UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Annie TUMMINO, *et al.*,	)	
***Plaintiffs*,**	)	**No. 12-CV-763 (ERK/VVP)**
v.	)	
	)	**(Korman, J.)**
Dr. Margaret HAMBURG, Commissioner of Food and Drugs, *et al.*,	)	**(Pohorelsky, M.J.)**
***Defendants*.**	)	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR STAY PENDING APPEAL

By its Order dated April 5, 2013 (ECF #85), and judgment entered on April 10, 2013 (ECF #87), this Court entered a mandatory injunction directing the Food and Drug Administration (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. On remand, the FDA may determine whether any new labeling is reasonably necessary. Moreover, if the FDA actually believes there is any significant difference between the one- and two-pill products [Plan B One-Step and Plan B, respectively], it may limit its over-the-counter approval to the one-pill product." *Tummino v. Hamburg*, __ F. Supp. 2d __, No. 12-763, 2013 WL 1348656, at *31 (E.D.N.Y. Apr. 5, 2013) (hereinafter *Tummino II*). Defendants have filed a notice of appeal to the Second Circuit from the Order and judgment. Pursuant to Fed. R. Civ. P. 62(c) and Fed. R. App. P. 8(a)(1)(A), (C), defendants respectfully move the Court to stay its Order and judgment pending appeal.

If the Court is not inclined to grant our motion for a stay pending appeal, the government moves for a temporary administrative stay of the Court's Order and judgment pending resolution by the Court of Appeals of a stay motion to that court under FRAP 8(a)(2).

Such an administrative stay would allow both this Court and the Court of Appeals to consider a stay pending appeal on a non-emergency basis, with full briefing. If this Court enters a temporary administrative stay but denies a stay pending appeal, defendants will promptly inform this Court of any Court of Appeals decision regarding a stay pending appeal. In view of the short time before the government is required to take steps to comply with the Court's order, which is effective on May 6, we respectfully request a ruling on the stay motion by the end of the day on Thursday, May 2, so that, if necessary, we may seek an emergency stay from the Court of Appeals.

The remedy the Court ordered was erroneous, for at least two reasons. First, the Court exceeded its authority by issuing an order concerning the "one-pill product," *i.e.*, Plan B One-Step (PBOS), a drug product that was not the subject of the Citizen Petition that is the basis of this action before the Court. Rather, PBOS was the subject of a supplemental new drug application (SNDA), and the Court recognized it "do[es] not have any authority to review the denial of the Plan B One-Step SNDA for the purpose of granting relief." *Tummino II*, 2013 WL 1348656, at *34. Second, the Court exceeded its authority, under principles of administrative law and the Federal Food, Drug, and Cosmetic Act (FDCA), by issuing a mandatory injunction ordering FDA "to make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days," rather than remanding to the agency for further administrative action. In such a situation, the appropriate remedy is to vacate an administrative agency's decision and to order the agency to reconsider its decision or provide a more complete explanation. The Court cannot pretermit the rulemaking process and foreclose public participation in that process by instead immediately mandating a particular substantive outcome. As set forth below, in view of these errors, the government has a substantial likelihood of success on appeal, and the balance of harms tips decidedly in the government's favor. Accordingly, it is entitled to a stay pending appeal.

A stay will not harm the plaintiffs because all of them are at least 15 years old and will soon be able to obtain at least one emergency contraceptive containing levonorgestrel (*viz.*, PBOS) without a prescription, and without having to request that drug from behind the pharmacy counter, at retail establishments that have a pharmacy counter, whether or not the pharmacy counter is open. On April 30, 2013, FDA approved an amended SNDA that had been submitted earlier by Teva Branded Pharmaceutical Products R&D, Inc. (Teva), to seek to market PBOS with no prescription requirements for any consumer but with a labeling restriction providing that the drug is not intended for use by, or sale to, consumers under age 15. *See* Decl. of Dr. Janet Woodcock, Director, FDA Center for Drug Evaluation and Research ¶ 3 (annexed hereto as Exhibit A). In that amended SNDA that FDA has now approved, Teva indicated that it will distribute PBOS to retailers with an on-site pharmacy, where it may be placed in the family planning or female health aisle (rather than kept behind the pharmacy counter) and may be sold during the retailer's normal operating hours, whether or not the pharmacy is open. The approved packaging will state that the drug is "not for sale to those under 15 years of age | proof of age required | not for sale where age cannot be verified," and the UPC code will prompt the cashier to request proof of age. The current approval does not include the lawful marketing of a prescription product for younger age groups, so the previous "dual marketing regime" for that product would end. *Id.*[1]

Teva had submitted that amended SNDA before the Court issued its April 5 Order,[2] and FDA's approval of the amended SNDA was not undertaken to comply with that Order.[3] *Id.* Thus,

[1] For persons under 15 years old, generic equivalents of Plan B, containing the two-pill levonorgestrel-based emergency contraceptive, remain available with a prescription. Woodcock Decl. ¶ 3(f).

