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Debating Contraception, Defining Motherhood: Women, Doctors, and the State in the Politics of Birth Control

by

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List of Abbreviations

Chapter 1

ABCL – American Birth Control League
AMA – American Medical Association
BCCRB – Birth Control Clinical Research Bureau
BCR – Birth Control Review
CFLBC – Committee on Federal Legislation for Birth Control
CMH – Committee on Maternal Health
CRB – Clinical Research Bureau
CSV – Committee for the Suppression of Vice
FDA – United States Food and Drug Administration
MRC – Maternity Research Council
MS – Margaret Sanger
NBCL – National Birth Control League
NYSSV – New York Society for the Suppression of Vice
PPFA – Planned Parenthood Federation of America
YMCA – Young Men's Christian Association

Chapter 2

AHA – American Hospital Association
AMA – American Medical Association
CSD – Committee on Safety of Drugs
IRB – Institutional Review Board
IVF – In-Vitro Fertilization
NDA – New Drug Application
NIH – National Institutes of Health
Ob-gyn – Obstetrician/Gynecologist
OC – Oral Contraception
PFDA – Pure Food and Drug Act
PMA – Pharmaceutical Manufacturers Association
PPFA – Planned Parenthood Federation of America
PPI – Patient Package Insert
SNDA – Supplemental Drug Application
WFEB – Worcester Foundation for Experimental Biology

Chapter 3

ACOG – American College of Obstetricians and Gynecologists
ACRHD – Advisory Committee for Reproductive Health Drugs
BTC – Behind-the-Counter
CDER – Center for Drug Evaluation and Research
CRR – Center for Reproductive Rights
CWA – Concerned Women for America
EC – Emergency Contraception
FR – *Federal Register*
GAO – United States Government Accountability Office
IUD – Intrauterine Device
IVF – In-Vitro fertilization
NDAC – Nonprescription Drugs Advisory Committee
NFPRHA – National Family Planning and Reproductive Health Association
NIH – National Institutes of Health
NOW – National Organization of Women
NRA – National Research Act
OTC – Over-the-Counter
PP – Practice Pattern
PPFA – Planned Parenthood Federation of America
R&D – Research and Development
RHTP – Reproductive Health Technologies Project
SNDA – Supplemental New Drug Application

Conclusion

AFDC – Aid to Families with Dependent Children
TANF – Temporary Assistance for Needy Families

Introduction

I first learned about Plan B from my mother. A few days before I left home to begin my first semester at Wesleyan University, she and I were in the car on our way to do some last minute shopping for dorm room supplies. From behind the wheel, my mother casually mentioned that she had read in that morning's newspaper that a certain kind of birth control was going to be made available over-the-counter. I nodded with quiet interest, telling myself to remember that the drug was available should I ever need it, and the conversation moved on.

It was not until the fall of 2009, when I took on this project, that I began to understand the full weight of that brief exchange. That moment could not have been more wholly emblematic of our respective generational differences as feminists. My mother came of age at a time when many women were profoundly questioning the role of physicians in their lives and were rejecting what they believed to be the over-medicalized experiences of women. As a counter to this over-medicalization, feminists began to assert that they, too, possessed knowledge that could help guide them in decisions about their bodies.

In this respect, my mother was no exception. My mother, who gave me my first copy of *Our Bodies, Ourselves,* who always reminded me that she left the Catholic Church because of its position on contraception, and who gave me a lesson in sex education when I was in first grade and came home from school asking what a "virgin" was—my mother saw Plan B as another important means by which women could reclaim control over their own bodies, without the help of doctors or any other

authority. As for me, I didn't find Plan B to be anything out of the ordinary, and I certainly did not understand the history behind the drug like my mother did.

This thesis, on its most empirical level, is a study of three "episodes" in the history of birth control in the United States. I am but one of many scholars to have taken an active interest in such a history. The era of second-wave feminism in the 1970s saw a profound resurgence of scholarship on birth control. Until this time, histories of birth control had oscillated between stories of triumphant technologies and the scientists behind them or, at the opposite end of the spectrum, accounts of Margaret Sanger's radical rebellion in a time of social conservatism.[1] The feminist historiographies that emerged in the 1970s took a markedly different approach. Linda Gordon's *Woman's Body, Woman's Right: Birth Control in America*, first published in 1976, is a story about a struggle for power. Gordon, a Marxist-feminist, illuminates the ways in which birth control had historically served as a divisive issue between women of different social standings.[2] Her work thus served as a warning to feminist activists of her own generation to move beyond single-issue debates and look for ways in which to unite women across all economic classes to overcome gender-based oppression.

Other works of this period took on more recent technologies in contraception. Barbara and Gideon Seaman's *Women and the Crisis in Sex Hormones* is a severe critique of the myriad ways in which hormonal therapies—whose ultimate

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[1] See, for example, Norman E. Himes, *Medical History of Contraception* (New York: Schocken Books, 1963), and David Kennedy, *Birth Control in America: The Career of Margaret Sanger* (New Haven and London: Yale University Press, 1970).
[2] Linda Gordon, *Woman's Body, Woman's Right: Birth Control in America* (New York: Penguin Books, 1990).

medical benefits were uncertain—had emerged as treatments for nearly every disease unique to women's bodies. Reducing women's bodily experiences to sex hormones, they argued, was a profoundly dangerous endeavor. In their examination of oral contraceptives, the Seamans' posit that the developers of this technology had purposely overlooked reports of adverse side effects and had not conducted nearly enough clinical trials before the drug was introduced on the market.[3] Barbara Ehrenreich and Deirdre English's *For Her Own Good: 150 Years of Experts' Advice To Women* also frame recent birth control technologies as having only served to medicalize the experience of pregnancy and maternity.[4]

There is an important commonality among all these historiographies: rather than tell a story of "top-down" hierarchy, in which those wielding power (for our purposes: doctors) are omnipotent and those at the bottom (here: women) passive subjects, these scholars have done important work to illuminate the ways in which, within these relationships, there existed what Foucault would call a "multiplicity of force relations."[5] No longer content to accept medical expertise as paramount, these scholars worked to encourage women to trust their own understandings of the body and to resist clinical authority.

While the 1970s did indeed see an outpouring of feminist scholarship on the history of birth control, other historiographies emerged at this time that seemed to omit women's experiences with contraception nearly entirely. James Reed's *The Birth*

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[3] Barbara Seaman and Gideon Seaman, *Women and the Crisis in Sex Hormones* (New York: Rawson Associates Publishers, Inc, 1977).
[4] Barbara Ehrenreich and Deirdre English, *For Her Own Good: 150 Years of Experts' Advice to Women* (New York: Anchor Press/Doubleday, 1979).
[5] Michel Foucault, *History of Sexuality, Volume I: An Introduction* (New York: Vintage Books Edition, 1990) 95.

Control Movement and American Society: From Private Vice to Public Virtue traces the story of several actors within the medical community who worked during the early 20th century to encourage the profession to extend their authority over birth control.[6] While I find Reed's work to ultimately fall more in line with earlier "top-down" stories of power, he raises an important point: the birth control movement of the Progressive Era arrived at a precarious time for the medical profession and medical authority. The early 20th century for the medical community was a period fraught with sectarian strife between physicians of differing classes, backgrounds, geographic locations, and beliefs as to how medicine should be practiced. While the 1910 Flexner Report effectively eliminated all forms of medical education besides the university system (thus consolidating the medical domain as being rooted in scientific practice), it was not until the post-World War II era that physicians fully established their authority in American society. Importantly, however, the Progressive Era marked the beginning of a period in which, as Paul Starr writes, "physicians were able to see social interests defined so as to conform with their own."[7] Reed's work picks up on this trend of redefining social issues in regards to birth control, and traces the ways in which individuals within the profession worked to convince the community as a whole of the need to adopt contraception into the medical program.

More recent historiographies, while not addressing the medical profession specifically, have taken issue with other myths of power that surround birth control. Elizabeth Siegal Watkins, in *On the Pill: A Social History of Oral Contraceptives, 1950-*

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[6] James Reed, *The Birth Control Movement and American Society: From Private Vice to Public Virtue* (Princeton: Princeton University Press, 1978).
[7] Paul Starr, *The Social Transformation of American Medicine* (New York: Basic Books, Inc, 1982) 144.

1970, and Lara Marks' *Sexual Chemistry: A History of the Contraceptive Pill* have both contest the idea that oral contraceptives led to women's immediate liberation from domesticity and that the technology was directly responsible for the sexual revolution of the late 1960s.[8] Watkins and Marks, like their scholarly predecessors of the 1970s, highlight the ways in which oral contraception held broadly different implications for women depending on their class, race, and (in Marks' case) nationality.

These historians have sought to illuminate the ways in which certain groups have influenced perceptions of birth control and they have done important work to give a voice to those previously silenced in this history. And yet, there is one actor who is conspicuously absent from nearly all the accounts discussed thus far: the state. In these historiographies, the state has been relegated to the background as a pervasive but intransmutable power.[9]

I see the state as having played a different role in this history. In the most recent episode of birth control history, the state, through the regulatory power of the United States Food and Drug Administration (FDA), made what I believe to be an important change in the way in which women can access birth control. With the advent of the Plan B pill, the FDA enabled women to access the drug without a physician's prescription—a seeming break from those scholars who have asserted that the state has only worked to reinforce medical authority over birth control. This change thus begs the questions: How did the FDA arrive at such a decision? Was

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[8] Elizabeth Siegal Watkins, *On The Pill: A Social History of Oral Contraception, 1950-1970* (Baltimore and London: Johns Hopkins University Press, 1998); Lara Marks, *Sexual Chemistry: A History of the Contraceptive Pill* (New Haven and London: Yale University Press, 2001).

[9] Watkins and Marks' work are perhaps exceptions to this contention. These scholars have highlighted moments in which the state made itself known through various actions. They have not, however, given it the comprehensive treatment that I aim to provide in this thesis.

this the first time the FDA took such an active role in the birth control movement, or have there been other moments in the history of birth control in which the state has seemingly taken up the cause of feminists?

To answer these questions, my work in this thesis is thus twofold: First, I aim to meld the work of previous scholars and to illuminate the alliances and discordances forged between feminists and physicians throughout the birth control movement. Furthermore, I work to give the state renewed attention in this history and to illustrate the ways in which both feminists and doctors have used the state as a tool to bring about important changes in the status of birth control. Since *Woman's Body, Woman's Right,* Gordon has written extensively about the ways in which welfare policies in the United States have only served to reinforce traditional gender and class hierarchies.[10] She thus would probably not see much good in the state's involvement in birth control. In contrast, I believe that the demands of feminists have often been reflected in the state's policies concerning birth control. The FDA, through birth control, has done substantial work to give women the power to move beyond traditional gender roles, and I use this thesis to offer some concrete examples in support of this claim. No longer seen as an omnipotent wielder of power, the state becomes an actor in its own right. Thus in short, I move to "bring the state back" into the history of birth control.[11]

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[10] See Linda Gordon, "The New Feminist Scholarship on the Welfare State," in *Women, the State, and Welfare*, ed. Linda Gordon (Madison: University of Wisconsin Press, 1990).
[11] Theda Skocpol, "Bringing the State Back in: Strategies of Analysis in Current Research," in *Bringing the State Back in*, eds Peter B. Evans, Dietrich Rueschemeyer and Theda Skocpol (Cambridge and New York: Cambridge University Press, 1985). In this anthology, Skocpol and her co-editors work to counter what they see as an overemphasis on "society-centered" historical analyses. They aim to refocus research to be more "state-centered," and to highlight the ways in which the state can be a useful actor in bringing about social change.

To make my case, I explain, in Chapter 1, how feminists and physicians forged an alliance as a means of expanding access to birth control during the early 20th century. Admittedly, while the state is omnipresent throughout this episode, it does not, beyond some key judicial decisions, appear in a markedly overt manner. The FDA is absent from this episode, and purposely so; this chapter works to illuminate how birth control became medicalized—that is, how physicians as a community came to extend their medical expertise over a matter that had previously been considered to be a nonmedical or social issue—without FDA intervention.[12] It is this medicalization—this absolute medical authority over birth control—that the FDA slowly unravels in the two chapters that follow: first in the case of oral contraceptives, and next with the Plan B pill.

Birth Control, Contested Motherhood, and the State

A common thread between the three episodes that I explore is how the actors involved have understood motherhood. In the early days of the movement, birth control activist Margaret Sanger framed contraception as a means of protecting and insulating motherhood. In this regard, her work falls in line with a broader trend of the Progressive Era. Indeed, Sanger's campaign occurred at a time when, as Theda Skocpol has written, the state saw little paternalist welfare reform (reform directed at protecting the male industrial worker), but rather was more concerned with the

[12] For more on medicalization, see Nikolas Rose, "Beyond Medicalisation," *Lancet* 369 (2007): 700-701.

maternal welfare state; that is, reforms concerned with mothers and children.[13] This phenomenon is even more fascinating when we remember that women did not achieve the right to vote until 1920. Reforms of this period included the implementation of mothers' pensions (made available for widowed women in 44 states by 1920), the establishment of a federal Children's Bureau in 1912, and the passage of the Sheppard-Towner Infancy and Maternity Protection Act in 1921 (which funded pre- and post-natal clinics).[14] These programs were the result of trans-national networks of women activists who assured the state that, by valorizing motherhood, these measures would only work to protect the prevailing social order.[15] Just as Sanger promised with birth control, these reforms were all concerned with producing *better* mothers—rather than removing women from their traditional domestic roles.[16]

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[13] Theda Skocpol, *Protecting Soldiers and Mothers: The Political Origins of Social Policy in the United States*, (Cambridge: The Belknap Press of Harvard University Press, 1992). I use Skocpol's language here, and I recognize that these reforms may not be truly considered "maternalist" in the truest sense, since they only served to perpetuate a paternalist society in which the integrity of motherhood and the domestic roles of women were preserved. Skocpol uses the terms "maternalist" and "paternalist" to refer to intended benefactor of these reforms, mothers and industrial workers, respectively. See Skocpol 314-17.

[14] Maternal reform movements permeated American life at this time. In addition to demands for certain social policies, women also organized around environmental issues and the eugenics movement—in the name of extending their maternal abilities to better both the environment and the race. See Adam Rome, "'Political Hermaphrodites': Gender and Environmental Reform in Progressive America," *Environmental History* 11 (July 2006): 440-463; Laura L. Lovett, *Conceiving the Future: Pronatalism, Reproduction, and the Family in the United States, 1890-1938* (Chapel Hill: University of North Carolina Press, 2007); Wendy Kline, *Building a Better Race: Gender, Sexuality, and Eugenics From the Turn of the Century to the Baby Boom* (Chapel Hill: University of North Carolina Press, 2001.

[15] Sanger, as we shall see, ultimately circumvented state legislation in her quest to expand access to birth control, and is thus an important exception to this trend.

[16] Interestingly, Skocpol makes no mention of Sanger or the birth control movement in her work, presumably because the birth control movement was ultimately unsuccessful in achieving reform by the means which Skocpol has outlined, and because the birth control movement continued beyond the Progressive Era, when the era of the maternalist welfare state was on the decline, and thus is beyond the scope of Skocpol's work.

Modified maternal reform rhetoric appeared the 1970s with the onset of second-wave feminism. Here, women again demanded reforms—this time in order to help them move *beyond* their societal roles as mothers. The rhetoric for reform thus shifted from the preservation of motherhood to the choice of motherhood. Women now demanded that the state take measures to ensure their right to choose to enter the workforce alongside men. While oral contraceptives, which appeared on the market in 1960, were not developed with this shift in maternalism in mind, we can retrospectively read this technology as having enabled women to make such a choice. Indeed, as Linda Gordon has written, women of second-wave feminism (while critical about certain realities of oral contraceptives) indeed saw this technology as a "tool for autonomy, freedom, and higher aspirations."[17]

Second-wave feminism appeared out of a broader movement in American society that had begun nearly a decade earlier in the 1960s, in which citizens began to demand that the state take steps to guarantee the protection of certain rights. This era of rights-based liberalism was characterized by such movements as the Civil Rights movement, the consumer rights movement, and the environmentalist movement, but I focus here on a particular Federal Supreme Court case involving rights: *Griswold v. Connecticut*. This 1965 case struck down eight state laws banning the use of contraceptives, but moreover, it established the idea of a person's "right to

[17] Linda Gordon, *The Moral Property of Women: A History of Birth Control Politics in America* (Urbana and Chicago: University of Illinois Press, 2002), 288. Gordon has subsequently updated *Woman's Body, Woman's Right* to its latest inception as *The Moral Property of Women*. In this edition, Gordon remains true to her study of class warfare over birth control, examining the latest politics between feminists and the New Right.

privacy," which included the right of between (married) couples to make decisions concerning contraception without state interference.[18]

This right to privacy would appear again in the case of oral contraceptives, as we shall see in Chapter 2. When a controversy arose as to the safety of oral contraceptives the FDA, rather than restrict women's access to the drug by removing it from the market, instead instituted a policy change that ensured that women were afforded adequate information about the drug's hazards. With this information, women could thus privately assess whether the drug's potential harms were worth the benefit of preventing pregnancy (thus delaying maternity)—with the important help of her physician's power to prescribe the drug.

