

Minor Access Now: Unrestricting the Morning-After Pill  
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Abstract

In 2006, 82 percent of all teen pregnancies were unplanned, and among all age groups, teens have the largest proportion of pregnancies ending in abortion. Despite such indicting statistics, the FDA still requires minors to have a prescription for Emergency Contraceptive (EC), the only contraceptive effective after unprotected sex. A section of the FDA ban, however, reserves the right of states to allow minor access to EC. This paper will evaluate the accuracy of FDA reasoning behind limiting minor access and propose the creation of a Georgia Law allowing minors over the counter (OTC) access to EC along with a concurrent ad campaign to address the major issues surrounding this law. The policy calls for expanding funding to the Georgia Health and Human Services subcommittee to fund an EC task force. The task force will first conduct a comprehensive study establishing both the availability and knowledge of EC to teenagers. Following the study, vigorous public campaigns throughout Georgia will explain to teens how to use and access EC and highlight the general public's misconceptions about EC--specifically that EC causes an abortion and would increase teen sex.

Introduction

In 2006, teen pregnancy and abortion rates increased for the first time in fifteen years. The current teen birth rate is 75 live births per 1000 teens.<sup>1</sup> For adolescents among the 46 industrialized countries, the United States ranks second in pregnancy and birth rates and first in abortion rates.<sup>2</sup> The state of Georgia, ranked eighth nationwide in teenage pregnancy rates, requires a prescription for minors to access emergency contraceptive, the only contraceptive available after unprotected intercourse, defined as sex without the use of a contraceptive.<sup>3</sup> The ban on minor access is unfounded not only because it keeps an important contraceptive from teens, possibly raising abortion rates, but also due to flaws in the FDA's reasoning for the ban.

## Background

Since 1999, a form of Emergency Contraceptive (EC) has been available to all women with a prescription.<sup>4</sup> EC is the only contraceptive effective after unprotected sex.<sup>5</sup> The makeup of EC is 20 to 40 times more potent than a birth control pill. If taken within 72 hours of unprotected sex, the two pill system of EC works like a traditional contraceptive and impairs egg fertilization by immobilizing and reducing the number of sperm cells and stopping sperm passage into the uterus. EC is up to 89 percent effective in stopping fertilization. If the user is already pregnant, EC has no effect. In fact, the ingredients in EC nourish an established pregnancy.<sup>6</sup>

In spring 2003, Barr Pharmaceuticals submitted their marketed version of Emergency Contraceptive, called Plan B, to the FDA for over-the-counter (OTC) approval. When determining prescription status, the FDA first consults relevant advisory committees, the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs, to provide the FDA with the science-based advice of external experts. When these two FDA advisory committees met, they approved OTC access to Plan B with no age requirement. After receiving the advisory committees' input, the directors of two offices, the Office of Drug Evaluation V and the Office of Drug Evaluation III, review the application for OTC approval and make a decision. However, the director of the Center for Drug Evaluation and Research (CDER) can overrule the directors' decision on the OTC application.<sup>7</sup>

On May 6, 2004, the Acting Director for the Center for Drug Evaluation and Research (CDER) Steve Galson rejected the recommendations of the advisory committee and the Office directors and unexpectedly issued a non-approval letter for Plan B.<sup>8</sup> The

directors of the Office of Drug Evaluation V and of the Office of Drug Evaluation III disagreed with his decision and refused to sign the non-approval letter. In spite of these disagreements, on August 24, 2006 the FDA approved Barr's application and made Plan B available without a prescription to women 18 years and older. The FDA's ruling requires adolescents, those between the ages of fifteen and seventeen, to have a prescription for access to EC.<sup>9</sup>

#### Minor OTC Access: The Need for Change

Consensus exists among FDA advisors and many researchers that minors should have access to EC. According to Dr. Tina Raine, a professor of obstetrics and gynecology at the University of San Francisco Medical Center:<sup>10</sup>

Teenagers are likely to start having sex before they're ready and able. They are more likely to have accidents. And they're going to be the ones less likely to have a doctor to get a prescription. So to make it most difficult for them to get it doesn't really make sense.<sup>11</sup>

There are a number of theoretical explanations for how the FDA's current policy may be helping to increase the teen pregnancy rate. The current policy requires too tight of a time frame for minors to effectively use EC. Plan B only works within three days of unprotected sex, a strict constraint to require a prescription from minors. Furthermore, minors may feel a sense of shame from their parents or personal doctors knowing of their sexual encounters and be deterred from trying to obtain EC. Since Plan B is the only contraceptive available after unprotected sex, making minor access more difficult and shameful may increase the chance of teen pregnancy.

