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May 22, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Citizen's Petition seeking a switch of *Plan B*® and equivalent drugs

Dear Division of Dockets Management:

Please find enclosed four copies of a Citizen's Petition being submitted by the State of Wisconsin. 21 C.F.R. §§ 10.20 and 10.30. This Citizen's Petition seeks a switch of *Plan B*®, an emergency contraceptive drug approved in 1999 for sale and use on a prescription basis, to over-the-counter status and also a switch of any drugs equivalent to *Plan B*® from prescription to over-the-counter status.

Attached to each copy of the Citizen's Petition are two guides to the Petition: (1) "Complete Citations to Documents Cited in Citizen's Petition" provides full citations to referenced materials and (2) "Documents Cited in, and Attached to, Citizen's Petition" lists those of the cited materials (or excerpts of those materials) that accompany the Petition. Consistent with the exceptions noted in 21 C.F.R. § 10.20(c)(1) and the exclusion of irrelevant material noted in 21 C.F.R. § 10.20(c)(3), many of the referenced materials do not accompany the Petition.

If you have any questions or concerns about the format of these submissions, or their compliance with applicable requirements, please contact Sally Mueller at 608-267-2238 or muellersa@doj.state.wi.us. Thank you.

Sincerely,

Richard Briles Moriarty
Assistant Attorney General
State Bar No. 1017190

RBM:
Encls. (four copies of Citizen's Petition and attachments)

2006P-0223

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May 22, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

CITIZEN PETITION

The State of Wisconsin, by its attorneys, Peggy A. Lautenschlager, Attorney General, and Richard Briles Moriarty and Nelle R. Rohlich, Assistant Attorneys General, (Wisconsin) submits this petition pursuant to 21 C.F.R. §§ 10.25(a), 10.30 and 10.33 to request the Food and Drug Administration (FDA) to switch both *Plan B®*, an emergency contraceptive drug approved in 1999 for sale and use on a prescription basis, and any drugs equivalent to *Plan B®* to over-the-counter status.[1] For the reasons articulated in this Petition, *Plan B®* and equivalent EC drugs should long ago have been switched to OTC status. These switches are authorized under 21 U.S.C. § 353(b)(3), and mandated under 21 C.F.R. §§ 330.10(a)(4)(vi). *Plan B®* and equivalent EC drugs are safe and effective for OTC use by all women who are menstrual.

Pursuant to statutory directives, FDA regulations mandate, that a "drug shall be permitted for OTC sale and use by the laity unless, because of its toxicity or other potential for harmful effect or because of the method or collateral measures necessary to

[1]Over-the-counter is referred to as "OTC", the emergency contraception drugs marketed as *Plan B®* are referred to as "*Plan B®*", and all drugs equivalent to *Plan B®* currently available only by prescription, whether marketed as emergency contraception drugs or not, are referred to collectively as "equivalent EC drugs." The term "EC" includes *Plan B®* and equivalent drugs which may be used for emergency contraception purposes.

Abbreviated references to citations in the Citizen's Petition are to the lead or institutional author, year and page, e.g., "(Ashby 2005, p. 37)" and "(DHHS 2001, p. 9-4)", except where extra descriptors distinguish publications in the same year, e.g., "FDA Action 2005" and FDA Draft 2005". Two guides to the Petition and its supporting citations are attached. (1) "Complete Citations to Documents Cited in Citizen's Petition" provides full citations to cited materials other than laws, regulations and federal decisions. (2) "Documents Cited in, and Attached to, Citizen's Petition" lists those of the citations which, considering the exceptions noted in 21 C.F.R. § 10.20(c)(1) and the exclusion of irrelevant material noted in 21 C.F.R. § 10.20(c)(3), are attached to the Citizen's Petition.

its use, it may safely be sold and used only under the supervision of a practitioner licensed by law to administer such drugs." 21 C.F.R. § 330.10(a)(4)(vi). Relevant, peer-reviewed scientific literature established that *Plan B®* and equivalent EC drugs fall well outside that exception, such that "OTC sale and use" of *Plan B®* and equivalent EC drugs "by the laity" was and remains, mandated. 21 C.F.R. § 330.10(a)(4)(vi).

ACTION REQUESTED

Wisconsin requests FDA to switch *Plan B®* and equivalent EC drugs from prescription-only to OTC status without age restrictions. 21 U.S.C. § 353(b)(3); 21 C.F.R. §§ 330.10(a)(4)(vi); 21 C.F.R. § 310.200(b). Wisconsin also requests that FDA exempt from prescription-dispensing requirements any new drug eligible for filing an abbreviated new drug application because of its equivalence to *Plan B®*. 21 U.S.C. § 353(b)(3) and 21 C.F.R. § 310.200(b).

STATEMENT OF GROUNDS

A. FDA role and obligations.

FDA, a federal agency established by Congress (21 U.S.C. § 393), is part of United States Department of Health and Human Services ("DHHS"), another federal agency established by Congress (42 U.S.C § 3501). FDA is charged with "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). In 1992, Congress found that "prompt approval of safe and effective new drugs is critical to the improvement of the public health so that patients may enjoy

the benefits provided by these therapies to treat and prevent illness and disease." Prescription Drug User Fee Act of 1992, PL 102-571, § 102(1). FDA, and the Commissioner of Food and Drugs of FDA, were, at all times relevant, required to administer and comply with the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("the FD&C Act") and FDA regulations regarding the FD&C Act. The Commissioner is responsible by statute for assuring that FDA's actions comply with statutory requirements and directives and with FDA's regulations and established policies and practices. 21 U.S.C. § 393(d)(2).

One of the "core objectives" of the FD&C Act "is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Another "'primary purpose of the [FD&C Act] is the protection of the ultimate consumer's economic interests.'" *U.S. v. Lane Labs-USA Inc.*, 427 F.3d 219, 227 (3rd Cir. 2005). FDA is required, by statutory mandate, to administer the FD&C Act "in consultation with experts in science, medicine, and public health" (21 U.S.C. § 393(b)(4)) and, by FDA regulation, to approve a drug "for OTC sale and use by the laity unless, because of its toxicity or other potential for harmful effect or because of the method or collateral measures necessary to its use, it may safely be sold and used only under the supervision of a practitioner licensed by law to administer such drugs." 21 C.F.R. § 330.10(a)(4)(vi). By FDA regulation, drugs "generally recognized among qualified experts as safe and effective for use and as not misbranded" are to be given OTC status. 21 C.F.R. § 330.10.

