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<b>Citation</b>	The Presidential FDA: Politics Meet Science (2001 Third Year Paper)
<b>Accessed</b>	February 19, 2015 9:35:20 AM EST
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# The Presidential FDA: Politics Meet Science

Kate Cook

## Introduction

Of all the federal government agencies, the American public considers the Food and Drug Agency (hereinafter the FDA) the most respectable and trustworthy. Though one can never fully comprehend what informs the impulses and preferences of Americans, there are a few obvious reasons why the most closely watched of all regulatory agencies – the agency responsible for maintaining the safety of our national foods and drugs – enjoys great approval ratings. First, for the most part, American foods and medicines are safe. Second, unlike other countries, America has a rigorous threshold of safety that must be proven before a product can be deemed marketable. Third, and most important for the purposes of this paper, the public presumes that determinations of safety and effectiveness hinge upon scientific evidence and expertise *not politics*.

In fact, however, much of administrative law scholarship revolves around debates concerning which (if any) governmental branch constitutionally controls the federal agencies and their policies. And furthermore, whether these agencies are democratic.<sup>1</sup> The FDA's historical narrative begins with Progressive Era reforms and literature such as Upton Sinclair's The Jungle, which mobilized American support for creating federal agencies, such as the FDA to regulate food quality and production.<sup>2</sup> In their efforts to reform government,

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<sup>1</sup>See e.g., Martin Flaherty, *The Most Dangerous Branch*, 105 *Yale L.J.* 1725 (1996); Steven G. Calabresi & Saikrishna B. Prakash, *The President's Power to Execute the Laws*, 104 *Yale L.J.* 541 (1994); Lawrence Lessig & Cass Sunstein, *The President and the Administration*, 94 *Colum. L. Rev.* 1 (1994); Geoffrey P. Miller, *Independent Agencies*, 1986 *Sup. Ct. Rev.* 41.

<sup>2</sup>See Richard B. Stewart, *The Reformation of American Administration Law*, 88 *Harv. L. Rev.* 1667 (1975); see also F. Dell, *Upton Sinclair (1927)*; J. Harte, *This Is Upton Sinclair (1938)* (noting that as a writer Sinclair gained fame in 1906 with the novel *The Jungle*, a report on the dirty conditions in the Chicago meat-packing industry. In the story *Jurgis Rudkus*, a young Lithuanian immigrant, arrives in America dreaming of wealth, freedom, and opportunity. He finds work from the flourishing, filthy Chicago stockyards, where his New World

Progressives imagined that these agencies would draw upon objective science, free from political corruption, thus the Progressives deliberately stripped agencies of traditional democratic features found in governmental bodies: public support, accountability, and election.<sup>3</sup> The specialized staffing of administrative agencies continues to legitimize their active role in lawmaking, yet this specialization simultaneously threatens the delicate constitutional balance of power. For example, from its inception, administrative law (and constitutional law for that matter) has focused on how to design a system of checks which will minimize the risks of bureaucratic arbitrariness and overreaching, while preserving for the agencies the flexibility they need to act effectively.<sup>4</sup> Modern Congressional legislation broadly delegates power to administrative agencies,<sup>5</sup> and after once having made these delegations of power to make administrative law, the agency is free to do so provided it follows agency standards and procedures.<sup>6</sup>

In order to maintain the democratic character of American government, the legislative, executive and judicial branches each play a role in supervising the substance of what the FDA does. In spite of the familiar constitutional geography in which the three branches share power to “check” administrative agencies’ power, however, as of late, the FDA has increasingly been located in the hemisphere of the executive branch. Through presidential lawmaking and overt co-optation of policy areas previously understood to belong within the proper

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visions fade in the hopeless wage-slavery and in the chaos of urban life. The book won Sinclair fame and fortune, and led to the implementation of the Pure Food and Drug Act in 1906. It had the deepest social impact since Harriet Beecher Stowe’s Uncle Tom’s Cabin).

<sup>3</sup>See Richard B. Stewart, *The Reformation of American Administration Law*, 88 Harv. L. Rev. 1667 (1975); see also James Landis, *The Administrative Process* 24 (1938) (arguing that the rise of the regulation required a knowledge of the details of industry operation; and therefore, expertness solved the problem of administrative discretion).

<sup>4</sup>See Ernest Gellhorn & Ronald M. Levin, *Administrative Law and Process* at 2 (4<sup>th</sup> ed. 1997).

<sup>5</sup>See Gary Lawson, *The Rise and Rise of the Administrative State*, 107 Harv. L. Rev. 1237-41 (1994).

<sup>6</sup>See e.g., Lawrence C. Dodd & Richard L. Schott, *Congress and the Administrative State* (1979), at 2 (‘‘Although born of congressional intent, [the administrative state] has taken on a life of its own and has matured to a point where its muscle and brawn can be turned against its creator.’’); see also Jerry L. Mashaw, Richard A. Merrill & Peter M. Shane, *Administrative Law: The American Public Law System* (1998), at 56, 160-61 (noting ‘‘doubt whether existing connections between Congress and administrative bodies are effective means for accomplishing political responsiveness of administration, or dispassionately assessing the strengths and weaknesses of regulatory programs’’).

domain of either Congress or the so-called “fourth branch” – the administrative bureaucracy itself, President Clinton transformed public announcements into the first step in rulemaking under the Administrative Procedure Act (the APA). As I describe more fully below, Clinton’s public policy statements were translated into administrative proposals, inviting notice and comment just like the APA requires. Moreover, the president’s public announcements about, say the FDA’s initiative to regulate tobacco, greatly constrained the agency’s options for action.<sup>7</sup>

In sum, this paper assumes a highly political FDA, which during the Clinton regime became an effective vehicle to activate presidential policies, most prominently the attempt to regulate the tobacco industry.<sup>8</sup> While Congress maintained certain restrictive powers, the Clinton presidency was able to circumvent Congressional hurdles by strategically employing the FDA, (and other administrative agencies), to implement his domestic policy goals.<sup>9</sup> And although the Supreme Court has issued opinions that at least implicitly establish the president’s role in administrative decision-making,<sup>10</sup> it is unclear after FDA v. Brown & Williamson Tobacco Corp.<sup>11</sup> whether the president’s effective yet controversial lawmaking was constitutional.<sup>12</sup>

Drawing upon Alexander Hamilton’s theory of executive power expressed in the Federalist Papers, and upon

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<sup>7</sup>See Peter L. Strauss, *Presidential Rulemaking*, 72 *Chicago-Kent L. Rev.* 965-967 (1997).

<sup>8</sup>See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule, 61 *Fed. Reg.* 44, 396 (1996); Annex: Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food Drug and Cosmetic Act. See FDA v. Brown & Williamson, 120 S.Ct., 1291 (2000).

<sup>9</sup>A number of Washington journalists have written about President Clinton’s focus and reliance on the administrative sphere to effect his policy goals. See e.g., Alexis Simendinger, *An Executive Endgame Takes Shape*, *Nat’l J.* (February 26, 2000); Alexis Simendinger, *The Paper Wars*, *Nat’l J.* (July 25, 1998), at 1732; Robert Pear, *The Presidential Pen Is Still Mighty*, *New York Times* (June 28, 1998); James Bennet and Robert Pear, *How a Presidency Was Defined by the Thousand Parts of Its Sum*, *New York Times* (December 8, 1997). See also Peter Strauss, *Presidential Rulemaking*, 72 *Chicago-Kent L. Rev.* 965, 967 (1997) (noting that “the proprietary interest in particular outcomes that President Clinton has taken in public political actions appears to be a new phenomenon”).

<sup>10</sup>See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984): Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Ins. Co., 463 U.S. 29 (1983) (Rehnquist, J. dissenting).

<sup>11</sup>120 S. Ct. 1291 (2000).

