**No. 13-1690**

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE SECOND CIRCUIT**

ANNIE TUMMINO, et al.,
Plaintiffs-Appellees,

v.

MARGARET HAMBURG, Commissioner of Food and Drugs, et al.,
Defendants-Appellants

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

# PLAINTIFFS-APPELLEES' OPPOSITION TO DEFENDANTS-APPELLANTS' MOTION FOR A STAY PENDING APPEAL

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## I. Introduction

This case involves an unprecedented pattern of agency misconduct regarding a Citizen Petition seeking unrestricted access to emergency contraception. The result has been unreasonable delay and ongoing harm to women of all ages due to unnecessary restrictions on access to a product that the Food and Drug Administration ("FDA") itself has deemed safe and appropriate for unrestricted over-the-counter distribution.

A stay would cause substantial injury to Plaintiffs, and countless women, by leaving in place numerous "practical obstructions" which have the effect of depriving women of timely access to emergency contraception. *Tummino v. Hamburg*, No. 12-CV-763 (ERK)(VVP), 2013 WL 1921414 (May 10, 2013) ("*Stay Order*"), Defendants' Addendum ("Df. Add.") 210-11. Additionally, a stay will perpetuate – for months or years – the "administrative agency filibuster," that has resulted in unconscionable delay throughout these proceedings. *Tummino v. Hamburg*, No. 12-CV-763 (ERK)(VVP), 2013 WL 1348656 (Apr. 5, 2013) ("*Tummino II*"), Df. Add. 183.

Significantly, Defendants do not challenge the District Court's findings regarding the safety and efficacy of unrestricted over-the-counter access to levonorgesterel-based emergency contraception. Nor do they challenge the Court's well supported factual and legal findings that over a 12 year period, Defendants acted in an arbitrary and capricious manner that was "scientifically unjustified" with respect to the switch of emergency contraception from prescription to over-the-counter

status by allowing improper political influence to taint the process and through significant departures from agency policy and practice. *Id.* at 171.

Defendants base their request for a stay solely on a challenge to the propriety of the remedy ordered by the District Court, which "remanded to the FDA with the instruction to grant the Citizen Petition and make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days." *Id.* at 181. That remedy was appropriate based on the Court's findings of bad faith and purposeful delay. Indeed, "[t]his case presents the kind of 'rare circumstances' where a remand to the agency is not only unnecessary but would constitute an abuse of discretion." *Stay Order*, Df. Add. 218. Accordingly, Defendants' request for a stay should be denied.

## II. Facts and Proceedings

The findings in the District Court's opinions reveal a different narrative than that portrayed by Defendants. Over the last 12 years, Defendants have engaged in a pattern of arbitrary and capricious conduct ultimately culminating in the denial of the Citizen Petition. Critically, for over a decade, the FDA has had sufficient scientific evidence to support unrestricted over-the-counter approval of levonorgestrel-based emergency contraception for all ages and without any point-of-sale requirements.[1] *See*

[1] The products involve ingestion of 1.5 mg of levonorgestrel. The original product, Plan B, contains two doses of 0.75 mg taken 12 hours apart. *Tummino II*, Df. Add. 125-26. Plan B is no longer marketed, but generics of the product are sold. *Id.*

*Tummino II*, Df. Add. 129 (the FDA's Center for Drug Evaluation and Research has concluded that "Plan B One-Step should be approved for nonprescription use for all females of child-bearing potential") (internal quotation marks omitted); *Tummino v. Torti* (*"Tummino I"*), 603 F. Supp. 2d 519, 528-34 (E.D.N.Y. 2009)[2] (citing FDA 2003 advisory committee vote 23-4 to recommend "Plan B for over-the-counter status without age or point-of-sale restrictions," unanimous vote that "Plan B is safe for use in a non-prescription setting," and history of FDA review staff scientific findings to approve over-the-counter access without restriction).

The effort to bring these products over-the-counter began in 2001, when Plaintiff Association of Reproductive Health Professionals and others filed a Citizen Petition asking the FDA to switch Plan B "and any new drug eligible for filing an abbreviated new drug application because of its equivalence to . . . Plan B" from prescription only to over-the-counter status. Citizen Petition (Feb. 14, 2001), Df. Add. 2; *Tummino I*, 603 F. Supp. 2d at 526. For most of the time that the Citizen Petition was pending, the FDA considered various requests from the manufacturer of

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at 125. (Two-pill products herein referred to as "Plan B" unless otherwise indicated.) During this litigation, Plan B One-Step, a single 1.5 mg pill, was approved. Unless otherwise indicated, references to Plan B One-Step refer only to that product.

