Wesleyan University The Honors College

Procuring Plan B: Emergency Contraception, Sexual Norms and Social Control

by

Samantha Charm
Class of 2009

An essay submitted to the
faculty of Wesleyan University
in partial fulfillment of the requirements for the
Degree of Bachelor of Arts
with Departmental Honors in Sociology

Middletown, Connecticut April, 2009

Introduction

The controversy surrounding the switch of Plan B emergency contraceptive therapy from prescription to over-the-counter (OTC)[1] status has been unprecedented, dwarfing the debates around its original approval by United States Food and Drug Administration (FDA) for prescription use in 1999. The contention came not only from the debate within the FDA hearing but also from the unusual decision-making processes that led to the rejection of the producers of Plan B, Barr Laboratories' OTC status application. After significant delays, the FDA eventually approved a dual-label status thirty-three months after the original 2003 hearing. This is the current law, a compromise, which makes Plan B available over the counter in pharmacies for men and women over the age of seventeen but only by prescription for women seventeen and younger.

In the "Not Approvable" letter sent to Barr Laboratories in May 2004, six months after the Joint Committee hearing for OTC status, Dr. Steven Galson, the then-acting Director of FDA's Center for Drug Evaluation and Research (CDER), said "[W]e did not have sufficient data to approve this application now." He explained that the presenters did not adequately demonstrate that women under age sixteen could use emergency contraception "safely" (Galson 2004, 1). But many proponents of OTC status did not believe this justification for they saw the studies submitted in the hearing as having more than sufficiently established Plan B's safety and efficacy for adolescent women.

---

[1] A list of acronyms used in this paper can be found in Appendix A

Although politicians often criticize the FDA and other interested parties for being either too lenient or too strict, the integrity of the approval process has seldom been questioned. However, the decision in this case spurred accusations like this one from Dr. David Grimes, a consultant at the hearing: "Defying the published evidence, the international experience, the recommendation of two FDA advisory committees, and the advice of its own scientific staff, the agency caved in to political pressure" (Grimes, 2004). In one of many enraged articles published suggesting that the Bush administration and its ties to the religious right influenced the decision of the FDA, Paul Burstein, a doctor at University of Wisconsin Medical School commented, "It is a terrible message that the findings of scientists can be subject to the pressure of politicians, especially when the goal is the same - to prevent undesired pregnancies and to minimize the need for abortion" (Burnstein 2004, 2413- for other articles see Wood 2005 and Drazen 2004).

In the hearing, unintended pregnancy and the need for abortion were identified by both opponents and proponents of OTC emergency contraception as the problems that emergency contraception could help reduce. The ability of OTC Plan B to accomplish these goals was never questioned by either side. Thus those who sought to deny increased access to Plan B seemed to be at odds with their own stated goals. Why would they fight so hard against the switch of Plan B to OTC status if they desired to keep down the number of unintended pregnancy and the need for abortion?

Joseph Gusfield proposes that public problems are not objective facts. There can be competing constructions of the same problem, as is the case with unintended pregnancy. When Gusfield's theory of the structure of public problems is applied to

the debate over unintended pregnancy and emergency contraception, the 2003 FDA hearing to change Plan B to OTC status can be seen as a site of negotiation between two conflicting understandings of unintended pregnancy and the concepts of sexual morality imbedded within those understandings. Within this framework, the position of opponents of OTC Plan B can be understood as a reaction to the perceived threat against their accepted social norms of sexual behavior,

This paper uses the FDA hearing to examine the differing conceptions of female sexual morality held by opponents and proponents of OTC emergency contraception.[2] The paper goes on to explore how OTC access- but not prescription access- to Plan B has the potential to disrupt internal social controls, as well as informal forms of social controls that enforce the prevailing perspective on appropriate female sexual behavior. I argue that the symbolic public affirmation of sexual norms that comes with the FDA denying Plan B OTC status and the maintenance of the apparatuses of social control that impose those sexual norms were more important to the opponents than the reduction in the number of pregnancies themselves.

Proponents of OTC Plan B tried to avoid challenging the established system of social norms and sought instead to gain sexual autonomy for women by removing intermediate parties who often act as agents of social control. Because this autonomy is contingent upon invisibility from those institutional representatives, it is undermined by the age restriction put in place by the FDA's final decision. Therefore,

while Plan B was given OTC status, the dual label status reduced the threat that OTC Plan B posed to the prevailing social norms of female sexuality.

Emergency Hormonal Contraception

Emergency Contraception (EC) is a new medical technology in the United States. While most contraceptives are intended for use before or during intercourse, EC can be used within a short time after unprotected intercourse to reduce, but not eliminate, the risk of pregnancy. Emergency contraception[3] is a high dose of hormones, the same as those used in regular birth control pills, which can be taken within 72 hours of intercourse as a backup method of birth control in cases of nonuse of a standard method of birth control or in cases of contraceptive failure, such as a condom breaking.

The FDA approved the initial hormonal contraceptive pill in 1960. The first documented case of emergency postcoital contraception was published in the mid-1960s when physicians used this method to prevent pregnancy in a 13-year old girl who had been raped (Ellertson 1, 1996). In 1974, a Canadian physician name Albert Yuzpe published studies that presented guidelines for the safe and effective off -label use of high doses of regular birth control pills as a method of emergency

---

[2] I have to acknowledge that I am making two unified opposing groups whose beliefs are coordinated. There is variation within the sides of the OTC EC debate, but these are generalizations that I think apply to many if not most within either position.
[3] There are two methods of EC: the insertion of an emergency IUD and or the ingestion of emergency contraceptive pills. The use of the emergency IUD is rare in the United States, so the debates in America have been focused around oral

contraception. The Yuzpe Regimen consists of combined oral contraceptive pills that contain estrogen and progestin taken in two doses, 12 hours apart (Weiss, 1).

It was not until September of 1998 that the FDA approved a prescription whose official label use was emergency contraception. The Preven Emergency Contraception Kit made by Gynetics, Inc, which contained the Yuzpe Regimen, was found to be 75% effective in reducing risk of pregnancy when taken up to 72 hours after intercourse.[4] This combined estrogen-progestin EC has since been replaced by the progestin-only method, which a World Health Organization study showed to be more effective and to have fewer side effects (SIECUS, 2). In July 1999, the FDA approved the progestin-only Plan B for prescription administration in the United States, which led to the discontinuation of Preven. Plan B is an EC that contains levonorgestrel, a synthetic progestogen. It is administered in two 0.75 mg pills taken 12 hours apart. Its label states that it is 89% effective in reducing risk of pregnancy when taken within 72 hours.

The debate over the mechanisms of action and whether Plan B is a form of abortion is often cited as the reason for the public controversy about the drug. There are three theoretical mechanisms by which progestin-only, emergency contraceptive drug products like Plan B are thought to prevent pregnancy. The first mechanism is the prevention of ovulation. Second is the interference with the actual process of

---

emergency contraceptive pills (ECP), colloquially known as the "morning after pill." In this paper, when I refer to EC, I mean only the pills.

[4] On average, if 100 women in the second or third week of their cycle have in sexual intercourse without using any form of contraception, eight will become pregnant. If all 100 women take ECPs with the Yuzpe regimen within 72 hours, only two will become pregnant- a 75% reduction in pregnancy rate. If the women take progestin-

fertilization by altering uterine or cervical environments, which impedes the migration or capacitation of sperm. Third is the prevention of implantation by a direct effect on the endometrium of the uterus. It is this third hypothesized mechanism that is understood by some as a form of abortion. While the first two mechanisms have been directly demonstrated in experimental research, the third has not. Evidence for interruption of implantation after fertilization is very weak; however the lack of a reliable test for fertilization makes ruling out this mechanism extremely difficult (Davidoff, 5).