[2] FDA does not generally disclose the existence of an application before approval absent permission from or disclosure by the sponsor. 21 C.F.R. § 314.430.

[3] As the Court is aware, FDA issued a complete response letter to the PBOS sponsor on December 7, 2011, in response to its February 7, 2011, SNDA (agency docket no. 21-998/S-002), which sought to classify

the approval does not and was not intended to provide all of the relief that the Court required in the Order, but instead reflects FDA's judgment that Teva's application contained appropriate scientific data demonstrating that the product was safe and effective for nonprescription use for females ages 15 and up. Upon approving the amended SNDA, FDA granted Teva three years of marketing exclusivity for PBOS on the basis of actual use studies that Teva conducted in women age 15 and 16 that FDA found essential to approval. *Id*. FDA's approval of the amended SNDA affects only PBOS, and does not affect Plan B or its generic equivalents, which remain available without a prescription to women age 17 and older, and by prescription to women under 17.

STANDARD FOR A STAY PENDING APPEAL

Rule 62(c) of the Federal Rules of Civil Procedure provides that "[w]hile an appeal is pending from an interlocutory order or final judgment that grants, dissolves, or denies an injunction, the court may suspend, modify, restore, or grant an injunction." In this Circuit, four factors are considered before granting a stay pending appeal: "(1) whether the movant will suffer irreparable injury absent a stay, (2) whether a party will suffer irreparable injury if a stay is issued, (3) whether the movant has demonstrated a substantial possibility, although less than a likelihood, of success on appeal, and (4) the public interests that may be affected." *Torres v. New York State Bd. of Elections*, 462 F.3d 161, 207 (2d Cir. 2006) (quoting *Hirschfeld v. Board of Elections*, 984 F.2d 35, 39 (2d Cir. 1993)); *see also In re World Trade Center Disaster Site Litig.*, 503 F.3d 167, 170-71 (2d Cir. 2007). In *Mohammed v. Reno*, 309 F.3d 95 (2d Cir. 2002), the Second Circuit surveyed how different courts have analyzed the prospect of success necessary for issuing

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PBOS as an over-the-counter (OTC) drug product for consumers of all ages. However, the issuance of the complete response letter was not the definitive end of FDA's administrative process with respect to the prescription status of PBOS. As defendants have explained, after receiving a complete response letter, a drug sponsor has several options: it may withdraw its application, 21 C.F.R. § 14.110(b)(2); it may request an agency hearing, *id*. § 314.110(b)(3); it may seek review in the Court of Appeals, 21 U.S.C. § 355(h); or it may revise its application — for example, by amending the request — and resubmit it for approval, 21 C.F.R. § 314.110(b)(1). Here, Teva responded to the complete response letter by amending and resubmitting its SNDA to FDA. *See* Woodcock Decl. ¶ 3.

a stay, ultimately agreeing with the District of Columbia Circuit's approach, whereby "[t]he necessary 'level' or 'degree' of possibility of success will vary according to the Court's assessment of the other [stay] factors." *Id.* at 101 (quoting *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977)). The Court observed: "[t]he probability of success that must be demonstrated is inversely proportional to the amount of irreparable injury plaintiff will suffer absent the stay. Simply stated, more of one excuses less of the other." *Mohammed*, 309 F.3d at 101 (citing *Washington Metro. Area Transit Comm'n*, 559 F.2d at 843); *see also Citigroup Global Markets, Inc. v. VCG Special Opportunities Master Fund, Ltd.*, 598 F.3d 30, 36-38 & n.8 (2d Cir. 2010); *NRDC v. FDA*, 884 F. Supp. 2d 108, 121-23 (S.D.N.Y. 2012); *Safeco Ins. Co. of America v. M.E.S., Inc.*, No. 09-CV-3312 (ARR), 2010 WL 5437208, at *7 (E.D.N.Y. Dec. 17, 2010) (collecting cases indicating that the party seeking a stay does not need to demonstrate that it is more likely than not that it will succeed on the merits).

