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June 12, 2013

VIA ELECTRONIC COURT FILING
AND ELECTRONIC MAIL

The Honorable Edward R. Korman
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: *Tummino, et al. v. Hamburg, et al.*
Case No. 12-CV-763 (ERK/VVP)

Dear Judge Korman:

Plaintiffs respectfully submit this response to Defendants' letter, dated June 10, 2013, (ECF No. 103) advising the Court of their plan to make only Teva's brand name one-pill emergency contraception product, Plan B One-Step, available over-the-counter without age or point-of-sale restrictions. Defendants' letter also advises the Court that "FDA will not at this time take steps to change the approval status of the two-pill Plan B or its generic equivalents." *Id.*

The Court's April 5, 2013, Order (the "Order") and the April 10, 2013, Judgment directed Defendants "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." ECF No. 85 at 57 (emphasis added).[1]

Defendants contend that their plan to make Plan B One-Step available over-the-counter with a potential exclusivity agreement, complies with this Court's judgment. They further

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[1] The Court further stated that "if the FDA actually believes there is any significant difference between the one- and two- pill products, it may limit its over-the-counter approval to the one-pill product." *Id.*

request the Court to "confirm[] that the government's understanding is correct." ECF No. 103. But Defendants' proposal fails to comply with the Court's Order in two key respects: (1) Defendants actions as to the two-pill products do not comply with the Court's Order that two-pill products must be made available without point-of-sale restrictions; and (2) Defendants fail to provide adequate details regarding the timeline and process by which they will make Plan B One-Step and other one-pill levonorgestrel-based emergency contraceptives available without prescription or other restrictions.

Defendants were to comply with this Court's Order within 30 days of entry of Judgment, on or before May 10, 2013. Rather than taking any steps to comply, however, Defendants sought a stay, first from this Court and subsequently from the U.S. Court of Appeals for the Second Circuit. On June 5, 2013, the United States Court of Appeals for the Second Circuit granted that request in part and denied in part. *See* U.S. Court of Appeals for the Second Circuit Case No. 13-1690, ECF No. 85. As a result, the Second Circuit has ruled that "Insofar as the order mandates immediate over-the-counter access to the two-pill variants of emergency contraceptives, a stay is denied[.]" *Id.*

Defendants' filing on June 10, 2013, states that the FDA "will not at this time take steps to change the approval status of two-pill Plan B or its generic equivalents." *See* ECF No. 103. The letter responding to the Citizen Petition confirms the same even though the FDA has consistently taken the (incorrect) position that the Citizen Petition only ever requested over-the-counter unrestricted access as to two-pill emergency contraception products. *See* ECF No. 103-1. Defendants' proposal deprives women of more affordable emergency contraceptives creating an improper financial barrier to access for poor women and young women.[2] *See* ECF No. 98 at 7.

The announced decision by the U.S. Government to permit Teva-branded Plan B One-Step to be sold without point-of-sale and age restrictions is insufficient to comply with the Order. The Order stated that only if the agency determined there is a "significant difference" between these drugs, it may limit its over-the-counter approval to the one-pill product. Defendants have never met the burden to prove any "significant difference," nor has the FDA done so in its latest letter responding to the Citizen Petition or its June 10, 2013, letter to the Court. Instead, Defendants rely on arguments raised in earlier briefs as support for their conclusory assertions that the two products are different; these arguments have already been determined to be pretext for improper political motive and another example of the bad faith permeating the agency's consideration of the Citizen Petition. *See e.g.*, ECF No. 85 at 41-42. The Court already has considered and rejected Defendants' recycled arguments.

Defendants seek to rehash an already resolved and rejected argument that an "actual use" study provided by Teva (the "Actual Use Study") in connection with its Plan B One-Step

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[2] Although at this time, it is not clear whether the FDA will grant three years of exclusivity to unrestricted over-the-counter access to the manufacturer of Plan B One-Step, past practice shows that such exclusivity will result in higher cost for consumers which places an unjust burden and restriction on access to females who need this product.

