



# A Historical Look at the FDA's Approach to Regulation and Policymaking

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# **A Historical Look at FDA's Approach to Regulation and Policymaking**

Submitted to Professor Peter Hutt in Satisfaction of the Course Paper Requirement

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## ABSTRACT:

*This paper tracks the regulatory and policymaking procedures of the Food and Drug Administration. It looks at the FDA's interpretation of regulatory authority in its organic statute, its method of enforcing that statute over the years, and the manner it has communicated policy decisions. Particular attention is paid to the evolution of the FDA's development and use of guidance documents as a regulatory mechanism.*

## I. Introduction

The FDA has, for decades, been recognized as an agency uniquely situated for administrative innovation.<sup>1</sup> To those familiar with FDA, its influence on administrative law should come as no surprise.<sup>2</sup> The Food and Drug Administration is responsible for regulation of products comprising 25% of our nation's economy and its proposed 2010 budget is \$3.2 billion dollars.<sup>3</sup> FDA is charged with an enormous task, to protect the public health and the "consumer's pocketbook."<sup>4</sup> More impressive than its sheer size, however, is the evolution of the FDA's administrative procedures. The evolution of the agency's rulemaking approach as well as the transition to reliance on agency guidance documents as a primary source of communicating the agency's views is the focus of this paper. The paper is broken into two parts, each describing major outlets for agency administration, rulemaking and informal pronouncements. Each section describes the historical evolution

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<sup>1</sup> See Daniel P. Rothschild, *The FDA's Regulations- A Model for the Future?*, 32 FOOD DRUG COSM. L.J., 344, 346 (1977) ("FDA is uniquely qualified as a source of administrative innovation, because of the Agency's specialized jurisdiction, the volume of products it regulates, and its tradition of limited judicial review.") But see, Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L REV. 901 (2008); and Gary Lawson articles.

<sup>2</sup> Whether this influence has been positive or negative is still debated. For a critical discussion of FDA's advancements see Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L REV. 901 (2008). For a more approving account of the FDA's actions see Richard A. Merrill, *FDA and the Effects of Substantive Rules*, 35 FOOD DRUG COSM. L. J. 270 (1980); Fred H. Degnan, *FDA's Creative Application of the Law: Not Merely a Collection of Words* (2000).

<sup>3</sup> <http://www.fda.gov/oc/history/historyoffda/default.htm>;  
<http://www.fda.gov/bbs/topics/NEWS/2009/NEW02013.html>

<sup>4</sup> H. Thomas Austern, *Sanctions in Silhouette: An Inquiry into the Enforcement of the Federal Food Drug and Cosmetic Act*, 51 CAL. L. REV. 38, 38 (1963).

of FDA approach to each process and the circumstances surrounding the changes as well as the agency's treatment and impact of each regulatory tool.

## II. History of FDA Regulation

### A. Early Regulatory History of FDA

The FDA wasn't always the mammoth agency it is today. In fact, as one scholar described, "if [the 1906 Act] were all the United States had today, the FDA could probably fit into a couple of rooms in Rockville, and we would still not be sure what we were swallowing."<sup>5</sup> FDA's conception can be traced back to the 1899 Imported Foods Act. Then in 1906 Congress passed the Pure Food and Drug Act (1906 Act), which granted the FDA, then the Bureau of Chemistry<sup>6</sup>, the power to enforce interstate transports of illegal food and drugs.<sup>7</sup> The 1906 Act required the Secretaries of Treasury, Agriculture, Commerce and Labor to promulgate regulations to enforce the act.<sup>8</sup> These regulations took less than four months to create, and all of the substantive and procedural requirements of the Agency were detailed in less than 20 pages.<sup>9</sup>

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<sup>5</sup> Fran Hawthorne, *Inside the FDA: The Business and Politics Behind the Drugs We Take and the Food We Eat* 40 (2005).

<sup>6</sup>In 1901 the Division of Chemistry became the Bureau of Chemistry and in 1906 the Bureau began to issue Food Inspection Decisions pursuant to the Pure Foods Act of 1906. In 1927, the Food, Drug, and Insecticide Administration was established to administer the 1906 Act, (44 Stat. 976, 1003 (1927)—from Hutt 1984 article.) and in 1930 that agency was renamed the Food and Drug Administration.( 46 Stat. 392, 422 (1931). FDA was transferred from USDA to the Federal Security Agency in 1940, 54 Stat. 1234, 1237 (1940); to the Department of Health, Education, and Welfare in 1953, 67 Stat. 631 (1953); and to the Department of Health and Human Services in 1979, 93 Stat. 668, 695 (1979)." Language from Hutt article 1984.)

<sup>7</sup> John P. Swann, Ph.D., *History of the FDA, FDA History Office* (adapted from George Kurian, ed., A Historical Guide to the U.S. Government (New York: Oxford University Press, 1998)), <http://www.fda.gov/oc/history/historyoffda/default.html>

<sup>8</sup> Peter Barton Hutt, *About Fairness in Applying the Law*, FDA CONSUMER, June 1981.

<sup>9</sup> *Id.*

Under the 1906 Act, the FDA functioned mainly as a regulatory police officer<sup>10</sup> The agency's main powers were investigative, with most agency effort spent examining food and drugs for evidence of adulteration or misbranding.<sup>11</sup> If the FDA believed they had found a violation, they referred the case to a United States Attorney for either civil or criminal prosecution.<sup>12</sup>

## **B. The Administrative Procedure Act**

In 1946 Congress forever changed the way agencies regulated industry and created policy. The Administrative Procedure Act (APA) prescribes detailed procedures agencies must follow when conducting a variety of regulatory activities such as administrative hearings, criminal or civil enforcement, formal or informal rulemaking to name a few. Given the agency's reliance on case by case enforcement at the time the APA was passed, the FDA was concerned mainly with its procedures governing administrative hearings. A brief overview of the APA's requirements for rulemaking is needed to understand the agency's later shift in regulatory approach.

Section 553 of the APA details the requirements for agency rulemaking. The APA authorizes two types of legally binding rules. First, formal rulemaking requires rules be made on a record after an opportunity for an agency hearing.<sup>13</sup> Second, informal rulemaking, commonly referred to as notice and comment rulemaking, only requires notice of the proposed rule,

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<sup>10</sup> Joel E. Hoffman, *Seventy-fifth Anniversary Commemorative Volume of Food and Drug Law*, Edited and Published by the Food and Drug Law Institute Series (1984); H. Thomas Austern, *Sanctions in Silhouette: An Inquiry into the Enforcement of the Federal Food Drug and Cosmetic Act*, 51 CAL. L. REV. 38, 41 (1963); Eric Claey's, *The Food and Drug Administration and the Command-and-Control Model of Regulation*, 49 ST. LOUIS L.J. 105, 105 (2004); Peter Barton Hutt, *Food and Drug Regulation in Transition*, 35 *Food Drug and Cosm. L. J.* 283, 285 (1980) ("The Agency began as a relatively passive policeman...").

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*; Peter Barton Hutt, *About Fairness in Applying the Law; The 1940's: The Initial Implementation of the New Statute*, 45 *FOOD DRUG COSM. L. J.* 21, 22 (1990).

<sup>13</sup> 5 U.S.C. § 553(c)

opportunity for public comment, and a statement of the rule's basis and purpose.<sup>14</sup> Formal rulemaking is typically disfavored by agencies and only employed when mandated by statute.<sup>15</sup> Regulations created pursuant to these procedures are referred to as legislative rules and are binding. Regulations or policies created without adherence to those procedures are non-legislative and non-binding. Nonetheless, the APA acknowledges categories of nonlegislative rules for which it does not require either formal or informal rulemaking requirements, "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" and exempt these from either formal or informal requirements.<sup>16</sup> Such interpretative pronouncements are sometimes referred to collectively as publication rules.<sup>17</sup>

At the time the APA was passed, the FDA engaged in primarily case by case enforcement. The FDA had authority to promulgate formal regulations pursuant to Section 701 of the 1938 Federal Food, Drug and Cosmetic Act (FDCA). Section 701(a) broadly states that the Secretary can "promulgate regulations for the efficient enforcement of this Act."<sup>18</sup> Indeed, H. Thomas Austern, known as the "dean of the food and drug bar" noted in 1961 that the agency had "probably the broadest powers of rulemaking found in the federal government."<sup>19</sup> But for the first thirty years after passage of the act, this provision was interpreted to confer the power to create only interpretative, non-binding regulations.<sup>20</sup> Congress listed in Section 701(e) various circumstances where the FDA could create substantive rules that had the force of law, but also

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<sup>14</sup> 5 U.S.C. § 553(b)(3)

<sup>15</sup> Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1466 (1992).