<sup>12</sup>See FDA v. Brown & Williamson Tobacco Corp. 120 S. Ct. 1291 (2000) (holding that the FDA lacks authority to regulate cigarettes and other tobacco products because Congress did not intend to grant such authority to the FDA given the rich legislative history whereby Congress had regulated various aspects of the tobacco industry and tobacco products for years).

modern functional analysis of the Presidency (and the administrative state), I conclude that the Clinton administration employed a constitutional and preferable model of lawmaking to that of independent agencies. Thus, under a president's watch, the FDA should be given the authority to regulate tobacco and any other products, when such rules would serve to effectuate the president's domestic policy and so long as the proposed regulations do not interfere with *explicit* Congressional intent to the contrary.

This paper proceeds in four parts. Part I. maps the powers of the various branches over the FDA. Part II. describes the Clinton administration's tobacco regulation. Part III. analyzes the repercussions of the failed lawsuit, and Part IV., the conclusion, peaks at the new Bush administration and suggests reasons why Bush would be wise to adopt Clinton's style of presidential lawmaking through the FDA (and other agencies) so long as such action has been reasonably delegated to the agency.

One last word on the enigma of executive power and its relationship to the administrative state. Interestingly, in spite of the constitutional restrictions on their power to legislate, the American public has long assumed presidents can and do enjoy the power to control domestic and foreign policy. Consider, for example, the issues posed to presidential candidates during a campaign. Thus, due to media coverage and the tone of their campaign promises, the public assumes that the president has broad authority to make laws. I would further suggest that most Americans have not fully considered which governmental branch oversees administrative agencies.

Focusing on the FDA's attempt to regulate tobacco under the direction of the Clinton Administration posits a possible transformation of public perceptions about the FDA – from an independent body to a highly political arm of the executive. However, the executive is expected to make use of his administration and “take care that the laws are faithfully executed.”<sup>13</sup> Therefore, rather than critiquing or celebrating this transformation in the public eye, I hope to enrich the reader's understanding of the complexity of adminis-

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<sup>13</sup>Article II. of the Constitution.

trative law and executive power, while exploring the inter-dynamics of modern separation of powers puzzles. Though, I suggest there are benefits in this public politicization of the FDA, the paper also recognizes the limitations and possible drawbacks posed by politicizing decisions about food and drug safety.

## **Part I. The FDA in Relation to the Three Branches of Government: An Overview**

### **A. Congressional Influence**

In addition to the national public and the media, Congress polices the activities of the FDA. Although the FDA is located in the executive branch, Congress still possesses multiple mechanisms to control the agency. First, as alluded to above, the Senate has the power to decline to approve the president's nominee for commissioner of the FDA.<sup>14</sup> Though most nominees are approved, the confirmation hearings still provide the Senators with a highly publicized forum to air their concerns about regulatory matters and to extract policy commitments from nominees.<sup>15</sup> The FDA, like every agency, needs a minimum degree of legislative support if it is to maintain its programs and obtain funding for them.

In fact, Congress requires FDA officials to testify before its committees more than any other agency.<sup>16</sup>

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<sup>14</sup>For example, President Clinton failed in his effort to install as Surgeon General an obstetrician, who has a record of performing abortions, because the Senate refused to vote on the nomination. Such cases are rare, however, because the Senate generally recognizes a President's strong interest in filling high government positions with personnel of his own choosing.

<sup>15</sup>Most recently, during the confirmation hearing of Bush's nominee for Health and Human Services Secretary, Tommy Thompson, Senator Clinton made news asking Thompson whether he would undo the FDA's approval of RU-486. See Thompson Will Review Abortion Pill Safety, Des Moines Register 4, (Jan. 20, 2001).

<sup>16</sup>For example, between September 1971 and July 1977, FDA officials were called to testify before congressional committees a total of 198 times. Notably, the inauguration of a Democratic President in 1977 and appointment of a new Commissioner did not markedly diminish congressional interest in overseeing FDA's performance. See Peter Barton Hutt & Richard A. Merrill, Food and Drug Law at 19 (Foundation Press 1991).

Congressional oversight influences the content of FDA's requirements and the efficacy of its enforcement powers. Significantly, the Congressional power to oversee the activities of regulatory agencies can be exercised as a means to reign in the president and his administration.<sup>17</sup> If the president is of a party different from that of the party controlling Congress, Congress can seize its oversight powers, requiring agency testimony, holding hearings, etc. For example, the arrival of Republican President Reagan in 1981, combined with the change in party control of the Senate, significantly reduced Congressional oversight, but Congressional pressure resumed following the Senate elections in 1986.<sup>18</sup>

In spite of these apparent Congressional "checks" on agency power, some scholars have questioned whether the increased use of hearings and other public oversight tools, represent a decline in Congressional power over agencies rather than an emergence of power.<sup>19</sup> That is, the Congressional oversight of agencies occurs in committees or subcommittees not on the floor of the House or Senate.<sup>20</sup> Not to mention Congress cannot impose statutory – and most budgetary – punishments without the agreement of the full Congress.<sup>21</sup> This would involve overcoming significant collective action problems and incurring transaction costs. Moreover, Congressional oversight tends to conserve the status quo, since Congressional committees usually focus on administration in reaction to strongly registered complaints by constituents. Therefore, although agencies must answer to Congress, they often are able to proceed without too many Congressional hassles.

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<sup>17</sup>See Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* at 19 (Foundation Press 1991)(describing the oversight check on executive power:

Fewer than 20 percent of its appearances deal with legislation affecting the agency. In most years no more than two appearances concern the agency's budget. The remainder, an average of almost 30 hearings a year, are 'oversight' hearings in the conventional sense. Our purpose is not to argue that FDA should be left alone to do its work, but simply to document that it is not left alone.

*Id.* at 19.

<sup>18</sup>See Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* at 19 (Foundation Press 1991).

<sup>19</sup>Mathew D. McCubbins, Roger C. Noll & Barry R. Weingast, *Administrative Procedures as Instruments of Political Control*, 3 *J.L. Econ. & Org.* 243 (1987).

<sup>20</sup>See e.g., Barry Weingast, *The Congressional-Bureaucratic System: A Principal Agent Perspective*, 44 *Pub. Choice* 147, 150 (1984).

<sup>21</sup>See Terry M. Moe, *An Assessment of the Positive Theory of 'Congressional Dominance,'* 4 *Legislative Studies Q.* 475, 486-90 (1987).

## B. The Judiciary

The courts' review of agency action (or inaction) furnishes an important set of controls on administration behavior. Different from the political controls exercised through OMB review (described below) or Congressional oversight, the judiciary regularly operates to provide relief for the individual person who is harmed by a particular agency decision.<sup>22</sup> In fact, sometimes judicial review might even counter the oversight activities of the executive and Congressional branches.<sup>23</sup> Judicial review can provide legitimacy of agency regulation, by providing an assumed objective and independent check on administrative decisions.<sup>24</sup>

## C. The Executive

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<sup>22</sup>See Ernest Gellhorn & Ronald M. Levin, *Administrative Law and Process* at 71 (4<sup>th</sup> ed. 1997).

<sup>23</sup>Most recently in *FDA v. Brown & Williamson Tobacco Corp.* 120 S. Ct. 1291 (2000) the Supreme Court held the FDA lacked statutory authority to regulate tobacco.

<sup>24</sup>See Ernest Gellhorn & Ronald M. Levin, *Administrative Law and Process* at 72 (4<sup>th</sup> ed. 1997).



The Executive Office of the President includes not only the president's personal advisors, but also regulatory units, such as the Office of Management and Budget (OMB). The OMB has the primary responsibility for formulating the annual executive budget that the president submits to Congress. Thus, the OMB receives budget requests from the individual agencies and modifies these budgets in accordance with the administration's priorities.<sup>25</sup> Furthermore, under the president's direction, the OMB reviews the agencies' requests for substantive legislation, and it also reviews agency officials' proposed testimony before Congressional committees to ensure that the testimony be consistent with the Administration's position.<sup>26</sup> Thus, as an agent of the executive, the OMB serves to control the substance and process of FDA regulations.

