narrow partisan interest, however, politics ceases to serve a useful purpose. So although the FDA is a creature of the executive branch and no one expects it to be completely independent from politics, independence of the role of science at FDA has been essential, for example, to prevent disastrous approval of thalidomide in the United States at a time when an untold number of babies worldwide incurred limb reduction defects as a result of prenatal exposure to the drug.

For much of its early history, the small if growing agency, still very different from its wide-ranging contemporary counterpart, was largely spared excessive political intercession. Since the late 1960s, however, the FDA has been the subject of creeping politicization and a progressive loss of independence. First to go was the apolitical practice of selecting the FDA commissioner from within the career ranks (*3*). FDA is a subagency within the Department of Health and Human Services (DHHS), and by 1981 DHHS rescinded the independent rulemaking authority that had been "subdelegated" to the FDA (*4*, *5*). That same year, a presidential executive order swept away another measure of FDA independence by mandating review of the agency's regulation by the Office of Management and Budget (OMB), which sits within the Executive Office of the President (*4*–*7*). Finally, by force of the Health Omnibus Programs Extension Act of 1988, the appointment of the FDA commissioner, formerly the prerogative of the DHHS secretary, was to require presidential nomination and Senate confirmation (*8*). Though generally viewed as the mark of an independent agency, as opposed to pure presidential appointment, the process of nomination and confirmation also introduces a measure of politicization due to the involvement of the White House and the Senate.

This progressive erosion of political and administrative autonomy became all too apparent when FDA Commissioner Margaret A. Hamburg recommended in 2011 that Plan B One-Step (the levonorgestrel-containing "morning-after pill" used to prevent pregnancy) be approved for over-the-counter (OTC) marketing and sale to all females of childbearing potential on the strength of the agency's scientific review (*9*). That same day, however, against the backdrop of an election year rife with pro-life/pro-choice debates, DHHS Secretary Kathleen G. Sebelius proceeded to override Commissioner Hamburg's recommendation, citing inadequacy of the "data presented to support the application" (*9*). Up to that point, approval and nonapproval recommendations made by an FDA commissioner were traditionally treated as final (*9*). It was not until 2013 that the Plan B case came to a close when a federal judge instructed the FDA to grant all levonorgestrel-containing emergency contraceptives OTC status, without age or point-of-sale restrictions. This example highlights how traditions of what decisions are committed to an FDA commissioner can be upended and thus may only serve as a partial promoter of independence.

Attempts to curtail the FDA's independence have come from both sides of the political aisle. Among the drugs caught up in political contention, none proved more prominent than mifepristone. Presently approved for early pregnancy termination through day 70 of gestation, mifepristone, also known as RU-486, faced intense political controversy throughout its 30-year history. Congressional lawmakers sponsored 25 bills and advanced five FDA-appropriation-constraining amendments, intent on preventing the approval of mifepristone, none of which were ever enacted. Lawmakers held four public hearings, commissioned a Government Accountability Office report, and held up the confirmation of FDA commissioner nominee Jane E. Henney until she provided, as requested, a written pledge to refrain from "soliciting a manufacturer for RU-486" (*10*). Moreover, lawmakers corresponded directly with the FDA commissioner, filed a citizen petition with the FDA, and submitted testimony to the FDA Advisory Committee for Reproductive Health Drugs. Op-Ed contributions and "Dear Colleague" letters circulating among members of Congress abounded. Executive branch interventions were equally momentous. In one such case, at a time when mifepristone was still the subject of an importation ban, a memorandum from President Clinton directed DHHS Secretary Donna E. Shalala to "promptly assess initiatives by which… [DHHS] can promote the testing, licensing, and manufacturing…of RU-486 (*11*)." As the immediate superior of then FDA Commissioner David A. Kessler, Secretary Shalala played a key role in the ultimate approval of mifepristone.

Drug approval is not the only target of legislative and executive branch political interference at the FDA. Similar interventions impeded the FDA from banning the chemical sweetener saccharin (*12*), regulating dietary supplements (*12*), barring carcinogenic color additives (*7*, *12*), prohibiting sulfite-based food preservatives (*7*, *12*), halting the interstate sale of raw milk (*4*, *12*), labeling drug ingredients (*5*), and requiring Reye's syndrome warning labels for aspirin-containing products (*4*, *7*). Comparable political wrangling characterized the decade-long row over switching the status of emergency contraceptives from prescription-only to over-the-counter (*9*). More recently, attention has shifted to Menaflex, a collagen meniscal implant whose initial approval appears to have been the subject of undue congressional interposition (*13*). It was only after additional internal reviews that the clearance of Menaflex was revoked on the grounds that substantial equivalence to a legally marketed safe and effective device could not be demonstrated (*13*). The case serves as a useful reminder that even when formal review processes are robust, political pressure can be informally pressed.