B. Approving *Plan B*® and equivalent EC drugs for OTC status was mandated years ago and continues to be mandated.

FDA has confirmed that OTC "drugs play an increasingly vital role in America's health care system" and that "there are more than 80 therapeutic categories of OTC drugs." (CDER 2006.) FDA has also confirmed that "OTC drugs generally have these

characteristics": (a) "their benefits outweigh their risks," (b) "the potential for misuse and abuse is low," (c) the "consumer can use them for self-diagnosed conditions," (d) "they can be adequately labeled" and (e) "health practitioners are not needed for the safe and effective use of the product." (CDER 2006.) *Plan B®* and equivalent EC drugs have all of these characteristics. (CPR 2001, pp. 4-5.)

FDA, describing the switch process in a recent publication, identified "the key question for the FDA" when considering a prescription to OTC switch to be "whether patients alone can achieve the desired medical result without endangering their safety." (FDA Now Available 2006.) FDA identified a major consideration in evaluating potential switches to be "whether consumers will be able to understand and follow label directions, whether patients can diagnose the condition themselves--or at least recognize the symptoms they want to treat--and whether routine medical examinations or laboratory tests are required for continued safe use of a drug." (FDA Now Available 2006.) While the ability to self-diagnose is important, FDA has still switched drugs to OTC status that were "intended to treat diseases like asthma or vaginal fungal infections, which cannot be consumer-diagnosed." (FDA Now Available 2006.) FDA acknowledges that, with proper labeling of OTC drugs that is "written so consumers, including individuals with low reading comprehension, can understand them," consumers can, in some cases, actually "get more information in the OTC labeling than they would get from their doctors." (FDA Now Available 2006.) Applying these criteria, relevant, peer-reviewed scientific literature long ago confirmed that *Plan B®* and equivalent EC drugs should be available OTC to all women who are menstrual.

Wisconsin's requests in this Petition are supported by declarations by FDA, and FDA officials, that *Plan B®* and equivalent EC drugs are safe and effective for OTC use for all women who are menstrual. In April, 2004, the Director of FDA's Office of New Drugs summarized why switching *Plan B®* to OTC status was mandated:

> In my opinion, these studies provide adequate evidence that women of childbearing potential can use Plan B safely, effectively, and appropriately for emergency contraception in the non-prescription setting. The data submitted by the sponsor in support of non-prescription use of Plan B are fully consistent with the Agency's usual standards for meeting the criteria for determining that a product is appropriate for such use. . .Such a conclusion is consistent with how the Agency has made determinations for other OTC products, including other forms of contraception available without a prescription. Further, I believe that greater access to this drug will have a significant impact on the public health by reducing the number of unplanned pregnancies and the number of abortions.

(GAO 2005, p. 28.)

Since at least 1997, two years before *Plan B®* was approved for prescription use, FDA has publicly deemed EC "safe" and "effective." In June 1996, FDA, on its own volition and without any licensing applications, "decided to present the issue of the safety and effectiveness of combined oral contraceptives for post-coital emergency use to the [Reproductive Health Drug and Urologic Product] Advisory Committee." (FDA 1997). The Advisory Committee "unanimously concluded that the four regimens" of EC it reviewed were all "safe and effective for postcoital emergency contraception." (FDA 1997. *See also* Brown 1999, p. 39.) FDA "agreed with this conclusion" and itself concluded that experience with EC "in Europe and New Zealand has demonstrated the regimens to be safe", that there was no evidence of any significant adverse effects and that there "are numerous published articles that support the effectiveness of oral contraceptive pills for emergency use." (FDA 1997.)

In February 1997, FDA announced the Commissioner's conclusion that EC, when used as directed, was "safe and effective for use as postcoital emergency contraception." Two months later, DHHS issued a memorandum to all Title X regional health administrators directing "that Title X grantees should consider the availability of emergency contraception the same as any other method which has been established as safe and effective." (DHHS 1997.) "The DHHS memorandum essentially directed all Title X delegate agencies to include emergency contraceptive pills as part of their standard family planning services." (Brown 1999, p. 39.)

FDA also expressly stated that the 1997 announcement was "intended to encourage manufacturers to make this additional contraceptive option available." (FDA 1997). By February 1998, FDA approved a new drug application filed by Gynetics for prepackaged EC as a prescription drug; the company began marketing the product as *Preven*™ in September 1998. (Brown 1999, p. 39; FDA Preven 1998.) On July 28, 1999, FDA approved an application to market *Plan B*® as a prescription drug. (CDER 1999). FDA later characterized the *Plan B*® approval request as having been a "Priority Review – Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease." (CDER 2005.) *Plan B*®, containing "only progestin" (CDER 2004), is "about 89% effective" at preventing pregnancy (DHHS 2002, p. 2). Until Gynetics sought to market *Preven*™ on a prescription basis, no manufacturer had applied to market EC on either a prescription or OTC basis. Until 2003, no manufacturer sought to market EC on an OTC basis and, at that time, *Plan B*® and *Preven*™ were "the only dedicated products specifically marketed for emergency contraception" while eighteen other products had "been declared safe and effective for use" as EC by FDA. (Trussell 2004, p. S31, Table 1.)

On February 14, 2001, more than 70 medical and public health organizations filed a Citizen Petition with FDA requesting FDA to switch EC, including *Plan B*®, to OTC status. (CPR 2001, pp. 1-9 (Petition) and 10-59 (attachments).) The Petition articulated grounds upon which that switch was appropriate, supported by both citations and attached documents. (CPR 2001, pp. 1-9 (Petition and attachments.) It confirmed – more than five years ago – that relevant, peer-reviewed scientific literature had established all FDA criteria for the requested switch:

> First, EC is safe for self-medication because it is not toxic to the woman (or to the embryo or fetus if a pregnancy had been previously established in the woman); it has a low risk of abuse or overdose; overdose is unlikely to lead to serious consequences; and its side effects are well known and minor. Second, EC is effective when self-administered. Its administration is simple and relies only on assessments as to the time elapsed since sexual intercourse that can be

> independently made by the woman, and any interaction between EC and other drugs would be nonfatal and unlikely to seriously affect EC's efficacy. Third, the condition EC treats – contraceptive failure or failure to use contraception during intercourse – is one that is readily diagnosable by a woman, and EC has no contraindications that would pose any danger to the patient. Fourth, the existing patient labeling for *Preven*™ and *Plan B*® is tailored to self-administration in that it is simple, clear, comprehensive and easy to follow. Finally, switching EC to OTC status will promote public health because EC is only effective for a short time after unprotected sex, and it works most effectively 'if used within twenty-four hours of unprotected sex. Because contacting a physician and obtaining and filling a prescription hinder women from obtaining EC in a timely fashion, making EC available OTC will allow more women to use the treatment, and enable more women to prevent unwanted pregnancies, to the benefit of public health.

