IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, *et al.,*

Plaintiffs,

CV-12-0763 (ERK/VVP)

v.

MARGARET HAMBURG, *et al.*,

Defendants.

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EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, in her individual capacity, as an organizer with National Women's Liberation, and on behalf of women who need Emergency Contraception; ERIN T. MAHONEY, in her individual capacity, as an organizer with National Women's Liberation, and on behalf of women who need Emergency Contraception; CAROL GIARDINA, in her individual capacity, as an organizer with National Women's Liberation, and on behalf of women who need Emergency Contraception; KELLY MANGAN, in her individual capacity, as an organizer with National Women's Liberation, and on behalf of women who need Emergency Contraception; STEPHANIE SEGUIN, in her individual capacity, as an organizer with National Women's Liberation, and on behalf of women who need Emergency Contraception; LORI TINNEY, in her individual capacity, as an organizer with National Women's Liberation, and on behalf of women who need Emergency Contraception; JENNIFER BROWN, in her individual capacity, as an organizer with National Women's Liberation, and on behalf of women who need Emergency Contraception; CANDACE CHURCHILL, in her individual capacity, as an organizer with National Women's Liberation, and on behalf of women who need Emergency Contraception; and FRANCIE HUNT, as an organizer with National Women's Liberation, and on behalf of women who need Emergency Contraception; ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS, on its own behalf and on behalf of its members and women who need Emergency Contraception; and NATIONAL LATINA INSTITUTE FOR REPRODUCTIVE HEALTH, on its own behalf and on behalf of women who need Emergency Contraception; ROBERT JAFFE; AURORA DEMARCO; ANGELICA JAFFE; CATHERINE LEDERER-PLASKETT; ALIZA LEDERER-PLASKETT; JONATHAN MARKS; GABRIELLE MARKS; TRACY GAFFIN; ANAYA KELLY by and through her next friend AMBER KELLY,

CV-12-0763 (ERK/VVP)

Plaintiffs,

v.

MARGARET HAMBURG, in her official capacity as Commissioner of Food and Drugs; KATHLEEN SEBELIUS, in her official capacity as Secretary of the Department of Health and Human Services,

Defendants.

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SECOND AMENDED SUPPLEMENTAL COMPLAINT

Plaintiffs, by and through their undersigned attorneys, hereby further supplement their Fifth Amended Complaint, and in support thereof aver the following:

1. Plaintiffs file this supplemental complaint to set forth events that have occurred since this Court issued its March 2009 Order granting summary judgment in Plaintiffs' favor, and to challenge Defendants' actions on remand following that Order as arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A).

2. The FDA's treatment of requests for over-the-counter access to emergency contraception, both before and after this Court's March 2009 Order, is a tale of unwarranted delays, denials, and departures from normal procedures. It is also a quintessential example of continuing to move the goalposts so that the desired goal—unrestricted over-the-counter access to a safe and effective emergency contraception product—can never be attained.

3. The evidence of safety and efficacy of emergency contraception, which has been before the FDA for more than a decade, demonstrates that it should be made available without prescription, or other restrictions, to all women.

4. In its March 2009 Order, this Court granted Plaintiffs' motion for summary judgment and vacated the FDA's denial of a Citizen Petition seeking over-the-counter access to emergency contraception on the basis that the agency had acted in bad faith and in an arbitrary and

capricious manner. Since then, Defendants have engaged in similar—and in some instances exactly the same—behavior that caused this Court to remand the matter in the first place.

5. Defendants' bad faith actions, including their establishment and maintenance of an age-restricted, behind-the-pharmacy-counter, dual prescription/nonprescription regime for emergency contraception, have caused and continue to cause significant harm to Plaintiffs and the public.

6. Plaintiffs seek: (a) immediate and permanent injunctive relief requiring Defendants to permit all levonorgestrel-based emergency contraception products to be made available to women of all ages without a prescription; (b) a declaratory judgment that the FDA's actions on remand with respect to the Citizen Petition and the Plan B One-Step supplemental new drug application, including but not limited to the denial of both, violated the Administrative Procedures Act; and (c) such other equitable relief as the Court may deem appropriate.

