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Emergency Contraception, Teenagers, and the Prospect of Over-the-Counter Availability

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On behalf of the National Campaign to Prevent Teen Pregnancy, I write to support the application filed with the Food and Drug Administration by Women's Capital Corporation to make emergency contraception (specifically, Plan B®) available over-the-counter (OTC). There is good reason to think that sexually active teenagers in particular might benefit from wider availability of emergency contraception, which OTC status provides, and it is with this particular population in mind that I write.

There has been much progress related to teen pregnancy in recent years. The rate of births declined 31 percent between 1991 and 2002, and the pregnancy rate declined 27 percent between 1990 and 1999. The teen abortion rate is also down, as is the percentage of high school teens who have had sex; in 1991, 54 percent of high school teens had had sex; in 2001, the number had fallen to 46 percent (1). But even with these declines, the United States *still* has the highest rates of teen pregnancy and birth in the fully industrialized world; 35 percent of teen girls become pregnant at least once before turning 20; and U.S. taxpayers shoulder at least $7 billion each year in direct costs and lost tax revenues associated with teen pregnancy and childbearing. Each year, close to 900,000 teens become pregnant, and in 2002, almost four-fifths (80 percent) of births to teens were to unmarried teens. Among these unmarried teens, pregnancy is rarely planned or fully intended (2).

Simply put, teen pregnancy in the United States is a deeply serious problem. Both teen mothers and their children face adverse consequences in many domains — health, education, income, and others as well. For example, more than two-thirds of teenage girls who begin their families before age 18 never complete high school, thereby limiting their preparation for well paid work and making it likely that they will face a future mired in poverty. Children who grow up in a single-parent family, which is the typical life course for the child of a teen mother, are five times more likely to be poor than children in two-parent families. In fact, research shows that virtually all of the increase in child poverty from 1970 to 1996 was related to increases in the number of single-parent families. In the 1970s, some of this increase was the result of rising divorce rates. Since the early 1980s, however, *all* of the increase has been driven by growth in the number of never-married mothers. Half of first out-of-wedlock births are now to teens and this group of never-married mothers is most at risk of poverty and long-term welfare dependency. Moreover, the children of teen mothers are 50 percent more likely than children born to older mothers to repeat a grade in school and are at a significantly increased risk of at least the following: growing up without a father, welfare dependency, low birth weight and prematurity, depression, mental retardation, insufficient health care, inadequate parenting, and abuse and neglect (3)

With all this in mind, the National Campaign to Prevent Teen Pregnancy was organized in 1996 by a diverse group of individuals who had concluded that the problem of teen pregnancy was not receiving the intense national focus that it deserved; that too

few Americans understood the central role that teen pregnancy plays in child poverty, out-of-wedlock childbearing, and welfare dependency; and that there was merit in both raising the profile of this problem and in pushing hard for solutions. The National Campaign is a nonprofit, nonpartisan initiative that works hard to reduce the conflicts that so often surround efforts to reduce teen pregnancy. Our view is that there are many reasonable pathways to reducing teen pregnancy and that in a large and increasingly diverse country, there is room for — and merit in — a variety of approaches. The Campaign's goal is to reduce the rate of teen pregnancy by one-third between 1996 and 2005. Recent demographic analyses suggest that the goal might well be met.

So where does emergency contraception (EC) and the OTC application fit into all this? I would emphasize three straightforward ideas. The first is that although unintended pregnancy is very common among American women, it is especially common among teens. About half (49 percent) of the approximately 5.4 million pregnancies occurring annually in this country are unintended, but among teens, the problem is greater. Almost 80 percent of pregnancies among teens are unintended, meaning that at time of conception, these young women were not actively seeking to become pregnant (4).

These high levels of unintended pregnancy reflect the simple fact that for teens, sex is often unplanned. When asked about this reality, teens will commonly say things like, "I wasn't really planning to have sex." "It just happened." "I sort of don't remember what happened..." They will say that they just weren't prepared, or sometimes that they were forced to have sex or didn't know how to get out of a difficult situation. Some say that they were drunk or high: nearly 1/4 of sexually active teens and young adults age 15 to 24 report having unprotected sex (not using a condom) because of alcohol or drug use (5). And some will say they were in love and got carried away. Moreover, many sexually active teens use contraception inconsistently or not at all. A major federal survey completed in 1995 showed that about one-third of sexually active teens who do use contraception use it inconsistently (6). It is for just such very human situations — unplanned, often unprotected sex — that emergency contraception has obvious value and relevance.

Second, making EC available more easily — OTC — helps to reach teens especially. They are often skittish about seeking care for problems relating to their sexual lives, whether for a possible infection, pregnancy test or, in this case, an episode of unprotected sex. They worry about cost, about confidentiality, about doctors and clinics and medicine generally. And when they do seek care for reproductive health problems, they may not know where to go or who to call, and not all services are welcoming. By making EC more easily available, the chances of teens using this method early (within the requisite "window") increase, thereby avoiding unintended pregnancy. In this context, it is important to add that available evidence shows that teens are not inclined to use EC frequently (7).