<sup>16</sup> 5 U.S.C. § 553(b)(A)

<sup>17</sup> Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 804 (2001).

<sup>18</sup> Federal Food, Drug and Cosmetic Act § 701(a), 21 U.S.C. § 371 (a) 1970.

<sup>19</sup> H. Thomas Austern, *Sanctions in Silhouette: An Inquiry into the Enforcement of the Federal Food Drug and Cosmetic Act*, 51 CAL. L. REV. 38, 40 (1963).

<sup>20</sup> Katherine Tongue Watts and Thomas W. Merrill, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467, 558 (2002).

required that the FDA employ formal rulemaking procedures to create such rules. Rules created by this method often took years to enact, and, therefore, FDA enforcement of the act continued primarily through case-by-case adjudication.<sup>21</sup>

### C. A New Approach to Regulation

During the late 1960's and early 1970's the FDA majorly shifted its rulemaking approach under Section 701(a) of the 1938 Act. The sea change of the FDA's approach to regulation was a result of both internal and external forces.<sup>22</sup> External forces contributing to this change include both Congressional action and judicial approbation. Within FDA, personnel changes proved to be the spark that ignited the flame of a wholesale transformation in the agency's regulatory approach.

One of the most influential factors was the aggressive Congressional expansion of FDA's responsibilities in the next few decades. The Durham-Humphrey Amendment of 1951 (prescription drugs), the 1958 Food Additive Amendments, the Color Additives Amendments of 1960 (also known as The Delaney Clause), the Drug Amendments of 1962, and The Medical Device Amendments of 1976 all resulted in an exponential increase in FDA's jurisdiction.<sup>23</sup> When first enacted the FDCA spanned only fifteen pages in the *U.S. Code*, in recent years it has surpassed 200 pages.<sup>24</sup> Correspondingly, the agency's regulations spanned 585 pages in 1956 and grew to 1,718 in 1969, and its budget grew from \$5.1 million in 1955 to \$72 million agency in 1970.

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<sup>21</sup> The FDA did create some regulations under Section 701(a), and clearly preferred this method.

<sup>22</sup> Food and Drug Administration History Office, Oral History Interviews: Brandenburg, p 61.

<sup>23</sup> *Id.*

<sup>24</sup> Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L REV. 901 (2008) (“[T]he latest edition of the [FDCA] occupies 230 pages.”).

Increased responsibilities left the agency searching for more efficient means of regulation.<sup>25</sup> Rules created pursuant to Section 701(e) – also called “rulemaking on a record” or “legislation by adjudication” – could sometimes take more than ten years to create.<sup>26</sup> This desire for efficiency along with the complexity of the new amendments and industry advancement prompted the agency to pursue policymaking through regulation.<sup>27</sup> By the late 1960’s and early 1970’s FDA’s interpretation of its rulemaking power granted by section 701(a) changed dramatically. The agency began to assert that Section 701(a) granted the FDA the power to create legally binding regulations.<sup>28</sup> One of the first examples of FDA’s reliance on Section 701(a) to create binding rules is the “substantial evidence” rule issued by the agency in 1969, which prescribed the kind of clinical test necessary to prove a drug’s effectiveness to the FDA.<sup>29</sup>

If this change in FDA’s perception of its rulemaking power is attributable to one individual, his name is Peter Barton Hutt.<sup>30</sup> Following the surprise retirement of his predecessor William Goodrich, Hutt started as Assistant General Counsel of the FDA, on Sept. 1, 1971.<sup>31</sup> Hutt is often credited with FDA’s “discovery” of its general rulemaking authority.<sup>32</sup> He believed

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<sup>25</sup> Fred H. Degan, *FDA’s Creative Application of the Law: Not Merely a Collection of Words* (2000).

<sup>26</sup> Robert W. Hamilton, Rulemaking on a Record by the Food and Drug Administration, 50 *TEX. L. REV.* 1132, 1142 (1971-1972).

<sup>27</sup> Wayne Pines, *Behind FDA’s Regulations*, *FDA CONSUMER*, Nov. 10, 1974

<sup>28</sup> The FDA was not alone in its new found interest in informal rulemaking. “Scholars, in the meantime, were awakening to the advantages of informal rulemaking over case by case adjudication.” Peter L. Strauss, *From Expertise to Politics: The Transformation of American Rulemaking*, 31 *WAKE FOREST L. REV.* 745, 755 (1996).

<sup>29</sup> Richard A. Merrill, *FDA and the Effects of Substantive Rules*, 35 *FOOD DRUG COSM. L. J.* 270, 272 (1980)

<sup>30</sup> Food and Drug Administration History Office, “Oral History Interviews: Brandenburg at 62; Food and Drug Administration History Office, “Oral History Interviews: Hile at 18 (“Hutt...literally pushed the Food and Drug Administration into modern times in regards to implementing the full intent and spirit of the Administrative Procedures Act.”).

<sup>31</sup> Francis McKay, *Lawyers of the FDA—Yesterday and Today*, 30 *FOOD DRUG COSM. L. J.* 621, 626-27 (1975)(explaining that the position was given the title “Chief Counsel” in October 1974).

<sup>32</sup> Katherine Tongue Watts and Thomas W. Merrill, *Agency Rules with the Force of Law: The Original Convention*, 116 *HARV. L. REV.* 467, 558 (2002); Eric Claeys, *The Food and Drug Administration and the Command-and-Control Model of Regulation*, 49 *ST. LOUIS L.J.* 105, 120 (2004)(“ Hutt’s entrepreneurship and the Second Circuit’s statutory construction gave the FDA the power to make legislative rules...”).

that “all of the regulations issued by the Agency are enforceable in the courts.”<sup>33</sup> The first of many judicial opinions addressing this issue came in 1967 with the Supreme Court’s decision in *Abbott Laboratories v. Gardner*.<sup>34</sup> The Supreme Court ruled against the FDA in *Abbott Laboratories*, holding that the FDA regulations created pursuant to Section 701(a) constituted final agency actions and were subject to pre-enforcement judicial review.<sup>35</sup> The FDA thereafter adopted the view that if 701(a) regulations were judicially reviewable, then they also were legally binding and more than merely interpretative.<sup>36</sup> Hutt also believed the 1938 Act should be thought of as a constitution, and that its broad language permitted the FDA to create any regulations reasonably related to the Act’s purpose that wasn’t specifically prohibited.<sup>37</sup> The *Abbott Laboratories* decision coupled with Hutt’s expansive view of FDA’s rulemaking authority transformed the agency’s regulatory structure.

In 1973, the Supreme Court confirmed of the agency’s interpretation of Section 701(a). *Weinberger v. Hynson, Wescott & Dunning, Inc.*, is known for “dispelling ‘[w]hatever doubts might have been entertained regarding the FDA’s power under section 701(a) to issue binding regulations.’”<sup>38</sup> Thus began the era of informal rulemaking by the FDA. In an interview with FDA Consumer magazine in November 1974, Hutt described the change in FDA’s perception of regulation, shifting from a case-by-case enforcement process to one of explicit regulation

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<sup>33</sup> Wayne Pines, *Behind FDA’s Regulations*, FDA CONSUMER, Nov. 10, 1974

<sup>34</sup> 387 U.S. 136 (1967).

<sup>35</sup> 387 U.S. 136 (1967).

<sup>36</sup> Stephen Hull McNamara, *The New Age of FDA Rule-Making*, 31 FOOD DRUG COSM. L.J. 393, 394-95 (1976).

<sup>37</sup> Peter Barton Hutt, *Philosophy of Regulation Under the Federal, Food Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L. J. 177, 178 (1973). For a different perspective, see H. Thomas Austern, *Philosophy of Regulation, A Reply to Mr. Hutt*, 28 FOOD DRUG COSM. L. J. 189 (1973).