In spite of the FDA's long history, the agency was not recognized in Congressional legislation until 1988.<sup>27</sup> Moreover, until 1988 the head of the agency – the Commissioner of Food and Drugs – was appointed by the Secretary of Health and Human Services. Since 1988 however, the FDA Commissioner must be appointed by the president with the advice and consent of the Senate.<sup>28</sup> Because of the public interest in food and drug regulations the FDA is a highly visible administrative agency. “The potential sensitivity of its decisions always have given the Commissioner a direct line to the Secretary of HHS and, sometimes the White House as well.”<sup>29</sup>

Formally placing the responsibility of appointing the Commissioner of the FDA in the hands of president rather than the Secretary makes explicit the importance of the job, exposes the inherently political nature

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<sup>25</sup>31 U.S.C.A. § 16.

<sup>26</sup>See Ernest Gellhorn & Ronald M. Levin, *Administrative Law and Process* at 62 (4th ed. 1997) (noting that this “clearance” procedure gives rise to intense negotiations between OMB staff and agency officials, and usually a compromise solution).

<sup>27</sup>See 102 Stat. 3048, 3120–22 (1988).

<sup>28</sup>See Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* at 15 (Foundation Press 1991) (discussing the changes made in the 1988 statute § 903(b)(1)).

<sup>29</sup>See Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* at 15 (Foundation Press 1991).

of the job, and suggests that indeed the executive is properly located in the executive branch of government. That is, the FDA does not have the same independence of presidential control that “independent agencies” enjoy. Indeed, the Commissioner can be removed from her position at the will of the president for any or no reason.<sup>30</sup> Supreme Court doctrine has construed the president has the power to remove an employee (as designated by Congress) as evidence of whether or not the executive has authority to control the policies of the agency in question.<sup>31</sup>

Interestingly, prior to the statutory grant that the Commissioner shall be appointed by the president – back when the Health and Human Services Secretary appointed this head – few administrative transitions resulted in a high level of resignations or reassignments among the agency’s middle and upper-level managers.<sup>32</sup> Thus, many observers have noted that unlike some of its peer agencies, the FDA has historically operated without substantial political influence.<sup>33</sup> Nonetheless, multiple political organizations pull the FDA in different directions (sometimes contradictory): Congress, the president, the consumer protection lobby, the pharmaceutical lobby, and the bureaucracy in general. To fully expose and compare the relative influence and strength of these political bodies is beyond the scope of this paper; suffice it to say however, that every decision the FDA faces will create political results—effecting given constituencies and harming others.

## D. The Public

One final check on agency discretion and policies lies outside of the constitution – the public. The American public keeps careful watch on the FDA’s activities, more than any other regulatory agency. And this public

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<sup>30</sup>See Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* at 15,16 (Foundation Press 1991).

<sup>31</sup>See *Morrison v. Olson*, 487 U.S. 654 (1988); *Humphrey’s Executor v. United States*, 295 U.S. 602 (1932).

<sup>32</sup>See Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* at 16 (Foundation Press 1991) (concluding that the Agency’s relatively stable workforce demonstrates the Agency’s independence or apolitical character).

<sup>33</sup>See Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law* at 16 (Foundation Press 1991).

interest in the laws concerning food and drugs makes sense, given that all humans need food and medicines, and all humans have preferences and opinions about which products are safe. Thus the public, through the media, internet services, and general fascination in the American Presidency, is able to monitor and influence the FDA's activities.

## II. Presidential Control of

### The Food and Drug Agency

#### A.

#### The Clinton FDA

The FDA's effort to regulate tobacco best captures the executive branch's successful power-grab of the FDA's priorities. By setting the agenda of the Food and Drug agency, Clinton advertised the political fabric of the agency, and he demonstrated that presidential supervision of administration can be exercised in a positive, pro-regulative way.<sup>34</sup>

On August 10, 1995, President Clinton held a press conference to announce publication of a proposed rule to reduce youth smoking. He explained his new policy as follows:

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<sup>34</sup>Cf. Cynthia R. Farina, *Undoing the New Deal Through the New Presidentialism*, 22 Harv. J. of L. & Pub. Pol. 227 (1995) (arguing that presidential control of administration is inherently anti-regulatory).

Today I am announcing broad executive action to protect the young people of the United States from the awful dangers of tobacco.... Today, and every day this year, 3,000 young people will begin to smoke; 1,000 of them ultimately will die of... diseases caused by smoking... Therefore, by executive authority, I will restrict sharply the advertising, promotion, distribution and marketing of cigarettes to teen-agers. I do this on the basis of the best available scientific evidence... Fourteen months of study by the Food and Drug Administration confirms what we all know: Cigarettes and smokeless tobacco are harmful, highly addictive and aggressively marketed to our young people... So, today I am authorizing the Food and Drug Administration to initiate a broad series of steps all designed to stop sales and marketing of cigarettes and smokeless tobacco to children.<sup>35</sup>

After this statement, Clinton enumerated six specific steps included in the rule to restrict marketing and advertising of tobacco to children, and he quipped that Congress could make the rule unnecessary by itself passing legislation containing these limits.<sup>36</sup> This announcement initiated the public comment period required for rulemaking under the APA.<sup>37</sup> The final rule deviated from the President's proposal; however, Clinton personally announced the issuance of the adopted rule in a Rose Garden ceremony.<sup>38</sup>

Arguably, President Clinton's public announcements, and claims that regulating tobacco was "his" proposal effectively co-opted the proposals of then FDA Commissioner, David Kessler. In fact, throughout much of 1995, the controversial Kessler attempted the unprecedented feat of seriously regulating tobacco products.<sup>39</sup> Suffering from the Democrat's loss of Congress and other early administration blunders, at first the Clinton staff found Kessler's proposal terrifying.<sup>40</sup> Gradually, however, Kessler was able to convince the Vice-President and prominent Clinton advisor, Dick Morris, and finally the President himself, to regulate

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<sup>36</sup>The President's News Conference, 31 Weekly Comp. Pres. Doc. 1415 (August 10, 1995) (heeding the President's call, some congressional members proposed said legislation, but it failed to pass).

<sup>37</sup>Following the comment period, the FDA with the participation of the White House, the OMB and the Justice Department staff, spent over nine months preparing the final rule. See Regulations Restricting Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule, 61 Fed. Reg. 44, 396 (1996); Annex: Nicotine in Cigarettes and Smokeless Tobacco Is A Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44, 619 (1996).

<sup>38</sup>Remarks Announcing the Final Rule to Protect Youth From Tobacco, 32 Weekly Comp. Pres. Doc. 1490 (August 23, 1996).

<sup>39</sup>See David Kessler, A Question of Intent: A Great American Battle with a Deadly Industry, (2001); see also John Carey, Bringing Big Tobacco Down to Size, Business Week 22 (Feb. 5, 2001).

<sup>40</sup>See John Carey, Bringing Big Tobacco Down to Size, Business Week 22 (Feb. 5, 2001).

the dangerous product responsible for over 400,000 deaths in America each year—tobacco.<sup>41</sup> According to Kessler, after reading the FDA’s gathered evidence, Clinton fumed, “I want to kill them. I just read all those documents, and I want to kill them.”<sup>42</sup> Thus, with the President on-board, Kessler now had the proper ammunition to launch his regulatory attack.

Complementing his unapologetic use of administrative agencies, President Clinton relied heavily on media coverage of him “unveiling” administrative action as a means to gain support for his policies.<sup>43</sup> “Clinton himself unveiled, regardless whether he initially had ordered in a formal way, quantities of administrative work product – reports, grants, guidance, rulings, regulations, even lawsuits.”<sup>44</sup> Political scientists note that the presidential use of the bully pulpit has increased steadily with time, with the most recent presidents going public the most frequently.<sup>45</sup> And President Clinton proved no exception. Clinton’s announcement of the tobacco rule, considered above, gave the public the impression that the FDA would indeed adopt a final rule based on “his” proposal.<sup>46</sup> According to at least one administrative law scholar, Clinton’s “unveiling” in August of 1995, effectively locked the FDA into acting in accord with his publicly noted rule.<sup>47</sup>

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<sup>41</sup>FDA v. Brown & Williamson Tobacco Corp. 120 S. Ct. 1291, at 1297 (2000).