(CPR 2001, pp. 4-5, citations omitted.)

In early 2001, the American College of Obstetricians and Gynecologists approved a resolution that supported switching EC, including *Plan B*®, to OTC status. (Boggess 2002, p. 162). In that resolution, the College "stressed that if emergency contraception were available, it could contribute to substantial reductions in the U.S. abortion rate." (Boggess 2002, p. 162.)

In April, 2003, Women's Capital Corporation (then the manufacturer of *Plan B*®) submitted an application to switch *Plan B*® from prescription-only to OTC status. (GAO 2005, p. 1.) Under standard FDA procedure, two offices within the Center for Drug Evaluation and Research (CDER) were charged with reviewing the OTC application. (*Id.*) For the *Plan B*® application, the two offices charged with the review were the Office of Drug Evaluation V, which includes the Division of Over-the-Counter Products and the Office of Drug Evaluation III, which includes the Division of Reproductive and Urologic Drug Products. (*Id.*)

Both offices recommended OTC status for *Plan B*® following their review. (GAO 2005, p. 2.) In December 2003, a joint meeting of two FDA advisory committees, the Nonprescription Drugs Advisory Committee (NDAC) and the Advisory Committee for Reproductive Health Drugs (ACRHD) agreed. (*Id.*) They recommended in a vote of 23 to 4 that the proposed OTC switch for *Plan B*® be approved. (*Id.*) FDA review staff also

agreed that *Plan B®* should be granted OTC status. (*Id.*) Wisconsin has not located any other switch application in the history of FDA that, after a similar history of internal recommendations, was not thereafter approved for OTC sale and use.

The Acting Director of CDER, however, signed a "not-approvable" letter for the OTC switch, asserting "safety concerns about the use of Plan B in women under 16 years of age without the supervision of a practitioner licensed by law to administer the drug." These actions were so unprecedented the GAO was asked by elected representatives to review them. (GAO 2005, p. 3.) GAO determined that these actions were unusual because, among other things, they were "contrary to the recommendations of the joint advisory committee and FDA review staff" in contrast to previous prescription-to-OTC switch decisions made from 1994-2004:

> "FDA's joint advisory committee considered 23 OTC switch applications during this period; the *Plan B®* OTC switch application was the only 1 of those 23 that was not approved after the joint committee voted to recommend approval of the application. (*Id.*) Also, the *Plan B®* action letter was the only one signed by the Director of CDER, in this case the Acting Director of CDER, instead of the directors of the offices or divisions that reviewed the application, who would normally sign an action letter." (GAO 2005, p. 5.)

The directors did not sign the action letter because they disagreed with the decision. (Id.)

Although in August 2005, FDA declared that *Plan B®* was "safe" and "effective" for OTC sale and use by older adolescents and adult women, it has refused access to all women by claiming to be concerned about the sufficiency of studies expressly focused on how increased access might alter sexual behavior by younger adolescents. (FDA Action 2005.) In May 2004, FDA claimed that greater access to *Plan B®* might cause decreased condom usage among younger adolescents, which might, in turn, cause more sexually transmitted diseases among younger adolescents. (FDA Decision 2004.) Based on these

purported concerns, FDA then denied OTC access to *Plan B®* to all women who are menstrual regardless of age.

GAO concluded the purported reason for the May 2004 "not-approvable" decision was unusual. (GAO 2005, p. 6.) "[T]here are no age-related marketing restrictions for safety reasons for **any** of the prescription or OTC contraceptives that FDA has approved, and FDA has **not** required pediatric studies for them." (*Id.* (emphasis added).) "All FDA-approved OTC contraceptives are available to anyone, and all FDA-approved prescription contraceptives are available to anyone with a prescription. . .FDA did not identify any issues that would require age-related restrictions in its review of the original application for prescription Plan B, and prescription Plan B is available to women of any age." (*Id.*)

During calendar year 2004, the same year that FDA was refusing to approve OTC status to *Plan B®* based on alleged concerns over insufficient studies of adolescent sexual behavior, FDA approved, for OTC sale and use by persons as young as 12 years old, several drugs that, used as directed, provided substantially less health benefits than *Plan B®* and were known to cause substantially graver health problems than *Plan B®*. (CDER Report 2005, p. 27.) The 2004 approval of those drugs for OTC sale and use to persons as young as 12 years of age included:

- drugs for vaginal infections (*Monistat 1 Combination Pack* for "anytime use");
- drugs containing pseudoephedrine in tablet form (*Mucinex-D Extended Release, Mucinex-DM, Claritin-D 12 Hr. Extended Release Tablets* and *Claritin-D 24 Hr. Extended Release Tablets*);
- drugs containing ibuprofen in oral suspension form (*Children's Advil Allergy & Sinus Elixir* and *Children's Elixsure IB*);
- drugs containing a combination of *Loratadine* and *pseudoephedrine hydrochloride* as active ingredients (*Claritin-D 12 Hr. Extended Release Tablets* and *Claritin-D 24 Hr. Extended Release Tablets*);
- drugs containing a combination of *Guaifenesin* and *pseudoephedrine hydrochloride* as active ingredients (*Mucinex-D Extended Release*).

- drugs containing a combination of *Guaifenesin* and *dextromethorphan* as active ingredients (*Mucinex-DM*).

(CDER Report 2005, p. 27.)

As disclosed in the review documents regarding those drugs and their review history, at the website maintained by the FDA for Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm), none of those drugs were preceded by any studies expressly focused on behavior by adolescents or children. Undercutting any potential validity to the purported reasons for not allowing all women who are menstrual OTC access to *Plan B®* are, among other things, the following:

1. FDA-approved labels for *Monistat 1 Combination Pack* for "anytime use," a drug approved in 2004 for OTC sale and use by persons as young as 12 years old without any studies focused on adolescent behavior, stated that using the product could "damage" condoms and, as a result, "fail to prevent pregnancy or sexually transmitted diseases (STDs)." (Labels and reviews accessible at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=MONISTAT%203%20COMBINATION%20PACK.)