<sup>38</sup> Joel E. Hoffman, *Seventy-fifth Anniversary Commemorative Volume of Food and Drug Law* 21 (1984) (Edited and Published by the Food and Drug Law Institute Series) (citing *National Nutritional Foods Ass’n v. Weinberger*, 512 F.2d 688, 696 (2d Cir.), *cert denied*, 423 U.S. 827 (1975)). Several subsequent judicial opinions confirmed this view. See *Ciba Corp. v. Weinberger*, 412 U.S. 640 (1973); *Weinberger v. Bentex Pharmaceuticals*, 412 U.S. 645 (1973); *U.S.V. Pharmaceutical Corp. v. Weinberger*, 412 U.S. 655 (1973); *National Nutritional Foods Ass’n v. Califano*, 603 F.2d 327 (2d Cir. 1979).

promulgation.<sup>39</sup> Hutt considered regulations to be the “most effective and efficient means of by which industry-wide regulation can be achieved.”<sup>40</sup> During this period, the FDA continued to issue guidelines and additional forms of policy statements, but the relative merits of informal rulemaking compared to other forms of regulation was dominating the debate.<sup>41</sup>

This shift in regulatory approach coupled with the agency’s new expansive jurisdiction required corresponding changes within the agency. In October 1969, the Deputy Undersecretary for Health Education and Welfare, Frederic Malek, conducted a review of the operating procedures and organization of the agency.<sup>42</sup> The report describes serious problems within the agency given lack of formalized procedures.<sup>43</sup> This situation improved, however, when Hutt, committed to create detailed policies and procedures for the agency, was joined by newly-appointed FDA Commissioner Alexander Schmidt in 1973.<sup>44</sup> As a former medical school dean, Schmidt reportedly managed the agency much like a medical school, requiring collegial weekly meetings of all key staff in the agency.<sup>45</sup> The group, consisting of sixteen individuals including Dr. Richard J. Crout, FDA Chief Counsel Peter Hutt, the directors of each center, Schmidt and others came to be known as the FDA Policy Board.<sup>46</sup>

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<sup>39</sup> Wayne Pines, *Behind FDA’s Regulations*, FDA CONSUMER, Nov. 10, 1974.

<sup>40</sup> Peter Barton Hutt, *Philosophy of Regulation Under the Federal, Food Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L. J. 177, 183 (1973).

<sup>41</sup> See Donald P. Rothschild, *The FDA’s Regulations – A Model for the Future?* 32 FOOD DRUG COSM. L.J. 345 (1977); Richard A. Merrill, *Administrative Rule-Making*, 30 FOOD DRUG COSM. L.J. 478 (1975).

<sup>42</sup> Frederic V. Malek, *Analysis and Recommendations—The Food and Drug Administration Organizational Review*, 25 FOOD DRUG COSM. L.J. 22 (1970).

<sup>43</sup> *Supra* note 35.

<sup>44</sup> <http://www.fda.gov/AboutFDA/CommissionersPage/PastCommissioners/ucm113416.htm>, accessed June 19, 2009.

<sup>45</sup> <http://www.fda.gov/oc/history/oralhistories/crout/part2.html>; <http://www.fda.gov/oc/history/oralhistories/schmidt/part3.html> “I ran the agency the way those people conceived a university should be run--that is, in a truly collegial style, which is what the policy board was.”

<sup>46</sup> Alexander Schmidt, *Twenty Questions for the Commissioner*, 29 FOOD AND DRUG COSM. L.J. 596, 600 (1974).

The Policy Board set all major policy directions for the agency.<sup>47</sup> The Board met at 8:30 a.m. on Mondays and lasted most of the morning.<sup>48</sup> One attendee recalls such meetings being referred to among the group as a “stay-at-home-go-away.”<sup>49</sup> The Board discussed myriad of issues, including major regulations, and internal policies such as how the agency should behave, who can speak for the agency, what is the status of minutes, etc.<sup>50</sup>

The importance of the Policy Board in solidifying the FDA’s new regulatory scheme cannot be overstated. In fact, Commissioner Schmidt cites the successful creation of the agency’s administrative regulations and the creation of the Policy Board as the most significant action during his tenure as commissioner.<sup>51</sup> As Dr. J. Richard Crout describes, he and Peter Hutt would wrestle with questions such as, “how do you answer the mail, how do you handle appeals, what's the role of a petition, what's the meaning of a guideline.”<sup>52</sup> Peter Hutt recalls that,

“[Dr.] Crout wanted to have the flexibility of providing informal advice to the industry so that the industry would have a good idea of how to proceed if they wanted to be certain to have FDA agreement. He agreed with me that we didn’t want to put out prescriptive regulations that would say you MUST do it this way but he wanted to be able to say, if you do it this way we will accept it, if you do it any other way you better come in and talk to us and make sure it’s acceptable.”<sup>53</sup>

The struggle to codify FDA’s administrative procedures was not resolved with Policy Board agreement however. In September 1975, the FDA published a notice of rulemaking regarding the new administrative procedures.<sup>54</sup> Five days before they were to go into effect, the American College of Neuropsychopharmacology (“the College”) sued the FDA. The College claimed the FDA did not follow APA procedures, by not promulgating the regulations subject to the notice

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<sup>47</sup> *Id.*; Alexander Schmidt, *Twenty Questions for the Commissioner*, 29 FOOD AND DRUG COSM. L.J. 596, 600 (1974).

<sup>48</sup> *Id.*

<sup>49</sup> Food and Drug Administration History Office, “Oral History Interviews: Barkdoll.”

<sup>50</sup> *Id.*

<sup>51</sup> <http://www.fda.gov/oc/history/oralhistories/schmidt/part3.html>

<sup>52</sup> <http://www.fda.gov/oc/history/oralhistories/crout/part2.html>

<sup>53</sup> Telephone Interview with Peter Barton Hutt, January 17, 2009.

<sup>54</sup> Administrative Practices and Procedures, 40 Fed. Reg. 40682 (Sept. 3, 1975).

and comment requirements of APA § 553.<sup>55</sup> The district court agreed, and the Commissioner acquiesced, realizing that obeying the court order rather than challenging it would be the quickest form of action.<sup>56</sup> Thus, FDA's proposed administrative procedure regulations were published on September 3, 1975.<sup>57</sup>

Consistent with the Policy Board's goals, the FDA also began to use extensive preambles to regulations in the Federal Register to explain the purpose of the regulation.<sup>58</sup> Before the agency would publish regulations, it would receive comments pursuant to the APA's notice and comment rulemaking requirements. Sixty days after proposing the regulation, the agency would compile the comments and respond to each in a detailed preamble to the final regulation.<sup>59</sup> Preambles described the agency's decision-making process and provided a good paper trail for any future court challenges to a regulation.<sup>60</sup>

The FDA wasn't the only agency to recognize the advantages of informal rulemaking, however. The efficiency of the process quickly led to informal rulemaking becoming the choice regulatory tool for agencies.<sup>61</sup> This exponential increase in agency discretion led individuals across all branches of government to consider ways to reign in agency promulgation of regulations. Additional requirements imposed by the judicial, executive, and legislative branches led to what many refer to as the "ossification" of notice and comment rulemaking. Congressional requirements such as the Unfunded Mandates Reform Act of 1995, the Paperwork Reduction

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<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> Virgil O. Wodicka, *1970's: The Decade of Regulations*, 45 FOOD DRUG COSM. L.J. 59, 61 (1990); Food and Drug Administration History Office, "Oral History Interviews: Hile" (explaining that prior to Hutt's tenure preambles may have been 100 words long, and Hutt began publishing preambles as long as one hundred pages).

<sup>59</sup> Wayne Pines, *Behind FDA's Regulations*, FDA CONSUMER, Nov. 10, 1974

<sup>60</sup> *Id.*

<sup>61</sup> John C. Carey, *The FDA's Policymaking Quandary: Is Guidance Reform and Appropriate Solution?* (1997), in Peter Barton Hutt, ed., *Food and Drug Law: An Electronic Book of Student Papers* (citing ADMINISTRATIVE CONFERENCE OF THE U.S. A GUIDE TO FEDERAL AGENCY RULEMAKING ix (2d ed. 1991)).