Throughout the end of the 20th century, the state made even stronger efforts to help women move beyond motherhood and enter the labor force in a move to encourage what Ann Shola Orloff calls "employment for all."[19] Gone were the days of the maternal welfare state, especially after the repeal of Aid to Families with Dependent Children in 1996—the last of the policy measures to have emerged out of the Progressive Era—that provided federal funds as a sort of income for full-time caregivers (usually women). By the time Plan B arrived in the late 1990s, both the federal and state legislatures had instituted many affirmative action measures to

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[18] John W. Johnson, *Griswold v. Connecticut: Birth Control and the Constitutional Right to Privacy* (Lawrence: University Press of Kansas, 2005).

[19] Ann Shola Orloff, "From Maternalism to 'Employment for All:' State Policies to Promote Women's Employment across the Affluent Democracies." In *The State after Statism: New State Activities in the Age of Liberalization* ed. Jonah D. Levy (Cambridge and London: Harvard University Press, 2006), 230. While U.S. policy in recent years has been especially successful in helping women move beyond motherhood, Orloff is critical of the way in which the neo-liberal state has failed to provide for women who choose both motherhood *and* employment, when compared to the policies of Social-Democrat states in Europe. Instead of providing subsidized childcare or extended maternity leaves, the U.S. has left working mothers to rely upon market forces to find caregivers for their children.

remedy the gender and racial imbalances in the workplace to further encourage women and minorities to fully enter the workforce. Title IX, passed in 1972, worked to ensure that women had the same educational opportunities as men in order to compete for similar jobs. Thus the Plan B pill, in this schema, served as another tool enabling women to choose (rather than be saddled with) motherhood.

Protecting Children and Controlling Sexuality

Also underlying this thesis is a story about how certain rhetorical themes have consistently appeared in opposition to the demands of birth control proponents. The concern that birth control might threaten the safety and innocence of children has been especially pervasive throughout this history. As Nichola Biesel has written, birth control's outlawing in the late 19th century was justified as a necessary measure to protect American youth from engaging in immoral and promiscuous behavior. Biesel supports her claim by noting that legislation outlawing contraceptives was always linked to bans of obscene literature. Thus contraceptives were seen as enabling adolescents, "afflicted with lust from reading pornography," the opportunity to "sin while affording themselves and their partners protection from disease and pregnancy."[20] By controlling pornography and contraceptives (and using the rhetoric of protecting children to justify this control), the state was promoting a Victorian notion of sexuality, in which sexual restraint and propriety were championed; by the time Sanger began her activist campaign in the early 1900s, the link between contraception and promiscuity was entrenched in American thought. Partly as a

[20] Nichola Biesel, *Imperiled Innocents: Anthony Comstock and Family Reproduction in Victorian America* (Princeton: Princeton University Press, 1997) 40.

move to undo this entrenchment, Sanger believed contraception needed to be placed in the hands of some societal authority who could mediate access to birth control.

In the case of oral contraceptives, concerns about the drug's implications for adolescent sexuality were conspicuously absent. In some ways, this absence reflects the success of Sanger's work to associate birth control with a respected mediator figure. The state's decision to allow only physicians to control women's access to contraception represented an implied understanding that physicians would properly mediate who could and could not access birth control—without the repercussions of pregnancy. Thus fears of promiscuity were quelled, as both the public and the state were assured that physicians would use their best medical judgment when prescribing birth control.

While fears of sexual permissiveness were dampened with oral contraceptives, they dramatically reappeared in regards to the Plan B pill. As we shall see, the contention over whether to make Plan B available over-the-counter was never truly an issue of the drug's safety, but was rather rooted in fears of the drug's potential to encourage promiscuity—expressed as a need to protect children. Indeed, actors involved in the Plan B debate expressed fears that, if doctors no longer mediated a woman's right to access to the drug, Plan B could go so far as to become something of an "Urban Legend" that would "lead adolescents to form sex-based cults."[21] Others wrote that, by placing Plan B in the pharmacy next to "candy bars and toothpaste," children would come to see the drug (and thus sex) as a toy, without

[21] Curtis Rosebraugh, Internal Food and Drug Administration (FDA) Memo, as qtd by L.L. Wynn and James Trussell, "Images of American Sexuality in Debates over Nonprescription Access to Emergency Contraceptive Pills," *Obstetrics and Gyncology* 108 (2006): 1272-1276, 1272.

dangers or repercussions.[22] Underlying these speculations was a fear about the consequences of removing physicians' "policing" role from contraception. As L.L. Wynn and James Trussell have explained: "Rhetoric about disciplining pharmaceuticals [again became] displaced language for talking about disciplining sexuality."[23]

With these themes of motherhood, morality and protecting children in mind, let us now turn to the three episodes in the history of birth control already described here in brief, paying special attention to the interactions between feminist activists and physicians as each group works to serve its own interests through birth control, while exploring the ways in which these groups used the state as a tool to bring about change.

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[22] Pamela Wong, "FDA Withholds Morning-After Pill From Non-Prescription Use," Concerned Women for America (CWA) press release, 05/07/2004.
[23] L.L. Wynn and James Trussell, "Zygotic bodies" 27.

Chapter 1:
Margaret Sanger and the Birth of the Birth Control Clinic

Introduction

This chapter examines the work of Margaret Sanger and the birth control movement in early 20th century America. Margaret Sanger, née Margaret Higgins, was born in 1883 in Corning, New York to a devout Irish Catholic family, the sixth of eleven children. Sanger, in her autobiography, recounts a happy, quiet childhood, spent attending school and looking after her siblings. While enrolled at Claverack College, a finishing school for girls, Sanger's mother died of tuberculosis. Having endured 18 pregnancies in total, her mother's health had always been frail. In the wake of her mother's death, Sanger left Claverack for a time to look after her family. She eventually returned to her studies, enrolling at White Plains Hospital to train as a nurse. It was during this time that she met her future husband, William Sanger, and the two were married in 1902. The Sangers', having relocated to New York City, began to make a name for themselves in various Socialist and other New York left-wing circles, mingling with the likes of anarchist Emma Goldman, and muckraker author Upton Sinclair. It was during this time when Sanger began working as a traveling nurse in the crowded tenement houses of downtown New York City. She was often called upon to visit women in labor and assist the attending physician with the birth. Sanger, in her autobiography, noted these experiences as having opened

her eyes to the need to educate women about birth control methods.[1] She recounted instances in which, after a woman had just borne her umpteenth child, she would ask Sanger and the doctor if there were a way to prevent future pregnancies. Sanger herself was oblivious to any such methods, and the physician on hand generally only scoffed at the woman. Thus the question went unanswered. Sanger observed these women, living in cramped conditions and unable to afford another child, and grew continually more concerned. From desire to help these women grew an activist spirit and Sanger began to publicly advocate for the legalization of birth control.[2] Sanger would continue her activism well into the 20th century, as this chapter will explain. Sanger's tenure as the leader of the birth control movement included: various milestone judicial rulings that worked to expand access to birth control, the establishment of a birth control organization that would eventually become the Planned Parenthood Federation of America (better known as Planned Parenthood), and important work to connect interested philanthropists with willing clinical researchers who would go on to develop the first oral contraceptives in the early 1960s (as will be explained in Chapter 2 of this thesis). After a long and successful career of activism, Sanger retired to Tucson, Arizona, where she died in 1966.

Margaret Sanger was far from the first person to advocate for birth control.[3] Her story is important, however, because it was due to her lobbying that birth control

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[1] "Birth control," as it is used in this chapter, is any means by which a woman limits the number of pregnancies she has. The most commonly used methods at this time were condoms, douches and pessaries (an early diaphragm).

[2] Under the Comstock Laws the dissemination of information on birth control was illegal, as I shall explain later in this chapter.

[3] For the history of the pre-Sanger birth control movement, see Linda Gordon, "Voluntary Motherhood: The Beginnings of Feminist Birth Control Ideas in the United States," in *Women and Health in America*, ed. Judith Walzer Leavitt, (Madison: University of Wisconsin Press, 1984).

methods, as they existed for women, became associated with the medical community. Her early activism paved the way for the eventual development of a distinctly medical birth control technology—the oral contraceptive pill—that both doctors and women enthusiastically embraced. Sanger was successful in gaining the attention of the medical community and advocating for the establishment of the clinic as *the* source of birth control information. Her ability to recognize that social acceptance of birth control was not possible without the endorsement of the medical community was key to her finding success where others had failed. In this chapter, I will examine the key alliances that Sanger forged with the medical community in her quest to ensure that every American woman could easily and legally access birth control—despite the lack of a major state intervention.

Historical Framework

Before beginning any history of the birth control movement, the question should be posed: why was a birth control movement necessary? What were the historical conditions that had led to birth control's status as illegal in the United States? To answer these questions, we must look at two historical events: first, the outlawing of abortion, and second, the passage of the "Comstock Laws." Both of these events were entangled with the broader social trends of combating immorality and preserving the traditional Victorian American family. I begin first with abortion.

Until the 1850s, abortion was a wholly legal and socially acceptable practice; James C. Mohr estimates that about one in five pregnancies was aborted at this time.[4] While some women who sought abortions did so as a result of premarital affairs, abortions were more common among married women who simply did not desire to have any more children. The reason most Americans found abortion unobjectionable is rooted in old notions of pregnancy. Before "quickening" (the moment when a woman first feels the fetus move within the uterus), the fetus was not thought to be a living being. As such, pre-quickening abortions were thought of as normal and permissible, and were considered "on a continuum extending back through the various forms of contraception, not on a continuum reaching forward towards various degrees of murder."[5]

Why, then, did abortion become an illegal procedure? As Mohr explains, it is largely due to the lobbying efforts of the medical profession. Doctors began to publicly condemn abortions for two reasons. First, physicians had dismissed the idea that quickening was the first relevant moment in pregnancy. While little scientific research had been conducted on the exact mechanisms of pregnancy, physicians by this point understood that quickening was no more than a rather bizarre sensation during pregnancy and had no implications for fetal development. Without this marker or any other physically perceptible event in pregnancy to which to look, physicians believed that gestation could not be interrupted at any point after conception.

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[4] James C. Mohr, "Patterns of Abortion and the Response of American Physicians, 1790-1930." In *Women and Health in America*, ed. Judith Leavitt, *Abortion in America: The Origins and Evolution of National Policy, 1800-1900*, (New York: Oxford University, 1979).
[5] Mohr, "Patterns" 118.

Moreover, at the time, it was midwives or "irregular" (unlicensed) physicians who offered abortions. As part of a larger crusade against quack medicine, the American Medical Association (AMA), founded in 1847, launched a major campaign against abortion to effectively eliminate these practitioners from the profession. The credibility of the medical profession was still tenuous, and the AMA was actively working to ground its work in science as a means of supporting claims to authority over the body. Anything or anyone who practiced outside of the realm of "science," then, had to be removed from its ranks.[6]

Physicians successfully convinced legislators of the need to outlaw abortion and by 1870 nearly forty states had passed anti-abortion legislation.[7] Birth control, too, was linked to medical quackery, and although the medical profession did not launch such a devastating campaign against it, there were many "irregular" doctors who offered contraceptive methods such as pills, powders, and "secret remedies" that were completely useless and ineffective, thus detracting from the authoritative image of medical science. In the second half of the 19th century, even stranger birth control methods like electrical belts and bath mixtures appeared on the market.[8]

The campaign against abortion and birth control was part of a widespread movement to eradicate immorality and obscenity from American life and to uphold the Christian values to which the majority of Americans subscribed at the time. The passage of the "Comstock Laws" in 1873 is another such example of the

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[6] For an excellent examination of the politics of the medical profession in the 19th and 20th century, see Paul Starr, *The Social Transformation of American Medicine* (New York: Basic Books, Inc, 1982).
[7] James Mohr, *Abortion in America: The Origins and Evolution of National Policy* (London and New York: Oxford University Press, 1978) 200.
[8] Linda Gordon, *Woman's Body, Woman's Right* (New York: Penguin Books, 1990) 164.

government's fight to preserve traditional Victorian social values. The Comstock Laws were the result of extensive lobbying on the part of the laws' namesake, Anthony Comstock. Comstock was apparently always concerned with combating the various vices of society. He served for the Union Army during the Civil War, spending his tour of duty in peaceful Florida. There, with no battles to be fought, Comstock spent the majority of his time attending religious services chastising his fellow comrades for imbibing.[9] After the war, he relocated to New York in the mi-1860s where he began an active campaign against obscenity by purchasing obscene books from book dealers and subsequently reporting the material to the police.[10] In 1872, he established the Committee for the Suppression of Vice (CSV) within the Young Men's Christian Association (YMCA) as a means of funding these purchasing endeavors.[11] The CSV, still under Comstock's leadership, broke from the YMCA in 1874 to become the New York Society for the Suppression of Vice (NYSSV) and began a lobbying campaign in both Congress and the New York State Legislature to outlaw *all* immoral literature in the US, including materials explaining how to obtain and/or employ birth control and abortions. Comstock was highly successful; Congress passed a federal law in 1873 making it illegal to use the mail to distribute obscene material. The law stated: "Every obscene…article, matter, thing, device or substance; and every article or thing designed…for preventing conception or

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[9] For Anthony Comstock's biography, see Nichola Biesel, *Imperiled Innocents: Anthony Comstock and Family Reproduction in Victorian America* (Princeton: Princeton University Press, 1997).
[10] "Obscene," as Comstock used it, generally referred to materials sexually explicit in nature.
[11] For more on the YMCA's own concerns about vice and immorality, see Beisel, *Imperiled Innocents*.

producing abortion…is declared nonmailable matter."[12] A few years after this federal law, about a dozen states, including New York, passed their own versions of this law that, significantly for our purposes, provided that a physician with the right to distribute information on birth control if the female patient was deemed too ill to risk becoming pregnant. Section 1145 of the New York State law stated:

> An article or instrument, used or applied by physicians lawfully practicing, or by their direction or prescription, *for the cure or prevention of disease*, is not an article of indecent or immoral nature or use, within this article. The supplying of such articles to such physicians or by their direction or prescription, is not an offence under this article (emphasis added).[13]

Thus, by the time Margaret Sanger began her campaign in the early 20th century, abortion was a criminal act and thus birth control was more than ever a necessary institution if women were to have any control over the frequency of their pregnancies. The Comstock Laws severely limited its accessibility, however.[14]

Forging An Alliance

Nichola Beisel has explained how the ideology behind Comstock's legislation stemmed from a desire to protect children from corruption and promiscuity.[15] Sanger, however, evidently interpreted these laws as being concerned with insulating the prevailing social hierarchy between men and women, for she was especially careful to never make claims about the potential birth control offered for women

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[12] U.S.C 1461-62, Title 18, Chapter 71: "Obscenity," as qtd by C. Thomas Dienes, Appendix A: Federal Legislation Relating to Birth Control, *Law Politics and Birth Control*, (Chicago: University of Chicago Press, 1972), 313. This clause of the law becomes important later in the birth control movement, as will be explained.
[13] New York Legislation Relating to Birth Control, as qtd by Dienes, *Law, Politics and Birth Control.*
[14] According to Beisel, Comstock was responsible for the arrest of ninety-seven people between 1872 and 1900 for selling information on either abortion or birth control.
[15] Beisel, *Imperiled Innocents.*

who wanted to move beyond their societal roles as child bearers, as Carole R. McCann has explained.[16] Making this claim would have only furthered Comstock and his followers' claims that the traditional social hierarchy was being subverted. She instead promoted birth control as a means of affording mothers enough time after giving birth to regain their health before bearing their next child. Never was there an overt implication that women would use contraception to simply avoid motherhood completely.

