UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Thurgood Marshall U.S. Courthouse 40 Foley Square, New York, NY 10007 Telephone: 212-857-8500

MOTION INFORMATION STATEMENT

Docket Number(s): 13-1690

Caption [use short title]

Motion for: Stay pending appeal

Annie Tummino, et al., Plaintiffs-Appellees,

v.

Margaret Hamburg, Commissioner of the Food and

Set forth below precise, complete statement of relief sought:

Stay pending appeal of the district court's mandatory i

injunction

MOVING PARTY:

☐ Plaintiff ☑ Defendant

☐ Appellant/Petitioner ☐ Appellee/Respondent

OPPOSING PARTY: Annie Tummino, et al.

MOVING ATTORNEY: Adam Jed

OPPOSING ATTORNEY: Janet Crepps

[name of attorney, with firm, address, phone number and e-mail]

United States Department of Justice
950 Pennsylvania Avenue, NW Room 7420
Washington, D.C. 20530

Center for Reproductive Rights 37-3600
120 Wall Street, 14th Floor
New York, NY 10005
(917) 637-3600

Court-Judge/Agency appealed from: Eastern District of New York, Korman, J.

Please check appropriate boxes:

Has movant notified opposing counsel (required by Local Rule 27.1):
☑ Yes ☐ No (explain):

Opposing counsel's position on motion:
☐ Unopposed ☑ Opposed ☐ Don't Know

Does opposing counsel intend to file a response:
☑ Yes ☐ No ☐ Don't Know

FOR EMERGENCY MOTIONS, MOTIONS FOR STAYS AND INJUNCTIONS PENDING APPEAL:

Has request for relief been made below? ☑ Yes ☐ No

Has this relief been previously sought in this Court? ☐ Yes ☑ No

Requested return date and explanation of emergency:

The district court has granted a temporary stay pendin

Is oral argument on motion requested? ☐ Yes ☑ No (requests for oral argument will not necessarily be granted)

Has argument date of appeal been set? ☐ Yes ☑ No If yes, enter date:

Signature of Moving Attorney:
/s/ Adam Jed **Date:** May 13, 2013

Service by: ☑ CM/ECF ☐ Other [Attach proof of service]

ORDER

IT IS HEREBY ORDERED THAT the motion is **GRANTED DENIED**.

FOR THE COURT:
CATHERINE O'HAGAN WOLFE, Clerk of Court

Date: By:

Form T-1080 (rev. 7-12)

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

GOVERNMENT'S MOTION FOR A STAY PENDING APPEAL

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INTRODUCTION AND SUMMARY

The government respectfully asks this Court for a stay pending appeal of the district court's order of April 5 and judgment of April 10 which require the Food and Drug Administration (FDA) to approve levonorgestrel-based emergency contraceptive drugs for nonprescription sale to persons of all ages. The district court denied a full stay pending appeal on May 10, but granted a temporary stay, provided that the government file its motion with this Court by noon on May 13.

The district court's order concerns two different drugs, both of which contain levonorgestrel, a synthetic hormone that reduces the chance of pregnancy if taken within three days of sexual intercourse. The original levonorgestrel emergency contraceptive drug — Plan B — consists of two pills with the second pill to be taken 12 hours after the first. It is currently available by prescription to all persons, and to persons 17 and older without a prescription. The newer drug — Plan B One-Step — is a single pill. At the time of the district court's order in this case, Plan B One-Step was available on the same terms as Plan B. As a result of a supplemental new drug application approved by FDA on April 30, however, Plan B One-Step is now approved to be made available without prescription to all persons 15 and older. (In this motion we refer to the original Plan B and its generic equivalents as the "two-pill" drug and to Plan B One-Step and its generic equivalents as the "one-pill" drug.)

The district court ordered that FDA make "levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age

restrictions[.]" Although the district court rejected the government's position in the strongest terms, the court plainly exceeded its jurisdiction in ordering FDA to take any action on the one-pill drug and to make any of these drugs available without a prescription or any other restriction without conducting a rulemaking.