Act, the Regulatory Flexibility Act, the Data Quality Act, the Small Business Regulatory Enforcement Fairness Act have all contributed to the widely accepted notion that informal agency rulemaking has become “ossified.”<sup>62</sup> According to an April 2009 Government Accountability Office report, “a straightforward rulemaking make take up to 3 ½ to nearly four years from initiation to final publication.”<sup>63</sup> Typically, only the degree of ossification present had been debated. Recent scholarship, however, has called into question the core ossification thesis.<sup>64</sup> Regardless of the truth of this assertion, it is true that many agencies have increasingly relied on alternatives to notice and comment rulemaking.<sup>65</sup> These alternatives, along with other means of informal agency policymaking is the topic of the second half of this paper.

### III. History of FDA’s Interpretative Regulatory Pronouncements

Statements of agency interpretation and policy are not a modern invention. The Department of Interior used tools during the mid-nineteenth century.<sup>66</sup> Not until the FDA published its “Good Guidance Practices” on February 18, 1997 did American administrative law

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<sup>62</sup> See Richard B. Stewart, *Administrative Law in the 21st Century*, 78 N.Y.U.L. REV. 437, 448 (2003) (“Major rules take a minimum of five years to be adopted. Judicial review involves additional delay...”); Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rule-making Process*, 41 DUKE L.J. 1385 (1992) (looking at the evidence and causes of ossification). Mark Seidenfeld, *Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEX. L. REV. 483 (1997). For a more detailed discussion of individual causes of ossification see John C. Carey, *The FDA’s Policymaking Quandary: Is Guidance Reform and Appropriate Solution?* (1997), in Peter Barton Hutt, ed., *Food and Drug Law: An Electronic Book of Student Papers*.

<sup>63</sup> GAO report pg 22

<sup>64</sup> See Lisa Schwartz Bressman, *Procedures as Politics in Administrative Law*, 107 COLUM. L. REV. 1749, 1819-1820 (2007); Jason Webb Yackee and Susan Webb Yackee, *Administrative Procedures and Bureaucratic Performance: Is Federal Rulemaking “Ossified”?*, Legal Studies Research Paper Series, Paper No. 1079 (2009).

<sup>65</sup> John C. Carey, *The FDA’s Policymaking Quandary: Is Guidance Reform and Appropriate Solution?* (1997), in Peter Barton Hutt, ed., *Food and Drug Law: An Electronic Book of Student Papers*; Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L. REV. 901 (2008), Erica Seiguer and John J. Smith, *Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances*, 60 FOOD DRUG L.J. 17, 29-30 (2005). For an overview of various agencies reliance on interpretative rules and Xxx see Michael Asimow, *Public Participation in the Adoption of Interpretative Rules and Policy Statements*, 4 ACUS 615 (1974-1977). For a look at the current judicial treatment of guidance documents and their importance to administrative agencies, see Sam Kalen, *The Transformation of Modern Administrative Law: Changing Administrations and Environmental Guidance Documents*, 35 ECOLOGY L.Q. 657 (2008).

<sup>66</sup> Sam Kalen, *Changing Administrations and Environmental Guidance Documents*, 23 NAT. RESOURCES & ENV’T 13, 14 (2008).

have a distinct category of legal documents called “guidance.”<sup>67</sup> Furthermore, it is arguable that the FDA has developed and expanded the use of guidance as an alternative to notice and comment rulemaking more so than any other agency.<sup>68</sup> “Since the start of this decade there has been a striking increase in the number of FDA – issued documents intended to give guidance to the regulated industry but not adopted through public procedures.”<sup>69</sup> Guidance was not the start of the FDA’s informal pronouncements though. Since 1899 the agency has used numerous tools to communicate its policies and interpretation of statutory commands.

### **A. Food Inspection Decisions & Service and Regulatory Announcements**

Beginning in 1899, the Department of Agriculture’s Division of Chemistry, charged with enforcing the 1899 Imported Food Act, issued Food Inspection Decisions. Food Inspection Decisions (FIDs) were interpretations of the Imported Food Act and the first statements of interpretation or policy in the food and drug world.<sup>70</sup> Hundreds of these decisions were published, but only the first thirty-nine of which were interpretations of the 1899 Act.<sup>71</sup> Food Inspection Decisions beginning with number forty (FID-40) interpreted the 1906 Federal Food Drug and Cosmetic Act.<sup>72</sup> The final Food Inspection Decision was issued in 1934, FID- 212.<sup>73</sup>

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<sup>67</sup> Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 159 (2000) (noting however that such terms had previously been used in Japan and Korea).

<sup>68</sup> For a discussion of FDA’s general disregard for Constitutional and Congressional requirements in the furtherance of such objectives, see Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L REV. 901 (2008). Additionally, the FDA is not the only agency to heavily use this APA exception. For a discussion of four other agencies use of interpretive rules and statements of policy see Michael Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 MICH. L. REV. 3 (1977).

<sup>69</sup> Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 168 (2000) (“The rate per year for the 1990s is about four hundred percent greater than the rate for the 1980s.”).

<sup>70</sup> Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L REV. 901 (2008).

<sup>71</sup> <http://www.fda.gov/AboutFDA/WhatWeDo/History/ResearchTools/ResearchingFDAwithPublishedPrimarysources/default.htm>

<sup>72</sup> Paul B. Dunbar, *Federal Food, Drug and Cosmetic Law: Administrative Reports 1907-1949*, Introduction (Chicago: Commerce Clearing House, c. 1951). Xv.

<sup>73</sup> *Id.*

The agency included FIDs in collection of published documents called Service and Regulatory Announcements (SRAs). The Bureau of Chemistry began to issue Service and Regulatory Announcements in 1914; they were initially published monthly and then on an irregular basis.<sup>74</sup> The aim of these publications was to “aid manufacturers by informing them about statutory requirements applicable to their products.”<sup>75</sup> Food Inspection Decisions and Service Regulatory Announcements informed industry of changes affecting enforcement of the 1906 act.<sup>76</sup> However, the SRAs included formal Food Inspection Decisions as well as other “policy matter that did not have the formality of FIDs, subject to prompt change if developments warranted.”<sup>77</sup> SRAs were published until shortly after the Congress passed the 1938 Federal Food Drug and Cosmetic Act (FDCA).<sup>78</sup> The Bureau stopped issuing interpretive service announcements with No.28 in 1923, due mainly to the fact that “the legal requirements of the 1906 Act had become fairly well understood.”<sup>79</sup>

## **B. Trade Correspondence**

The passage of the 1938 Federal Food Drug and Cosmetic Act (FDCA), which greatly expanded FDA’s regulatory powers, spurred a host of questions from industries required to

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<sup>74</sup> Paul B. Dunbar, *Federal Food, Drug and Cosmetic Law: Administrative Reports 1907-1949*, Introduction (Chicago: Commerce Clearing House, c. 1951).

<sup>75</sup> Paul B. Dunbar, *Federal Food, Drug and Cosmetic Law: Administrative Reports 1907-1949*, XV (Chicago: Commerce Clearing House, c. 1951).

<sup>76</sup> Peter Barton Hutt, *About Fairness in Applying the Law; The 1940’s: The Initial Implementation of the New Statute*, 45 FOOD DRUG COSM. L. J. 21, 23 (1990). Additionally, beginning in October 1906, “the U. S. Department of Agriculture issued ‘Rules and Regulations for the Enforcement of the Food and Drugs Act’ as Circular No. 21 from the Office of the Secretary.”

<http://www.fda.gov/AboutFDA/WhatWeDo/History/ResearchTools/ResearchingFDAwithPublishedPrimarysources/default.htm>.

<sup>77</sup><http://www.fda.gov/AboutFDA/WhatWeDo/History/ResearchTools/ResearchingFDAwithPublishedPrimarysource/s/default.htm>. ; Paul B. Dunbar, *Federal Food, Drug and Cosmetic Law: Administrative Reports 1907-1949*, Introduction (Chicago: Commerce Clearing House, c. 1951).

<sup>78</sup><http://www.fda.gov/AboutFDA/WhatWeDo/History/ResearchTools/ResearchingFDAwithPublishedPrimarysource/s/default.htm>.

