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# The Delicate Dance of Immersion and Insulation: The Politicization of the FDA Commissioner

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I.

## Abstract

The Food and Drug Administration never has been and never will be completely insulated from politics; it exists and operates as an integral part of the federal government in Washington, DC, not in a vacuum. Nevertheless, the FDA Commissioner has become a more political entity since 1988, the year in which Congress made the position subject to Senate confirmation. Whether considered beneficial or adverse, this politicization of FDA deserves examination—from the two decades preceding the 1988 Act, to the motivation

behind the Act, to the Act itself, and through the present. This paper will endeavor to conduct such an examination.

## I.

### Introduction

The Food and Drug Administration, an agency which today monitors \$1 trillion worth of products that account for 25 cents of every consumer retail sales dollar spent,<sup>1</sup> can trace its genesis back to 1839, when Congress appropriated \$1000 to the Commissioner of Patents for “the collection of agricultural statistics, and for other agricultural purposes.”<sup>2</sup> From the Patent Office in the State Department, FDA shifted to the Department of Agriculture (USDA) and then to the Federal Security Agency, before settling in 1953 in the Department of Health, Education, and Welfare (HEW)—which in 1979 became the Department of Health and Human Services (HHS), and where FDA has resided ever since.<sup>3</sup>

Despite its extensive and rich institutional history, it was not until 1988—nearly 150 years after the initial congressional appropriation to the Patent Office—that FDA was formally created by statute.<sup>4</sup> In passing the Food and Drug Administration Act (1988 Act), codified as Section 903(b)(1) of the Food Drug & Cosmetic

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<sup>1</sup>Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law: Cases and Materials* 17 (1991); “History of FDA,” on FDA website, available at <http://www.fda.gov/oc/history/historyoffda/fulltext.html> (last updated January 21, 2003).

<sup>2</sup>Peter Barton Hutt, *Symposium on the History of Fifty Years of Food Regulation Under the Federal Food, Drug, and Cosmetic Act: A Historical Introduction*, 45 *Food Drug Cosm. L.J.* 17 (1990) (quoting 5 Stat. 353, 354 (1839)).

<sup>3</sup>FDA took its current name in 1930. Hutt, *Symposium* at 18; “Designation and Location of FDA in Federal Government,” on FDA website, available at <http://www.fda.gov/opacom/morechoices/designat.html> (last updated October 15, 2001).

<sup>4</sup>Before 1988, FDA and its predecessor organizations were all created by administrative action. Peter Barton Hutt, *Investigations and Reports on the Food and Drug Administration*, in Richard M. Cooper (ed.), *Food and Drug Law* 41 (1991).

Act (FD&C Act), Congress established FDA as an agency of HHS; with a Commissioner of Food and Drugs appointed by the President with the advice and consent of the Senate; and laid out the Commissioner's general powers and responsibilities.<sup>5</sup>The FDA Commissioner's organizational rank is Executive Level IV, three levels below the HHS Secretary and on the same tier as the Assistant Secretaries of HHS.<sup>6</sup> The FDA Commissioner serves at the pleasure of the President, who can remove the Commissioner from office for any or no reason.<sup>7</sup> Prior to 1988, FDA Commissioners were appointed by the Secretary of HHS and thus not subject to Senate confirmation.<sup>8</sup>

Passage of the 1988 Act apparently met with little more than mild, fleeting interest. As the *Washington Post* reported at the time: "Relatively few people took notice last week when a bill to make the commissioner of the Food and Drug Administration subject to confirmation sailed through the Senate."<sup>9</sup> That perhaps the 1988 Act was simply a case of form catching up to function might help explain the reaction. Today, however, 15 years after its passage, it is apparent that the 1988 Act has had some profound consequences on

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<sup>5</sup>102 Stat. 3048, 3120-22 (1988). The FDA Act of 1988 (21 U.S.C.A. § 393) provides in relevant part: § 393. Food and Drug Administration (Current through P.L. 108-6, approved 02-13-03)

(a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration")...

(d) Commissioner

(1) Appointment

There shall be in the Administration a Commissioner of Food and Drugs (hereinafter in this section referred to as the "Commissioner") who shall be appointed by the President by and with the advice and consent of the Senate.

(2) General powers

The Secretary, through the Commissioner, shall be responsible for executing this chapter and for—

(A) providing overall direction to the Food and Drug Administration and establishing and implementing general policies respecting the management and operation of programs and activities of the Food and Drug Administration;

(B) coordinating and overseeing the operation of all administrative entities within the Administration;

(C) research relating to foods, drugs, cosmetics, and devices in carrying out this chapter;

(D) conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration; and

(E) performing such other functions as the Secretary may prescribe.

<sup>6</sup>5 U.S.C.A. § 5315. *In re Kessler*, 100 F.3d 1015, 1017 (DC Cir. 1996) ("Dr. Kessler's actual rank... is a Level IV: the same grade as the typical assistant secretary of a department or a member of a Commission (Executive Level IV is the journeyman level of those appointed by the President and confirmed by the Senate).")

<sup>7</sup>Hutt & Merrill at 16.

<sup>8</sup>The Appointments Clause of the Constitution, Art. II, § 2, cl. 2, requires Senate confirmation of officers appointed by the President.

<sup>9</sup>Michael Specter, *New Freedom for FDA Commissioner?*, *Washington Post*, Feb. 9, 1988, at A21.

the post of FDA Commissioner—and, more generally, on FDA itself. Although it carved out an autonomous identity for the FDA Commissioner in the 1988 Act, Congress necessarily and officially injected a certain dose of politics into FDA, the level of which has fluctuated over time. The result is a Catch-22: Although Congress sought to grant it independence in the 1988 Act, FDA arguably has become more politicized since that time—as viewed primarily through the FDA Commissioner appointment process.

## II.

### Structure and Operation of FDA

FDA is located within the Executive Branch and it operates within HHS; the 1988 Act neither gave FDA statutory authority separate from HHS nor made it an independent regulatory agency.<sup>10</sup> The FD&C Act vests authority in the HHS Secretary, who in turn delegates it (through the Assistant Secretary for Health) to the FDA Commissioner.<sup>11</sup> The Commissioner heads FDA and is assisted by a number of deputy commissioners in carrying out agency business.<sup>12</sup> Also integral to effective operation of the agency is the chief counsel for FDA, who, although officially an employee of HHS, “carries tremendous internal political weight” as the Commissioner’s lawyer.<sup>13</sup>

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<sup>10</sup>James T. O’Reilly, *Food and Drug Administration* (2<sup>nd</sup> ed.) 2-4 (1993).

<sup>11</sup>O’Reilly at 2-2. The substantive contents of the FD&C Act, although of course significant, will be addressed only as they pertain to the subject matter of this paper—in order to maintain a properly manageable scope.

<sup>12</sup>The positions are Deputy Commissioner, Deputy Commissioner for Policy, Deputy Commissioner for External Affairs, Deputy Commissioner for Operations, and Deputy Commissioner for Management and Systems. “Deputy Commissioners and Their Predecessors,” on FDA website, *available at* <http://www.fda.gov/opacom/morechoices/depcomm.html> (last updated February 26, 2002).

The FDA Commissioner may, with HHS approval, reshuffle the agency organizational structure. O’Reilly at 2-6.

<sup>13</sup>O’Reilly at 2-6; Hutt & Merrill at 17. Alexander Schmidt, the late former FDA Commissioner, once remarked: “Perhaps my favorite nonconsumer question is the one that the reporter always asks when he wants to show me he’s really got inside dope: ‘Mr. Commissioner,’ he asks, ‘who really runs FDA—you or Peter Hutt?’” *Twenty Questions for the Commissioner*, 29

In practice, the HHS Secretary has given nearly complete authority on FDA matters to the Commissioner—indicative of the “considerable decisional independence” with which FDA has operated for most of its existence.<sup>14</sup> Understandably, FDA Commissioner is widely considered among the most prominent posts in government and thus has drawn fittingly prominent individuals to the job. Indeed, wrote Peter Barton Hutt and Richard Merrill, “FDA’s visibility and the potential sensitivity of its decisions always have given the Commissioner a direct line to the Secretary of HHS and, sometimes, to the White House as well.”<sup>15</sup>

Over time, FDA has endured the tip of a double-edged sword with regard to carrying out its mission. FDA continually receives high marks from the public; polls show that more than two-thirds (67%) of Americans have a positive view of FDA.<sup>16</sup> Yet FDA is also among the most scrutinized agencies in Washington: In fact, during the last few decades, FDA “has become perhaps the most thoroughly analyzed government agency in history.”<sup>17</sup> The primary channel for most of the recent criticism of FDA, whether warranted or not, has been congressional hearings. As one author has observed: “The Commissioner of the FDA is a favorite witness because the FDA’s requirements are controversial; its mistakes can have enormous and life-threatening effects in some cases, and its policies and practices are in any event a first-class media event for newspeople covering Congress.”<sup>18</sup> Also significant is the fact that FDA relies on the support of Congress for funding sufficient to maintain its programs and to fulfill its agenda.