Plan B had been used as a prescription-only medicine since 1999 with limited controversy. However, it became an extremely contentious topic and politically charged issue in public debate when Women's Capital Corporation (later acquired by Barr Laboratories) put in an application to the FDA for over the counter status for Plan B in April of 2003.

The FDA Hearing

A joint session of the FDA's Nonprescription Drugs Advisory Committee (NDAC) and the Advisory Committee for Reproductive Health Drugs (ACRHD) was scheduled to discuss Barr's Laboratories' application. In addition to these two regular FDA committee members, the participants also included four voting outside consultants, one non-voting active industry representative and ten non-voting FDA participants. [5] The hearing took place from 8:00 a.m. to 5:00 pm on December 16,

---

only ECPs within 72 hours, only one will become pregnant- an 89% reduction in the pregnancy rate (Trussell, 2006).

[5] Names, job titles and affiliations of these participants can be found in Appendix B

2003. It was broadcast live to the public over the Internet. The purpose of the Advisory Committee, stated NDAC Chairman, Louis R. Cantilena, was to determine whether Plan B meets regulatory requirements for nonprescription status. After the hearing, the committees would vote on six questions regarding Plan B's safety and efficacy, the ability of the consumer to self-recognize the condition and correctly take the drug without a doctor's direction, and the benefits versus the risk of possible misuse and abuse.

After introductions, the president and chief operating officer of Barr Research, Carole Ben-Maimon, presented the sponsor's case for giving Plan B OTC status. Barr Laboratories argued, citing both outside and in-house actual-use studies, that women can safely and properly use Plan B without the supervision of a doctor. Barr's presentation was followed by a series of reports by non-voting FDA officials in regards to the agency's internal review of the product, the labeling, and the studies supplied by the pharmaceutical company. After reviewing the available scientific data regarding progestin-only EC, the FDA presenters reported that the data suggested Plan B was both safe and effective for women to use OTC.

While the aforementioned process is typical of NDAC hearings, the open public hearing that followed differed in this case. An open public hearing is an option in every similar FDA hearing, yet it doesn't take place unless there are invested outside groups or people willing to request time to speak, prepare materials and a position statement well in advance, and travel to the hearing. For many hearings, this option is either not used, or only used by a few people. However, in this joint session, all two hours of time allowed for an open public hearing were requested and used by

forty-two different speakers. This transformed the FDA hearing into a new place for political activism, moving the debate far beyond just the science addressed in the beginning of the hearing.

The hearing concluded with a vote by all twenty-seven present eligible committee members who were asked if Plan B should be switched to OTC status. Twenty-three of the committee members voted in favor of making Plan B available over the counter without a prescription, while four committee members voted against expanded access to Plan B.[6] Despite the support of the overwhelming majority of the advisory committee, on May 6, 2004 the FDA issued a "not approvable" letter to Barr Laboratories, citing insufficient sampling of adolescents younger than sixteen to determine the drug's safety for that age group (Galson 2004, 1). Barr resubmitted its application in July of 2004, with a provision that Plan B would remain available by prescription only for girls under the age of sixteen. The FDA let deadline after deadline pass for a decision on Barr's revised dual-label application. Over a year later, the then acting commissioner of the FDA, Lester Crawford, announced an indefinite delay to allow for more discussion of the FDA's authority to create a dual-label, and the possibility of practical enforcement of such a label (SEICUS, 4-7).

The FDA came under intense criticism after the rejection of the first application and again after its non-decision on the second. Susan Wood, Director of the Office of Women's Health, resigned in protest of the FDA's handling of this decision. Medical authorities as well as many media sources condemned the FDA's actions with such articles titled "A Sad Day for Science at the FDA " and "Politics

---

[6] For a person-by-person breakdown of the final vote see Appendix B.

Trumps Science at the U.S. Food and Drug Administration," implying that they believed the decisions were compromised by pressures from morally conservative political and religious groups (Wood 2005, Grimes 2004). On August 24, 2006, the FDA finally approved the nonprescription sale of Plan B for women and men over the age of 17. Women under this age can still gain access to Plan B with a prescription.

Literature Review

Joseph Gusfield defines a social problem simply as "something about which 'someone ought to do something.'" He further distinguishes this definition, recognizing that not all social problems are public problems, which are those issues that come into the "arena of public action," for example a federal agency like the FDA, for resolution (1981, 5). Public problems are not "simple mirrors of objective condition"; they are historically created and there can be multiple constructions of the same problem simultaneously or over time (Hilgartner and Bosk 1988, 53). Gusfield argues that the structure of a problem is strongly tied to how it will, or in other cases won't, be solved (1981, 6). In Gusfield's model, the structure of a problem is centered on three elements of the attributions of responsibility: the ownership or the power to define a problem, the causal responsibility or "the sequence that factually accounts for the existence of the problem," and the political responsibility or the person or group given responsibility for solving the problem (1981, 13-14).

Constance Nathanson suggests that this model is particularly important when looking at the construction of unintended pregnancy as a public problem, because one of its main characteristics in the contemporary United States has been the failure of

any one group to claim and keep ownership over it. More specifically, the causal responsibility and therefore political responsibility for the problem have fluctuated as ownership shifted between moral and medical authorities (For a historical contextual explanation for the construction and fluctuations, see Nathanson 1991).

Nathanson also argues that when unintended pregnancy is discussed as a public problem it is not the pregnancy itself but instead the sexual actions of the female which caused the pregnancy being debated:

> [The problem of unintended pregnancy] is not primarily reproductive, but sexual. Pregnancy can be terminated by abortion, but there is no action that can eliminate the association of pregnancy with sexual activity. It is the evocation of nonmarital sexuality rather that nonmarital childbearing that gives the…label its symbolic force (1991, 5).

The reproductive aspect of pregnancy can be remedied; it is the "unorthodox' female sexuality that is at the base of the public problem (1991,5). In this theory, Nathanson purposefully does not delineate what behaviors constitute unorthodoxy because the definition and understanding of socially acceptable sexual behavior varies temporally as well as by the player trying to claim ownership over the problem. As I will argue later in this paper, the base of the debate within the FDA hearing is proponents and opponents of OTC EC advocating for different definitions of unorthodoxy.

Nathanson addresses unorthodoxy, or what Peter Conrad would call deviance, as a socially determined definition. No act is inherently deviant but instead is labeled as such by a society. Sex is no exception; it is only deviant under certain conditions, which are not static. Because of this malleability, social groups try to enforce their own definitions and conditions for deviance through social sanctioning, or social

control (Conrad and Schneider 1992, 6). Social control is the means by which society enforces adherence to social norms or minimizes or tries to eliminate deviance. Institutions, according to DeLamater, have three main methods of social control. First they provide a set of norms or moral codes that are internalized by adherents and form the basis for self-controls. Second, people who occupy roles within the institution apply those moral codes to their interactions, which is the basis for informal controls. Finally institutions may have sanctioning systems that are activated when norms are violated (1981, 264). The most commonly thought of institution of social control is criminal justice system, but other institutions, such as medicine, also have social control functions (Conrad and Schneider 1992, 7-8).

