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December 5, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Subj: Docket No. 2001P-0075 (concerning a proposal to "Switch Status of Emergency Contraceptives From Rx to OTC")

Dear Sir or Madam:

On November 25, 2003, the Food and Drug Administration announced a meeting of the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs, to be held on December 16, 2003, for the purpose of considering a proposal to make Plan B or levonorgestrel-only "emergency contraception" ("EC") available without a prescription. 68 Fed. Reg. 66113 (Nov. 25, 2003). The agency invited written comments. *Id.*

On behalf of the United States Conference of Catholic Bishops, we submit the following comments in opposition to the proposal to make EC available without a prescription.

Interest of the United States Conference of Catholic Bishops

The United States Conference of Catholic Bishops is a nonprofit corporation organized under the laws of the District of Columbia. All active Catholic bishops in the United States are members of the Conference. The Catholic Church, the largest religious denomination in the United States, has over 66 million adherents in over 19,000 parishes throughout the country. The Conference advocates and promotes the pastoral teaching of the bishops in such diverse areas as education, family life, health care, social welfare, immigration, civil rights, and the economy.

Our opposition to the proposal to make EC available over-the-counter stems from our concerns for promoting the dignity of human life, maintaining public health, and protecting family life.

Approval of over-the-counter use of EC is objectionable for several reasons.

1. EC can have an abortifacient effect. To make it more widely available through over-the-counter use would conflict with a trend in law and medicine which recognizes the human embryo as a human subject and a patient deserving of protection.

2. Many women are currently unaware that EC can have an abortifacient effect. This is a matter that would be of deep concern to many women were they aware of it. Over the counter use will only guarantee continued unawareness by excluding the participation of physicians who might otherwise provide this information.

3. EC carries significant risks and is contraindicated for many women. Indeed, the package insert says that EC is *not* to be used as a routine method of contraception. Making EC available over-the-counter would eliminate the clinical oversight necessary to ensure that EC is not used routinely. In particular, it would eliminate the clinical monitoring and follow-up needed to address the risk of ectopic pregnancy, a potentially life-threatening condition.

4. The potential for misuse of EC is especially grave in the case of minors. Over-the-counter availability for EC will make it possible for a minor to have ready access to the drugs without ever seeing a physician or notifying her parents. The Administration, if anything, should be *encouraging* physician involvement and parental notification, not thwarting it as this proposal, if adopted, would do. Over-the-counter access to EC may also increase risk-taking behavior and promiscuity, an especially acute problem in the case of teenagers who have higher rates of sexually transmitted disease in this country than their counterparts in other developed nations.

5. Availability of EC is not likely to significantly reduce abortions. Indeed, as we have noted, EC itself can have an abortifacient effect. Regions that have made the drugs available have not seen a reduction in abortions.

6. Over-the-counter availability of EC would likely increase the pressure already being placed on pharmacies and pharmacists to violate their conscience.

More detailed comments follow.

Comments

The FDA has regulatory authority to exempt drugs from prescription requirements "when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling."[1] Plan B availability over-the-counter does not meet these standards.

[1] 21 C.F.R. § 310.200(b).

I. The Abortifacient Properties of EC and the Implications for Informed Consent

The drug regimen under consideration can act as an abortifacient, rather than as a contraceptive in the traditional sense of that term. Therefore it is unsafe and may be toxic to developing human embryos, recognized in law and medicine as human subjects and patients in their own right. Making this regimen readily available for self-medicating also excludes the participation of a clinician who can ensure that women receive properly informed consent about the abortifacient property of the drug, a factor that would be of deep concern to many women.

A. Abortifacient Aspects

Beginning in 1964, proponents of intrauterine devices (IUDs) decided to alter the medical definition of "conception" to equate it with implantation of the embryo in the womb. This was done so that such devices could be labeled "contraceptives" even if they were found to act by interfering with implantation.[2]

Semantics, however, do not change the biological fact that human life begins at fertilization. Embryology textbooks overwhelmingly recognize this fact:

> Human development begins after the union of male and female gametes or germ cells during a process known as fertilization (conception).... This fertilized ovum, known as a zygote, is a large diploid cell that is the beginning, or primordium, of a human being.[3]

> The development of a human begins with fertilization, a process by which the spermatozoon from the male and the oocyte from the female unite to give rise to a new organism, the zygote.[4]

> Almost all higher animals start their lives from a single cell, the fertilized ovum (zygote).... The time of fertilization represents the starting point in the life history, or ontogeny, of the individual.[5]

Any deliberate intervention to end a newly conceived human life or prevent its further survival and development is morally tantamount to abortion. There is substantial evidence that EC may act in this way, by impeding the development of the embryo or by interfering with the process of implantation.