It is against this backdrop that the 1988 Act and its effects on appointment of the FDA Commissioner—as well as FDA generally—must be viewed. The politicization of FDA over the past 15 years, although brief,

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Food Drug Cosm. L.J. 596, 600 (1974).

<sup>14</sup>Hutt & Merrill at 16. *See also* O’Reilly at 2-3.

<sup>15</sup>Hutt & Merrill at 15.

<sup>16</sup>The Harris Poll #51, October 17, 2001, on Harris Interactive website, *available at* [http://www.harrisinteractive.com/harris\\_poll/printerfriend.asp?PID=262](http://www.harrisinteractive.com/harris_poll/printerfriend.asp?PID=262). In 2000, Harris Poll #62 (October 18, 2000) reported that 62% of Americans viewed FDA favorably.

*But see* the metaphorical observation of a former FDA Commissioner: “[T]he FDA is somewhat like a referee in a football game. While most people cheer loudly for the home team, and a few even cheer for the visiting team, nobody ever cheers for the referee. And yet, like the referee, the FDA often has to make the difficult calls—and without the benefit of an instant replay.” Frank E. Young, *For Every Thing There is a Season*, 45 Food Drug Cosm. L.J. 7, 15 (1990).

<sup>17</sup>Hutt, *Investigations and Reports* at 41.

<sup>18</sup>O’Reilly at 2-14.

has grown quite intense at times.

### III.

## Politics & FDA Before the 1988 Act

During the 1970s, FDA received an extraordinary amount of congressional attention, perhaps more than any other regulatory agency.<sup>19</sup> That decade was punctuated by hearings conducted by Senator Edward Kennedy (D-Mass.) to investigate charges by FDA employees that “FDA was dominated by the pharmaceutical industry and was inadequately protecting the public against unsafe and ineffective new human and animal drugs.”<sup>20</sup> Even though the allegations proved largely unsubstantiated, after an internal investigation and an investigation by a review panel appointed by the HEW Secretary, the hearings produced somewhat of a political maelstrom. In the aftermath of the hearings, Kennedy proposed subdividing FDA into a Drugs and Devices Administration and a Food and Cosmetics Administration; the proposals were intended to elevate the Commissionship to a Senate-confirmed office with statutory powers over the statutorily established FDA within HEW.<sup>21</sup>

Although it never materialized, the subdivision proposal foreshadowed, to some extent, the ultimate modification of FDA in 1988. It also illustrated just how tightly the political vise can grip FDA and how acutely that grip is felt within the agency. As then- Commissioner Alexander Schmidt remarked, at the time, about his decision to make public certain materials related to his own investigation of charges made at the Kennedy hearings:

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<sup>19</sup>Hutt & Merrill at 19 (noting that between 1971 and 1977, FDA officials were called to testify before congressional committees 198 times).

<sup>20</sup>Hutt, *Investigations and Reports* at 49.

<sup>21</sup>O’Reilly at 2-2.

I have been criticized recently by friends inside and outside FDA for taking steps that, and I quote, ‘play into our critics hands,’ or ‘make me appear weak.’ . . . I have said that FDA needs and welcomes constructive criticism; that the Kennedy hearings have served to spotlight certain errors in our drug approval process; and that FDA will be better and stronger because of the hearings.<sup>22</sup>

The competing pressures are understandable, given that FDA is entrusted to ensure the safety of food, drugs, cosmetics and medical devices for the entire nation. Attempting to carry out this momentous task within such a political climate makes it even more difficult—a lesson FDA Commissioners have learned all too well over the years.

The recollections of former FDA Commissioners provide perhaps the best illumination into the intimate and sometimes prickly relationship between the agency and politics. This examination will begin with a few Commissioners who served prior to 1988, before the top position required Presidential appointment and Senate confirmation. The experiences of these Commissioners will help place in proper historical context the 1988 Act and its aftermath.

The FDA Commissioner simply cannot divorce himself from politics; to do so would ignore the reality in which he and the agency operate.<sup>23</sup> As Charles Edwards, who served as FDA Commissioner from 1969 to 1973, explained: “To try to take politics out of FDA, first of all will not happen, and second, should not happen. Politics basically are good if handled properly because politics reflects the views of various people in society.”<sup>24</sup> During his tenure, Edwards steered FDA through a period of turmoil on numerous fronts. For example, FDA was assigned responsibility for regulating biologics and radiological health; there were also massive recalls of cancer-linked cyclamates, botulism-suspected Bon Vivant vichyssoise, and mercury-tainted swordfish and tuna.<sup>25</sup> “It became very obvious,” Edwards recognized, “that if we were going to survive as a meaningful entity, then we knew we had to reach out to Congress.”<sup>26</sup> To that end, Edwards

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<sup>23</sup>If I use such a phrase as “himself” or “he,” I also intend it to refer to “herself” or “she” in the alternative; I have omitted the alternative in the text simply for stylistic purposes.

<sup>24</sup>Interview with author, March 22, 2003.

<sup>25</sup>“FDA Commissioners and Their Predecessors,” on FDA website, *available* at <http://www.fda.gov/opacom/morechoices/comm1.html> (last updated November 20, 2002).

<sup>26</sup>Interview with author.



said he made it an immediate priority to establish a good relationship with Congress.<sup>27</sup> The position of FDA Commissioner, in Edwards' view, requires a certain degree of equanimity and versatility: "If you have a strong Commissioner and a Commissioner that is truly running FDA, then he has to have the ability to understand both the science of what he is talking about and the political ramifications of the decision he is about to make. . . . The key is not to be whipsawed by the science or the politics of it."<sup>28</sup> Upon reflection, although he received input from other sources, such as the White House, Edwards believes—and is proud of the fact—that he and his staff were able to run FDA basically free from interference.<sup>29</sup>

Alexander Schmidt, who succeeded Edwards and served as Commissioner from 1973 to 1976, considered his professional background both a curse and a blessing. Prior to becoming FDA Commissioner, Schmidt had served as dean and a professor at the University of Illinois College of Medicine in Chicago. He acknowledged candidly: "[U]nless you are an old Washington hand, you go into [the job] quite naïve and you don't know things you should know. My maturing took a huge step a few weeks after that first Kennedy hearing. I didn't know what in the hell was going on or what in the hell was happening to me."<sup>30</sup> Nevertheless, Schmidt believed that his professional experiences made him an attractive candidate for the job. "[T]he Nixon administration wanted a certain kind of appointment," Schmidt explained. "So, in a way, I think I fit what the administration was looking for, and that was a Republican person from the academic field who

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Edwards tells an interesting story about his assumption of office. After accepting the Nixon administration's offer to become FDA Commissioner, Edwards had planned initially to serve as an assistant to HEW Secretary Robert Finch for a short while, in order to get a sense of what was going on in FDA. But two days after he arrived in Washington, the newspapers leaked the story that Edwards would become the new Commissioner—prompting the current Commissioner, Herbert Ley, to resign. Finch then called Edwards and told him, "The job is yours." Edwards went over to Ley's office—the two men had never met—which had a long conference table with piles of neatly stacked papers. Edwards recalled: "I asked him what were the major problems of the agency. He pointed to the papers and said, 'There they are.' He tossed me a toy football and said, 'The ball is in your court.'"

<sup>27</sup>Interview with author. Edwards remains close friends with congressmen he worked with as Commissioner, such as retired Rep. Paul Rogers (D-Fla.) and Sen. Edward Kennedy.

<sup>28</sup>Interview with author.