Both Conrad and Irving Zola acknowledge an increasing pervasiveness of medicine into many aspects of life. “Medicine,” Zola argues, “is becoming a major institute of social control, nudging aside, if not incorporating, more traditional institutions like religion and law.” He sees the medicalization of society as caused by the “complex technological and bureaucratic system,” which has led to “reliance on the expert” (1972, 487). This expertise of the medical profession is rooted in science, which is seen as an ultimate truth. Foucault argued that discourse and “knowledge linked to power, not only assumes the authority of 'the truth' but has the power to make themselves true” (Hall 1997, 49). With this kind of power, the medical community has been able to take ownership, in Gusfield’s formulation, over an increasing number public problems, or forms of deviance. But control over a new public problem is not gained without conflict and competition from other powers that also want to protect and assert their control.

Much of the power of medicine's designation of something as deviant, or as an illness, resides in its claim to moral neutrality, resting on that concept of scientifically verifiability. "Illness, in the medical perspective assumes something undesirable that should be eradicated" (Zola 1975, 86). Conrad suggests that the designation of illness as undesirable is not fact but instead closely tied to the moral structure of society (1992, 35).

Many people have argued that the medical construction of social problems shifts from treating them as crimes to seeing them as signs of illness, if not illnesses themselves, absolving the ill of personal responsibility and therefore moral condemnation. This is what Zola calls the myth of accountability because "though his immoral character is not demonstrated in his having a disease, it becomes evident in what he does about it" (1972, 490). A person is still morally accountable for treating the disease.

The medical model of deviance locates the illness-the source of deviant behavior- and therefore the treatment, in the individual, as opposed to at the societal level (Conrad and Schneider 1992, 35). The individual focus of the medical model does not then (explicitly) address the societal norms or moral issues that may underlie social problems, like unintended pregnancy, if they come under a medical definition. The focus stays on the deviant rather than social norms that designate them as deviant.

In the case of unintended pregnancy, the label of 'illness' in the conventional sense does not necessarily apply. However Nathanson proposes that after oral contraceptives were put on the market, unintended pregnancy also began to follow

this transformation from immorality to sickness that Conrad identifies, with a shift in focus from the transgression of moral norms to prevention by way of technology, thereby placing it within the medical model. This change, in line with other examples that Conrad uses, like alcoholism or mental illness, does not directly alter the negative evaluation of the sexual behavior, but it does transform responsibility of the deviant in relation to that behavior (Nathanson 1991, 48-49 and Conrad and Schneider 1992). Nathanson goes on to validate Zola's idea of the myth of accountability, arguing that the sexual morality of women became redefined to depend on their conformity to contraceptive use (or treatment) rather than the conformity of their sexual actions (1991, 71).

Gusfield observes that there are different constructions or types of deviants who represent varying degrees of threat to societal norms. They therefore elicit different responses from those he calls "designators of deviance" (1968, 59). Gusfield proposes four types of deviants, three of particular importance to this essay: Repentant Deviant, the Sick Deviant, and the Enemy Deviant. The Repentant Deviant recognizes the legitimacy of the norms that she breaks and feels shame for her actions. As he explains, "There is consensus between the designator and the deviant; [her] repentance confirms the norms" (1967, 179). A Sick Deviant's actions are determined to be caused by illness, not a dismissal of norms. Because of agreement with public norms, Repentant Deviants and Sick Deviants do not pose a serious threat to societal norms and the designators of deviance. The Enemy Deviant, on the other hand, is a person who accepts her own behavior as legitimate and therefore undermines the public norm. The designation of a behavior as deviant requires the

designators to be more organized and more powerful than those labeled deviants. Because Enemy Deviants propagate a competing public norm, "anything increasing the deviant's power to organize and attack the norm threatens the social dominance symbolized in the norm." (Gusfield 1968, 62). In situations where Enemy Deviants begin to gain collective power, the designators need most to strengthen and enforce the norm.

Methodology

Kai Erikson writes, "The critical variable in the study of deviance, then is the social audience rather than the individual actor" (Gusfield 1968, 55). Therefore, in looking at unintended pregnancy and unorthodox female sexuality as deviance, this paper does not examine the female deviants themselves but instead the designators of deviance. I chose to analyze a government hearing because of what Gusfield describes as "the representational character of government officials" and how their decisions allow them "to define the public norms of morality and designate who violates them" (1968, 57). Governmental acts have both instrumental and symbolic functions. Instrumental functions are those that directly influence people's behavior, and depend on enforcement of the law. Symbolic aspects of law influence the designation of the public norms by placing higher value on the moral norms of one group than another or others (Gusfield, 1967). To assume a common normative consensus in the society of the United States- and most modern societies- would ignore numerous divisive characteristics like race, class and religion. However, Gusfield says, "agents of government are the only persons in modern society who can

legitimately claim to represent to the total society. Their specific and limited interests are disclaimed in preference to a public and total interest" (1968, 56). While Americans now might contest the accuracy of describing the government's claim as "legitimate," its actions do at least have the pretense of representing the whole country. So the decision of a federal agency, like the FDA, does at least symbolically represent a decision of the whole country. When social norms are threatened by Enemy Deviants, a governmental body like the FDA has the power to give symbolic support and strengthen the challenged social norms or to accede to their attempts to shift the terms of deviance.

The complete transcript of the FDA hearing to discuss switching Plan B to OTC status is available on-line at the FDA website.[7] The committees are made up of government employed doctors and scientists. In the open hearing portion of this hearing, there were also speakers that represented many of the major non-governmental players. This included representatives from large pro-EC organizations like Planned Parenthood and the National Family Planning and Reproductive Health Association, large opposition groups like Concerned Women for America, and the Catholic Medical Association, as well as individuals.

The FDA, even more than other government agencies, has this norming power while being framed as based solely on science and medicine- devoid of moral judgment. This allows for an examination of the strategies used to change social norms when they cannot be outwardly addressed. To do this, I read through the transcript observing how different players discussed and portrayed the main micro-

level actors, their behavior, and their relationships with each other in accordance to their stance on OTC EC. I first looked at the stories (personal, second-hand or hypothetical) told about the female potential users of Plan B. Second, I looked for descriptions of doctors and their interaction with female patients seeking Plan B.

I applied the framework of DeLamater's three levels of social controls to the depictions of these actors. Within the representations of women are understandings of responsibility and sexual morality, which I used as a basis for analysis of DeLamater's first level of social control: social norms and internal social controls. I used characterizations of the doctor-patient relationship to investigate the role of informal social controls, DeLamater's second level of social control. Ultimately, I came to explore how the opinions around the distribution of Plan B and rhetorical strategies used by the two groups- opponents and proponents of OTC EC- to express those opinions, promote different systems of sexual morals and norms, as well as strengthen or subvert other forms of social control to reinforce their conceptions of social norms.

The Public Problem(s) of Unintended Pregnancy

Both sides of the debates around OTC status for Emergency Contraception acknowledge unintended pregnancy (and the resulting abortions, though this will not be as specifically addressed in this analysis) as a public problem. But what is the problem of unintended pregnancy and how does it differ in their understandings of it? Unintended pregnancy came into the public arena as a serious public problem in the

---

The transcript can be found at

last fifty years. Pregnancy is a visible (public) sign of sexual (private) behavior. "Unintended pregnancy" is generally used to categorize the social problem represented by the sexual activity, pregnancy and childbearing of unmarried women between puberty and marriage. The connotation of label, however, is not in direct correlation to the words in the title, given that unwanted pregnancy can occur within as well as outside marriage; not every pregnancy in a marriage is wanted. However, generally the term is assumed in public policy discourse- including this FDA hearing, to refer to young women whose pregnancies occur outside of marriage. This label is used to signal and demand awareness of young unmarried women's departure from age and gender based norms of sexual and reproductive propriety.