McCann argues that Sanger avoided this challenge to traditional social roles in order to broaden her appeal to various conservative groups in society, such as eugenicists, physicians and legislators. While this may have been true, I argue that, above all, Sanger was most concerned with appealing to the medical profession. Though the legitimacy of the medical profession was still only a burgeoning entity, the state's response to the community's concerns over abortion indicated that, on issues of morality and maintaining the social order, physicians were emerging as an important authority. An endorsement from the medical community, Sanger believed, would lend a sense of legitimacy and morality to the birth control movement.

How then would Sanger convince the medical community to endorse birth control when its members had hitherto rejected the practice as quack medicine? As I aim to show in this chapter, Sanger introduced the idea to the medical community that there were indeed instances when pregnancy posed a major threat to the well being of a woman. Childbearing at the time was a dangerous endeavor; often it could even result in death of the mother. Until the 1950s, few childbirths occurred in the

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[16] Carole McCann, *Birth Control Politics in the United States, 1916-1945* (Ithaca: Cornell University Press, 1994).

hospital setting and it was largely midwives who oversaw the birthing process, not doctors. The New York State Comstock Law had already acknowledged this danger by providing a loophole for physicians to legally provide birth control in order to protect the health of a mother. If Sanger could convince physicians to greatly expand the instances in which they saw the need to prescribe birth control (in the name of preserving a woman's health), she believed it was only a matter of time before it would naturally become more socially acceptable. Let us now turn and examine the key moments of Margaret Sanger's birth control movement that led to the medicalization of birth control.

Developing a Rhetoric

Margaret Sanger did not immediately know that she would frame birth control as a medical issue. Indeed, in the early days of the movement, she was quite radical in her rhetoric. In the first issue of *Birth Control Review* in 1917 (a publication that Sanger founded and edited), Sanger defined pregnancy as a disease that was responsible for not only frail, sick women but greater social problems such as divorce, poverty, even war.[17] She would eventually refine her rhetoric, however, and frame her campaign in more pragmatic issues of the time.

At first, Sanger tried to frame her argument for birth control as an issue of free speech. She arrived at this decision after an article she wrote for the Socialist publication *The Call*—in which she explained the basic biology of sexual reproduction—was censored under the New York State Comstock Law. Sanger

[17] Sanger, "Shall We Break This Law?" *Birth Control Review,* 1 (1917): 4.

believed the law was in violation of a person's right to free speech and thus she began publishing more incendiary articles about reproduction and birth control in the hope of being arrested and testing her free speech argument in the courts. Sanger got her wish in August of 1914, when she was arrested for the circulation of her pamphlet *Woman Rebel*. Her letters reveal that, upon her arrest, she solicited advice on how to proceed from two attorneys who specialized in free speech issues.[18] Unfortunately, Sanger never appeared in court. Instead, she fled to Europe soon after being arrested, out of fear that she would indeed lose the case and spend time in jail.[19]

During her time abroad, Sanger spent time engaging with various social reform activists of the time, most notably meeting Havelock Ellis—a pre-Freudian sexologist who eventually became Sanger's lover.[20] At Ellis' urging, Sanger traveled to Holland in 1915 to learn about the recently established free clinics where birth control information was made available. These clinics were the result of several seemingly disparate institutions, much like that which Sanger would forge with American physicians. In this coalition, however, it was not physicians but

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[18] See Letter to Theodore Schroeder from MS, August 19, 1914, 80-81; Letter from James F. Morton Jr., to MS, August 27, 1914, 82-84, *The Selected Papers of Margaret Sanger: Vol. I: The Woman Rebel, 1900-1928*, ed. Esther Katz (Urbana: Illinois University Press, 2003).

[19] Historians have been critical of Sanger's decision to flee. In her autobiography, Sanger claims that her trial date was inexplicably changed to an earlier date without her being notified and, as such, she feared that she did not have time to prepare an adequate case. David Kennedy has noted that this is simply untrue, and has cited her flight as an example of her "continuing uncertainty of purpose" in the movement. While I do not agree that this uncertainty was pervasive throughout her entire career, I do agree that this decision to flee seems to contradict her initial intentions. See David Kennedy, *Birth Control in America: The Career of Margaret Sanger* (New Haven: Yale University Press, 1971) 25.

[20] Sanger's letters and biographies reveal that, in addition to her two marriages (first to William Sanger and then later to James Noah Slee), she took several lovers throughout her lifetime.

eugenicists, specifically the Dutch neo-Malthusian League who, along with feminists played a key role in the clinical model.[21]

Dr. Aletta Jacobs, the first female physician in Holland, pioneered these clinics in the late 19th century. For Jacobs, birth control was only part of a larger program of infant and maternal health promotion that she implemented through the establishment of free clinics for poor women and children. Jacobs met much hostility from the medical community for her birth control program, and it was actually the Dutch neo-Malthusian League who adopted and implemented Jacob's medicalization of birth control.[22] Though it was not until 1931 that the neo-Malthusian League established the first clinic dedicated solely to birth control (under the direction of Dr. Johannes Rutgers), Dutch midwives and physicians (hired by the League) were trained to fit pessaries (what would be known as diaphragms later in the 20th century) beginning in the 1890s. It was Jacobs who popularized the pessary and believed so much in its efficacy that, according to her memoir, she refused to counsel women on any other method of birth control.[23]

The pessary would become the method that Sanger, too, would most often recommend. At these clinics, Rutgers explained to Sanger that, unless someone familiar with the female anatomy fit the newly developed Mensinga pessary to each individual user's body, it was not a very effective method for preventing pregnancy.[24]

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[21] Neo-Malthusians played a role in the American birth control movement as well, and Sanger did indeed engage with members of this political group. For a greater discussion on this exchange, see Gordon, *Woman's Body, Woman's Right*.
[22] Aletta Jacobs, *Memories*, trans., Annie Wright (New York: The Feminist Press at the City University of New York, 1996).
[23] Ibid.
[24] Pessaries are devices that, when inserted inside a woman's vagina, prevent sperm from passing through the cervix, thus preventing pregnancy. Women had been using some sort of blocking

Thus the pessary made physicians imperative to the employment of effective birth control, as they were presumably the only members of society whose training adequately prepared them for such a task.

Sanger, evidently inspired by the Dutch clinical model, was now convinced that clinics were the way to provide women access to birth control information. She returned to the U.S. in the summer of 1916 with plans to again test the Comstock Laws, but this time in a different context.[25] She would now test the clause in the New York State Comstock Law which stated that birth control could be prescribed by physicians when acting "for the cure or prevention of disease" in the patient. Physicians at the time largely interpreted this clause to mean that a woman could be given information on birth control if she had a life-threatening illness such as tuberculosis or influenza—diseases in which pregnancy would greatly impede a woman's recovery from the disease. Sanger believed that by opening a clinic she could test—and ultimately broaden—this definition of disease prevention; she hoped to align pregnancy itself with illness in such a way that would make birth control a permissible practice in all circumstances. The clinic would serve all clients, whether considered ill (by the prevailing standards) or not, and would provide them with information about contraceptive methods. Ultimately unable to find a willing physician to direct the clinic, however, Sanger and two other nurses decided to run it instead. The Brownsville Clinic (in Brownsville, Brooklyn) opened on October 16,

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device for this purpose for centuries, but only in the late 19th century were improvements made on the device to greatly improve its efficacy in preventing pregnancy.

[25] Comstock's death in 1915 marked the steep decline of the anti-vice movement, and as World War I had recently broken out, the courts apparently grew concerned with other issues. As such, the original obscenity charges against Sanger were dropped.

1916.[26] In the nine days it operated, Sanger estimated that the clinic served perhaps 500 women before New York City police raided and shut it down, arresting Sanger and the other two nurses in the process.[27]

A Legal Litmus Test

In July of 1917, Sanger was found guilty of violating Section 1142 of New York Penal Law for having distributed information on how to prevent conception without a license to practice medicine. If Sanger had been a licensed physician, or if it had been physicians treating patients instead of nurses, the clinic may have been protected under Section 1145 of New York Penal Law (which stated that physicians had the right to prescribe birth control). It was this statue, of course, that Sanger had originally intended to test, but when she decided to proceed despite the lack of a willing physician to oversee the clinic, the nature of her purpose was changed. Even if the court had been convinced that Section 1145 should be interpreted more broadly, it could not in good faith exculpate Sanger, who was not a doctor and thus had no state- recognized authority to diagnose and treat disease.

Sanger brought the case to the New York State Court of Appeals, where Justice J. Crane upheld the original court's decision against Sanger, reiterating the mistake Sanger had made in not employing a physician to distribute birth control information at the clinic. The decision stated: This exception [Section 1145 of the Penal Law]…is broad enough to protect the *physician* who in good faith gives such

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[26] Advertisements for the clinic included a direct appeal to anti-abortionists, saying "Do not kill, do not take life, but prevent; Safe, harmless information can be obtained of trained nurses."
[27] Margaret Sanger, *An Autobiography* (New York: W.W. Norton & Co, 1970).

help or advice to a married person to cure or prevent disease (emphasis added).[28] Despite this reiteration, the decision marked a major achievement for the birth control movement: Judge Crane explicitly employed a definition of disease that was broad enough to encompass pregnancy as such a condition. In his ruling, he wrote: "'Disease,' by Webster's International Dictionary, is defined to be, 'an alteration in the state of the body, or of some of its organs, interrupting or disturbing the performance of the vital functions, and causing or threatening pain and sickness; illness; sickness; disorder.'"[29] In effect, Sanger had achieved exactly what she had intended with her clinic: a liberal interpretation of the Comstock Law's "disease" provision. Now she was left to the task of convincing the medical profession to adopt this expanded disease definition with regard to pregnancy.

The Birth of the Birth Control Clinic

A movement within the medical profession to medicalize birth control had begun several years prior to Judge Crane's 1918 ruling in the Brownsville case. One of the first doctors to publicly support this change was Dr. William J. Robinson. Robinson, editor of "Medico-Pharmaceutical Critic and Guide," wrote several editorials beginning in 1907, in which he made his claims for the medicalization of birth control while criticizing the idea that public opinion on birth control could be swayed by the work of birth control leagues. In 1915, he wrote, "…one well-

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[28] Decision by Justice J. Crane, *People of the State of New York v. Sanger, Appellant*, Margaret Sanger Papers Microfilm Edition: Library of Congress Collection.
[29] Ibid.

balanced and determined man can often accomplish more than a big society."[30] Around the time that Sanger planned to launch her clinic, she consulted with Robinson to gauge the medical community's attitude toward birth control. While Robinson expressed personal support for the practice, his opinion did not reflect that of the broader medical community. According to Robinson, the American Medical Association (AMA) considered birth control to be "outside of its domain."[31] While there remained a few physicians however who, like Robinson, published in various medical journals and delivered speeches to medical societies in a move to build momentum for the medicalization of birth control, the community at large remained unyielding to such a change.

Sanger decided to open another clinic in 1923. Justice Crane's 1918 decision had made it clear that, legally, only licensed physicians could dispense birth control information. Sanger recruited Dr. Dorothy Bocker (at the time a director of the Georgia State Board of Health's Division of Child Hygiene), to direct the clinic on a two-year contract. At the clinic, which was called the Clinical Research Bureau (CRB), Bocker would consult married women on birth control while simultaneously collecting statistics about each patient's experience with the various birth control methods to assess how effective each was at preventing pregnancy.[32] She found the most effect methods to be spermicidal jelly and the Mensinga pessary. The clinic

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[30] William J. Robinson, "Birth Control Leagues," *The Medico-Pharmaceutical Critic and Guide* (May 1915): 166-7.
[31] Letter from William J. Robinson to MS, September 13, 1916, *Papers Vol I,* 198-9.
[32] Data collected included a patient's maternal history, including number and nature of pregnancies and miscarriages, a general health history, and types of contraceptive methods previously employed. Dorothy Bocker, *Birth Control Methods* (New York: Birth Control Clinical Research Bureau, 1924).

operated as the medical branch of the American Birth Control League (ABCL), a league that promoted birth control through the distribution of pamphlets and publications. It opened to the public on January 1, 1923.

Concurrently, Dr. Robert Latou Dickinson, a prominent gynecologist and president of the American Gynecological Society, spearheaded a movement for birth control that was gaining significant momentum within the medical community. Dickinson approached birth control from the perspective of a "Christian gentleman and an orthodox physician."[33] According to James Reed, Dickinson saw it as his duty as a physician to protect the sanctity of marriage and prevent divorce. One means of achieving this, according to Dickinson, was by ensuring that the sexual needs of husbands were met—while still controlling the number of children a woman bore—in order to ensure the "health, happiness and usefulness for progeny, parents and community."[34] Thus it was up to physicians, with their expertise in physiology and their claims as maintainers of the social order, to enlighten their patients to the methods of birth control. While Dickinson and Sanger were by default united because of their common interest, the two had a strained relationship; Dickinson was adamantly opposed to a medical movement being led by a laywoman, especially a "radical" like Sanger. In fact, Dickinson often used Sanger's media image as a rallying point to encourage physicians to support his cause. Medicalizing birth

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[33] James Reed, *The Birth Control Movement and American Society: From Private Vice to Public Virtue* (Princeton: Princeton University Press, 1978), 160.
[34] Robert L. Dickinson and Stevens Bryant, *Control of Conception: An Illustrated Medical Manual* (Baltimore: Williams and Wilkins Company, 1931). This book is a detailed guide to understanding intercourse and conception and was intended to educate physicians on the various methods of birth control so they could share the information with their male patients (birth control was not yet integrated into medical education).

control, he argued, would take control away from Sanger and would sequester (what Dickinson considered to be) her pesky publicity stunts. In a 1916 address to a group of Chicago physicians, he explained: "We as a profession should take hold of this matter [contraception] and not let it go to the radicals, and not let it receive harm by being pushed in any undignified or improper manner."[35]

A few months after Sanger opened the Clinical Research Bureau (CRB), Dickinson established the Committee on Maternal Health (CMH). The CMH, much like the CRB, provided women with birth control in a clinical setting while collecting data and conducting research on birth control methods. Unable to gain an official endorsement from the New York Obstetrical Society, Dickinson's clinic was backed financially by Gertrude Minturn Pinchot (a spurned Sanger supporter). Dickinson planned to present the findings of this clinic to the members of the New York Academy of Medicine, in order to convince them that birth control methods should be formally included in physicians' medical education.[36] Unfortunately, the CMH was much less successful in recruiting patients than the CRB; in three years of operation, the CMH only saw 124 patients.[37] Meanwhile, Sanger's clinic flourished; a

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[35] Dickinson, as qtd by James Reed, *The Birth Control Movement and American Society,* 167. Dickinson was likely skeptical of Sanger in part because of his own medical background. Educated at a proprietary school in a pre-Flexner Report society (a school later discredited as a result of the 1910 Report), Dickinson had worked hard to establish his own legitimacy within the profession; his interest in birth control and his later research efforts in the subject area reflected a desire to be taken seriously in a profession that laid increasing importance on scientific evidence.
[36] That Dickinson and Sanger both concerned themselves more with state-level medical politics rather than national speaks to the true disunity among the profession at the time. While the national umbrella organization, the American Medical Association (AMA) had existed since 1847, physicians were also organized under—and were often much more active within—state-level associations. See Starr, *American Medicine*, Chapter 3.
[37] Reed, *Birth Control Movement*, 174.

year after opening, Dr. Bocker counted 1208 women as having been consulted and treated at the Clinical Research Bureau.[38]

Sanger was evidently unimpressed by Bocker's work, however, and did not renew her contract after two years of medical direction.[39] Dr. Hannah Stone replaced her, and under her direction the CRB took a much more active role in engaging with the medical profession. Letters reflect extensive lobbying of the New York Academy of Medicine by both Sanger and Stone to encourage an official endorsement of the BCR's work from the institution.[40]

Between 1925 and the early 1930s, Sanger, Dickinson, and the New York Academy of Medicine were involved in a series of convoluted bureaucratic negotiations. In New York State, all clinics were required to obtain a license from the Board of Charities before operating. Both Sanger and Dickinson's clinics were denied licenses, but so long as the clinics were framed as research bureaus (literally, the word "clinic" could not appear in the title), medical work could continue to be conducted there.[41] Frustrated by the dismal results of the Committee of Maternal Health and concerned that he did not have enough data to present a compelling

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[38] Bocker, *Birth Control Methods*. The CMH's failure has been attributed to the clinic's requirement that only women who had been referred by a physician be treated. Dickinson imposed this requirement to respect that the clinic was in accordance with the law's provision that only very ill women receive birth control. Sanger's clinic, on the other hand, did not require a referral and was of course not as stringent on its interpretation of "sick" women.