[2] Citations to *Tummino I* are to the published version of the opinion in the Federal Supplement. For ease of reference, however, a copy of the opinion is included in the Plaintiffs' Addendum ("Pl. Add.") 1-30. Additionally, by order dated March 6, 2013 (the "Mar. 6, 2013 Order"), the District Court amended *Tummino I*. Mar. 6, 2013 Order, Pl. Add. 31-32. Unless otherwise indicated, citations to *Tummino I* refer to sections of the opinion left unaltered by the Mar. 6, 2013 Order.

Plan B and subsequently, Plan B One-Step, known as supplemental new drug applications ("SNDAs), to put their products over-the-counter. Throughout these proceedings, Defendants "inextricably tied" the consideration of the Citizen Petition with the SNDAs. *See Tummino I*, at 523, 543; *see also Tummino II*, Df. Add. 164, 172.

In 2005, after years of inaction, Plaintiffs brought this litigation to compel the FDA to act on the Citizen Petition. The lawsuit uncovered numerous examples of significant departures from FDA policies and procedures as to both the Citizen Petition and the SNDAs. For example, despite the fact that the FDA had helped craft the actual use[3] study performed by the Plan B sponsor in connection with its first SNDA, the FDA subsequently denied that application largely on the grounds that the study was inadequate. *Tummino I,* at 526, 532. The evidence also showed that the decision to deny the Plan B SNDA was made by the Commissioner "*before* FDA staff had completed their scientific reviews of the data." *Id.* at 530.

[3] An actual use study simulates over-the-counter use of a product to predict if a drug will be used correctly by the target population. *See* Decl. of Cynthia C. Harper, Ph.D. in Support of Pls.' Mot. for Prelim. Inj. and Summ. J. (Feb. 16, 2012) ¶ 5, Pl. Add. 70-71. The FDA typically does not require subjects of any particular age to be included in actual use studies. *Id.* ¶¶ 9, 20, Pl. Add. 72, 76. Rather, "the Agency has a long history of extrapolating findings from clinical trials in older patients to adolescents." *Tummino I*, 603 F. Supp. 2d at 527 (internal quotation marks omitted). The FDA has not articulated any basis for refusing to extrapolate in the emergency contraception context. *Tummino II*, Df. Add. 143-44 ("The FDA's failure to extrapolate involves . . . perhaps the most significant unexplained departure from FDA practice ordered by the Secretary.").

The record is clear that from early on the process was tainted by improper political interference which "significantly affect[ed]" FDA's decision-making on the over-the-counter switch, including "pressure coming from the White House." *Id.* at 529. In June of 2006, the FDA denied the Citizen Petition. *Id.* at 536.

In August 2006, the FDA approved a SNDA to make Plan B available over-the-counter for consumers 18 and older, creating an unprecedented dual-tier marketing regime under which women needed either government-issued photo-identification or a prescription to access the product. *Id.* at 536. "At the FDA's insistence, the sponsor agreed to . . . to distribute the product only to licensed pharmacists, and to direct pharmacies to keep Plan B behind-the-counter." *Id.* This decision was one among many "suspect" moves. *Id.* at 523, 546 ("[T]he evidence strongly suggests that even the decision to permit the OTC [over-the-counter] sale of Plan B to women over the age of 18 was made solely to facilitate the confirmation of Dr. von Eschenbach as Commissioner of the FDA.").

Based on this record, in 2009, the District Court concluded that the FDA's denial of the Citizen Petition was "arbitrary and capricious" and "not the result of reasoned and good faith agency decision-making." *Id.* at 523. The Court remanded to the agency to reconsider the Citizen Petition, but directed the FDA "to make Plan B available to 17 year olds without a prescription," finding that "[a] remand would serve no purpose" because the exclusion of 17 year olds "runs counter to the evidence

and is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* at 549-50 (internal quotation marks omitted).