<sup>29</sup>*Id.*

<sup>30</sup>"FDA Oral History Program: Interview with Alexander M. Schmidt" (conducted March 8-9, 1985), on FDA website, available at <http://www.fda.gov/oc/history/oralhistories/schmidt/part4.html> (created January 17, 2002).

had some management skills and might be able to manage FDA.”<sup>31</sup>

Indeed, Schmidt’s experiences illustrate the important duty of FDA Commissioners to strike a delicate balance between the proper degree of immersion in and insulation from politics. Schmidt was mindful of the fact that FDA needed sufficient independence to function effectively and that it was his job to ensure this, a notion reinforced to him by professionals within the agency. Thus, he made a deal with then-HEW Secretary Casper Weinberger: “I would keep Cap and the White House informed of anything they needed to be or should be informed of so they wouldn’t be surprised and they wouldn’t get hit on the back of the head with a wet fish or whatever, and I would run the agency well. And in return for that, they would leave me alone.”<sup>32</sup> The arrangement worked out swimmingly, in Schmidt’s estimation. He had ample authority and discretion over FDA decisionmaking, and he still enjoyed solid support from Weinberger—for which, as he admitted, he was particularly grateful during the Kennedy hearings. The simple but unmistakable lesson here, in Schmidt’s words: “There is an advantage to being a member of the party in power.”<sup>33</sup>

But with the good comes the bad and, as FDA Commissioner, Schmidt also encountered the other edge of the proverbial double-edged sword discussed above. He articulated the familiar frustration experienced by many science- and medically-trained professionals within FDA: “[M]ost people who instigate the controversy or fight with FDA don’t understand science or what science is or the limitations of science or when science leaves off and something else begins. That something else is really politics. The principal reason is that there is not a rigorous differentiation of science and politics.”<sup>34</sup> Effecting such a differentiation, however, remains a near-herculean task—and perhaps one that does not comport with the external realities that surround FDA.<sup>35</sup>

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<sup>31</sup> “Interview with Alexander M. Schmidt,” *available at* <http://www.fda.gov/oc/history/oralhistories/schmidt/part2.html> (created January 17, 2002). Schmidt observed that, in this regard, the Reagan administration followed along the same track as that of Nixon.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> Interestingly, but not surprisingly, the American public considers scientists (51%) and doctors (50%) to be professions of “very great” prestige—trouncing the perceived prestige of members of Congress (27%) and lawyers (15%). Scientists and

Where Schmidt acutely felt the sting of politics as FDA Commissioner, his successor, Donald Kennedy, who served from 1977 to 1979, actually tended to relish the give-and-take with Congress. “I was a Commissioner who liked a political struggle, if I liked the objectives,” Kennedy explained, noting that he befriended members of Congress from both parties. “I enjoyed jousting with Congress. Sometimes it was fun because they made it fun.”<sup>36</sup> Kennedy admitted, however, that he benefited because his party, the Democrats, controlled the White House and both chambers of Congress during his tenure as Commissioner: “It is much harder when that is not the case—if you have a sufficient amount of insulation and influence, you can accomplish a lot more.”<sup>37</sup> Kennedy’s impact on FDA was unquestionably valuable in terms of rejuvenating the agency and elevating its prestige in the public eye after a period of tumult, according to one author who studied Kennedy closely. “By raising the tone of the FDA Kennedy improved its public image,” observed Herbert Kaufman, noting Kennedy’s cordial relationship with Congress. “By reestablishing its good name, he helped raise its tone. Indeed, the two elements are so closely related that they may be two sides of the same coin. . . . In the FDA they rose, thanks in large measure to the administrative behavior of the chief.”<sup>38</sup>

Even Kennedy’s entrance into office was comfortable, setting the tone for his tenure. HHS Secretary Joseph Califano held a swearing-in ceremony for him with a Bible, Kennedy recalled, “but this was really window-dressing because I could have just walked into the job as Commissioner.”<sup>39</sup> Kennedy also recognizes the other

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doctors are the top two professions thought to have “very great” prestige. The Harris Poll #54, October 16, 2002, on Harris Interactive website, *available at* [http://www.harrisinteractive.com/harris\\_poll/prINTERfriend.asp?PID=333](http://www.harrisinteractive.com/harris_poll/prINTERfriend.asp?PID=333).

<sup>36</sup>Interview with author, March 20, 2003.

<sup>37</sup>*Id.*

<sup>38</sup>Herbert Kaufman, *The Administrative Behavior of Federal Bureau Chiefs* 147 (1981). Kaufman elaborated on Kennedy: “He treated his colleagues with respect, was receptive to their ideas, encouraged inventiveness, and did his homework assiduously when they put proposals before him. He helped create a collegial environment, at least in headquarters. The rejuvenation of the agency might have happened without him, but it probably was speeded and intensified because of the way he conducted himself as commissioner.” *Id.* at 143.

<sup>39</sup>Interview with author.

side of the coin and sympathizes with what Schmidt, as a Republican appointee, endured as Commissioner. He thinks the political attacks leveled at Schmidt by his Democratic critics—namely, that he and the agency were too friendly to the pharmaceutical industry—was “unfair targeting” and simply untrue.<sup>40</sup>

The infusion of politics into the Commissionership is one reason for what Schmidt considered the relatively high turnover of FDA Commissioners—“crummy continuity,” he called it—from the mid-1960s to the mid-1980s.<sup>41</sup> “With the exception of Charlie [Edwards] and me, you had one- to two-year commissioners since [George] Larrick,” Schmidt explained. “[M]y prediction is that the current commissioner [Frank Young], who’s been there only a few months, is going to be taken out of that job within a week or two or three [to become assistant secretary of health].”<sup>42</sup> Such a lack of continuity hinders the FDA’s effectiveness in carrying out its mission. This hurts the agency itself and, ultimately by extension, the American public.

Frank Young, FDA Commissioner from 1984 to 1989, echoes some of Schmidt’s chief observations in discussing his own experiences.<sup>43</sup> Young considered stability the “linchpin” for the operation of FDA because it gives the agency “experienced leadership” and “sustained direction.”<sup>44</sup> Noting that he became the FDA’s fourth Commissioner in seven years when he assumed office, Young recalled: “When I first arrived at the FDA, I felt a bit like a parachutist jumping into unknown territory. I can only imagine how hard it was for the FDA’s career professionals to have commissioners coming and going like Greyhound buses in the night.”<sup>45</sup>

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<sup>40</sup>Id.

<sup>41</sup> “Interview with Alexander M. Schmidt,” available at <http://www.fda.gov/oc/history/oralhistories/schmidt/part3.html> (created January 17, 2002).

<sup>42</sup>Id. Frank Young actually served for more than five years as FDA Commissioner (1984-1989). The accuracy of Schmidt’s prediction, of course, is less important than his sentiments underlying it.

<sup>43</sup> As a general matter, the author appreciates Young’s ability to turn a metaphor in describing his experiences.

<sup>44</sup> Frank E. Young, *Strengthening the FDA Through Stability, Modernization, and Statesmanship*, 43 *Food Drug Cosm. L.J.* 447, 448 (1988).

<sup>45</sup>Id. Upon his departure from FDA, Young’s tenure as Commissioner was the longest since that of George Larrick (1954-1965); it was then eclipsed by his successor, David Kessler (1990-1997).

Tied to the notion of stability, in Young’s view, is the statesmanship required of FDA—through “dignity, vision, and objectivity”—to deal with its various and oft-conflicting constituencies.<sup>46</sup> But Young pointed out that statesmanship is a two-way street. While FDA must be willing to accept constructive criticism from Congress, that criticism should be factually fair and reasonably based. To that end, he has urged, FDA should ask members of Congress to refrain from “grandstanding” on FDA issues: “Many politicians have built careers by bashing the bureaucrats. As I have said here before, only eighteen inches separates a pat on the back from a kick in the behind, but that difference is profound.”<sup>47</sup>

To accord it an autonomous identity and to bolster its credibility, Schmidt recommended establishing FDA as an independent agency by law, with the Commissioner subject to Senate confirmation—auguring the heart of the 1988 Act: “[T]he commissioner ought to be protected from politics to the extent of that kind of appointment. I think the agency ought to be left in HHS, but be independently chartered by legislation. . . . [T]hat would solve an awful lot of problems.”<sup>48</sup> Schmidt was not the first person to advance this proposal, to be sure, but the proposal takes on additional weight, given his front-line experiences in the position. Whether and to what extent the 1988 Act has had the salutary effects forecast by Schmidt remains unclear—and is a principal focus of this paper.<sup>49</sup>

Schmidt’s recommendation garnered momentum during the winter of 1985-1986, as efforts in both chambers of Congress took shape to create FDA officially by statute and to make the FDA Commissioner subject to Senate confirmation. In the House of Representatives, Henry Waxman (D-Calif.) led the charge, while

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<sup>46</sup>*Id.* at 458.

<sup>47</sup>Young, *For Every Thing There is a Season* at 10.

<sup>48</sup>“Interview with Alexander M. Schmidt,” available at <http://www.fda.gov/oc/history/oralhistories/schmidt/part4.html> (created January 17, 2002). Schmidt described how he was part of an earlier unsuccessful effort supporting such legislation: “Then I forget what happened, but the thing fell apart, and we couldn’t get it through.”