<sup>42</sup>See David Kessler, A Question of Intent: A Great American Battle with a Deadly Industry, (2001); see also John Carey, Bringing Big Tobacco Down to Size, Business Week 22 (Feb. 5, 2001).

<sup>43</sup>See Elena Kagan, Presidential Administration, draft on file with the author at 40.

<sup>44</sup>See Elena Kagan, Presidential Administration, draft on file with the author at 40.

<sup>45</sup>See Samuel Kernell, Going Public: New Strategies of Presidential Leadership (3d ed. 1997); see also Jeffrey Tulis, The Rhetorical Presidency (1987); George C. Edwards III, The Public Presidency: The Presidency: The Pursuit of Popular Support (1983).

<sup>46</sup>The President’s News Conference, 31 Weekly Comp. Pres. Doc. 1415 (August 10, 1995).

<sup>47</sup>See Elena Kagan, Presidential Administration, draft on file with the author at 42.

## B.

### Benefits of Clinton's

#### New Style of Lawmaking

Some might find Clinton's commanding treatment of the FDA offensive to the notion of separation of powers. And others might object to Clinton's actions on the basis that disinterested experts and scientists – not political agents – should direct the policies established by agencies like the FDA. Yet under his watch President Clinton gave the FDA (and other agencies) a direct public accountability. I have discussed how Clinton managed the administration as a means to employ his domestic policies and circumvent the hostile Congress. This wise move came at the cost of *constant* public awareness of his “unveilings” and therefore created a built-in public check on his actions. Put simply, in order to get the credit for the actions taken, especially the achievements made by “his” agencies, Clinton also had to accept the blame and responsibility for “his” agencies.

Moreover, the Clinton management style, brought an increased energy to the agencies and their missions. President Clinton was able to energize the bureaucracy into action, thus making his Presidential administration more unified and effective in its execution of the laws.<sup>48</sup> Below I explore the two central defenses for recognizing the president's broad powers to control the administration: accountability and efficiency.

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<sup>48</sup>See Charles Fried, *Order and Law: Arguing the Reagan Revolution---A First Hand Account* (1991), at 153.

ii.

## The Accountable Administration

If Congress has delegated power to an executive official, I suggest this power simultaneously resides in the president himself. Accordingly, unless Congress clearly states otherwise, delegations of power to executive officials, such as the Commissioner of the FDA, should be construed to also delegate power to the president to guide his chosen Commissioner in rulemaking. This default rule renders actions taken by executive agencies and their policies transparent. Allowing the public to engage in the political process with an informed idea of the executive's policies establishes accountability over the bureaucracy.<sup>49</sup>

Thus, this default rule inevitably and publicly sheds light on the alternative “black box” of decision-making – the “Fourth Branch” otherwise known as the bureaucracy. The president, unlike bureaucratic officials, comes to office only after receiving the majority of Americans' support in a national election.<sup>50</sup> Because the culminating effects of the president's regulatory decisions will likely become apparent through the media and inherent public interest in the American presidency, the president is likely to refrain from taking any action that significantly risks losing public approval.<sup>51</sup>

Furthermore, the president's active oversight of administrative policies does not mean that the FDA will suddenly lose its scientific and technical expertise. Quite the contrary, by adopting (or co-opting) the admittedly controversial proposal to regulate tobacco, the Clinton administration was able to garner greater

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<sup>49</sup>See Charles Fried, *Order and Law: Arguing the Reagan Revolution---A First Hand Account* (1991), at 153. (noting that “[T]he lines of responsibility should be stark and clear, so that the exercise of power can be comprehensible, transparent to the gaze of the citizen subject to it.” *Id.* at 153.

<sup>50</sup>See Lawrence Lessig & Cass Sunstein, *The President and the Administration*, 94, at 98, 105-6 *Colum. L. Rev.* 1 (1994).

<sup>51</sup>The modern president's dedication to public opinion is well known with continual polling efforts and monitoring approval rates.

public support, ignite the many other skeptical workers under Kessler who would not have been “on board” otherwise. Since the president has self-interest in maintaining broad public support either for legacy or for re-election reasons, his proposals for agency action will often be the same as the administrative experts. Presidents have a strong incentive to “try to build an institutional capacity for effective governance.”<sup>52</sup> Thus, the default rule of assuming that the president be held accountable for administrative actions taken during his office, effectively forces “sunshine” on otherwise unlimited, and unaccountable power held by agencies. It further ensures that the president will not allow small interest groups to capture the policies or decisions made by an executive agency. Granting the president the ability to make laws through his administration, *as delegated by Congress*, best realizes the democratic spirit of our constitution.<sup>53</sup> Though some might fear a constitutional interpretation that places broad power in the executive, political accountability serves as the ultimate effective check on executive energy. Finally, this clear statement rule encourages Congress to deliberate with greater care about the degree of delegation desirable.<sup>54</sup> In fact, Congress might even refrain from delegating in difficult areas where it lacks a clear intent and legislative vision, thus this presumption might push Congress away from its tendency to duck hard questions inherent in administrative law.

## ii. Efficient Execution

Due to the way in which the presidency evolved in the convention, the Constitution did not adhere to the

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<sup>52</sup>See Terry M. Moe & Scott A. Wilson, *Presidents and the Politics of Structure*, 57 *L. & Contemp. Probs.* 1, at 11.

<sup>53</sup>See Martin Flaherty, *The Most Dangerous Branch*, 105 *Yale L.J.* 1725 (1996).

<sup>54</sup>See *Ethyl Corp. v. EPA*, 541 F.2d 1, 68 (D.C. Cir. 1976) (expressing a distrust of broad congressional delegations in part because congress appears to be punting the hard questions); but see *Hampton v. Mow Sun Wong*, 426 U.S. 88, at 113 n.5 (1976) (suggesting that presidential action enables accountability and that this should ease concerns about broad grants of discretion. )



Montesquieuan doctrine of the separation of powers. Instead the convention delegates created a government with intermingling powers in spite of separate and independent personnel and branches.<sup>55</sup> Constitutionally equipped with the veto power, the authority to recommend legislation, and the vice-president's presiding over the Senate, the executive branch shares lawmaking power with Congress. Moreover, the language of Article II., "[T]he executive power shall be vested in the President of the United States of America," differs sharply from that of Article I.: "All legislative Powers *herein granted* shall be vested in a Congress of the United States." (emphasis added). The broad vesting in Article II., combined with the specification of certain presidential functions and duties presupposes that "executive power" had an agreed upon meaning.<sup>56</sup> Because the delegates' knowledge of the subject from history, political philosophy, and experience, it seems evident that some of them, at least, thought of executive power as contingent and discretionary.<sup>57</sup> The vesting clause in Article II. compared with that of Article I. further bolsters the theory that the constitutional delegates imagined an executive power as a broad authority to act unilaterally in given circumstances, this power extends beyond the ordinary rules prescribed by the Constitution.<sup>58</sup>

By far the most expressive Federalist analysis (and defense) of the executive branch was made by Alexander Hamilton in *Federalist Essays* 67 through 77.<sup>59</sup> Most importantly, Hamilton provided a clear understanding of the bounds and necessity of executive power. Energy. "Energy in the executive," he wrote, "is a leading character in the definition of good government." For Hamilton, this quality, was animated through "decision, activity, secrecy, and dispatch" identified as "vigor and expedition."<sup>60</sup> And this executive energy was essential for national defense, a "steady administration of the laws," protection of property against unlawful combinations, and "security of liberty against the enterprises and assaults of ambition, of faction and of

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<sup>55</sup>See Forest McDonald, *The American Presidency*, 179.