<sup>79</sup> Paul B. Dunbar, *Federal Food, Drug and Cosmetic Law: Administrative Reports 1907-1949*, Introduction (Chicago: Commerce Clearing House, c. 1951).

comply with the law and regulations.<sup>80</sup> After passage of FDCA in 1938, and until 1946, FDA issued responses to inquiries regarding enforcement of FDCA as advisory opinions called “Trade Correspondence.”<sup>81</sup> These were not legally binding, not published, and not compiled or reviewed in any systematic way by FDA. They were, however, distributed to staff and kept at FDA headquarters, available for inspection.<sup>82</sup> In November 1945, the FDA began a new series of Trade Correspondence, labeled “TC1-A”, “TC2-A”, etc.<sup>83</sup> The FDA released a total of 431 trade correspondences before the FDA, adhering to the APA, discontinued the use of Trade Correspondence in exchange for a more formal process for announcement of policy.<sup>84</sup> Beginning in 1946, FDA policies were published in the Federal Register as “Statements of General Policy or Interpretation.”<sup>85</sup> The amount of statements released by the FDA decreased after the change, partly due to the increased formality and partly due to the time since passage of the 1938 Act.<sup>86</sup>

### C. Compliance Policy Guides

In 1968, initiated by Deputy Commissioner Winton B. Rankin, the FDA created the Compliance Policy Guide system.<sup>87</sup> Rankin envisioned a system that would “compile and revise the previous sources of policy information for incorporation into a single issuance system, and provide the format and mechanics for compiling and disseminating all future policy

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<sup>80</sup> Paul B. Dunbar, *Federal Food, Drug and Cosmetic Law: Administrative Reports 1907-1949*, Introduction (Chicago: Commerce Clearing House, c. 1951); Joel E. Hoffman, *Seventy-fifth Anniversary Commemorative Volume of Food and Drug Law*, Edited and Published by the Food and Drug Law Institute Series (1984).

<sup>81</sup> Paul B. Dunbar, *Federal Food, Drug and Cosmetic Law: Administrative Reports 1907-1949*, Introduction (Chicago: Commerce Clearing House, c. 1951); 21 CFR 40694 (1975).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> Vincent A. Kleinfeld and Charles Wesley Dunn, *Federal Food, Drug, and Cosmetic Act: Judicial and Administrative Record, 1938-1949* (Chicago: Commerce Clearing House, c. 1949)

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> Compliance Policy Guide, 1973 Transmittal No. 73-1 (12/03/73) Issuing office, EDRO, Division of Field Operations.

information.”<sup>88</sup> The first Compliance Policy Guide Manual was released by the Bureau of Compliance in 1969, but contained few policies.<sup>89</sup> In 1972, Assistant Commissioner of Compliance Sam D. Fine ordered the reissuance of the Compliance Policy Guides.<sup>90</sup> The 1973 Compliance Policy Guide Manual introduction explains that “[the Guides] describe the agency’s official policy on a compliance matter if a policy has been established. By contrast, the administrative guidelines outline the conditions which must be present before the agency will invoke the legal sanctions of any act enforced by the FDA.”<sup>91</sup> The FDA website further explains that statements made in the CPG do not create any rights but “are intended for internal guidance.”<sup>92</sup>

#### **D. Advisory Opinions & Guidelines**

Advisory opinions are now the name given to trade correspondence created between 1938 and 1946, compliance policy guides, any notices in the Federal Register that are not the proposed or final regulations.<sup>93</sup> Advisory opinions are formal positions of the FDA, can be amended and revoked, but if industry conducts business in a manner proscribed in an advisory opinion, no adverse action will be taken by FDA.<sup>94</sup> The FDA’s regulations state, however, that in “unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion before amending or revoking the opinion.”<sup>95</sup>

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<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116791.htm>

<sup>93</sup> 21 C.F.R. § 10.85 (d) (2000).

<sup>94</sup> 21 C.F.R. § 10.85 (e), (g)

<sup>95</sup> 21 C.F.R. § 10.85 (f)

Along with Trade Correspondence and Compliance Policy Guides, FDA “guidelines” were considered a type of advisory opinion.<sup>96</sup> As explained above, the idea of guidelines was created in the context of FDA’s Policy Board and was included in the procedural regulations promulgated in 1975. The regulations defined the new tool,

“Guidelines relate to such matters as performance characteristics, preclinical and clinical test procedures, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. Guidelines state procedures or standards of general applicability which are not legal requirements but which are acceptable to the Food and Drug Administration for a subject matter-which falls within the laws administered by the Commissioner, e.g., a protocol for a particular type of animal toxicity test or human clinical trial.”<sup>97</sup>

The proposed regulations emphasized that a person does not have to follow the procedure in the guideline. The Commissioner further explained that a person may, but should not feel required to discuss any divergence from a guideline with FDA. “Until modified or revoked, they would represent the formal opinion of the agency and bind the agency to that position.”<sup>98</sup> FDA Consumer magazine praised the benefits of the new regulations, stating “it will be a lot easier for any member of FDA’s publics—consumer, industry, professional—to make his voice heard in Agency decisions.”<sup>99</sup>

### **E. Other Agency Policy Pronouncements**

In addition to guidelines, the FDA issues recommendations, agreements and memorandums of understanding, which advise various entities of FDA’s positions and views without rising to the level of regulations.<sup>100</sup> The FDA enters into memorandums of understanding (MOUs) with entities such as federal, state and local governments, academic

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<sup>96</sup> 21 C.F.R. 40729 (1975) Peter B. Hutt, Lewis A. Grossman, and Richard A. Merrill, *Food and Drug Law: Cases and Materials* 1368 (3d ed. 2007).

<sup>97</sup> 21 C.F.R. § 40730 (1975).

<sup>98</sup> 21 C.F.R. § 40696 (1975).

<sup>99</sup> Emil Corwin, *Putting FDA’s Procedural House in Order*, FDA CONSUMER, July August 1975

<sup>100</sup> 21 C.F.R. § 10.90

institutions and others to “define lines of authority or responsibility, or to clarify cooperative procedures.”<sup>101</sup> These are formal, but nonbinding agreements.<sup>102</sup> In a 1996 proposed regulation, the FDA declared that “well over a thousand such documents exist,” referring to various types of agency pronouncements described above and additionally, points to consider, blue book memos.<sup>103</sup>

## **F. Non-binding Status of Policy Statements**

In 1977, an FDA regulation declared that advisory opinions, including trade correspondence, compliance policy guides, and guidelines, would be binding.<sup>104</sup> In October 1992, however, the agency announced that, pending a final rule, advisory opinions and guidelines would no longer bind the agency, bind the public, nor confer any rights upon the public.<sup>105</sup> In the preamble to the proposed changes, FDA indicated the changes were an attempt to bring FDA’s practice in line with current case law, and be “consistent with principles of estoppel and sound public policy.”<sup>106</sup> FDA explained this switch was to ensure such documents were not misleading to the public given judicial treatment of such guidelines as non-binding and to ensure FDA’s treatment of them did not conflict with the recent court decision, *Community Nutrition Institute v. Young* (CNI).<sup>107</sup> CNI held that regulatory “action levels,” which limited FDA’s discretion as to when they would enforce certain statutory provisions, were binding substantive rules, and, as such, must be promulgated through notice and comment rulemaking

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<sup>101</sup> <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/default.htm>

<sup>102</sup> *Id.*

<sup>103</sup> 61 Fed. Reg. 9181, 9182 (1996)

<sup>104</sup> 42 Fed. Reg. 4680, 4708-10 (1977) (codified as amended at 21 C.F.R. 10.85, 10.90 (1997)).

<sup>105</sup> Administrative Practices and Procedures; Advisory Opinions and Guidelines, 57 Fed. Reg. 47,314, 47-314 (Oct. 15, 1992).

<sup>106</sup> Administrative Practices and Procedures; Advisory Opinions and Guidelines, 57 Fed. Reg. 47,314, 47-314-15 (Oct. 15, 1992).