<sup>49</sup>This will be addressed in greater detail below.

William Proxmire (D-Wisc.) did so in the Senate.<sup>50</sup>

Calling his bill “a long overdue measure,” Waxman noted that FDA was the only major federal health and safety agency whose head was not subject to Presidential appointment and Senate confirmation: “There is no good reason to exempt the FDA Commissioner from accountability to the Congress.”<sup>51</sup> Proxmire argued that political pressure applied on FDA by the Reagan administration had subverted the agency’s ability to evaluate the emerging science necessary to ensure and preserve the safety of food, drugs, cosmetics and devices for the American public. In particular, Proxmire cited the Reagan administration’s revocation of the FDA Commissioner’s authority to ban cancer-causing color additives; its opposition to complete labeling of all ingredients used in drugs; and, in the wake of the aspirin-Reyes Syndrome link, its initial pressure on FDA to make warning labels only voluntary. “[T]he FDA Commissioner can no longer be just another hired hand of the administration,” Proxmire declared. “We need a tough, independent FDA Commissioner who can resist powerful political and economic interests.”<sup>52</sup> Neither measure made it out of committee, but the groundwork was laid.

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<sup>50</sup>The House measure was H.R. 3909. The Senate measure was S. 2025 (cosponsored by Sen. Howard Metzenbaum (D-Ohio)). Discussion of the substance of the ultimate 1988 Act will begin with the efforts of Waxman and Proxmire, even though, as noted above, calls for a Senate-confirmed Commissioner had been made in previous years.

<sup>51</sup>131 Cong. Rec. 36121 (1985). In hearings the next year on his proposed legislation, Waxman mentioned that he thought the FDA Commissioner post should be subject to confirmation by both the House and the Senate. *Senate Confirmation of the FDA Commissioner; and Reauthorization of Research Activities by ADAMHA: Hearing on H.R. 3909 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99<sup>th</sup> Cong., 2d Sess. 6 (1986).

<sup>52</sup>132 Cong. Rec. S 471 (1986).

#### IV.

##### The Food and Drug Administration Act of 1988

During the 1980s, the Reagan administration sought to deregulate the drug approval process. As a result, in 1981, FDA approved more new drugs than it had in any single year since 1962.<sup>53</sup> Additionally, the deregulation produced declines in the number of FDA inspections, product seizures and legal actions.<sup>54</sup> Arthur Hull Hayes, the FDA Commissioner appointed by Secretary of HHS Richard Schweiker in 1981, was “ideologically consistent” with the priorities of the Reagan administration and “sought to infuse FDA rulemaking activities with the regulatory relief priorities of the president.”<sup>55</sup> This philosophical shift in FDA exemplified “the clear response of a bureaucracy to a leadership stimulus.”<sup>56</sup> The Reagan administration made two particularly significant changes affecting FDA: It transferred to the HHS Secretary the authority to decide important regulatory issues, and it empowered the Office of Management and

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<sup>53</sup>B. Dan Wood & Richard W. Waterman, *Bureaucratic Dynamics: The Role of Bureaucracy in a Democracy* 55 (1994).

<sup>54</sup>*Id.* at 55-57.

<sup>55</sup>*Id.* at 54-55.

<sup>56</sup>*Id.* at 57 (noting the uncertainty in “whether the changes in the FDA’s enforcement program were consistent with presidential preferences or just those of the FDA’s new leadership”).

Budget (OMB) to review all FDA regulations.<sup>57</sup>

That an agency or department would set forth to accomplish the priorities of the President in office seems fairly unremarkable, but this notion assumes a greater volatility in practice when that agency is FDA. Such was the case during the 1980s, as many in Washington decried what they viewed as the improper encroachment of politics into science. For example, FDA scientists had advocated a ban on the interstate sale of raw milk, and the agency had sought for some time to require labels on aspirin bottles warning of Reye's syndrome, an often-fatal disease of the brain that can afflict children who use aspirin.<sup>58</sup> HHS overruled FDA on banning raw milk sales and delayed for two years the decision to require Reye's syndrome warnings on aspirin labels.<sup>59</sup>

The volume escalated when consequences of FDA action or inaction became publicized. Proxmire charged that the "Commissioners to serve during the Reagan administration have been kept on increasingly short leashes."<sup>60</sup>

The climate even led Schmidt, who had served as Com-

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<sup>57</sup>Specter at A21.

<sup>58</sup>Specter at A21; Merriam Webster Medical Dictionary, *available at* <http://www.intelihealth.com/cgi-bin/dictionary.cgi?t=9276&st=&p=%7E> (visited March 21, 2003).

<sup>59</sup>Specter at A21.

<sup>60</sup>132 Cong. Rec. S 470 (1986). The two Commissioners who served during the Reagan administration were Arthur Hull Hayes (1981-1983) and Frank Young (1984-1989).



missioner nearly a decade before, to tell state regulators: “We have more politicization of the agency than is either warranted by rational politics or good for the American people.”<sup>61</sup> Frank Young, who served for most of Reagan’s second term, was the last Commissioner not subject to Presidential appointment and Senate confirmation. Although he recognized that politics is always embedded within the office of the FDA Commissioner, he felt “a strong need for the Commissioner to be as independent as possible.”<sup>62</sup> Noting that there has been a “progressive politicization” of the FDA Commissioner and the public health professional in general, Young elaborated:

The Commissioner has to be independent and focus on scientific issues that are presented to him. Of course you live in a political environment and are molded by the political climate. But FDA is too much of a public health agency, so it cannot be a handmaiden of partisan politics. It must rise to the level of public health—with a capital P and a capital H.<sup>63</sup>

The 1988 Act was passed in the penultimate year of Young’s tenure in office and was to be applied to his successor as Commissioner.

The 1988 Act itself has a relatively sparse legislative history and apparently engendered little debate within Congress. Waxman once again sponsored the House legislation, H.R. 1226, and Al Gore sponsored the Senate legislation, S. 223 (with Amendment No. 1401). The language in both chambers echoed that of the previous efforts, discussed above; the bills, after all, were substantively identical. In fact, the House did not

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<sup>61</sup>Michael L. Millenson, *FDA Politicization Called Hazardous to Health*, Chicago Tribune, Oct. 20, 1985 (contained in 132 Cong. Rec. S 470 (1986)).

<sup>62</sup>Interview with author, March 20, 2003.

hold hearings on the 1988 Act because it had done so on the earlier legislation unsuccessfully introduced by Waxman.<sup>64</sup> In reporting favorably H.R. 1226 to the whole House, the Committee on Energy and Commerce Report, which totaled only four pages, concluded that “Senate confirmation is a constructive and worthwhile process. . . that provides the Congress with an invaluable opportunity for oversight.”<sup>65</sup> The report also noted that the Committee did not receive any “agency views” on the legislation.<sup>66</sup>

Waxman reiterated his belief that “Senate confirmation is a constructive and worthwhile process,” pointing out that aside from the FDA Commissioner, the head of every major federal health and safety agency—including FAA, EPA, OSHA, NHTSA, CPSC and NRC—was subject to Presidential appointment and Senate confirmation.<sup>67</sup> According to the language in the Findings section of the bill, imposing these requirements would enhance “the independence and integrity” of FDA and its Commissioner.<sup>68</sup> In introducing the Senate version of the bill, Gore sharply criticized the Reagan administration for “launch[ing] a quiet assault” on FDA.<sup>69</sup> Citing the Reye’s syndrome issue, he claimed that “special interests and partisan politics have replaced sound scientific policy”—resulting in “[m]orale among FDA professionals. . . at an all-time low.”<sup>70</sup> These rationales did not go unchallenged by some academics. “The legislators do not provide justification for this change based on any neutral principles of good government,” wrote one professor at the time. “Indeed, all the reasons presented in the legislative history are political ones. . . . Politics matter, and structure is a weapon in the battle.”<sup>71</sup>

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<sup>64</sup>The pertinent aspects of those hearings on the earlier legislation, H.R. 3909, will be discussed below.

<sup>65</sup>H.R. Rep. No. 70, 100<sup>th</sup> Cong., 1<sup>st</sup> Sess. 2 (1987).

<sup>66</sup>*Id.* at 4.

<sup>67</sup>133 Cong. Rec. 4044-45 (1987).

<sup>68</sup>134 Cong. Rec. 18888 (1988).

<sup>69</sup>133 Cong. Rec. 660 (1987).

