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 REPLY IN SUPPORT OF MOTION FOR A STAY PENDING APPEAL

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

A. The district court exceeded its authority by ordering FDA to change from prescription to nonprescription status the one-pill levonorgestrel drug, whose brand name is Plan B One-Step. *See* Mot. 12-15. Plaintiffs' opposition fundamentally misconceives the nature of the FDA drug approval process and of the citizen petition.

The gist of plaintiffs' position is that the government should have approved Teva's first supplemental new drug application ("SNDA") for Plan B One-Step to make it available without prescription regardless of age, rather than the amended SNDA which provides for nonprescription sales to persons 15 and older. Although they insist that the district court "was not acting on the SNDA" (Opp. 18), they do not dispute that the district court required FDA to make the one-pill drug available without prescription to all persons. They make no attempt to reconcile the district court's order on the one-pill drug with the court's statement that it "did not order [FDA] to make Plan B One-Step [the brand name of the one-pill drug] . . . available." May Order at 2. Nor do plaintiffs dispute that the district court's ruling rested substantially on its view that the government's decision not to approve the initial Plan B One-Step SNDA was unreasonable and "'obviously political.'" Opp. 6 (quoting Order at 11); *see also* May Order at 2-3 (stating that the court's order "was entirely consistent with the initial decision of the FDA" to approve the Plan B One-Step SNDA).

Plaintiffs defend the district court's assertion of jurisdiction over the one-pill drug — Plan B One-Step and its generics — on the ground that the citizen petition independently asked FDA to make that drug available to all persons without prescription. Opp. 19-20. But plaintiffs identify nothing in the petition or, for that matter, in their district court filings, to support this assertion. The petition, which was filed in 2001, before Plan B One-Step was even manufactured, addressed "Plan B, and any new drug eligible for filing an abbreviated new drug application because of its equivalence to . . . Plan B." Citizen Pet. at 1. A drug is "eligible for filing an abbreviated new drug application because of its equivalence to" another drug only if it is a generic version of that initial drug, *e.g.*,, it has the same "conditions of use . . . in the labeling" as the "listed drug," "the dosage form, and the strength of the new drug are the same as those of the listed drug," and "the labeling proposed for the new drug is the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(i), (iii), (v); *see also PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2574-76 (2011). Because Plan B One-Step (the one-pill drug) contains a different dosing regimen and different labeling than Plan B (the two-pill drug), Plan B One-Step is not "eligible for filing an abbreviated new drug application because of its equivalence to . . . Plan B" (Citizen Pet. at 1). Accordingly, when FDA acted on the petition in 2011, it properly understood the petition to encompass only Plan B and generic versions of that drug, and plaintiffs at no point suggested otherwise.

Although plaintiffs declare that "[t]he District Court made clear that the Citizen Petition encompasses" both drugs (Opp. 19), the court did not — and could not — so conclude. Plaintiffs merely quote language from the district court's stay order stating: "'[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.'" Opp. 20 (quoting May Order at 2). The court used the word "equivalent" without regard to the statutory standard and did not suggest that Plan B One-Step was "eligible for filing an abbreviated new drug application because of its equivalence to . . . Plan B" (Citizen Pet. 1), and any such conclusion would have been clear error.

Indeed, the district court itself distinguished between the two drugs: its order requires FDA to make the one-pill drug available for all ages without prescription but does not necessarily require FDA to make the two-pill drug similarly available. *See* Order at 57 (if "FDA actually believes there is any significant difference between the one- and two-pill products," the agency may "limit its over-the-counter approval to the one-pill product"). Anomalously, the court's order thus requires action with respect to the one-pill drug that was not the subject of the citizen petition but does not likewise require action with respect to the two-pill drug that was the subject of the citizen petition.

B. The district court was equally incorrect to declare that it could require FDA to grant the citizen petition and further to approve either the one-pill or the two-pill

drug for nonprescription sale without first going through the statutorily mandated processes. *See* Mot. 15-18.

