RECENT CASES

ADMINISTRATIVE LAW — FOOD AND DRUG LAW — EASTERN DISTRICT OF NEW YORK REJECTS FDA LIMITATIONS ON PLAN B EMERGENCY CONTRACEPTION AS ARBITRARY AND CAPRICIOUS. — *Tummino v. Hamburg*, 936 F. Supp. 2d 162 (E.D.N.Y. 2013).

Plan B and Plan B One-Step are emergency contraceptives that a woman can take in the days following intercourse to reduce the risk of pregnancy.[1] Plan B was approved for U.S. prescription use in 1999; the similar but more advanced Plan B One-Step followed in 2009.[2] In December 2011, Department of Health and Human Services (HHS) Secretary Kathleen Sebelius directed the Food and Drug Administration (FDA) to deny a Supplemental New Drug Application (SNDA) seeking approval for Plan B One-Step as an over-the-counter (OTC) drug without age restrictions.[3] The FDA complied with the directive.[4] Shortly after rejecting the SNDA for Plan B One-Step, the FDA also denied a citizen petition that had similarly sought OTC availability of Plan B for women of all ages.[5] Recently, in *Tummino v. Hamburg*,[6] Judge Korman of the Eastern District of New York ruled that the FDA's denial of the citizen petition was an arbitrary and capricious deviation from FDA policy.[7] One basis for this ruling was the Secretary's deviation from a convention of noninterference with the FDA drug approval process.[8] Although Judge Korman's ultimate conclusion may be adequately supported by the other bases he articulated, he should not have treated a deviation from mere convention as a deviation from formal policy.

In 1999, the FDA approved Plan B for prescription use only.[9] The *Tummino* plaintiffs[10] brought suit in 2005 challenging FDA denial of a

---

1 *Tummino v. Hamburg* (*Tummino II*), 936 F. Supp. 2d 162, 164 (E.D.N.Y. 2013).

2 *Id.* The two pills contain the same dose of the same active ingredient, but Plan B divides this dose between two pills, while Plan B One-Step, as the name suggests, is only one pill. *Id.*

3 *See* Memorandum from Kathleen Sebelius, Sec'y of Health & Human Servs., to Margaret A. Hamburg, Comm'r of Food & Drugs 2 (Dec. 7, 2011), *available at* http://www.hhs.gov/news/press/2011pres/12/20111207a.pdf [hereinafter Sebelius Memorandum].

4 *Tummino II*, 936 F. Supp. 2d at 187.

5 Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, FDA, to Bonnie Scott Jones, Ctr. for Reproductive Rights 3 (Dec. 12, 2011), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM283545.pdf [hereinafter Citizen Petition Denial Letter].

6 936 F. Supp. 2d 162.

7 *Id.* at 197.

8 *Id.* at 170.

9 *Id.* at 164.

10 The plaintiffs consisted of a group of "organizations and individuals concerned with women's health, as well as minors and their parents." *Id.* at 165.

citizen petition[11] seeking OTC access to Plan B regardless of age.[12] In 2006, the FDA approved the medication for OTC use in adults, but maintained the requirement of a prescription for adolescents seventeen and younger.[13] The plaintiffs continued to press their argument that the denial of the citizen petition was arbitrary and capricious, and that Plan B should be made available regardless of age.[14] Further, they argued that a remand was insufficient because "the agency has acted so improperly and in such bad faith that it cannot be trusted to conduct a fair assessment of the scientific evidence"; accordingly, they requested an order mandating OTC access.[15] In 2009, Judge Korman ruled that the denial of the citizen petition was arbitrary and capricious, but he concluded that remand was the appropriate remedy.[16] Although he suggested that the FDA's process had been impermissibly politicized and conducted in bad faith,[17] Judge Korman reasoned that the remand might be fruitful in light of President Obama's then-recent appointment of a new FDA Commissioner.[18] He therefore vacated the denial of the citizen petition and remanded the petition to the FDA.[19]