On remand, Defendants engaged in the same bad faith that had preceded the District Court's 2009 decision. *Tummino II*, Df. Add. 128. For over two and a half years, the FDA refused to take any steps to reconsider the Citizen Petition. *Id.* Instead, the agency informed Plaintiffs that it believed that "the best way" to comply with the order was "to review a supplemental new drug application expected to be submitted by the sponsor of [Plan B One-Step]" for over-the-counter access for all ages. *See* Letter from Frank Amanat to Suzanne Novak (Aug. 13, 2010), Pl. Add. 33. In November 2010, Plaintiffs filed a motion to hold Defendants in contempt.

In December of 2011, the FDA recommended approval of the Plan B One-Step SNDA because "science-based evidence" established that the drug is "safe and effective and should be approved for nonprescription use for all females of child-bearing potential." *Tummino II*, Df. Add. 129 (quoting Statement from FDA Commissioner Margaret Hamburg, M.D., on Plan B One-Step (Dec. 7, 2011), Pl. Add. 36). In a wholly unprecedented move, Defendant Sebelius overruled this decision, for reasons that were "obviously political." *Tummino II*, Df. Add. 134-35.

The denial of the Citizen Petition was inevitable after Defendant Sebelius ordered the FDA to reject the SNDA because the data that the Secretary (unreasonably) found lacking in the SNDA was also lacking in the Citizen Petition. *Tummino II*, Df. Add. 133; *Stay Order*, Df. Add. 205. The District Court additionally

found the FDA's denial of the Citizen Petition was "unsound" based on numerous significant departures from agency policies and failures to acknowledge and consider relevant data within its possession. *Tummino II*, Df. Add. 164-72.

These facts led the Court to conclude that Defendants had, for a second time, denied the Citizen Petition for reasons that were arbitrary and capricious and politically motivated. *Id.* at 180. Accordingly, the Court remanded with directions that Defendants, "grant the Citizen Petition and make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days." *Id.* at 181-82.

Just prior to the expiration of the Court's 30 day deadline, the FDA announced that it had approved an amended SNDA allowing Plan B One-Step to be sold on the shelf in retail locations with an on-site pharmacy, without a prescription, to those 15 and older with proof of age. *Stay Order,* Df. Add. at 208-09. As a result, Plan B One-Step will not be available by prescription to anyone. All other levonorgestrel products remain subject to the restrictions imposed on Plan B – they can only be sold behind-the-counter at pharmacies, to women 17 and older with government-issued photo identification and to all others only by prescription. *Id.* at 215.

## III. Argument

For Defendants to receive a stay, four factors must be considered:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially

> injure the other parties interested in the proceeding; and (4) where the public interest lies.

*In re World Trade Center Disaster Site Litigation*, 503 F.3d 167, 170 (2d Cir. 2007). Here, Defendants have failed to establish any of these factors.

### A. Plaintiffs Will Be Substantially Injured By A Stay

A woman's inability to take emergency contraception within 24-hours of having unprotected sex can have life-altering consequences: unintended or unwanted pregnancy. Defendants do not and cannot refute this point. It also cannot be credibly contested that the scientifically unjustified restrictions on emergency contraception that are currently in place prevent women from accessing emergency contraception during the narrow window within which it is effective. *See Tummino II*, Df. Add. 126 (emergency contraception is most effective when taken immediately after intercourse and preferably no later than 24 hours later); *id.* at 131-32 (discussing impact of behind-the-counter regime). The result of these baseless restrictions has been to "deprive the overwhelming majority of women of their right to obtain contraceptives." *Id.*

Even after the eleventh hour approval of the Plan B One-Step amended SNDA, all women must show government-issued identification, thereby revealing their identity and address, to obtain emergency contraception. This requirement has a disproportionate impact on adolescents, women of color and low income women, many of whom lack the necessary identification. *Stay Order*, Df. Add. 211-12. Those

under 15 must still obtain a prescription, as must all women without proper identification. Young women under the age of 15 cannot obtain Plan B One-Step; their only option is to obtain a prescription for a two-pill product. *Id.* at 210-11. In addition, many women do not live near a store with an on-premise pharmacy. *Id.* 211-12. These restrictions continue to harm all Plaintiffs by impairing their ability to access emergency contraception.