An extensive review of the literature lists eleven possible modes of action for emergency contraception, seven of which can be abortifacient, that is, designed to prevent the implantation or survival of the embryo.[6] These possible modes include

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[2]*See* G. Grisez, ABORTION: THE MYTHS, THE REALITIES, THE ARGUMENTS 111-116 (1970).
[3]K. Moore, ESSENTIALS OF HUMAN EMBRYOLOGY 2 (1988).
[4]T. Sadley, LANGMAN'S MEDICAL EMBRYOLOGY 3 (1995).
[5]B. Carlson, PATTEN'S FOUNDATIONS OF EMBRYOLOGY 3 (1996).
[6]H. Croxatto, *et al., Mechanism of action of hormonal preparations used for emergency contraception: a review of the literature*, 63 CONTRACEPTION 111-21 (2001) at 111.

interference with zygote development, with transportation to the uterus, and with endometrial receptivity. While noting the ethical and practical barriers to quantifying the abortifacient mode of action in human beings,[7] this review cites studies showing strong evidence that levonorgestrel has an abortifacient mode of action. One major study of levonorgestrel's effects is summarized as follows:

> Preovulatory administration had no effect on ovulation, whereas at the level of the endometrium, it caused divergent effects depending on the time of drug intake. Factors believed to be critical for implantation, such as integrins, steroid receptors, or leukemia inhibitory factor, among others, were changed in ways which are *likely to alter endometrial receptivity.*[8]

A study subsequently published in the same journal also concluded that high doses of levonorgestrel interfere with endometrial receptivity:

> Our results revealed marked endometrial changes both in the proliferative and secretory phases of the cycle. The detected surface alterations correspond to previous findings in experimental animal model and in human endometrium.... Very likely, these changes embody the mainstream of the contraceptive effect.[9]

Another study, reviewing literature on the mode of action of both Plan B and Preven, concluded: "The evidence to date supports the contention that use of EC does not always inhibit ovulation even if used in the preovulatory phase, and that it may unfavorably alter the endometrial lining regardless of when in the cycle it is used, with the effect persisting for days."[10]

EC, then, can be toxic and unsafe for human embryos. This impact should enter into the FDA's consideration of whether to make Plan B more widely available.

B. Both Law and Medicine Regard Human Embryos as Morally Significant and Deserving of Protection

The trend in federal law is toward recognition of the early human embryo as a protectable human subject. For example, since 1996 federal law has prohibited federal funding of :

> (1) the creation of a human embryo or embryos for research purposes; or

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[7] *Id.* at 119.
[8] *Id.* at 117 (emphasis added).
[9] G. Ugocsai, *et al., Scanning electron microscopic (SEM) changes of the endometrium in women taking high doses of levonorgestrel as emergency postcoital contraception*, 66 CONTRACEPTION 433-7 (2002) at 436.
[10] C. Kahlenborn, *et al., Postfertilization Effect of Hormonal Emergency Contraception,* 36 THE ANNALS OF PHARMACOTHERAPY 465-70 (2002) at 468.

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero . . .[11]

In keeping with this longstanding congressional judgment that the early human embryo deserves protection from research risks, the Department of Health and Human Services, in framing a new charter for the Secretary's Advisory Committee on Human Research Protections, has enjoined that committee to "provide advice relating to the responsible conduct of research involving *human subjects* with particular emphasis on ... pregnant women, embryos and fetuses."[12]

Similarly, since 2002 the federal government has recognized the human embryo "from conception" as a "child" eligible for receiving prenatal care under the State Children's Health Insurance Program.[13]

This trend is in full accord with the growing recognition of the developing human embryo as a patient of modern medicine. For example, the American Academy of Pediatrics, which is dedicated to providing health care to children, recognizes the unborn child as a patient of the pediatrician:

> The purview of pediatrics includes the physical and psychosocial growth, development, and health of the individual. This commitment begins prior to birth when conception is apparent and continues throughout infancy, childhood, adolescence and early adulthood, when the growth and developmental processes are generally completed.[14]

The FDA has no mandate to promote and facilitate ways of preventing pregnancy that may cause the death of developing human life already conceived. Making EC available over-the-counter will reverse the legal and medical trend toward greater recognition and protection of human embryonic life, by making chemical agents that can destroy such life so easily obtainable.

