



# Ending the Charade: Revisiting the Ban on Political Influence in FDA Decision Making in Light of Tummino v. Torti

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Ending the Charade: Revisiting the Ban on Political Influence in FDA Decision Making  
in Light of *Tummino v. Torti*

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Abstract:

The wide scope of discovery and judicial review in *Tummino v. Torti* is directly traced to the prohibition against political motivations in agency decision-making. The FDA in evaluating the OTC switch application for Plan B was most likely influenced by the Bush White House political agenda. As the case law stands, *Tummino* was decided correctly because political influence in agency decision-making is seen as bad faith and not as sufficient rationale for decisions. However, within in the past thirty years Presidents have become successfully increasingly aggressive about use administrative agencies such as the FDA to accomplish their political agendas. As this trend seems unlikely to dissipate any time soon, a better judicial approach would be to allow agencies to admit to political influences in their decision-making. This would then allow judges to determine if the political influence was permissible or if it prevented the agency from accomplishing its mandate. Furthermore, it would reduce temptation to manipulate the scientific record to support agency conclusions when those conclusions were actually based on policy judgments.

In the recent decision in *Tummino v. Torti*<sup>1</sup> the District Judge, Judge Korman, chastised the Food and Drug Administrative (FDA) for bowing to political pressures while evaluating an over the counter switch for an emergency contraception known as Plan B. The decision was notable because, unlike most cases of judicial review of administrative agency decisions, the scope of discovery and the opinion of the court were not limited to the administrative record generated by the FDA. This was largely a result of the perceived ‘bad faith’ of the FDA in its treatment of the Plan B application, which itself was based on the political influence of the Bush White House on the FDA.

However, the *Tummino* case is an opportunity to reconsider the role of the executive branch on administrative agencies such as the FDA. While the FDA is rightfully seen as a scientific nonpartisan agency, in recent years its agenda has been increasingly influenced by various Presidential administrations<sup>2</sup>. Indeed, the FDA is hardly unique in this trend of increasing executive capture of administrative agencies. While the Bush White House may have unduly pressured the FDA to avoid approving an over the counter switch for Plan B, its involvement is hardly unusual in the modern history of the FDA. When considered against the backdrop of the current reality of the administrative state, the decision-making in *Tummino* does not seem faulty.

Contrary the trend of increasing presidential influence, the prevailing policy of the courts is to uniformly reject all obvious political influence as arbitrary and capricious. Under this current policy, political motivations are treated as corrupting and suspect

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<sup>1</sup> 603 F.Supp.2d 519 (E.D.N.Y. 2009).

<sup>2</sup> See James T. O’Reilly, *Losing Deference in the FDA’s Second Century: Judicial Review, Politics and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939 (2008).

while scientific rationales are legitimate. Based on current law, *Tummino* was correctly decided on the grounds that the FDA based its decision on motivations that were arbitrary and capricious.

This paper proposes that the reality of the administrative state and the policies of administrative law be harmonized. There ought to be judicially allowed room for agencies to admit that their decisions were partially motivated by the agenda of the President at the time. This would allow agencies such as the FDA to ‘drop the charade’ maintaining that Presidents such as Reagan, Clinton, Bush and now Obama do not influence the agencies’ agenda, priorities and decisions. In turn, that would allow courts to better oversee the increasing political influence of the White House and to check it when inappropriate. In addition, this new policy would prevent agencies such as the FDA from attempted to use scientific evidence and uncertainty to justify what are in reality political decisions. Essentially, this paper argues that honesty is the best policy.

Part I will document the history of the FDA’s decision on the over the counter application of Plan B. It will also explore the holding of *Tummino*. Part II will discuss the importance of the bad faith exception—how undue political motivations were characterized in *Tummino*—to the administrative law rule that courts only look at the administrative record. Part III will examine the deliberative process privilege, which is a privilege that usually shields administrative agencies somewhat from judicial scrutiny. It will also look to see why the court allowed such expansive discovery, to the point of even requiring higher-level FDA officials to testify. Part IV will address two key problems with rejecting FDA and other agencies political motivations. The first problem will be the problem of the political reality, namely that the Presidential control of the

administrative state has grown tighter. The second problem will be the problem of scientific evidence, or that because agencies such as the FDA have an incentive to couch their decisions in terms of scientific evidence and uncertainty they are tempted to manipulate the scientific record to justify legitimate political concerns and influences.

## I. Background

### *FDA's Approval Process of Plan B*

Plan B is an emergency contraceptive pill, meaning that it works prior to implantation of a fertilized egg and does not interrupt or harm an established pregnancy<sup>3</sup>. It is time sensitive, which means that it may be more effective as an over the counter medication as opposed to a medication that women must find a doctor to prescribe<sup>4</sup>.

In 1998, the FDA approved emergency contraception by prescription only. As a response, in 2001 the Association of Reproductive Health Professionals and sixty-five other organizations filled a citizen's petition, asking the FDA to switch Plan B (which then required a prescription) to over the counter (OTC) status<sup>5</sup>. Citizen petitions are requests for agency action on scientific and safety issues that any individual, group or company can file, thus creating a mechanism to facilitate public input on FDA

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<sup>3</sup> U.S. Gov't Accountability Office, Food and Drug Administration: Decision Process to Deny Initial Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual, 16 (2005), available at <http://oversight.house.gov/Documents/20051116110800-24167.pdf> [hereinafter GAO Report].

<sup>4</sup> *Id.* at 16-17.

<sup>5</sup> *Id.* at

regulations<sup>6</sup>. The FDCA authorizes individuals to submit citizen's petitions, provided they follow a certain form<sup>7</sup>. It also requires that the Commissioner shall respond to each petitioner within 180 days of receipt of the petition, either approving its requests, denying those requests or explaining why the agency has been unable to reach a decision on the petition<sup>8</sup>. However, generally, this deadline is rarely met though usually the agency will initially respond that a substantive determination is not yet feasible<sup>9</sup>. Therefore, the FDA is required to respond to these petitions, but is not required to act upon them as long as they are acknowledged.

In 2003, after some encouraging meetings with the FDA staff as to the probability of approval, the Plan B sponsor (then Women's Capital Corporation and now Barr Pharmaceuticals, Inc.) submitted a supplemental new drug application (SNDA) requesting that Plan B be switched from prescription only to OTC status without age or point of sale restriction. Using an NDA to switch from prescription to OTC status is not unusual. Almost all Rx-OTC switches have occurred through the NDA process, since the FDA finished publishing the tentative final OTC monographs in the Federal Register<sup>10</sup>.