It is clearly established that legally unjustified restrictions on a woman's right to access contraception which delay, or altogether prevent, access to birth control, implicate and impair the exercise of their fundamental rights. *See, e.g., Carey v. Population Servs. Int'l*, 431 U.S. 678, 685 (1977) (holding that decision whether to beget a child is at "the very heart" of the "right of personal privacy" recognized by the Constitution). Such harm cannot be adequately compensated by a monetary award and is, therefore, irreparable. *See Wisdom Imp. Sales Co. v. Labatt Brewing Co.*, 339 F.3d 101, 113 (2d Cir. 2003). *See also Elrod v. Burns*, 427 U.S. 347, 373 (1976) (holding that loss of constitutional "freedoms . . . unquestionably constitutes irreparable injury").

Defendants mistakenly assert that the harm to Plaintiffs must be "imminent and irreparable." Df. Br. 19. The Court must determine, however, "whether issuance of the stay will substantially injure" Plaintiffs. *In re World Trade Center Disaster Site Litigation*, 503 F.3d at 170. Defendants fail to cite any precedent in support of their claim that injury must be "imminent."

Defendants' claim that Plaintiffs must allege "an[] imminent intention to buy the drugs at issue," Df. Br. 19, evinces a fundamental misunderstanding of the purpose of "emergency" contraception. Unlike other forms of contraception upon which women rely regularly, these products, by definition, are used in unexpected situations, such as when a primary form of contraception fails. Defendants' suggestion that Plaintiffs are required to allege that they "will purchase the one-pill or two-pill drugs in the near future," Df. Br. 19, is impossible to reconcile with the intended use of "emergency" contraception. Plaintiffs could require it tomorrow, as could all women of child-bearing age, and they have a right to privacy to make the decision whether to use these products without having to explain the circumstances. The salient fact is that if Defendants' current "nonsensical" and scientifically unsupported rules restricting access to emergency contraception remain in place, *Stay Order*, Df. Add. 215, Plaintiffs, and the women whose interests they represent, will undoubtedly be substantially injured.

**B. Defendants Will Not Be Harmed by a Stay**

Defendants assert that they will be irreparably harmed by restating their claim that the Court improperly ordered the FDA to make these products available over-the-counter "outside of the statutorily required process for doing so." Df. Br. 4. As discussed, *infra* at 14-20, Defendants have failed to establish that they are likely to succeed on this claim and, therefore, have failed to establish that they will be irreparably harmed. Any argument that harm will result because compliance will

circumvent the proper and ordinary operation of the regulatory process is particularly misplaced given the Defendants' improper and substantial departures from that process. *Tummino I*, 603 F. Supp. 2d at 547-48; *Tummino II*, Df. Add. 165-68.

### C. The Public Interest Will Not Be Served by a Stay

For over a decade, Defendants have acted against the scientific evidence and based on improper political motivation to deprive women and girls timely access to emergency contraceptives. Where, as here, Plaintiffs are litigating a matter of serious concern which involves the fundamental right of access to time-sensitive contraception and to make one's own decisions in matters of childbearing, the public interest lies in favor of swift execution of a judgment which promotes these interests. *Carey*, 431 U.S. at 697 (for adults and minors, restrictions on access to contraceptives that significantly burden the right to decide whether to bear children must pass constitutional scrutiny); *Tummino II*, Df. Add. 163 (restrictions on access to emergency contraceptives implicate the constitutional right to obtain and use contraceptives). The risk and reality of forced unwanted pregnancy is an injury that compounds as more time elapses. Further delay is contrary to the public interest. *Cf. Pub. Citizen Health Research Grp. v. FDA*, 724 F. Supp. 1013, 1021 (D.D.C. 1989) (holding unreasonable a seven year delay in issuing a regulation impacting on women's health).

The public health, and therefore, the public interest, benefit from unrestricted access to emergency contraception. As one FDA official observed, "[a]ny system placing barriers to access would defeat the purpose of the drug and lessen its public

health potential." *Tummino I*, 603 F. Supp. 2d at 533 (internal quotation marks omitted). These benefits include the potential to decrease unwanted teen pregnancy by up to 70 percent and reducing teen abortions. *Id.* at 529.

Defendants argue that a stay of the District Court's Order is in the public interest because the public relies on the FDA's classifications of drugs "as a reflection of the agency's considered judgment regarding the safety and proper use of a drug without a doctor's prescription" and a stay will "prevent public uncertainty regarding the status of the drugs at issue here." Df. Br. 19-20. But, as the District Court correctly explained: "This argument ignores the fact that the FDA found that the drug was safe and could be used properly without a doctor's prescription, and was prepared to make it available over-the-counter for all ages." *Stay Order*, Df. Add. 214. Thus, with denial of a stay, the public can have confidence that the FDA's scientific, rather than political judgment is being vindicated. *Id.* at 214-15 (the government's appeal "is the cause of any uncertainty, and that that appeal is taken solely to vindicate the improper conduct of the Secretary and possibly for the purpose of further delaying greater access to emergency contraceptives for purely political reasons").