Supplemental New Drug Application ("SNDA") offers data that is necessary for the agency to determine that levonorgestrel-based emergency contraception is safe for over-the-counter use by women of all ages.[3] However, on numerous occasions, this Court has held that the Actual Use Study was not necessary to its determination that the FDA must make levonorgestrel-based products available over-the-counter, including most recently at argument on Defendants' Motion to Stay the April 5, 2013, Order:

> [E]xcluding… th[e] one study on actual use, the Plaintiffs were still entitled to win under the policies that the FDA has applied and which they violated one-by-one in this case. So that if I am right, they're entitled to their relief and the study that Teva submitted the actual use study is not essential.

See Transcript on oral argument on Defendants' Motion for Stay, May 7, 2013, at 30:20 - 31:2; *Id.* at 32:5 – 14 (same, adding that "you've given [Teva] exclusivity which in my view, they're not entitled to"); *Id.* at 55:18 – 25, 58:21 – 59:2, 62:11 – 20, 63:18 – 64:4, 64:22 – 24 (same).

Plaintiffs respectfully request that this Court determine that Defendants' proposal set forth in its June 10, 2013, letter does not constitute compliance with the Court's April 5, 2013, Order in that it denies unrestricted access to two-pill levonorgestrel products.

In addition, Defendants' June 10, 2013, letter states that FDA is inviting the sponsor of Plan B One-Step to submit a SNDA to market that product as a non-prescription product available without point-of-sale or age restrictions and that FDA will approve the application "without delay." This vague assurance, in light of the repeated and numerous delays for years in this case, is not adequate to comply with the Court's Order. Defendants, at a minimum, should be required to approve any SNDA on a fixed schedule. Under the circumstances, a period of no more than 10 days should be wholly adequate. Defendants state that "[i]f FDA grants Teva marketing exclusivity, the scope of that exclusivity may affect the labeling that could be approved for generic equivalents of [Plan B One-Step]." ECF No. 103. Defendants do not specify the impact that a grant of marketing exclusivity would have on generic equivalents, specifically, whether the FDA intends to continue point-of-sale or age restrictions for other levonorgestrel-based emergency contraceptives. Plaintiffs object to Defendants' proposal because it does not entail the removal of unjustified age or point-of-sale restrictions for all products, including more affordable options.[4]

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[3] Moreover, as the Order fully explains, the evidence regarding the one-pill products applies with equal force to the two-pill products. See ECF No. 85 at 42-48.

[4] Plaintiffs are concerned that Defendants have not stated if they are now granting any form of exclusivity to Plan B One-Step which could perpetuate politically motivated restrictions as to the other one-pill products. *See* ECF No. 85 at 47. This Court has recognized such an unwarranted grant of exclusivity increases the cost of the drug, thereby perpetuating an impediment to access to emergency contraception for many poor women and adolescents. *See* ECF No. 98 at 7; *see also* Hearing Tr. at 35:14 – 36:1; 29:5 – 11; 30:4 – 11; 31:14 – 18; 32:18 – 33:2; 38:6-7.

More than twelve years has passed since the Citizen Petition was filed. Women and girls have waited long enough for the government to remove the unscientific and politically motivated barriers to emergency contraception.

Defendants' claim that they have complied with the Court's Order rings hollow.[5] More than two months have elapsed since this Court ordered the two-pill levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions. This is a drug for which every hour of delayed or burdened access risks more unintended or unwanted pregnancies. The time for delay has been exhausted by the government.

Plaintiffs respectfully request that if the Court determines that Defendants' proposal set forth in its June 10, 2013, letter does not constitute compliance with this Court's Order, that the Court shall direct Defendants to make two-pill levonorgestrel-based emergency contraceptives immediately available over-the-counter with age or point-of-sale restrictions.

Thank you for Your Honor's attention concerning this matter.

Respectfully submitted,

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[5] Defendants, 60 days after this Court's Order act as if no time has passed even though they allowed the 30 days to elapse and are under an Order from the Second Circuit's to immediately make two-pill products available. Arguably, this conduct weighs against a finding in the government's favor as to compliance.

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