C. Failure to Counsel Women on EC's Mode of Action Violates Standards of Informed Consent

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[11]The version of this provision in current law is Sec. 510 of Division G of Pub. L. No. 108-7, the Consolidated Appropriations Resolution of 2003 (retained in law into January 2004 through a Continuing Resolution).

[12]U. S. Department of Health and Human Services, "Charter, Secretary's Advisory Committee on Human Research Protections," October 1, 2002, at http://ohrp.osophs.dhhs.gov/sachrp/charter.pdf (emphasis added).

[13]U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Final Rule: State Children's Health Insurance Program; Eligibility for Prenatal Care and Other Health Services for Unborn Children , 67 Fed. Reg. 61955, 61974 (Oct. 2, 2002) (amending 42 C.F.R. § 457.10).

[14]American Academy of Pediatrics, *Policy Statement: Age Limits of Pediatrics* (RE8116), 81 PEDIATRICS 736 (May 1988).

Ready access to Plan B without a prescription will also effectively prevent many women from obtaining informed consent about its abortifacient mode of action. The current package insert contains unclear and misleading language about this mode of action:

> Plan B is believed to act as an emergency contraceptive principally by preventing ovulation or fertilization (by altering tubal transport of sperm and/or ova). In addition, it may inhibit implantation (by altering the endometrium). It is not effective once the process of implantation has begun.[15]

The insert is unclear because it states that Plan B may "inhibit implantation" but does not indicate what this means. It does not clearly state that the drugs may inhibit the implantation of human embryos in the uterine lining and therefore lead to their death. The insert is also misleading in suggesting that the drug does not act once the process of implantation has begun, since (as noted above) the scientific literature indicates that levonorgestrel interferes in this very process by reducing receptivity of the endometrium. It may have been accurate to say that the drug is not effective once the process of implantation is completed, but that is not the claim in the package insert.

Plan B has been labeled and advertised as a "contraceptive," and widely promoted as *not* causing abortions. Many women are thus unaware that the drug may cause the deaths of their newly conceived embryonic children. Making the drug so easily available over-the-counter can only serve to further this confusion, by sending the message that the drug is not medically or morally controversial. One would not expect drugs with such serious effects to be as easily obtainable as aspirin. Further, over-the-counter availability removes from the process of obtaining the drugs a clinician who can provide personal counseling and respond to questions about mode of action. Thus some medical experts have recommended active informed consent about the drugs, encouraging clinicians to inquire as to whether their patients consider conception morally relevant and then providing appropriate informed consent before prescribing EC. "If a postfertilization mechanism of hormonal EC use violates the morals of any woman," they note, "the failure of the physician or care provider to disclose that information would effectively eliminate the likelihood that the woman's consent was truly informed."[16]

II. Public Health Concerns

A. Potential for Misuse

The Plan B package insert indicates that EC is *not* to be used as a routine method of contraception.[17] Making EC available without a prescription and over-the-counter will

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[15]Plan B Package Insert, pg. 1, available at www.go2planb.com/package_insert.pdf (accessed 12/03/03).
[16]*See* C. Kahlenborn, *et al.*, *supra* note 10, at 468.
[17]*See* www.go2planb.com/package_insert.pdf, page 5, accessed 12/01/03 ("Plan B is not recommended for routine use as a contraceptive.").

eliminate the clinical oversight that exists now to ensure that EC is not used routinely and even frivolously.

The potential for routine use also raises significant questions about safety. Claims about the safety of EC are premised on occasional or one-time use of the pills. It has been argued that contraindications and risks that accompany ordinary hormonal contraceptives need not be a concern of the physician prescribing EC because EC is used rarely, only in "emergencies."[18] Yet EC availability over-the-counter effectively nullifies this argument, by encouraging women to choose it routinely. The risks and contraindications attendant to ordinary contraceptives will then also apply to EC users, perhaps further aggravated by the large doses of hormones administered at one time. Women who select EC for routine use would not have the benefit of clinical supervision for these risks and contraindications.