<sup>107</sup> 818 F. 2d 943 (D.C. Cir. 1987); Administrative Practices and Procedures; Advisory Opinions and Guidelines, 57 Fed. Reg. 47,314, 47-315 (Oct. 15, 1992).

procedures to be valid.<sup>108</sup> While the CNI opinion concerned regulatory action levels, not advisory opinions or guidelines, the FDA's preamble explains that this decision "calls into question FDA's procedures for issuing advisory opinions and guidelines that purport to be binding FDA."<sup>109</sup>

This announcement was criticized by many.<sup>110</sup> One organization, the Indiana Medical Device Manufacturers Council, submitted a citizen petition to the FDA in May 1995 requesting the FDA allow public participation on this issue.<sup>111</sup> The Subcommittee on National Economic Growth, Natural Resources and Regulatory Affairs and the Subcommittee on Human Resources and Intergovernmental Relations held a joint hearing on the issue on September 14, 1995.<sup>112</sup> Succumbing to these pressures, in March 1996, the FDA issued requests for comments on this issue in the Federal Register.<sup>113</sup> This resulted in publication of the FDA's "Good Guidance Practices" (GGP's) in 1997.<sup>114</sup>

## **G. Guidance Documents**

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<sup>108</sup> 818 F. 2d 943, 949 (D.C. Cir. 1987).

<sup>109</sup> Administrative Practices and Procedures; Advisory Opinions and Guidelines, 57 Fed. Reg. 47,314, 47-314-15 (Oct. 15, 1992).

<sup>110</sup> See Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating it Too*, 47 CATH. U.L. REV. 113 (1997) ("The proposed wholesale renunciation of hundreds of formal advisory opinions and guidelines on which regulated firms have come to rely cannot, however, be justified.") However, FDA explained that "[a]lthough most comments agreed with the agency's position that guidance should not be binding on the public, a number did argue that FDA should be required to follow its own guidance." The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961, 8962-63 (Feb. 27, 1997).

<sup>111</sup> Guidance Documents; The Food and Drug Administration's Development and Use; Request for Comments, 61 Fed. Reg. 9181 (Mar. 7, 1996).

<sup>112</sup> John C. Carey, *The FDA's Policymaking Quandary: Is Guidance Reform and Appropriate Solution?* (1997), in Peter Barton Hutt, ed., *Food and Drug Law: An Electronic Book of Student Papers*.

<sup>113</sup> Guidance Documents; The Food and Drug Administration's Development and Use; Request for Comments, 61 Fed. Reg. 9181 (Mar. 7, 1996).

<sup>114</sup> The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb. 27, 1997).

At some point between 1992 and 1996, the FDA introduced the term guidance documents. Both terms appear in the 1993 Federal Register.<sup>115</sup> The FDA explained in 1996, however, that “[g]uidance documents currently are issued under a number of different names, (e.g., guidelines, guidance, points to consider, blue book memos, compliance policy guides, etc.)”<sup>116</sup> In 2000, FDA ensured that the nomenclature “guidelines” would only live on in administrative law history, as they formally switched to using the term “guidance document” for all forms of agency guidance.<sup>117</sup> Prior to the issuance of this final rule, a book on FDA regulations explained that “[i]n between regulations and guidance documents are “guidelines.”<sup>118</sup> While this switch in nomenclature does correspond to the shift from binding to nonbinding status of these documents, there is nothing in the Federal Register to support this specific alignment. This should not be taken as proof of the falsehood of the statement, but rather, simply reinforce the confusion at that time surrounding the status of both guidelines and guidance documents.

## **H. Guidance Document Reform**

In 1997 Congress again amended the FDA’s organic statute. The Food and Drug Modernization Act of 1997 (FDAMA) codified parts of the agency’s 1997 Good Guidance Practices and specified additional requirements.<sup>119</sup> One important requirement was that notwithstanding the non-binding nature of guidance documents, “the Secretary shall ensure that employees of the [FDA] do not deviate from such guidances without appropriate justification

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<sup>115</sup> International Conference on Harmonization; Studies in Support of Special Populations; Geriatrics; Draft Guideline, Availability, 58 Fed. Reg. 21082 (Apr. 16, 1993) and Guidance Documents on Refusal to File New Drug Applications, Availability 58 Fed. Reg. 38770 (July 20, 1993).

<sup>116</sup> Guidance Documents; The Food and Drug Administration’s Development and Use; Request for Comments, 61 Fed. Reg. 9181, 9182 (Mar. 7, 1996).

<sup>117</sup> Administrative Practice and Procedures, Good Guidance Practices, 65 Fed. Reg. 56468, 56475 (Sept. 19, 2000)(“all guidelines are now treated as guidance documents”).

<sup>118</sup> Fred H. Degnan, *FDA’s Creative Application of the Law: Not Merely a Collection of Words* 11 (2000).

<sup>119</sup> While typically, direct Congressional endorsement of agency action would be considered positive, however, Lars Noah refers to FDAMA as just another instance of the FDA finding a “convenient shortcut[] for communicating its expectations to regulated entities.” Lars Noah, *The Little Agency That Could (Act With Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L. REV. 901, 905 (2008).

and supervisory concurrence.”<sup>120</sup> Additionally, FDAMA required the FDA to create an agency system equipped to hear complaints concerning the FDA’s guidance document procedures, to “maintain electronically and update and publish periodically in the Federal Register a list of guidance documents.”<sup>121</sup> FDAMA also requires the FDA to allow and consider public comments prior to implementation of guidance documents that are “initial interpretations of a statute or regulation, changes in interpretation or policy of more than a minor nature, complex scientific issues, or highly controversial issues.”<sup>122</sup> For guidance documents that “set for existing practices or minor changes in policy” public comment at the time of implementation is adequate.<sup>123</sup> Lastly, FDAMA directed the FDA to evaluate the Good Guidance Practices and issue final regulations consistent with FDAMA prior to July 2000.<sup>124</sup>

The last major amendments to FDA’s regulatory procedures occurred in 2000 as prescribed by FDAMA.<sup>125</sup> The agency proposed the changes in February 2000 and received eighteen comments, mainly from trade organizations supporting the changes.<sup>126</sup> As defined by the 2000 amendments, “guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency’s interpretation of or policy on a regulatory issue.”<sup>127</sup> The FDA maintained the Level 1 and 2 divisions introduced in the 1997 Good Guidance Practices and explained the procedures for developing each. Level 1 guidance includes “initial interpretations of statutory or regulatory requirements,” major changes in

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<sup>120</sup> Food and Drug Administration Modernization Act of 1997 § 405, 21 U.S.C. 371(h)(1)(a) (1997). For a discussion regarding the murkiness of what “appropriate justification” encompasses, see James Hunnicutt, *Another Reason to Reform the Federal Regulatory System: Agencies’ Treating Nonlegislative Rules as Binding Law*, 41 B.C. L. REV. 153 (1999).

<sup>121</sup> Food and Drug Administration Modernization Act of 1997 § 405, 21 U.S.C. 371(h)(1)(a) (1997).

<sup>122</sup> Food and Drug Administration Modernization Act of 1997 § 405, 21 U.S.C. 371(h)(1)(a) (1997).

<sup>123</sup> Food and Drug Administration Modernization Act of 1997 § 405, 21 U.S.C. 371(h)(1)(a) (1997).

<sup>124</sup> Food and Drug Administration Modernization Act of 1997 § 405, 21 U.S.C. 371(h)(1)(a) (1997).

<sup>125</sup> FDAMA required the FDA to evaluate the effectiveness of their Good Guidance Practices before July 1, 2000 and promulgate a regulation consistent with FDAMA “specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.”

<sup>126</sup> Administrative Practices and Procedures; Good Guidance Practices, 65 Fed. Reg. 56468 (Sept. 19, 2000).

<sup>127</sup> 21 C.F.R. § 10.115 (2000).

interpretation or policy, or guidance related to complex scientific issues or highly controversial issues.<sup>128</sup> Level 2 includes all guidances not classified as Level 1.<sup>129</sup> The procedures for promulgating Level 1 are much more detailed than those for Level 2 guidances.

### **Level 1**

“FDA can seek or accept early input from individuals or groups outside the agency. For example, FDA can do this by participating in or holding public meetings and workshops. After FDA prepares a draft of a Level 1 guidance document, FDA will: (A) Publish a notice in the Federal Register announcing that the draft guidance document is available; (B) Post the draft guidance document on the Internet and make it available in hard copy; and (C) Invite your comment on the draft guidance document...After FDA prepares a draft of a Level 1 guidance document, FDA also can: (A) Hold public meetings or workshops; or (B) Present the draft guidance document to an advisory committee for review. After providing an opportunity for public comment on a Level 1 guidance document, FDA will: (A) Review any comments received and prepare the final version of the guidance document that incorporates suggested changes, when appropriate; (B) Publish a notice in the Federal Register announcing that the guidance document is available; (C) Post the guidance document on the Internet and make it available in hard copy; and (D) Implement the guidance document.”