ARGUMENT

I. DEFENDANTS HAVE A SUBSTANTIAL LIKELIHOOD OF SUCCESS ON APPEAL.

A. The Court Exceeded its Subject Matter Jurisdiction in Reviewing the Agency's Denial of Teva's SNDA for PBOS and Ordering Agency Approval of PBOS for Unrestricted OTC Availability.

This Court lacks subject matter jurisdiction to review any aspect of Teva's February 2011 SNDA for PBOS, including the HHS Secretary's December 2011 directive to the FDA Commissioner to issue a complete response letter that rejected that SNDA. A district court does not have jurisdiction to review such agency action. Jurisdiction over such action is vested by the FDCA exclusively in the appropriate court of appeals on a petition for review brought by the sponsor whose application was denied. *See* 21 U.S.C. § 355(h). The Court acknowledged this limitation on its subject matter jurisdiction, observing that "the only decision subject to review 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." *Tummino II*, 2013 WL 1348656, at *19.

That Citizen Petition did not request FDA action as to all "levonorgestrel-based emergency contraceptives" as the Court's remedy addresses. The Citizen Petition sought agency action only on Plan B (the original two-pill product) and its generic equivalents. *See* Admin. R. at CP 21 [Case No. 05-366] (requesting that "the Food and Drug Administration (FDA) switch from prescription to over-the-counter (OTC) status two FDA-approved emergency contraceptive drugs, Preven [which is no longer marketed] and Plan B, and any new drug eligible for filing an abbreviated new drug application because of its equivalence to" those drug products). The Court's determination that the agency's denial of the Citizen Petition was arbitrary and capricious could support relief only with regard to that agency action. Thus, the relief awarded must be limited to the specific products covered by the Citizen Petition and not to other products such as PBOS. But, the Court's Order authorizes FDA to comply with its injunction by lifting the restrictions on PBOS without making any change to the two-pill Plan B, as long as FDA "actually believes there is any significant difference between the one- and two-pill products." *Tummino II*, 2013 WL 1348656, at *31.

Moreover, the Court's decision undertakes an extensive review of Teva's February 2011 PBOS SNDA, the end result of which is an Order to FDA to reverse its December 2011 agency action and make available PBOS without a prescription or point-of-sale restriction to all ages. The Court first ordered FDA to "make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions." *Id*. at *31. It then went on, however, to expressly preclude FDA from complying with this directive by means of "administrative rulemaking proceedings." *Id*. at *32. But FDA's regulations allow it to effect such a change from a prescription drug product to OTC in only two possible ways – by approving a drug sponsor's SNDA or through a notice-and-comment rulemaking proceeding (which may be

initiated *sua sponte* by the Commissioner or in response to a citizen petition).[4] If the rulemaking option is foreclosed, as it is under the Court's Order, then the only available way for FDA to comply with the Court's directive is to request that Teva's submit an SNDA for PBOS seeking the same changes as the February 2011 SNDA, as to which FDA issued the complete response letter in December 2011, and to grant that SNDA. Thus, the Court essentially directs FDA to reverse its decision on Teva's February 2011 SNDA for PBOS, something the Court concededly lacks the power to do.

Thus, despite the Court's recognition that it does "not have any authority to review the denial of the [PBOS] SNDA for the purpose of granting relief," *id*. at *19, the relief it ultimately granted is precisely the change Teva had unsuccessfully sought in its February 2011 SNDA for PBOS. The Court therefore encroached upon the exclusive jurisdiction of the courts of appeals to review and provide relief with respect to SNDAs. *See Merritt v. Shuttle, Inc.*, 245 F.3d 182, 187 (2d Cir. 2001) ("statutes . . . that vest judicial review of administrative orders exclusively in the courts of appeals also preclude district courts from hearing claims that are 'inextricably intertwined' with review of such orders") (citation omitted); *see also FCC v. ITT World Communications Inc.*, 466