By age 19, seven in ten American teens have engaged in intercourse<sup>12</sup> More than three-quarters of teen females report their first sexual experience was with a steady

boyfriend, a fiancé, a husband or a cohabitating partner. This policy does not attempt to reduce the amount of underage intercourse that occurs; rather it intends to address the fact that 25 percent of sexually active teens do not use contraception during their first sexual experience and that those who do use contraception are not always protected from unplanned pregnancy. Condoms fail for 17 of every 100 women, and 54 percent of women who had an abortion used a contraceptive method that failed.<sup>13</sup> Since EC is the only contraceptive available if other means fail or if the user engages in unprotected sex, this policy intends to provide a method to decrease the number of abortions and pregnancies that occur because of failures in other forms of contraception.

#### Flaws in FDA Reasoning

In spite of EC's prospects for lowering teen abortions and pregnancies, Steve Galson believed that adolescents needed health care supervision to use EC. He based his rejection of minor access to Plan B on beliefs that OTC access would increase rates of unprotected teenage sex and sexually transmitted disease (STD) transmissions and lead to minor dependence and that minors would be unable to take Plan B correctly.<sup>14</sup> However, a number of published, peer-reviewed studies assessing the effects of minor access dispute the director's logic behind prohibiting minors' EC access.<sup>15</sup>

A study by Dr. Raine of 1020 women, ages 15-24, found that "there were no significant differences in observed parameters (pregnancy, condom use, unprotected sex, routine OC use) between adolescents (15-17 years old) and adults (18-24 years old)."<sup>16</sup> This study divided the subjects into three groups. The pharmacy access group obtained EC at their local pharmacy without a prescription, the advance provision group was provided with EC and the standard access group required subjects to obtain a prescription

for access. Among these three groups, Raine found that ease of access to EC had no effect on frequency of condom use or STD transmission rates. Among the three groups, the frequency of unprotected intercourse and number of partners did not have statistically significant differences.<sup>17</sup> Research contradicted the CDER director's belief that access to EC would increase rates of unprotected sex, finding that "advance provision of EC did not increase frequency of unprotected intercourse and did not decrease condom use...compared to a control group."<sup>18</sup>

Dr. Melanie Gold, an associate professor of pediatrics and the director of adolescent medicine research at the University of Pittsburgh, conducted an additional study which divided 301 women aged 15-20 into two groups.<sup>19</sup> The advance EC group received EC educational information and one EC dose along with the option of two additional EC doses. The control group received EC education and information on how to request EC. Throughout the eight month study, only 15 percent of the advance EC group requested an additional dose of EC. The fact that very few minors requested more than one dose of EC disproves the director's idea that minors would depend on EC as a form of contraception.

The director's reasoning that minors would take EC incorrectly also has scholarly contradiction. When a company submits a drug for OTC review to the FDA, it must include a use study that observes how a random sample used the drug. Barr Pharmaceutical's use study for Plan B determined that women under 16 took EC correctly 82 percent of the time, while women over 17 used the drug correctly 78 percent of the time.<sup>20</sup>

The CDER director's reasoning for the ban on EC is unfounded. An FDA review staff reviewed the studies outlined above to address the director's concerns and determined that increased minor access to EC:

Did not result in (1) inappropriate use by adolescents as a substitute form of contraception, (2) an increase in the number of sexual partners or the frequency of unprotected intercourse, or (3) an increase in the frequency of STDs.<sup>21</sup>

#### Disregarded Protocol

Not only is the CDER director's reasoning for banning OTC access to minors unfounded, but the FDA also disregarded protocol when evaluating Plan B. While reviewing a lawsuit against the FDA that addressed the availability of EC, US Magistrate Judge Viktor Pohorelsky found numerous instances of unethical FDA behavior. The first incidence of protocol abuse is that the FDA took non-scientific considerations into account during discussions regarding Barr Pharmaceutical's appeal to provide OTC access for Plan B. FDA Deputy Commissioner for Operations Janet Woodcock stated that the agency rejected minor access "to appease the Bush administration's constituents."<sup>22</sup> Pohorelsky also found evidence that the FDA veiled their discussions concerning the final decision. High level FDA officials, who are generally uninvolved in OTC approvals, participated in Plan B decision making; a United States Government Accountability Office study indicated that these officials may have swayed decisions before all scientific analysis culminated.<sup>23</sup> Additionally, Judge Pohorelsky stated that he found "indications of potential retaliation by upper management against FDA employees who disagree with management's views that Plan B OTC-access be restricted."<sup>24</sup>

In all OTC considerations before Plan B, the agency deemed extrapolating data from adults to adolescents scientifically appropriate and did not analyze differences in their cognitive ability. Age-related marketing restrictions do not exist in any other OTC contraceptive, and before Plan B the FDA had never required pediatric studies on a contraceptive.<sup>25</sup> The FDA's disregard of protocol led to restricted minor access.