<sup>70</sup>*Id.*

<sup>71</sup>Susan Bartlett Foote, *Independent Agencies Under Attack: A Skeptical View of the Importance of the Debate*, 1988 Duke L.J. 223, 230, 232 (1988). Foote rejected the justification of placing FDA in line with the other major federal health and safety agencies: “These agencies were formed in the 1960s and 1970s, when a powerful Congress won greater agency autonomy from the executive branch. . . . The FDA, by contrast, has its roots in the Progressive era, and its ties to the executive branch are due to historical accident, not inequitable treatment.” *Id.* at 230-31.

Although passage of the 1988 Act originated with Democratic lawmakers in both chambers, there does not appear from the legislative record to have been much, if any, opposition from their Republican counterparts. Moreover, there is little evidence of any vehement opposition from the Reagan administration.<sup>72</sup> Waxman had anticipated vocal resistance from the White House; Gore, testifying at the hearings on Waxman's initial legislation, urged that the expected opposition be "heavily discount[ed]... as merely a knee-jerk reaction."<sup>73</sup> But any tension between the executive and legislative branches over the legislation was not evident from the hearings.<sup>74</sup> In fact, the Reagan administration's spokesman at the hearings, Donald Ian MacDonald, acting assistant secretary for health in HHS, was mild and measured in objecting to the legislation: "[W]hile we recognize the significance of the mission of FDA and consequently the importance of its Commissioner, we do not believe this change in the current appointment procedure for the Commissioner is necessary. . . . We do not see it as a necessary change, but would not struggle to disagree with you."<sup>75</sup>

And so the legislation passed with more of a proverbial whimper than a bang. What remained to be seen among interested participants and observers was whether the 1988 Act would more insulate from or infect with politics the position of FDA Commissioner.

## V.

### Aftermath of the 1988 Act

Upon passage of the 1988 Act, Gore predicted that requiring Presidential appointment and Senate confirmation of the FDA Commissioner would be an invaluable improvement: "In the past, the current arrangement

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<sup>72</sup>Interestingly, passage of the 1988 Act did not occasion much reaction from former FDA Commissioners. As Donald Kennedy recalled: "It made only a ripple, in my memory. I think I said, 'That's interesting,' but it was not a big event." Interview with author.

<sup>73</sup>*Hearing on H.R. 3909* at 6.

<sup>74</sup>Despite extensive research, the author was unable to find any evidence of substantial opposition of the White House to the 1988 Act.

<sup>75</sup>*Hearing on H.R. 3909* at 29-30.

has resulted in serious delays in decisionmaking—delays that have endangered the public health and cost industry millions of dollars. I think we will all benefit from an independent and accountable FDA.”<sup>76</sup> Fifteen years later, the irony in Gore’s statement is glaring: Delays in filling the post of FDA Commissioner since the 1988 Act have been markedly greater than prior to it. Between 1940 and 1988, the average length of time for filling the post was  $2\frac{1}{2}$  months.<sup>77</sup> Since 1988, however, the average length of time to fill the position for three Commissioners has been nearly  $1\frac{1}{2}$  years (17 months).<sup>78</sup> FDA simply cannot be expected to operate at its optimal effectiveness without a permanent leader at the helm for such long periods.

Advocates of the 1988 Act tend to characterize the delays more as a result of necessary contemplative deliberation, rather than the product of political wrangling over an acceptable nominee or of the larger political climate. As Gore put it: “The Senate is by nature a patient institution, not to mention one that demands patience. Senators have shown that they are willing to take the time to make the review process valuable and productive.”<sup>79</sup> Jane Henney, who served as FDA Commissioner from 1998 to early 2001 and was thus subject to Senate confirmation, considers at least some delay necessary given the significance of FDA’s responsibilities. “The agency is so important at the end of the day to the American public, so the administration should wait it out until it gets the right person,” she said. “The lagtime that has been created has been due to a lack of appreciation over kind of person needed to do that job.”<sup>80</sup> According to Henney, every candidate for Commissioner should possess three basic criteria “before their name gets to the trial balloon stage:” (1) a substantive scientific or medical background to understand the public health issues;

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<sup>76</sup>134 Cong. Rec. S725-02 (1988).

<sup>77</sup>Walter Campbell was appointed as the first FDA Commissioner, by that name, in 1940. “Milestones in U.S. Food and Drug Law History,” on FDA website, available at <http://www.fda.gov/opacom/backgrounders/miles.html> (last updated on August 5, 2002).

<sup>78</sup>The experiences of the three FDA Commissioners since the 1988 Act—David Kessler, Jane Henney and Mark McClellan—will be discussed below.

<sup>79</sup>*Hearing on H.R. 3909* at 6.

<sup>80</sup>Interview with author, March 21, 2003.

(2) senior managerial experience, because they will be running a very complex organization in FDA; and (3) not be from regulated industry because of the FDA's fundamental interest in consumer protection.<sup>81</sup>

The line between thoughtful deliberation and partisan political delay, however, is a thin one and can only be stretched so far. When Henney became Commissioner 21 months after the departure of her predecessor, David Kessler, she recognized that “some of the delay was noticeable—people were clearly waiting for the Commissioner to come on board.”<sup>82</sup> Henney had an institutional advantage of having served as Deputy Commissioner for Operations at FDA from 1992 to 1994, so she knew how the agency operated. “I was coming back to my own team,” she explained, noting that she had recruited much of the personnel and had helped organize the centers. “So from day one, I could step in and be Commissioner.”<sup>83</sup> But Henney acknowledged that most incoming Commissioners do not have the benefit of having worked previously at FDA; she estimates that ordinarily it would take six months to a year to become fully comfortable in the job.<sup>84</sup>

Delays in Presidential nomination or Senate confirmation only compound this adjustment period—thus, debilitating the Commissioner from the outset and hampering effective operation of FDA even further. Consider the critique of Michael Friedman, who served as lead Deputy Commissioner of FDA for the nearly two years between Kessler's departure and Henney's arrival, on the requirement of Senate confirmation for the FDA Commissioner:

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<sup>81</sup>Id.

<sup>82</sup>Id.

<sup>83</sup>Id.

<sup>84</sup>Id.

[A]lthough this change was meant to elevate the profile of the office, it probably has materially contributed to the delays in filling the post. Not only has the commissioner’s selection become the arena for ideological contests, it only takes an objection from one senator to paralyze the selection process. Over the past 5 years, a permanent, confirmed commissioner has been in charge only about one-third of the time. Consistent agency leadership cannot exist in such a fractured environment. The fact that many good, positive actions were taken during that period in no way makes up for the other opportunities lost.<sup>85</sup>

After enduring the delays and political struggles to install an FDA Commissioner, the question naturally shifts to whether doing so is worthwhile—that is, whether the FDA Commissioner, the agency and the public at large enjoy any benefits from the 1988 Act.

Henney believes going “through the fire of a Senate confirmation,” as she did, enhances the prestige of the Commissionership.<sup>86</sup> “There is a certain amount of respect and stature when you are Senate confirmed,” she explained. “They have placed their mark of approval on your presence in government. It is a mark of merit and stature within government and internationally, because you are seen as a senior part of the administration.”<sup>87</sup>

FDA Commissioners who served prior to 1988, however, are less confident that the benefits of Senate confirmation are so concrete. Although Edwards thinks Senate confirmation is important on paper because it adds stature to the position—and anything done to enhance stature is good—he does not believe it has made much difference as a practical matter. “Senate confirmation is not the ingredient that makes for success or failure,” Edwards said.<sup>88</sup> Of paramount importance, according to Edwards, is “the personality of the individual Commissioner and whether or not people respect you—regardless of who confirmed you.”<sup>89</sup>

Donald Kennedy does not think the 1988 Act has made much difference because it “did not provide any sort

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<sup>86</sup>Interview with author.

<sup>87</sup>Id.

<sup>88</sup>Interview with author.

<sup>89</sup>Id. In hindsight, Edwards admits: “If I had my druthers, I wish I had been confirmed by the Senate.” He remembers talking about it with the White House and HHS, but in the end, it was not of “earth-shaking” importance and “made no practical difference in the way we ran FDA.”

of political fig-leaf for the Commissioner.”<sup>90</sup> Kennedy recalls that during his tenure as Commissioner, there was some talk about why the FDA Commissioner—as such a visible and influential regulatory position—was Executive Level 5, instead of Level 3 or 4.<sup>91</sup> However, Kennedy never considered that a particularly powerful argument because, to him, rank never really mattered much: “More important was how much leeway the Commissioner had within the agency. Congress and the media, or anyone, didn’t pay any attention to whether or not the Commissioner was appointed with the advice and consent of the Senate.”<sup>92</sup> Indeed, Kennedy believes he had more authority in HEW with respect to regulation than did his successors after the 1988 Act, which he thinks has given the White House greater control over the Commissioner.<sup>93</sup>

Frank Young, the last Commissioner not subject to Senate confirmation, concurs with Kennedy. “Senatorial confirmation pins a Commissioner’s hands down— that is part of the point,” Young observed. “That can be a destructive event.”<sup>94</sup> Subjecting an FDA Commissioner nominee to Presidential appointment and Senate confirmation inherently politicizes the position; the injection of the two political branches into the process makes it inevitable. But this mechanism raises the issue of to what extent the politicization will permeate FDA itself. For Young, a serious difficulty of having a senatorially confirmed position is that “not only does it politicize the office of Commissioner, but it also politicizes one level down from the Commissioner to the Deputy Commissioners.”<sup>95</sup>

In fact, Henney was quite mindful of this hazard when she assumed office. Although she had to be confirmed

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<sup>90</sup>Interview with author.