I. Parties

A. Plaintiffs

7. Plaintiffs Tummino, Mahoney, Giardina, Mangan, Seguin, Tinney, Brown, Churchill and Hunt were previously Coordinators with The Morning-After Pill (MAP) Conspiracy. From February 2004 until around early 2009, the MAP Conspiracy was a coalition of feminist organizations leading the grassroots movement to make the Morning-After Pill an over-the-counter drug by raising public consciousness about the ways that women have to conspire to obtain it. The MAP Conspiracy organized speak-outs where women publicly testify from their own experience about their need for the Morning-After Pill and the obstacles they face obtaining it. Members of the MAP Conspiracy also testified at the December 2003 FDA public hearings on the Barr application for approval of over-the-counter status for Plan B.

8. After 2009, The MAP Conspiracy was folded into National Women's Liberation (NWL). NWL is a national feminist group with several priority areas that include the fight for unrestricted access to birth control and abortion for all women regardless of age. Since 2009, Plaintiffs Tummino, Mahoney, Giardina, Mangan, Seguin, Tinney, Brown, Churchill and Hunt have continued their feminist organizing to lead the grassroots movement to make the Morning-After Pill an over-the-counter drug through their work as organizers in National Women's Liberation (NWL). Plaintiffs' organizing, through NWL, with regard to the Morning-After Pill consists of, *inter alia*, raising public consciousness about why women need the Morning-After Pill, organizing speak-outs where women publicly testify from their own experience about their need for the Morning-After Pill and the obstacles they face obtaining it and petitioning the FDA and HHS to make all forms of emergency contraception available OTC without any restrictions.

9. Plaintiff Tracy Gaffin is a resident of Miami, Florida, and is the mother of two daughters aged 14- and 12-years-old, respectively, and a son aged 9-years-old. She sues on behalf of herself and her children under the age of 17 because she wants her children, in particular her daughters, to be able to obtain emergency contraception without prescription and without any restriction on its point of sale so as to maximize the likelihood they will avoid unwanted pregnancy.

10. Plaintiff Anaya Kelly is a resident of Gainesville, Florida and is 14-year old young woman. She sues on behalf of herself through her next friend and mother, Amber Kelly, because she wants to be able to obtain emergency contraception without prescriptions and without any restriction on its point of sale so as to maximize the likelihood that she, and all other women, will avoid unwanted pregnancy.

B. Defendants

11. Margaret A. Hamburg, M.D. is the Commissioner of Food and Drugs, top official of the Food and Drug Administration (FDA). (Andrew C. von Eschenbach is no longer acting commissioner). Hamburg is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. She is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health. She is sued in her official capacity.

12. Kathleen Sebelius is the Secretary of the Department of Health and Human Services ("HHS"). Secretary Sebelius has asserted that she, as the person "responsible for executing" the Federal Food, Drug, and Comestic Act, has authority to overrule FDA drug approval decisions and to make final decisions regarding the over-the-counter availability of emergency contraception. She participated in and directed FDA actions that Plaintiffs claim were arbitrary and capricious. She is sued in her official capacity.

II. Factual Allegations

A. Background

13. In 2001, Plaintiff Association of Reproductive Health Professionals and sixty-five other organizations filed a Citizen Petition asking the FDA, in relevant part, to switch Plan B, a levonorgestrel-based emergency contraception product, and all and any new drug eligible for filing an abbreviated new drug application because of its equivalence to Plan B, from prescription-only to over-the-counter ("OTC") status.

14. During the same period, the manufacturer of Plan B submitted a series of supplemental new drug applications ("SNDAs") in an attempt to have that drug switched to OTC status.

15. As far back as 2001, the FDA noted that the Citizen Petition met the criteria for unrestricted OTC availability and was supported by scientific data.

16. Numerous studies, including label comprehension and actual use studies, provided more than enough data to support the conclusion that all women, regardless of age, could understand the Plan B label and use the product safely and effectively without consultation with a practitioner.

