

March 13, 2007, Human Services Committee Public Hearing
Testimony in Support of Senate Bill 1343 *An Act Concerning Compassionate Care for Victims of Sexual Assault*

Testimony of Dr. Frank Davidoff, MD, MACP

Editor Emeritus, *Annals of Internal Medicine*
Executive Editor, Institute for Healthcare Improvement
143 Garden Street
Wethersfield, CT 06109

Senator Harris, Representative Villano and distinguished members of the Committee, my name is Dr. Frank Davidoff. I am Editor Emeritus of the *Annals of Internal Medicine* and the Executive Editor of the *Institute for Healthcare Improvement*. I formerly served as a member of the federal Food and Drug Administration's Non-Prescription Drug Advisory Committee. In my four years as a member of that committee, I participated in decisions on making many drugs, including emergency contraception, available over-the-counter.

What is Emergency Contraception?

I am going to start with the basics – what emergency contraception is, and what it is not. Currently, the only dedicated, emergency contraceptive product is marketed under the name Plan B. Plan B is approved by the FDA for over-the-counter use, however, the product must be stored behind the pharmacy counter and women under 18 years of age must have a prescription in order to obtain the medication. Plan B consists of two pills, taken 12 hours apart, and containing the hormone levonorgestrel, which is the same ingredient found in many birth control pills.

Plan B is most effective when taken immediately after unprotected intercourse – that's to say, if no other contraceptive methods were used. Delaying the first dose by just 12 hours increases the odds of pregnancy by almost 50% and the medication's ability to prevent pregnancy continues to decrease linearly with time after that. Thus, any and all delay, results in an increased risk of pregnancy.

Plan B is a safe drug; as one of the members of the FDA Advisory Committee put it, "Plan B is the safest drug this committee has reviewed while I've been on it." Its only side effect is nausea in some patients, and vomiting occurs in an even smaller number. In this connection it's very important to remember that pregnancy carries far greater risks than Plan B. Pregnancy can result in serious medical complications, and there is a small but very real risk of death.

It's also extremely important to make it clear that Plan B is not the abortion pill, RU-486, although many people confuse the two. Plan B does not work if a woman is already pregnant and will not have any effect on an existing pregnancy. In fact, data show that when Plan B is used after pregnancy is established, it increases neither the rate of pregnancy loss nor the frequency of fetal abnormalities.

How does Plan B work?

I recently co-authored an article in the October 11, 2006, *Journal of the American Medical Association*, which summarized what's currently known about the mechanism of action of Plan B. Our study was based on all of the available research to date. What we found, first, was published evidence clearly indicating that Plan B can prevent sperm from reach the egg to fertilize it. The drug does that by thickening the layer of mucus that covers the uterine cervix, and through which the sperm need to travel.

Second, the research also shows that Plan B prevents ovulation if it's taken prior to the ovulation stage of a woman's menstrual cycle. Despite claims that Plan B may work to prevent fertilized ova from implanting, an exhaustive review of the available studies on the mechanism of Plan B has revealed no evidence to support that hypothesis. In fact, the most careful and rigorous study that's been done to date, which was published just last month in the scientific literature, showed that while Plan B was nearly 100% effective in preventing pregnancy when it was used before ovulation occurred, it was almost completely ineffective in preventing pregnancy when it was used after ovulation and fertilization had occurred.

Taken together, the available scientific evidence is incompatible with the possibility that Plan B prevents implantation or development of a fertilized egg. Let me say that again. There is no convincing scientific information to support the claim that Plan B interferes with implantation or development of a fertilized egg.

Implications for the care of rape victims

So what do these scientific data mean in relation to the Connecticut Catholic Hospital's protocol for rape victims? To put it simply, the Catholic Hospital's protocol is not based on the existing medical evidence. It also compromises patients' rights to the highest standard of medical care.

According to the Connecticut Catholic Conference, the Catholic hospitals' protocol will deny Plan B to any woman who is deemed to be ovulating, based on a spot urine test. According to several scientific studies, however, that test has been proven to be highly inaccurate. The Catholic hospitals' protocol also makes it clear that the decision to deny care is based on the assumption that once a woman is "in the ovulation stage of her cycle, Plan B cannot have a contraceptive effect," and goes on to assert that "In these cases, the only objective of administering Plan B is to impede the implantation of a fertilized ovum." Those assumptions are, of course, not correct because, as I stated earlier, there's another mechanism by which Plan B can and does prevent pregnancy in the ovulation stage of a woman's cycle – namely, it prevents sperm from ever reaching the egg by thickening the cervical mucus.

A hospital protocol for the care of rape victims that is based on an incomplete understanding of women's reproduction, lack of knowledge about the mechanisms of action of Plan B, and a laboratory test that is grossly inaccurate is morally and ethically unacceptable.

Let me conclude by reminding you of one of the fundamental ethical principles in medicine: respect for patients' autonomy. That principle means that patients have the ultimate right to determine what happens to their own bodies. By refusing to provide Plan B – a safe, effective, approved, and legal therapy – to some patients, the Catholic Hospitals are violating one of patients' most fundamental rights. The decision whether or not to receive that therapy rightfully belongs with the patient, not with a flawed protocol based on flawed information.

I urge the members of this Committee to reject the proposed interference with patients' fundamental rights, and do what is right for women who have experienced the trauma and horror of rape.