<sup>91</sup>Id.

<sup>92</sup>Id.

<sup>93</sup>Id. As noted above, HEW became HHS in 1979.

<sup>94</sup>Interview with author.

<sup>95</sup>Id.

by the Senate, Henney sought to prevent the politics from “brush[ing] down through the rest of the agency.”<sup>96</sup> Not surprisingly, she said, this produced great tension with the White House personnel office, which desired a strong presence of political appointees in FDA. With the backing of HHS Secretary Donna Shalala, Henney reduced the number of political appointees in FDA (aside from the Commissioner) from 17 to one, filling the positions with career appointees instead.<sup>97</sup> “FDA needed to be seen as a nonpolitical agency,” she said. “There were some very important signals I wanted to send: I would be leading policy and making enforcement decisions based on science, not on political whims.”<sup>98</sup>

Since the 1988 Act, however, politics has gripped the FDA Commissioner—particularly as viewed through the appointment and confirmation process—with ever-greater force. The experiences of the three FDA Commissioners who have been subject to the 1988 Act offer poignant illustrations of this politicization.

## VI.

### Post-1988 Act FDA Commissioners

#### David Kessler (1990-1997)

David Kessler, appointed by the first President Bush as FDA Commissioner in 1990, was the first head of the agency subject to Senate confirmation. Any anticipation about operation of the 1988 Act was quickly rendered anticlimactic: Kessler was confirmed on the basis of written answers to 13 written questions by Senators Kennedy and Orrin Hatch (R-Utah) without a public hearing.<sup>99</sup> There were no live hearings because

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<sup>96</sup>Interview with author.

<sup>97</sup>Id. Upon Henney’s insistence, the one remaining political appointee would have neither a policy position nor a line management position. But Henney noted: “Under the new Commissioner [Mark McClellan], this has all changed.”

<sup>98</sup>Id.

<sup>99</sup>136 Cong. Rec. 36391 (1990); Hutt, *Investigations and Reports* at 49.



consideration of Kessler’s appointment occurred at the end of the legislative session; the Senate was anxious to confirm him—the Commissionership had been vacant for nearly a year by that time—and thus expedited his nomination.

At the “confirmation hearing,” Gore remarked upon the “truly historic step” of the Senate confirming an FDA Commissioner, proud of the oversight and accountability that “we fought so hard for when we enacted the Food and Drug Administration Act 2 years ago.”<sup>100</sup> Thus, Gore was more than a bit miffed, and perhaps embarrassed, that the Senate would have to settle for written questions and answers upon which to confirm Kessler. He placed the blame “squarely” on the Bush administration, whom he accused of playing politics with Kessler’s nomination: “[T]he administration. . . has left this important agency without a Commissioner since November last year [1989], which has known for months who the nominee would be, but waited until the last possible moment to nominate him, which knew that this would be the first time a prospective Commissioner would come before the Senate, but didn’t seem to care.”<sup>101</sup> The degree of truth, if any, to Gore’s charges is unclear. The paradox, however, is not: Although one of Congress’ chief aims in the 1988 Act was to excise partisan politics from the selection of the FDA Commissioner, they were on conspicuous display here—even before “consideration” of Kessler’s nomination.

Kessler himself received high praise from the three Senators who spoke in the Congressional Record for his nomination: Kennedy, Hatch and Gore. Hatch captured the general sentiments of the trio when he expressed confidence that Kessler would exhibit “competent and strong leadership” as FDA Commissioner and bolster public confidence in the agency: “I have known Dr. Kessler for many years, and his reputation, experience, and dedication to public service make him the right choice for FDA.”<sup>102</sup> Kessler submitted answers to written questions on a range of issues, from FDA’s enforcement mechanisms to its food protection

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<sup>100</sup>136 Cong. Rec. 36389 (1990).

<sup>101</sup>136 Cong. Rec. 36390 (1990).

<sup>102</sup>Id.

program to biotechnology to its funding and to its supposed need for “revitalization.” On this last issue, Kessler answered: “Revitalization is crucial if we are to restore the agency’s credibility and stature, and strengthen the morale of agency employees.”<sup>103</sup> He then set forth what he considered the steps necessary for revitalization—an indication of the forceful tone he would set as FDA Commissioner: “enhancing the authority and accountability of leadership at all levels; improving decisionmaking by ensuring that actions taken by the agency have a sound scientific basis; and using the appropriate management tools to guide the agency’s activities and allow it to function more effectively.”<sup>104</sup>

As Commissioner, Kessler’s audacity (or pugnacity, depending on one’s point of view) ruffled more than a few feathers. Kessler sought FDA authority to regulate tobacco products, on the ground that nicotine is a drug—perhaps “the most ambitious public health initiative in the history” of the agency.<sup>105</sup> He led the tobacco initiative and ran it “out of a makeshift ‘war room’ in his office.”<sup>106</sup> The Supreme Court ultimately held, after Kessler left office, that FDA lacked authority in the FD&C Act to regulate tobacco products.<sup>107</sup> Trained as both a lawyer and a doctor, Kessler, now dean of the Yale Medical School, steeled himself for the adversarial nature of his tenure in office. He explained his approach as FDA Commissioner this way: “In general, you wake up in the morning, you decide what you think is right, what is consistent with the policies of the administration, and you go about your job, usually with no one telling you what to do, and only hearing if you’re wrong, that you shouldn’t have gone in that direction.”<sup>108</sup> His supporters admired his courage in taking on the tobacco industry—“an American Goliath,” as Kessler called it<sup>109</sup>—while his critics denounced his arrogance in overstepping the bounds of his office. As Donald Kennedy, one of Kessler’s predecessors, commented: “If I [liked political struggles] to a degree, then David Kessler is double that. He

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<sup>103</sup>136 Cong. Rec. 36392 (1990).

<sup>104</sup>*Id.*

<sup>105</sup>Sheryl Gay Stolberg, *Overloaded FDA Is Facing Biggest Challenge, Tobacco*, N.Y. Times, Aug. 3, 1997.

<sup>106</sup>*Id.*

<sup>107</sup>*Food and Drug Administration v. Brown & Williamson*, 529 U.S. 120 (2000).

<sup>108</sup>Interview, *Morning Edition*, National Public Radio, March 12, 2002.

<sup>109</sup>Stolberg, *Overloaded FDA*.

really made smoking an issue, when he didn't have to; he could have ducked it altogether."<sup>110</sup>

Upon reflection, Kessler said he valued his time as FDA Commissioner and “wouldn't have traded it for anything,” despite “the white heat [and] the intensity” of the job.<sup>111</sup> Although Kessler acknowledged the difficulty of finding the right person to lead FDA, given the qualifications needed and tremendous responsibilities of the job, maintaining a permanent FDA Commissioner is crucial for the agency to achieve its goals.<sup>112</sup> “There's no way that you can take on the real tough issues without having permanent leadership,” he explained. “A permanent director's job is to put their body in between that whole outside world, all that political pounding, and the people at the agency who do their work. A permanent FDA commissioner needs to take that pounding and absorb it and protect the rank and file.”<sup>113</sup> Permanency, however, is one feature decidedly not promoted by the 1988 Act—indeed, as discussed above, the average delay in filling the Commissionership since making it subject to Senate confirmation has been 17 months.

Jane Henney (1998-2001)

**Responsibility for such delay rests not only with Congress, but with the White House as well. Although Kessler left office in early 1997, President Clinton did not submit Jane Henney's nomination to the Senate until June**

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<sup>110</sup>Interview with author. Kennedy told the New York Times that FDA “is the perfect example of the kind of agency that a politician doesn't want to be seen on the street with.” Stolberg, *Overloaded FDA*. Kennedy's comment is interesting, given that FDA ranks high in public opinion polls, as discussed above.