There is no clear guidance from the FDA as to which drugs are appropriate to OTC status and which drugs ought to remain prescription only. The statutory definition of prescription drugs includes drugs that "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is

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<sup>6</sup> Jordan Paradis, Alison W. Tisdale, Ralph F. Hall & Efrosini Kokkoli, *Evaluating Oversight of Human Drugs and Medical Devices: A Case Study of the FDA and Implications for Nanobiotechnology*, 37 J.L. MED. & ETHICS 598, 618 (Winter 2009)

<sup>7</sup> 21 C.F.R. §10.30 (2009).

<sup>8</sup> 21 C.F.R. § 10.30(e)(2) (2009).

<sup>9</sup> PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASE AND MATERIALS*, 1559 (3rd ed. 2007).

<sup>10</sup> *Id.* at 527.

not safe for use except under the supervision of a practitioner licensed by law to administer such drug.”<sup>11</sup> Therefore, the key factors that the FDA considers when determining the OTC/prescription status of a drug are toxicity, which is fairly straightforward, potentiality for harmful effect, which allows for the FDA to conduct a broad inquiry and method of use, which “encompasses all aspects of the circumstances under which a drug is used, including broad questions of social policy.”<sup>12</sup> As a result, there is relatively little the FDA cannot consider when deciding whether to switch a drug from prescription to non-prescription status.

The advisory committees that reviewed the SNDA, the Nonprescription Drug Advisory Committee and the Reproductive Health Drugs Advisory Committee, voted in favor of a prescription to OTC switch for plan B. In fact, the members of the joint advisory committee voted 23 to 4 to allow Plan B to be marketed over the counter<sup>13</sup>. However, in response to criticism by a small minority on the committee, Barr amended the SDNA to allow nonprescription access to women sixteen and older only. Despite this amendment, senior management at the FDA decided that the Plan B application was not approvable. This was because, “the Commissioner and senior CDER management believed that the number of adolescents in the actual use study was inadequate.”<sup>14</sup>

It is important when considering the story of Plan B to remember that this was not the first time the FDA has overruled the recommendations of drug review panels to switch a medication to OTC status. For example, in the mid-1970’s the FDA disapproved of a SNDA for a prescription expectorant drug named “Benylin”, despite the

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<sup>11</sup> 21 U.S.C. § 353(b)(1)(A).

<sup>12</sup> Hutt et al., at 524.

<sup>13</sup> GAO report at 14.

<sup>14</sup> Quoted in *Tummino v. Von Eschenbach*, 427 F.Supp.2d 212, 219 (E.D.N.Y. 2006).



fact that the OTC Drug Review panel had recommended its switch in OTC status<sup>15</sup>. In fact, the FDA Commissioner at the time even overruled an Administrative Law Judge who ruled that Benylin is safe for OTC<sup>16</sup>. Benylin was used as a cough drug, and therefore it was unlikely to have the political baggage of emergency contraception. Advisory committees are very useful, and the FDA often relies on their recommendations. However, the FDA is free to reject these recommendations.

After receiving additional data, the FDA issued a letter indicating that the scientific evidence was sufficient to support Plan B as an OTC product only for women seventeen years of age or older<sup>17</sup>. On August 24, 2006, five years after the Citizen's Petition and three years after the SDNA, the FDA issued a final decision on the SDNA for Plan B. Plan B was made available without a prescription for women eighteen years and older but only through venues with a licensed pharmacist on staff. It is important to note that although the FDA took a long time to respond to the SDNA, it ultimately did respond.

The response from Congress to the FDA's rejection of OTC status for Plan B indicated a distrust of the motivations behind the FDA's decision. Senator Hillary Clinton, as well as twenty-three other US senators, requested that the Government Accountability Office (GAO) join with the Senate to investigate the Plan B decision<sup>18</sup>. The GAO found four irregularities in the treatment of the SDNA. First, the directors of the Office of Drug Evaluation and the Office of New Drugs, who would normally be responsible for signing off on such action letters, did not sign the 'not-approvable' letter

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<sup>15</sup> Hutt et al., at 527.

<sup>16</sup> GAO report at 15.

<sup>17</sup> *Id.* at 16.

<sup>18</sup> *See* GAO report.

largely because they disagreed with the decision<sup>19</sup>. Second, the FDA’s senior leadership was uncharacteristically highly involved with the Plan B OTC switch. For example, the GAO investigators found that “FDA review staff told us that they were told early in the review process that the decision would be made by high-level management”<sup>20</sup>. Third, the GAO investigators found that the evidence suggested that the decision to not approve Plan B was made even before the review process was completed, maybe even months beforehand<sup>20</sup>. Lastly, the GAO found that “the Acting Director of CDER’s decision was novel and did not follow the FDA’s traditional practices”<sup>21</sup>. It is hard to imagine that the GAO report did not inform the judicial decisions in *Tummino*, and in fact, it is cited frequently in the court documents.

### *The Case Itself*

The plaintiffs filed several causes of action that can be grouped into administrative law claims and constitutional law claims. The plaintiffs made administrative law claims in their first cause of action (that the FDA’s denial of OTC switch for persons of all ages is arbitrary and capricious), the second cause of action (the FDA has exceeded statutory authority) and the fifth cause of action (the FDA’s failure to approve the OTC for Plan B was an unreasonable delay)<sup>22</sup>. The plaintiffs also brought several constitutional law claims, such as the third cause of action (the right to privacy) and the fourth cause of action (sex discrimination)<sup>23</sup>. However, the court generally

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<sup>19</sup> *Id.* at 5.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> Second Amended Complaint, ¶¶ 60-62, 67-68, 2005 W.L. 6029405 (2005).

<sup>23</sup> *Id.* ¶¶ 63-66

avoided engaging in the constitutional law questions and focused solely on the administrative law questions<sup>24</sup>. Therefore, this paper will focus on the administrative law issues.

The ensuing court case was notable from an administrative law standpoint for several reasons. First, the magistrate judge allowed for an expansive scope of discovery<sup>25</sup>. The court did not confine itself to the administrative record. In addition, higher-level FDA officials were required to testify. This is something that was virtually unprecedented. Expanding the scope of discovery and requiring FDA testimony raises important policy questions about the interaction between the courts and the FDA. Namely, this case raises the question of where to set the boundaries between the FDA and political actors. If any political motivation or interaction constitutes bad faith, the expansive scope of discovery in this case is justified. However, if there was no bad faith, the FDA perhaps ought to be accorded more privacy than the court allowed it.

The question what constitutes bad faith leads into the holding of this case. Judge Korman found that the FDA had acted in an impermissible manner, largely because the delays and treatment of Plan B seemed exceptional and motivated by political considerations. He then ordered that Plan B be made over the counter for women seventeen and older and that the FDA reconsider its decisions regarding the Plan B switch to OTC use<sup>26</sup>. Judge Korman found that “the FDA simply has offered no evidence that age restriction would be unenforceable at 17 rather than 18” in response to the FDA’s justification of the need for administrative convenience to support its decision to

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<sup>24</sup> See Carmel Shachar, *Administrative Law v. Constitutional Law: The Correct Decision on FDA’s Treatment of Plan B*, 37 J.L. MED. & ETHICS 523 (2009).

