



U.S. Department of Justice

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*271 Cadman Plaza East
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May 1, 2013

**BY ELECTRONIC COURT FILING
AND COURTESY COPY BY HAND DELIVERY**

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

Re: *Tummino v. Hamburg, No. 12-CV-0763 (ERK/VVP)*

Dear Judge Korman:

The government has today filed a notice of appeal from the Court's April 5 decision (and April 10 judgment) in the above-referenced action. The government has also moved for a stay pending appeal of the Court's injunction directing FDA to "make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days." We respectfully submit courtesy copies of the notice of appeal, the motion for stay, and the memorandum and declaration in support of that motion.

As detailed in the papers supporting the motion for a stay pending appeal, FDA yesterday approved an amended supplemental new drug application (SNDA) submitted by the sponsor of Plan B One-Step in March 2012, pursuant to which that drug is now available without a prescription to consumers age 15 and over. Although FDA did not take that action for purposes of complying with the April 5 Order, the approval has the effect of ensuring that all of the plaintiffs in this case (including the youngest of them) now have access without a prescription and without significant point-of-sale restrictions to at least one form of emergency contraceptive containing levonorgestrel. As a result, no plaintiff will be harmed by a stay. On the other hand, for reasons set forth in the motion, the government has a substantial likelihood of success on the merits of an appeal, and both defendants and the public interest will be substantially and irreparably harmed by the denial of a stay.

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. The public interest will not be served by reclassification of drugs as non-prescription by order of a court, without appropriate agency decision-making procedures being

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followed. 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, but is no longer, available. Depending on the outcome of the appeal, the problem would be exacerbated because products with incorrect labeling will presumably remain on pharmacy shelves even after an appellate ruling reversing the injunction.

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 any motion defendants might make 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.

We appreciate the Court's time and considered attention to this matter.

Respectfully submitted,

LORETTA E. LYNCH
United States Attorney
Eastern District of New York

By: /s/ {FILED ELECTRONICALLY}
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Encl.: Notice of Appeal
Motion for Stay Pending Appeal
Memorandum of Law in Support of Motion for Stay Pending Appeal
Declaration of Janet Woodcock, with Exhibit

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cc (by email and ECF notification):

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