[39] Bocker's removal from the CRB may have had something to do with Dickinson's influence. Dickinson, as head of the Committee on Maternal Health, made several visits to the CRB and reported that Bocker's research methods were inadequate and "lacked the proper scientific reserve." *Paper, Vol I*, 494 fn1.

[40] Sanger and Stone believed that if members of the New York Academy of Medicine would submit to a tour of the CRB, they would be convinced of its legitimacy. These letters reflect numerous invitations to—and subsequent refusals—of member physicians to pay the clinic a visit. See Letter to Dr. Linsly Williams from MS, June 3 1929, Letter to Dr. John A. Hartwell, June 17, 1929, and Letter to MS from Dr. Ira S. Wile, January 2, 1930, all Margaret Sanger Papers Microfilm Edition: Library of Congress Collection

[41] McCann, *Birth Control Politics*, 77.

report to the Academy, Dickinson, in 1925, contacted Sanger about the possibility of combining research efforts. Dickinson assured Sanger that if she allowed members of the New York Academy of Medicine to oversee the CRB, and if the clinic severed all ties with the American Birth Control League (ABCL), then the Board of Charities would cease their objections and authorize a license to establish a clinic not beholden to any research requirements. Sanger followed his advice, and the CRB broke from the American Birth Control League (ABCL) to become the Birth Control Clinical Research Bureau (BCCRB). According to Dickinson's proposal, five physicians from the former CRB's advisory board and five from that of the CMH would create the Maternity Research Council (MRC), and would oversee the BCCRB. This new clinic, for Sanger, meant more funding, an opportunity for birth control to gain legitimacy within the Academy of Medicine, and the potential to open more clinics across the United States if the MRC was successful. For Dickinson, the MRC was a chance to finally exercise complete medical control over birth control. The MRC never came to fruition, however. Dickinson still could not secure a license from the Board of Charities, and with criticism of both Sanger's CRB and Dickinson's CMH mounting within the Academy of Medicine, Sanger began to believe that the medical community was not ready to wholeheartedly take on a birth control clinic just yet. She ultimately backed out of the merger with Dickinson and continued to direct the BCCRB without his help, instead working to recruit gynecologists and obstetricians to work "as consultants and visiting physicians on our [BCCRB's] staff."[42]

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[42] Letter from MS to Adolf Meyer, December 12, 1929, Margaret Sanger Papers Microfilm Edition: Sophia Smith Collection.

Birth Control and the Law

It should be noted that, while Sanger devoted a significant amount of time to dialogues with members of the medical community, she also worked with various New York State and federal legislators to write bills that would effectively legalize birth control by amending the Comstock Laws. This lobbying was done by various national organizations called birth control leagues, which Sanger led. The first, the American Birth Control League (ABCL), was created in 1921 as a counter to Mary Ware Dennett's National Birth Control League (NBCL). Dennett was another actor in the birth control movement who was in constant competition with Sanger for recognition as *the* leader of the movement.[43] The ABCL consisted a network of state and local chapters of birth control leagues; by 1926 it counted 37,000 women as members.[44] The organization worked towards achieving various goals, including education, research and international promotion of birth control, but I focus here specifically on its legislative campaigns. Both the NBCL and ABCL sought to amend the Comstock Laws, but the groups differed in what specifically in the laws needed to be changed. Dennett's NBCL, and the Voluntary Parenthood League (VPL) that Dennett founded after the NBCL disbanded in 1919, sought legislation that would remove the words "materials for the prevention of conception" from the list of materials deemed obscene by federal law. This change would effectively make

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[43] That Sanger refused to ever cede power of the movement, whether to Dickinson or Dennett, was a terrific character flaw that probably led to unnecessary stalling within the movement on more than one occasion.

[44] The ABCL was fairly inactive and bureaucratically inefficient during this time. It would later become a major institution in 1942, under new leadership and a new name: Planned Parenthood Federation of America (PPFA), more commonly known simply as Planned Parenthood.

contraceptives and contraceptive information legally accessible to all women, regardless of whether a woman sought the help of a physician. Sanger and her biographers have called these proposed legislative changes "open bills."[45] The ABCL at first supported these "open bills," but as Sanger shifted the framing of her argument for birth control from an issue of free speech to a medical concern (especially after the 1918 Brownsville Clinic ruling), so too did the type of legislative amendment she supported change. Sanger's bills, called "doctors-only bills," addressed Section 1145 of the New York State Comstock Law. Sanger did not take issue with the law's provision that only physicians could prescribe birth control, and did not move to remove birth control from the list of obscene materials. Rather, she wanted to remove the words "for the cure or prevention of disease" from the law. Thus the law would read: "An article or instrument, used or applied by physicians lawfully practicing…is not an article of indecent or immoral nature or use." This reform would leave little question that birth control was solely to be controlled by physicians, as it would otherwise be considered illegal under the law. Removing the disease clause, however, would leave it to a physician to act in his own discretion as to when to provide contraception. Between 1917 and 1927, Sanger and the American Birth Control League (ABCL) were successful in finding three separate New York State legislators who introduced these "doctors-only" bills for a vote. None of them passed, however.

In 1928, Sanger resigned from the ABCL over a power struggle with another administrator. She remained, however, in control of the Clinical Research Bureau.

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[45] For more on the legislative efforts of the ABCL and VPL, see David M. Kennedy, *Birth Control in America*.

Now left to focus almost exclusively on lobbying both the medical community and Congress to openly endorse the medicalization of birth control, Sanger founded the National Committee on Federal Legislation for Birth Control (NCFLBC) in 1929, establishing state and regional chapters across the US, with headquarters in D.C. Members of the committee inundated legislators (at both the federal and state level) with mailings on the need for birth control. In D.C., Sanger and several other committee members visited individual Congressmen to explain the "doctors-only" bill they had drafted. Between 1930 and 1936, eleven "doctors-only" bills were introduced in Congress, sponsored by eight different Congressmen. Though some of these bills found their way on to the floor for debate, none were ever passed. Sanger would ultimately find success with the state not through legislative amendments, but with judicial review.

United States v. One Package of Pessaries

In 1933, Sanger ordered a case of pessaries from Japan with the intent that Dr. Stone would prescribe them to patients of the CRB. New York customs officials seized the package of pessaries, citing a violation of Section 305 of the Tariff Act of 1930, which stated, "All persons are prohibited from importing into the United States from any foreign country…any article whatever for the prevention of conception or for causing unlawful abortion." Stone filed a claim to have the pessaries returned to her, since she was a physician who intended to prescribe them to her patients as medically needed, as Section 1145 of the NYS Comstock law provided for. The case went before a judge in 1935. At the trial, various

gynecologists and obstetricians, including Robert Dickinson, testified that "to prevent disease and preserve life, it is often imperative that a contraceptive be prescribed." The court ruled in Stone's favor, but the government appealed the case. Judge Augustus N. Hand, in the 1936 appeals decision, upheld the original decision and, furthermore, delivered a ruling that proved monumental for the birth control movement. He wrote:

> It is true that in 1873, when the Comstock Act was passed, information now available as to the evils resulting in many cases from conception was most limited…Its [the Comstock Act's] design…was not to prevent the importation, sale or carriage by mail of things which might intelligently be employed by conscientious and competent physicians for the purpose of saving life or promoting the well-being of their patients.[46]

Effectively nullifying the importation ban on contraceptives, the ruling went on to question why a clause to allow physicians to act in "good faith" and prescribe birth control had been omitted from the original federal Comstock Bill. Hand ended by explaining that he hoped this new ruling, as it pertained to importations, would soon be applied to laws concerning mailings. In effect, Hand had set a major precedent in a move towards the legalization of birth control (at least when prescribed by doctors). Sanger was overjoyed at the results of the case. There was still ground to cover, however; while Judge Hand's ruling had indeed provided for the legal importation of birth control when ordered by physicians, there still had been no

[46] Decision by Augustus Hand, *U.S. v. One Package of Japanese Pessaries*, Circuit Court of Appeals 1936. The Margaret Sanger Papers (microfilmed), Sophia Smith Collection.

amendment to the federal Comstock Law.[47] Thus, without a pre-existing illness, physicians presumably had no reason to prescribe birth control.[48]

A Changing Tide within the AMA

U.S. v. One Package of Pessaries was evidently quite influential within the medical community, nonetheless. This was reflected in a major change in policy which was implemented soon after the 1936 ruling. Dickinson had been successful in convincing the American Medical Association (AMA) to investigate birth control by creating a Committee on Contraception in 1935 (one year before Judge Hand's decision). By this time, birth control had become a thriving lay market; James Reed estimates that Americans were spending $250 million on birth control products every year, with $200 million spent on douche powders, $38 million on condoms and $1 million on pessaries.[49] Birth control evidently promised great economic benefits in addition to its potential to extend the authority of the medical community.[50]

The Committee on Contraception (of which Dickinson himself was not a member) issued its first report in 1936, with disappointing results. The report, which appeared in *Journal of the American Medical Association*, effectively denied the existence of any truly effective birth control methods, saying "no contraceptive ethic other than actual continence is intrinsically 100 per cent safe." The report was also quite

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[47] It would not be until 1965, with Griswold v. Connecticut, that the last of the Comstock Laws would be nullified.
[48] While it did nothing to expand the definition of disease, by leaving the ultimate decision to prescribe in the hands of the physician, the report established "right to privacy" language that will become important in later birth control episodes.
[49] Reed, "Doctors, Birth Control and Social Values," in *Women and Health in America: Historical Readings* ed. Judith Waltzer Leavitt (Madison: University of Wisconsin Press, 1984) 132.
[50] The specialty of gynecology had also developed substantially by this point in history.

critical of laypeople's (such as Sanger) involvement in the research process.[51] Though the report was disappointing, the AMA voted to continue conducting research on birth control and would issue a new report the following year, to which Dickinson responded by supplying the Committee with myriad reports on the efficacy of various birth control methods.[52]

Between the issuance of the first and second reports, Judge Hand issued his influential ruling in *U.S. v. One Package*. It was in the wake of this ruling that the AMA Committee on Contraception issued its second report in February 1937. Its recommendations were a surprising contrast to the initial findings of 1936, and the report completely reversed the findings of the first report. The recommendations were as follows:

1. That the American Medical Association take such action as may be necessary to make clear to physicians their legal rights in relation to the use of contraceptives.
2. That the American Medical Association undertake the investigation of materials, devices and methods recommended or employed for the prevention of conception, with a view to determining physiologic, chemical and biologic properties and effects, and that the results of such investigations be published for the information of the medical profession.
3. That the Council on Medical Education and Hospitals of the American Medical Association be requested to promote thorough instruction in our medical schools with respect to the various factors pertaining to fertility and sterility, due attention being paid to their positive as well as to their negative aspects.[53]

In June of that year, the AMA voted to adopt all of the report's recommendations, effectively acknowledging birth control as being within the scope of the medical

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[51] American Medical Association (AMA), "Report of Reference Committee on Executive Session," *Journal of the American Medical Association*, 106 (1936): 1910-11.
[52] Reed, *The Birth Control Movement*.
[53] American Medical Association (AMA), "Report of Reference Committee on Executive Session," *Journal of the American Medical Association*, 108 (1937): 2217-18.

profession. Both Sanger and Dickinson certainly counted the AMA report as a success; Sanger so much so that she dissolved the National Committee on Federal Legislation, as she felt the organization's goals had been met.[54] The report did not, however, represent a *complete* realization of Sanger's goals, as it still outlined certain criteria to be assessed before a physician prescribed birth control. As guidelines to consider, the report suggested that physicians take "the patient's general health, the character of previous pregnancies…and *the incidence of inter-current* [sic] *illness* (emphasis added)" into account. Later the report said that physicians should be "free to give information concerning contraception when required to meet the *medical* needs of patients (emphasis added)."[55] Despite the caveat, the report was nonetheless an important step in the medicalization of birth control and, in turn, its acceptance into American society.

Conclusion

The AMA's 1937 report was a major milestone in the birth control movement. It effectively acknowledged that doctors had the authority to help women prevent pregnancy under certain circumstances. Furthermore, the report marked Sanger's success in medicalizing birth control without direct state intervention. Soon after this report, contraception began appearing in the curricula of medical schools; by 1940, 60% of approved medical schools provided instruction

[54] Letter from MS to Mrs. Anne Archbold, June 11, 1937. The Margaret Sanger Papers (microfilmed): Sophia Smith Collection.
[55] AMA, "Report," (1937).

on birth control techniques.[56] In 1942, the AMA endorsed this curriculum change, saying that physicians should be "taught the clinical considerations and therapeutic application of contraceptive methods."[57] By allying her cause with the medical profession, Sanger had successfully legitimized birth control without any direct state intervention. While Sanger did indeed rely upon several key judicial decisions, she had achieved her goals without amendment to the Comstock Laws.

The movement still had much ground to cover, however. Especially after Sanger retired from the movement in the early 1940s and the American Birth Control League was renamed as the Planned Parenthood Federation of America (PPFA), the movement changed its focus from convincing the medical profession to further embrace birth control to establishing a trans-national network of birth control clinics—clinics of which, though run by physicians (usually marginalized female doctors), professional medical groups were deeply critical.[58] These clinics, often located in urban centers, catered to women of a lower socio-economic status, which members of conservative medical organizations found unbecoming to the practice of medicine. Nevertheless, the stage had been set for the introduction of a distinctly medical birth control technology, the oral contraceptive pill, which would effectively catalyze physicians of even the most conservative professional medical groups to wholeheartedly embrace birth control.

Afterward

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[56] Lara Marks, *Sexual Chemistry: A History of the Contraceptive Pill* (New Haven: Yale University Press, 2001) 120.
[57] As qtd by Marks, *Sexual Chemistry*, 120.
[58] Joyce M. Ray and F. G. Gosling, "American Physicians and Birth Control, 1936-1947," *Journal of Social History* 18 (1985): 399-411.

In the movement to medicalize birth control, Sanger lost the support of some key feminists. Specifically, the National Birth Control League and Voluntary Parenthood League were outraged by Sanger's tactics, as they sought to make birth control information directly accessible to all women by asking for state intervention to directly repeal the Comstock Laws. Various Suffragettes, too, contacted Sanger to express their support for birth control itself, but not the means by which Sanger wanted to achieve its social acceptance.[59] These women were deeply concerned about the consequences of granting physicians sole authority over birth control. In a Letter to the Editor that appeared in the November 1930 issue of *Birth Control Review*, Caroline Nelson, a birth control activist who led a Birth Control League in California, explained her concerns:

> For the birth controllers to go to our legislative bodies to ask that the medical profession be appointed sole lawful guardian of the Birth Control knowledge is not only not good sense, but dangerous. Dangerous, because we do not know what the medical profession is going to do with this special privilege of handling this knowledge…[60]

Having observed similarly minded reform movements that had achieved results through the direct lobbying of the state, these fears were understandable. And these concerns over the medicalization of birth control would appear in a later episode of birth control, as we shall see. It was these exact concerns that later drew the state to intervene on medical authority over birth control in a major way.

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[59] See Letter from Mary Chapman Catt to Margaret Sanger, November 24, 1920, *Papers Vol I* 290-1.

[60] Caroline Nelson, "To The Editor," *Birth Control Review*, 14 (1930): 333. Nelson and Sanger had been in correspondence for many years about the direction of the birth control movement. See Letter from Caroline Nelson to MS, June 12, 1915, *Papers Vol. I* 136-140.

Chapter 2:
Risking Motherhood:
Pills, Politics, and Patient Package Inserts

Introduction

I now depart from the story of Margaret Sanger to examine another important episode in the history of birth control in America: the United States Food and Drug Administration (FDA)-approval of the first oral contraceptive, Enovid, in June of 1960.[1] The approval of this drug and the subsequent reaction of the medical community marked a major shift in attitudes towards birth control. Enovid, which was made accessible to women only through a doctor's prescription, helped to firmly establish birth control and pregnancy prevention as falling to the medical profession.