Moral, medical, and socio-economic philosophies of unintended pregnancy and its causes have spurred many organizations and programs that advanced ways to reduce rates of unintended pregnancy. The popularity and pervasiveness of different approaches have waxed and waned over time with the popularity and power given to those sponsor institutions. Two constructions of unintended pregnancy, which have become dominant in the contemporary United States and can be seen in the FDA hearings, are what I refer to the Behavioral Definition and the Protection Definition.

Nathanson, in her discussion of teen pregnancy, which applies to the Behavioral definition, claims that the adolescent pregnancy label draws attention not primarily to reproductive behavior, but sexual behavior. According to her, "It is the evocation of non-marital sexuality rather than non-marital childbearing that gives the label its symbolic force" (1991, 4-5). The behavioral definition places the causal

---

<http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf>

responsibility on the sexual behavior itself and societal acceptance of sexual permissiveness. Within this definition, the way to decrease unintended pregnancy is to reduce sexual activity outside of relationships that could include a child.

The Protection Definition puts the causal responsibility of unintended pregnancy on the failure to use contraceptives that can prevent this outcome, which in many cases can be attributed to "social, political, and health-care system barriers limiting women's access to contraceptive services" (Nathanson, 164). Within this definition, the way to combat unintended pregnancy is to increase access to various contraceptive devices so sexual behavior would less often lead to pregnancy.

(Re)Defining unorthodoxy

Both the Behavioral and Protection definitions have concepts of morality imbedded within them. They have expectations for women's sexual behavior and therefore also conceptions of "unorthodox" or deviant female sexual behavior as Nathanson proposed. Kai Erikson, in concurrence with Conrad's definition, observes that "[d]eviance is not a property inherent in certain forms of behavior; it is a property conferred upon these forms by audiences which directly or indirectly witness them" (Gusfield 1968, 55). As taboo as it is as a topic, sex itself is not considered deviant. It has (shifting) boundaries that define sexual behavior's normative or non-normative status. The FDA hearing is a space that has the power to define or redefine what is deviant female sexual behavior and therefore, within the arguments around Plan B, sexual morality is being defined and debated. While the word "moral" is only

used four times in the eight hours of debate, but both opponents and proponents repeatedly delineate normal and "responsible" (read moral) sexual activity.

Reiss (1960) identified two main systems of norms around sexual behavior, or what Charon (1979) terms perspectives, that emerged in the United States. The relational perspective[8]- the historically dominant perspective- is "person-centered sexuality." It sees sexual activity as a means of expressing emotional intimacy and should therefore be limited to relationships that are psychologically and emotionally intimate. The morality of sexual behavior is contingent of the quality of the relationship. This perspective is implicit in the Behavioral Definition of the problem of unintended pregnancy. Traditionally the appropriate quality of the relationship that makes sex acceptable is marriage, an opinion that is still advocated for by many. However, as Slater also noted, there has been increasing permissibility of premarital sex when there is a focus on the relationship as part of the process of marriage as essentially practice for a future marriage (1973 in DeLamater 1981, 266).

Reiss contrasts this with the recreational perspective of "body-centered sexuality," or what might colloquially be called casual sex. It assumes that the purpose of sexual activity is physical pleasure and requires only consent by both parties (though deviance can also be influenced, as will all these orientations by the acceptability or status of the partner.) This type of activity is exactly what the Behavioral Definition of unintended pregnancy cites as the cause of unintended pregnancy.

In contrast, the Protection Definition, which treats unintended pregnancy as a

disease, as Zola's theory of the myth of accountability suggests, defines the morality of sexual behavior around a woman's use of contraception. One of the few times morality is directly referenced in the hearing is by Robert Carroll, an opponent of FDA approval and a retired physician, disapprovingly but accurately identifies this consequence of medicalization of sexuality: "Our young people have been encouraged to engage in sexual activity with the understanding that it was safe and morally acceptable as long as contraceptives were used" (FDA, 188). Because within it morality is contingent on contraceptive use and not the characteristics of the relationship between two people, the Protection Definition of sexual behavior[9] can be consistent with both the relational and recreational perspectives. By advocating this Protection Definition of the morality of unplanned pregnancy, supporters of OTC emergency contraception become, in the eyes of opponents, what Gusfield defined as Enemy Deviants, because they would designate protected casual sex behaviors as moral. Not only does individual women's behavior often violate traditional sexual rules, many of those women accept the recreational perspective on sex. However, it is the collective nature of the pro-OTC position expressed by proponents of OTC Plan B that really threatens the relational perspective as a public norm.

"The lifting of a deviant activity to the level of a political, public issue is a sign that its moral status is at stake, that legitimacy is a possibility" (Gusfield 1967, 188). Both opponents and proponents see expanded access to contraception as offering the potential opportunity for a change in public moral status of certain female

---

[8] Because of its earlier emergence and general dominance, I sometimes refer to this perspective as the "traditional" or "conventional" perspective.

sexual behaviors. But such a change is controversial and divisive. As such, supporters of OTC Plan B, in order to increase their chances of success in the hearing, want to avoid direct outward challenge to the norms and placement into the category of Enemy Deviant (even if their beliefs would place them there; consultation of writing in sources outside of the FDA hearing confirms that for many they do).

James Trussell, a voting consultant at the hearing, and his co-author L. L. Wynn observed this strategic choice of proponents of Plan B to keep as much as they could away from a moral discussion that might challenge conventional sexual norms. Organizations like Planned Parenthood and the Nation Family Planning and Reproductive Health Association, who are known generally to use rhetoric of sexual choice and freedom, or women's rights, avoided these kinds of terms entirely (Trussell 2006, 300). They did not want to play the role of the Enemy Deviant precisely because it is a more controversial and threatening position that may warrant a more forceful response.

To portray themselves as Sick Deviants rather than Enemy Deviants, Proponents of OTC Plan B placed their direct discourse in a medical frame and played to conventional ideas of sexual morality. First, they talked about the switch to OTC as addressing "health consequences" of unintended pregnancy and emergency contraception as a "therapy for women who desire pregnancy prevention" (FDA, 28-29).

In Barr Laboratories presentation, Dr. Ben-Maimon said that Plan B was for women who have had "unprotected sexual intercourse" (FDA, 30). But in using this term, she

---

[9] Because of its later emergence and its subordination to the relational perspective, I

is referring to any sexual intercourse where pregnancy is a risk. This term was continually qualified during the hearing to place the events of unprotected sex into situations that are (at least close to) morally permissible in the medical perspective of sexual morality as well as to downplay those situations that are not.

For example, Barr Laboratories and its supporters identified situational categories in which women may benefit from Plan B as, "contraceptive failure, coercive sex or rape, or unprotected sex" (FDA, 32). The first category places the failure on the medical technology and not the woman, who has been responsible and used a primary form of contraception that failed, such as a broken condom. The second category is women who experienced sexual assault and would have used contraception, but did not have the opportunity to do so. Women who engaged in unprotected sex, in this case meant as non-contraceptive sex, violate the norms of the medical perspective on sexual behavior. They are mentioned last in this first list enumerated by Barr laboratories, are referenced quantitatively the least of those three categories, even though Barr Laboratories itself found that forty percent of participants in its actual use study had intercourse without any form of contraception (FDA, 128). This was the only statistic on non-contraceptive sex, whereas multiple parties gave national and annual rates for both contraceptive failures and sexual assault. Only once in the entire hearing is non-contraceptive sex mentioned by proponents without one of the other two categories in the same sentence. Proponents of OTC EC tried to ameliorate the medical norm violations by coupling them with situations that do not break those norms.