### **Level 2**

“FDA will: (A) Post the guidance document on the Internet and make it available in hard copy; (B) Immediately implement the guidance document, unless FDA indicates otherwise when the document is made available; and (C) Invite your comment on the Level 2 guidance document...If FDA receives comments on the guidance document, FDA will review those comments and revise the document when appropriate. If a version is revised, the new version will be placed on the Internet. You can comment on any guidance document at any time...FDA will revise guidance documents in response to your comments when appropriate.”

The rules clarify, however, that the FDA will not seek comments before issuing a Level 1 guidance document if it is not “feasible or appropriate.”<sup>130</sup> If a Level 1 guidance document is issued without prior public participation though, the FDA will allow comments after publication of the guidance document, review those comments, and make revisions if necessary.<sup>131</sup> Given the procedural regulations that now govern the issuance of guidance documents, some FDA

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<sup>128</sup> Good Guidance Practices, 21 C.F.R. § 10.115 (b) (2000).

<sup>129</sup> 21 C.F.R. § 10.115 (2000).

<sup>130</sup> 21 U.S.C. §371, 10.115

<sup>131</sup> *Id.*

employees have commented that “in practice they take as long as rules to develop.”<sup>132</sup> As one scholar notes, “[i]t would not be far-fetched to [say] . . . that the FDA now proposes to issue its important regulations mostly in accordance with the notice-and-comment rulemaking procedure set forth in the APA, as it was understood before 1970.”<sup>133</sup>

FDA and Congress were not the only entities interested in increasing oversight and accountability of guidance documents. Almost ten years after the FDA first established its comprehensive policy for the issuance and development of guidance documents, President Bush issued Executive Order 13,422 in 2007. Executive Order 13,422 and the Office of Management and Budget’s (OMB) corresponding “Final Bulletin for Good Guidance Practices” (bulletin), extended inter-agency review to agency guidance documents.<sup>134</sup> The executive order required agencies to provide the Office of Information and Regulatory Affairs (OIRA) advance notice of any significant guidance document.<sup>135</sup> Additionally, the OMB bulletin created a sub-division of significant guidance documents, entitled “economically significant” guidance documents. The bulletin requires notice in the Federal Register, opportunity for comments, response to comments, before issuing a final economically significant guidance document.<sup>136</sup> According to FDA Policy Advisor, Eric Flamm, the FDA had never classified any guidance document as “economically significant,” thus bringing it within the scope of OMB’s requirements.<sup>137</sup> On

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<sup>132</sup> Erica Seiguer and John J. Smith, *Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances*, 60 FOOD DRUG L.J. 17, 24 (2005).

<sup>133</sup> Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 169 (2000).

<sup>134</sup> Exec. Order No. 13,422, 72 Fed. Reg. 2764 (Jan. 23, 2007); Memorandum for the heads of executive departments and agencies, and independent regulatory agencies, Rob Portman, M-07-13, April 25, 2007

<sup>135</sup> Exec. Order No. 13,422, 72 Fed. Reg. 2764 (Jan. 23, 2007).

<sup>136</sup> Memorandum for the heads of executive departments and agencies, and independent regulatory agencies, Rob Portman, M-07-13, April 25, 2007

<sup>137</sup> Email from Eric Flamm, February 27th, 2009 FDA Policy Advisor, “FDA never categorized any guidances it sent to OMB as economically significant under the executive order.”

January 30th, 2009, President Obama revoked Executive Order 13,422.<sup>138</sup> It remains to be seen what requirements, if any, the Obama Administration will impose on agency guidance documents.

## I. Criticism of Guidance Documents

The amount of analysis and revision FDA's guidance document process has received begs the question of whether this process is a favorable means of agency policymaking.

Professor Todd Rakoff best summarizes the two schools of thought regarding FDA's use of guidance documents, "[it] can be seen either as an example of thoughtful and balanced institutional creativity, or as a brazen attempt to subvert the APA as construed by the courts."<sup>139</sup>

Criticisms generally fall into three categories: that the FDA will treat them as de facto rules, that there is too little transparency, accountability and public involvement, and that the entire system creates more confusion than clarity.<sup>140</sup> Each of these will be discussed in turn.

The process for developing and issuing guidance documents is no longer the dark scenario described by the D.C. Circuit, "[I]aw is made without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations."<sup>141</sup> The imposition of numerous procedural rules governing the issuance of agency guidance documents however has not assuaged concerns by many that the process lacks accountability, transparency, and meaningful public participation. Many administrative law scholars criticize agency reliance on guidance documents for its abandonment of accountable

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<sup>138</sup> Exec. Order No. 13,497

<sup>139</sup> Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 170 (2000).

<sup>140</sup> See generally Stephen M. Johnson, *Good Guidance Good Grief!*, 72 MO. L. REV. 695 (2007); Lars Noah, *The Little Agency That Could (Act With Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L. REV. 901, 905 (2008).

<sup>141</sup> *Appalachian Power v. EPA*, 208 F.3d 1015,1020 (D.C. Cir. 2000)

policymaking.<sup>142</sup> Professor Rakoff criticizes, “[w]hat the FDA did was to take the APA’s lenient attitude toward interpretative rules and policy statements and convert it into a wholly alternative system of regulation.”<sup>143</sup>

Even though guidance documents are not legally binding, administrative law scholars, agency employees and industry representatives all express concern that, in practice they operate the same.<sup>144</sup> “Even though those documents do not have legally binding effect, they have practical binding effect whenever the agencies use them to establish criteria that affect the rights and obligations of private persons.”<sup>145</sup> In a 2005 study of industry perspectives on FDA guidance documents, one subject responded, “in practice most of those interviewed said that industry treats guidances no differently than rules.”<sup>146</sup> “From the industry’s point of view, it is more a combination of grudging acceptance, plus fear, plus desire for a gold star that can be used in marketing, plus the natural tendency of anyone to gripe about whoever is in a position of authority over them.”<sup>147</sup>

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<sup>142</sup> Thomas McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385, 1442 (1992).

<sup>143</sup> Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 167-68 (2000).

<sup>144</sup> For discussion of the concerns this possibility raises and the likelihood of it occurring, see Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 407 (2007) (“guidance documents often have rule-like effects on regulated entities”); Gwendolyn McKee, *Judicial Review of Agency Guidance Documents: Rethinking the Finality Doctrine*, 60 ADMIN L. REV. 371, 384-85 (2008) (“this seemingly tentative language does not disguise reality; the FDA produced the guidance because it expects that producers will follow its suggestions.”); Lars Noah, *The Little Agency That Could (Act With Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L. REV. 901, 905 (2008); James Hunnicut, *Another Reason to Reform the Federal Regulatory System: Agencies’ Treating Nonlegislative Rules as Binding Law*, 41 B.C. L. REV. 153 (1999).

<sup>145</sup> Robert Anthony, *Unlegislated Compulsion: How Federal Agency Guidelines Threaten your Liberty*, Cato Policy Analysis No. 312, August 11, 1998. Anthony, however, does believe that interpretative rules may be treated by an agency as practically binding in a very narrow set of circumstances, “to the extent that they interpret specific statutory or regulatory language.” Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like-Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1314 (1992).

<sup>146</sup> Erica Seiguer and John J. Smith, *Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances*, 60 FOOD DRUG L.J. 17, 29-30 (2005) (“most business people don’t know the difference between a reg and a guidance, so by and large the business field does not care. All they want is clarity.”); see also Edwin Brown Williams, *Regulations- The Industry View*, 24 FOOD DRUG COSM. L. J. 301 (1969).

<sup>147</sup> Fran Hawthorne, *Inside the FDA: The Business and Politics Behind the Drugs We Take and the Food We Eat* 124 (2005).