17. The FDA, however, denied the Citizen Petition in 2006, claiming, *inter alia*, that it did not contain sufficient data to show that Plan B could be used safely and effectively by women under the age of 17. The FDA also denied two SNDAs from the drug sponsor requesting an OTC switch, claiming that there was insufficient data regarding adolescents.

18. The FDA eventually granted an SNDA in 2006, partially approving Plan B for OTC status, but with an unprecedented regime that required women under 18 to obtain a prescription for the product, Plan B to be sold only in pharmacies and health clinics, the drug to be kept behind the counter, and consumers to present government-issued identification to obtain the product (the "BTC regime").

19. In 2005, Plaintiffs filed this lawsuit, challenging, *inter alia*, the FDA's arbitrary and capricious actions and seeking to end the agency's refusal to follow the scientific evidence showing that OTC status is appropriate for Plan B.

B. This Court's March 2009 Order and Subsequent FDA Actions in Response

20. On March 23, 2009, this Court granted summary judgment in Plaintiffs' favor (the "Order"), holding that the FDA's denial of the Citizen Petition's request for unrestricted OTC status for emergency contraception and its denials of successive applications from the Plan B drug sponsor violated the Administrative Procedures Act because these decisions were made in bad faith and were arbitrary and capricious. *Tummino v. Torti*, 603 F. Supp. 2d 519, 542, 544-49 (2009).

21. This Court found that the FDA's decision on Plan B was not the result of good faith decision making, took political considerations into account, had implausible justifications, and departed in significant ways from the agency's normal procedures for requested OTC switches.

22. Some of the departures from normal agency procedures the Court noted were: FDA upper management wresting control over the decision-making process from staff that normally would issue the final decision; the FDA denying full OTC access without age restriction against the recommendation of the scientific review staff; FDA staff discussing the OTC switch with the White House; and, the FDA insisting on additional data for adolescents even though data on adolescents already existed and the FDA had a long history of extrapolating data from adults to adolescents, particularly with respect to contraception.

23. The Court found that the FDA's stated concerns about the inadequacy of data available for young adolescents and its focus on adolescent cognitive development in its evaluation of Plan B as an OTC drug, which resulted in a decision to approve OTC use of Plan B with an age restriction stemmed from political pressure rather than permissible health and safety concerns.

24. Based on these findings, the Court ordered the FDA to permit the Plan B drug sponsor to make Plan B available to 17 year olds without a prescription, under the same conditions that Plan B was then available to women over the age of 18. It further vacated the FDA's denial of the Citizen Petition and remanded the matter for reconsideration of the Citizen Petition and consideration of whether to approve Plan B for OTC status without age or point-of-sale restrictions.

25. The FDA complied with the portion of the Order requiring it to change the age cutoff from 18 to 17 within 30 days. It refused, however, to comply with the remainder of the Order.

26. Indeed, following remand from this Court, Defendants have continued to engage in arbitrary and capricious actions; Defendants have ignored science and allowed politics to control the decision making regarding emergency contraception.

C. The FDA's Plan for Complying with the Court Order to Reconsider the Citizen Petition Was Arbitrary and Capricious

27. For over two and a half years, the FDA refused to take any steps to reconsider the Citizen Petition. It argued that it could comply with the Court's Order by waiting indefinitely for and ruling on a drug application for a related levonorgestrel-based emergency contraception product (Plan B One-Step), while at the same time refusing to apply the data from that application to the Citizen Petition.

28. This plan was made in bad faith, depriving Plaintiffs of a fair and honest consideration of the Citizen Petition.

29. Even if approval of the Plan B One-Step SNDA had been assured at the time the FDA made this plan, such action would still have deprived Plaintiffs of fair and honest consideration of the Citizen Petition.

30. Ruling on the Citizen Petition would have paved the way for full OTC status not only of Plan B, but of two levonorgestrel-based emergency contraception generic products currently marketed, as well as any new generics.

31. In contrast, approval of the Plan B One-Step SNDA would permit full OTC status only for Plan B One-Step, and prohibit other emergency contraception products from being available OTC for three years.

32. The FDA's admission that it planned to indefinitely ignore the Court's Order to reconsider the Citizen Petition prompted Plaintiffs to move for contempt.