<sup>56</sup>See Forest McDonald, *The American Presidency*, 181.

<sup>57</sup>See Forest McDonald, *The American Presidency*, 181.

<sup>58</sup>For sources illuminating each clause of each article of the Constitution, see *The Founders' Constitution*, ed. Philip B. Kurland and Ralph Lerner, 5 vols. (Chicago, 1987).

<sup>59</sup>The *Federalist* No. 70 (A. Hamilton) (I. Kramnick ed. 1987), at 402 (arguing that "'energy in the executive is a leading character in the definition of good government'").

<sup>60</sup>The *Federalist* No. 70 (A. Hamilton) (I. Kramnick ed. 1987), at 402.

anarchy.”<sup>61</sup>

President Clinton’s style of presidential lawmaking mirrors Hamilton’s energetic descriptions on many levels. For example, his method of directing administration was extremely effective in setting new agency priorities and creating a broad domestic policy agenda. And no matter one’s opinion on the substance of his domestic policies, President Clinton was unequivocally successful in “waking up” the career bureaucrats, as well as the policies they oversee.

In conclusion, presidential lawmaking in the model of Clinton’s administration invites accountability and efficiency while maintaining the multiple checks on presidential power. Furthermore, compared to the alternative, that agencies not expected to answer to the general public are given wide discretion to make critical public policy decisions, I think the expansive and energetic Presidency is not a threat to democracy. As noted above, the modern president directly depends on public approval, and therefore, a president will only take regulatory action that is supported by the majority of the nation. Most importantly, the very vehicle for President Clinton’s style of controlling administrative activity relies on explicit public announcements, ceremonies and “unveilings.” Thus, at all times, the Clinton model of dictating administrative activity gave detailed notice to Congress and the public what his agency officials hoped to accomplish through the substance of their rules.

### **III. Judicial Review of Executive Power**

#### **A. FDA v. Brown & Williamson:**

##### **The End of The Executive FDA?**

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<sup>61</sup>The Federalist No. 70 (A. Hamilton) (I. Kramnick ed. 1987), at 402.

Whether or not President's Clinton innovative and energetic use of the administrative state violated the delegation doctrine or Congressional intent is a matter of construction. The case, FDA v. Brown & Williamson Tobacco Corp.,<sup>62</sup> gave the Supreme Court an opportunity to opine on the constitutionality of the FDA regulating tobacco. Though the court chose to focus on whether the agency itself was authorized by Congress to regulate tobacco, the Court also implicitly reviewed and rejected the use of executive power, or at least the use of its delegated authority to impose tobacco regulations through the FDA. In fact, the Court stated that its decision was constitutionally required per doctrine of separation of powers, "regardless of how likely the public is to hold the executive Branch politically accountable."<sup>63</sup>

As discussed above, following President Clinton's announcement in 1995 that the reduction of tobacco use in general, and youth smoking in particular, would become a priority on his Administration's regulatory agenda, the FDA issued a proposed rule.<sup>64</sup> The rule asserted FDA jurisdiction under 21 U.S.C. §353(g)(1), and labeled nicotine a "drug" and cigarettes a "drug delivery device" under the FDCA. After issuing the final regulation in August 28, 1996,<sup>65</sup> a group of tobacco manufacturers brought suit against the FDA challenging the validity of the rules.<sup>66</sup> The plaintiff companies moved for summary judgement on the grounds that the FDA did not have the necessary statutory authority to regulate tobacco, and these regulations violated the First Amendment.<sup>67</sup> Agreeing that the FDA could regulate marketing, accessibility, and labeling, the District Court granted the motion in part, but also denied it in part, finding that the advertising and promotion

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<sup>62</sup>120 S. Ct. 1291 (2000) (holding that Congress's previous actions regarding the regulation of tobacco since 1965 had precluded the FDA regulation of tobacco while acknowledging the agency's position of jurisdiction rested on reasonable interpretation of the Federal Food Drug and Cosmetic Act (FFDCA)).

<sup>63</sup>FDA v. Brown & Williamson Tobacco Corp. 120 S. Ct. 1291 (2000).

<sup>64</sup>See Excerpts from Clinton News Conference on His Tobacco Order, N.Y. Times, Aug. 11, 1995, at A18. In response to the FDA's proposed rule the agency received a record 700,000 public comments. See also Brown & Williamson, 120 S. Ct. at 1297.

<sup>65</sup>See Brown & Williamson, 120 S. Ct. at 1297.

<sup>66</sup>Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1379 (M.D.N.C. 1997).

<sup>67</sup>See Brown & Williamson, 120 S. Ct. at 1299.

regulations exceeded the scope of 21 U.S.C. § 360(j). Thus, applying the Chevron test,<sup>68</sup> the district court found that Congress had expressed no clear intent to withhold regulatory authority from the FDA and that the FDA permissibly construed the FDCA when it asserted jurisdiction under 21 U.S.C. § 360j(e).

The Court of Appeals for the Fourth Circuit affirmed in part and reversed in part, holding that Congress never intended to grant the FDA jurisdiction to regulate tobacco products.<sup>69</sup> The appellate court focused on an anomaly: the products would at the same time have to be shown “safe” enough to be placed in the marketplace in order to be regulated by the FDCA, yet “dangerous” enough to be governed by the FDA regulations.<sup>70</sup> The Supreme Court affirmed.

According to the five Justice majority, the FDCA did not empower the FDA to regulate tobacco.<sup>71</sup> In reaching the conclusion that the FDA lacked the authority to regulate cigarettes and other tobacco products, Justice O’Connor analyzed numerous statutory enactments regarding tobacco that post-date the primary enabling act at issue, examined numerous forms of legislative history, and gave reduced attention to the key statute’s text.<sup>72</sup> The Court found that Congress had directly spoken on this issue, thereby precluding the FDA’s jurisdiction over tobacco at the threshold.

The core objective pervading the entire FDCA was product safety, and since its creation the FDA has sought to prevent the marketing of products when the potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.<sup>73</sup> As noted by the Fourth Circuit, the problem here was that the FDA had exhaustively denoted tobacco products as unsafe and “dangerous” causing death and great

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<sup>68</sup>Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). The familiar Chevron test subjects agency regulations to a two-tiered analysis, first asking whether Congress had a clear intent when it enacted the organic or enabling statute. Second, if Congress has not clearly addressed the question at issue and the statute is silent or ambiguous, then the court will defer to the agency’s interpretation of the statute, provided that the interpretation is reasonable.

<sup>69</sup>Brown & Williamson v. FDA, 153 F.3d 155, 175 (4<sup>th</sup> Cir. 1998).

<sup>70</sup>Brown & Williamson v. FDA, 153 F.3d 155, 175 (4<sup>th</sup> Cir. 1998).

<sup>71</sup>FDA v. Brown & Williamson Tobacco Corp. 120 S. Ct. 1291, at 1316 (2000).

<sup>72</sup>FDA v. Brown & Williamson Tobacco Corp. 120 S. Ct. 1291 (2000).

<sup>73</sup>United States v. Rutherford, 442 U.S. 544, 566 (1979).

pain in its rulemaking.<sup>74</sup> Therefore, the majority concluded that the FDA’s attempts to regulate tobacco would effectively “burn the candle at both ends.” Concluding that a ban on tobacco products would plainly contradict Congressional policy, the Court held that there was no room for tobacco products within the FDCA’s regulatory scheme.