The court's sweeping order fundamentally misapprehends the process by which FDA can change the status of a prescription drug to nonprescription. Under the Federal Food, Drug and Cosmetic Act, drug manufacturers, or "sponsors," may ask FDA to change the status of a prescription drug to nonprescription by filing a supplemental new drug application (SNDA). The sponsor must provide evidence that the drug is safe and effective under the proposed conditions of use and with the proposed labeling — that is, without a prescription. 21 U.S.C. § 355(b)-(d); 21 C.F.R. § 310.200(b); *see also* 21 C.F.R. § 314.71. A drug sponsor who is dissatisfied with FDA's action on its SNDA may seek judicial review, and such review must be sought directly in the court of appeals. 21 U.S.C. § 355(h).

The statute also authorizes FDA to change a drug from prescription to nonprescription status "by regulation," but it sets out no circumstances in which the Commissioner is required to promulgate such a regulation or even initiate rulemaking. 21 U.S.C. § 353(b)(3); s*ee also* 21 C.F.R. § 310.200(b). If FDA has considered prescription status in the context of an SNDA, it would ordinarily have no reason to exercise its discretion to initiate rulemaking to revisit the issues for the same drugs that were determined in its consideration of the sponsor's application.

In 2011, FDA declined to approve an SNDA for Plan B One-Step, to market the drug without perscription to people of all ages. The sponsor (Teva) could have — but did not — seek judicial review of that decision under 21 U.S.C. § 355(h). Instead, the sponsor submitted an amended SNDA (approved by FDA on April 30, 2013) to market the drug without prescription to persons 15 and older. The district court itself recognized that it has no authority to order relief with respect to Plan B One-Step, but its order of relief cannot be reconciled with that purported recognition.

The only drug properly at issue in this case is the two-pill drug, Plan B and its generic equivalents, which is the subject of a citizen petition that asked FDA to make "Plan B, and any new drug eligible for filing an abbreviated new drug application because of its equivalence to . . . Plan B [i.e. generic version]" available without prescription to persons of all ages. FDA first denied the citizen petition in 2006. After the district court reversed the denial, plaintiffs offered no new independent studies that would have provided FDA with reason to initiate rulemaking, and FDA denied the petition again in 2011.

In its order, the district court required FDA to make the two-pill and one-pill products available without prescription to all ages. In so doing, the court decided not only that it would dispense with the ordinary practice of remanding for the agency to reconsider or further explain its decision — here the denial of the citizen petition — but also that it would order FDA to skip the statutorily required rulemaking process altogether and change the status of both the one-pill and two-pill drugs to make them

nonprescription for people of all ages. The court improperly based its decision almost entirely on its view that FDA should have approved the SNDA for Plan B One-Step, which it acknowledged it had no jurisdiction to review. But apart from that error, the court contravened axiomatic principles of administrative law in concluding that rulemaking would be "futile" because the result might not accord with the court's own view of the proper outcome.

Because the district court plainly overstepped its authority, there is a substantial likelihood that the government will prevail in this appeal. The balance of harms and the public interest also strongly support a stay. Absent a stay, the government will be required to make drugs available without prescription or age restriction, outside of the statutorily required process for doing so. The plaintiffs will not suffer harm — irreparable or otherwise — if a stay is granted. All the named plaintiffs are age 15 or older and will be able to purchase Plan B One-Step without a prescription as a result of FDA's recent approval of the SNDA. Although one plaintiff also sues on behalf of her minor children, no plaintiff has alleged any intent to buy Plan B or Plan B One-Step in the immediate future. This is not a class action, and there is no basis for preferring plaintiffs' view of the public interest to that of the agency.

In sum, we respectfully ask that the Court grant a stay pending appeal.[1]

[1] We have contacted counsel for plaintiffs, and they have indicated that they oppose the relief requested in this motion.

STATEMENT

I. Statutory and Regulatory Background

1. Under the Federal Food Drug and Cosmetic Act, FDA may change the status of a drug from prescription to nonprescription in either of two ways: by approving a supplemental new drug application or by promulgating a regulation.

A drug sponsor may ask FDA to change a drug from prescription to nonprescription status by filing an SNDA, and FDA is authorized to approve the application if it concludes that the sponsor has submitted an adequate basis for concluding that the drug is safe and effective under the proposed conditions of use and with the proposed labeling —without a doctor's prescription. 21 U.S.C. § 355(b)-(d); 21 C.F.R. § 310.200(b); *see also* 21 C.F.R. § 314.71. A sponsor may seek judicial review of FDA's action, and that review must be directly in the court of appeals. 21 U.S.C. § 355(h).