<sup>111</sup>NPR Interview. Kessler added that his six-and-a-half year tenure as Commissioner “almost seemed like a lifetime.”

<sup>112</sup>Commenting on the Commissionership vacancy, ultimately filled last October with Mark McClellan (see below), Kessler laid out an array of desired qualifications: “You'd probably want an MD, you want someone who knows food and drug regulation, who could manage a large agency of 10,000 people, who has Washington experience, who has a backbone of steel, who's acceptable to a Republican administration, who can be confirmed by a Democratic Senate, who's willing to accept a low salary with political uncertainty, willing to relocate and be subject to all the conflict-of-interest rules.” NPR Interview.

<sup>113</sup>Id.

**1998.<sup>114</sup> Henney, the first and only female FDA Commissioner, recognized from the outset that, as successor to the confrontational Kessler, she would have to tread gingerly on the political minefield. She prepared to face a Republican-controlled Senate that was no admirer of her predecessor and that was soon preparing to hold the impeachment trial of the President who nominated her.**

Although she was the first FDA Commissioner nominee who faced full Senate confirmation hearings, Henney was not sure she would even make it to that point. “At the time, the Republicans had vowed that no other Clinton appointee would be approved—that was right out of the box,” she recalled. “Everybody was bleak that the confirmation would go through. The Clinton administration...told me this might go on a long time.”<sup>115</sup> Henney knew she “wasn’t a political chip” because all of her previous government experience had been in career service—she had served in the FDA under Kessler (1992-94) and for nearly a decade before that at the National Cancer Institute.<sup>116</sup> “So when people on the Senate side and in the Administration said it was nothing personal,” Henney said, “it never felt personal.”<sup>117</sup>

As the process inched forward, Henney sought to ease the hostility that still lingered in Congress over Kessler’s

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<sup>114</sup>One professor of food and drug law sharply rebuked the White House for the delay: “Is the Clinton administration trying to tell us it doesn’t care about the FDA?... You would have expected that the administration would have made every effort to fill the job right away. Instead it acted positively bashful after suffering its fill of bashes while Kessler was commissioner.... Tired of squabbling with a Republican-controlled Congress over various decisions by Kessler’s FDA, the Clinton administration may have decided to lower the agency’s profile for a while, to keep Congress from squawking.” Eric F. Greenberg, *New FDA Commissioner May Be What Doctor Ordered*, Chicago Daily Law Bulletin, Nov. 11, 1998.

<sup>115</sup>Interview with author.

<sup>116</sup>Id.

<sup>117</sup>Id.

tobacco regulation effort and the ongoing debate over whether FDA should approve RU-486 (mifepristone), a controversial French abortion drug.<sup>118</sup> At the hearing on her nomination, Henney pledged to work closely with Congress: “I am deeply committed to building bridges of communication and breaking down the barriers that have kept the Agency from being as effective and productive as it should be.”<sup>119</sup>

Behind the scenes, Henney was conducting courtesy visits to members of the Senate Labor and Human Resources Committee, which was to determine whether to recommend her nomination to the full Senate for confirmation. “It was kind of a thing where you had to win them one by one,” she said. “You really had to find out where people were coming from and how to address them, and without losing your principles—both from a public health point of view and personally, ethically.”<sup>120</sup> Henney tells the story of one particular courtesy visit to a Senator on the Committee to illustrate this delicate but necessary task:

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<sup>118</sup>FDA ultimately approved RU-486 in September 2000, when Henney was Commissioner.

<sup>119</sup>9/2/98 Cong. Testimony (Pg. Unavail. Online), 1998 WL 18088268.

<sup>120</sup>Interview with author.

In his office, I noticed a fly-fishing rod and reel on the wall. I knew his issue was going to be RU-486 and it would be testy. When he came out, I told him that I liked to fly-fish, also. We chatted about that for a while. Then he said, “You know what I have to ask you tomorrow?” I said, “Yes.” He said, “And you’ll answer me forthrightly?” I said, “Yes.” He said, “O.K., see you tomorrow.” That was our meeting. When I greeted him the next day, I said, “Just remember, Senator: This is catch-and-release.” That is a fly-fishing term that means you can hook me, but you’ve got to let me go (out of this Committee).<sup>121</sup>

The Committee eventually recommended Henney’s nomination by voice vote, but it encountered a roadblock of opposition, over the tobacco and RU-486 issues, erected by several Republicans, led by Don Nickles (R-Okla.), the majority whip; Nickles placed a hold on the nomination.<sup>122</sup>

Nickles charged that under Kessler’s “regime, particularly during the Clinton Administration,” partisanship in FDA obstructed it from performing its essential functions: “[T]he FDA was involved in a lot of political activity. Under the leadership of David Kessler, the Agency too often became a tool of the Administration to push its liberal political agenda. One area where this was particularly offensive was the FDA’s attempt to regulate tobacco.”<sup>123</sup> Indeed, the ring in Nickles’ charges echoed quite closely that of the congressional Democrats who led the passage of the 1988 Act a decade earlier. The symmetrical politicization of FDA had come full circle. Nickles lifted his hold on the nomination after Henney promised that, as Commissioner, she would not solicit an American manufacturer for RU-486 nor actively facilitate final approval of the

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<sup>121</sup>Id.

<sup>122</sup>Eric Schmitt, *Nomination for FDA Post Nears Approval in Senate*, N.Y. Times, Oct. 21, 1998.

<sup>123</sup>144 Cong. Rec. S12689 (1998). During Henney’s confirmation process, the Fourth Circuit had reversed the federal district court’s ruling that had recognized FDA authority to regulate tobacco. In 2000, as noted above, the Supreme Court affirmed 5-4 the Fourth Circuit’s decision rejecting FDA regulatory authority over tobacco.

drug.<sup>124</sup> Nickles then supported Henney’s nomination, declaring: “I am confident that she will be a very able administrator who will not play politics. In my opinion, she doesn’t have a political agenda.”<sup>125</sup> After extensive confirmation hearings—six hours long and 100 questions, Henney remembers—the Senate approved her nomination; she became FDA Commissioner in November 1998.<sup>126</sup>

Henney’s tenure as Commissioner lasted a little more than two years, until the second President Bush took office in January 2001. Partisan politics served as bookends to Henney’s term as head of FDA. Henney had hoped that, like her predecessor Kessler, she would be asked to remain in office by the incoming President of a different party—at least for the short term—but that was not the case; Bush accepted her letter of resignation, which she had filed as a routine matter in December 2000, a few days before his inauguration.<sup>127</sup> Congressmen from both parties had tried to convince the Bush White House to retain Henney, but to no avail.<sup>128</sup> As a veteran of Washington, however, Henney was prepared for the repercussions of the change of guard:

I was mature enough to know what the process was. It was bittersweet in that I loved my job at FDA and every minute I spent there. I knew that part of the job is that you are vulnerable to the wishes of the party in power and they can ask you to leave at any time. It’s one of those “It’s nothing personal” things. It was like I had done this before—hard to get in and difficult to leave.<sup>129</sup>

The decision to replace Henney was widely expected. As Commissioner, Henney authorized FDA approval of RU-486, a controversial decision that all but sealed her fate. The juxtaposition in Washington was telling:

On the day Tommy Thompson, Bush’s choice for HHS Secretary, testified at his confirmation hearings that

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<sup>124</sup>144 Cong. Rec. S12691 (1998); Schmitt, *Nomination for FDA Post Nears Approval in Senate*; Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 Wake Forest L. Rev. 571, 583 (2001).

<sup>125</sup>144 Cong. Rec. S12690 (1998).

<sup>126</sup>Interview with author. In a speech soon after she assumed office, Henney joked: “I was given the opportunity to have a question-and-answer period as part of this session, which I declined. Since the Senate provided me the opportunity to answer so many questions during the confirmation process, I was not sure I had any new answers left.” *Remarks of the Commissioner of Food and Drugs*, 54 Food & Drug L.J. 1 (1999).

<sup>127</sup>Interview with author; Rick Weiss, *Thompson Signals He’ll Initiate New HHS Review of Abortion Drug*, Washington Post, Jan. 20, 2001, at A8.

<sup>128</sup>Id.; Id.

he would review FDA’s approval of RU-486, Henney was clearing out her desk at FDA—having received word the previous evening that she would not be retained and that she should be out of her office within 24 hours.<sup>130</sup>

Mark McClellan (2001-present)

The Commissionership remained vacant for 21 months between Henney’s departure and Senate confirmation of Mark McClellan in October 2002, the same amount of delay between Kessler and Henney. The nomination and confirmation process of McClellan offers a particularly colorful, and arguably disturbing, glimpse of the entrenchment of politics into the position of FDA Commissioner.