[4] The Court agreed in *Tummino I* that these were the only options available to FDA for achieving a change to a drug's prescription status. *Tummino v. Torti*, 603 F. Supp. 2d 519, 525 (E.D.N.Y. 2009) (*Tummino I*). The court held in its Order, however, "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." *Tummino II*, 2013 WL 1348656, at *32. The Court opined that 21 U.S.C. § 353(b)(3)'s language is permissive rather than mandatory, and that 21 C.F.R. § 10.30 allows FDA to change a drug's prescription status in response to a citizen petition by regulatory fiat without having to initiate a rulemaking proceeding. *Id*. Contrary to the Court's interpretation, however, the language in 21 C.F.R. § 10.30 does not expand the Commissioner's power or authorize her to take agency actions that she would not be authorized to take in contexts outside of a citizen petition, and it does not mean that a citizen petition authorizes the Commissioner to effect a change to OTC other than by rulemaking or by approval of an SNDA. It simply means that the Commissioner has the authority, in response to a citizen petition, to pursue an otherwise available course of agency action that is different from what the petition proposed. The Court's own decision in *Tummino I* supports at least a substantial possibility that the Court's construction of the regulation will be reversed on appeal. The Court should, in any event, have deferred to this reasonable interpretation by FDA of its own statute and regulations, which is supported by the plain language. *See Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 150-151 (1991).

U.S. 463 (1984); *Telecommunications Research & Action Ctr. (TRAC) v. FCC*, 750 F.2d 70, 77 (D.C. Cir. 1984) (statutes that vest judicial review of administrative orders exclusively in the courts of appeals extend to "any suit seeking relief that *might* affect the Circuit Court's *future* jurisdiction") (emphasis added).

Because the Court articulated that it does not have jurisdiction to review – or, therefore, to order relief with respect to – PBOS, there clearly is at least a substantial possibility that the government will prevail on the appeal. Thus, the Court should stay its Order and judgment.

B. The Court Exceeded Its Authority In Ordering A Change for Plan B From Prescription To OTC Instead of Remanding to the Agency For Further Action.

The remedy the Court ordered with respect to the levonorgestrel-based emergency contraceptives that was the actual subject of the Citizen Petition – the two-pill product Plan B – was also erroneous. And there is a substantial likelihood that the Court of Appeals will so rule because the specific relief this Court awarded – in the nature of a mandatory injunction directing FDA to approve all "levonorgestrel-based emergency contraceptives" for unrestricted OTC marketing within 30 days – exceeded the Court's authority.

Having found the agency's denial of the Citizen Petition to be arbitrary and capricious, the Court erred in ordering a circumvention of the administrative process, substituting its judgment for the agency's, and directing a specific substantive regulatory course of action. The relief directed by the Court is essentially in the nature of mandamus because it directs the outcome of how an agency is to exercise its authority, rather than directing the agency to exercise its authority in conformance with the law as stated by the Court. *See Norton v. So. Utah Wilderness Alliance (SUWA),* 542 U.S. 55, 63-65 (2004). It is well-established, however, that mandamus is an "extraordinary remedy" that "will issue only to compel the performance of a clear and nondiscretionary duty." *Pittston Coal Group v. Sebben*, 488 U.S. 105, 121 (1988); *see also*

SUWA, 542 U.S. at 63; *Califano v. Yamasaki*, 442 U.S. 682, 698 (1979); *Association of Am. Med. Colleges v. Califano*, 569 F.2d 101, 111 n.80 (D.C. Cir. 1977) ("it is to be employed only under exceptional circumstances, for courts will intervene to disturb the determinations of administrative officers only in clear cases of illegality"). Moreover, even when mandamus is granted, courts are not to direct or influence the exercise of discretion of the officer or agency in the making of the decision. *See Wilbur v. United States*, 281 U.S. 206, 218 (1930) (a court cannot, pursuant to its mandamus jurisdiction, "direct the exercise of judgment or discretion in a particular way"); *SUWA*, 542 U.S. at 64; *United States ex rel. Schonbrun v. Commanding Officer, Armed Forces*, 403 F.2d 371, 374 (2d Cir. 1968); *see also Environmental Defense Fund*, 578 F.2d at 339 (courts must "proceed with particular caution, avoiding all temptation to direct the agency in a choice between rational alternatives."). The Court neither considered nor adhered to these precedents but instead granted a mandatory injunction that directed the exercise of judgment or discretion in a particular way.

Rather than issuing a directive to the agency as to what specific action to take, the Court should have remanded to the agency for compliance with its legal ruling. It is well-established that if the agency record does not support the action under review, if the agency did not consider all the relevant factors, if the agency did not furnish an adequate explanation for its decision, or if the reviewing court cannot evaluate the challenged agency action on the basis of the record before it, then

> the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation. The reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry.