2. FDA, in the same year that it denied OTC access for *Plan B®*, approved *Monistat 1 Combination Pack* for "anytime use" by persons as young as 12 years of age to treat vaginal fungal infections even though those "diseases cannot be self-diagnosed." (FDA Now Available 2006.)

3. The FDA-approved labels for *Claritin-D 24 Hr. Extended Release Tablets*," a drug approved in 2004 for OTC sale and use by persons as young as 12 years old without any studies focused on adolescent behavior, warn against using that drug while "taking a prescription monoamine oxidase inhibitor (MAOI)" - apparently trusting persons as young as 12 years of age, to whom that drug may legally be sold, to both comprehend that warning and to heed it. (Labels and reviews accessible at

http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=CLARINEX%20D%2024%20HOUR).

4. Before *Mucinex-D Extended Release, Mucinex-DM, Claritin-D 12 Hr. Extended Release Tablets* and *Claritin-D 24 Hr. Extended Release Tablets* were approved in 2004 for OTC sale and use by persons as young as 12 years old, without any studies focused on adolescent behavior, it was recognized that *pseudoephedrine* in tablet form is a critical ingredient used in illegal meth labs to make methamphetamine. (Executive Office 2002, pp. xi and 89.)

Before May 2004, FDA had also approved for OTC sale and use by persons as young as 12 years old, without any studies focused on behavior by adolescents or children, drugs such as Tylenol containing acetaminophen. Acetaminophen causes more overdoses and overdose deaths than any other drug and is frequently the drug of choice for adolescent suicide attempts. (Mayo 2006. See also Hall 1999, pp. 19-20).

FDA's approval of these drugs – drugs that merely provide temporary relief and can cause serious health risks compared to its refusal to allow women who are menstrual access to *Plan B®* – despite the permanent benefits of avoiding unwanted pregnancies and childbirths and the minimal adverse effects of *Plan B®* - underscores that FDA's articulated rationale for its refusal was, and remains, arbitrary and capricious. In July 2004, an editorial in *British Medical Journal*, responding to the expressed rationale of FDA for denying the *Plan B®* application that data regarding usage by females 16 and younger was lacking, stated that "no reason existed to suspect that levenorgestrel's hazards, in that population or any other, would turn out to be as great as **aspirin** or paracetamol." (Fenichel 2004, p. 183 (emphasis added).)

When FDA issued a not-approvable letter in May 2004, refusing to make *Plan B®* available OTC, that action was not properly grounded on "consultation with experts in

science, medicine, and public health" as mandated under law. 21 U.S.C. § 393(b)(4). In its review of the *Plan B®* switch application, the GAO reported:

> The rationale for the Acting Director of CDER's decision was novel and did not follow FDA's traditional practices. The Acting Director was concerned about the potential impact that the OTC marketing of Plan B would have on the propensity for younger adolescents to engage in unsafe sexual behaviors because of their lack of cognitive maturity. The Acting Director further concluded that because these differences in cognitive development made it inappropriate to extrapolate data from older to younger adolescents in this case, there was insufficient data on the use of Plan B among younger adolescents. FDA review officials disagreed with the Acting Director's rationale and noted that the agency had not considered behavioral implications resulting from differences in cognitive development in prior OTC switch decisions.

(GAO 2005, p. 27.) FDA review officials, including those from the Office of New Drugs and members of the joint advisory committee, determined that adolescents were adequately represented in the actual use study of *Plan B®*. (GAO 2005, p. 27. *See* Raymond 2003.) During a December 2003 public meeting, members of the joint advisory committee voted 27 to 1 that the actual use study data were generalizable to the overall population of OTC users, including adolescents. (GAO 2005, p. 29.)

Before the "not-approvable" decision, relevant, peer-reviewed scientific literature confirmed that switching *Plan B®* and equivalent EC drugs to OTC status was as safe and effective for females 16 and younger as for females 17 and older (*e.g.,* Raymond 2002, pp. 342-48; Raymond 2003, pp. 17-23; Kosunen 1999, p. 91; Lete 2003, pp. 204-05) and also that switching *Plan B®* and equivalent EC drugs to OTC status would result in no significant differences in either comprehension or usage between females 16 and younger and females 17 and older. (*e.g.,* Raymond 2002, pp. 342-48; Raymond 2003, pp. 17-23; Kosunen 1999, p. 91; Lete 2003, pp. 204-05.)

A 2001 study reported in a peer-reviewed journal in 2002, examined comprehension levels of EC use among women. Seventy-six of the 656 subjects were 16 or younger. According to the study, comprehension levels of EC use among this subgroup of females 16 or younger remained high. (Raymond 2002, pp. 344 and 347.) While "less-educated and less-literate women were less likely to understand the

objectives than more-educated women, understanding was generally high in all subgroups examined" (Raymond 2002, p. 347). The labels used in the study were modeled on those earlier approved by FDA for use with *Preven*™ and *Plan B*® as prescription drugs. (Raymond 2002, pp. 342 and 347; FDA Preven 1998; FDA 1999.) The "study design and questionnaire were heavily influenced by [FDA's] comments on early drafts of the protocol" (Raymond 2002, p. 342). Based "on advice from [FDA] and consultants, the minimum desired sample size was increased to 575" (Raymond 2002, p. 343) and, at "the request of [FDA], the study included questions that were asked when the subject had differing degrees of access to the label" (Raymond 2002, p. 348). Before April 2004, the report of that 2001 study was, in other relevant, peer-reviewed scientific literature, noted as a model for both testing and reporting label comprehension in OTC contexts. (Brass 2003, p. 411, text and n. 14; Burapadaja 2002, p. 280.) The OTC label used for that study for *Plan B*® (Raymond 2002, pp. 342 and 347) was substantially easier to comprehend, and was substantially more likely to result in that drug being used as directed, than the labels for any of the drugs FDA approved by OTC use by persons as young as 12 years of age in 2004 (*see* pp. 10-11 supra).