#### Safety: Why the FDA Should Have Allowed this Drug

Making EC available to minors OTC passes all FDA OTC requirements and therefore should be allowed. When determining the OTC status of a drug, besides analyzing studies, the FDA evaluates five criteria for the drug. Following are the criteria and a discussion on minor access to EC in each category.<sup>26</sup>

**1. Have an acceptable safety profile.** The studies conducted by Dr. Gold, Dr. Raine and Barr Pharmaceuticals show that Plan B has little effect on the sexual behavior of minors. The American Academy of Pediatrics, American Medical Association and FDA research scientists all insist that Plan B can be safely dispensed to adolescents without a prescription.<sup>27</sup>

**2. Have a low potential to be abused.** The academic studies conducted showed that minors do not view Plan B as a daily form of contraception. For example, when minors had unhampered access to Plan B, only fifteen percent of study participants used EC more than once in an eight month period.<sup>28</sup>

**3. Have a positive benefit-risk assessment.** The risks of taking EC include minor side effects such as nausea, breast tenderness, lower abdominal pain, fatigue, headache, irregular menstruation, dizziness, vomiting, and diarrhea. However, since the

benefit of EC is not a cure for an ailment, but rather a reduction in pregnancy, a comparison of benefits and costs is difficult. The drug has been deemed safe for those above 18, and as referenced above, there is little difference in behavior between minors and adults. It can be assumed that if the FDA deemed the drug to have a positive benefit-risk assessment for adults, then the same could be concluded for minors.

**4. Be needed for a condition that is self-recognizable, self-limiting and requires minimal intervention by a health care practitioner.** The “condition” that Plan B protects against is the potential for unwanted pregnancy. The cause of this “condition,” unprotected sex or the failure of a contraceptive method, is inherently self-recognizable, and no diagnosis from a health care practitioner would be necessary. Members of the FDA joint advisory committee voted 27 to 1 that evidence demonstrated that *all* consumers could follow Plan B instructions successfully without health care practitioner intervention.<sup>29</sup>

#### Policy Proposal

This paper proposes the creation of a Georgia Law allowing minors OTC access to EC along with a concurrent ad campaign to address the major issues surrounding this law. Due to a specific section of the FDA ban, a legislative act by the Georgia Legislature will effectively overturn the ban in Georgia. The bill will address pharmacist protocol regarding EC, the enactment of a Plan B task force and the allocation of funding. The Health and Human Services appropriation committee of the Georgia Legislature will provide funding for pharmacist training and the creation of an EC task force within Georgia’s Division of Public Health.<sup>30</sup>

The Georgia bill will require pharmacists to complete online training in communicating with minors. This training will include instructions on how to administer EC and emphasize the purpose of EC as a back-up to other forms of contraception. Training will be provided by Planned Parenthood or the Department of Health. Furthermore, each pharmacy will receive a list of written guidelines to follow when dispensing EC to minors. The protocol will be as follows: before providing EC, pharmacists must establish the date of the patient's last menstrual period to rule out current pregnancy and confirm that the time since unprotected intercourse is less than 72 hours. If patients are currently pregnant or intercourse took place more than 72 hours ago, pharmacists will explain that EC will have no effect. Pharmacists must ask if the patient is using another form of contraception. If the patient is not, then the pharmacist will stress that proper usage of EC is as a backup form of contraception and that EC does not protect against STD transmissions.

The EC task force will conduct a survey to establish Georgia minors' knowledge and understanding of EC. Depending on the survey responses, the task force will then work to educate the general population on EC's usage. A successful educational campaign will ensure safe usage of the drug and establish that EC be used only as a last resort.

Allowing OTC access to EC for minors will provide a valuable option to teenagers who, due to either a personal mistake or to the failure of another contraceptive form, engaged in unprotected sex. Because EC provides an option other than teen abortion or teen pregnancy for these teenagers, it has the potential to decrease the number of teen abortions and pregnancies.

## Educational Campaign

After state legislation allows minor OTC access in Georgia, a task force will be established. The task force's first step will be a comprehensive study determining teenagers' existing knowledge of EC. The survey will include the three following questions to be answered with yes or no:

1. Have you heard of Emergency Contraception?
2. Do you know that Emergency Contraception is a contraceptive that can be taken up to seventy-two hours after unprotected sex?
3. Did you know that you can access Emergency Contraception without a prescription at any pharmacy?

Surveys will be distributed in paper form to health clinics, hospitals and pharmacies across Georgia with directions on how to return them to the task force. The survey will also be available online at the Department of Health's website. Principals at public schools across Georgia will receive copies of the survey and be asked to include it in their sex-education classes. The task force will also provide the surveys to private practices across the state and ask doctors to distribute it to minor patients. The task force will begin the survey in September. The survey period will end six months later in March, allowing the EC task force to consolidate and prepare their findings before presenting them to Georgia congresses' budget appropriations committees in April and May.