Shortly after the remand, the FDA approved Plan B One-Step subject to the same restrictions as Plan B: namely, it could be sold to adolescents sixteen and younger only with a prescription.[20] The manufacturer of Plan B then filed an SNDA that sought OTC access to Plan B One-Step for women of all ages.[21] In December 2011, the FDA, through Commissioner Margaret Hamburg, announced that it was prepared to approve the SNDA because the Center for Drug Evaluation and Research had determined that the benefits of nonprescription

---

[11] The "citizen petition" is the FDA's idiosyncratic way of fulfilling the Administrative Procedure Act's mandate that government agencies "shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e) (2012). Within 180 days of receiving each petition, the FDA Commissioner is required to issue a response that approves, denies, or tentatively responds to the petition's request. 21 C.F.R. § 10.30(e)(2) (2013).

[12] *Tummino II*, 936 F. Supp. 2d at 165.

[13] *Id.* at 164.

[14] *Id.* at 166.

[15] Combined Reply Memorandum in Further Support of Plaintiffs' Motion for Summary Judgment and Memorandum of Law in Opposition to Defendants' Motion to Strike at 9, Tummino v. Torti (*Tummino I*), 603 F. Supp. 2d 519 (E.D.N.Y. 2009) (No. 05-CV-366).

[16] *See Tummino I*, 603 F. Supp. 2d at 524.

[17] *See id.* at 548–49 ("The FDA simply has not come forward with an adequate explanation, nor has it presented any evidence to rebut plaintiffs' showing that it acted in bad faith and in response to political pressure." *Id.* at 548.).

[18] *Id.* at 549.

[19] *Id.* at 550. The plaintiffs did win outright on one issue: the availability of Plan B to seventeen-year-old women without a prescription. Judge Korman found that the scientific evidence in the record did not support a distinction between seventeen- and eighteen-year-olds and ordered the FDA to extend Plan B's OTC availability to seventeen-year-olds. *Id.*

[20] *Tummino II*, 936 F. Supp. 2d at 164.

[21] *Id.* at 166.

availability outweighed the risks.[22] However, HHS Secretary Sebelius, "invoking her authority under the Federal Food, Drug, and Cosmetic Act to execute its provisions," ordered Commissioner Hamburg to deny the SNDA.[23] In her memorandum ordering the denial, Secretary Sebelius registered her concern about the "commonly understood" cognitive gulf between the youngest menarcheal girls and the class of females aged seventeen and over for whom the drug was already available OTC.[24]

Secretary Sebelius's directive was in one sense unprecedented: although Congress had explicitly vested responsibility for providing guidance to the FDA in the HHS Secretary,[25] an "unbroken practice of deference to the FDA" had previously governed HHS policy with regard to FDA rulemaking.[26] Nevertheless, the FDA acquiesced, and the plaintiffs' citizen petition — which had been pending for three years — was denied five days later.[27] The decision quickly proved controversial: commentators in the medical community alleged that Secretary Sebelius's directive violated longstanding HHS convention and was "based on politics rather than science."[28]

The plaintiffs filed suit again in the Eastern District of New York, alleging that the FDA denial of the Plan B One-Step SNDA was arbitrary and capricious and that the subsequent denial of the citizen petition was therefore arbitrary and capricious.[29] The plaintiffs moved for summary judgment, asking that the citizen petition be granted and that the FDA be required to make Plan B available OTC without age restrictions.[30] The FDA cross-moved for summary judgment, claiming that the decision to reject the citizen petition was justified: there was "no set [FDA] policy of extrapolating data from adults to pediatric

---

[22] *Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step*, U.S. FOOD & DRUG ADMIN. (Dec. 7, 2011), http://www.fda.gov/NewsEvents/Newsroom/ucm282805.htm.

[23] *Id.*

[24] Sebelius Memorandum, *supra* note 3, at 1.

[25] *See* 21 U.S.C. § 393(d)(2)(A) (2012).

[26] Adrian Vermeule, *Conventions of Agency Independence*, 113 COLUM. L. REV. 1163, 1208 (2013).

[27] *Tummino II*, 936 F. Supp. 2d at 169.