<sup>25</sup> *Tummino v. Von Eschenbach*, 427 F.Supp.2d 212 (E.D.N.Y. 2006).

<sup>26</sup> *Tummino v. Torti*, 603 F.Supp.2d 519, 549 (E.D.N.Y. 2009).

limit Plan B to those over seventeen<sup>27</sup>. Furthermore, the scientific evidence supported the contention that seventeen year olds could safely take Plan B without a doctor's supervision<sup>28</sup>.

The opinion avoided constitutional law questions and focused on questions of administrative law. However, despite the careful avoidance of constitutional questions, the opinion in *Tummino* reflects and was colored by politics and policy judgments. For example, Judge Korman felt comfortable remanding the SDNA to the FDA because due to the election of President Obama and the subsequent changeover in FDA leadership, the FDA can be "trusted to conduct a fair assessment of the scientific evidence" and that evaluating such evidence was best left to the expertise of the FDA and not the courts<sup>29</sup>.

*Tummino* allowed the court a broad scope, both in discovery and in consideration. The broadness of this scope was directly related to the issue of the ever-increasing influence that the executive branch has on the FDA. Because the court focused almost entirely on administrative law questions, *Tummino* provides an excellent lens through which to examine the interplay between the reality of the administrative state and the judicial review of agency proceedings.

## II. Judicial Review of Agency Proceedings

One of the major points of contention in *Tummino* was whether to allow discovery beyond the administrative record. Discovery beyond the record entailed

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<sup>27</sup> *Id.* at 550.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at 549.

discovery into communications and correspondence between individuals within and outside of the FDA as well as testimony of certain FDA decision makers. Discovery beyond the record would mean that certain normally privilege documents would be presented to the court but also that the Judge could consider more than just the administrative record while evaluating the FDA’s decision-making process. The magistrate judge ultimately allowed discovery beyond the administrative record<sup>30</sup>. However, the decision to allow discovery beyond the record raises many policy questions about the role of politics and science in FDA, and other agency, decision making.

In most cases, “a court reviewing an agency decision is confined to the administrative record compiled by that agency when it made the decision”<sup>31</sup>. This is referred to as the ‘record rule’. This stems from the APA, which limited the scope of judicial review largely to the administrative record<sup>32</sup>. The policy behind the ‘record rule’ expresses a desire to prevent the judiciary from supplanting the agency’s judgment with its own. The ‘record rule’ prevents judgment substitution by requiring that “the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.”<sup>33</sup> Therefore, the default scope of discovery and judicial review in *Tummino* would have been to review only the record that the FDA produced.

However, there are exceptions to the ‘record rule’. Since the “central point of judicial review was to respond to open-ended delegation of discretionary power by

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<sup>30</sup> *Tummino v. Von Eschenbach*, 427 F.Supp.2d 212 (2006).

<sup>31</sup> *National Audubon Soc. V. Hoffman*, 132 F.3d 7, 14 (FED. CIR. 1997).

<sup>32</sup> The Administrative Procedure Act, 5 U.S.C §706.

<sup>33</sup> *Camp v. Pitts*, 411 U.S. 138, 142 (1973).

ensuring a firm check on agency decisions that might be “irrational or discriminatory”<sup>34</sup>.” For example, the scope of discovery may be expanded and the record may be supplemented when the record does not support the agency action, when the agency has not considered all the relevant factors or when the reviewing court does not have enough information to evaluate the challenged action on the basis of the administrative record<sup>35</sup>.

A showing of bad faith or improper behavior by agency decision makers is one of the more common reasons used to justify expanding the scope of review<sup>36</sup>. Essentially, the showing of bad faith rebuts the presumption of regularity entitled to an agency and its administrative record<sup>37</sup>. Another exception to the ‘record rule’, agency inaction, also has much in common with bad faith. Under the APA a court can compel agency action unlawfully withheld or unreasonably delayed<sup>38</sup>. Because the record may be limited in situations in which agencies do not act, courts are often guided by ‘TRAC’ factors when reviewing cases of agency inaction. TRAC factors include any Congressional timetables, a rule of reason, whether the proposal regulation is economic or affects human health and welfare, the agency’s other priorities and activities, and the interest affected<sup>39</sup>. At the bottom line, in delay cases, “the agency must justify its delay to the court’s satisfaction.”<sup>40</sup> This indicates that the court in delayed actions is looking to understand if and why there is a unusual delay and that usually hinges upon whether the agency is acting in good faith or not.

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<sup>34</sup> Thomas Miles, Cass Sunstein, *The Real World of Arbitrariness Review*, 75 U. CHI. L. REV. 761 (2008).

<sup>35</sup> Florida Power & Lights Co. v. Lorion, 470 U.S. 729, 744 (1985).

<sup>36</sup> Hoffman, 132 F.3d at 14.

<sup>37</sup> San Luis Obispo Mothers for Peace v. NRC, 751 F.2d 1287, 1329 (D.C. CIR. 1984).

<sup>38</sup> APA, 5 U.S.C. §706.

<sup>39</sup> In re Barr Laboratories, Inc., 930 F.2d 72, 74-75 (D.C.CIR. 1991).

<sup>40</sup> Cutler v. Hayes, 818 F.2d 879, 898 (D.C.CIR. 1987).

Once bad faith is shown, the court may even require administrative officials to testify as to their actions. However, the Supreme Court counseled “where there are administrative findings that were made at the same time as the decision...there must be a strong showing of bad faith or improper behavior before such inquiry can be made.”<sup>41</sup> Therefore, even under the exceptions there is a sense that expanding the scope of discovery beyond the administrative record and probing into the mental processes of the administrative decision makers is undesirable<sup>42</sup>. Government transparency is an important value. However, too much government transparency can make it difficult for the administrative state to run smoothly and protect itself from capture from industry and other interested groups.

The opinion in *Tummino* underscores the importance of defining bad faith reasonably. Judge Korman did not decide the case based on the plaintiffs’ claims that the FDA violated their rights to privacy and equal protection under the Fifth Amendment<sup>43</sup>. The only APA claim brought was the charge that the FDA’s actions are “arbitrary and capricious”, which generally would limit discovery and the scope of judicial review to the administrative record unless bad faith was shown<sup>44</sup>. The access the plaintiffs had to FDA records and testimony that would have otherwise been unavailable hinged entirely on whether the court thought the White House agenda impermissibly influenced the FDA’s decision-making process.

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<sup>41</sup> *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971).

<sup>42</sup> *U.S. v. Morgan*, 313 U.S. 409, 422 (1941).

<sup>43</sup> *Claims from Second Amended Complaint*, ¶¶ 63-64 & 65-66 2005 W.L. 6029405 (2005).