Writing for the four dissenters, Justices Stevens, Souter, Ginsburg, and Breyer – Justice Breyer offered three attacks on the majority’s opinion. First, Justice Breyer posited a reading of the statute under which the FDA could regulate tobacco without banning it, thereby avoiding the majority’s conundrum that only permissible regulatory action was in fact impermissible.<sup>75</sup> Second, Breyer voiced his doubts about relying on later Congressional inaction or enactments as a means to interpret existing statutes. Underscoring that Congress had never directly come to terms with the question of FDA authority, the dissent noted that after the FDA claimed jurisdiction Congress considered *yet failed to enact* legislation to deny it such authority. The legislative record, therefore, was “critically ambivalent.”<sup>76</sup> Finally, he emphasized that changes in available information—as to the activities of the tobacco companies and as to scientific understanding—along with a policy change accompanying a change of presidential administration, amply justified the FDA’s shift in position.<sup>77</sup>

### **B. Resuscitating Executive Lawmaking: The Twilight Zone**

The question whether the president has the constitutional power to make law persists as a constitutional mystery. The formal concept of the law-enforcement executive was most famously asserted by Justice Black

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<sup>74</sup>61 Fed. Reg. 44412.

<sup>75</sup>See *FDA v. Brown & Williamson Tobacco Corp.* 120 S. Ct. 1291, 1322-26 (2000).

<sup>76</sup>*FDA v. Brown & Williamson Tobacco Corp.* 120 S. Ct. 1291, 1326 (2000).

<sup>77</sup>*FDA v. Brown & Williamson Tobacco Corp.* 120 S. Ct. 1291, 1328-30 (2000).

in Youngstown Sheet & Tube Co. v. Sawyer.<sup>78</sup> Noting that the constitution does not grant the president any broad powers of lawmaking, Justice Black formulaically stated that “[the] President’s power, if any, to issue the order must stem either from an act of Congress or from the Constitution itself.”<sup>79</sup>

Justice Jackson’s concurring opinion, in Youngstown however, posited a more forgiving and more fluid conception of the executive power to make laws. And in fact it is Justice Jackson’s interpretation of the executive that has stood the test of time.<sup>80</sup> Noting three possible categorical sources of executive power, Justice Jackson suggested that the president’s power is at its maximum when the president acts pursuant to express or implied authorization of Congress.<sup>81</sup> Accordingly, when the president acts in the absence of either a Congressional grant or denial of authority, “there is a zone of twilight in which he and Congress may have concurrent authority, or in which its distribution is uncertain.”<sup>82</sup> Finally, if the president acts in contradiction to the express or implied will of Congress his power is at its “lowest ebb” and thus, actions taken in this third category could not be constitutionally justified.<sup>83</sup>

Thus, adopting the twilight zone as a constitutional possibility, and a useful lens to determine the constitutionality of executive action, President Truman’s seizure of the steel mills remains unconstitutional. Importantly, however, in the twilight zone the seizure was unconstitutional not because, as Justice Black believed, the executive always lacks such powers unless expressly granted by Congressional statute or the

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<sup>78</sup>343 U.S. 549 (1952).

<sup>79</sup>Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 549 (1952) (Black, J.).

<sup>80</sup>See for example, Dames & Moore v. Regan, Secretary of Treasury, 453 U.S. 654 (1981) (Rehnquist, J.) (noting that the Jackson typology is the most helpful expression of constitutional bounds of executive power; however, even Jackson’s description of power might be too rigid a depiction of the awesome powers of an Executive).

<sup>81</sup>See Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 549 (1952) (Jackson, J., concurring).

<sup>82</sup>See Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 549 (1952) (Jackson, J., concurring).

<sup>83</sup>See Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 549 (1952) (Jackson, J., concurring) (noting that President Truman’s seizure of the steel mills fell within this third category since congress had previously explicitly rejected plant seizure as a means of handling labor disputes.)

enumerated power in the constitution. But rather, President Truman's seizure of the steel mills was unconstitutional *precisely because* Congress had already spoken on the specific subject, impliedly reserving this power for itself, and effectively pre-empting the president's actions.<sup>84</sup> Likewise, the Clinton White House thrived in the twilight zone, using directive authority to achieve and maintain an efficient administration in areas where Congressional intent is silent and the Congress acquiesced to the president's actions.

When Congress designated an agency official as "a lawmaker," the agency official was an agent of the executive branch and therefore an agent of Clinton's policies.<sup>85</sup> Significantly, President Clinton's public announcements and policy initiatives directed agency officials to propose rules; he did not direct the promulgation of the rules.<sup>86</sup> This distinction is important because such interpretative statements are not legally binding,<sup>87</sup> and as such President Clinton's exercise of power was unequivocally within his Article II powers.

C.

### Changed Circumstances

The FDA's 1996 assertion of authority to regulate tobacco was based on its construction of the Food, Drug

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<sup>84</sup>See Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 549 (1952) (J. Jackson and J. Frankfurter concurring).

<sup>85</sup>See Elena Kagan, Presidential Administration, draft on file with the author at 54-57 (acknowledging that while cases such as Bowsher v. Synar, 478 U.S. 714 (1986) and Morrison v. Olson, 487 U.S. 654 (1988) suggest that Congress may limit the President's capacity to direct administrative officials in the exercise of their substantive direction, these cases do not recognize congressional power to prohibit certain forms of presidential involvement in administrative action).

<sup>86</sup>See Elena Kagan, Presidential Administration, draft on file with the author at 58-9 (noting that in essence Clinton technically exercised a "procedural power" authorized by Article II and shielded from the congressional power acknowledged in the removal cases).

<sup>87</sup>See, e.g., American Mining Congress v. Mine Safety & Health Admin., 995 F.2d 1106 (D.C. Cir. 1993); Pacific Gas & Elec. Co. v. FPC, 506 F. 2d 33 (D.C. Cir. 1974).

and Cosmetic Act (“FDCA”), as enacted in 1938.<sup>88</sup> The FDA relied heavily on changed circumstances for asserting jurisdiction now over tobacco; namely, its discovery that tobacco companies were knowingly using cigarettes as a means to deliver “a day’s supply of nicotine.”<sup>89</sup> Following its enactment of the FDCA Congress enacted numerous statutes that regulated various aspects of the tobacco industry and tobacco products, all the while, the FDA declined to regulate tobacco products. Drawing upon the FDCA text, a myriad of legislative materials, and a limited parsing of interrelated statutory texts, the majority held that Congress did not grant the FDA authority to regulate tobacco products.<sup>90</sup> The Court further shared what appears to be a new context for application of the clear statement doctrine: “we are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion.”<sup>91</sup> Therefore the court concluded that the 1938 law, plus seven subsequent tobacco regulations revealed that “Congress has created a distinct regulatory scheme to address the problem

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<sup>88</sup>Pub. L. No. 52-675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-95 (1994)). The FDA’s assertion of regulatory authority is found at 61 Fed. Reg. 44619-5318 (1996). For critiques of the 1996 FDA assertion of authority to regulate tobacco products, see Richard A. Merrill, *The FDA May Not Regulate Tobacco Products as ‘Drugs’ or as ‘Medical Devices,’* 47 Duke L.J. 1071, 1093 (1998) (featuring arguments by a law professor who also served as tobacco counsel and concluding that “Congress did not give the FDA jurisdiction over tobacco products.... And on the several occasions when Congress considered its options, it made conscious decisions to deal with the subject in other ways, through different instruments’”), and Lars Noah & Barbara A. Noah, *Nicotine Withdrawal: Assessing the FDA’s Effort to Regulate Tobacco Products*, 48 Ala. L. Rev. 1, 7 (1996) (“[T]he FDA regulations exceed the Agency’s delegated authority.’”). But see Cass R. Sunstein, *Is Tobacco a Drug? Administrative Agencies as Common Law Courts*, 47 Duke L.J. 1013, 1019 (1998) (“[R]eviewing courts should uphold the regulation, principally by reference to the appropriate role of contemporary administrative agencies.’”).

<sup>89</sup>*FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291, 1321-22 (2000) (Breyer, J., dissenting) (citations omitted); see also *id.* at 1320-22 (quoting various scientists’ statements regarding nicotine’s effects and the use of cigarettes as a means to deliver nicotine and satisfy consumers’ desire for “drug action”).