The statute also authorizes the Commissioner to change the status of a drug from prescription to nonprescription "by regulation." 21 U.S.C. § 353(b)(3). This grant of discretionary authority sets out no circumstances in which the Commissioner must undertake rulemaking.

2. FDA has by regulation established a "citizen petition" procedure that may be used for any subject matter under FDA's purview. *See* 21 C.F.R. § 10.20 *et seq.* The citizen petition process allows an "interested person" to "petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any

other form of administrative action." 21 C.F.R. § 10.25(a). When a citizen petition is filed, "[t]he Commissioner may initiate a proceeding to issue . . . a regulation." *Id.* § 10.25(b); *see id.* § 10.40. FDA may consider agency priorities and resources in determining what action to take on a petition. *See* 21 C.F.R. § 10.30(e). FDA's decisions concerning citizen petitions are final agency actions and thus reviewable in district court under the Administrative Procedure Act. 21 C.F.R. § 10.45(g).

Because a citizen petition may address any subject in FDA's purview and may be used to "petition the Commissioner to issue, amend, or revoke a regulation or order," 21 C.F.R. § 10.25(a), a citizen petition may request that FDA change a drug's status "by regulation" under 21 U.S.C. § 353(b)(3). Thus, by filing a citizen petition, an "interested person" can ask FDA to promulgate a regulation that moves a drug from prescription to nonprescription status. *See* 21 C.F.R. § 310.200(b).

II. Facts and Procedural History

This district court's order concerns two related drugs, "Plan B" and "Plan B One-Step," as well as their generic equivalents. Both drugs contain levonorgestrel, a synthetic hormone that can prevent pregnancy. The original drug, Plan B, is two pills to be taken 12 hours apart. The newer drug, Plan B One-Step, is a single pill.

A. Prior proceedings regarding Plan B — the two-pill drug

1. Plan B has been available by prescription since 1999. In 2004, Plan B's manufacturer filed an SNDA to sell Plan B to women 16 years old or older without a prescription. In 2006, following FDA's decision not to approve that SNDA, the

sponsor submitted and FDA approved an amended SNDA, authorizing sale of Plan B without a prescription to persons 18 years old and older.

In 2001, prior to the filing of the SNDAs by Plan B's sponsor seeking to lower the nonprescription age, a number of individuals and organizations filed the citizen petition that is at issue here. The petition asked FDA to allow nonprescription sale to women of all ages of "Plan B, and any new drug eligible for filing an abbreviated new drug application because of its equivalence to . . . Plan B" — meaning generic versions of Plan B, *see* 21 U.S.C. § 355(j). FDA denied the petition for nonprescription status for all ages in 2006, shortly before approving the SNDA allowing nonprescription sale of Plan B to persons 18 years old and older.

2. Plaintiffs brought suit and, following FDA's denial of their citizen petition, sought review of that decision. In 2009, the district court held that FDA's denial of the citizen petition was arbitrary and capricious. The court held that the agency's process had been tainted by irrelevant considerations and that the agency had deviated from its normal procedures and substantive policies to reach a desired result. *Tummino* v. *Torti*, 603 F. Supp. 2d 519, 544-49 (E.D.N.Y. 2009). The court ordered FDA to allow nonprescription sale to 17-year-olds and remanded to FDA to reconsider the citizen petition.

B. The SNDA for Plan B One-Step — the one-pill drug

Although a request for rulemaking with regard to Plan B One-Step is not part of the citizen petition, FDA's consideration of SNDAs by Plan B One-Step's sponsor

forms a crucial part of the district court's opinion, and we therefore set out that history briefly before describing the district court's ruling.

Plan B One-Step has been available since 2009. Unlike the market for the two-pill drug, which now consists entirely of generic equivalents to the originally-approved Plan B, the market for the one-pill drug includes the originally approved Plan B One-Step and a generic equivalent. The one-pill drug currently accounts for approximately 85% of the market for levonorgestrel emergency contraceptives.