Opening salvos were lobbed across the editorial pages of the *New York Times*. Three months after Bush took office, William Schultz, FDA Deputy Commissioner for Policy during the Clinton administration (1994-1999), contended that Thompson’s decision to review approval of RU-486 was preventing the installation of a permanent FDA Commissioner. “The reason for the holdup at the FDA appears to be abortion politics,” he wrote. “It is time for the administration to bite the bullet, announce that the nation will abide by the decision already made on RU-486, and get on with the business of nominating a commissioner of the Food and Drug Administration.”<sup>131</sup> In response, Henry Miller, an FDA official from 1979 to 1994, rejected the charge of abortion politics. “Even in the best of times, it is a difficult job to fill,” wrote Miller, citing the thorny issues facing the Commissioner, the relatively low salary and the small number of political appointees at the agency. “The position should not be awarded as a political plum, and politics should be banished from the eventual incumbent’s decisionmaking, insofar as that is possible.”<sup>132</sup>

The path that led to McClellan’s eventual nomination assumed, at times, a circus-like appearance. In a highly

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<sup>130</sup>Weiss at A8.

<sup>131</sup>William B. Schultz, *The Leaderless FDA*, N.Y. Times, April 17, 2001.

<sup>132</sup>Henry I. Miller, *At the Helm of the FDA*, N.Y. Times, April 21, 2001. Miller acknowledged in his letter to the editor that he “was asked but declined to be considered for the job.”



unusual move, Secretary Thompson privately circulated the name of his choice to fill the Commissionership, Lester Crawford, and suggested in public remarks that the appointment was a foregone conclusion: “And so all we have to do is get the president to announce it and have the FBI do the background check. And we’re confident we’ll get it done as quickly as we possibly can.”<sup>133</sup> Apparently, Thompson presumed to have White House support for Crawford where he did not; Crawford was eventually named Deputy Commissioner for FDA in February 2002.<sup>134</sup>

Thompson’s premature announcement highlighted a Commissioner search in which Senate Democrats rejected a White House candidate, Michael Astrue, general counsel for a biotechnology company in Cambridge, Mass., because of his ties to the pharmaceutical industry, which is regulated by FDA.<sup>135</sup> On the flip side, a top White House official—thought to be Karl Rove, Bush’s chief political adviser—vetoed the potential nomination of Alistair J.J. Wood, a drug-safety expert at Vanderbilt University, because Wood was considered an overly aggressive regulator.<sup>136</sup> “The president is getting squeezed from all sides,” observed David Kessler at the time. “The job of the agency is to protect public health, and it needs leadership.”<sup>137</sup> By July 2002, a year-and-a-half after Henney left office, the FDA Commissioner was the highest-ranking federal post still vacant.<sup>138</sup>

In the fall of 2002, Bush formally announced McClellan as his choice to head FDA. Although McClellan had impressive credentials as a physician and economist, with experience in both the Clinton White House (as deputy assistant secretary of the treasury for economic policy) and the second Bush White House (as the top adviser on healthcare issues), he had not worked extensively in regulatory affairs nor managed a staff the size of FDA (more than 10,000 employees).<sup>139</sup> At his confirmation hearings, McClellan reiterated

<sup>133</sup>Sheryl Gay Stolberg, *Health Secretary Promotes FDA Choice*, N.Y. Times, Oct. 3, 2001.

<sup>134</sup>Sheryl Gay Stolberg, *Deputy Is Appointed to Direct Food and Drug Agency as Impasse Continues*, N.Y. Times, Feb. 26, 2002.

<sup>135</sup>Stolberg, *Health Secretary Promotes FDA Choice*.

<sup>136</sup>Marc Kaufman, *FDA Commissioner’s Position Remains Empty*, Washington Post, July 15, 2002, at A15.

<sup>137</sup>Sheryl Gay Stolberg, *Bush in Political Hot Spot in Picking an FDA Chief*, N.Y. Times, Feb. 8, 2002.

<sup>138</sup>Kaufman, *FDA Commissioner’s Position Remains Empty*.

<sup>139</sup>Marc Kaufman, *Bush Adviser Tabbed for FDA Post*, Washington Post, Sept. 25, 2002, at A25.

the promise of many of his predecessors to keep an open mind and ear and to work amicably with Capital Hill: “Transparency and responsiveness start with the interactions between the Commissioner’s office and Congress. . . . [I will] ensur[e] that sound science, careful empirical analysis, and ethical integrity are the foundation for FDA’s decisions.”<sup>140</sup>

McClellan’s confirmation process was uneventful, perhaps too much so.<sup>141</sup> The Health, Education, Labor, and Pensions Committee unanimously recommended McClellan’s nomination to the full Senate, but only three Senators were present for the initial phase of McClellan’s questioning.<sup>142</sup> Such sparse attendance seemed to make a mockery of the 1988 Act and suggested that it is functionally toothless. At the very least, it is difficult to reconcile with the gravity behind Gore’s support for that eventual legislation in his 1986 testimony: “[T]he Senate deserves an opportunity to review the nomination of an individual so critical to the public health.”<sup>143</sup> The full Senate unanimously confirmed McClellan as FDA Commissioner by voice vote in October 2002, before its adjournment.<sup>144</sup>

## VII.

### Conclusion

FDA is of profound and unquestionable importance in Washington and to the American public, with its \$1.6 billion annual budget and responsibility for 80 percent of the country’s food and all medical products.<sup>145</sup> In requiring Senate confirmation of the FDA Commissioner, Congress in part sought to elevate the status of the

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<sup>140</sup>10/7/02 Cong. Testimony (Pg. Unavail. Online), 2002 WL 100237849.

<sup>141</sup>The only minor bump was Sen. Jeff Bingaman’s (D-N.M.) temporary block of McClellan’s nomination to protest a regulation that gives separate legal status to fetuses by permitting states to classify fetuses as “unborn children” eligible for health programs for uninsured low-income people. National Desk, *Dispute on Fetuses Stalls Nomination*, N.Y. Times, Oct. 12, 2002, at A17.

<sup>142</sup>Kevin New, *McClellan Sails Through Senate Committee*, BIOWORLD Today, Oct. 8, 2002. This Committee was formerly known as the Labor and Human Resources Committee.

<sup>143</sup>*Hearing on H.R. 3909*.

<sup>144</sup>Politics & Policy, *Senate Confirms McClellan as FDA’s Chief*, Wall St. Journal, Oct. 18, 2002, at A4; National Desk, *Senate Approves President’s Nominee to Head the FDA*, N.Y. Times, Oct. 18, 2002, at A26.

<sup>145</sup>Stolberg, *Bush in Political Hot Spot*; Politics & Policy, *Senate Confirms McClellan as FDA’s Chief*.

post to correspond to that importance. Whether the enhanced prestige of the Commissionership, through the 1988 Act, has produced any real changes rests in the eye of the beholder—or the holder of office; after all, as discussed above, Henney appreciated the stature that accompanied the requirement, while some of her predecessors discounted its tangible effects. Interestingly, both Henney and Young would prefer to have the FDA Commissioner be appointed to a six-year term with Senate confirmation; there would then be an option for the Commissioner to be reappointed for another six-year term.<sup>146</sup> The two former Commissioners believe this procedure would promote bipartisanship and longevity in the post.<sup>147</sup>

Michael Friedman has suggested even eliminating the Senate confirmation requirement altogether. “Neither congressional oversight nor Executive Office expectations,” he argued, “would be diminished by returning the commissioner’s job to a high visibility presidential appointment.”<sup>148</sup> Of course, stripping the Commissionership of its Senate confirmation requirement would be unthinkable in Washington and, in practical terms, highly unlikely.

When Gore testified at congressional hearings about the legislation that eventually became the 1988 Act, he was asked if requiring Senate confirmation would adversely impact the independence of the FDA Commissioner. He responded: “I do not think so. Indeed, I think it would enhance that person’s independence, because instead of being subject to the whim of an immediate superior, he would have the extra insulation afforded by this new role played by a second branch of Government.”<sup>149</sup> With the Senate layered on top of the FDA Commissioner as “extra insulation,” as it has been for the past 15 years, the Commissioner must be ever-mindful of the fragile line between protection and suffocation. And even then, regardless of form, politicization of FDA springs eternal.

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<sup>146</sup>Interviews with author. The reappointment would not require another Senate confirmation.

<sup>147</sup>*Id.*

<sup>148</sup>Friedman at 2332.

<sup>149</sup>*Hearing on H.R. 3909.*