Currently, oral contraceptives carry significant risks, including a risk of heart attacks, blood clots, and cervical cancer.[19] Oral contraceptives are contraindicated for women with diabetes, breast cancer, liver problems, headaches, heart disease or a history of heart disease, deep vein thrombosis or a history of deep vein thrombosis, and women over 35 who are smokers.[20]

Already Planned Parenthood is promoting the use of EC by women for whom ordinary contraceptives are contraindicated, a reckless experiment on women's health that could expand without meaningful restraint if EC is available over-the-counter.[21] The potential for routine use of EC has also been confirmed by a United Kingdom study that found "high levels of repeat use" of EC among all age groups.[22]

The potential for misuse is especially grave in the case of minors. Over-the-counter availability for EC will make it possible for minors to have ready access to the drugs without seeing a physician or notifying their parents. The Administration should seek to encourage physician involvement and parental notification, not thwart it as this proposal would do.

B. Ectopic Pregnancy Risk

Making EC available without a prescription eliminates critical clinical monitoring and follow-up to address the risk of ectopic pregnancy. Although the original clinical

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[18] "Above all clinicians need to remind themselves that they are not starting someone on the COC pill. It is not necessary to weigh the woman, do a breast examination, take a cervical smear, undertake urinalysis, or measure serum cholesterol. It cannot be stressed enough that you are prescribing *emergency* contraception." A. Glaiser, *Safety of Emergency Contraception*, 53 JAMWA 219 (Supp. No. 2, 1998) at 220.

[19] *See* R. Hatcher, *et al.*, CONTRACEPTION, 17th Edition (1998), 414-18.

[20] *Id.* at 420.

[21] "Almost every woman who needs emergency contraception can safely use ECPs - even women with contraindications to the ongoing use of oral contraceptives may use them." www.plannedparenthood.org/library/ BIRTHCONTROL/EC.html, accessed 12/01/03.

[22] *See* J. Rozien, *Repeat Use of Emergency Contraception: How Frequent Is It?*, 27 JOURNAL OF FAMILY PLANNING AND REPRODUCTIVE HEALTH CARE 197 (2001) at 201.

trials for EC did not find a significantly increased ectopic risk,[23] later experience with EC in both the United Kingdom and New Zealand has prompted medical authorities to warn physicians about the danger of ectopic pregnancy following use of the drugs. In the United Kingdom, the Committee on Safety of Medicines found 12 ectopic pregnancies out of 201 unintended pregnancies following the use of levonorgestrel. The Committee urged follow-up for women who have taken the drugs and did not experience a normal period afterwards.[24] In New Zealand, the Center for Adverse Reactions Monitoring reported three ectopic pregnancies following use of progestogen-only EC. Citing these reports and recent medical literature, the Center urged prescribers "to advise women about the possibility of ectopic pregnancy if contraceptive failure occurs with any oral progestogen-only method, and the importance of promptly seeking medical help if symptoms suggestive of ectopic pregnancy develop."[25]

To make EC available over-the-counter will exacerbate this risk of potentially life-threatening ectopic pregnancy. Common side-effects of EC, nausea and abdominal pain, coincide with the symptoms of an ectopic pregnancy. Women who are not under clinical supervision are unlikely to distinguish between the common side-effects of the drugs and the symptoms of a potentially life-threatening ectopic pregnancy.

C. Sexually Transmitted Diseases

Easy access to Plan B over-the-counter may also increase risk-taking behaviors and promiscuity. Publicity campaigns have promoted EC as a widely-available "back up," should a woman not use regular contraception. "Plan B" has been specifically advertised as an alternative course should "Plan A," the plan to contracept or to avoid intercourse, fail.

Most women using contraceptives are generally concerned with not getting pregnant. They are generally not concerned about preventing sexually-transmitted diseases. Should Plan B be available over-the-counter, younger women taught to rely on this "back-up" may well choose it as their primary method of avoiding pregnancy.

Extensive EC publicity campaigns have already promoted risk-taking sexual behaviors, especially among young women. Ads developed by the Women's Capital Corporation to market Plan B target younger audiences. One ad shows a group of young men standing outside a dormitory, with the message: "So many men. So many reasons to have back-up contraception." Another shows fraternity members on a soccer field, with the message: "Delta Delta Thi. 27 Upstanding Young Men. 34 Billion Sneaky Little

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[23]Medical Officer Review of NDA 21,045: Levonorgestrel 0.75 mg tablets (2) for Emergency Contraception, at pg. 28, July 31, 1997, available at www.fda.gov/cder/foi/nda/99/21-045_Plan%20B_medr.pdf (accessed 12/02/03).