In 2011, Plan B One-Step's manufacturer submitted an SNDA to make Plan B One-Step available without prescription to people of all ages. After reviewing the sponsor's submissions, including proprietary materials, FDA officials concluded that women of all ages could safely and effectively use Plan B One-Step without a prescription. The Secretary of Health and Human Services determined, however, that the proffered studies did not include sufficient data to demonstrate that the youngest adolescent age groups would be able to use the drug safely without a prescription, and FDA declined to approve the SNDA. Plan B One-Step's manufacturer did not seek judicial review of FDA's action. Instead, it submitted an amended SNDA seeking approval to market the drug without prescription to persons 15 and over.

On April 30, 2013, FDA approved the amended SNDA which now authorizes sale of Plan B One-Step without prescription but with a label providing that the drug is not intended for use by, or sale to, persons under age 15. Woodcock Decl. ¶ 3. Because FDA approved the SNDA "on the basis of actual use studies" conducted by

the drug sponsor "in women age 15 and 16 that FDA found essential to its approval," FDA granted the sponsor "three years of exclusive marketing" to persons age 15 and 16., pursuant to 21 U.S.C. §§ 355(c)(3)(E)(iv) & (j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(5). *Ibid.*

C. Denial of the Plan B citizen petition and the present litigation

After the district court's 2009 remand order, FDA reopened the docket in the Plan B citizen petition, permitting submission of additional information. Neither the petitioners nor other plaintiffs in this suit submitted new independent studies, however, and instead continued to rely on substantially the same materials. FDA thus again denied the citizen petition regarding the two-pill drug in 2011. FDA explained that the citizen petitioners had not submitted any data demonstrating the safety or efficacy of the drug in adolescents who take it without prescription.

Plaintiffs sought judicial review of the denial of the Plan B citizen petition, and on April 5, 2013, the court held that FDA's denial of the petition was arbitrary and capricious. The court predicated its analysis of the Plan B citizen petition on its view that the Secretary's denial of the SNDA for Plan B One-Step (which it had no jurisdiction to review) was "obviously political." Order at 11. Stressing that the Secretary had reached a different conclusion than FDA officials with regard to the Plan B One-Step SNDA, the court reasoned that the denial of the citizen petition regarding Plan B did not accurately reflect the agency's judgment and was not entitled to deference. *See id.* at 36. The court dismissed FDA's explanation for the denial of

the Plan B citizen petition — that no supporting data had been submitted — as "pretext" and "filler." *Id.* at 40-41.

In determining an appropriate remedy, the court expressly refused to remand to FDA as contemplated by the APA. *Id.* at 56. Instead, the court ordered FDA "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 57. The court qualified its order to the limited extent of stating that if "FDA actually believes there is any significant difference between the one- and two-pill products," FDA could "limit its over-the-counter approval to the one-pill product," *ibid.*, even though no decision concerning the one-pill drug was before the court. The court made clear that it was not allowing FDA to conduct the rulemaking that the FDCA requires before making such a change. *Ibid.*

D. Stay proceedings before the district court

On May 10, the district court denied the government's motion for a stay pending appeal. The court declared that the hormonal contraceptive drugs covered by its order would be "among the safest drugs available to children . . . on any drugstore shelf." May Order at 1. Because, the court explained, "the Secretary's decision" (presumably referring to the denial in 2011 of the first Plan B One-Step SNDA) was "politically motivated, scientifically unjustified, and contrary to agency precedent" and "could not provide a basis to sustain the denial of the Citizen Petition" — which concerned only Plan B and its generic equivalents — the court had

ordered FDA "to grant the Citizen Petition filed by the plaintiffs and make levonorgestrel-based emergency contraceptives available over-the-counter and without point-of-sale or age restrictions." *Id.* at 2.

The court responded to the government's contention that it had no jurisdiction with respect to the one-pill drug by stating that it did "not order the defendants to make Plan B One-Step—the widely known brand name emergency contraceptive—available." *Id.* at 2. The court also stated, however, that "the effect of my decision was to make levonorgestrel-based emergency contraceptives available without a prescription and without any point-of-sale or age restrictions" and that it applies to "both" the "one-pill" and "two-pill" levonorgestrel drugs. *Id.* at 3. The court reiterated that its remedy "was entirely consistent with the initial decision" of FDA officials to approve the Plan B One-Step SNDA, and that the court "adopted and completely agreed" with that decision. *Ibid.* The court rejected the government's arguments as "frivolous," *id.* at 14, 20, and additionally stated that any remand to the agency, even with an order to conduct a rulemaking, would be "futile." *Id.* at 15.