1. When a court finds that an agency has erred, the court ordinarily must remand back to the "agency for decision of [the] 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). Plaintiffs declare that this is one of the "rare cases" in which a court may refuse to remand to allow an agency to conduct its statutory responsibilities, *see* Opp. 13-15, 17-18, but they have not and cannot meet their burden of showing that further agency action "would be utterly futile," *Watson* v. *Geren*, 569 F.3d 115, 134 (2d Cir. 2009), *reh'g denied*, 587 F.3d 156 (2009). Such a course would be extraordinary in any controversy; it is particularly anomalous when a court purports to dictate the terms on which a drug should be sold to the public.[1]

The court cited several inadequacies in the agency's explanation for its denial of the citizen petition, including FDA's asserted failure to address certain studies as well as "unexplained departures" from what the court viewed as FDA's usual practice of

[1] Although plaintiffs repeatedly suggest that the procedural history of this case necessarily renders it one of the "rare cases" in which a court can direct the outcome of an agency decision, the only authority offered for this contention — *Earth Island Inst.* v. *Hogarth*, 494 F.3d 757, 770 (9th Cir. 2007) — bears no resemblance to this case. Faced with a request to loosen labeling requirements for "dolphin-safe" tuna, Congress tasked an agency with conducting three specified studies and making required findings, all within a mandated schedule. The court vacated findings made without the benefit of the studies and declined to remand because the agency had given "no indication that [it] wants another chance to do what Congress asked it to do" and the statutory "deadline to conduct the studies ha[d] passed." *Id.* at 769-70.

extrapolating data from older to younger individuals and addressing concerns about improper use by young adolescents through labeling restrictions. Order at 42. It is axiomatic that the agency should be permitted to reconsider its decision in light of these objections, a principle that applies with particular force here because so much of the district court's reasoning regarding the citizen petition was based on its understanding of the Plan B One-Step SNDA proceedings that formed no part of the administrative record in this case. The agency should also be afforded the opportunity to address other issues that may be germane to a decision to commit limited resources to a rulemaking, such as the rapidly declining market share of the two-pill drug, which now accounts for only an estimated 15% of the levonorgestrel-based emergency contraceptive market. *See* Mot. 8.

Evaluation of the petition in light of the concerns raised by the district court may be enhanced if petitioners or other members of the public submit evidence regarding potentially relevant issues. For example, petitioners or others may address the extent to which existing nonproprietary studies of two-pill usage by older individuals can be extrapolated to young adolescents. They might also submit studies that include users of these younger ages or that establish the assertion that comprehension difficulties will not affect safety and efficacy of self-medication, *e.g.*, evidence that anticipated errors of taking the second dose later than instructed will not render the drug ineffective. Petitioners might likewise submit evidence to support the contention that the requirement to show identification will pose unacceptable

difficulties for persons eligible to obtain the product without prescription. (Although petitioners had ample opportunity to present such evidence to the agency in the past, they did not do so.)

In urging that a remand can serve no useful purpose, plaintiffs also confuse conclusions reached by FDA during the course of considering Teva's initial SNDA for Plan B One-Step, with the agency's consideration of the citizen petition on the two-pill drug. Plaintiffs declare, for example, that FDA "has already determined the 'safety and efficacy' of emergency contraception for all women of child-bearing age" (Opp. 17), referring to FDA's proposed action on the initial Plan B One-Step SNDA that was reversed by the Secretary. But FDA has never found that Plan B — the two-pill drug — would be safe and effective for all ages without prescription, and FDA officials thus denied the citizen petition based in part on the absence of evidence in the docket.

In sum, there is no basis for predicting the outcome of a remand in advance. What is clear, however, is that a remand is proper regardless of the agency's ultimate conclusions.

2. Even if the district court could decide for the agency that it must grant the citizen petition, the court could not order FDA to act outside of its statutorily-required procedures, but rather could only mandate that FDA take action consistent with those procedures. *See* Mot. 15-16, 17-18. Plaintiffs err in urging that a remand is unnecessary on the theory that FDA can change the status of the one-pill and two-pill

drugs without proceeding by regulation. Opp. 16-17. 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), which, in turn, requires the steps necessary to propose promulgating a regulation about the drugs, *see* 5 U.S.C. § 553; 21 C.F.R. §§ 10.25(a) & (b), 10.3, 10.40(a).[2]

FDA's regulations explain that the agency may itself initiate a rulemaking to change a drug's classification without the filing of a citizen petition, *see* 21 C.F.R. § 310.200(b), and that "any interested person" may "initiate[]" "[a] proposal" to change a drug's classification by filing a citizen petition or an SNDA. *Ibid.* FDA's regulation describing procedures for switching a drug to nonprescription status does not empower FDA to change a drug's status without conducting a rulemaking (*see* 21 U.S.C. § 353(b)(3)) or approving a properly-filed SNDA (21 U.S.C. § 355(b)-(d)). FDA's regulation does not — and could not — authorize FDA to act outside of the statutorily-mandated procedures. *See also Thomas Jefferson Univ.* v. *Shalala*, 512 U.S. 504, 512 (1994) ("agency's interpretation of its own regulations" "must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation") (internal quotation marks omitted).