The episode of birth control history that we are about to examine differs thematically from the other two episodes addressed in this thesis. In this episode, there is a striking absence of any contention between competing interest groups over controlling access to birth control. Rather, this chapter explores how the FDA, through its ability to regulate the safety of contraceptive technologies, acted in a way that began to undo the medicalization of birth control. This chapter explains how the state first became invested in birth control and how it came to take up feminist demands for changes in birth control policy. This chapter thus does the work to lay the foundation for a later episode in birth control history in which the state further weakened medical authority over contraception, as it removed barriers to a birth control technology that allowed women greater ease in accessing it.

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[1] Oral contraceptives are hormone therapies taken by women to suppress ovulation.

The History of the FDA

By the time Enovid was first approved for contraceptive use in 1960, the FDA had greatly evolved since its inception as a regulatory agency. Indeed, in the episode of birth control history explained in Chapter 1 of this thesis, the FDA was never even mentioned (Sanger was advocating for the pessary, technically a medical device and thus not subject to FDA review at the time). The FDA was established in 1906, under the Pure Food and Drug Act, a law that was passed in part as a response to the public's disgust with the practices of the meat industry (Upton Sinclair's *The Jungle* has often been noted for bringing these practices to light). The law required food and drugs to be labeled with a list of ingredients, and to specify the amount of each ingredient used. As the government official responsible for championing the bill, Harvey Wiley (who first headed the agency), was most concerned with the public health issues contaminated food presented, the agency scrutinized the labels of foods much more heavily than those of drugs in the first few years; according to Peter Temin, only "135 of the first 1,000 judgments obtained under the 1906 law concerned drugs."[2]

The de-emphasis on drug regulation changed in the late 1930s as a result of the Elixir Sulfanilamide scandal. Elixir Sulfanilamide was a liquid version of an early antibacterial drug. The Elixir was introduced on the market in 1937, but was quickly discovered to be quite toxic to humans—the drug was linked to over 100 deaths. Even more frighteningly, it was soon realized that the FDA did not have the

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[2] Peter Temin, *Taking Your Medicine: Drug Regulation in the United States* (Cambridge: Harvard University Press, 1980) 32.

authority to prosecute the manufacturer, Massengill Co., for the deaths; it could only fine the company for mislabeling the drug. The resulting public outrage led Congress to include stricter drug regulations in the Food, Drug and Cosmetic Act (a bill which had been continually introduced on the House and Senate floor since 1933)—which finally passed in 1938. The new law, among other things, called for more stringent labeling requirements for drugs, more scrutiny of drug advertisements (for potentially false claims about the drug) and, most notably, required drug manufacturers to prove to the FDA that a drug was *safe* for use before introducing it to the market.[3]

This was the climate in which the FDA approved Enovid, first in 1957 as a treatment of gynecological disorders, and later in 1960 as an oral contraceptive. Shortly after the drug's approval, however, Congress instituted major legislative changes that greatly expanded the FDA's regulatory power (and that would also have an impact on later regulation of oral contraceptives). The Kefauver-Harris Drug Amendments, passed by Congress and signed into law by President John F. Kennedy on October 10th 1962, granted the agency broader regulatory power over the drug market. The amendments, which were passed in reaction to the thalidomide drug scare, now required drug manufacturers to prove that the drug in question was both safe for consumption and *effective* in treating its intended diseases.[4] The amendments also called for more stringent regulation of drug advertisements and required that manufacturers provide doctors with informational inserts about each drug's potential

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[3] Importantly, the law did not define "safety," and left it to FDA officials to judge. This would become important later during a controversy over oral contraceptives.

[4] Thalidomide was a drug that had been used by pregnant women in Europe to treat morning sickness that was soon discovered to cause terrific birth defects in the users' children. While the drug was never officially approved for use in the US, the photographs of these birth defects incited a public outrage and incited Congress to push through more stringent drug regulations.

side effects (although these inserts were intended for physicians and not passed on to patients). Once only a "policeman of safety," the Kefauver-Harris Amendments transformed the FDA "into an arbiter of value, quality, and success in scientific achievement."[5]

Consumer Rights

Around the same time the Kefauver-Harris Amendments were passed, American society saw the rise of a new consumer rights movement. This period was epitomized by such events as the proposal of the "Consumers' Bill of Rights" (proposed by President Kennedy in 1962), the publication of muckraker books such as Rachel Carson's 1962 book *Silent Spring* and Ralph Nader's *Unsafe at any Speed* in 1965 (in which both authors took a consumer-rights tone in their arguments for the regulation of specific industries), and a popularization of *Consumer Rights* magazine. The consumer rights movement represented a concerted demand among Americans for safer products and a heightened ability to exercise choice in the marketplace.[6] This "rights" rhetoric also appeared in more radical movements such as the Civil Rights movement and, later, the feminist movement.

The consumer rights movement and the FDA's newfound regulatory power would sharply converge in the late 1960s when the safety of oral contraceptives came under heavy scrutiny. Because of the drug's potentially fatal (but rare) side effects—thrombosis and thromboembolism—the FDA decided that all packages of oral

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[5] William J Curran, "Governmental Regulations of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies," *Daedalus* 98 (1969): 542-94, 542.
[6] For more on the consumer movement, see Lawrence B. Glickman, *Buying Power: A History of Consumer Activism in America* (Chicago and London: University of Chicago Press, 2009).

contraceptives were to be accompanied by a patient package insert (PPI) that explained all possible side effects of a drug.[7] The PPI was required in an effort to ensure that all OC-users could make an informed decision as to whether or not they considered the drug to be safe. It was this patient package insert that, I argue, marked the state handing back some authority over contraception to women.

Lara Marks has illuminated an important contrast between Great Britain and the United State's respective handling of oral contraceptives' side effects. The British government, in 1969, responded to reports of the link between thromboembolism and oral contraceptives by simply by prohibiting physicians from prescribing high-dose versions of oral contraceptives (which were believed to be linked to a higher incidence of thromboembolism), thereby removing them from the market. In contrast, the FDA chose not to impinge upon medical authority and ultimately left the decision of whether to prescribe high-dose oral contraceptives to physicians themselves (although the FDA did indeed have the power to remove the drug from the market if it had chosen to do so). This divergence in approach, Marks argues reflects just how profound the U.S.'s trust in the medical profession's authority over birth control had become.[8] I, of course, see the United State's policy in a different light, and I argue that the requirement of the patient package insert was actually emblematic of the state responding to feminists' demands.

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[7] Thrombosis refers to the development of a major blood clot in an artery or vein. Thrombosis can develop into thromboembolism if the clot comes loose at its original site and travels through the veins to another part of the body. Thromboembolism can be fatal if the clot blocks the blood flow of major arteries, or if the clot travels to the lungs (causing a pulmonary embolism) and blocks the flow of oxygen. I use "thrombosis" and "thromboembolism" interchangeably in this chapter.

[8] Lara Marks, "'Not Just a Statistic': the History of USA and UK Policy over Thrombotic Disease and the Oral Contraceptive Pill, 1960s-1970s," *Social Science and Medicine* 49 (1999): 1139-1155.

Let us now turn and examine the story of the development of oral contraceptives to understand how the state became involved in birth control and why it intervened on medical authority.

Development of Oral Contraceptives[9]

By the 1960s, Margaret Sanger had all but retired from the birth control movement. Having relocated to Tucson, Arizona in the early 1940s, Sanger left leadership of the new birth control organization Planned Parenthood Federation of America (PPFA) to a new generation of birth control advocates.[10] From her home in Tucson, Sanger orchestrated meetings between philanthropist Katherine McCormick (who would fund the project) and biologist Gregory Pincus (who, through a partnership with obstetrician John Rock, would eventually develop the first oral contraceptive). Beyond this networking role however, Sanger was largely uninvolved in the newly developing politics of birth control.

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[9] The story I tell here has been recounted in various ways by several historians, most notably in Lara Marks, *Sexual Chemistry: A History of the Contraceptive Pill* (New Haven: Yale University Press, 2001); Elizabeth Siegal Watkins, *On the Pill: A Social History of Oral Contraceptives, 1950-1970,* (Baltimore and London: Johns Hopkins University Press, 1998); and Andrea Tone, *Devices and Desires: A History of Contraceptives in America* (New York: Hill and Wang, 2001). Recent scholars have challenged this traditional narrative and have highlighted the more subtle contributions of numerous scientists. For this story, see Renee M. Courey's doctoral dissertation, "Participants in the Development, Marketing and Safety Evaluation of the Oral Contraceptive, 1950-1965: Mythic Dimensions of a Scientific Solution," (PhD diss., University of California at Berkeley, 1994). I tell the traditional narrative here because it sufficiently reveals the extent to which the state was involved in the development of oral contraceptives.

[10] PPFA, officially established in 1942, was the largest and best-organized version of the American Birth Control League (ABCL). For a history of the PPFA, see Carole McCann, *Birth Control Politics in the United States, 1916-1945* (Ithaca: Cornell University Press, 1994).

Sanger had been aware of the possibility of a form of contraception using sex hormones as early as 1912.[11] This belief was not wholly without precedent—scientists had isolated the two major hormones in female reproduction, estrogen and progesterone, in the 1920s and by the early 1940s had found a way to manufacture both hormones cheaply and quickly.[12] One of the first sex hormones to be widely marketed for use in women was DES, or diethylstilbestrol, a synthetic form of estrogen. DES was initially synthesized in 1938 and was simultaneously introduced on the market in 1941 by 12 pharmaceutical companies.[13] The drug was first labeled as a treatment for "gonorrheal vaginitis, senile vaginitis, and menopausal symptoms."[14] It was later approved to treat infertility. Physicians and researchers were greatly optimistic about the potentials of DES, and the drug was heavily tested as a treatment for various illnesses during the 1940s and 1950s.[15] Up to this point, however, no scientist had shown interest in studying DES (or any other synthetic version of estrogen, for that matter) for its potential as a contraceptive. Rather than lobby the state to research the matter, Sanger decided instead to seek out private

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[11] Renee M. Courey, "Development of the Oral Contraceptive."
[12] For more on the early testing and marketing of sex hormones, see Nelly Oudshoorn, *Beyond the Natural Body: An archeology of sex hormones* (London; Routledge, 1994).
[13] Roberta Apfel and Susan Fisher, *To Do No Harm: DES and the Dilemmas of Modern Medicine,* (New Haven and London: Yale University Press, 1984) 18.
[14] Ibid, 19.
[15] DES was later discovered to cause birth defects in the children of women who had taken the drug during pregnancy. Susan Bell has written an excellent study of the embodied health movement in which these children (later called DES daughters) have taken part. See *DES Daughters: Embodied Knowledge and The transformation of Women's Health Politics*, (Philadelphia: Temple University Press, 2009).

researchers who were willing to take on the project.[16] She found just the person in 1950, when she was introduced to Gregory Pincus.

Gregory Pincus

Gregory Pincus was a scientist with a background in reproductive physiology. During a professorship at Harvard University in the 1930s, he famously conducted some of the first studies of in-vitro fertilization using rabbits—attracting much attention from the press, where apprehensive references to Aldous Huxley's *Brave New World* abounded. Sanger approached Pincus in the early 1950s about the possibility of developing a hormonal contraceptive.[17] Pincus at this point had established the Worcester Foundation for Experimental Biology (WFEB) a private research facility where he continued his research, having been denied tenure at Harvard (a fact James Reed attributes to Pincus' Jewish background in a time when anti-Semitism was rampant within academia and the publicity his research had garnered in the press).[18] He quickly signed on to the project. Pincus had little in the way of financial support for the project, but luckily Sanger had been in touch with a private philanthropist, Katharine McCormick, who was interested in getting involved in the birth control movement.

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[16] Disease-specific research at the time was still largely dependent on private philanthropists and lay health organizations. This began to change when philanthropist Mary Lasker, head of what became the American Cancer Society in 1946, successfully lobbied the federally-funded National Research Council to fund the Society's research. The path for state-funded research on less conventional illnesses like pregnancy, however, had yet to be cleared and evidently Sanger was not interested in taking on this cause. For more on Lasker's work, see Angela Creager, "Mobilizing Biomedicine: Virus Research Between Lay Health Organizations and the US Federal Government, 1935-1955." In *Biomedicine in the Twentieth Century: Practices, Policies and Politics*, ed. Caroline Hannaway (Amsterdam: IOS Press, 2008).

[17] For a more detailed biography of Gregory Pincus, see Reed, *The Birth Control Movement,* Chapter 25.

[18] Reed, *The Birth Control Movement*, 320-21.

Katharine McCormick

McCormick was an extremely wealthy woman who had been active in the women's suffrage movement of the 1920s. Her husband was afflicted with schizophrenia and while he was alive she dedicated most of her funds towards research on his disease. After his death in 1947, however, she abruptly abandoned these projects and she got in contact with Margaret Sanger. Throughout nearly every step in the research on hormonal contraceptives, it was McCormick (not the state or pharmaceutical companies) who supported the work financially, beginning with a $50,000 grant in 1953, with the funding increasing exponentially as the work progressed.

At the WFEB, Pincus had conducted several large-scale animal trials in which he administered combinations of progesterone and estrogen. The resulting effect was a suppressed ovulation cycle in mammals. The ability to prevent a female's ovaries from releasing an egg promised amazing potential for the development of an effective contraceptive. The next logical step was to test the hormones in humans and see if it remained as successful. This is where John Rock, whose work Pincus had long been familiar with, entered the picture.

John Rock

John Rock provided the guidance of an active medical practitioner that was vital to the clinical research of oral contraceptives. Rock, an obstetrician, had been introduced to the birth control movement early in his career, having been a member of the American Medical Association (AMA)'s Committee on Contraception that issued the favorable report on birth control in 1937. Within the medical community,

Rock was widely recognized as a respectable physician due to his outwardly religious nature; his Catholic background would become a major focal point of the press after Enovid was introduced to the public in 1960. Rock, like Robert Dickinson, was very much interested in remedying issues in reproduction as a means of protecting and preserving marriage. Unlike Dickinson, however, Rock believed the key to the preservation of marriage was to help women bear children, rather than inhibit reproduction. He explained: "without children, a couple could hardly be a family."[19] In 1926 Rock became the director of the sterility clinic at Harvard's Free Hospital for Women, where he worked with infertile married women. During his tenure, Rock experimented with in-vitro fertilization (IVF), surgical "tubal reconstruction" to counter blocked fallopian tubes, and also tried to remedy male infertility.

At the same time, as biographers Margaret Marsh and Wanda Ronner explain, Rock believed that once a couple had achieved their ideal family size, "they should have access to a full range of contraceptive options."[20] Furthermore, Rock recognized the various hardships pregnancy could pose for a couple. He neatly compiled his views on childbearing and pregnancy in a book entitled *Voluntary Parenthood*, in which he explained:

> Fear of a family is one of the bitterest fruits of ignorance. This does not refer, of course, to quite legitimate apprehensions in those cases where pregnancy would be a menace to the health of the mother or where disease or congenital defects would threaten the children. More common today are the couples who think they have something of greater importance to do than

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[19] As qtd by Margaret Marsh and Wanda Ronner, *The Empty Cradle: Infertility in America from Colonial Times to the Present* (Baltimore and London: Johns Hopkins University Press, 1996) 173.
[20] Margaret Marsh and Wanda Ronner, *The Fertility Doctor: John Rock and the Reproductive Revolution* (Baltimore: Johns Hopkins University Press, 2008) 147.

> raise a family. Babies would prevent them from traveling or cut them off from the amusements to which they are accustomed…[21]

Rock also acknowledged that couples that truly could not afford a child should be afforded effective birth control methods. Thus it was a seemingly natural progression for Rock to move from infertility to contraception. The focus of his practice, however, remained helping women conceive, rather than preventing it, and he gained a major following of affluent, white women who were desperate to become pregnant.[22]

Rock had been testing the effects of combined progesterone and estrogen therapies on his infertile patients independently of Pincus since the early 1950s. In these experiments he noticed that after women used these hormones for a period of time they ultimately increased their fertility once they stopped the therapy. This novel effect became known as the "Rock rebound."[23] Pincus, who knew about Rock's reputable infertility clinic, invited Rock to join him in his experiments with hormone therapies; Rock agreed. The regimens to be tested were combinations of progesterone, estrogen and a steroid that had been found necessary in order to fully inhibit ovulation—without it, the therapy allowed ovulation about 15% of the time.[24]

Clinical Trials Begin

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[21] John Rock and David Loth, *Voluntary Parenthood* (New York: Random House, 1949), 9.
[22] Marsh Ronner, *The Empty Cradle*. In the post-World War II baby boom era, infertility came to be what Marsh and Ronner characterize as a "national preoccupation." This was a period when parenthood (for middle class, white couples) was an expected component of married life. As such, infertile couples often travelled many miles to get to the most prestigious infertility clinics at Duke University, Yale University, and Rock's own clinic at the Women's Free Hospital.
[23] Marsh and Ronner, *The Fertility Doctor,* 155.
[24] Elizabeth Siegel Watkins, *On the Pill: A Social History of Oral Contraceptives, 1950-1970* (Baltimore and London: Johns Hopkins University Press, 1998), 29.