[24]*See* Chief Medical Officer's Update No. 35, January 2003, www.doh.gov.uk/cmo/cmo_35.htm#20, accessed 12/01/03.

[25]*See* Dr. M. Harrison-Woolrych, *Prescriber Update Articles Progestogen-Only Emergency Contraception and Ectopic Pregnancy*, October 2002, available at www.medsafe.govt.nz/Profs/PUarticles/ectopic.htm#1 accessed 12/01/03, citing M. McCann and L. Potter, *Progestin-only oral contraception: a comprehensive review*, 50 CONTRACEPTION S44-S49 (1994).

Sperm." The clear message here is that casual sexual involvement, particularly for college-age women, is without adverse consequences if one has ready access to this "back-up."

Already teenagers in the United States have higher sexually-transmitted disease ("STD") rates than their counterparts in developed countries. According to the Alan Guttmacher Institute, "U.S. teenagers have higher STD rates than teenagers in other developed countries -- for example, England, Canada, France and Sweden -- because they have more sexual partners and probably lower levels of condom use."[26]

In Washington, in the year EC was first made available through a pilot program in pharmacies, the rate of chlamydia increased from 169 cases per 100,000 in 1997 to 193 per 100,000 in 1998.[27] The increase was a dramatic reversal of a steadily downward trend in chlamydia through 1996.[28] In the five years that EC has been made available over-the-counter, cases of chlamydia have increased 56%.[29]

These problems are compounded by the fact that many STD's are asymptomatic. Providing access to EC over-the-counter would eliminate the opportunity for physicians to screen sexually active teenagers and others for STDs.

D. Impact on Abortion Rates

Advocates of making EC available over-the-counter contend that such availability will significantly reduce abortions. Such promises are false. First, as noted above, the drugs themselves can have an abortifacient action. Second, regions that have made the drugs widely available have not seen such reductions. In Washington state, in 1998, the year that EC was first made readily available, the abortion rate fell just 1.3%,[30] the same rate at which the abortion rate had been falling in Washington (and in the nation as a whole) in most years beginning with the early 1990's.[31]

III. Potential for Coercion of Pharmacists

If Plan B were to be made available over-the-counter, new pressures would be placed on pharmacies to provide it despite the sincere conscientious objections of pharmacies and individual pharmacists. Already, a bill in Nevada has been introduced to

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[26]Alan Guttmacher Institute, *Facts In Brief: Teenagers Sexual and Reproductive Health – Developed Countries*, 2 (January 2002), available at www.guttmacher.org/pubs/fb_teens.pdf (accessed 12/02/03).
[27]*See* Washington State Department of Health, *Sexually Transmitted Disease Morbidity*, 2002, at 5, available at /www.doh.wa.gov/cfh/STD/2002_STDmorb.pdf, accessed 12/01/03.
[28]There had been a slight increase from 1996 to 1997, 2.4 more cases per 100,000. *See id.*
[29]*See* note 11 *supra*. In the year before EC was made available in pharmacies, annual cases of chlamydia numbered 9,523; by 2002 the number had risen to 14,936.
[30]*See* Washington State Department of Health Center for Health Statistics, Abortion/Pregnancy Data, available at www.doh.wa.gov/ehsphl/chs/chs-data/abortion/2001/ATAB2_2001.htm (accessed 12/02/03).
[31]*See* Alan Guttmacher Institute, *Trends in Abortion in Washington, 1973-2000*, at 3 (graphic showing the national trend and the Washington trend in abortion rates), January 2003, available at www.agi-usa.org/pubs/state_ab_pt/washington.pdf (accessed 12/02/03).

override pharmacists' moral or religious objections and require them to fill prescriptions for EC.[32] In one case, an Ohio pharmacist employed by K-Mart claims to have suffered recriminatory action for failing to dispense progestin-only pills.[33] It is worth noting that a federal judge allowed the pharmacist to raise a claim under the Ohio conscience law, which provides: "No person is required to perform or participate in medical procedures that result in abortion, and refusal to perform or participate in the medical procedures is not grounds for civil liability nor a basis for disciplinary or other recriminatory action."[34] Forty-five other states have similar laws, but their protections for pharmacists and pharmacies that decline to dispense EC are uncertain in light of the narrow interpretation often given to the word "abortion."[35]

Acknowledging the pressures that pharmacists may face, the American Pharmacists Association has passed a resolution respecting their conscience rights: "The APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal."[36]

Conclusion

"Emergency contraception" carries its own risk of potentially serious adverse effects on women. It imposes these risks and disrupts a woman's healthy reproductive functioning to serve the lifestyle goal of avoiding a pregnancy seen as untimely. As such it fits poorly into any traditional model of medicine, let alone emergency medicine. Proposals to make EC available over-the-counter compound the problem. Such proposals risk causing serious harm to women and their developing unborn children, ignoring

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[32]*See* AB 144, 72nd Sess. Nevada. Fortunately, the bill did not pass.