<sup>44</sup> *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985).

### III. Deliberative Process Privilege

It is highly unusual for FDA officials to have to testify in court cases, as they were required to do in *Tummino*. This is in part because of deliberative process privilege, which serves to act as a shield for agency decision makers against judicial review. By rejecting deliberative process privilege, the *Tummino* court set the stage to evaluate the FDA's decision-making process for bad faith.

Deliberative process privilege protects the decision-making processes and policy discussions of governmental agencies and executive departments<sup>45</sup>. This generally includes materials that if revealed would “expose an agency’s decisionmaking process in such a way as to discourage candid discussion within the agency and thereby undermine the agency’s ability to perform its functions.”<sup>46</sup> As a common-law judicial privilege, it protects material that is pre-decisional and deliberative or not factual<sup>47</sup>.

The deliberative privilege process draws heavily upon the Morgan doctrine. In *Morgan v. US*, the Supreme Court stated that courts cannot examine the inner processes of an administrator’s mental state in reaching an administrative conclusion.<sup>48</sup> The Morgan doctrine and the widespread acceptance of the deliberative process principle imply that our jurisprudence places a relatively high value on administrative secrecy.

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<sup>45</sup> See Michael Ray Harris, *Standing in the Way of Judicial Review: Assertion of the Deliberative Process Privilege in APA Cases*, 53 ST. LOUIS U. L.J. 349, 349 (2009).

<sup>46</sup> *Dudman Communications Corp. v. Department of the Air Force*, 815 F.2d 1565, 1568 (D.C. CIR. 1987).

<sup>47</sup> See *In re Sealed Case*, 121 F.3d 729, 737 (D.C. CIR. 1997).

<sup>48</sup> 304 U.S. 1, 18 (1938).



The intended result of the deliberative process privilege is to allow for candid and open discussion among government officials<sup>49</sup>. In turn open discussion will allow for better decision-making<sup>50</sup>. This has the benefit also of having agencies be judged only on their final decisions and avoids creating public confusion about the policies of an agency<sup>51</sup>. On the other hand, the deliberative process privilege can be characterized as one that promotes secrecy. A popular sentiment in American political history is the need for government transparency. As James Madison wrote, a “popular Government without popular information, or the means of acquiring it, is but a Prologue to a Farce or a Tragedy; or, perhaps, both.”<sup>52</sup> Deliberative process privilege can have a chilling effect on judicial review of agency decision-making. This is because an agency can use this privilege to “shield an agency’s reliance on evidence outside the scope of its statutory authority, as well as wholly biased, one-sided decisions.”<sup>53</sup>

Deliberative process privilege is not absolute. Instead, it may give way when the plaintiff demonstrates sufficient need for the contested information<sup>54</sup>. Factors to consider include “the relevance of the evidence, the availability of other evidence, the seriousness of the litigation, the role of the government and the possibility of future timidity by

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<sup>49</sup> See e.g. *EPA v. Mink*, 410 U.S. 73, 87 (1973).

<sup>50</sup> See Michael N. Kennedy, *Escaping the Fishbowl: A Proposal to Fortify the Deliberative Process Privilege*, 99 NW. U. L. REV. 1769 (2005).

<sup>51</sup> See *Petroleum Info. Corp. v. U.S. Dep’t of Interior*, 976 F.2d 1429, 1437 n. 10 (D.C. CIR. 1992) (Ginsburg, J.).

<sup>52</sup> Letter from James Madison to W.T. Barry (Aug. 4th, 1822) in 9 *The Writings of James Madison* 103 (Gaillard Hunt ed., 1910) (quoted in Michael Ray Harris, *Standing in the Way of Judicial Review: Assertion of the Deliberative Process Privilege in APA Cases*, 53 ST. LOUIS U. L.J. 349, 349 (2009)).

<sup>53</sup> Michael Ray Harris, *Standing in the Way of Judicial Review: Assertion of the Deliberative Process Privilege in APA Cases*, 53 ST. LOUIS U. L.J. 349, 349 (2009)).

<sup>54</sup> *In re Sealed Case*, 121 F.3d at 737.

government employees.”<sup>55</sup> In situations where there is a claim of governmental misconduct, the government cannot hide behind deliberative process privilege<sup>56</sup>. The purpose of the APA is for courts to review the whole record for arbitrary or capricious decision-making. Preventing this level of review through deliberative process privilege raises problematic questions about the balance of power between these executive agencies and the judicial branch<sup>57</sup>. However, it is unclear if plaintiffs merely need to alleged misconduct or if they must make some evidentiary showing to justify denying deliberative process privilege<sup>58</sup>.

The FDA, for much of its existence, has been a relatively private agency, perhaps out of necessity due to the subject matter it handles. As Peter Barton Hutt noted, “The Food and Drug Administration is the largest repository of private scientific research in the world. [it] receive[s] mountains of important data and information...that is available nowhere else.”<sup>59</sup> In addition he noted that, “since 1938 virtually none of it has been divulged.”<sup>60</sup> In response to the Freedom of Information Act (FOIA) the FDA proposed to make this information available for public disclosure upon request, which was codified in 37 Fed. Reg. 9128 (May 5, 1972). Clearly, the FOIA as well as the FDA’s regulations show that it is important for the public to have access to the information within the FDA files.

However, the plaintiffs in *Tummino* asked for more than just the data on Plan B’s safety, effectiveness and functionality. They were primarily interested in the interaction

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

<sup>56</sup> *Id.* at 738.

<sup>57</sup> Michael Ray Harris, 53 ST. LOUIS L.J. at 393.

<sup>58</sup> Michael N. Kennedy, 99 NW. U. L. REV. at 1787.

<sup>59</sup> Hutt et al, at 1589.

<sup>60</sup> Hutt et al, at 1589.

between the FDA, its leadership, and the White House and requested “any documents that demonstrate or indicate unusual involvement of upper level FDA management in the FDA’s process regarding Plan B”<sup>61</sup>. This, they hoped, would help show bad faith on the part of the FDA.

The FDA characterized the plaintiffs’ request as suggesting that “a federal agency were required to collect and include in the administrative record all documents in any form in its possession that related to a particular topic, whenever it is sued on that topic”<sup>62</sup> which would generate an astounding number of documents. Furthermore, even FOIA has an exemption that applies to “inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than the agency in litigation with the agency”<sup>63</sup>. The FDA deals with many sensitive decisions every day. Allowing courts to frequently probe into its decision making process by denying it deliberative process privilege may ultimately hamper the FDA in its ability to carry out its mission.