The first trials were conducted in 1954 on 50 women at Rock's infertility clinic, with impressive results: ovulation was suppressed in all subjects (and furthermore, seven of the 50 women were able to become pregnant after stopping the therapy).[25] The following year, two trials were conducted using solely progesterone therapy to assess whether the hormone caused any major side effects were conducted: one on 23 female medical student volunteers at the University of Puerto Rico School of Medicine, the other, much more ethically questionable, on a total of 28 institutionalized women and men the Worcester State Hospital.[26] With wholly successful results in each of these trials, Rock and Pincus moved to conduct large-scale clinical testing of oral contraceptives. Puerto Rico was chosen as the test site and in April 1956, 100 volunteers were initially enrolled in the study. By November 1958, 830 women had participated in the study for at least one month (one ovulation cycle). The maximum amount of time a subject was allowed to take the therapy was "37 consecutive cycles," or about 3 years. The study was concluded in late 1959.[27] During the study, many women complained of side effects such as nausea, dizziness and headaches, side effects at which Pincus generally scoffed and discredited as "woman problems," but ultimately offered the women antacids and noted the effects in the final report of the trial.[28] Having achieved a near-perfect rate of ovulation suppression in the study with relatively minor side effects, Rock and Pincus were confident that they had developed a safe oral contraceptive that was

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[25] Andrea Tone, *Devices and Desires: A History of Contraceptives in America* (New York: Hill and Wang, 2001), 218.
[26] Why men were included in the trial is unclear.
[27] Watkins, *On the Pill,* 32.
[28] For more on the post-colonialist implications of this study see Annette Ramirez de Arellano, *Colonialism, Catholicism, and Contraception,* (Chapel Hill: University of North Carolina Press, 1983).

more effective at preventing pregnancy than the currently available methods of birth control. Rock and Pincus, having partnered with G.D. Searle Pharmaceuticals to market the pill, were confident that the drug was ready for American women.[29] The next and last step was to submit the drug for FDA approval.

FDA Approval

Searle had submitted a new drug application (NDA) for Enovid to the FDA in 1957 (several years the Puerto Rico trials concluded), for use as a treatment of dysmenorrheal, endometriosis, permenorrhea (various gynecological disorders) and infertility. That Searle first applied to market Enovid only as a treatment for gynecological disorders at first seems peculiar; the drug had already been proven as an effective contraceptive. Suzanne Junod and Lara Marks have explained that, when dealing with hormone drugs at least, this was standard practice among pharmaceutical companies. Pharmaceuticals often first submitted an NDA for a "narrow range" of indications before subsequently filing a supplemental new drug application (SNDA) for use as a treatment against a broader list of illnesses.[30] Indeed, as we saw earlier, DES underwent this exact approval process during the 1940s. The agency apparently approved the drug with little objection, as Searle had adequately proven that the drug was not fatal, that it did not "adversely affect the

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[29] Searle was known as an "ethical" pharmaceutical company, meaning it advertised its products directly to physicians rather than consumers (as a sign of respect for medical authority). The company's "ethical" status would be important in perpetuating the respectable image of Enovid, further severing birth control's ties to obscenity and immorality.
[30] Suzanne White Junod and Lara Marks, "Women's Trials: The Approval of the First Oral Contraceptive Pill in the United States and Great Britain," *Journal of the History of Medicine* 57 (2002): 117-60, 128.

reproductive system or the menstrual system," and that it did not render the woman permanently sterile.[31] By 1959 over 500,000 women were on the drug.

In December 1959, Searle submitted an SNDA to expand Enovid's labeling to include use as an oral contraceptive. It again appears as though the FDA approved the drug without much concern over potential public controversy; Junod and Marks write that FDA reviewers "saw it as no more than a routine bureaucratic process of new drug review."[32] Searle initially asked the FDA to simultaneously consider the safety of Enovid in doses of progestin in 10, 5, and 2.5 milligrams as part of one application (the FDA had approved the drug in 1957 only in doses of 10 milligrams). Lower doses of progestin had been noted for a higher incidence of breakthrough bleeding (bleeding during the ovulation cycle at times other than menstruation) however, and as some believed that this bleeding perhaps indicated that ovulation had not been suppressed, FDA officials were hesitant to consider doses other than those that had already been approved. Searle thus revised the SNDA and asked for approval of only the 10-milligram dose; a 5-milligram dose would be approved separately two years later.[33] The application was assigned for review by Dr. Jose deFelice, a recently certified obstetrician-gynecologist (Ob-gyn) and in addition to reviewing the 20 volumes of clinical trial data that Searle submitted, the FDA sent a survey to 75 Ob-gyns at various American medical schools asking their thoughts on Enovid's potential safety as a contraceptive. Their responses were largely optimistic, although some raised concerns about the potential

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[31] Ibid 32.
[32] Ibid 129.
[33] This decision became important later, when it was discovered that higher dose formulas of Enovid was linked to rare, but sometimes fatal cases of thromboembolism.

teratogenic effects (birth defects) of the drug in pregnant women. Some physicians wrote that their patients had reported side effects similar to those noted during the Puerto Rico clinical trials such as headaches, cramps, nausea and breakthrough bleeding. Furthermore, questions were raised as to the overall long-term safety of the drug; Enovid, unlike most drugs of the time, was to be taken daily for prolonged periods of time by otherwise-healthy women. As the initial clinical trials had not been conducted to measure the long-term effects of the drug (no woman in the trial had taken the drug consistently for more than three years), FDA officials decided to limit the amount of time a woman was allowed to take Enovid to two years (this requirement was later dropped in 1966). The final approval of the SNDA was issued on June 23, 1960.[34] That the FDA approved Enovid despite reports of adverse side effects (although more dangerous side effects such as thromboembolism had yet to be observed) indicated that the state had weighed these effects against the potential dangers of pregnancy, and had found the side effects to be less risky than pregnancy itself. The FDA's approval of Enovid marked the institutionalization of medical authority over birth control within the state, as physicians were now the sole mediators of access to the drug.

An Evolved Image of Birth Control

Immediately after its introduction to the market, oral contraception was widely embraced by American women; Elizabeth Siegel Watkins writes that, by 1965, 6.5 million (married) women were using it—making the Pill, as it became commonly

[34] Junod and Marks, "Women's Trials."

known—the most popular form of birth control.[35] Its introduction to the public marked the beginning of an evolution in the power dynamic between a female patient and her doctor; for the first time, it was women who were diagnosing the issue (a desire to prevent unwanted pregnancy) and asking for the prescription without the prompting of a physician. The physician simply wrote the prescription and generally asked the patient to come back for biannual follow-ups (when he would renew the prescription).

With the approval of oral contraceptives, the FDA effectively moved birth control to the private clinical practice. Although the American Medical Association (AMA) had, in 1937, technically acknowledged birth control as a practice requiring the intervention of the medical community, women still primarily accessed pessaries (now known as diaphragms) via public clinics, especially those clinics that were part of the Planned Parenthood Federation of America (PPFA) network; According to James Reed, before oral contraception was introduced, less than 20% of contraceptive-seeking women obtained birth control from private physicians.[36] Now with the Pill, doctors could offer a "much-sought-after service that commanded good fees, lent the prestige of science to the general practitioner, and involved none of the awkwardness of diaphragm fitting."[37]

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[35] Watkins, *On the Pill,* 34. Unmarried women are excluded from this statistic because the most comprehensive study of the time, conducted by Princeton University's Office of Population Research, did not account for them. See Norman Ryder and Charles Westoff, *Reproduction in the United States, 1965* (Princeton: Princeton University Press, 1971).
[36] While physicians did indeed oversee these clinics, it was generally not a very lucrative position and was usually filled by marginalized physicians (like women). Many middle-class, white women (many of whom later embraced the Pill) were disdainful of these clinics, as they viewed them as being intended for poor minorities.
[37] Reed, *The Birth Control Movement,* 364-5.

Enovid was just one milestone in the extension of the medical profession's gaze over reproductive health. In addition to the new field of infertility that had emerged by this time, the act of childbirth had now been moved from the private home to the hospital setting. Judith Waltzer Leavitt has written that, by 1950, 88% of childbirths occurred in the hospital, and by 1960, "it was unheard of" for women to deliver outside of this venue.[38] Clearly obstetricians and gynecologists had become major authorities over many aspects of women's reproductive health and with Enovid (and all subsequent brands of oral contraceptives), they were now the gatekeepers to contraception.

This gatekeeper relationship did not evolve by chance. G.D. Searle explicitly encouraged doctors to use Enovid as a means of ensuring regular contact with female patients. One Searle newsletter encouraged its salesmen (known at the time as detail men and now more commonly known as drug representatives) to assure a physician that "Enovid is…His drug; control of his patient on a month-to-month basis if he desires…Making the role of the physician assume greater importance in family planning."[39] Enovid took out ads in major medical journals and circulated reports on the drug labeled "For the Medical Profession Only," in which the company promised that the drug was "as safe as the normal state of pregnancy."[40]

This is not to say that doctors forced Enovid on patients. Indeed, from nearly every angle, the Pill was hailed as a "wonder drug." Immediately after its

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[38] Judith Waltzer Leavitt, *Brought to Bed: Childbearing in America 1750 to 1950* (New York and Oxford: Oxford University Press, 1977) 171.
[39] As qtd by Watkins, *On the Pill*, 36. This shift in language from "birth control" to a more unassuming "family planning" further added to the respectability of the Pill.
[40] Ibid 38. Recall that Searle was an "ethical" pharmaceutical house, and thus did not advertise to patients directly.

approval, popular media widely praised the arrival of this new technology, with stories about the drug appearing in women's magazines, major newspapers, and science journals alike. Articles appeared telling the triumphant story of Pincus and Rock, who had joined forces "in the interest of progress."[41] Women's magazines ran stories explaining the way in which the Pill worked inside the body to help readers understand the new technology. It seemed that nearly every media outlet from the *New York Times* to *Playboy* gave the Pill praise for one reason or another.[42] And as the numbers reflect, women themselves responded quite positively to the new technology.

Backlash Against the Pill

As we have just seen, the Pill in its first years on the market was widely embraced by both women and doctors. Enthusiasm for the new drug began to wane, however, as reports of major side effects began to make news. The first major adverse effect was reported in the British journal *Lancet* in November 1961.[43] A physician there reported that a female patient had developed a severe blood clot (thromboembolism) after going on the pill. Physicians in the United States began to note these side effects at the same time—by 1962, 26 cases of thromboembolism in oral contraceptive-users had been reported to the FDA, six of them fatal.[44] The agency responded quickly; in August 1962, it asked Searle to issue to a "Dear

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[41] Ibid, 42.
[42] Ibid, 42.
[43] G.D. Searle introduced Enavid (same chemical formula as the American Enovid) in Britain around the same time as in the United States.
[44] Lara Marks, "'Not Just a Statistic."

Doctor" letter to about 275,000 physicians, explaining the recent reports of a possible link between Enovid and thromboembolism.[45] The letter asked doctors to report any observations of adverse side effect in their Pill-users to the FDA.[46] It was initially difficult to discern first, whether oral contraceptives were indeed the true cause of these episodes (as thromboembolism is itself a rare disease that is linked to a variety of causes), and second, whether thromboembolism was linked to a particular brand or dosage of oral contraception.

In January 1963, the FDA convened an ad-hoc advisory committee to further investigate the side effects of oral contraceptives.[47] Using death reports that had been submitted to the agency and to Searle, as well as clinical records of Ob-gyns and Planned Parenthood centers, the report concluded that, while there was a slightly elevated death rate from thromboembolism among users of Enovid, the statistical evidence was ultimately inconclusive. The committee recommended further study of the issue, citing that there had been problems in reporting and documenting cases of thromboembolism. Meanwhile, concerns of other possible side effects of oral contraceptives had been raised in both medical journals and popular media, including fears that the Pill was linked to breast cancer, cervical cancer, and strokes.

In the wake of these concerns, the FDA assembled its first permanent advisory committee in 1965—the Advisory Committee on Obstetrics and

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[45] This was the exact moment when the state was receiving reports about the teratagonic effects of thalidomide in Europe. The FDA was thus probably on heightened alert for potential adverse side effects of drugs, especially those like oral contraceptives, whose long-term effects the agency had already acknowledged were unclear.
[46] FDA Advisory Committee on Obstetrics and Gynecology, "Report on the Oral Contraceptives," Washington DC: U.S. Department of Health, Education, and Welfare, 1966.
[47] By 1965, seven different pharmaceutical companies had introduced their own version of the Pill on the market.

Gynecology (all FDA advisory committees hitherto had been ad hoc)—which was assigned to investigate the various side effects of oral contraceptives. On the issue of thromboembolism, the committee conducted a retrospective epidemiological study comparing the deaths in Pill-users versus non-Pill-users.[48] The report again found that the data was too inconclusive to make a judgment either way and called for further investigation of the issue.[49] In its research on oral contraceptives' carcinogenic effects, the report was again inconclusive, this time citing the fact that cancers generally take at least ten years after carcinogenic exposure to appear, a time that had not yet lapsed for Pill-users.[50] Ultimately, in addition to the recommendations that studies of the drug continue and that better data be collected on cases of thromboembolism, the report concluded by, in essence, deferring to medical authority and asking physicians to use their best judgment when prescribing the pill. It stated:

> Each physician must evaluate the advantages and the risks of this method of contraception in comparison with other available methods or with no contraception at all. He can do this wisely only when there is presented to him dispassionate scientific knowledge of the available data.[51]

As an interim solution, the FDA asked Pill manufacturers to amend the drug's label to ask doctors to encourage their patients to quickly report any symptoms such as "persistent headache…leg pain or swelling, chest pain, change in vision, etc." It was

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[48] For a greater explanation of all the types of studies conducted on the side effects of oral contraceptives, see Lara Marks, "Not Just a Statistic."
[49] FDA, "Report on the Oral Contraceptives."
[50] Ibid 7.
[51] Ibid 13.

not necessary, the FDA decided, to require doctors to inform women that the drug was linked to thrombosis, as the reports had not yet led officials to this conclusion.[52]

At the same time, officials in Britain were investigating the side effects of oral contraceptives. British scientists had first found what they believed to be conclusive evidence of a link between oral contraceptives and thromboembolism in 1964. By 1967, the Committee on Safety of Drugs (CSD), the British drug regulatory agency, had gone so far as to identify particular brands and dosages of oral contraceptives that increased rates of thromboembolism.[53] The final report came in 1969, in which the authors concluded that a married oral contraceptive-user had a risk of hospitalization due to thromboembolism that was 6.3 times that of a nonuser.[54] The study also noted that versions of the Pill with higher doses of estrogen led to an even higher risk of thromboembolism. In response to these reports and mounting pressure from the media, the chairman of the Committee on Safety of Drugs (CSD) in late 1969 publicly recommended that physicians only prescribe versions of the Pill that contained 5 mg or less of estrogen; only four of the twenty-one types of oral contraceptives on the market at that time met this requirement.[55]

Concurrent to British scientists' research, Dr. Richard Sartwell, a professor at the Johns Hopkins Medical School and a member of the FDA Advisory Committee on Obstetrics and Gynecology, had in 1965 initiated a large-scale retrospective study

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[52] As qtd by Suzanne White Junod, "Women over 35 Who Smoke: A Case Study in Risk Management and Risk Communications, 1960-1989." In *Medicating Modern America: Prescription Drugs in History*, eds. Andrea Tone and Elizabeth Siegal Watkins (New York and London: New York University Press, 2007), 102.
[53] Marks, "Not Just a Statistic," 1146.
[54] Food and Drug Administration (FDA), "Second Report on the Oral Contraceptives," Washington DC: Department of Health, Education, and Welfare, 1969. Why the authors restricted their study to married women is unclear.
[55] Marks, "Not Just a Statistic," 1149.

reviewing the case histories of and conducting interviews with former thromboembolism patients of 43 hospitals spanning five cities. The study (known as the Sartwell Report) ended in 1968 and concluded that users of the Pill had an elevated risk of thromboembolism that was 4.4 times that of a non-user. It also noted that oral contraceptives with higher doses of estrogen further increased this risk. In light of these British studies, and after having been informed of the imminent results of Sartwell's report, FDA Commissioner James L. Goddard issued a "Dear Doctor" letter on June 28, 1968 to physicians explaining the new findings.[56] Goddard also explained that manufacturers would again be required to modify the labeling of OC products, this time to explain the positive link between oral contraceptives and thromboembolism.