<sup>90</sup>The majority’s logic was that the FDA lacks its asserted power because if tobacco could be regulated as a “drug,” “device,” or “combination product,” then the FDCA would require the FDA to ban tobacco products, or at least cigarettes. *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291, 1301-3 (2000). Thus, the majority concluded that post-enactment history, including both subsequent laws and a wide variety of legislative and regulatory statements of individuals, revealed a legislative assumption that tobacco products would continue to be sold. *Id.* at 1303-6. Importantly, the majority nowhere denied that the FDCA’s text by its terms conferred on the FDA power to act as it did (although without mentioning tobacco in the text). Therefore, the dissent argued that if the majority was correct about FDA’s jurisdiction, then the Court should merely have faulted the FDA’s chosen limited remedy and instead have required banning tobacco products entirely. *Id.* at 1322-23 (Breyer, J., dissenting). The dissent further argued, that the FDA had remedial discretion and a broader set of regulatory options than concluded by the majority. *Id.* at 1322-26 (Breyer, J., dissenting).

<sup>91</sup>*FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291, at 1315 (2000).



of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA.”<sup>92</sup>

Importantly, the majority’s conclusion that past Congressional regulatory actions should be interpreted as conclusive proof that any and all regulation of tobacco resided within the sole control of Congress, overlooked the FDA’s assertion of changed circumstances. That is, in 1995, new evidence of internal industry acknowledgements of nicotine’s effects and discussions of cigarettes as a means to deliver nicotine constituted new information that, in its view, sufficed to give the FDA the factual basis to assert jurisdiction that it had previously lacked.<sup>93</sup> For example, in the early 1990s the FDA discovered evidence concerning the number of deaths caused by tobacco, ways in which tobacco affects the structure or function of the body, and when knowledge of these effects was gained.<sup>94</sup> Given that these new revelations changed the circumstances of FDA regulatory actions, the dissent vigorously argued that the FDA should be found to have the discretion in exercising its remedial power, and that if the majority’s statutory reading was correct, then the FDA erred not in asserting jurisdiction, but rather in failing to ban cigarettes all together.<sup>95</sup>

The FDA’s new revelations gathered by its experts suggest that the prior Congressional regulations should not be read as pre-empting FDA action but rather suggest a new realm of twilight. Precisely what Justice Jackson envisioned when describing the dynamics of power to make laws between the Congressional and executive branches. Jackson reasoned, “Congressional inertia, indifference or quiescence may sometimes,

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<sup>92</sup>FDA v. Brown & Williamson Tobacco Corp. 120 S. Ct. 1291, at 1307 (2000). For a critique of the Court’s analysis of congressional intent as fixed and ‘knowable’ see William W. Buzbee, *The One Congress Fiction in Statutory Interpretation*, 149 Penn. L. Rev. 171 (2000). He writes:

The Court’s heavy emphasis on the FDA’s long-time declination to regulate tobacco products is of questionable logic. The majority read FDA statements declining to regulate tobacco as reflecting an FDA belief that it could never assert such authority, but as the dissent argued, the FDA’s official regulatory acts (versus scattered statements by individual FDA regulators) revealed an agency that for years either lacked the political will or factual basis to regulate tobacco products.

Id. at 197.

<sup>93</sup>For a review of this new evidence see Cass R. Sunstein, *Is Tobacco A Drug? Administrative Agencies as Common Law Courts*, 47 Duke L.J. 1013, (1998).

<sup>94</sup>See FDA v. Brown & Williamson, 120 S.Ct. at 1321-22 (Breyer, J., dissenting); see also Cass R. Sunstein, *Is Tobacco A Drug? Administrative Agencies as Common Law Courts*, 47 Duke L.J. 1013, (1998).

<sup>95</sup>See FDA v. Brown & Williamson, 120 S.Ct. at 1322-23 (Breyer, J., dissenting).

at least as a practical matter, enable, if not invite, measures on independent presidential responsibility.”<sup>96</sup> Arguably, the Congress suffers collective action problems in the area of tobacco regulation, given that tobacco corporations are well organized, strong lobbyists. Yet reigning in the corporations, which produce a drug responsible for killing 400,000 Americans every year is supported by the majority of the American public.<sup>97</sup> Therefore, perhaps the unitary figure of the president is best suited to risk (and exploit) his national political role to perform this task. In reference to the twilight zone of executive power, Jackson rooted it in a contextual and contingent source, he wrote: “In this area, any actual test of power is likely to depend on the imperatives of events and contemporary imponderables rather than on abstract theories of law.”<sup>98</sup> This rich fact based inquiry does not have hard and fast lines. And as such I would posit the change of circumstances in the FDA’s discovery of the dangers of tobacco in combination with its statutory authority to regulate in the area and the president’s vested authority in Article II. to see that the laws are faithfully executed surely provide a strong defense for Clinton’s attempt to regulate tobacco.

## V. Conclusion

In Youngstown, Justice Jackson noted that considerations of whether a president has acted within the powers vested in him by the constitution, depend upon context and the facts of the situation.<sup>99</sup> Therefore, the Supreme Court’s decision in Brown & Williamson<sup>100</sup> should not be read as broad condemnation of executive control of administrative policies. Because the case involved the controversial issue of regulating tobacco,

<sup>96</sup>See Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 549 (1952) (Jackson, J., concurring).

<sup>97</sup>See FDA v. Brown & Williamson, 120 S.Ct. at 1297.

<sup>98</sup>Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 549 (1952) (Jackson, J., concurring).

<sup>99</sup>See Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 549 (1952) (Jackson, J., concurring).

<sup>100</sup>See FDA v. Brown & Williamson Tobacco Corp. 120 S. Ct. 1291 (2000).

a staple of many states' economies with a history of specific regulations, the case should be limited to its facts. As I have argued above, allowing the president to control his administration is a positive good that serves his self interests of re-election and legacy, but much more importantly, a unified executive serves the general public through efficient and transparent executive action.

Following the Supreme Court's rejection of the FDA's regulatory authority over tobacco, President Clinton urged the Republican-led Congress to pass legislation that would grant the FDA the needed authority.<sup>101</sup> "If we are to protect our children from the harms of tobacco," President Clinton charged, then "Congress must now enact provisions of the FDA rule."<sup>102</sup> Senator John McCain sponsored a law that would delegate authority to the FDA to regulate tobacco in 1998. However, McCain failed to break a Republican-led filibuster, and remains skeptical. He admitted, "having encountered the influence of the special interests, especially the tobacco companies... in a \$50 million campaign, I'm not optimistic that we will be able to pass a new FDA bill."<sup>103</sup>

To what extent if any the FDA's priorities will change under the Bush Administration remains to be seen. However, there are a few hints already. Perhaps one of the more interesting moments of the presidential debates in the fall of 2000 occurred when then-candidate George W. Bush was asked what he would do if elected about the FDA's approval of the abortion pill RU-486. Pro-life and Pro-choice viewers alike were on the edge of their seats, ready to hear Bush either condemn the pill or curry favor with the pro-choice soccer

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<sup>101</sup>See Major Garrett, Clinton Calls on Congress to Grant FDA authority to regulate Tobacco, <allpoliticscnn.com> (posted 6:00pm 3/21/2000).

<sup>102</sup>See Major Garrett, Clinton Calls on Congress to Grant FDA authority to regulate Tobacco, <allpolitics.com> (posted 6:00pm 3/21/2000).