With regard to whether a stay would cause irreparable injury to the plaintiffs, the district court noted that some people do not have photo identification to show that they are old enough to buy these drugs over the counter and that some women may wish to buy Plan B (rather than Plan B One-Step), which is available only at a pharmacy counter, and to do so while their local pharmacy is closed. *Id.* at 7-8. The court cited journal articles about access to contraception and the effects of photo

identification requirements on voting, although it did not identify any allegations relevant to plaintiffs in this case. *See id.* at 7-10. The court additionally criticized the statutory and regulatory regime under which the Plan B One-Step sponsor will receive limited marketing exclusivity for studies related to the use of Plan B One-Step in women ages 15 and 16. *See id.* at 5-7, 10.

The district court gave FDA until noon on Monday, May 13 to seek a stay pending appeal from this Court. *Id.* at 1.

ARGUMENT

In considering a request for a stay pending appeal, this Court considers the movant's likelihood of success and the impact on the parties and the public interest that will result from granting or denying a stay. *See In re World Trade Ctr. Disaster Site Litig.*, 503 F.3d 167, 170 (2d Cir. 2007). "[T]he degree to which a factor must be present varies with the strength of the other factors, meaning that more of one [factor] excuses less of the other." *Ibid.* (internal quotation marks omitted).

I. The Government Has A Likelihood of Success on the Merits.

A. The district court has ordered FDA to "make levonorgestrel-based emergency contraceptives available without a prescription and without any point-of-sale or age restrictions," an order that applies to "both" the "one-pill" and "two-pill" levonorgestrel drugs. Order at 57; May Order at 2-3. The court issued that ruling notwithstanding its repeated protestations that it has no authority to rule on Plan B One-Step (the one-pill drug), and notwithstanding the fact that the 2001 citizen

petition addressed only "Plan B [the two-pill drug], and any new drug eligible for filing an abbreviated new drug application because of its equivalence to . . . Plan B" — meaning generic versions of Plan B, *see* 21 U.S.C. § 355(j).

At the core of the court's order is its strongly stated view that the Secretary of HHS should have agreed with FDA officials who would have approved the SNDA filed by Plan B One-Step's sponsor, which sought to sell Plan B One-Step without prescription to persons of all ages. As the district court noted, the Plan B One-Step sponsor could have, but did not, seek review in a court of appeals "which would have jurisdiction to review it [under] 21 U.S.C. § 355(h)." Order at 34. Instead, Plan B One-Step's manufacturer submitted an amended SNDA, which FDA approved on April 30, 2013. *See* Woodcock Decl. ¶ 3. As a result of FDA's regulatory action, Plan B One-Step need not be dispensed by a pharmacist and will be available for sale to persons 15 years old and older during a retailer's normal operating hours, whether the pharmacy is open or not. *Id.* ¶ 3 (a) & (c).

The district court made abundantly clear in denying the stay application that it found this action inadequate, and declared that its order was consistent with the view of FDA officials who would have approved the original SNDA that would have made Plan B One-Step available nonprescription without age restrictions.

The district court correctly recognized, however, that "I do not have any authority to review the denial of the Plan B One-Step SNDA for the purpose of granting relief." Order at 34-35. Although the court repeatedly declared that it has

not, in fact, exercised that authority, its assertions are flatly at odds with its ruling and its order to "make levonorgestrel-based emergency contraceptives available without a prescription and without any point-of-sale or age restrictions," including "both" the "one-pill" and "two-pill" levonorgestrel drugs. Order at 57; May Order at 2-3. For example, in denying FDA's motion for a stay, the district court stated that it did "not order the defendants to make Plan B One-Step—the widely known brand name emergency contraceptive—available[.]" May Order at 2. It made no effort to reconcile that statement with its declaration that "the effect of [its] decision was to make levonorgestrel-based emergency contraceptives available without a prescription and without any point-of-sale or age restrictions" including "both" the "one-pill" and "two-pill" levonorgestrel drugs, and its statement that its ruling "was entirely consistent with the initial decision of the FDA" to approve the Plan B One-Step SNDA. *Id.* at 2-3. The court plainly erred in asserting the authority that it disclaimed and in ordering action with respect to levonorgestrel contraceptives that were not even put at issue by the citizen petition.