Finally, I would stress that making emergency contraception more widely and easily available is consistent with a strong message to teens that abstinence from sex is

their best option by far. These messages are not at odds, but in fact complementary. Campaign polling data consistently show that American adults and teens both agree that the most prudent course of action for teens is that they refrain from sex until they are adult enough to make wise, responsible decisions about their sexual conduct. For example, over 90 percent of both adults and teens agree that teens should be given a strong message from society that they should refrain from sex until they are at least out of high school. The majority of Americans also support providing contraceptive services to sexually active teens (8). Simply put, the majority view in this country is that for teens, abstinence is better than contraception (in this case, EC), but contraception is better than pregnancy. Both less sex and more contraception have driven rates of teen pregnancy down over the last decade (9); both work and Americans support more of both.

Given this high level of support for delaying sex until after adolescence, it is not surprising that a number of programs have been developed to encourage teens to postpone sexual involvement. Although the vast majority of these programs have not yet been evaluated using high quality research methods (10), it is reasonable to think that at least some of them help teens postpone sex for some period of time. At present, a very well designed randomized evaluation of 5 abstinence programs is underway, so we will know more soon about the ability of these programs to help teens delay first sex. One approach to helping teens delay first sex that has been assessed carefully by at least one team of investigators is the so-called "abstinence pledge." Bearman et al concluded that the abstinence pledge can help some teens delay the first sex under particular circumstances (11). And a recent survey conducted by the Northern Kentucky University found that teens who made an abstinence pledge had sex for the first time a year later — at age 17.6 — than non-pledging students (12).

But both of these studies and others as well also make clear that the pledge and other approaches to abstinence do not work in all situations and for all teens. The Northern Kentucky University survey found, for example, that 61 percent of those who had taken abstinence pledges had broken them within a year. In addition, the survey found that pledge takers are less likely to use protection when they first have sex. These teens were not planning to have sex and therefore they are not prepared and do not necessarily possess the knowledge of how to successfully protect themselves from an unplanned pregnancy.

The point is simply that even when abstinence is a teenager's clear plan and intent, it is not always carried out. In these instances, it is important to have a back-up plan. When we remove barriers to EC, we ensure that teens who have not planned for but still have sex (as well as those who experience a contraceptive accident) are able to avoid unintended pregnancy. As such, the request to move EC to OTC status rises above the "culture wars" over sex, abstinence and contraception.

We encourage the FDA to approve EC for sale over the counter. Further, we call upon the manufacturers to provide an appropriate educational program that will improve awareness and access for this vulnerable group of girls and young women. The National

Campaign believes that teens stand to gain a lot by making emergency contraception more accessible and we look forward to supporting the FDA and the manufacturers in this process.

References:

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FDA ADVISORY COMMITTEE MEETING
ON APPLICATION TO SWITCH PLAN B® FROM RX TO OTC
DECEMBER 16, 2003
LOGISTICS

Attending the meeting. *The advisory committee meeting will be held in the Ballroom of the Gaithersburg Hilton in Gaithersburg, MD. It is scheduled to begin at 8am and is open to the public.*

Location: Gaithersburg Hilton; 620 Perry Parkway; Gaithersburg, MD 20877
301.977.8900 (phone)

Submitting Written Comments
Via Postal Mail:
Documents Management Branch HFA - 305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Via E-mail: somersk@cder.fda.gov
Via Fax: 301-827-6776

Presenting Oral Comments
Following formal presentations, an open public hearing will begin at approximately 11am.

To participate, contact Karen Somers with the name of speaker, organization, contact information (mailing address, e-mail address, phone and fax numbers), brief overview of presentation, and length of time requested. **All requests must be submitted by December 5** and time allotted may be limited. Prior to the meeting, FDA staff will contact speakers to confirm participation.

Contact: 301-827-7001 (phone); 301-827-6776 (fax); somersk@cder.fda.gov
If you bring handouts on the day of the meeting, inform the staff at the registration table. Please bring at least 30 copies for the advisory committee members and others at the head table. Audio-visual/media equipment is available, but arrangements for equipment must be made in advance.

Submitting written comments to FDA Docket after December 5
Submit comments on-line: www.fda.gov/dockets/ecomments
Click on the subject 01P-0075 "The Switch Status of Emergency Contraceptive from Rx to OTC" (As of November 19, 2003, this online docket is not yet open.)

For additional information regarding this meeting, call the FDA Advisory Committee Hotline: 1-800-741-8138, and press 3-3-2 or check the FDA Advisory Committees' webpage http://www.fda.gov/oc/advisory/acdrugs.html.