In a simulated use study reported in a peer-reviewed journal in 2003, usage of *Plan B*® on an OTC basis was tested. (Raymond 2003, pp. 17-23.) FDA "reviewed the protocol, and a number of the agency's comments were incorporated into the study design and analysis plan." (Raymond 2003, p. 18.) Females 16 and younger were a "subgroup" which contained twenty-nine of the 585 subjects. (Raymond 2003, p. 19.) The study confirmed that "nearly all subjects used the product appropriately and safely" and that "potentially vulnerable groups, such as minors and less-educated women, were **not** substantially more likely than others to use the product in a contraindicated or incorrect manner and did not have notably higher risks of adverse events or pregnancy." (Raymond 2003, pp. 21-22 (emphasis added).)

In 1999, relevant, peer-reviewed scientific literature reported a questionnaire study of the use of EC among Finnish teenagers. (Kosunen 1999, p. 91.) That study covered 8416 females who were 14 and 8051 females who were 15. (Kosunen 1999, p. 91.) Of the 16,457 study subjects who were either 14 or 15, only 545 did not know what EC was and 782 had actually used EC; more than 60% of those 782 females who were 14 and 15 and had used EC had only used EC once; and usage of EC had not increased adolescent sexual activity. (Kosunen 1999, p. 91.)

In 2003, relevant, peer-reviewed scientific literature reported on a nationwide observational study on the use of EC in Spain in which 1.9% of its 4390 study subjects, that is over 800 study subjects, were 15 or younger and had requested EC during the 2002 study period. (Lete 2003, p. 204.) More than 80% of the study subjects correctly requested EC within 48 hours after unprotected intercourse. (Lete 2003, p. 204.)

By April 2004, relevant, peer-reviewed scientific literature confirmed that switching EC to OTC status was as safe and effective for females 16 and younger as for females 17 and older (*e.g.*, Raymond 2002, pp. 342-48; Raymond 2003, pp. 17-23; Kosunen 1999, p. 91; Lete 2003, pp. 204-05) and also confirmed that switching EC to OTC status would result in no significant differences in either comprehension or usage between females 16 and younger and females 17 and older. (*e.g.*, Raymond 2002, pp. 342-48; Raymond 2003, pp. 17-23; Kosunen 1999, p. 91; Lete 2003, pp. 204-05.)

Relevant, peer-reviewed scientific literature published after May 2004 confirmed that females 16 and younger use *Plan B®* correctly and that OTC access for females 16 and younger would be at least as safe and effective as for females 17 and older. (Harper 2004, p. 1160.) A 2003 study published in October 2004 focused solely on females 16 and younger and determined that, of its 52 study subjects, all but one "reported taking the second dose of *Plan B®* as instructed" and all but three "reported no problems in following directions." (Harper 2004, p. 1160.) Relevant, peer-reviewed scientific

literature by many of the same researchers published in 2005 definitively confirmed that "adolescents were equally capable as adults in taking EC correctly, with the youngest adolescents, under 16 years, showing the best results" and that "[t]hese results are consistent with findings from our previous study that specifically examined young adolescents: an observational study of 13 to 16 year olds showed that correct use of EC, the effect on the menses, and the adverse effects were consistent with data on adult women and that there was no reason to restrict access in this age group." (Harper, 2005, p. 490, citing Harper, 2004.)

The Committee on Adolescence of the American Academy of Pediatrics, based on relevant, peer-reviewed scientific literature, adopted a Policy Statement in 2005 stating that easier access to EC increased usage without increasing sexual activity and concluded: "Emergency contraception has tremendous potential to reduce unintended pregnancies in teens and adults." (Committee 2005, pp. 1031-32.)

In May 2004, the National Institutes of Health, a division of DHHS, confirmed that contraceptive products other than EC, such as male and female condoms and spermicides, are freely sold OTC so that they "can be purchased by anyone, without a doctor's prescription." (NIH 2004.) As of May 2004, spermicides could "be purchased in most drug and grocery stores." (NIH 2004.) OTC access is appropriate for these contraceptive products. OTC access is, and has been, even more appropriate for *Plan B®* and equivalent EC drugs.

Unlike the articulated FDA rationales for not switching *Plan B®* to OTC status in 2004 and 2005, FDA had, in 2003, addressed concerns from studies about potential HIV infection from a spermicide sold OTC for use by females, throughout their childbearing years, by initiating rulemaking to change labels while retaining the spermicide in OTC status. (FDA 2003.) In 2005, FDA issued extended draft guidelines regarding the

labeling and use of male condoms while retaining the OTC status of that contraceptive method without regard to the ages of the users or their partners. (FDA Draft 2005.)

C. The ongoing lack of OTC access for *Plan B*® and equivalent EC drugs has serious adverse effects on a daily basis.

Relevant, peer-reviewed scientific literature has established that, when EC usage increases, rates of unintended pregnancies decline significantly. (Trussell 2004, p. S31 and studies cited. *See also* Marciante 2001, pp. 1444-45.) Relevant, peer-reviewed scientific literature established that, when EC is made more accessible for potential consumers merely by allowing pharmacists to prescribe EC, usage substantially increases. (Raine 2000, pp. 1, 6; Marciante 2001, pp. 1444-45; Hayes 2000. p. 206; Soon 2005, pp. 878, 881-82; Harper 2005, p. 483. *See also* Rebar 2005.) After British Columbia, in 2000, granted pharmacists authority to prescribe EC, usage increased 51.9% among females 10 to 14 and 54.9% among females 15 to 19. (Soon 2005, p. 881.) Similar substantial correlations were confirmed in California after pharmacists were authorized to prescribe EC without any physician prescription. (Harper 2005, p. 483; Raine 2000, pp. 1, 6. *See also* Marciante 2001, pp. 1444-45 (Washington); Hayes 2000, p. 206 (Washington).) Had FDA switched *Plan B*® to OTC status, larger increases in EC usage would have occurred than in the situations studied, where consumers still faced barriers obtaining prescriptions from either physicians or pharmacists. (Soon 2005, p. 881; Jackson 2003, pp. 8, 11-15.) Relevant, peer-reviewed scientific literature confirmed that so many pharmacies refuse to carry EC as to constitute a barrier to access. (Espey 2003, p. 918.)

Relevant, peer-reviewed scientific literature has established that substantially increased usage has occurred when FDA has switched other drugs to OTC status. When nicotine patches were switched to OTC status in 1996, several peer-reviewed studies later confirmed usage substantially increased. (Hyland 2004, pp. 3-8; Shiffman 1997,

pp. 308-10. *See also* Reed 2005, pp. 2132-36.) This also allies to EC. In "New Zealand, a shift to over-the-counter status led to a 15% increase in pharmacy sales of emergency contraceptive pills" over a short time period. (CPR 2004, pp. 7-8.)