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INDEPENDENCE FOSTERED

Advocates intent on affording the FDA with political insulation have sought to enhance its stature and independence for half a century. In 1975, the Senate Committee on Labor and Public Welfare called for granting the FDA "a measure of independence." Similar sentiments followed in short order, replete with the suggestion that the FDA commissioner be appointed to a 5-year cross-administration term. In 1991, a Blue-Ribbon "Advisory Committee on the Food and Drug Administration" judged that the FDA "enjoys less independence in its dealings with Congress and the public than other consumer health agencies" (*14*). The committee concluded that "dramatic steps must be taken to enhance the FDA's status and independence" (*14*). Two key recommendations followed. First, the "the Secretary of HHS should redelegate to the Commissioner authority to issue regulations" (*14*). Second, the "FDA should be removed from the Public Health Service [which reports to the Assistant Secretary for Health] and the Commissioner should report directly to the Secretary of HHS" (*14*). Absent adoption of the aforementioned recommendation, "Congress should consider establishing the FDA as a free-standing agency" (*14*).

More recently, seven former FDA commissioners stepped into the fray, recommending the recasting of the FDA as an independent federal agency apart and distinct from the DHHS (*1*, *2*). Essential pillars of independence to be embodied in the "new" FDA are to comprise rule-making authority subject to selective Office of Information and Regulatory Affairs (OIRA)–OMB oversight of important regulations, and more independence in its ability to manage litigation (in coordination with the U.S. Department of Justice) (*1*, *2*). A modicum of budgetary independence could be attained were the FDA to follow the example of an independent regulatory agency such as the U.S. Securities and Exchange Commission. Under such circumstances, the heretofore requisite reviews of the FDA appropriations request by DHHS and OIRA-OMB would no longer be required. Instead, the FDA appropriations request would be submitted directly to Congress (*1*, *2*). Further budgetary independence could potentially be secured by emulating the Federal Communications Commission, which is funded entirely by regulatory fees. Although the FDA is funded, in part, by prescription drug user fees, this otherwise insufficient revenue stream must be seen for its potential to compromise the consumer protection mission of the agency. Taken together, some combination of these structural modifications stands to mitigate political interference, reduce administrative logjam, simplify appropriations requests, and afford a modicum of budgetary independence.

Transformations along these lines have precedents. The Social Security Administration (SSA) was formerly an operating division of the DHHS but was made independent in 1994 to insulate it from "short-term political pressures." Additional protection from political churn could be derived by appointing FDA commissioners to 6-year cross-administration terms in keeping with recommendations of the Institute of Medicine (*15*). Implementation of 6-year terms would powerfully signal that the FDA commissioner is administration independent, and to a point, apolitical. Six-year terms are presently being served by the director of the National Science Foundation and the commissioner of the SSA (*15*).

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INDEPENDENCE IN PERSPECTIVE

Regardless of its relative state of independence, the FDA is unlikely to ever be completely shielded from political buffeting. It is, after all, a constituent of the federal government and as such inseparable from ever-present political machinations. Former FDA Commissioner Charles C. Edwards concluded that "to try to take politics out of FDA, first of all will not happen, and second, should not happen. Politics basically is good if handled properly because politics reflects the views of various people in society" (*7*). When science and politics collide, the optimal path is to delineate, as transparently as possible, the contribution of each. Determining the basic facts about safety, efficacy, or adverse events reporting should be science-driven and as apolitical as possible. Determining whether the typical standards for review should be changed for special classes of drugs or devices, by contrast, is an inherently political judgment and should be transparently marked as such. What was so troubling about the Plan B case, for example, was the absence of a robust transparent political debate; instead, we saw a sudden, conclusory, and conclusive determination by the secretary that clothed itself in the language of science but may have been purely political. In that not all political judgments are partisan, the hope is, that when values clash, an independent FDA will navigate the conflict with the nation's best interest in mind.

Congressional or executive branch mobilization to codify in law the independence of the FDA is far from certain. The fate and stature of the FDA rest in the hands of lawmakers who may be reluctant to alter the status quo for fear of losing leverage. Failure to codify in law the independence of the FDA now or in the near future must be viewed as an opportunity missed. ■

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