---

sometimes refer to this as the alternative or medical perspective.

Several pro-OTC EC speakers recounted personal stories in regards to EC, but none verbally admitted to having had non-contraceptive sex. Eight women (six from National Organization for Women) described their past experiences taking EC. Six carefully clarified that they had used contraception that failed. One woman recounted how, "the condom came off inside [her] while [she] was having sex," (FDA, 194). Of the two women who did not describe contraceptive failure, one qualified her lack of primary contraceptives because of a medical condition that excluded the pill as an option (FDA, 221). The final women disclosed none of the circumstances around her need for EC. But neither of the women ever directly stated that she had sex without contraception; they simply did not clarify what happened during the actual event. They did not directly admit to violating responsible medical norms.

But possibly more importantly, proponents of OTC EC actually sought to outwardly confirm the publicly accepted morals rather than openly oppose them as an Enemy Deviant would. They wanted to place their version of the medical perspective on female sexuality squarely within the relational perspective and not within the recreational perspective. Proponents of OTC Plan B tried to play up and reaffirm current constructions of sexual morality to convince the voters and their opponents that the product was not (solely) for women who deliberately violated sexual norms. To do this, they repeatedly described characteristics and circumstances of women's sexual behavior and use of Plan B that were morally acceptable in the relational perspective of female sexual behavior, as well as downplayed those situations that fit the recreational sexual perspective.

The women who spoke about their personal experiences with Plan B were very careful to place themselves in the moral realm in the relational perspective by identifying that they were with a romantic (as opposed to simply sexual) partners. Often the relationship descriptors were in the same sentence as the women's reason for needing to use Plan B. For example, one NOW member said, "I was in a serious relationship and the condom broke," (FDA, 192). Most women called their sexual partners their boyfriend and qualified with other details to show the seriousness of their relationship, like the length of time that they had been together. One woman noted that her contraceptive failure happened just after she and her boyfriend moved in together (FDA, 177). Another even clarified that her boyfriend in the story was now her husband (FDA, 215). Not one woman spoke about having sex outside of a relationship. These stories portray women using Plan B as in serious relationships that are clear steps towards marriage. That construction places these sexual experiences within moral norms in the relational perspective, at least for those who do not specify marriage as a requirement for legitimate sexual activity.

Despite OTC EC's supporters' attempts to deny challenging moral norms, opponents claimed that OTC availability would encourage violations of norms for both the medical and relational perspectives. Opponents invoked the recreational perspective that proponents were trying to desperately to avoid, by claiming that EC increases promiscuity or casual sex. Opponent physician Robert Carroll claimed it is "self evident that over-the-counter availability of the morning after pill will lead to increased promiscuity and its attendant physical and psychological damage (FDA, 189). They argued that rates of sexually transmitted diseases would increase

dramatically due to reduced contraceptive use (FDA, 201-202). These two ideas are also linked in the opponents' description, suggesting that casual sex and non-contraceptive sex are correlated. OTC EC would not only encourage violation of morality within the relational perspective but also within the medical perspective promoted by the proponents of OTC EC themselves.

Discipline and Internal Self Control

In addition to attacking the norms themselves, opponents also discredited these deviant women and their ability to create moral systems. Systems of norms are the basis for the formation of self-controls (DeLamater 1981, 264). Both proponents and opponents of OTC EC created archetypes of women and their relationship to sexuality, though not necessarily accurate and definitely not all encompassing, which they used as rhetorical strategies to sway public opinion (Price 2005, 13). These prototypical users have specific and extreme levels of bodily discipline in part as ways to substantiate certain types of social control over others. Proponents of OTC EC portray women as having very self-disciplined sexuality in order to put more weight on the role of internal social controls. In contrast, opponents characterize women as having an undisciplined sexuality to in order to invalidate women's ability to internalize systems of norms for self-control and justify more reliance on external forms of social control.

The stories told by proponents of OTC EC, as described in the last section, clearly characterize women as always in control and making good decisions. Wynn and Trussell describe the character as "the responsible sexual decision maker whose

decision to prevent pregnancy is foiled by a torn condom" (2006, 1274). Proponents also refer to female rape survivors as potential users and beneficiaries of OTC EC. A supporter of OTC EC, a forensic nurse, gave a vivid personal description of her own rape during which she "was tied to [her] bed, gagged, and raped at knifepoint" (FDA 207). The image presented is that of a survivor of sexual assault whose power for decision-making violently ripped from her hands, but who desires control back- that EC would give her. OTC EC is portrayed by supporters as a tool used by women to help regain power over her decisions and her body. This complete faith in the ability of women to have and apply self-controls suggests that other forms of social control are less necessary.

While both sides use the sexual abuse scenarios to argue their case, opponents of OTC EC describe them in a very different way that emphasizes not how women can use EC but instead how OTC EC could be used by men, particularly male assailants. The (hypothetical) sexual assaults described by opponents of OTC EC are committed by coercive rather than violent assailants, which implies that women don't have strong self-controls and are easily swayed by ill-intentioned men. Robert Marshall, a state legislator from Virginia, suggests, "playboys, adolescent males will be the main beneficiaries of [OTC EC]" (FDA, 165). His statement indicates an understanding that men, who also gain access to Plan B with OTC status, would have the power over how OTC EC would be used. Easily accessible EC would be a "welcome tool for the adult sexual predator", stated Jill Stanek of Concerned Women for America. "They could keep a stash in their bedroom drawer or their pocket to give to their victims after committing each rape" (FDA, 227). Opponents of OTC talk

about OTC EC in terms how men can use it in acts of sexual assault, not by how it can be used as a tool by the women in those same situations. Women are given no agency or power in these sexual assaults or in relation to the use of EC.

In regard to sex and sexual decision-making, women are painted as without control- whether it is because they are taken advantage of or because they are undisciplined. Jennifer Taylor of Human Life International makes this assertion most clearly. She takes the same stories which proponents of OTC use to describe responsible sexual decision-making to make the opposite point:

> Another common thread that runs through these stories is the inability to control themselves in sexual situations. As a young woman how sad it is to know that these women are slaves to their bodies (FDA, 239).

Physician Robert Carroll states, "It is *self-evident* that over-the-counter availability of the morning after pill will lead to increased promiscuity" (FDA, 189 my emphasis). There is an assumption that if women are left to make decisions on their own and the negative consequences of those decisions, like pregnancy, can be minimized, they will choose unsafe, immoral casual sex. These arguments that expanded access to EC would lead to irresponsible behavior reflect the assumption that women do not have the ability to make competent, responsible decisions on their own, which justifies the intervention of a more capable authority.

Outside Authority and Informal Control

The conception of women as unqualified decision-makers supports opponents of OTC EC insistence on the importance of a woman's consultation with a doctor

which functions as an informal social control. Since women are portrayed as not reliable for their own self-control, others must help them do so. Therefore opponents of OTC EC want this authority in the hands of physicians. Opponents describe the appointment with a doctor as an educational opportunity for the woman to meet with a professional with more knowledge of medical technology. Those who oppose expanded access to Plan B contend that the OTC status of EC would impede on the beneficial doctor-patient relationship, in which physicians can talk to their patients about contraception, risks, and good sexual decision-making. Susan Crockett, a Bush administration appointee to the RHDAC, made this argument as part of her reasoning for her vote against OTC status for Plan B: "[A]s an OB-GYN I'm going to go down kicking and screaming before I allow somebody to break that relationship between myself and my patients because I value the education component so much in that relationship I have with my patients" (FDA, 406).