Ultimately, in *Tummino*, the magistrate judge ruled that the FDA was prohibited from withholding on the basis of the deliberative process privilege<sup>64</sup>. As a result, the plaintiffs were also allowed to conduct depositions of key leadership of the FDA at this time<sup>65</sup>. The leadership required to testify included Steven Galson, Director of Center for Drug Evaluation and Research (CDER) at the FDA from 2001 to 2007, Lester Crawford, the Commissioner of the FDA in 2005, and Janet Woodcock, the current direct for CDER

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<sup>61</sup> Pl. Ltr. Aug. 29, 2006, at 4 (Quoted 2006 WL 5303773, 12 (2006)).

<sup>62</sup> 2006 WL 5303773 (E.D.N.Y.) (2006).

<sup>63</sup> 5 U.S.C. § 552(b)(5) (2006).

<sup>64</sup> *Tummino v. Von Eschenbach*, 427 F.Supp.2d 212 (E.D.N.Y. 2006)

<sup>65</sup> *Id.* at 236.

at the FDA<sup>66</sup>. In addition the magistrate judge allowed the plaintiffs to serve subpoenas for documents from the White House to the FDA and to elicit testimony from a former member of the White House staff, Jay Lefkowitz about the connection between the White House and the FDA's leadership during the Plan B decision making process<sup>67</sup>.

The District Judge in this case tried to narrow the focus of discovery somewhat by not completely rejecting deliberative process privilege. Instead, he maintained that “I think the issue is not going to be whether it's deliberative or not. The issue is going to be does it demonstrate bad faith on the part of the agency.... So the [M]agistrate [Judge]'s determination seems to me to turn on whether or not this evidence ... indicates the agency was acting in bad faith.” Tr. Conf July 26, 2006 (docket No. 185), at 14; *id.* at 13 (“the instruction to the [M]agistrate [Judge] should be is that if in his judgment it is deliberative, these documents evidence bad faith, that they should be disclosed”)<sup>68</sup>. However, this did little to limit the scope of discovery in *Tummino*.

Certainly, a showing of bad faith is and should be an exception to deliberative process privilege. The FDA noted when arguing against additional discovery, “Congress has assigned the responsibility for determining the prescription status of drugs to the *Secretary of Health and Human Services*, and given that the prescription status of Plan B has engendered an extraordinary level of interesting...the notion that the involvement of high level FDA officials in deciding the status somehow constitute “bad faith” is

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<sup>66</sup> See Center for Reproductive Rights, *Tummino v. von Eschenbach (NY)* (2009), <http://reproductiverights.org/en/case/tummino-v-von-eschenbach-ny>.

<sup>67</sup> Decision and Order, *Tummino v. von Eschebach*, CV 05-366 (ERK)(VVP) (E.D.N.Y. Nov. 06 2006).

<sup>68</sup> Quoted in Memorandum of the Defendant, 2006 WL 5303773, 2 (E.D.N.Y) (2006).

specious.”<sup>69</sup> The FDA may have acted in bad faith throughout this process—the delay for example is hardly laudatory—however, this situation raises clear questions about whether upper level political involvement in the FDA is evidence of bad faith.

## V. Two Problems

The *Tummino* treatment of the FDA revealed two problems with the current approach to the courts reviewing FDA’s, and other agencies’, decisions. First of all, despite the increasing influence the president and the executive play in the administrative state, agencies are still penalized for incorporating the political into their decisions. This in turns puts pressure on agencies, such as the FDA, to find scientific reasons for political decisions. While an emphasis on science before politics has value, requiring scientific justification when the justifications are really only political can result in another problem. When agencies must call upon science to mask the role of politics, the scientific evidence can often be manipulated. Thus, scientific uncertain can turn into scientific certainty and vice versa. The problems of political exclusion and scientific malleability in judicial review are intertwined and influence each other.

### *The Political Problem*

Since the Supreme Court’s ruling in *Motor Vehicles Manufacturers Ass’n v. State Farm Mutual Auto Insurance Co.*<sup>70</sup>, judicial review has been constructed to legitimate

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<sup>69</sup> *Id.* at 13.

<sup>70</sup> 463 U.S. 29 (1983).

scientific expertise over politics in administrative decision-making<sup>71</sup>. In that case the court upheld the National Highway Traffic Safety Administration's decision to rescind a seat belt requirement solely on technocratic justifications. In doing so, the court ignored the motivation this agency had to change its rule to comply with new President Reagan's administrative goals, although then-Justice Rehnquist, in a partial dissent, did find it reasonable to change policies based on the election of a new President<sup>72</sup>.

Since then most courts when reviewing agency decision-making have evaluated the administrative record in two ways. First, the judges check to see if there was any undue political influence. Second, the judges look to see if the scientific evidence supports the agency's conclusions. This approach has "promoted vigorously the control of administrative policy by bureaucratic experts, not only by enabling them to fill the space that Congress might have occupied by also by requiring that agency action bear the indicia of essentially apolitical, "expert" process and judgment."<sup>73</sup> The expectation of the judiciary is that scientific experts, not politicians, will run the administrative state. The FDA is not supposed to be an exception to this technocratic model.

The *Tummino* ruling was clearly in line with current judicial policy. The magistrate judge, when allowing discovery beyond the administrative record, raised the possibility of bad faith (one of the exceptions to the record rule) by referencing deviations from the technocratic model. He noted that, "[t]he professional staff of the FDA voiced

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<sup>71</sup> Kevin M. Stack, *The President's Statutory Powers to Administer the Laws*, 106 COLUM. L. REV. 263, 307 n.191 (2006) (noting that State Farm can be seen as "common contemporary shorthand for the requirement that agencies rationalize their decisions in terms of statutory criteria and that a change of administration is not a sufficient basis for agency action").

<sup>72</sup> 463 U.S. at 59 (Rehnquist, J., concurring in part and dissenting in part).

<sup>73</sup> Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2270 (2001).

strenuous objections to the consideration of such matters [the impact that OTC access for emergency contraception might have on adolescent sexual activity] as being beyond the mandate of the agency”<sup>74</sup>. The magistrate judge then took the resignation of the Director of the Office of Women’s Health (and a non-political employee of the FDA) over the Plan B decision as “further support for the plaintiffs’ position that improper considerations, unrelated to science or to the mandate of the FDA, has prompted the FDA’s decisions concerning Plan B.”<sup>75</sup> Judge Korman, in his ruling in *Tummino*, echoed the magistrate judge’s conclusion that bad faith was present because the FDA had been influenced by politics.

However, the technocratic focus in *Tummino* and in the wider case law ignores important relatively recent changes in the relationship between the White House and the administrative agencies. As Elena Kagan noted, “President Clinton, building on a foundation President Reagan laid, increasingly made the regulatory activity of the executive branch agencies into extensions of his own policy and political agenda...by exercising directive authority of these agencies.”<sup>76</sup> Reagan required executive agencies to submit to the OMB’s Office of Information and Regulatory Affairs for Presidential review of any major rule, which gave the president substantial control over these agencies.<sup>77</sup> Clinton continued to use this strategy he inherited from his predecessors but to trigger agency action and regulate instead of deregulate<sup>78</sup>.