D. The FDA's Denial of the Plan B One-Step SNDA Was Arbitrary and Capricious

33. In February of 2011, the Plan B One-Step sponsor submitted an SNDA, including supporting studies, seeking to make One-Step OTC for all ages.

34. In communications that began years before this submission, the FDA informed the drug sponsor that it must include new adolescent-specific data with its SNDA.

35. The Plan B One-Step's drug sponsor bowed to the FDA's demands, worked closely with the FDA in devising studies, and conducted studies in which 680 adolescents participated. The studies included a sample of subjects that allowed the researchers to conclude that the target population of the SNDA is able to correctly use emergency contraception in an OTC setting.

36. The data that was submitted to the FDA in support of the Plan B One-Step SNDA confirms what the previous studies regarding Plan B showed—that emergency contraception is safe and effective for women of all ages when self-administered. In particular, the actual use study on Plan B One-Step found that teens of all ages are capable of understanding the indications for emergency contraception and using it correctly.

37. On December 7, 2011, Dr. Margaret Hamburg, Commissioner of Food and Drugs, issued a statement in which she announced that the FDA's Center for Drug Evaluation and Research ("CDER") had completed its review of the Plan B One-Step SNDA. The statement set forth key conclusions that had been reached based on the data submitted, including that adolescent females could use Plan B One-Step properly without the intervention of a healthcare provider. She explained that CDER experts agreed that Plan B One-Step had met the OTC standards and should be approved for all women of child-bearing potential, and that her independent review confirmed that Plan B One-Step should be approved for OTC use without age restrictions.

38. On the same day, for apparently what is the first time, the Secretary of Health and Human Services, Defendant Kathleen Sebelius, asserted authority to overrule an FDA drug approval decision. She directed the FDA to deny Plan B One-Step's SNDA, stating that she "carefully considered FDA's Division Director Summary Review of Regulatory Action,," and, that based on that review, she "concluded that the data submitted for this product do not establish that prescription dispensing requirements should be eliminated for all ages."

39. In a public statement, Defendant Sebelius stated that the studies submitted with the SNDA "did not contain data for all ages for which this product would be available for use." She noted that "it is commonly understood that there are significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age, which I believe are relevant to making this determination." Defendant Sebelius specifically noted that 10% of girls start menstruating at age 11.

40. Prior to Defendant Sebelius issuing her directive, there were communications between the White House Staff and her or her staff about the potential OTC switch for Plan B One-Step.

41. The actions and reasoning leading to the ultimate denial of the Plan B One-Step SNDA mirror the actions and reasoning that led to the denials of the earlier switch applications for Plan B that prompted this Court to rule that the agency's actions were arbitrary and capricious and taken in bad faith.

42. Actual use studies consider the way that the target population of a particular product will use that product. The actual use studies for Plan B One-Step did not include any 11 and 12 year olds because so few 11 and 12 year olds ever use emergency contraception. Even if the studies had included the rare 11 year old who seeks emergency contraception, no conclusions could be drawn about 11 year olds as a group given the incredibly small number of users that age.

43. The FDA typically does not require subjects of any particular age to be included in actual use studies. Indeed, it is unusual for actual use and label comprehension studies to include persons under 18. In fact, the FDA has a long history of extrapolating findings from clinical trials in older patients to adolescents.

44. A determination of whether a switch to OTC of a drug like Plan B is appropriate is normally handled at the Office Director level within the FDA and would not require approval or sign-off by a higher level official such as the Commissioner of Food and Drugs or the Secretary of Health and Human Services.

45. Decisions regarding OTC switches are not normally discussed with the White House.

46. When the agency has not been confident of the applicability of manufacturers' studies in OTC switches to younger consumers, it has required a label warning, rather than an age restriction or outright denial.

47. There is no justification for why the review of the Plan B One-Step SNDA differed in so many significant ways from the review of other switch applications.

E. The Second Denial of the Citizen Petition Was Arbitrary and Capricious

48. Although the FDA had previously indicated to the Court that it would indefinitely defer reconsidering or ruling on the Citizen Petition because it believed a decision on Plan B One-Step SNDA would satisfy the Court's Order, it issued a denial of the Citizen Petition hours before argument on Plaintiffs' motion for contempt.