On August 1, 1969, the FDA Committee on Obstetrics and Gynecology issued its "Second Report on the Oral Contraceptives," which presented comprehensive studies of various potential side effects. The Sartwell Report was included as the major study of thromboembolism. On the issue of carcinogenic potential, the report's authors still could not draw any conclusions, and none of the other studies included had reflected any other potential side effects. As thromboembolism was dangerous, but rare, and the Pill was not linked to cancer, the report reached a conclusion similar to that of the 1966 report—but with one minor but important change, as Elizabeth Siegal Watkins has noted. The report read: "Both the physician *and the layman* must evaluate the risks of hormonal contraceptives…They can do so wisely only when they have access to all available

[56] Junod, "Women over 35 Who Smoke."

information, accurately and dispassionately presented" (emphasis by Watkins).[57] Setting the stage for later debates about the drug's safety, The FDA was now calling for the patient herself to be included in this risk/benefit evaluation. Now the question remained: How would the FDA ensure that each woman was provided enough information to adequately make such an assessment? The answer to this question ultimately came from the combined efforts of the FDA and Congress.

The Pill, Consumer Rights and the Women's Health Movement

By the time the FDA's "Second Report on the Oral Contraceptives" was issued in 1969, the American public had become increasingly frustrated with the FDA's seeming inability to produce a conclusive answer concerning a potentially fatal drug that, by that time, 8.5 million women were taking every day. The Pill's potential side effects, especially thromboembolism and cancer, had become a recurring topic within popular media; Elizabeth Siegal Watkins notes that—by 1966—stories on the medical controversy had appeared on the front page of the *New York Times* and in several editions of the *Washington Post* as well as the *Saturday Evening Post*, *Redbook*, *McCall's* and *Ladies' Home Journal*.[58] Barbara Seaman's book, *The Doctor's Case Against the Pill* (published in September 1969, but completed before the second FDA report was released), has often been cited as *the* piece of journalism that spurred Congress to action.[59] Seaman, who was not actually a trained physician, was a health columnist for *Ladies' Home Journal* and *Brides* magazine. During her tenure, she received

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[57] As qtd by Watkins, *On the Pill,* 95.
[58] Watkins, *On the Pill,* 84-86.
[59] Watkins, *On the Pill*; Lara Marks, *Sexual Chemistry;* Linda Gordon, *Women's Body, Women's Right.*

numerous letters from women who believed they were experiencing adverse side effects as a result of the Pill, but whose physicians refused to take their complaints seriously. Seaman decided to investigate the issue further, and her research culminated in *The Doctor's Case Against the Pill*.[60] Seaman's book, which included extensive interviews with both physicians and Pill-users themselves, took a consumer-rights tone in its accusations that pharmaceutical companies had purposely withheld information about the drug from physicians, and that doctors were not adequately informing their patients about the Pill's potential side effects. She wrote that, "for the vast majority" of American women, the act of taking the Pill was "an act of *uninformed* consent" (emphasis in original).[61] While she strongly encouraged readers to consider alternative birth control methods, Seaman did not ultimately recommend that all women stop using the Pill. Rather, she encouraged women to critically consider the risks of oral contraceptives in light of the evidence she had compiled in the book.[62]

This book appeared at a moment when a new movement was gaining momentum among women. This movement, known now as the women's health movement, was comprised of feminist activists who had grown frustrated with what they considered to be the paternalism of American medicine. They were critical of how "medicalized" women's bodily experiences had become, and argued for a

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[60] "The Book that Brought Consumer Advocacy to the Medical System: Barbara Seaman's The Doctors' Case Against the Pill," *Healthfacts* September 1995.
[61] Barbara Seaman, *The Doctor's Case Against the Pill* (New York: Peter H. Wyden, Inc, 1969) 5.
[62] Ibid.

"return" of the female body from doctors to women.[63] To counter this overly medicalized experience, this period saw the popularization of gynecological self-help books, a resurfacing of midwifery, and the rise of feminist-run health clinics. In this framework, a demand that women be more informed of the potential risks of the Pill fell directly in line with the broader rhetoric of the movement—and Seaman's book certainly served to further motivate the campaign.

The demands of the women's health movement, at least with respect to oral contraceptives, did not go unnoticed. In 1969, Gaylord Nelson, a United States Senator and Chair of the Senate Subcommittee on Monopoly, decided to take on the issue of oral contraception safety as part of an ongoing series of Senatorial hearings. The purpose of addressing the Pill in these hearings, according to Nelson was "to explore the question of whether users of birth control pills are being adequately informed concerning the pill's known health hazards."[64] It was in these hearings that issues of informed consent and how to properly convey the risks of the Pill to women came to the forefront.

The Nelson Hearings

The Hearings on Competitive Problems in the Drug Industry, known more commonly as the Nelson Hearings, were a series of Senatorial hearings led by Senator Gaylord Nelson that spanned across two decades. As the name implies, these

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[63] For more on the women's health movement, see Sheryl Burt Ruzek, *The Women's Health Movement: Feminist Alternatives to Medical Control* (New York: Praeger Publishers, 1978).
[64] Gaylord Nelson, "Present Status of Competition in the Pharmaceutical Industry: Oral Contraceptives," Hearings before the Subcommittee on Monopoly of the Select Committee on Small Busniess, U.S. Senate, 91st Congress: 2nd Session, January 14, 1970.

hearings, which began in May 1967, served as a major investigation into the ethics of various pharmaceutical practices. In his opening remarks at the first hearing, Nelson explained that as the drug market had proven itself to be inelastic to supply and demand trends—that is, despite major increases in a given drug's price, demand remained relatively constant—the state now needed to investigate ways in which to bring costs down.[65] The hearings, which continued to convene periodically until the late 1980s, addressed such matters as price variations of certain drugs across state lines, unethical ties between pharmaceutical companies and the medical profession, and issues in pharmaceutical-sponsored clinical research. The hearings did not address problems unique to specific drugs until November 1967, when the committee turned its attention to chloramphenicol.

Chloramphenicol was an antibiotic that had been on the market since 1950. While it was widely hailed as a "wonder drug" (as it seemed to cure everything from typhoid to meningitis to high fevers to acne), it was also found to cause rare but fatal side effects, leaving the state in a conundrum as to how to proceed.[66] As the drug had been proven to have amazing therapeutic potential, there was strong motivation to allow it to remain on the market—despite its possibly fatal effects. In 1952 the FDA required manufacturers to modify the drug's labeling to encourage doctors to use the drug only as a last resort. Despite this relabeling, reports of chloramphenicol-related fatalities continued to frequently appear in news reports—it

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[65] Gaylord Nelson, Statement during Hearings before the Subcommittee on Monopoly, U.S. Senate, 90th Congress, 1st Session, May 15, 1967. With the state's recent passage of both Medicare and Medicaid in 1965, the state now had a direct interest in controlling the costs of prescription drugs.

[66] For a detailed history of chloramphenicol in the United States, see Thomas Maeder, *Adverse Reactions* (New York: William Morrow and Company, Inc, 1994).

appeared that the FDA's actions had been ineffective in curbing doctors' prescribing habits. Senator Nelson decided to take on the issue during his hearings in November 1967. While little change occurred in the way the FDA, the publicity the Nelson hearings received (they were televised and widely broadcasted) was effective in greatly lowering the demand for chloramphenicol.

The Nelson Hearings and Oral Contraceptives

When the committee took on the oral contraception (OC) controversy in 1970, its members recognized that, like chloramphenicol, the meaning of OC "safety" was relative to each user's experience. Chloramphenicol was deemed safe only when all other therapies had failed and the patient's condition would be fatal without treatment. In the case of oral contraceptives, however, whether there was a life-threatening disease that the drug cured was of course relative to how pregnancy was perceived. Dr. Roy Hertz, a physician who had led the Task Force on Carcinogens as part of the FDA Advisory Committee's report on oral contraceptives, explained it neatly when he stated at the hearings: "…The problem with respect to the oral contraceptives about the evaluation [of safety] is whether or not an unwanted pregnancy constitutes a preexisting pathological state. This is a definition which we have neither socially nor medically come to any grips with."[67] Somewhat prophetically, Hertz added:

> It is difficult to make the kind of balance of "risk against benefit" that you have made with respect to a potent drug such as chloramphenicol, and I think that what we are now seeing is the evolution of our social and medical values,

[67] Roy Hertz, Statement during Hearings before the Subcommittee on Monopoly, U.S. Senate, U.S. Senate, 91st Congress: 2nd Session, January 15, 1970.

> weighing all of the potential methodologies such as intrauterine devices and other traditional contraceptive agents, legalized abortion, and innumerable medical procedures…which will in the end evolve a population practice which will become socially acceptable.[68]

When the FDA approved Enovid in 1960 for use as a contraceptive, the agency had weighed the safety of the drug against relatively minor side effects such as headaches and nausea (side effects fairly common to other drugs on the market at the time). When compared to other existing birth control methods on the market (namely: diaphragms and condoms), oral contraceptives had a higher efficacy rate of preventing unwanted pregnancy, and were thus the safest method of birth control the state had encountered thus far. With the appearance of potentially fatal side effects like thromboembolism and fears about the drug's carcinogenic potential both having emerged after the drug was approved, however, the safety of oral contraception became much more difficult to assess. Moreover, by this point in time another birth control technology, the intrauterine device (IUD), had appeared on the market and, while not nearly as popular as the Pill, was seemingly just as effective at preventing pregnancy and thus presented as a comparable, safer alternative to oral contraceptives.[69]

Several different solutions to the oral contraception problem were considered during the hearings. The proposals included: (1) imposing a five-year moratorium on the sale of oral contraceptives until further research had been conducted; (2) limiting

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[68] Ibid. During the hearings, several feminist activists purposely disrupted the proceedings in protest of the fact that, of all the experts invited to speak, only one was a woman (a female physician). These women were angry that Nelson would not allow any laywomen to speak and present their personal experiences with the Pill. This is a contrast to another hearing we will encounter in Chapter 3, in which several laywomen were allowed to present experiential evidence about another birth control technology.

[69] Ironically, one brand of IUD, the Dalkon Shield, was later found to cause severe side effects in its users.

the instances in which OC could be prescribed (only when all other methods proved ineffective); (3) encouraging doctors to prescribe the latest birth control technology, the intrauterine device (IUD); (4) removing higher dose versions of OC from the market (which had been shown to lead to a higher incidence of adverse side effects); and (5) completely removing all oral contraceptives from the market. Ultimately, the issue was resolved by FDA Commissioner Charles C. Edwards, who announced during the last day of hearings that the FDA would immediately require all oral contraceptives to be accompanied by a patient package insert (PPI) explaining the "the potential dangers of the pill and the risks involved."[70] Senator Nelson had introduced legislation on the Senate floor the day before that would in effect impose the same regulation, as he was uncertain if such a mandate was within the regulatory power of the FDA. Edwards assured him, however, that the FDA did indeed have this authority, saying that the patient package insert was necessary to ensure the "safe use of the drug."[71] He went on to say: "The action we must take now, immediately…is to help inform the 8.5 million American women now taking oral contraceptives of the risk involved."[72] The day after the hearings, the *New York Times* published a copy of the proposed pamphlet, entitled "What You Should Know About Birth Control Pills." The pamphlet, which was 600 words long, explained "in lay language" the various risks of the Pill. The pamphlet also encouraged women to

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[70] Charles C. Edwards, Statement during Hearings before the Subcommittee on Monopoly, U.S. Senate, 91st Congress, 2nd Session, March 4, 1970.
[71] Ibid.
[72] Ibid.

seek the advice of their physician at several different points, clearly trying to appease the medical community's apprehension of the PPI.[73]

This was the first time in FDA history that a patient package insert had ever been called for. While all drugs were required to be accompanied by a packet that explained their side effects, these packets were intended for the physician and were not extended to patients. Never had drug companies been mandated to provide this information directly to the patient (it was always understood that physicians were the best authority to assess and interpret the side effects and judge whether the therapy was safe for the patient). By mandating that all women be provided a minimum amount of information about the drug, the FDA was moving beyond its reliance upon doctors to communicate the risks of the Pill and was instead communicating this information directly to patients. It was through this action that the state granted women some important authority over birth control to allow them to privately decide whether or not the drug's risks were worth the benefit of preventing pregnancy.

Reaction to the Patient Package Insert

Feminist activists and members of the burgeoning women's health movement responded positively to the requirement of the patient package insert (PPI). According to Lara Marks, many women activists "saw patient package inserts as an empowering device that would enable women to make more informed decisions on their own without being totally dependent on doctors."[74] In this respect, the Congressional hearings and Senator Nelson's inquiry into whether or not the risks of

[73] Watkins, *On the Pill*, 121.
[74] Marks, "Not just a statistic," 1150.

the Pill were being adequately conveyed to consumers represented an alliance between the state and feminist interests (although activists did not acknowledge it at the time and were instead critical of the seemingly paternalist nature of the hearings).

The American Medical Association (AMA), in contrast, was not nearly so enthusiastic. In 1970, the organization issued a resolution officially condemning the PPI, "on the grounds that it would confuse and alarm many patients."[75] In an editorial that appeared in the *Journal of the American Medical Association*, one author wrote:

> In his [the physician's] judgment, he simply doesn't want the patient to be additionally stressed by receiving a litany of possible adverse reactions…In his experience and judgment, such a PPI would cause more harm than benefit to the patient.[76]

Physicians clearly saw the patient package insert as a profound infringement upon clinical authority. Because of political stalling on the part of the AMA and the Pharmaceutical Manufacturers Association (PMA)—organizations who, according to Suzanne White Junod, went so far as to claim that the PPI was an "illegal intrusion into the practice of medicine"—a patient package insert as informative as that which was published in the *New York Times* only finally appeared in the late 1970s.[77] In the interim, the FDA asked the AMA to mail physicians "modified" patient package inserts to hand out to their patients when prescribing the Pill, contradicting the essence of the package insert, which was of course to convey information directly to the patient. Feminist activists were outraged at this compromise, and many

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[75] As qtd by Marks, "Not Just a Statistic," 1150.
[76] F. Gilbert McMahon, "Editorial: The Patient Package Insert," *Journal of the American Medical Association* 233 (1975): 1089.
[77] Junod, "Women Over 35 Who Smoke," 105.

submitted petitions to the Department of Health, Education and Welfare (DHEW) (the department that oversees the FDA and which later became known as the Department of Health and Human Services) explaining their frustration. Some even staged sit-ins at the DHEW Commissioner's office.[78] Another compromise was brokered, requiring a short insert to be included with packages of oral contraceptives. This insert briefly explained that thromboembolism had been linked to the Pill, and instructed the reader to seek out an 800-word booklet (written by the FDA, the AMA and the ACOG) from her physician if she desired more information. This compromise marked another nebulous balance between respecting physician authority and patient autonomy. It was only in 1978 that the PPI was sufficiently updated to include extensive information about the potential side effects of the drug and was likely in line with what both Senator Nelson and feminist activists had originally envisioned when the PPI was initially proposed.[79]

Conclusion

The decision to include a patient package insert (PPI) was ultimately only a modest solution to the problem posed by oral contraception and its potentially harmful side effects. It was far from the extreme measures that Britain imposed, in which the state removed the most harmful types of the Pill from the market. The FDA's decision was quite novel, however, when we consider its implications for the

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[78] Watkins, *On the Pill*, 122.

[79] Ibid 128. Watkins explains that this decision was made not because of continued feminist activism, but to remain consistent with a precedent the FDA had set a year prior, when it required that women receive an informational packet about the risks of estrogen before undergoing hormone replacement therapy.

issue of how to assess the safety of pregnancy. The state was not prepared to make the decision as to how dangerous pregnancy was in comparison to the potentially fatal side effects of the Pill. Thus the state here was asking women to make their own assessment of what pregnancy meant to them. To make this assessment, the FDA needed to ensure that women were informed of all the risks the drug presented; this is where the patient package insert (PPI) entered. As Senator Nelson said: "It is important that women be informed about all aspects of the use of the pill so that they are able to make an intelligent, personal decision about their use."[80] By offering women the patient package insert the state had thus begun to unravel medical authority over contraception. It would further this unraveling in a major way in the next episode that we shall examine.