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<sup>74</sup> 427 F.Supp.2d at 233.

<sup>75</sup> 427 F.Supp.2d at 233.

<sup>76</sup> 114 HARV. L. REV. at 2245.

<sup>77</sup> Exec. Order No. 12,291 §3, 3 C.F.R. 127, 128-30 (1981).

<sup>78</sup> Kagan, 114 HARV. L. REV. at 2282.

In fact, Clinton's use of the FDA shows that *Tummino* was not the first case in which a President attempted to use FDA rulemaking to further his domestic agenda. A frequently cited example of Presidential influence on the FDA is 1996 rule about advertising and distribution of tobacco products to minors<sup>79</sup>. Clinton made teen smoking a campaign issue in 1996 and lead public relations efforts to announce its proposal and adoption<sup>80</sup>. In fact, when Clinton announced the publication of a proposed rule to reduce teen smoking he used language such as, "I am announcing broad executive action to protect the young people of the United States from the awful dangers of tobacco", "Therefore, by executive authority, I will restrict sharply the advertising" and "I am authorizing to the Food and Drug Administration to initiate a broad series of steps all designed to stop sales..."<sup>81</sup>. However, despite his involvement in drafting the proposal and his role as the public face of the proposal, the final documents issued by the FDA say nothing about Clinton's involvement in the rulemaking. Instead, the final documents focus on the technocratic concerns of the FDA. They contain regulations for tobacco manufacturers and vendors, health-related justification and a defense of FDA jurisdiction<sup>82</sup>.

These regulations were the subject of *FDA v. Brown & Williamson Tobacco Corp.*<sup>83</sup> In the Supreme Court's review of these regulations President Clinton's name is not mentioned even once, and his role is whitewashed from the discussion of the

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<sup>79</sup> See *Id.* at 2282. See also Peter L. Strauss, *Presidential Rulemaking*, 72 CHI.-KENT L. REV. 965 (1997).

<sup>80</sup> Strauss, 72 CHI.-KENT L. REV. at 965.

<sup>81</sup> The President's News Conference, 2 Pb. Papers 1237-38 (Aug. 10, 1995).

<sup>82</sup> Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (Aug. 28, 1996) (codified at 21 C.F.R. pts. 801, 803, 804, 807, 820 & 897).

<sup>83</sup> 529 U.S. 120 (2000).



regulations. Clearly, from an administrative law point of view, the FDA was correct to refrain from including Clinton's political influence in their documents, although the regulations were ultimately struck down. However, this experience suggests that by providing motivation for agencies to bury the involvement of Presidents in their rule making leads to an incomplete judicial review of agency decision-making. The FDA teen smoking story shows that Presidential involvement in FDA's affairs is not unprecedented. It also shows that Presidents of either political leaning often hijack the FDA's decision-making process.

After the examples set by Reagan and Clinton, the potential of administrative agencies as a tool to further presidential agendas—and avoid potential battles with hostile Congressmen—has been cemented. The gene is out of the bottle and certainly any future presidents will understand the value of incorporating agency action into their political agendas. In fact, scholars such as Kagan have applauded this development as increasing administrative accountability and effectiveness<sup>84</sup>. Lawrence Lessig documents a shift in the judiciary from a belief in an independent and scientific administrative state seen earlier in the twentieth century to a view that the administrative state “cannot be understood in the neutral, scientific, apolitical sense in which it was understood by the founders of the administrative state...[i]t is instead now seen by all to be essentially ‘political’”<sup>85</sup>. Therefore, it seems a fairly uncontroversial conclusion that the administrative state, and the FDA as part of that complex, has become politicized and will never be independent from political influences.

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<sup>84</sup> 114 Harv. L. Rev. at 2384.

<sup>85</sup> Lawrence Lessig, *Understanding Changed Readings: Fidelity and Theory*, 47 STAN. L. REV. 395, 435 (1995).

It seems odd, at best, to penalize the FDA—other any other agency—simply for not resisting the agenda of the President. The President, as a nationally elected figure, seems to have some public mandate to dictate which issues should get priority on administrative agencies’ ‘to do lists’. While the FDA’s primary responsibility ought to be to ensure public safety, it is possible for the President to influence its agenda without undermining its focus. There is a difference between allowing a decision on bald Presidential political calculation and Presidential guidance. In the case of an agency simply hiding behind a Presidential decree, courts could still determine the decision to be arbitrary because “he said so” is not good reasoning full stop<sup>86</sup>. However, when coupled with factual and scientific evidence, admissions of Presidential influence could help develop a fuller administrative record<sup>87</sup>. This could benefit judicial review by allowing judges to evaluate the interaction between the executive political agenda and the nonpolitical responsibilities of the FDA or other administrative agencies.

Obviously, it will be difficult to distinguish between permissible and impermissible political influences. Kathryn Watts distinguishes between ‘legitimate’ political influences as being policy considerations and political value judgments and ‘illegitimate’ political influences as being raw political goals or pure partisan politics<sup>88</sup>. A key factor ought to be the interplay between the political goals and the purpose of the agencies. For example, Clinton’s push for teen smoking regulations were a political goal but resulted in regulations that furthered the FDA’s goal of protecting public health and

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<sup>86</sup> Nina Mendelson, *Disclosing ‘Political’ Oversight of Agency Decision Making*, 108 MICH. L. REV. 52 (2010).

<sup>87</sup> Kathryn Watts, *Proposing a Place for Politics in Arbitrary and Capricious Review*, 119 YALE L.J. 2, 55-56 (2009).

<sup>88</sup> *Id.* at 56.

welfare. In fact, Clinton's involvement might give additional justification to the FDA's decision to regulate tobacco because as President (and an elected figure, unlike most of the decision-makers in the FDA) he has a public mandate to further his proposed policy agenda. One might argue that those voting for Clinton knew that he was interested in regulating teen smoking and therefore the public gave approval to use the FDA in such a way. Legitimate political influences ought to be reflected in the record to give a judicial reviewer a better understanding of not only the agency's decision making in reaction to Presidential pressure but also how voters might have a change of attitudes towards what an administrative agency ought to accomplish.

On the other hand, illegitimate political influences, such as those that prevent the agency from accomplishing its mandate, ought to still be rejected by the courts. *MA v. EPA*<sup>89</sup> illustrates a situation in which illegitimate political influences were rejected and one in which even if some political influences would be allow they would still be rejected. There were worries that the Bush administration tampered with global warming data reported by federal agencies to introduce greater doubt and uncertainty as to the scientific evidence and placed a good deal of pressure on the EPA to refuse to regulate greenhouse gasses<sup>90</sup>. Jody Freeman and Adrian Vermeule characterized the Supreme Court's reaction as expertise forcing, or an "attempt by courts to ensure that agencies exercise expert judgment free from outside political pressures, or especially political pressures emanating from the White House or political appointees in the agencies."<sup>91</sup> Expertise forcing, they say, is directly against the rationale of *Chevron*, which

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<sup>89</sup> 549 U.S. 497 (2007).