Defendants also claim if they succeed on their appeal, "some women may mistakenly believe that they can obtain the drug without a prescription after they are no longer able to do so." Df. Br. 20. As the District Court observed, "this argument comes with ill grace from the defendants, who have added significant confusion by putting in place a convoluted triple-tiered marketing scheme that will only increase the

confusion that already prevents women from obtaining timely access to emergency contraceptives." *Stay Order*, Df. Add. 215. Moreover,

> This argument . . . is largely an insult to the intelligence of women. If women can no longer obtain Plan B without a prescription at certain locations, they will go to locations where it is available. On the other hand, if a stay is granted, the prejudice to those who need ready access to emergency contraceptives is a certainty, and is likely to continue until the resolution of the appeal—a period of time which is difficult to predict.

*Id.*

This Court should reject Defendants' request to maintain a "status quo" where bad faith and arbitrary and capricious decision-making have prevailed over the scientific judgment of the FDA. Here, the public interest weighs against issuance of a stay. *See, e.g., Cooper v. Town of E. Hampton*, 83 F.3d 31, 36 (2d Cir. 2006) (denying stay and weighing important public interest involving party invoking constitutional right to speak on a matter of public concern); *Daniels v. City of N.Y.,* 138 F. Supp. 2d 562, 565 (S.D.N.Y. 2001) (denying stay where public interest weighs in favor of litigating a controversial matter of serious public concern and where unnecessary delay, including stay pending appeal, is against interest in expeditious resolution).

### D. Defendants Are Not Likely to Succeed on the Merits

#### 1. The District Court's Remedy Was Appropriate In Light of Defendants' Arbitrary and Capricious Conduct and Because Remand Would Be Futile.

Defendants incorrectly argue that the District Court did not have the authority to order the FDA to grant the Citizen Petition and make all levonorgestrel-based

emergency contraception available over-the-counter without age or point-of-sale restrictions. Df. Br. 15-18. The unique circumstances of this case justify the District Court's Order because a remand would serve no purpose and, in fact, would perpetuate Defendants' scientifically unsupported restrictions, improper political motivations, and bad faith decision making. *See, e.g.*, *Fla. Power & Light, Co. v. Lorion*, 470 U.S. 729, 744 (1985) (the proper course, except in "rare cases" is remand to the agency). *See also, Earth Island Inst. v. Hogarth*, 494 F. 3d 757, 770 (9th Cir. 2007) ("Although the ordinary remedy when a court finds an agency's action to be arbitrary and capricious is to remand for further administrative proceedings, a court can order equitable relief or remand with specific instructions in 'rare circumstances.'" (citing *Fla. Power & Light, Co.*, 470 U.S. at 744)).

As the District Court explained:

> This case presents the kind of 'rare circumstances' where a remand to the agency is not only unnecessary but would constitute an abuse of discretion. First, the FDA is not the problem. The cause of the rejection of over-the-counter sale of levonorgestrel-based emergency contraceptives is the Secretary of Health and Human Services. She has not changed her position. A remand would thus be futile.

*Stay Order*, Df. Add. 218 (citations omitted). While Defendants complain that the Court "erred by predetermining what the outcome of the rulemaking process 'should' be," Df. Br. 18, it is the Secretary who has predetermined the outcome: ongoing denial of unrestricted over-the-counter access. Defendants' claim that during rulemaking the Secretary will consider "new information," Df. Br. 18, ignores that the

FDA has already determined that these products are appropriate for over-the-counter distribution. *Tummino II*, Df. Add. 129; *Tummino I*, 603 F. Supp. 2d at 528. New information is not necessary. A change in the Secretary's politically motivated position would need to occur to make a remand anything but futile.