[28] Alastair J.J. Wood et al., Perspective, *The Politics of Emergency Contraception*, 366 NEW ENG. J. MED. 101, 102 (2012); *see also Tummino II*, 936 F. Supp. 2d at 170 ("The motivation for the Secretary's action was obviously political. 'It was the first time a cabinet member had ever publicly countermanded a determination by the F.D.A., the agency charged with ensuring the safety of foods and medicines.'" (quoting Gardiner Harris, *White House and the FDA Often at Odds*, N.Y. TIMES, Apr. 3, 2012, at A1)). Both Plan B and Plan B One-Step are "among the safest drugs sold over-the-counter." *Tummino II*, 936 F. Supp. 2d at 168.

[29] First Amended Supplemental Complaint at 16, 19, *Tummino II*, 936 F. Supp. 2d 162 (No. 12-CV-763).

[30] *Tummino II*, 936 F. Supp. 2d at 169.

populations," and there was no direct evidence that the drug was safe for use by the youngest menarcheal girls.[31]

Judge Korman held that the FDA had departed from established policies and practices without explanation and that these departures were therefore arbitrary, capricious, and unreasonable.[32] Mindful that he had jurisdiction to review the denial only of the citizen petition and not of the SNDA,[33] Judge Korman nevertheless analyzed both administrative processes, writing: "The Citizen Petition Denial Letter, which came five days after the denial of the Plan B One-Step SNDA, was clearly prompted by the Secretary's action, despite the FDA's fanciful effort to make it appear that it undertook an independent review of the Citizen Petition."[34] He found that "Secretary Sebelius's directive to the FDA to reject the Plan B One-Step SNDA forced the agency to ride roughshod over the policies and practices that it has consistently applied in considering applications for switches in drug status to over-the-counter availability."[35] Judge Korman invoked *INS v. Yang*,[36] which provides that if an agency "announces and follows — by rule or by settled course of adjudication — a general policy by which its exercise of discretion will be governed, an irrational departure from that policy (as opposed to an avowed alteration of it)" may be overturned as arbitrary, capricious, or an abuse of discretion under the Administrative Procedure Act.[37]

Under that rubric, Judge Korman found first that the Secretary's intervention itself was "politically motivated, scientifically unjustified, and contrary to [HHS] precedent [of nonintervention],"[38] noting that the Secretary's arguments were "so unpersuasive as to call into question her good faith."[39] Second, despite "ample evidence" that Plan B One-Step was safe and effective for older adolescents, the Secretary's

---

[31] *Id.*

[32] *See id.* at 169–70, 187.

[33] "The Plan B One-Step sponsor has not taken an appeal to the Court of Appeals for the District of Columbia, which would have jurisdiction to review it." *Id.* at 184 (citing 21 U.S.C. § 355(h) (2012)).

[34] *Id.* at 192. Judge Korman justified casting the lens of judicial scrutiny upon the SNDA for two reasons: First, the Secretary's memorandum left the FDA with "no possible basis on which to approve the Citizen Petition." *Id.* at 184. Second, to ignore the propriety or lack thereof of the Secretary's actions would strip the court of the capacity to engage in meaningful judicial review. *Id.*

[35] *Id.* at 169.

[36] 519 U.S. 26 (1996).

[37] *Tummino II*, 936 F. Supp. 2d at 169 (quoting *Yang*, 519 U.S. at 32); *see also* Office of Commc'n of the United Church of Christ v. FCC, 560 F.2d 529, 532 (2d Cir. 1977) ("[C]hanges in policy must be rationally and explicitly justified . . . .").

[38] *Tummino II*, 936 F. Supp. 2d at 192. Secretary Sebelius "overruled the FDA in an area which Congress entrusted primarily to the FDA and which fell within the scope of the authority that the Secretary expressly delegated to the Commissioner." *Id.* at 170 (citation omitted) (citing 2 FDA STAFF MANUAL GUIDES § 1410.10 (2012)).