Florida Power & Light Co. v. Lorion, 470 U.S. 729, 744 (1985); *see also INS v. Ventura*, 537 U.S. 12, 16, 18 (2002); *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976) (*en banc*).[5] This Court acknowledged these principles in *Tummino I*, noting that: "When a court reviewing an agency decision rules in favor of the plaintiff, it generally remands to the agency rather than granting affirmative relief." *Tummino I,* 603 F. Supp. 2d at 549. It went on to recognize a limited exception to this general remand rule in situations where the record has already been fully developed, and that remand would fail to serve any useful purpose; it however rejected plaintiffs' suggestion that that exception be applied in the case, both because the leadership of FDA "can be trusted to conduct a fair assessment of the scientific evidence" on remand and *also* because "a decision whether Plan B, a systemic hormonal contraceptive drug, may be used safely without a prescription by children as young as 11 or 12, is best left to the expertise of the FDA, to which Congress has entrusted this responsibility; it should not be made by a federal district court judge." *Id*. at 549. Although the Court's latest opinion proceeds differently on the first aspect, the expertise of the agency in this area remains.

Here, the proper course of action should have been to remand for further agency consideration, or for elaboration of the basis for a decision not to proceed with rulemaking as to Plan B. The Court's Order interferes with and thereby undermines the regulatory procedures governing FDA's drug approval process. A drug approval decision involves scientific judgments as to whether statutory and regulatory factors are met that warrant deference to those charged with the statutory responsibility to make those decisions. The agency alone has the necessary information and scientific expertise to assess the data and information required to make a determination that a drug is safe and effective.

[5] This principle is echoed in FDA's own regulations. *See* 21 C.F.R. § 10.45(i)(1), (2).

Nevertheless, the Court declined to remand to the agency. Instead, it stepped into FDA's shoes, directed the scientific conclusions that the agency must draw from the record before it, and granted relief beyond the scope of the Citizen Petition. It failed to cite to or distinguish *Lorion*, *Ethyl Corp.*, or their progeny, or to explain why a remand would fail to serve a useful purpose at this point.[6] Indeed, over the past eight years, FDA has invested thousands of hours reviewing and acting upon multiple iterations of SNDAs, generic competitors, as well as the Citizen Petition. On remand, FDA would reconsider, consistent with any governing legal ruling by the Court, the Citizen Petition regarding Plan B and its generics in light of the applicable scientific data or information. Thus, at a minimum, the government has a substantial possibility of success on the merits of this point on appeal, and a stay is appropriate.

II. A STAY WILL NOT HARM PLAINTIFFS.

The plaintiffs – including the most recently added plaintiff – are all over age 15 and therefore will soon be able to obtain at least one emergency contraceptive containing levonorgestrel (*viz.*, PBOS) without a prescription at retail establishments that have a pharmacy counter. Thus, an injunction is not required to afford relief to any of the plaintiffs.[7] They can purchase the product whenever the store is open (regardless of whether the pharmacy is open) by showing proof of age.[8] Accordingly, all the plaintiffs in this case will soon have access to

[6] The one situation where *Tummino I* had recognized a limited exception to the general remand rule – where the record had already been fully developed, so that remand would fail to serve any useful purpose – clearly does not apply here, since the Court considered materials that had never been submitted to the Citizen Petition docket.

[7] Even assuming *arguendo* that Teva's previous point-of-sale restrictions could somehow have caused a justiciable injury-in-fact to any of the plaintiffs, its newly-approved amended SNDA largely dispenses with those restrictions in favor of a new point-of-sale regime proposed by Teva that is even less demanding of consumers. The Court has no evidence before it that any plaintiff will suffer injury-in-fact under this new regime; certainly, the specific point-of-sale restrictions that this Court found to potentially cause injury to some consumers of emergency contraceptives are no longer in place for PBOS.

[8] The requirement to show proof of age to purchase a product has been held not to impair a legally-protected interest. *See* ***Error! Main Document Only.****Whalen v. Roe,* 429 U.S. 589, 599, 601-02 (1977)*; see also Immediato v. Rye Neck Sch. Dist.,* 73 F.3d 454, 463 (2d Cir. 1996)*; Barry v. New York,* 712 F.2d 1554, 1559

levonorgestrel-containing emergency contraceptives without meaningful restrictions or impediments. Therefore, no plaintiff has a basis to assert harm from a stay of the Court's Order and judgment pending appeal.