Also critical is the fact that the District Court remanded once before and "defendants engaged in the same bad faith that resulted in [the] initial remand. They delayed the decision for three years, and, ultimately, improper political influence prevented the FDA from granting the petition." *Stay Order*, Df. Add. 219. The agency misconduct that led to the District Court's Order directing the FDA to grant the Citizen Petition was not limited to the unprecedented interference by the Secretary. In its 2009 Order, when the Secretary was not a party to the litigation, the Court found that the FDA had bowed to political pressure and had departed from its own policies and procedures. *Tummino I*, 603 F. Supp. 2d at 544-49. And in its April 5, 2013 Order, the Court cites numerous examples of how the FDA, in once again denying the Citizen Petition, significantly deviated from its own policies. *See Tummino II*, Df. Add. 165-68; *id.* at 172 ("[T]he agency's decision cannot withstand any degree of scrutiny, not only because of its unexplained failure to follow [] FDA policies . . . but also because of its disregard for the scientific evidence that the FDA had before it."). The Court's Order was appropriate to remedy years of arbitrary and capricious conduct, including an "agency process . . . corrupted by political interference." *Stay Order*, Df. Add. 219.

Defendants incorrectly assert that the only avenue open to the District Court was to remand for rulemaking. Df. Br. 15-18. Prior proceedings in this case prove otherwise. In *Tummino I*, the Court remanded to the FDA for reconsideration of the Citizen Petition, but also ordered the FDA, within thirty days of its order, "to permit . . . the Plan B drug sponsor to make Plan B available to 17 year olds . . . under the same conditions as Plan B is now available to women over the age of 18." 603 F. Supp. 2d at 550. The FDA promptly complied. *See Stay Order*, Df. Add. 220 n. 4 ("The agency accomplished [the change] without rulemaking by inviting Teva to submit a tailored supplemental application for this change.").

A drug can be switched from prescription to over-the-counter status if the sponsor or "any interested person" requests such a switch, and the FDA approves. *See Tummino I*, 603 F. Supp. 2d at 525, as amended by Mar. 6, 2013 Order, ECF No. 78, Pl. Add. 31-32.[4] In addition, the FDA can switch a drug from prescription to over-the-counter status without being asked to do so. 21 C.F.R. § 310.200(b) (drugs "shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary . . ."); Decl. of Mary Pendergast, J.D., LL.M. in Support of Pls.' Mot. for Prelim. Inj. and Summ. J. (Feb. 8,

[4] The default status for drugs is over-the-counter. *See* 21 C.F.R. §§ 310.200(b), 330.10(a)(4); *Tummino I*, 603 F. Supp. 2d at 525. A drug is suitable for over-the-counter use when it is found to be safe and effective for self-administration and when its labeling clearly provides directions for safe use and warnings regarding unsafe use, side effects, and adverse reactions. 21 C.F.R. § 310.200(b).

2012) ("Pendergast Decl.") ¶¶ 6-7, 16, 26-27, Pl. Add. 53, 58-59, 62-64. The District Court, therefore, accurately concluded that "no statute or regulation requires the FDA to engage in administrative rulemaking upon approval of a citizen petition or *sua sponte* reconsideration of a drug's prescription-only status." *See Tummino II*, Df. Add. 181; *see also id.,* Df. Add. 143 ("[T]he FDA's options in responding to over-the-counter switch applications are not as limited as they represent.").

Finally, Defendants claim rulemaking is necessary to solicit and consider information regarding the "safety and efficacy of different forms of emergency contraceptives in young adolescents without expert medical guidance." Df. Br. 20. The FDA, however, has already determined the "safety and efficacy" of emergency contraception for all women of child-bearing age. *See Tummino II*, Df. Add. 129; *Tummino I*, 603 F. Supp. 2d at 527-28. Rulemaking is also unnecessary to determine "the effects of a photo identification requirement on older users," when the District Court already determined such restrictions are scientifically unjustified and politically motivated. Df. Add. 156-58. Defendants' final claim is that rulemaking is necessary to evaluate any claims of "market exclusivity" by name brand drug manufacturers. However, this contradicts their constant refrain that the Citizen Petition and the SNDA processes have nothing to do with one another.

Defendants' incorrect insistence on rulemaking would also perpetuate the "administrative agency filibuster" that has plagued this process. *Stay Order*, Df. Add. 220. As the District Court explained:

> [O]ne of the devices the FDA has employed to stall proceedings was to seek public comment on whether or not it needed to engage in rulemaking in order to adopt an age-restricted marketing regime. After eating up eleven months, 47,000 public comments, and hundreds of thousands, if not millions, of dollars, it decided that it did not need rulemaking after all. The plaintiffs should not be forced to endure, nor should the agency's misconduct be rewarded by, an exercise that permits the FDA to engage in further delay and obstruction.