[39] *Id.* at 171.

memorandum did not limit the scope of the denial to girls age twelve and younger.[40] Judge Korman listed a number of other deviations from FDA practice, including a failure to follow protocol in extrapolating data from studies of older populations to make judgments regarding younger populations,[41] a failure to rely on labeling to mitigate risk of the drug's misuse,[42] and an unusually stringent point-of-sale restriction.[43] The court ordered the FDA to grant the citizen petition and to make Plan B and Plan B One-Step available without prescription or age restriction within thirty days.[44]

The *Tummino* court levied a number of critiques in its lengthy opinion. Nevertheless, the opinion's first and most central critique was that the Secretary's intervention was *itself* an unacceptable departure from a "general policy" established by the agency. This inquiry is not only discordant with the existing jurisprudential framework for evaluating agency deviations from policy, but it may also impermissibly aggrandize the role of the judiciary by encroaching on congressional and executive powers.

Although Judge Korman was careful to note that he had no actual authority to review the Plan B One-Step SNDA denial,[45] his opinion nonetheless depended on his reading of the history of the SNDA petition and denial. In particular, the opinion adopted a three-step analysis that specifically predicated the fate of the citizen petition on the court's evaluation of Secretary Sebelius's directive: first evaluating the internal reasoning and logic of Secretary Sebelius's memorandum, subsequently applying that logic to the SNDA rejection, and finally examining that rationale as a predicate for the rejection of the citizen peti-

---

[40] *Id.* at 174. The Assistant U.S. Attorney representing Commissioner Hamburg indicated that the Commissioner was bound by Secretary Sebelius's memorandum and thus was unable to independently assess the question of whether the Plan B One-Step safety studies were inadequate with respect to women between the ages of twelve and seventeen. *See id.*

[41] *See id.* at 175–79. He found this error particularly egregious in light of the conclusions reached at a December 16, 2003, meeting of the "Advisory Committee" — a group of experts empaneled by the FDA to provide a recommendation on the Plan B SNDA. The Advisory Committee strongly favored extrapolating safety data from older populations to pediatric populations. *See id.* at 176.

[42] *Id.* at 179–80. "[A]ge-based labeling restrictions have 'been [the FDA's] long-standing way of [ ] instructing consumers whether they should or should not use a product in a young age group, and [the Plan B marketing regime is] a substantial deviation from that practice.'" *Id.* at 173 (second, third, and fourth alterations in original) (quoting Jenkins Deposition at 113:7–16, *Tummino I*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009) (No. 05-CV-366)).

[43] *See id.* at 180–84.

[44] *Id.* at 197. The FDA initially filed an appeal and moved to stay the order, Tummino v. Hamburg, No. 13-1690, 2013 WL 2435370, at *1 (2d Cir. June 5, 2013), but shortly thereafter it decided to comply with the order and submitted a plan for doing so, Tummino v. Hamburg, No. 12-CV-763, 2013 WL 2631163, at *1 (E.D.N.Y. June 12, 2013). Judge Korman approved the plan, ending the litigation. *Id.* at *2.

[45] *See Tummino II*, 936 F. Supp. 2d at 184.

tion. This maneuver was critical because, as Judge Korman reasoned, "it is not possible to exercise meaningful judicial review over the denial of the Citizen Petition without considering the propriety of the Secretary's actions regarding the Plan B One-Step SNDA."[46] Indeed, the opinion openly announced that the mere existence of the memorandum was central to its analysis: in detailing the "unexplained departures" that rendered the denial arbitrary and capricious, Judge Korman put the Secretary's "[u]nprecedented [i]ntervention" front and center, describing it as "[p]erhaps the most significant departure from agency practice" in this case.[47]

However, the court's justification for this view may not withstand scrutiny. In one sense, it is easy to imagine why Judge Korman could have viewed the HHS custom of noninterference with FDA drug approval as a "general policy." HHS, after all, had formally assigned drug-approval authority to the FDA.[48] Moreover, there is arguably good reason for HHS to stay out of the FDA's drug approval process: without such a policy, "[a] radical pro-business [HHS] secretary could . . . bypass the clinical trial system and the F.D.A. approval process and decide to approve a drug. A different secretary, one distrustful of the pharmaceutical industry, could stop a drug despite strong scientific support behind it."[49]