If the district court meant to issue an order only about the *generic* version of Plan B One-Step but exclude from its order "Plan B One-Step—the widely known brand name emergency contraceptive," May Order at 2-3, the order is equally erroneous. The generic one-pill drug is no more at issue in the citizen petition than the brand name product. Moreover, an order of this kind would stand the process for approving generic drugs on its head. Generic drugs must (with exceptions not

relevant here) have the same conditions for use and labeling as the reference listed drug, and the district court could not properly order FDA to make the generic one-pill product available for conditions of use never approved for Plan B One-Step itself. *See PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2574-76 (2011); 21 U.S.C. § 355(j)(2)(A)(i), (v). Any consideration of nonprescription availability and labeling changes to the generic version of the one-pill drug would also have to take into account any claims by the brand name Plan B One-Step sponsor to exclusivity based on its proprietary studies that were essential to the approval of Plan B One-Step for nonprescription use under age 17. *See* 21 U.S.C. § 355(c)(3)(E)(iv) & (j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(5).

B. The court was equally incorrect to assume that an order to grant the citizen petition could take the form of an order requiring FDA to approve a drug for nonprescription sale without age restrictions without first going through rulemaking.

1. Absent an application from a drug sponsor, FDA has the authority to change a prescription drug to nonprescription status only "by regulation." 21 U.S.C. § 353(b)(3). Thus, if FDA had determined that the citizen petition provided evidence that warranted initiation of a rulemaking proceeding, and that such action is consistent with agency priorities and resources, *see* 21 C.F.R. § 10.30(e), it would have undertaken the steps necessary to propose promulgating a regulation about the drug. *See* 21 U.S.C. § 353(b)(3); 21 C.F.R. §§ 10.25(a) & (b), 10.40(a). These include steps to provide notice and gather relevant information. *See* 21 C.F.R. § 10.3 (defining

"regulation"); 5 U.S.C. § 553 (procedures for promulgating regulations); 21 C.F.R. § 10.40 (procedures for FDA's promulgating regulations); *see also* 21 C.F.R. § 10.50(b).

The citizen petition process was not created to provide an alternative means of litigating agency actions on SNDAs when the drug sponsor chooses not to seek judicial review. FDA is certainly not required by the FDCA or its own regulations to reopen an inquiry into the denial of an SNDA based on a petition that offers no new evidence. But if the district court nevertheless believed that the agency erred in denying the citizen petition, the court plainly erred in ordering FDA to approve drugs for nonprescription sale without first engaging in the statutorily-mandated rulemaking process.

When a court finds that an agency has acted arbitrarily, the normal course, under established principles of administrative law, is to remand to the "agency for decision of a matter that statutes place primarily in agency hands." *INS* v. *Ventura*, 537 U.S. 12, 16 (2002) (per curiam); *accord Florida Power & Light Co.* v. *Lorion*, 470 U.S. 729, 744 (1985). A court certainly may not require an agency to act outside the scope of its authority and pre-determine the outcome of a rulemaking that has not yet occurred. Thus, even if a remand for FDA to reconsider whether to take any action on the citizen petition was not sufficient, the only additional step the court could order would have been that FDA grant the citizen petition and conduct a rulemaking — which it could properly order only if it concluded that the existing record on the citizen petition compelled FDA to initiate a rulemaking. The court's injunction turns

on its head the principle that a court may compel agency action only when the agency has failed to undertake a clear, nondiscretionary duty. *See Norton* v. *So. Utah Wilderness Alliance*, 542 U.S. 55, 63-65 (2004). And the court's order exceeds the court's authority in compelling FDA to act outside the required statutory procedures by changing a drug's status from prescription to nonprescription without undertaking rulemaking steps.