While an empirical study testing the hypothesis that guidance documents act as de facto rules is greatly needed, this information would be difficult if not impossible to accurately compile. Proof of this criticism can only be found in industry board rooms or discussions with attorneys faced with the decision to abide by the terms of the guidance documents.<sup>148</sup> No one formally complains or files suit for fear of establishing an adverse relationship with FDA, a relationship that industry relies on maintaining.<sup>149</sup> Others, however, have expressed concern that because guidance documents “do not even constrain agency officials” regulated entities are left “guessing about their rights and obligations.”<sup>150</sup>

## **J. Additional Areas for Research**

A comprehensive, yet detailed, overview of the century-long history of FDA rulemaking and policymaking is beyond the scope of one paper. One area ripe for additional research is a systematic study of the number and types of guidance documents promulgated per year. Initial research has been conducted by a few individuals. John C. Carey’s analysis of the FDA’s use of guidance between 1985 and 1995 provided a great starting point. His research showed that “between 1985 and 1989 the FDA issued 11.6 guidances per year, whereas, between 1990 and 1995 the FDA issued 60.7 guidances per year; an increase of approximately 425%.”<sup>151</sup> Erica Seiguer and John

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<sup>148</sup> For further evidence and research concerning industry view of agency guidance documents see Erica Seiguer and John J. Smith, *Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances*, 60 FOOD DRUG L.J. 17 (2005).

<sup>149</sup> See Lars Noah, *The Little Agency That Could (Act With Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L. REV. 901, note 30 (2008) (citing a 1993 Forbes article claiming “that 84% of survey respondents had failed to press potentially legitimate complaints against the FDA for fear of retaliation”); Robert A. Anthony, “Well, You Want the Permit Don’t You?” *Agency Efforts to Make Nonbinding Legislative Rules Bind the Public*, ADMINISTRATIVE LAW REVIEW, Winter 1992.

<sup>150</sup> Lars Noah, *The Little Agency That Could (Act With Indifference to Constitutional and Statutory Structures)*, 93 CORNELL L. REV. 901, 905 (2008).

<sup>151</sup> John C. Carey, *The FDA’s Policymaking Quandary: Is Guidance Reform and Appropriate Solution?* 47(1997), in Peter Barton Hutt, ed., *Food and Drug Law: An Electronic Book of Student Papers*.

J. Smith, M.D., J.D. also provided valuable research on this subject.<sup>152</sup> They compiled the number of Level 1 draft and final guidances issued in a three year period. Their data indicates that in 2001 FDA issued a total of 94 guidances, in 2002, FDA issued 99 total guidances, and in 2003 a total of 105.<sup>153</sup> While this is a substantial increase from the yearly average in the 1990's that John Carey reported, this could be due to an actual significant increase in the amount of guidances or varying research methodologies.<sup>154</sup> Pursuant to the FDA's Good Guidance Practices, the FDA publishes an "Annual Comprehensive List of Agency Guidance Documents" in the Federal Register.<sup>155</sup> This information can also be found on FDA's website. Each of the six centers within FDA manages their own list of active guidance documents. None of these sources provide a list divided by years, however, so a systematic yearly tally is difficult to accurately report.

Figure A below exhibits a continuation of the research conducted by John C. Carey in 1997, displaying the trend of FDA's promulgation of rules in the past ten years.<sup>156</sup> To compile the data reflected in Figure A, I counted the number of FDA rules listed in the Federal Register Index for each year. In addition, I used the legal research database, Westlaw to electronically

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<sup>152</sup> Erica Seiguer and John J. Smith, *Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances*, 60 FOOD DRUG L.J. 17 (2005).

<sup>153</sup> *Id.* at 26.

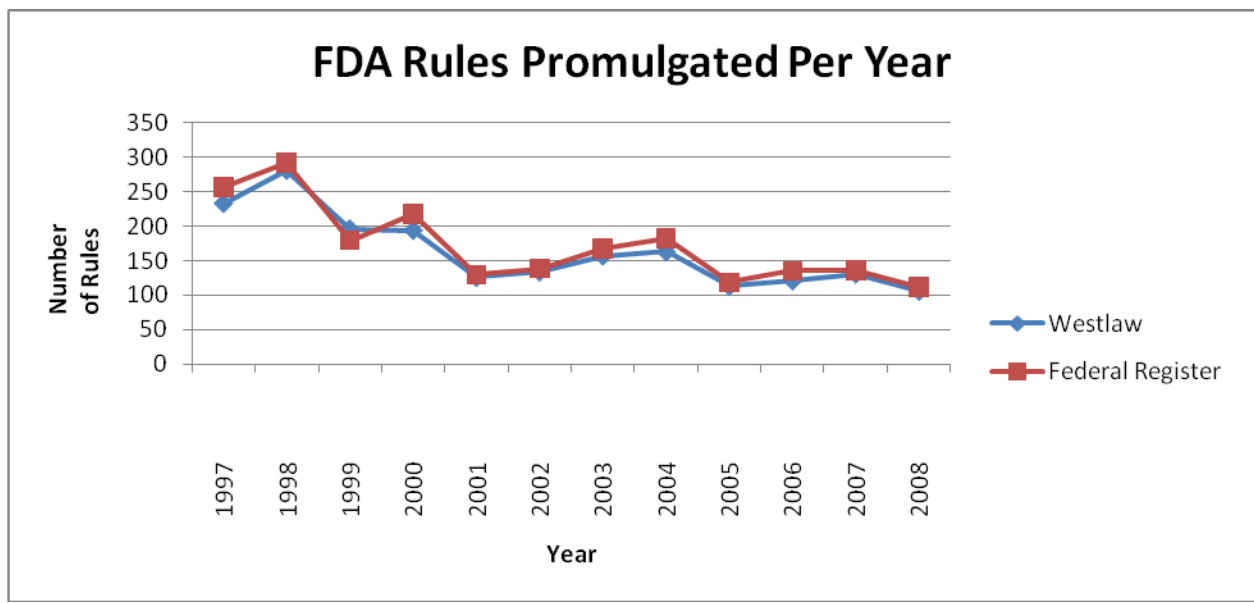
<sup>154</sup> John Carey used multiple sources to compile his data, including industry data and a letter from FDA Dockets Management Branch. Seiguer and Smith used "published record lists supplied by FDA." The variety of ways such data is kept, however, precludes the author's labeling of one method of compilation as "correct."

<sup>155</sup> However, no list was included in the 2001, 2002, 2003, or 2004 Federal Registers. The 2005 annual list states that "this list updates a comprehensive list that published October 24, 2001 (63 FR 53836)." 70 Fed. Reg. 824 (2005). The FDA provided no explanation why annual lists were omitted in the intervening years and nothing indicates that guidance was not issued during those years.

<sup>156</sup> Because his research is only available in a hard copy graphical representation, I could not add the numerical data he compiled. For John C. Carey's data of the years 1977-1997 see John C. Carey, *The FDA's Policymaking Quandary: Is Guidance Reform and Appropriate Solution?* (1997), in Peter Barton Hutt, ed., *Food and Drug Law: An Electronic Book of Student Papers*.

search the Federal Register for FDA final rules.<sup>157</sup> I included the results of both searches here, since neither method is error proof. Both methods may include rules that are merely corrections or withdrawals of other rules. The close correlation indicates, however, that, together, this data reflects the general trend of FDA rulemaking in the past ten years. Additional research is needed to assess the cause of such decreases and influxes in regulations. This is especially true when considered in context of the agencies increasing reliance on guidance document.<sup>158</sup>

**Figure A**



#### IV. Conclusion

The evolution of FDA's methods for creating regulations and policies has made it the subject of both harsh criticism and high praise. Overwhelming statutory responsibilities has

<sup>157</sup> In order to replicate this research for later years, I used the following "search string" in Westlaw: pr(agency: /3 "food and drug administration")& pr(action: /5 "final rule") & da("Year").

<sup>158</sup> John C. Carey's Third Year Paper cited supra note 156 provides an excellent initial analysis of this phenomenon. Written in 1997, however, the research and analysis needs comprehensively updated.

positioned the agency permanently searching for the most efficient and effective means of regulation and policy creation. Whether this has resulted in an erosion of agency accountability and public participation or a more efficient means of detailed policy creation and statutory interpretation will surely continue to be debated. More research and analysis is needed before we can begin to assess the effects of this change in regulatory approach. What is certain is that the past two decades have solidified the status of guidance documents as a major tool of FDA policymaking.