But even though noninterference may be normatively preferable, treating a convention of HHS deference to FDA decisionmaking as a "policy" for the purposes of hard look review is open to question. First, treating a convention as a policy does not fit within the extant corpus of *Yang* jurisprudence. Every past application of *Yang* dealt either with a substantive policy or with an explicitly articulated procedural policy; never has *Yang* been applied to unarticulated conventions of agency procedure. *Yang* itself concerned factors the Attorney General may take into consideration when deciding whether to waive deportation under the Immigration and Nationality Act.[50] All other circuit-level cases operate in a similarly substantive realm.[51]

---

[46] *Id.* at 184.

[47] *Id.* at 170.

[48] 2 FDA STAFF MANUAL GUIDES, *supra* note 38, § 1410.10.

[49] Daniel Carpenter, Op-Ed., *Free the F.D.A.*, N.Y. TIMES, Dec. 14, 2011, at A35, *available at* http://www.nytimes.com/2011/12/14/opinion/free-the-fda.html.

[50] INS v. Yang, 519 U.S. 26, 27 (1996).

[51] *See, e.g.*, Samuels v. Chertoff, 550 F.3d 252 (2d Cir. 2008) (considering the consistency of a Board of Immigration Appeals regulation with past Board practice); Venetian Casino Resort L.L.C. v. EEOC, 530 F.3d 925 (D.C. Cir. 2008) (considering the consistency of the Equal Employment Opportunity Commission policy on disclosure of confidential information); Mid-Continent Area Power Pool v. FERC, 305 F.3d 780 (8th Cir. 2002) (finding that a Federal Energy Regulatory Commission order did not irrationally depart from the Commission's prior explicitly enumerated policies on transmission service agreements); Harrington v. Chao, 280 F.3d 50, 58–59 (1st Cir. 2002) (remanding for further inquiry as to whether the Secretary of Labor provided ade-

Second, *Tummino* threatens to encroach upon the executive agency's prerogative — to paraphrase the hoary expression — to change its mind. It is uncontroversial that agencies must comply with their own formal regulations.[52] But *Tummino* conflates two distinct sources of authority: formal regulations and mere conventions. Conventions are distinct from law insofar as they "are generated, identified, and enforced through decentralized processes."[53] And while a court may choose to wade into the murky water of measuring how binding an agency's regulatory history may be on subsequent agency action,[54] there is strong authority that "courts may not invoke freestanding conventions to override written legal rules."[55] In some cases, "courts may indirectly *recognize* and *incorporate* conventions in the course of performing their usual duty of interpreting written laws."[56] But that is not what happened in *Tummino*, where there was no ambiguity in the statute granting HHS jurisdiction on this matter. Judge Korman therefore did not engage in statutory exegesis; the impermissibility of the Secretary's intervention — as a formal matter, separate from the content of the memorandum — was predicated solely on the lack of precedent for reassumption of delegated authority.[57] In condemning the Secretary's intervention, Judge Korman inappropriately elevated mere convention to a source of authority that superseded even written statute.

Third, because the focus on conventions led the court to ignore written law, the *Tummino* opinion threatens to encroach on the constitutional authority of the legislative branch. Judge Korman's holding essentially rejects the unambiguous language of the authorizing stat-

---

quate explanation for failing to bring Labor-Management Reporting and Disclosure Act enforcement action in contravention of past policy); Bd. of Trs. of Knox Cnty. Hosp. v. Shalala, 135 F.3d 493, 501–02 (7th Cir. 1998) (finding that a hospital had not sufficiently demonstrated a history of HHS past practice with regard to classifying hospitals as rural referral centers to qualify for *Yang* scrutiny); *see also* Sherwood v. Tenn. Valley Auth., 925 F. Supp. 2d 906 (E.D. Tenn. 2013) (concerning the power of the Tennessee Valley Authority (TVA) to require property owners to remove trees that exceed fifteen feet in height under transmission line easements in contravention of past practice under the TVA Act). These opinions share the same underlying framework: they all consider the unexplained departure from policies that were, at one time, given the formal imprimatur of the agency.