2. In denying a stay, the district court declared that any agency proceedings would be "futile" because the Secretary "has not changed her position" since she concluded that the 2009 SNDA for Plan B One-Step did not contain sufficient data to support nonprescription status of that drug for 11 to 13-year-olds. May Order at 20. The court described a rulemaking as "a national referendum" and stated that such a process is not warranted unless the court has "assurance[s]" as to the outcome of the process. *Ibid.*

Regardless of the court's own views on the wisdom or utility of obtaining viewpoints other than those of the petitioners, the FDCA requires FDA to act by promulgating a regulation. And for good reason, because the public rulemaking process allows all interested parties and members of the public to submit comments and evidence — not merely the handful of petitioners and plaintiffs, who in fact submitted no studies to FDA. The court's characterization of levonorgestrel-based emergency contraceptives as "among the safest drugs available to children . . . on any

drugstore shelf" (May Order at 1), does not relieve the agency of its statutorily mandated procedures.

The district court further erred by predetermining what the outcome of the rulemaking process "should" be. In a rulemaking, the agency can solicit and receive information on any number of questions, including not only the safety and efficacy of different forms of emergency contraceptives in young adolescents without expert medical guidance, but also the other questions on which the court opined, including the effects of a photo identification requirement on older users and any claims by brand-name manufacturers to market exclusivity. Without having seen any of that information, neither the court nor the agency can conclude what the "right" regulation would be.

And even if the court's prediction that the only permissible outcome is complete nonprescription availability were correct, a remand for a rulemaking is not "futile." A court's prediction about the agency's future decision, following a rulemaking, based on one past decision made by the Secretary, does not permit it to order circumvention of that process. In 2011, the Secretary reviewed an SNDA filed for Plan B One-Step and concluded that the data submitted by the sponsor did not support nonprescription availability for all ages. In a rulemaking, new information will be submitted, and the Commissioner and Secretary will consider that information. There is no basis for assuming in advance the conclusions of the agency or the Secretary.

II. The Balance of Harms Strongly Favors a Stay.

A. A stay will cause no injury of any dimension to plaintiffs, much less imminent and irreparable injury. None of the plaintiffs has alleged any imminent intention to buy the drugs at issue. All of the named individual plaintiffs are 15 or older, and Plan B One-Step has now been approved for nonprescription sale to them. And all but one named individual plaintiff are over 17 and therefore can buy *all* levonorgestrel emergency contraception without prescription. The district court noted that one named plaintiff added in 2012 alleged that she sued not only on her own behalf but also on behalf of her then-14 and 12-year-old daughters and 9-year-old son**.** But there is no allegation that her children (or any other plaintiff) will purchase the one-pill or two-pill drugs in the near future. *See* Second Am. Supp. Compl. ¶ 9, at 4.

Notwithstanding plaintiffs' submission to the district court that they sued to obtain legal changes "for all other women" (Plaintiffs' Opposition to Defendant's Motion for a Stay, Dkt. 95, at 16; *accord ibid.* (suit "on behalf of all women") (quoting complaint)), this is not a class action, and the absence of any imminent harm to the actual plaintiffs strongly militates in favor of a stay.

B. There is also no basis for accepting plaintiffs' conception of the public interest over that of the agency that is charged with implementing the drug approval scheme established by Congress. The public properly relies upon FDA classification 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. Woodcock Decl. ¶ 5; *cf. Henley* v. *FDA*, 77 F.3d 616, 620 (2d Cir. 1996) ("FDA's determination of what labeling best reflects current scientific information regarding the risks and benefits of [the drug] involves a high degree of expert scientific analysis").

A stay of the court's order will maintain the status quo under the regulatory framework and prevent public uncertainty regarding the status of the drugs at issue here pending the government's appeal. Woodcock Decl. ¶ 5. If the status of these drugs is changed and later reversed, some women may mistakenly believe that they can obtain the drug without a prescription after they are no longer able to do so. *Ibid.* The problem would be exacerbated because products with incorrect labeling will presumably remain on pharmacy shelves even after an appellate ruling reversing the injunction. *Ibid.* The district court was mistaken in dismissing this confusion because it is only the result of "the government's appeal." May Order at 11. The court was also mistaken in assuming that because immediate nonprescription availability without any age restriction may ease access to the drugs at issue, a stay should be denied. *Id.* at 12.

CONCLUSION

For the foregoing reasons, the Court should stay the district court's mandatory injunction pending final resolution of the government's appeal.

Respectfully submitted.

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MAY 2013

CERTIFICATE OF SERVICE

I hereby certify that on May 13, 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/ Adam Jed
ADAM JED