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[2] Indeed, plaintiffs have previously argued (in trying to establish that the district court had jurisdiction at all) that their request for an "OTC switch" falls under "21 U.S.C. § 353(b)(3) that authorizes the Secretary '*by regulation* [to] remove drugs subject to section 355 of this title from the [prescription] requirements." Mem. Of Law In Support of Pls.' Mot. for S.J., Doc. 236, No. 05-cv-366, at 53 (E.D.N.Y. Mar. 31, 2007) (alterations in original, emphasis added).

FDA's response to the district court's decision in 2009, which required FDA to lower the cutoff age for nonprescription sale of Plan B from 18 to 17, is not to the contrary. *See* Opp. 16. In response to that order, FDA solicited a new SNDA from the Plan B drug sponsor, noting that when the agency had considered the sponsor's prior SNDA, FDA officials had concluded that the sponsor's submitted data demonstrated that Plan B is safe and effective when used without a prescription by persons who are 17 years old.[3] Although the government believed that the court overstepped its authority in ordering the change, the evidence in the SNDA supported approving the new application, and FDA did not appeal that 2009 ruling. *See* 21 U.S.C. § 355(b)-(d) (authorizing FDA to change a drug's status by granting an SNDA that makes the requisite evidentiary showings); *see also* 21 C.F.R. §§ 314.71, 314.50.

II. The Balance of Harms Strongly Favors a Stay.

A. Plaintiffs urge that this Court need not grant a stay pending appeal regardless of whether "the harm to Plaintiffs [is] 'imminent and irreparable.'" Opp. 9 (quoting Mot. 19). But the absence of any such showing by plaintiffs strongly militates in favor of granting a stay. This is not a class action, and there is no demonstration that any of the plaintiffs will be injured as a result of a stay. As we

[3] FDA had previously determined that age 18 was the appropriate cutoff based on certain enforceability concerns, but on remand from the district court, FDA reconsidered those concerns and determined that the data were sufficient to support nonprescription status for persons 17 and older.

have explained (Mot. 19), and as plaintiffs do not dispute, every named plaintiff may buy emergency contraception without prescription, and no plaintiff has alleged — much less shown — that they have or will encounter substantial difficulty in doing so.

Instead, plaintiffs assert injuries at the highest level of generality and on behalf of women generally. For example, in response to the present age cutoffs for buying these drugs without a prescription (15 for Plan B One-Step and 17 for Plan B), plaintiffs urge that some have no identification, but notably do not claim that *they* have no identification. Opp. 8. And plaintiffs argue that *any* age restriction "'will substantially injure' [them]" (Opp. 9) because purchasers "must show government-issued identification, thereby revealing their identity and address." Opp. 8.

B. Plaintiffs' assertion that the public interest precludes issuance of a stay simply recapitulates their view that the district court's order is proper and will be sustained. Plaintiffs cannot otherwise justify the train of events that the denial of a stay will set in motion. Under the scenario contemplated by plaintiffs, manufacturers would be required to submit applications for new labels and face the prospect of proceeding with labeling requirements that might soon be vacated. It might similarly be necessary to devise a mechanism by which the producers of Plan B generics would submit new proposed labeling and then proceed to take action in accordance with those labels during the pendency of the appeal. *See PLIVA,* 131 S. Ct. at 2574-76 (label of generic drug must ordinarily be identical to originally-approved drug). This process could be justified only if plaintiffs were substantially certain to obtain

affirmance of the district court's order. And consumers will derive little benefit and possible harm if manufacturers briefly make the drugs at issue available for a larger group of persons without prescription and then revert to a different regulatory regime. *See* Mot. 20.

CONCLUSION

For the foregoing reasons, and those stated in the government's motion, 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 24, 2013, I electronically filed the foregoing reply in support of the government's motion for a stay pending appeal 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 C. JED