<sup>103</sup>See Major Garrett, Clinton Calls on Congress to Grant FDA authority to regulate Tobacco, <allpoliticscnn.com> (posted 6:00pm 3/21/2000).

moms. But with the exception of administrative law geeks, the audience was disappointed and perhaps confused with Bush's honest answer. He quipped that as president he would not be able to control the approval of the drug. In fact, the only way to revoke a drug approval is if some new information is discovered demonstrating that the drug is unsafe.<sup>104</sup>

Nonetheless, in his confirmation hearing the Bush nominee for Secretary of Health and Human Services (HHS), Tommy Thompson, a major antiabortion activist was asked whether he might attempt to revoke the approval of RU-486.<sup>105</sup> Certainly as secretary of HHS Thompson will oversee the FDA and therefore he will have the power to direct the FDA to conduct a safety review. Indeed, during his confirmation hearings Thompson affirmed that he "intended to look into the safety of mifepristone."<sup>106</sup> Thus, no matter the constitutional restrictions on the executive's power over his administrative agencies, the public (and the Senate) are mindful of the political questions under the FDA's consideration and control.

In addition, Andrew Card the White House Chief of Staff has noted that the Bush administration is reviewing the FDA's approval of the drug.<sup>107</sup> And a recent CNN story noted that the major pharmaceutical and biotechnology companies are urging the Bush administration not to appoint an anti-abortion candidate to serve as commissioner of the FDA.<sup>108</sup> Quite naturally, they fear that other medications may become vulnerable to politics if FDA's recent approval of the abortion RU-486 is overturned.<sup>109</sup> Other recent developments reveal just how political the decisions of the FDA can be: two Republicans introduced legislation on February 6, 2001 that would tighten controls over who can provide patients with the abortion pill.<sup>110</sup> In

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<sup>104</sup>See Thompson Says He'll Review RU-486, Wall Street Journal (Jan. 23, 2001).

<sup>105</sup>See Thompson Says He'll Review RU-486, Wall Street Journal (Jan. 23, 2001).

<sup>106</sup>See Politics & Policy FDA: RU-486, Blood Filtering, Claritin, Tobacco, in American Political Network, (Jan. 29, 2001).

<sup>107</sup>See Politics & Policy FDA: RU-486, Blood Filtering, Claritin, Tobacco, in American Political Network, (Jan. 29, 2001).

<sup>108</sup>Cabinet in Place, On to Lower Layers of Government, <Cnn.com/20001/ALLPOLITICS/stories/02/05/thenextlayer.ap/index.html> (visited Feb. 5, 2001).

<sup>109</sup>Cabinet in Place, On to Lower Layers of Government, <Cnn.com/20001/ALLPOLITICS/stories/02/05/thenextlayer.ap/index.html> (visited Feb. 5, 2001) (noting that drug manufacturers are promoting a number of well-known scientist-physicians who have not taken a public position on abortion).

<sup>110</sup>Senator Tim Hutchinson and Representative David Vitter introduced the legislation. See Rhonda Rowland, GOP Lawmakers Seek to Restrict Who Can Dispense Abortion Pill, <Cnn.com/2001/health/02/06/abortion.pill/index.html>

spite of these Congressional threats, the FDA maintains that the drug is safe, and if the sort of restrictions proposed by the legislators were necessary then the agency would have promulgated them in the first place. A spokeswoman for the FDA said that it is unprecedented for the FDA to overrule a FDA decision.<sup>111</sup> Thus, the press, the Congress and the president's administration are all involved in creating and exposing the political style of food and drug regulation.

Interestingly, tobacco industry supporters are breathing easier since the election of President Bush.<sup>112</sup> Though the Clinton administration filed suit in 1999 to try to recover the federal government's cost of treating sick smokers and to collect damages for profits allegedly earned through fraudulent practices, many on Capitol Hill believe the case will fizzle under Bush.<sup>113</sup> Moreover, members of Congress have thrown their hats into the debate, "I don't think we're going to see a continuation of the suit from the Justice Department," Republican Ernie Fletcher said. Fletcher represents a tobacco-growing district in Kentucky and obviously opposes the lawsuit. On the other side of the aisle, Democrat Bob Graham from Florida has been quoted on his concern that "the new administration may abandon that suit or downgrade its commitment to it. What was said during the campaign didn't give you a lot of hope."<sup>114</sup> Therefore, even if the FDA is more scientific than political, neither legislators nor the press portray it as such.

Moreover, the future of the former Clinton administration's lawsuit depends on the Justice Department as much as the FDA. Health groups have noted that Attorney General John Ashcroft worries them, given that

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(visited 2/14/01).

<sup>111</sup>Senator Tim Hutchinson and Representative David Vitter introduced the legislation. See Rhonda Rowland, *GOP Lawmakers Seek to Restrict Who Can Dispense Abortion Pill*, <Cnn.com/2001/health/02/06/abortion.pill/index.html> (visited 2/14/01).

<sup>112</sup>For example, Bush received about \$90,000 from tobacco companies during the campaign, compared with \$8,000 that went to Al Gore, according to the Center for Responsive Politics, a nonpartisan watchdog group. Moreover 83% of the \$8 million total dollars given to candidates in the last election cycle (2000), went to Republican candidates.

<sup>113</sup>Nancy Zuckerbrod, *Bush May Block Anti-Smoking Efforts*, AP Online (Feb. 6, 2001).

<sup>114</sup>Nancy Zuckerbrod, *Bush May Block Anti-Smoking Efforts*, AP Online (Feb. 6, 2001).

as a Missouri senator Ashcroft killed legislation in 1998 that would have raised cigarette taxes and clarified the FDA's authority to regulate nicotine.<sup>115</sup> And as for the Bush administration's FDA policy on tobacco regulation, Jim Bunning, a Kentucky Senator predicts, "The FDA is going to keep its snoot off the farm and out of tobacco."<sup>116</sup> It comes as little surprise that this is the same Senator Bunning who authored the proposal to strip the FDA of all funding because of its efforts to regulate tobacco.

The administration has maintained a cautious and vague stance on its tobacco policy. For example, while campaigning, Bush said he would support the FDA through "the authority necessary to discourage teen-age smoking,"<sup>117</sup> however, Bush did not provide any details for what his administration will to enforce this discouragement. This last point is important, because when the FDA takes action (even mild action) the American public respects the FDA stamp of safety and assumes that the drug is indeed legitimately sold. Former FDA Commissioner, David Kessler agrees that no regulatory authority is better than weak oversight. "Regulation could have the negative effect of giving it (tobacco) the stamp of government acceptability."<sup>118</sup> No matter his party, the modern president must meet the infinite public expectations that he will accomplish tangible tasks.<sup>119</sup> Justice Jackson captured the nuances and complexity of the American presidency years ago. He wrote:

In drama, magnitude and finality his decisions so far overshadow any others that almost alone he fills the public eye and ear. No other personality in public life can begin to compete with him in access to the public mind through modern methods of communications.

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<sup>115</sup>Nancy Zuckerbrod, Bush May Block Anti-Smoking Efforts, AP Online (Feb. 6, 2001).

<sup>116</sup>Nancy Zuckerbrod, Bush May Block Anti-Smoking Efforts, AP Online (Feb. 6, 2001).

<sup>117</sup>Nancy Zuckerbrod, Bush May Block Anti-Smoking Efforts, AP Online (Feb. 6, 2001).

<sup>118</sup>Nancy Zuckerbrod, Bush May Block Anti-Smoking Efforts, AP Online (Feb. 6, 2001).

<sup>119</sup>See for example, Bruce Buchanan, *The Citizen's Presidency: Standards of Choices and Judgement* (1987); Bert A. Rockman, *The Leadership Question: The President and the American System* (1984); Theodore J. Lowi, *The End of Liberalism: The Second Republic of the United States* (2<sup>nd</sup> ed. 1979), at 302.

Justice Jackson.<sup>120</sup> Furthermore, the demands of twenty-four hour media coverage simultaneously impose a check on presidential power while giving the president a critical tool for controlling public perception and his own administration. It is unfair and unwise to expect so much from a single person without giving him or her the energy, as Alexander Hamilton called it, to effectively “take care that the laws be faithfully executed.”

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<sup>120</sup>Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579 (1952) (Jackson, J., concurring).