[33]*See Brauer v. Kmart,* No. C-1-99-618 (S.D. Ohio Jan. 23, 2001) (pending).

[34]O.R.C. § 4731.91(D).

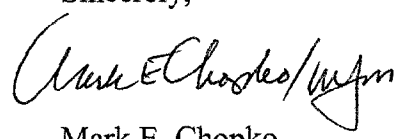
[35]*See* ALASKA STAT. § 18.16.010(B) (struck down in part in *Valley Hospital Ass'n v. Mat-su Coalition for Choice*, 948 P.2d 963 (Alaska 1997); ARIZ. REV. STAT. § 36-2151;ARK. CODE ANN. § 20-16-601; CAL. HEALTH & SAFETY CODE § 123420; COLO. REV. STAT. § 18-6-104; CON. AGENCIES REGS. § 19-13-D54(F); DEL. CODE ANN. tit. 24, § 1791; FLA. STAT. ANN. § 390.0111(8); GA. CODE ANN. § 16-12-142; HAW. REV. STAT. ANN. § 453-16(D); IDAHO CODE § 18-612; 720 ILL. COMP. STAT. 510/13; IND. CODE ANN. §§ 16-34-1-3 to -7; IOWA CODE ANN. §§ 146.1 -.2; KAN. STAT. ANN. §§ 65-443 to 444; KY. REV. STAT. ANN. § 311.800; LA. REV. STAT. ANN. § 40:1299.3; LA. REV. STAT. ANN. § 40:1299.32; LA. REV. STAT. ANN. § 40:1299.33; ME. REV. STAT. ANN. tit. 22 §§ 1591 - 1592; MD CODE ANN., HEALTH-GEN.I § 20-214; MASS. GEN. LAWS ANN. ch. 112, § 12I and ch. 272, § 21B; MICH. COMP. LAWS ANN. §§ 333.20181 to .20184 and 333.20199; MINN. STAT. ANN. §§ 145.414, .42; MO. ANN. STAT. § 197.032, § 188.100 to .120; MONT. CODE ANN. § 50-20-111; NEB. REV. STAT. §§ 28-337 to 28-341; NEV. REV. STAT. §§ 449-191and 632.475; N.J. STAT. ANN. §§ 2A:65A-1 to -4; N.M. STAT. ANN. § 30-5-2; N.Y. CIV. RIGHTS LAW § 79-I; N.C. GEN. STAT. § 14-45.1(E), (F); N.D. CENT. CODE § 23-16-14; OKLA. STAT. ANN. tit. 63 § 1-741; OR. REV. STAT. §§ 435.475(1), .485; PA. CONS. STAT. ANN. tit. 43, § 955.2, tit. 18, § 3213(D) and 16 PA. CODE §§ 51.1-51.61; R.I. GEN. LAWS § 23-17-11; S.C. CODE ANN. § 44-41-40 to -50 ; S.D. COD. LAWS ANN. §§ 34-23A-12, to -15; TENN. CODE ANN. § 39-15-204 to -205; TEX. OCC. CODE ANN. §§ 103.001 to .004, UTAH CODE ANN. § 76-7-306 ; VA. CODE ANN. § 18.2-75; WASH. REV. CODE § 9.02.150 ; W.VA. CODE §§ 16-2F-7 and 16-2B-4; WIS. STAT. ANN. §§ 253.09, 441.06(6), 448.03(5); WYO. STAT. ANN. § 35-6-105 to -106, 35-6-114.

[36]American Pharmacists Association, 145th Annual Meeting and Exposition, March 21-25, 1998; adopted by the 1998 House of Delegates as an association policy, available by searching at www.aphanet.org. under search terms, "conscientious refusal" (accessed 11/25/03).

standards for informed consent, increasing rates of sexually transmitted disease, and violating conscience rights. To approve such proposals would be a grave mistake.

Thank you for your consideration of these comments.

Sincerely,



Mark E. Chopko
General Counsel