52 Thomas W. Merrill, *The* Accardi *Principle*, 74 GEO. WASH. L. REV. 569, 569 (2006).

53 Vermeule, *supra* note 26, at 1182.

54 *See* Joshua I. Schwartz, *The Irresistible Force Meets the Immovable Object: Estoppel Remedies for an Agency's Violation of Its Own Regulations or Other Misconduct*, 44 ADMIN. L. REV. 653, 655 (1992) (noting that the legal landscape is unsettled on both the rationale and scope of the principle that agencies are bound by their own regulatory actions).

55 Vermeule, *supra* note 26, at 1183.

56 *Id.*; *see also* GEOFFREY MARSHALL, CONSTITUTIONAL CONVENTIONS 15 (1984) ("A distinction can be seen . . . between using conventions [to clarify the law] and directly applying them or enforcing them as law.").

57 *See Tummino II*, 936 F. Supp. 2d at 169–70.

ute[58] by criticizing HHS's reallocation of statutory power from the FDA back to itself as "[u]nprecedented."[59] In essence, Judge Korman decried as an unacceptable departure the FDA's acquiescence to the directive of its superior — a statutory imperative. This approach could threaten to elevate judges' disagreements with similarly "unprecedented" actions into a rationale for denying a department's right to reassume its previously delegated authority.[60] But, as *United States v. Mead Corp.*[61] held, "a reviewing court has no business rejecting an agency's exercise of its generally conferred authority to resolve a particular statutory ambiguity simply because the agency's chosen resolution seems unwise."[62]

As a practical matter, Judge Korman had a multitude of other justifications for his ultimate holding that the FDA acted arbitrarily and capriciously in denying the citizen petition. *Tummino* could have been premised strictly, for instance, on the contention that the Sebelius memorandum was so substantively inadequate that it resulted in an arbitrary and capricious outcome.[63] But in utilizing *Yang* to support the proposition that HHS may not have unfettered ability to reclaim its statutory authority to direct FDA actions, *Tummino* not only runs afoul of *Yang*'s jurisprudential framework, but may also improperly expand judicial power by encroaching on executive agencies and on Congress. *Tummino* therefore risks undermining legitimate parent-agency oversight by constricting the extent to which the original holders of statutory authority may exercise that authority. Instead of risking this outcome, Judge Korman might have narrowed the number of grounds upon which his conclusion rested.

---

[58] *See* 21 U.S.C. § 393(d)(2)(A) (2012) (establishing that the Secretary, through the Commissioner, is responsible for execution of the statutory scheme).

[59] *Tummino II*, 936 F. Supp. 2d at 170; *see id.* ("She overruled the FDA in an area which Congress entrusted primarily to the FDA and which fell within the scope of the authority that the Secretary expressly delegated to the Commissioner." (citation omitted) (citing 21 U.S.C. § 393(d)(2))). There is an odd tension between the claims that Congress entrusted authority "primarily" to the FDA and that the Secretary had delegated said authority to the FDA. A review of the statutory scheme reveals that 21 U.S.C. § 393(d)(2) simply empowers the Secretary to work through the FDA Commissioner to give effect to the Secretary's formally granted powers.

[60] Even commentators who praised Judge Korman's decision noted that *Tummino* was unusual in its assertive judicial interference with agency decisionmaking. *See* Pam Belluck, *Judge in Contraceptives Case: Tough, but Hard to Pigeonhole*, N.Y. TIMES, June 15, 2013, at A1.

[61] 533 U.S. 218 (2001).

[62] *Id.* at 229.

[63] Indeed, Judge Korman spent several pages deconstructing the Sebelius memorandum sentence by sentence for procedural, logical, and scientific defects. *See Tummino II*, 936 F. Supp. 2d at 171–74.