This idealized discussion that Crockett wants to encourage is not necessarily an open consideration of options or collaboration between doctor and patient about the right course of action. Another opponent of OTC EC, Dr. John Bruchalski, expresses simply the function of informal social controls that these consultations play: "Conversations lead to trust. Trust leads to following advice" (FDA, 197). A purpose of the information exchange is to get the patient to act in accordance with the doctor's wishes.

Instead of focusing on the informational asymmetry, proponents of OTC EC address the power asymmetry. A patient is required to give her doctor certain information in order to receive the EC that she is seeking. Several speakers mentioned

feeling interrogated by medical professionals. Kelly Mangan of NOW referred to the "prying questions" that the nurse asked about Kelly's relationship with her partner, how long she had known him and other questions that do not seem relevant in determining the medical appropriateness of EC (FDA, 194). Wynn and Trussell critiqued the these appointments arguing that "women complain of being subjected to a moralizing medical gaze that evaluated not their health but their moral decisions- namely their decisions to have sex and use contraception" (Wynn 2006, 1275.). Doctors, in this situation, act as agents of social control reaffirming public norms.

Because of the doctor's position of power, this compulsory disclosure can function as a form of confession and shaming. Confession of whatever sexual activity that brought her to need emergency contraception to a moralizing body, like religious confession, becomes a form of repentance and makes the patient into a Repentant Deviant. Dr. Albert Thomas used the word "permission" instead of prescription (FDA, 244). Doctors act as gatekeepers in this situation, and they can compel conformity to normal sexual standards of behavior. This does not necessarily mean a change in behavior but a conformity and legitimization of those norms. Nathanson writes that the most dangerous sign of deviance is not to have the appropriate shame for one's actions, which in Gusfield's terms would be defined as an Enemy Deviant (Nathanson 1991, 108). The doctor can be an agent of shaming and require from the woman a show of penitence- an admission of their wrongdoing and therefore a legitimization of the public norms that they broke. Whether this admission of guilt is true or simply symbolic is less important, for either way it forces a shift of women from Enemy Deviant to Repentant Deviant. Keeping the doctor directly engaged in a

women's sexual behavior helps regulate and dilutes the threat of the delegitimization of the norms of sexual behavior that opponents support.

Visibility and Concealment

"The negotiation of visibility is central to social control of private sexual behavior" (Nathanson 1991, 212). Problematic behavior can only be corrected and controlled if that behavior is made visible. Pregnancy is the visible outcome of the sexual behavior. It is used as both an indication that sexual behavior occurred and a visible punishment for engaging in that behavior. Pregnancy, and since the advent of contraception (primary and emergency), the visit to a doctor are the channels through which unorthodox sexual behavior becomes visible. Without these methods of visibility, sexual behavior becomes invisible. This is the argument that opponents of OTC EC make in regards to sexual assault in order to defend the need for doctor's oversight. But this invisibility is exactly what proponents of OTC EC are hoping for as a result of increased access because the invisible can be ignored and cannot be regulated.

Opponents of OTC EC point out the dangers of losing visibility both by eliminating pregnancy and doctors visits for EC. Jill Stanek of Concerned Women for America reminds the panel at the hearing that "Pregnancy may be a sign of ongoing sexual abuse," and without it or a meeting with a physician safeguards against such abuse are gone (FDA, 228). OTC EC will be used as tools for assailants because as Judie Brown, President of American Life League describes "Pills such as Plan B are designed with one purpose in mind: to destroy the evidence that a sexual encounter

has occurred that could result in the conception of a child" (FDA, 214). The destruction of evidence of the sexual encounter does in fact make it invisible. Visible deviance cannot be ignored because it runs the risk of been seen as condoning that deviance. To opponents of OTC EC, allowing the sexual encounters to become invisible is the same kind of approval because deviance that cannot be seen cannot be regulated.

Invisibility is what proponents of OTC EC desire. They want to give women control over their own behavior: "Most importantly, we as women should and must be allowed to make reproductive decisions for ourselves without interference from others, without judgment from others, and without the need for someone else's approval" (FDA, 173-4). But there is a dual meaning of the concealment through which OTC EC gains invisibility (Nathanson 1991, 212). It is a method for giving women the sexual autonomy that Linda Freeman of the National Organization for Women pleads for in the previous quote. But it also acknowledges the strength of social norms that make concealment necessary.

Undermining Autonomy

By taking a route of least resistance and not outwardly fighting for a new set of sexual norms, proponents of OTC access gained sexual autonomy for women that is conditional, based on invisibility. High-level anti-OTC FDA officials who stalled the release of a decision in the case identified this weakness and instituted the age restriction, which undermined the invisibility for all women, and therefore the reproductive autonomy gained by women through this decision.

A dual status label, where an OTC drug has a prescription requirement for a subpopulation, is very unusual and requires specific measures to allow enforcement of this limitation. The drug with a comparable age restriction is Nicorette, a nicotine replacement therapy approved by the FDA in 1996 for OTC sale for consumers 18 years of age or older (IFC 2006, 6.4). In the recommendations to the FDA for how to enforce the dual label status for Plan B, several industry comments and the American Pharmacists Association (APA) suggested similar approaches to enforcement as applied to Nicorette, like "requiring pharmacies to keep a dual-status drug behind the pharmacy counter and have it dispensed only by pharmacists or some other type of learned intermediary," and requiring identification- like a driver's license or government identification- to prove the customer meets the age restriction (IFC 2006, 7.4.1-4).

By adding an age restriction for the purchase of Plan B, the medication is moved behind the counter for all women regardless of age. With a drug behind the counter, women have to ask the pharmacist for it, which recreates a site for shaming and visibility as previously discussed. Some argue this could be the case even if Plan B was fully OTC because a woman still has to hand the EC to the cashier. However, a cashier does not possess the institutional power of the pharmacist. A woman is in a similar power position with the pharmacist as she is with the doctor. Women (and men) are forced to make themselves visible to the pharmacist who requires identification to verify age, which contains personal information like name and address in addition to age. The pharmacists can also ask probing questions about the woman's sexual history to determine if EC is medically appropriate. In a study of

barriers to emergency contraception, Jean Shoveller found that the women in her study reported, "receiving subtle and sometimes not-so-subtle messages [from pharmacists] about their sexual 'choices'" (2004, 18).[10] Shoveller's study looks only at the participants' feelings, which may have misread the provider's words or body language. However, the intentionality of the shaming is less important than its perception by the woman. The shaming in some cases is clearly intentional and can be accompanied by the pharmacist's refusal to fill the prescription.[11] A New Hampshire pharmacist denied a 21 year-old single mother EC after berating her so harshly that she sat in the parking lot crying and was too humiliated to seek Plan B from another pharmacist (Cantor 2004, 2008 and Cowan 2005).

After non-judgmental staff attitudes, the next most important attribute of emergency contraceptive services for women is privacy of consultation (Seston 2007, 183)[12]. Behind-the-counter access introduces a form of informal social control that was not present in doctor's office because privacy becomes an issue. In a doctor's office, the conversation takes place in a closed off or sectioned off space. In a pharmacy, the consultation often happens at the counter, where a customer can be

---

[10] This study takes place in British Columbia, Canada however because Canada has a very similar behind-the-counter policy around emergency contraception and surveys have shown similar attitudes towards EC in the two countries, I think that the findings are applicable to the United States.