49. In remanding to the FDA to reconsider its decision on the Citizen Petition, this Court expressed trust that the newly appointed FDA leadership would "conduct a fair assessment of the scientific evidence." But the FDA chose to do no assessment whatsoever of the data related to the Citizen Petition and Plan B.

50. Rather, it drew conclusions about and denied the Citizen Petition regarding Plan B based on its review of the Plan B One-Step SNDA. According to the FDA: "[a]s a scientific matter, if additional data regarding the OTC use by younger women were needed for Plan B One-Step, that type of data would also be needed for Plan B, but those Plan B One-Step studies would not be transferable to Plan B. Instead, there would need to be new studies conducted using Plan B and its labeling, because it has more complicated directions for use." The FDA concluded that the One-Step data was indeed necessary, and therefore that such additional data would be necessary to grant the Citizen Petition.

51. Years before the Plan B One-Step SNDA was submitted, however, the FDA had already concluded that additional data were necessary for the SNDA and communicated that conclusion to the Plan B One-Step sponsor.

52. Thus, the FDA's chosen course of action reveals a preordained determination that the FDA would not grant the Citizen Petition. Before the Plan B One-Step SNDA was even filed, the FDA had already determined that eventually it would: (a) deem the Plan B One-Step adolescent-specific data to be necessary; and (b) use that determination to conclude that the data supporting the Citizen Petition was insufficient.

53. The FDA further based its second denial on the vacated first denial, specifically the 2005 determination that the Citizen Petition/Plan B files could not support an OTC switch because of insufficient data on adolescents. These were the very findings that the Court had found to be infiltrated with politics, taken in bad faith, and arbitrary and capricious.

54. The FDA failed to give the Citizen Petition fair and honest consideration and departed from normal agency procedures by: (a) refusing to review the existing Citizen Petition/Plan B files to determine, *inter alia*, if sufficient data exists to support an OTC switch for all age groups; (b) denying the petition on the basis of determinations made regarding another product; and, (c) insisting on additional teen-specific data in support of the requested OTC switch.

55. There is no justification for such departures.

56. Moreover, the FDA's reasoning for denying the Citizen Petition for lack of additional, teen-specific data focusing on the two-pill nature of Plan B is simply implausible.

57. That the FDA deems a difference in dosage from one pill to two so "complicated" as to necessitate additional studies is simply not credible.

58. There are no specific documents or information that must be submitted with an OTC switch request. Actual use and label comprehension studies are not always required, particularly if a drug has previously been approved for OTC use, like levonorgestrel-based EC has been—in two-pill form—since 2006.

59. Moreover, the FDA has had sufficient evidence, including actual use and label comprehension studies that contained data on adolescents, to make emergency contraception available OTC for women of all ages since it began consideration of the matter. The data shows that there is no scientific basis for a distinction between adults and adolescents. This information is further supported by research on the oral contraceptive pill, which is arguably the most extensively studied medication in the history of pharmaceuticals.

F. The Stark Contrast Between the FDA's Treatment of Emergency Contraception and Other OTC Switch Requests

60. Despite the abundance of evidence supporting OTC status for emergency contraception for women of all ages, the FDA has repeatedly stated that it does not believe sufficient evidence exists.

61. In contrast, it is rare for label comprehension and actual use studies to contain data on adolescents *at all*, and the FDA has granted OTC status to numerous drugs without such studies and with studies that do not contain data on adolescents.

62. The FDA has also approved OTC switches for numerous prescription drugs and classes of prescription drugs that could cause more severe side effects, even when they are used according to approved directions, than could the correct, or even incorrect, use of Plan B. Many of those unrestricted OTC drugs pose special risks for certain populations, including certain age groups.

63. Moreover, the FDA has approved full OTC switches for numerous prescription drugs and classes of prescription drugs whose directions for approved use are far more complicated than the directions for Plan B.

64. Ten years of delays, bad faith, political calculations and implausible reasoning demonstrates that efforts to make emergency contraception available OTC and unrestricted have not and will never be considered by the FDA in a fair, scientifically-based manner.