DHHS confirmed that types of EC "that contain both estrogen and progestin are about 75% effective at keeping a woman from getting pregnant." (DHHS 2002, p. 2.) This means that, "if 100 women had unprotected intercourse once during the second or third week of their cycle, about 8 percent would become pregnant; after treatment with ECPs, only 2 would become pregnant, a 75% reduction" if commenced promptly after unprotected intercourse. (Trussell 2004, p. S31 and studies cited. *See also* Marciante 2001, pp. 1444-45.) *Plan B®*, that contains "only progestin [is] about 89% effective" (DHHS 2002, p. 2), in other words, it is even more effective than EC that contain both estrogen and progestin.

Relevant, peer-reviewed scientific literature established that the sooner after unprotected intercourse a regimen of EC is commenced, the more likely it is that it will prevent pregnancy. (Weismiller 2004, p. 709.) As established by relevant, peer reviewed scientific literature, a regimen of *Plan B®* is more than 99% effective at preventing pregnancy if taken within the first few hours after unprotected sex, with effectiveness diminishing inversely, as time elapses, to between 95 and 96 % if commenced at 72 hours and to 90% or less if commenced five days after unprotected sex. (Weismiller 2004, p. 709.) Because there "is an inverse relationship between pregnancy and time since unprotected intercourse" (Weismiller 2004, p. 709), any delay between unprotected intercourse and commencing the regimen - such as delays caused by locating a willing physician, obtaining a prescription and then having that prescription filled – substantially reduces the effectiveness of *Plan B®*. (Weismiller 2004, p. 709.) A 2001 DHHS report identified, as one of the "[b]arriers to the more frequent use" of EC,

the "lack of access by patients to a physician who will prescribe the method." (DHHS 2001, p. 9-14.)

Relevant, peer-reviewed scientific literature has confirmed that first births to adolescent females result in significantly adverse consequences for those persons, compared to first births to adult females, regarding employment, education, propensity to single living arrangements, number of subsequent births and dependence on public support. (Olaussen 2001, p. 72, text and Table 3.) It has also confirmed that "the odds of less favorable outcomes increased almost consistently with decreasing age," that first births to persons 16 or younger resulted in "the highest risks of unfavorable outcomes" and that the odds of unfavorable outcomes were substantially higher for new mothers 11 to 15 years old than for new mothers in the next oldest group studied, new mothers 16 to 17 years old. (Olaussen 2001, p. 72, text and Table 3.)

Wisconsin is one of fifty States constituting the United States of America. Wisconsin has had, and will continue to have, compelling, direct and concrete interests in *Plan B*® and equivalent EC drugs being switched from prescription to OTC status and in FDA actions regarding those potential switches. Wisconsin has had, and will continue to have, substantial and concrete interests in assuring that each child born in Wisconsin is a wanted child and in reducing, among all Wisconsin women who are menstrual, unintended pregnancies, abortions and the birth of unwanted children.

Wisconsin has sovereign interests and duties that are absolute within its boundaries, except to the extent the Constitution and laws of the United States validly alter Wisconsin's sovereign position. *Doyle v. Continental Ins. Co.*, 94 U.S. 535, 541 (1876), *partly overruled on other grds., Terral v. Burke Const. Co.*, 257 U.S. 529, 532 (1922). The "'whole subject of the domestic relations of husband and wife, parent and

child, belongs to the laws of the States and not to the laws of the United States." *Hisquierdo v. Hisquierdo*, 439 U.S. 572, 581 (1979), citation omitted. Regulation of public health and safety issues is preeminently consigned to the States as part of their inherent police power. *E.g., Bacon v. Walker*, 204 U.S. 311, 317 (1907). Indeed, the "police power of a state extends beyond health, morals and safety, and comprehends the [State's] duty, within constitutional limitations, to protect the well-being and tranquility of a community." *Kovacs v. Cooper*, 336 U.S. 77, 83 (1949), *reh. denied*, 336 U.S. 921.

Broad and compelling interests of Wisconsin in matters relating to families, children and human health within its boundaries are expressed by numerous statutory schemes. Wis. Stat., § 767.01 (Circuit courts, funded by State appropriations, with broad authority regarding family issues); Wis. Stat., § 15.19 (creating as a separate agency, Wisconsin Department of Health and Family Services ("WisDHFS")). Several entire chapters of the Wisconsin Statutes are dedicated to issues involving families, children and human health. *E.g.,* Wis. Stat., chs. 46, 48, 49, 50, 51, 55, 58, 59, 146, 149, 150, 153, 250, 251, 252, 253 and 255.

Each "State has a 'compelling' interest in preventing teenage pregnancy" and a "strong interest" in the "prevention of illegitimate pregnancy." *Michael M. v. Superior Court of Sonoma County*, 450 U.S. 464, 470 and 472, n.7 (1981). For any Wisconsinite 15 or younger to become pregnant is of grave concern to Wisconsin. Over just three years, from 2000 to 2002, at least 332 Wisconsinites experienced both pregnancy and childbirth while they were 14 or younger. (DHHS Database, 2004. *See also* DHHS Health Status, 2004, 68, Table 46 (2000 births).)

Amongst Wisconsin females aged 15 to 17 years, the DHHS database reports that: (a) there were 721 induced abortions and 2493 births in 2001; (b) there were 632 induced abortions and 2202 births in 2002; (c) for the three year period of 2000-2002, the average total birth rate was 17.6 per 1000 and, (d) during that three year time period,

there were 7,220 births. (DHHS Database, 2004. *See also* DHHS Health Status, 2004, p. 68, Table 46 (2000 births).) For Wisconsin females aged 15 to 17 years in 2000, the pregnancy rate was 30 per 1000, the birth rate 19 per 1000 and the abortion rate 7 per 1000. (Guttmacher U.S. 2004, p. 8.)

For adolescents to experience pregnancy and childbirth imposes overwhelming burdens on them, with substantial direct and concrete consequences for governments responsible for them. As Congress found in 1984,

> pregnancy and childbirth among unmarried adolescents, particularly young adolescents, often results in severe adverse health, social, and economic consequences including: a higher percentage of pregnancy and childbirth complications; a higher incidence of low birth weight babies; a higher infant mortality and morbidity; a greater likelihood that an adolescent marriage will end in divorce; a decreased likelihood of completing schooling; and higher risks of unemployment and welfare dependency...