<sup>90</sup> Jody Freeman, Adrian Vermeule, *Massachusetts v. EPA: From Politics to Expertise*, 2007 SUP. CT. REV. 51, 55-62 (2007).

<sup>91</sup> *Id.* at 51.

harmonizes democratic politics and expertise as complementary<sup>92</sup>. Another example of impermissible considerations would be the charges that FDA officials harassed employees of the Bureau of Drugs when their decisions can contrary to drug manufacturers' interests<sup>93</sup>. Clearly, when the President is attempted to alter evidence and to pressure agencies to decline their mandate, courts ought to still reject political influence as an acceptable rationale for decision-making.

Returning back to *Tummino*, it is unclear which category *Tummino* falls into. The Plaintiffs charged “the FDA bowed to political pressure from the White House and anti-abortion constituents despite the uniform recommendation of the FDA’s scientific review staff to approve over-the-counter access to Plan B without limitation.”<sup>94</sup> Certainly Judge Korman agreed with the Plaintiff’s assessment that this was illegitimate political pressure, citing the timing of FDA’s approval of Plan B for women over eighteen as linked to the confirmation of Dr von Eschenbach as FDA commissioner<sup>95</sup>. In addition, the undue delays in consider the Citizen Petitions and the SNDA indicate that the FDA felt pressure to refrain from its true mission—to evaluate potential drugs for the consumer market.

However, there are some indications that the FDA’s actions were not outside legitimate political influence. Certainly the FDA has been influenced by Presidential agendas before, so the sensitivity the FDA had about Plan B related to the Bush administration’s policies are not extraordinary. In addition, as also discussed above, the FDA has rejected the recommendations of advisory committees in other situations.

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<sup>92</sup> *Id.* at 92.

<sup>93</sup> *See* Hutt et al., 1529.

<sup>94</sup> 603 F.Supp.2d 519, 538 (E.D.N.Y. 2009).

<sup>95</sup> *Id.* at 546.

While the FDA ought to make it a priority to respond to NDAs and Citizen Petitions, there is no fundamental right of access to drugs<sup>96</sup>. Plan B was already available by prescription, so there was perhaps less pressure to evaluate it since it was already available to the public.

### *The Scientific Problem*

A corollary of the political influence problem is the scientific evidence problems. Another problem raised by the blanket rejection of political influences in the administrative record is the pressure it puts on the scientific evidence. When agencies cannot admit the political motivations of their decision-making they are forced to manipulate the scientific record to support their decisions. This can be egregious, as in *MA v. EPA*, or it can be more moderate, such as suggesting scientific uncertainty when the evidence is fairly conclusive. This impulse to play with scientific certainty could be lessened if agencies were allowed to ‘come clean’ about their political influences.

Part of the scientific problem is that judges, as non-scientific experts, can only be so sophisticated when evaluating the scientific evidence in the administrative record. The first step in the judicial review of the scientific data is to see if it is certain or uncertain. If the evidence is certain, then the agency has based its decision making on reasons that are not arbitrary or capricious. If the scientific data is uncertain, that suggests that the agency has used other reasons beside the data. Unfortunately, “[t]his legal inquiry into the existence of uncertainty is not as easy a question for the court to answer as it might

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<sup>96</sup> See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007).

seem, given that the determination of certainty involves both reaching a certain level of scientific understanding and making normative judgments about the nature of science.”<sup>97</sup>

The scientific uncertainty problem raises its head in areas outside of agency decision-making. The Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals*<sup>98</sup> required judges to act as scientific gatekeepers on matters of expert testimony in order to ensure standards for relevance and reliability. However, manufacturers have capitalized on the scientific naivety of judges by suggesting scientific uncertainty even where there is none. For example, in 1994 the FDA required the manufacturer of Parlodel, a drug to stop postpartum lactation, to stop selling the drug due to increases in risks of hypertension, seizure and stroke<sup>99</sup>. However, when consumers sued the drug’s manufacturer many judges refused to allow expert testimony on the link between Parlodel and circulatory disorders or even threw out the case for lack of scientific uncertainty<sup>100</sup>. In this situation, the judges had required a higher level of certainty than the FDA.

Clearly, scientific uncertainty in the courts is an element that can be used to undermine effective judicial review. Problems could be minimized by using a weight-of-the-evidence approach, which looks at each piece of evidence in context as opposed to on its own for reliability<sup>101</sup>. However, the judicial attention devoted to the science seems somewhat misplaced. Agencies are quite good at evaluating the relevant science in their

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<sup>97</sup> Stephanie Tai, *Uncertainty About Uncertainty: The Impact of Judicial Decisions on Assessing Scientific Uncertainty*, 11 U. PA. J. CONST. L. 671, 674 (2009).

<sup>98</sup> 509 U.S. 579 (1993).

<sup>99</sup> David Michaels, Celeste Monforton, *Scientific Evidence in the Regulatory System: Manufacturing Uncertainty and the Demise of the Formal Regulatory System*, 13 J.L. & POL’Y 17, 39 (2005).

<sup>100</sup> *Id.* at 39.

<sup>101</sup> Thomas O. McGarity, *Science in the Regulatory Process: On the Prospect of Daubertizing Judicial Review of Risk Assessment*, 66 LAW & CONTEMP. PROBS. 155 (2003).

field. For example, despite the above mentioned example of *Mass v. EPA* there are few instances of the EPA using unreliable science or science inappropriately to support a final regulation<sup>102</sup>. Furthermore, there are better institutions to evaluate scientific disputes, such as the FDA's Public Board of Inquiry<sup>103</sup>.

In *Tummino* the FDA may have manufactured some scientific uncertainty in order to justify its treatment of Plan B in regards to adolescents. Officials in the FDA maintained that there was not enough evidence to allow OTC status of Plan B for adolescents, particularly young adolescents<sup>104</sup>. As the GAO noted, "there are no age-related marketing restrictions for any prescription or OTC contraceptives that FDA has approved, and FDA has not required pediatric studies for them...FDA identified no issues that would require age-related restrictions in the review of the original prescription Plan B new drug application."<sup>105</sup> The then acting director of the FDA countered the GAO report by arguing that the FDA explicitly considered the differing levels of cognitive maturity of adolescents of different ages, though he admitted this was an unprecedented rationale to reject an OTC switch application.<sup>106</sup> However, other FDA officials, such as the Director of the Office of New Drugs maintained that the FDA 'has a

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<sup>102</sup> Wendy E. Wagner, *The 'Bad Science' Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulations*, 66 LAW & CONTEMP. PROBS. 63, 72 (2003) (Quoting the National Research Council Findings: Hearing Before the House Subcomm. On Engery and Env't, 106th Cong. 106-97, at 46 (2000)).