This is, moreover, not a class action, so the extraordinary relief the Court ordered – directing FDA to make PBOS available OTC without restriction despite its lack of jurisdiction over FDA's decision concerning that drug, and directing FDA to dispense with rulemaking required by the regulatory framework to provide for public participation and instead to take immediate substantive action for Plan B – cannot be justified on the ground that Plan B or PBOS should be made available to others. In the exercise of its equitable power in a suit under the APA, a court must confine its remedy to redressing the injury asserted by the parties before the Court. *See Monsanto Co. v. Geertson Seed Farms,* 130 S.Ct. 2743, 2761 (2010).

III. DEFENDANTS AND THE PUBLIC INTEREST WILL SUFFER IRREPARABLE HARM ABSENT A STAY.

As set forth above, under Second Circuit precedent, the degree of irreparable injury that a movant must demonstrate to support a stay pending appeal is inversely proportional to the degree of probability of success on the merits of the appeal. *Mohammed*, 309 F.3d at 101. Because the government has demonstrated above a very substantial likelihood of success on appeal, the degree of irreparable injury it must demonstrate is reduced. That standard is readily met here because, absent a stay, the Court's decision will cause irreparable harm to the government, and to the public it serves.

FDA and the public would be irreparably and immediately harmed if a drug product that purported to be "FDA approved" were approved instead at the direction of a court. The public properly relies upon FDA classification of drugs as non-prescription as a reflection of the agency's judgment regarding the safety and proper use of a drug without a doctor's prescription. Thus, the

(2d Cir. 1983).

public interest will not be served by reclassification of drugs as non-prescription without agency approval. A stay of the Court's Order will prevent public uncertainty regarding the status of the drugs at issue here pending the government's appeal to the Second Circuit. Moreover, if the status of these drugs is changed and later reversed, it can lead to situations in which women mistakenly believe that they can obtain the drug without a prescription or at certain locations where it used to be available, but is no longer.

Further, FDA has long interpreted its regulations to provide that the agency cannot effect a change from prescription to OTC by simply granting a Citizen Petition. A change to OTC requires either the drug sponsor to submit an SNDA with supporting data or else the agency to conduct notice-and-comment rulemaking in which all interested members of the public — not only those who filed a Citizen Petition — may participate and assist in developing a complete record on which the agency can then base its expert decision. Permitting a member of the public to seek to alter the indication of an approved drug product by filing a petition, as the Court seems to do, would undermine the separate regulatory proceedings of citizen petitions and drug applications, interfere with proprietary interests drug companies have in their NDAs, and significantly weaken the incentives for drug innovators to invest in drug development, including seeking new indications. Because such a ruling would harm the public, the public interest favors a stay.

A. Failure to Grant a Stay Will Result in Substantial Market Confusion, Irreparably Harming FDA's and the Public's Interest in the Orderly Functioning of the Drug Regulatory System.

If FDA were required to comply with the Court's Order pending appeal, at least some emergency contraceptive drug products containing levonorgestrel would become available to all ages without a prescription or point-of-sale or labeling restrictions. If the Court's Order were to be found on appeal to be in excess of the Court's authority (which there is a substantial

probability of, for the reasons set forth above), FDA would take appropriate action to withdraw the unrestricted OTC approval and to reinstate the product's previous approval status. Such a rescission can reasonably be expected to cause substantial market confusion, harming FDA's and the public's interest in the orderly functioning of the drug regulatory system.

For example, now that PBOS is approved for OTC availability with a labeling restriction that the product is not for sale to consumers under age 15, and with a requirement of age verification by retail cashiers, retailers will train their employees on how the product may now be sold. Absent a stay, if FDA were required to approve the marketing of PBOS to women of all ages during the pendency of an appeal, those retailers would need to instruct their employees to make the product available without any age verification. If the Court Order were then to be vacated, the retailers would again need to instruct and retrain their employees as to how to re-impose the age restriction. The likely confusion of retail employees will only exacerbate consumer confusion as to the availability of PBOS.

In addition, if the Second Circuit vacates this Court's Order, the products held for unrestricted sale at the time the appeal is decided would be misbranded under the FDCA, 21 U.S.C. § 352. It is likely that the misbranded version of the product (*i.e.*, labeled for unrestricted OTC use) would exist alongside properly labeled versions of the product (labeled for OTC use only in women down to age 15) during a potentially extended transitional period while retailers clear their inventory and replenish their stocks. This circumstance would also confuse and thereby irreparably harm consumers.