42 U.S.C. § 300z(5). Congress further found "an unmarried adolescent who becomes pregnant once is likely to experience recurrent pregnancies and childbearing, with increased risks" while still an adolescent. 42 U.S.C. § 300z(7).

Many births to adolescent Wisconsinites are not their first births; about one in five of those who experienced childbirth between 2000 and 2002 had previously experienced childbirth. (DHHS Database 2004. *See also* DHHS Health Status 2004, p. 71, Table 48 (2000).) To ameliorate adverse effects of pregnancy and childbirth for adolescent Wisconsinites, the Wisconsin Legislature established special programs and funding for "school age parents" who try to continue their education. Wis. Stats. §§ 115.91 to 115.93. The fact that EC was not available OTC has substantially increased the situations in which Wisconsin had to expend resources to address those needs.

Wisconsin interests are directly and adversely affected by whichever choice adolescent Wisconsinites make in response to unintended pregnancies. (Zabin 1989, pp. 248, 250-55; Fleming 1993, pp. 561-62.) Abortions are more likely to result in medical

complications when obtained by teens than by adults at higher income levels. "Teens are more likely than older women to delay having an abortion until after 15 weeks of pregnancy, when medical risks associated with abortion increase significantly." (Guttmacher State 2004.) Relevant, peer-reviewed scientific literature confirmed that adolescent females sustain consequences that are substantially more adverse when they carry an unintended pregnancy to term and experience childbirth than when they have an induced abortion. (Zabin 1989, pp. 248, 250-55; Fleming 1993, pp. 561-62.)

Relevant, peer-reviewed scientific literature confirmed that in Wisconsin, "[c]hildren born to teenage parents are at increased risk for numerous problems including low birth weight, cognitive and behavioral problems, and substance abuse" and that "[t]een pregnancy costs [Wisconsin] taxpayers significant amounts each year." (Ashby 2005, p. 37.) It has also confirmed that in the United States "[i]n the year 2000, just over 820,000 women aged 15 to 19 became pregnant, and almost 30% of those pregnancies resulted in abortion," and that "[m]ore than half of adolescents have had intercourse by the age of 17 years, and most adolescent pregnancies are unintended." (Harper 2005, p. 484 (footnotes omitted).)

A 2001 DHHS report confirmed that "[u]nintended pregnancies occur among females of all socioeconomic levels and all marital status and age groups" but adolescents are among the few subgroups who "are especially likely to become pregnant unintentionally." (DHHS 2001, p. 9-4.) In 1994, only 22% of pregnancies among females nationwide who were 15 to 19 were "intended" (DHHS 2001, p. 9-4).

"Estimates of the overall cost to U.S. taxpayers for teenage childbearing range between $7 billion and $15 billion a year, mainly attributed to higher public assistance costs, foregone tax revenues resulting from changes in productivity of the teen parents, increased child welfare, and higher criminal justice costs. [Footnote omitted.]" (DHHS 2001, p. 9-4.) "Unintended births to teenagers, which account for about 40 percent of

teenage pregnancies, cost more than $1.3 billion in direct medical expenditures each year. [Footnote omitted.]" (DHHS 2001, p. 9-4.)

A sexually active teenage female who does not use contraceptives has a 90% chance of becoming pregnant within one year. (CWLA 2006.) Nearly 29,000 Wisconsin teenage females are "sexually active." (Guttmacher 2006, p. 1.) "Every tax dollar spent for contraceptive services saves an average of $4 that would otherwise be spent to provide medical care, welfare benefits, and other social services" and more "than $3 is saved in medical costs alone." (CWLA 2006.) Without family planning services, an additional 386,000 teenagers would become pregnant nationwide each year and, of these, 155,000 would give birth, increasing the number of teen births by about 25%, while 183,000 teenagers would have abortions, increasing abortions among teenagers by 58%. (CWLA 2006 citing Forrest 1996.)

Wisconsin also has concrete and direct interests that are adversely effected whenever Wisconsinites of any age who are either Medicaid recipients or potential Medicaid recipients become pregnant, experience pregnancy, have induced abortions, experience childbirth or become mothers. In 2002, 41% of the 68,510 births in Wisconsin were paid for by Medicaid funds. (WisDHFS 2004, p. 2.) The average Medicaid cost of a birth in Wisconsin in 2004 is estimated to be $9,391.53. (Comptroller 2005, p. 35.) Relevant, peer-reviewed scientific literature, established that use of *Plan B®* was a highly effective way to substantially reduce Medicaid expenditures. (Trussell 2001, pp. 790-93; Grimes 2002, p. E-180; Forrest 1996, pp. 188, 192-94. *See also* Trussell 2004, p. S35.) To the extent that Medicaid expenditures resulting from unintended pregnancies, births of unwanted children and other medical costs would have been reduced through OTC access to EC that would have freed scarce Wisconsin resources for reallocation to other compelling needs or priorities.

Unintended pregnancies that OTC access to EC could easily have prevented has drained and will drain Wisconsin resources. Wisconsin statutes appropriate funds for outreach to low-income pregnant women and for maternal and infant health projects. Wis. Stat. § 20.435(5)(ev). Wisconsin statutes also call for State revenues to fund many grants related to troubled pregnancies including, for example, grants to fund substance abuse day treatment services for pregnant and postpartum women and their infants (Wis. Stats. §§ 46.48(29) and 46.86), programs to "[p]revent and reduce the incidence of nonmarital pregnancy and increase the use of abstinence as a method of preventing nonmarital pregnancy" (Wis. Stat. § 46.99(2)4), adolescent pregnancy prevention services operated by tribes (Wis. Stat. § 46.995(3) and (4m)1) and State adoption information exchange programs (Wis. Stat. § 48.55). Unintended pregnancies that were avoidable through OTC access to EC and that instead called on these Wisconsin resources precluded reallocation of those resources to other critical needs and priorities.