*Tummino II*, Df. Add. 183. Under the "rare" circumstances present here, the District Court was correct to conclude that a remand was inappropriate.[5]

### 2. The Scope of Relief Afforded by the Citizen Petition Includes All Levonorgestrel Products

Defendants argue that it was error to include one-pill products within the relief that comes from directing the FDA to grant the Citizen Petition. In their view, the Court had no authority to take any action that overlapped with the relief sought in the first Plan B One-Step SNDA.[6] The Court was explicit, however, that it was not acting on the SNDA. *See Tummino II*, Df. Add. 158-59 ("The only decision subject to review

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[5] Defendants' reliance on *Norton v. So. Utah Wilderness Alliance*, 542 U.S. 55, 63-65 (2004), Df. Br. 16-17, is misplaced. *Norton* involved a claim brought pursuant to 5 U.S.C. § 706(1), under which, a court can compel an agency to perform a non-discretionary act. 542 U.S. at 64. By contrast, this action was brought pursuant to 5 U.S.C. § 706(2), which does not contain the limitations in § 706(1).

[6] To the extent Defendants suggest that 21 U.S.C. § 355(h) prevents any action by the District Court that, in effect, grants the Plan B One-Step SNDA, they are incorrect. That provision limits the appeal rights of an SNDA *applicant*, who has had an application denied or withdrawn. 21 U.S.C. § 355(h). It does not limit the jurisdiction of district courts to hear actions by other parties, even if directly related to the FDA's action on an SNDA. *See Bradley v. Weinberger*, 483 F.2d 410, 414 n. 1 (1st Cir. 1973) (distinguishing § 355(h) and finding that Plaintiffs had standing to challenge FDA action via citizen petition).

here is the denial of the Citizen Petition; I do not have any authority to review the denial of the Plan B One-Step SNDA for the purpose of granting relief."); *Stay Order*, Df. Add. 217 (same); *id.*, Df. Add. 205 ("I did not order the defendants to make Plan B One-Step . . . available.").

The District Court made clear that the Citizen Petition encompasses one- and two-pill products and that it was not ordering relief specific to Plan B One-Step, but rather, Plan B One-Step came within the relief that flowed from ordering the FDA to grant the Citizen Petition. As the Court explained: "If Teva could somehow benefit from the relief sought by the Citizen Petition, it was simply because the relief it sought from the FDA overlapped to a degree with the Citizen Petition." *Stay Order*, Df. Add. 217.

Defendants' argument here to exclude the one-pill product from the Court's relief further reflects their arbitrary and capricious misconduct throughout this case, including that they attempted to mislead the Court by claiming that studies were not available or inapplicable to both products. *Tummino II*, Df. Add. 165-71. The Court determined that Defendants possessed data from several sources, including two sources Defendants claimed they did not have, supporting approval of both products. *Id.* at 166-68. More important, Defendants insistence on additional data about the adolescent population for either product was always a scientifically unjustified pretext for improper agency decision-making and political motives. *Id.* 165.

The District Court correctly concluded that one- and two-pill products are equivalent for purposes of the Citizen Petition. *Stay Order*, Df. Add. 205 ("[T]he FDA rejected a Citizen Petition that sought unrestricted over-the-counter status for Plan B – the original two-pill emergency contraceptive product – and all drugs that are 'equivalent' to Plan B."). This conclusion is well-founded. *Tummino II*, Df. Add. 166-73. Most obvious, as the Court noted, one- and two-pill products "contain the same total dose of levenorgestrel," and data which applied to both products did not justify any restrictions. *See id.*, Df. Add. 125, 166-68. *See also* Pendergast Decl. ¶ 21, Pl. Add. 60.

In sum, Defendants have not demonstrated that they are likely to succeed on the merits of their appeal.

## IV. Conclusion

For the foregoing reasons, Defendants' Motion for Stay should be denied.

Dated: May 20, 2013

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that on May 20, 2013, I electronically filed the foregoing motion with the Clerk of the Court by using the appellate CM/ECF system.

I certify that the participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system

**/s/ Janet Crepps**
JANET CREPPS