B. The Government's Interest in Conferring Marketing Exclusivity Will Be Irreparably Harmed Absent a Stay.

Congress provided marketing exclusivity periods in the FDCA to encourage the development of new and improved drugs, thereby protecting and promoting the public health.

The FDCA provides that, when a drug sponsor invests funds to conduct or sponsor new clinical studies that FDA finds are essential to the approval of an SNDA, FDA is to grant three years of exclusivity with respect to the change approved in the SNDA. *See* 21 U.S.C. §§ 355(c)(3)(E)(iv), 355(j)(5)(E)(iv); 21 C.F.R. § 314.108(b)(5). This exclusivity bars FDA from approving that same change for a generic version of the drug for three years. Congress intended this exclusivity to provide an economic incentive for pioneer companies to engage in the expensive clinical research necessary to support the approval of significant changes to a drug's approval status, such as approval for use in new patient populations. *See AstraZeneca Pharm. v. FDA*, 872 F. Supp. 2d 60, 89-90 (D.D.C. 2012).

It is undisputed that, based on FDA's representations regarding the need for additional data to support approving PBOS for use without a prescription by younger age groups, Teva conducted actual use studies that included participation by sufficient numbers of 15 and 16 year olds. The agency deemed those studies essential to approval of non-prescription use of the drug by those age groups. The Court nevertheless implies in its decision that FDA cannot grant Teva marketing exclusivity for a change for PBOS from prescription to OTC simply because FDA issued a complete response letter to Teva in December 2011 and Teva chose not to file a petition for review to the court of appeals. This implication ignored the prospect that, instead of appealing, Teva could file an amended SNDA, which FDA could approve, leading to a grant of exclusivity. That is what happened when FDA recently approved Teva's 15-and-up amended SNDA and gave Teva three years of marketing exclusivity for the newly approved use.

To the extent the Court's decision can be read to deprive Teva marketing exclusivity under the circumstances here – that is, to the extent it can be read to require FDA to also approve generic versions of PBOS for nonprescription use without age restrictions – it will cause irreparable harm to the regulatory process by undermining the benefits to the public and to FDA

of the marketing exclusivity that the FDCA affords to drug sponsors. As noted, such exclusivity provides a critical incentive for drug development that advances FDA's goal of protecting and promoting public health. To the extent the Court's order is construed to eliminate Teva's entitlement to exclusivity, it undermines the incentive for drug companies to conduct new clinical research studies to support new uses or indications, because it permits competitors to take advantage of the investments of market innovators free of charge. Such a result would stifle rather than encourage innovation, to the detriment of the public.

CONCLUSION

For the foregoing reasons, defendants respectfully request a stay pending appeal. If this Court is not inclined to grant a stay pending appeal, defendants respectfully respect that the Court enter a temporary administrative stay of the Court's Order and judgment pending resolution by the Court of Appeals of any motion defendants might make to that court under FRAP 8(a)(2).

Dated: May 1, 2013

Respectfully submitted,

STUART F. DELERY
Acting Assistant Attorney General
Civil Division

IAN HEATH GERSHENGORN
Deputy Assistant Attorney General

SHEILA LIEBER
Deputy Director,
Federal Programs Branch

ERIC B. BECKENHAUER
Trial Attorney,
Federal Programs Branch
United States Department of Justice, Civil Division
20 Massachusetts Avenue, N.W.
Washington, DC 20530
(202) 514-3338

LORETTA E. LYNCH
United States Attorney
Eastern District of New York
271 Cadman Plaza East
Brooklyn, NY 11201-1820

By: /s/ {FILED ELECTRONICALLY}
F. FRANKLIN AMANAT (FA6117)
Assistant United States Attorney
Eastern District of New York
(718) 254-6024
franklin.amanat@usdoj.gov

Of Counsel:

DAVID J. HOROWITZ, Deputy General Counsel
ELIZABETH H. DICKINSON, Chief Counsel, Food and Drug Division
ANNAMARIE KEMPIC, Deputy Chief Counsel, Litigation, Food and Drug Division
SCOTT A. KAPLAN, Assistant Chief Counsel, Food and Drug Division
United States Department of Health and Human Services
Office of the General Counsel
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002