[11] While not addressed in this paper, the Bush Administration is currently trying to increasing the rights of health care providers (including pharmacists) not only to refuse to provide certain services based on their moral or religious beliefs but also to refuse to play any role in the service, which could include referring women to a pharmacist or pharmacy that would grant them access to EC. For more information about this process see http://birthcontrolwatch.org/extreme_hhs.html

[12] This was the most systematic study I found. It was allowed for the measurement of the strength of preference by offering A versus B scenarios to women in North West, England. Because of the strength of the methodology and the similar regulations and concerns around EC provision, I took the results to be applicable to the United States.

seen and overheard by other patrons who can also be agents of shaming and social control.

Placing an age restriction on Plan B was a way for both informal controls and visibility of sexual behavior to be kept in place even if drug technically gained over-the-counter status. Dual-label status still increase timely access to EC for a large body of women and is in many ways a victory for proponents of OTC EC. However by not explicitly challenging the sexual norms that make the use of EC unacceptable for women, the proponents of OTC EC were left vulnerable to informal social controls being reconstituted and continuing to control women's sexual behavior. While access to Plan B is now easier, it did not result in the sexual autonomy many had hoped for.

Conclusion

The FDA hearings on application to make Plan B OTC was an event that demonstrated the opposition of two groups that were both working, on the surface, towards the same goal of reducing rates of unintended pregnancy and abortion. The framework of Gusfield's structure of public problems helps illuminate the conflicting understandings of the causes of unintended pregnancy and constructions of morality imbedded within those understandings. To opponents, the hearing was not about the instrumental, behavioral impact on women's sexual and reproductive behavior that would result from expanded access to EC. The importance of the hearing lay within the symbolic realm of the social norms that would be validated and affirmed by the decision made by the FDA. The positions held by proponents and opponents of OTC EC supported incongruent social norms of female sexual behavior. In addition to challenging relational ideas of sexual morality themselves, OTC Plan B also

undermines internal and informal social controls that are in place to reinforce the sexual norms. Opponents fought against this change to maintain a traditional normative status of women's sexual behavior.

The proponents of OTC EC tried to deemphasize the inconsistencies between their system of moral judgment and their opponents', focusing on the ways that they are compatible. Proponents instead hoped the dismantling of external, informal social controls could help women gain sexual autonomy and shift the social norms by allowing women to make sexual decisions themselves with less interference of outside parties. However, by not outwardly advocating the alternative social norms, Proponents of OTC EC, left themselves vulnerable to the implementation of surrogate informal social controls. The possibility of establishing a new set of social norms was undermined by the age restriction put in place by the FDA's final decision. While the dual-label status may reduce physical barriers to EC, is has less of an impact on the social barriers to EC and women's sexual autonomy.

The analytic framework used in this paper is important because it recognizes the symbolic and moral debates within spaces that are designated as devoid of such discussions. Rachel Dresser, in a response to the public outrage about the FDA decision, suggested that "Rather than criticizing FDA officials for taking values into account, we should criticize them for failing to disclose which values affected the decisions" (2004, 10). Because, as Conrad and Zola argue, we cannot divorce medicine or science from our moral structures, Dresser suggests we should instead outwardly acknowledge those considerations. Even if these values are not made

public, it is important to acknowledge and examine how seemingly “neutral” arenas are used in strategies to bring about moral change.

Appendix A

Acronyms

OTC	Over The Counter
EC	Emergency Contraception
FDA	United States Food and Drug Administration
CDER	Center for Drug Evaluation and Research
NDAC	Nonprescription Drugs Advisory Committee
ACRHD	Advisory Committee for Reproductive Health Drugs
OB-GYN	Obstetrician and Gynecologist
ACOG	American College of Obstetricians and Gynecologists
NOW	National Organization for Women
APA	American Pharmacists Association

Appendix B

(Person's Final Vote on the question Should Plan B be given OTC status)
*Not present for final vote

Nonprescription Drug Advisory Committee (NDAC)

Louis R. Cantilena, Jr., M.D., Ph.D., Chair	(No)
Neal L. Benowitz, M.D.	(Yes)
Terrence F. Blaschke , M.D.	(Yes)
Leslie Clapp, M.D.	(Yes)
Frank F. Davidoff, M.D.	(Yes)
Julie A. Johnson, Pharm.D.	(Yes)
Y.W. Francis Lam, Pharm.D.	(Yes)
Sonia Patten, Ph.D., Consumer Representative	(Yes)
Wayne R. Snodgrass, M.D., Ph.D.	(Yes)
Mary E. Tinetti, M.D.	(Yes)
Donald L. Uden, Pharm.D.	(Yes)
Henry W. Williams, Jr., M.D.	(Yes)
Alastair Wood, M.D. *	
Karen M. Templeton-Somers, Ph.D. Executive Secretary SPONSOR *	

Advisory Committee for Reproductive Health Drugs (ACRHD)

Linda C. Giudice, M.D., Ph.D., Chair	(Yes)
Susan Crockett, M.D, Bush Appointee	(No)
Scott S. Emerson, M.D., Ph.D.	(Yes)
W. David Hager, M.D, Bush Appointee	(No)
Vivian Lewis, M.D.	(Yes)
Larry Lipshultz, M.D.	(Yes)
Charles J. Lockwood, M.D.*	
George A. Macones, M.D.,	(Yes)
Valerie Montgomery Rice, M.D.	(Yes)
Joseph Stanford, M.D, Bush Appointee	(No)
Lorraine Tulman, RN Consumer Representative	(Yes)

Voting Consultants

Abbey B. Berenson, M.D. -Professor of OB-GYN and Pediatrics at University of Texas Medical Branch at Galveston	(Yes)
James Trussell, Ph.D. - Office of Population Research at Princeton University.	(Yes)
Geri D. Hewitt, M.D. - Professor of the Department of OB-GYN and Pediatrics at Ohio State College of Medicine.	(Yes)
MichaeI F. Greene, M.D.- Professor of Obstetrics, Gynecology and Reproductive Biology at Harvard Medical School	(Yes)

Non-voting Representatives and Consultants:

Michael C. Alfano, D.M.D., Ph.D., Acting Industry Representative
Carole Ben-Maimon, M.D. Barr Labratories
Vivian Dickerson, M.D. American College of Obstetricians and Gynecologists
David Grimes, M.D. Family Health International

Non-Voting FDA Representatives:

Steven K. Galson, M.D., M.P.H., Director, Center for Drug Evaluation and Research
Sandra Kweder, M.D., Deputy Director, Office of New Drugs
Jonca Bull, M.D., Director, Office of Drug Evaluation V
Julie Beitz, M.D., Deputy Director, Office of Drug Evaluation III
Donna Griebel, M.D., Director, Division of Reproductive and Urologic Drug Products
Curtis J. Rosebraugh, M.D., M.P.H., Deputy Director, Division of OTC Drug Products
Andrea Leonard Segal, Team Leader, Division of Nonprescription Evaluation
Jin Chen, M.D., Ph.D., Medical Officer, Division of OTC Drug Products
Daniel Davis, M.D., M.P.H., Medical Officer, Division of Reproductive and Urologic Drug Products
Karen Lechter, J.D., Ph.D., Social Science Analyst, Division of Surveillance, Research, and Communication Support

Open Public Hearing

Proponents of OTC EC:

Dr. Melanie Gold, Professor in Adolescent Medicine at University of Pittsburgh
Dr. Vanessa Cullins, Planned Parenthood Federation of America
Dr. Gretchen Stuart, National Family Planning and Reproductive Health Association
Rachel Laser, National Women's Law Center
Dr. Felicia Stewart, Association of Reproductive Health Professionals
Linda Freeman, NOW New York State Reproductive Rights Task Force
Erin Mahoney, NOW New York State Reproductive Rights Task Force
Teresa Harrison, Ibis Reproductive Health
Kirsten Moore, Reproductive Health Technologies Project
Dr. Beth Jordan, Feminist Majority Foundation
Dr. Janet Engle, American Pharmacist Association
Hillary Flowers, no affiliation stated (personal experience)
Kelly Mangan, National Organization for Women (personal experience)
Heather Boonstra, Alan Guttmacher Institute

Karen Coleman, Forensic nurse
Alexandra Leader, Red Stockings Allies and Veterans
Amy Allina, National Women's Health Network
Stephanie Seguin, National Organization for Women (personal experience)
Jane Boggess, Public Health Institute
Silvia Henriquez, National Latina Institute for Reproductive Health
Vera Brown, National Organization for Women (personal experience)
Carol Petraitis, Clara Bell Duvall Project
Erika Gubrium, National Organization for Women (personal experience)
Kim Gandy, National Organization for Women
Deven McGraw, National Partnership for Women and Families
Andre Ulmann, HRA Pharmas
Dr. Erin Gainer, HRA Pharmas
Candi Churchill, Gainesville Women's Liberation
Rev. Robert Tiller, Religious Coalition for Reproductive Choice
Dr. Albert George Thomas, Physicians for Reproductive Choice in Health

Opponents of OTC EC:

Delegate Bob Marshall, State legislator from Virginia
Wendy Wright, Concerned Women for America
Carole Denner, RN, Concerned Women for America
Dr. Hanna Klaus, OB-GYN, no affiliation stated
Dr. Robert Carroll, Retired physician
Dr. John Bruchalski, Catholic Medical Association
Dr. Chris Kahlenborn, no affiliation stated
Dr. Daniel Hussar, Philadelphia College of Pharmacy (speaking as an individual)
Dr. William Colliton, Retired OB-GYN professor from the George Washington University Medical Center
Judie Brown, American Life League
Jill Stanek, Concerned Women for America
Jennifer Taylor, Human Life International

Works Cited

Burstein, Paul. "Response to the Fda, Politics, and Plan B." New England Journal of Medicine 350.23 (2004): 2413.

Cantor, Julie, and Ken Baum. "The Limits of Conscientious Objection- May Pharmacists Refuse to Fill Prescriptions for Emergency Contraception?" New England Journal of Medicine 351.19 (2004): 2008-12.

Charon, J. Symbolic Interactionism. Englewood Cliffs, New Jersey: Prentice-Hall, 1979.

Comfort, A. "Sexuality in a Zero Growth Society." Current 148 (1793): 29-34.

Conrad, Peter, and Joseph W. Schneider. Deviance and Medicalization: From Badness to Sickness. Philadelphia: Temple University Press, 1992.

Cowan, Tilly, and Meade Harris. "Pharmacists 'Denying Birth Control' ". 2005. BBC News. December 8 2008. <http://news.bbc.co.uk/2/hi/americas/4425603.stm>.

Davidoff, Frank, and James Trussell. " Plan B and the Politics of Doubt." Journal of the American Medical Association 296.14 (2006): 1775-78.

DeLamater, John. "The Social Control of Sexuality." Annual Review of Sociology 7 (1981): 263-90.

Drazen, Jeffery M. . "The Fda, Politics, and Plan B." New England Journal of Medicine 350 (2004): 1561-62.

Dresser, Rebecca. "Plan B: Politics and Values at the Fda, Again." The Hastings Center Report 34.6 (2004): 9-10.

Eggertson, Laura, and Barbara Sibbald. "Privacy Issues Raised over Plan B: Women Asked for Names, Addresses, Sexual History." Canadian Medical Association Journal 173.12 (2005): 1435-36.

Ellertson, Charlotte. "History and Efficacy of Emergency Contraception: Beyond Coca-Cola." International Family Planning Perspectives 22.2 (1996): 52-56.

"Emergency Contraception: The Science and Politics Driving the Debate." SIECUS Report 33.3 (2005).

FDA. Joint meeting of the Reproductive Health Drugs and Nonprescription Drugs Advisory Committee. Gaithersburg, Maryland, 2003. 1-413.

FDA Issues Not Approvable Letter to Barr Labs; Outlines Pathway for Future Approval Food and Drug Administration, 2004.

Fine, Michelle, and Sara I. McClelland. "The Politics of Teen Women's Sexuality: Public Policy and the Adolescent Female Body." Emory Law Journal 56.4 (2007): 993-1038.

Foucault, Michel. The History of Sexuality Volume 1. New York: Vintage Books, 1988.

Freidson. Profession of Medicine. New York: Harper & Row, 1970.

Galson, Steven. "Not Approvable Letter." Ed. Joseph A. Carrado. Bala Cynwyd, PA, 2004.

Grimes, David. "Emergency Contraception: Politics Trumps Science at the U.S. Food and Drug Administration." Obstetrics & Gynecology 104 (2004): 220-21.

Gusfield, Joseph. "Moral Passage: The Symbolic Process in Public Designations of Deviance." Social Problems 15.2 (1967): 175-88.

---. "On Legislating Morals: The Symbolic Process of Designating Deviance." California Law Review 56.1 (1968): 54-73.

---. The Culture of Public Problems: Drinking, Driving, and the Symbolic Order. Chicago: University of Chicago Press, 1981.

Hall, Stuart. Representation: Cultural Representation and Signifying Practices. London: Sage, 1997.

Hilgartner, S, and C. L. Bosk. "The Rise and Fall of Social Problems: A Public Arenas Model." American Journal of Sociology 94.1 (1988): 53-78.

ICF International. Drug Approvals: Circumstances under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an over-the-Counter Drug Product. Fairfax Food and Drug Administration, 2006.

Nathanson, Constance. Dangerous Passage: The Social Control of Sexuality in Women's Adolescence. Philadelphia: Temple University Press, 1991.

O'Toole, Leslie C., and Kevin B. Sobel-Read. "Pharmacist Refusal: A New Twist on the Debate over Individual Autonomy." Gender Medicine 3.1 (2006): 13-17.

Reiss, I. L. Premarital Sexual Standards in America. New York: Free Press, 1960.

Seston, Elizabeth M. "Women's Preferences for the Provision of Emergency Hormonal Contraception Services." Pharmacy World And Science 29 (2007): 183-89.

Shoveller, Jean. "Identifying Barriers to Emergency Contraception Use among Young Women from Various Sociocultural Groups in British Columbia, Canada." Perspectives on Sexual and Reproductive Health 39.1 (2007): 13-20.

Trussell, James, and L. L. Wynn. "The Social Life of Emergency Contraception in the United States: Disciplining Pharmaceutical Use, Disciplining Sexuality, and Constructing Zygotic Bodies." Medical Anthropology Quarterly 20.3 (2006): 297-320.

Weiss, Deborah. "A Brief History of Emergency Hormonal Contraception." Planned Parenthood Federation (2005).

Wood, Alastair. "A Sad Day for Science at the Fda." New England Journal of

Medicine 353 (2005): 1197-99.

Wynn, L. L., and James Trussell. "Images of American Sexuality in Debates over Nonprescription Access to Emergency Contraceptive Pills." Obstetrics & Gynecology 108 (2006): 1272-76.

Zola, Irving K. "Medicine as an Institution of Social Control." The Sociological Review 20.4 (1972): 487-504.

---. "In the Name of Health and Illness: On Some Socio- Political Consequences of Medical Influence." Social Science and Medicine 9 (1975): 83-87.