G. Harms Perpetuated by the FDA's Unprecedented Actions and Continuation of BTC Regime

65. All three levonorgestrel-based emergency contraception products currently marketed in the United States are governed by the unprecedented FDA-imposed BTC regime. Two of them are generic equivalents to Plan B: Next Choice and a product made by Perrigo R and D. Each of these products consists of two pills of 0.75 mg of levonorgestrel each, which the drugs' label directs women to take twelve hours apart. The manufacturer of Plan B no longer markets Plan B; since 2009, it has marketed Plan B One-Step, which is a single pill with 1.5 mg of levonorgestrel.

66. The FDA-mandated BTC regime imposes significant barriers and harms on consumers of emergency contraception, even those consumers who should be able to purchase it OTC. The FDA's delays and repeated arbitrary and capricious actions with respect to emergency contraception have perpetuated those harms. For example, permitting the product to be available only at pharmacies and health clinics imposes practical obstacles to access. Some consumers do not live near such businesses. Moreover, because pharmacies usually have limited hours, consumers who attempt to buy emergency contraception at certain times can face significant delay.

67. The requirement that consumers show government-issued identification also creates a potentially insurmountable barrier for the many consumers who do not have such identification. It also has the effect of requiring consumers to reveal their identity in order to purchase a product, implicating privacy concerns.

68. In addition, the BTC regime is complicated and unique, and many pharmacists implement it incorrectly in ways that block consumers' access. A recent study found that a 17-year-old attempting to buy EC faces an approximately one-in-five chance of being given the incorrect information that she cannot obtain the drug without a prescription because of her age. And pharmacists are more likely to misinform young women about the age cutoff in low-income neighborhoods, perpetuating a pattern of poor access to health care for low-income populations.

69. The cumulative effect of the barriers erected by the BTC regime undoubtedly prevents some women from accessing the drug in the short time window in which it is effective, thereby exposing them to an increased risk of unwanted pregnancy and frustrating the very purpose of OTC access. As a public health issue, the adverse effect of the dual-label status in limiting access to emergency contraception is more detrimental to adults than younger patients because the vast majority of women who need emergency contraception are adults.

70. Plaintiffs face irreparable harm if they are not afforded immediate injunctive relief permitting drug sponsors to make levonorgestrel-based emergency contraception available OTC without restrictions.

71. The public interest weighs in favor of immediate injunctive relief.

72. Neither the FDA, nor the public, benefits from keeping in place barriers to women trying to access a safe method of birth control that must be taken as soon as possible to prevent an unwanted pregnancy.

III. Causes of Action

FIRST CAUSE OF ACTION: ARBITRARY AND CAPRICIOUS

73. Plaintiffs hereby incorporate by reference ¶¶ 1-70 above and Plaintiffs' Fifth Amended Complaint.

74. Defendants' actions upon remand, including the plan for complying with this Court's Order requiring it to reconsider the Citizen Petition by reviewing the Plan B One-Step SNDA, the execution of that plan (consideration and denial of the Plan B One-Step SNDA), and the 2011 denial of the Citizen Petition were arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, in violation of 5 U.S.C. § 706(2)(A). Among other violations, Defendants:

a) acted in bad faith;

b) were improperly motivated by factors other than medicine and science;

c) repeated the same departures from its normal procedures that this Court previously found arbitrary and capricious;

d) required evidence of safety and efficacy for emergency contraception beyond that required for approval of any other drugs;

e) offered explanations for its decisions that run counter to the evidence before it;

f) offered explanations so implausible that it could not be ascribed to a difference in view or the product of agency expertise; and,

g) failed to provide a fair and honest consideration of the Citizen Petition.

SECOND CAUSE OF ACTION: EXCEEDS STATUTORY AUTHORITY

75. Plaintiffs hereby incorporate by reference ¶¶ 1-72 above and Plaintiffs' Fifth Amended Complaint.

76. Defendants' actions upon remand, including the plan for complying with this Court's Order requiring it to reconsider the Citizen Petition by reviewing the Plan B One-Step SNDA, the execution of that plan (consideration and denial of the Plan B One-Step SNDA), and the 2011 denial of the Citizen Petition, exceed the FDA's statutory authority in violation of 5 U.S.C. § 706(2)(C) in that they were improperly motivated by factors other than medicine and science and in that the FDA lacks authority to control the point of sale of nonprescription drug products.