After the survey establishes minors' level knowledge, one educational campaign highlighting the general misconception that EC causes an abortion will be geared toward the entire population, while another campaign promoting EC as a backup method for sexually active teens will appeal exclusively to minors. The teen campaign will highlight

safe usage of EC by reinforcing that EC does not protect against STDs and should be used as a backup contraceptive. Brochures stating how to access and when to use EC will be placed in schools, pharmacies, community health centers and Ob-Gyn offices. Funding will also provide an EC hotline staffed by health clinic workers for concerned teenagers.

The second campaign will address the general public's misunderstanding of EC's purpose. This campaign will state that by reducing the number of sperm and hampering sperm movement into the uterus, EC serves the same purpose as a contraceptive, not that of an abortion. This campaign will be manifest through public advertising on radio and television and through brochures distributed in hospitals, health clinics, pharmacies and Ob-Gyn offices. These ads will describe EC as a backup method of contraception that does not cause an abortion and that is available at pharmacies OTC. This campaign will serve to remove the stigma surrounding emergency contraception.

#### Benefits of Reducing Teen Abortion and Pregnancy

Allowing teen access to EC has enormous potential in decreasing abortion and pregnancy rates. A third of all teen pregnancies end in abortion, accounting for one-fifth of all American abortions.<sup>31</sup> Despite differing perspectives on abortion, all can agree that decreasing minor abortion is positive. Because EC has been available for minors in the US for a short time period, studies establishing the relationship between EC and teen abortions do not yet exist. However, the increased use of EC may account for averting 51,000 abortions in 2000.<sup>32</sup>

Unplanned pregnancies harm both the mother and society. For example, over 75 percent of unmarried teen mothers go on welfare within five years after their child's

birth, and 59 percent of teenage mothers drop out of high school before graduation. A child born to a teenage high school dropout is 10 times more likely than other children to grow up in poverty. Plan B will reduce unplanned pregnancy and could lessen the number of unmarried teen mothers and children on welfare.<sup>33</sup> Furthermore, potential teenage mothers avoid the strain of caring for a child during high school and therefore increase the likelihood that they will graduate. This increased graduation rate will raise the potential mothers' own personal productivity as well as productivity for society as a whole. Money spent preventively on EC information and distribution amounts to far less than the cost of raising a child.

#### Examples of Implementation

Unfortunately, teen abortion rates are higher in the US than in any other developed country. Among 46 countries in the developed world, US teen pregnancy and birth rates are second only to Russia. They are twice as high as in England, Wales and Canada, and eight times as high as in the Netherlands and Japan.<sup>34</sup> 38 other countries allow Plan B to adolescents prescription free.<sup>35</sup> Additionally, five states, Washington, California, New Mexico, Alaska, and Hawaii, have overturned the federal ban and allow pharmacists to dispense Plan B to teens without a prescription.<sup>36</sup>

#### Challenges

*“Emergency Contraceptive leads to an abortion and will increase teen sex.”* The advertising campaign will address the common misconception that EC causes an abortion. This reasoning represents a general misunderstanding of Plan B's contraceptive function. Members of the FDA observed that Plan B does not keep fertilized eggs from

implanting, which an abortion does.<sup>37</sup> In fact, when taken outside the effective time limit, the makeup of Plan B helps sustain pregnancy.<sup>38</sup> The advertising campaigns outlined in my policy will inform Georgians about the true nature of the drug, eliminating the belief that using EC is equivalent to having an abortion. Publicizing the results of the studies done on EC, which found no differences in frequency of sex between teenagers with and without access to Plan B, will assuage concerns that it will increase teen sex. Data is currently accumulating in the five states that allow minor access. Soon this data will show on a large scale the impact of Plan B on teenage behavior. Presumably, this information will also help to gain the support of the general population.

*“The political climate in Georgia will never allow legislation allowing Plan B.”*

The second challenge is the belief that a predominately conservative state like Georgia will shy away from discussing teen sex. However, it is in every politician’s best interest to support Plan B for its potential to reduce teen pregnancy and abortion rates and increase the welfare of teenagers and society.

## Conclusion

The FDA process that restricted minor access to Plan B was deeply compromised. The policy recommendations presented in this paper intend to provide Georgia minors a third alternative to teen pregnancy or abortion through increased access to EC. As described earlier, the OTC ban will be overturned through legislation. Pharmacists will be instructed on proper protocol, and teens’ preexisting knowledge of EC will be evaluated. Following the evaluations, the public will be informed of EC through different advertising venues and the placement of brochures throughout Georgia.

Expanding minor access has enormous potential to reduce teen pregnancy and abortion rates, benefiting both potential teen mothers and society as a whole.

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