As of November 2004, over 200,000 individuals were enrolled in Medical Assistance in Wisconsin under "Aid to Families with Dependent Children" or "AFDC-related" criteria and over 125,000 children and pregnant women were enrolled in Medical Assistance under the "Healthy Start" criteria. (Legis. Fiscal Bureau 2005, p. 5.) *See* Wis. Stats. §§ 49.19 and 49.45. Wisconsin also funds special programs, through substantial State revenues, under its "Badger Care" program to assist pregnant women and new mothers to have healthy pregnancies and children. Wis. Stat. § 49.665.

Wisconsin has compelling interests in reducing all situations in which any Wisconsin woman – regardless of age or economic status - is faced with the difficult choice between giving birth to an unwanted child or having an induced abortion. Each "State unquestionably has a "strong and legitimate interest in encouraging normal childbirth," [citation omitted], an interest honored over the centuries." *Maher v. Roe*, 432 U.S. 464, 478 (1977). The "'birth of [an "'unwanted'"] child may be a catastrophe not

only for the parents and the child itself, but also for previously born siblings.' [Citation omitted.]" *Hartke v. McKelway*, 707 F.2d 1544, 1552 (D.C.Cir. 1983), *cert. denied*, 464 U.S. 983 (1983). The birth of an unwanted child may well cause "'distress, for all concerned, associated with the unwanted child, and there is the problem of bringing a child into a family already unable, psychologically and otherwise, to care for it.' [Citation to *Roe v. Wade* omitted.]" *Dronenburg v. Zech*, 741 F.2d 1388, 1394 (D.C.Cir. 1984), *reh. denied*, 746 F.2d 1579 (D.C.Cir. 1984).

Wisconsin has compelling interests in removing any barricades to safe and effective methods through which any Wisconsin woman - not just Wisconsinites under 20 years or Wisconsin Medicaid recipients - may choose to avoid pregnancy. If *Plan B®* and other equivalent EC drugs are switched to OTC status, easier access would facilitate the ability of Wisconsin women, throughout their childbearing years, to make those individual choices more effectively and rationally than is presently feasible.

Wisconsin has compelling constitutional rights and duties to vigorously exercise its sovereignty, regarding family and public health issues,subject only to the supremacy of the United States Constitution and the proper exercise of superior authority of the federal government to the extent authorized by the United States Constitution. To the extent that FDA acted improperly and beyond its authority in not making *Plan B®* and other equivalent EC drugs available OTC, those actions constituted, and continue to constitute, unconstitutional impediments to Wisconsin's constitutional rights to assure that Wisconsin women who are menstrual may make their own decisions about reproductive health care and have access to safe and effective contraceptives.

Wisconsin has duties to protect the health, well-being and tranquility of the community made up of the constituents within its boundaries. To the extent that FDA acted improperly and beyond its authority in not making *Plan B®* and equivalent EC drugs available OTC, those actions constitute, and continue to constitute,

unconstitutional impediments to the constitutional rights of Wisconsin women who are menstrual may make their own decisions about reproductive health care and have access to safe and effective contraceptives.

"[R]estricting minors' access to contraceptives, because free availability to minors of contraceptives would lead to increased sexual activity among the young" cannot serve **any** legitimate governmental interests. *Carey v. Population Services, Intern.*, 431 U.S. 678, 694-95 (1977) (plurality). Instead, it "'would be plainly unreasonable to assume that [any government] has prescribed pregnancy and the birth of an unwanted child (or the physical and psychological dangers of an abortion) as punishment for fornication.' [*Eisenstadt v. Baird*,] 405 U.S.[438,] 448 [(1972).]" *Carey*, 431 U.S. at 694-95.

To the extent that FDA's failure to switch *Plan B®* to OTC status was grounded on moral concerns about potential increases in "sexual activity among the young" (*Carey*, 431 U.S. at 694-95), those rationales were not only erroneous – since relevant, peer-reviewed scientific literature confirmed that no such increase was likely – but also an unconstitutional impediment to the rights of younger adolescents to free access to safe and effective contraceptives. To that extent, FDA's failure to switch *Plan B®* to OTC status was even a more serious impediment to the rights of Wisconsinites 17 and older to free access to contraceptives, since they are being deprived, based on improper moral concerns, of OTC access which FDA admitted to be safe and effective for all females 17 and older.

Wisconsinites under 18 "are entitled to federal constitutional protection in making decisions about reproductive health care [citation to *Carey* omitted]" and "[c]onstitutional protection for minors is critical because pregnancy and sexually transmitted diseases impact as heavily, if not more heavily, upon minors. *See T.H. v. Jones*, 425 F.Supp. 873, 881 (D.Utah 1975), *aff'd on statutory grounds*, 425 U.S. 986, 96 S.Ct. 2195, 48 L.Ed.2d 811 (1976) ('The interest of minors in access to contraceptives is

one of fundamental importance. The financial, psychological and social problems arising from teenage pregnancy and motherhood argue for our recognition of the right of minors to privacy as being equal to that of adults.')." *Parents United for Better Schools, Inc. v. School Dist. of Philadelphia Bd. of Educ.*, 978 F.Supp. 197, 209 (E.D.Pa. 1997), *aff'd*, 148 F.3d 260 (3rd Cir. 1998).

OTC access to *Plan B®* and equivalent EC drugs was mandated long ago. Wisconsin petitions FDA to promptly correct its failure to approve *Plan B®* and equivalent EC drugs for OTC access by (a) immediately switching *Plan B®* from prescription to OTC status and (b) approving all other equivalent EC drugs for OTC access. Wisconsin expressly states that the switch of *Plan B®* from prescription to OTC status should not be delayed in any manner by consideration of whether equivalent EC drugs should be allowed for OTC access. Each day that passes without *Plan B®* being available OTC is another day that unwanted pregnancies, abortions and unwanted chidbirths occur that access to *Plan B®* would have prevented.

ENVIRONMENTAL IMPACT

A categorical exclusion is claimed under 21 C.F.R. § 25.30 or 21 C.F.R. § 25.31.

ECONOMIC IMPACT

Since the information listed under "D. Economic Impact" in 21 C.F.R. § 10.30 is to be provided only if requested by the Commissioner after review, Wisconsin refrains from providing that information at this time. Wisconsin notes that, in its "Statement of Grounds" above, it has articulated numerous substantial economic benefits that would accompany any switch of *Plan B*® or equivalent EC drugs to OTC status and represents that to the extent, if at all, any economic detriments would accompany such a switch, the economic benefits substantially outweigh any potential economic detriments.

CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Dated this 22nd day of May, 2006.

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