THIRD CAUSE OF ACTION: RIGHT TO PRIVACY

77. Plaintiffs hereby incorporate by reference ¶¶ 1-74 above and Plaintiffs' Fifth Amended Complaint.

78. Defendants' actions upon remand, including the plan for complying with this Court's Order requiring it to reconsider the Citizen Petition by reviewing the Plan B One-Step SNDA, the execution of that plan (consideration and denial of the Plan B One-Step SNDA), and the 2011 denial of the Citizen Petition, violate the Fifth Amendment to the United States Constitution and 5 U.S.C. § 706(2)(B) in that these actions infringe on the right to privacy of Plaintiffs and women who need emergency contraception without serving or being tailored to serve any compelling, significant, or legitimate governmental interest.

FOURTH CAUSE OF ACTION: EQUAL PROTECTION

79. Plaintiffs hereby incorporate by reference ¶¶ 1-76 above and Plaintiffs' Fifth Amended Complaint.

80. Defendants' actions upon remand, including the plan for complying with this Court's Order requiring it to reconsider the Citizen Petition by reviewing the Plan B One-Step SNDA, the execution of that plan (consideration and denial of the Plan B One-Step SNDA), and the 2011 denial of the Citizen Petition, violate the Fifth Amendment to the United States

Constitution and 5 U.S.C. § 706(2)(B) in that these actions discriminate on the basis of sex without serving or being tailored to serve any compelling, significant, or legitimate governmental interest.

81. Defendants' actions upon remand, including the plan for complying with this Court's Order requiring it to reconsider the Citizen Petition by reviewing the Plan B One-Step SNDA, the execution of that plan (consideration and denial of the Plan B One-Step SNDA), and the 2011 denial of the Citizen Petition, violate the Fifth Amendment to the United States Constitution and 5 U.S.C. § 706(2)(b) in that these actions discriminate on the basis of the exercise of the fundamental right to privacy to obtain contraception and to keep certain personal information private without serving or being tailored to serve any compelling, significant, or legitimate governmental interest.

FIFTH CAUSE OF ACTION: INFORMATIONAL PRIVACY

82. Plaintiffs hereby incorporate by reference ¶¶ 1-79 above and Plaintiffs' Fifth Amended Complaint.

83. Defendants' actions upon remand, including the plan for complying with this Court's Order requiring it to reconsider the Citizen Petition by reviewing the Plan B One-Step SNDA, the execution of that plan (consideration and denial of the Plan B One-Step SNDA), and the 2011 denial of the Citizen Petition, violate the right to informational privacy for Plaintiffs and women who are required by the government to disclose their name, age, and address to private parties in order to obtain Plan B. This requirement does not serve and is not tailored to serve any compelling, significant, or legitimate governmental interest.

IV. Prayer for Relief

WHEREFORE, Plaintiffs ask this Court:

84. To enter judgment declaring the FDA's actions on remand with respect to the Citizen Petition and the Plan B One-Step SNDA, including but not limited to the denial of both, in violation of 5 U.S.C. § 706;

85. To issue both a preliminary injunction and permanent injunction ordering Defendants to permit, within 30 days, the drug sponsors of Plan B One-Step, Plan B, Next Choice, Perrigo R and D's Levonorgestrel Tablets, and any drug eligible for filing an abbreviated new drug application because of its equivalence to Plan B or Plan B One-Step, to make the above-referenced products available over-the-counter without age or point of sale restrictions; and,

86. To grant such other and further relief as this Court should find just and proper, including attorneys' fees and costs.

Dated: May 23, 2012

Respectfully submitted,

/s/ Suzanne Novak

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∞Admission to D.C. Bar pending. Member of the Bars of Florida and New York. Practicing under supervision of a member of the District of Columbia Bar.