<sup>103</sup> See Sidney Shapiro, *Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA's Public Board of Inquiry*, 1986 DUKE L.J. 288 (1986).

<sup>104</sup> GAO report at 2.

<sup>105</sup> GAO report at 2.

<sup>106</sup> GAO report, at 32.

long history of extrapolating findings from clinical trials in older patients to adolescents in both prescription and non-prescription approvals.”<sup>107</sup>

The most logical narrative here, one that Judge Korman embraced in his opinion<sup>108</sup>, is that the high level FDA officials hid their political agenda behind a demand for more research on adolescents. The Bush White House had made its position on Plan B OTC status clear and the political appointees of the FDA were perhaps doing their best to respond to the pressure. However, the requirement that the rationales behind their decision-making be based on scientific facts and evidence meant that they could not reflect the pressures that led to their reluctance to approve OTC status for Plan B for all ages. This led to the need to demand studies on the sexual behavior of adolescents, particularly young adolescents, and the impact OTC Plan B would have on these women.

While this may be valuable information, it seems, as the GAO and Judge Korman noted, arbitrary and capricious to require these kinds of studies if all other contraceptives and OTC switch applications do not have to satisfy this requirement. It seems particularly arbitrary and capricious if the demand for more studies is based on political influences. However, acknowledging that in the current political climate the FDA must move carefully on applications such as Plan B seems less arbitrary and capricious and more honest and open. While obviously we want the FDA to treat similarly situated applications equally, there are certain times at which applications are different from the point of the agency that have to do with the sensitivity of the case. It would be better to acknowledge that when calling for additional scientific information than to hide behind

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<sup>107</sup> GAO report at 32-33.

<sup>108</sup> *Tummino v. Torti*, 603 F.Supp.2d 519 (E.D.N.Y. 2009).



scientific uncertainty when there is none or when it is normally not grounds for disapproval of the application.

In fact, when we consider that the FDA does not treat all applications equally, the call for additional scientific evidence in politically sensitive cases becomes more palatable. As the GAO noted in its report, the FDA already changes protocol to involve high-level management when directors of the reviewing offices would normally make the decision in highly visible and sensitive cases, such as the approval of thalidomide for the treatment of leprosy in 1998 and the approval of mifepristone for the termination of early pregnancy in 2000 (although these were not OTC switch applications)<sup>109</sup>. In fact, the Commissioner and the Director of CDER often become involved in cases when they have far-reaching impact, or in cases in which management has a different view or disagrees with the review staff, or any time when the management needs to make sure it is comfortable with the review staff's final decision<sup>110</sup>. It is hard to imagine that the management changes protocol for these sensitive cases for any other reason besides that sensitive cases require that the FDA produce a strongly reasoned and justified decision, no matter what the course.

Similarly, in sensitive cases the FDA wants to make sure that the scientific evidence behind its decision-making is impeccable. It would not be arbitrary for the FDA to admit that the political pressure means that it needs more information than usual to defend its decision-making. In fact, allowing the FDA to cite political influences as the reasons for requiring more information would prevent it from suggesting scientific uncertainty when there is little to none.

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<sup>109</sup> GAO report at 20-21.

<sup>110</sup> GAO report at 20.

Judges are good at evaluating policy and not as good at evaluating science. Administrative law seems structured to keep judges from evaluating what they are good at evaluating and confine them to what they are poor at evaluating. While we don't want judges, as unelected officials, to strike down policies left and right, they already, to a certain extent, do while evaluating administrative agency decision-making<sup>111</sup>. As Cass Sunstein and Thomas Miles found while analyzing Supreme Court and circuit court of appeals decisions that reviewing agency interpretations of the law, the application of the *Chevron* framework and whether the judges validate the agency determinations depends a great deal on the judges' political and ideological convictions<sup>112</sup>. However, requiring them on the face to evaluate scientific evidence creates the possibility that the courts or the agencies will manipulate the scientific evidence to suggest uncertainty when there is none. This is directly tied into the problem of increasing political influences that agencies cannot be honest and open about.

A better policy would be to have the courts ought to focus on something they have better knowledge of—the interplay between the policy motivations and scientific evidence. This would require still some evaluation of the scientific evidence underlying agency decisions. However, the inquiry would not end at the certainty of the evidence. Instead, courts should look at scientific evidence as one piece of the puzzle. They should also look at the political rationales, if there are any, behind agency decisions. This would reduce the pressure placed on scientific evidence to support agency decision-making. In the case of *Tummino*, it would allow the court to evaluate the political influence on the

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<sup>111</sup> See Thomas J. Miles and Cass R. Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of Chevron*, 73 U. CHI. L. REV. 823 (2006)

<sup>112</sup> *Id.* at 825-27.

treatment of Plan B within the actual context of the modern administrative state—one that is closely tied to the President and his agenda. Obvious political influences should not be treated as a shocking and disgraceful exception but acknowledged to occur frequently and to even be a positive motivation, as in the case of the teen smoking regulations.

## Conclusion

The *Tummino* case is a good example of the divergence between the realities of the administrative state and the jurisprudence that governs it. The facts of *Tummino* show an FDA whose decisions were clearly influenced by the agenda of the Bush White House. As a result, there was enough suggestion of bad faith for the magistrate judge to justify widening the scope of discovery to go beyond the administrative record and to require higher level FDA officials to testify. In addition, the political influence in the *Tummino* case caused the judge to hold that the FDA had acted arbitrarily and capriciously when deciding the status of Plan B and to remand the decision to an FDA now controlled by appointees of the Obama White House. Without the Bush White House agenda it is unlikely that either the magistrate judge or the district court judge would have found indicates of bad faith upon the part of the FDA.

However, it is not sensible to punish the FDA for something that is quite usual in the course of modern agency decision-making. Since Reagan's presidency, Presidents have been working to tie administrative agencies, such as the FDA, closer to their own political agendas. This can take the form of encouraging deregulation or it can be used to

urge additional regulation, as in the Clinton years. Another distinction in Presidential influence on agencies is the distinction between pushing an agency to be more sensitive to the priorities of the particular administration and preventing the agency from properly carrying out its mandate and purpose.

A more sensitive judicial regime would allow agencies to admit their political influences and motivations. This would allow agencies such as the FDA to be honest about the influence a President may have in setting their priorities and agendas. In *Tummino* it would have perhaps allowed the FDA to acknowledge that the Bush White House placed pressure on it to be at least very thorough in its investigation of an OTC switch for Plan B. While this new judicial regime would not excuse mandate hijacking, it would give more flexibility to reflect the increasing close relationship between administrative agencies' agendas and the agendas of the White House.