Afterward:
Setting the Stage for the Abortion Debate

The Catholic Church was perhaps the only American institution that did not wholly embrace the Pill upon its initial introduction in 1960. The Church, historically always opposed to all forms of contraception beyond the rhythm method, held little influence during the story of oral contraceptives we just encountered; indeed, as a result of the Vatican's 1968 *Humanae Vitae*, which condemned oral contraceptives as contrary to Church doctrine (in addition to nearly all other forms of birth control), the American Church lost a significant number of parishioners. Because the Church had lost such ground among the laity, however, clergymen would take on the next

[80] Gaylord Nelson, Statement during Hearings before the Subcommittee on Monopoly, U.S. Senate, 91st Congress, 2nd Session, January 14, 1970.

debate in reproductive health—abortion—in a much more forceful way, in part as a way to regain followers.[81] Indeed, it is because of the Catholic Church that the antiabortion movement (a movement whose politics we will become relevant in Chapter 3) gained momentum and quickly became one of the largest conservative movements in America to date.

[81] Linda Gordon, *The Moral Property of Women: A History of Birth Control Politics in America* (Chicago: University of Chicago Press, 2002) 303.

Chapter 3:
The Triumph of Choice:
The Fight for Emergency Contraception

Introduction

I now move to the third and most recent episode in birth control history: the campaign for and FDA-approval of the Plan B Pill, a form of emergency contraception (EC). Emergency contraception refers to a type of birth control employed after sexual intercourse.[1] It is not generally recommended as a primary method of birth control as it is not as effective at preventing pregnancy as other contraceptive methods like oral contraception or condoms are, but is intended for use when other birth control methods have failed or have not been used (hence the name "emergency").[2] While other birth control technologies have appeared on the market since the FDA approved oral contraceptives in 1960 (such as the intrauterine device (IUD), and the Depo-Provera injection), I focus here on emergency contraception because of the unique state intervention that occurred in response to various activist campaigns (that will be explained later in this chapter). The FDA first approved Plan B in 1997 as a prescription drug and later in 2006 as a behind-the-

[1] The most common type of emergency contraception (and the type I focus on in this chapter) appears in the form of a pill and contains active hormones similar to those found in oral contraceptives. The insertion of an intrauterine device (IUD) has also been found to be an effective method of EC, but is not a commonly employed method and thus I do not address it here.

[2] Emergency contraceptives are about 89% effective in preventing pregnancy. Oral contraceptives and condoms, when used correctly, are nearly 100% effective.

counter (BTC) drug, making it the only form of birth control (besides condoms) available to women without a prescription.[3]

In Chapter 2, we explored a birth control technology—the Pill—that was wholly emblematic of what Margaret Sanger had worked to achieve in Chapter 1 of this thesis: the firm assertion of birth control as a distinctly medical issue. This medicalization led to broader access to and use of birth control, as women now sought out prescriptions for the Pill in large numbers, and doctors obliged. Physicians, having once only quietly acknowledged birth control's legitimacy during the episode of birth control history explored in Chapter 1, now largely embraced their role as mediating women's ability to access contraception.

When the state required that all packages of oral contraceptives be accompanied by a patient package insert (PPI) explaining the possible safety risks of the drug directly to women, this mediator role was modified—somewhat. Through this PPI intervention, the FDA was effectively inviting women to partake in the risk/benefit assessment of oral contraceptives and use this assessment to determine whether or not the risks of an unplanned pregnancy outweighed the risks of the drug. The PPI was the state's solution to a need to balance high market demand for the Pill with the reality of the drug's rare, but potentially fatal, side effects. While doctors still maintained their prescribing power over the Pill, the imposition of the PPI signaled that they were no longer the sole authority over pregnancy.

[3] Behind-the-counter, as will be explained later in this chapter, refers to an instance in which a drug is technically available without a prescription, but it is kept behind the pharmacist's counter and is only available by request.

In this final episode, we shall explore the events that, I argue, mark the further unraveling of medical authority over birth control. By making Plan B available to women without a doctor's prescription, the FDA was now enabling women to access birth control and prevent pregnancy without first consulting a physician. Women in this case thus became the sole authority over their choice to employ contraception. Even more importantly, we shall see that, rather than resist this change, the medical community was widely supportive of changing the drug's status to over-the-counter (despite the implications this change had for their medical authority). Regardless of the support from nearly every angle for this change in authority over the drug, Plan B still became a deeply contested issue. In this chapter, I will examine the alliance between feminists and doctors that developed in a campaign to increase access to Plan B, the events that led to the drug's politicized nature, and the eventual FDA decision to make Plan B available without a physician's prescription.

Historical Framework

To understand why emergency contraception (EC) became such a controversial topic, we must first understand the political climate in which the drug was introduced. As we shall see, the Plan B pill, despite its contraceptive (not abortifacient) ability, became deeply embroiled in the impassioned discourse on abortion in America.

Until a few years before the 1973 Supreme Court Case *Roe v. Wade*, laws against abortions had remained unchanged since we last encountered them in

Chapter 1. In most states, abortions were illegal except when the pregnancy was a result of rape or incest, or when a physician deemed the procedure necessary to protect the woman's health. Perhaps a Margaret Sanger-esque movement to expand access to abortion—in which activists circumvented state intervention and encouraged doctors to broadly interpret this "protect a woman's health" clause—could have developed, if it had not been for the imposition of yet another impediment to obtaining the procedure: the existence in many hospitals of multi-member abortion boards (implemented in the 1940s and 1950s) that reviewed—and often rejected—a physician's recommendation for abortion. Thus abortions for American women were generally quite difficult to obtain.

Things began to change in the mid-1960s, as movement for the reform and/or repeal of these abortion laws began in several states—a movement that emerged as part of a broader feminist movement of the time. A central demand in this second wave of feminism was that women be granted greater "control over [their] own bodies."[4] Activists in this movement demanded access to abortions and contraception (technologies offering women greater control over their reproduction) in order to guarantee a woman's right to personhood and to allow them to enter the workforce alongside men. This rhetoric marked a major break from past women-led movements for reform. No longer were women demanding reforms as means to help women to be better mothers like we saw in Chapter 1—indeed, recall that protecting motherhood was one of Margaret Sanger's major claims for birth control.

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[4] Carol S. Weisman, *Women's Health Care: Activist Traditions and Institutional Change* (Baltimore and London: Johns Hopkins Press, 1998) 297.

Rather, the feminist movement of the late 1960s demanded reforms that would enable women to choose when and if to become mothers.

Importantly, many physicians joined feminists in the movement to reform abortion legislation (what later became known as the pro-choice movement). That feminists and physicians became aligned in a movement to broaden access to a reproductive technology is in itself far from a novel phenomenon; indeed, as has been the contention of this thesis, doctors and feminists have often forged alliances—albeit alliances that were at times strained and tenuous—as they worked to serve their respective professional or social interests. What is unique about the alliance presented in the pro-choice movement, however, is that now the doctor/feminist alliance was one that was "based on a feminist common denominator," as Linda Gordon has written.[5] Rather than appeal to the allure of increased medical authority as a compromise to gain support for a reproductive technology, feminists were now open in their desire for access to abortion to serve their own goals of controlling reproduction. And physicians, as a community, supported this goal and—especially after *Roe v. Wade*—adopted feminists' rhetoric. "Women's rights, equality, and opportunity" became the underlying themes of the pro-choice movement.[6] This concerted demand in the name of feminist goals would importantly reappear during the campaign for emergency contraception.

As a counter to abortion reform movements, antiabortion campaigns quickly assembled in the late 1960s. Especially active in the early years of the movement was

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[5] Linda Gordon, *The Moral Property of Women: A History of Birth Control Politics in America* (Urbana and Chicago: University of Illinois Press, 2002) 297.
[6] Ibid 297.

the Catholic Church. The Catholic Church's authority over issues such as divorce and contraceptives had greatly declined during the 1960s and thus Church leaders decided to take on abortion in part to reassert their authority in American society. Ideologically, the Catholic Church was opposed to abortion since it was contrary to the theological doctrine to protect and preserve life. Unlike contraceptives—an issue in which there was much contention among clergymen as to whether or not the technology was acceptable according to Church doctrine—there was little, if any, debate within the Church about the morality of abortion. As states began repealing or reforming their laws against abortion (by the time the Supreme Court handed down *Roe v. Wade* in 1973, 17 had decriminalized the procedure) the Catholic Church started to establish "Right to Life" committees intended to develop a rhetoric and strategy for a countermovement.

Earlier antiabortion activists of the 19th century had spurned women for being "selfish" and rejecting their motherly duty. By the 1970s, of course, this rhetoric was no longer viable, as by this point women had entered the workforce in large numbers and had achieved many milestones in working towards social equality (Title IX, measures in affirmative action, etc). The new campaign, as the Catholic Church ingeniously developed it, employed feminist activists' own "rights" rhetoric by advocating for the full rights of the woman's unborn child (hence the name "Right to Life").

Coinciding with a revival of religious evangelism, many Protestants joined the antiabortion movement in large numbers especially in the wake of *Roe v. Wade*. In building the New Right political coalition, the Republican Party identified members

of the Right to Life movement as a potentially monumental voting block. Republicans successfully adopted their concerns into the party's platform and identified these "Right to Life-ers" as important Republican constituents. By the late 1970s abortion was firmly rooted as one of the most divisive issues in America.

Abortion, Contested Motherhood, and Promiscuity

Various stereotypes of the Right to Life movement have emerged in popular media today. Indeed, as some extremists in the movement have been known to zealously picket abortion clinics, harass patients, and at times, even murder physicians who offer abortion services, it is easy to discredit the movement as radical and fanatical. It is important, however, to move beyond the extremist images with which we have been inundated and look to the ideological underpinnings of the movement in order to understand how it relates to emergency contraception. Kristin Luker, in trying to account for the significant number of women who have joined the Right to Life movement, has interpreted the Right to Life movement to be a "referendum on the place and meaning of motherhood."[7] Luker sees the movement as a reaction from women whose views on motherhood—that it is indeed the social role of women—were loudly rejected by second-wave feminism. The Right to Life movement for these women then, is not so much about a desire to protect the life of

[7] Kristin Luker, *Abortion and the Politics of Motherhood* (Berkeley: University of California Press, 1984) 193.

a potential child but to preserve and insulate the traditional family hierarchy; they are more aptly described as being "pro-family" than pro-life.[8]

As we have seen, anxieties about the de-valorization of motherhood are often linked to fears about abortion's implications for promiscuity and permissive sexuality—and abortion was no exception. Indeed, this fear has resonated among lawmakers, who have imposed restrictions on the ability of minors to obtain abortions by requiring parental notification and, in some cases, consent.

These fears about sexual promiscuity became relevant to emergency contraception as well. Indeed, while opponents often framed their arguments within a paradigm of safety and efficacy in order to resonate with the FDA, at the heart of these concerns was a fear of the drug's implication for promiscuity. With the Pill, any concerns over the drug's implications for promiscuity were quelled, since doctors served as firm gatekeepers to the drug. Without a doctor to mediate a woman's access to Plan B, however, who was to say who could and could not employ this technology? By making birth control available to women without a doctor's intervention, what was stopping children from engaging in promiscuity from a very young age? These questions have been pervasive throughout the Right to Life's rhetoric against emergency contraception, and as we shall see, these questions became the underlying cause for opposition to the technology's over-the-counter

[8] Adding to this contested motherhood, post-*Roe v. Wade* America also saw the introduction of various reproductive technologies such as in-vitro fertilization (IVF), sperm donation, and surrogate motherhood. These technologies, while not oppositional to reproduction, give new meanings to motherhood—ones that threaten this previously insulated tradition. See Gordon, *The Moral Property of Women.*

status. Let us now turn to the events that led to the development of emergency contraception in order to understand the debates drug that ensued over the drug.

Conceiving Emergency Contraception

In 1974, Canadian gynecologist Albert Yuzpe published the results of a study of the efficacy of a combination of ethinyl-estradiol and *dl*-norgestrel hormones (the active hormones in oral contraceptives) for use in post-coital contraception. In the study, Yuzpe treated 143 women who had been "exposed to pregnancy" in the preceding five days with a very specific regimen of these pills.[9] Of these women, only three became pregnant, or 2.4%. Yuzpe explained that this rate was similar to that achieved by the only other drug known to work as an emergency contraceptive, diethylstilbestrol (DES).[10] This use of hormones for post-coital contraception came to be known as the Yuzpe method.[11] Although the Yuzpe method was announced in 1974, it was not until 1998 that a dedicated emergency contraceptive product (that is, a product that is expressly approved by the FDA to be labeled and marketed as an effective therapy for preventing pregnancy post-coitus) was introduced in the United States.

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[9] Yuzpe found his sample by treating eligible women at the health clinic of the University of Western Ontario.

[10] DES, as explained in Chapter 2, was a drug approved in the 1940s for the treatment of various gynecological disorders. Studies of the DES' emergency contraceptive-ability appeared in the early 1970s—the exact moment when the FDA announced that the drug caused severe side effects in the offspring of its users. Thus, while it became known around several college campuses and hospitals that it could be used as a post-coital contraceptive, DES never gained much popularity as an emergency contraceptive, nor was it subject to a large-scale activist campaign, and is thus not addressed in this chapter.

[11] Albert Yuzpe et al., "Post Coital Contraception – A Pilot Study," *The Journal of Reproductive Medicine* 13 (1974): 53-58.

This conspicuous lapse of time between the announcement of an effective regimen of emergency contraceptives and introduction of a marketable product for approval to the FDA has been attributed to a fear among pharmaceutical companies of potential public backlash over the drug's side effects on a scale similar to that of oral contraceptives.[12] Largely because of this fear, there was a sharp decline in the research and development (R&D) in any new contraceptive technologies subsequent to the FDA's approval of oral contraceptives. In 1970, there were 13 pharmaceutical companies (nine based in the United States) investing in contraceptive R&D, but by 1987, that number had declined to four, with only one company that was based in the United States. Furthermore, by 1989, no U.S.-based company was manufacturing progestin or estrogen; it was all produced abroad.[13] This fear of backlash among US-based pharmaceutical companies should not be underestimated. The drama of the 1970 Nelson Hearings, the birth defects of DES, and the highly politicized debate over abortion were all well publicized issues that caused pharmaceutical company to think twice about investing in contraceptive technologies.

Despite the lack of a dedicated product, American physicians could still prescribe oral contraceptives for off-label use to be used for post-coital emergency contraception.[14] According to a 1982 FDA Drug Bulletin:

> Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not

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[12] Carl Djerassi, "The Bitter Pill," *Science* 245 (1989): 356-61.
[13] Ibid.
[14] "Off-label" use refers to an instance in which a physician prescribes a drug to treat an illness other than what the FDA approved it for. It is a common and legal practice. According to the Food Drug and Cosmetic Act, drug manufacturers are only prohibited from publicly advertising a drug's off-label use. Another example of an off-label use of oral contraceptives is the prescription of the drug to treat moderate acne in women.

> included in approved labeling. Such… 'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.[15]

And indeed, physicians on several college campuses and in some hospitals were aware of the Yuzpe method and willingly prescribed it. Without a dedicated product approved by the FDA, however, pharmaceutical companies could not advertise this technically off-label use of oral contraceptives and by and large both doctors and women remained unaware that such a thing as emergency contraception existed.

A Modern Margaret Sanger

Dr. Felicia Stewart, a long-time women's health advocate and physician who served as an advisor on family planning issues in the Clinton Administration, was one of the first people to publicly advocate for awareness campaigns that would increase the public knowledge about the existence of emergency contraception. Dr. Stewart, who passed away on April 13, 2006, has been dubbed the "mother of emergency contraception," and can be likened to a modern-day Margaret Sanger.[16] Stewart, like Sanger, aimed to alert women about the existence of birth control—specifically: emergency contraceptives—and to help them understand how to properly employ available methods. Unlike Sanger, Stewart herself was a member of the medical profession, having graduated from Harvard Medical School in 1969 (one of the first classes that included women). Moreover, Stewart was practicing medicine at a time when the alliance between the medical profession and feminist activists was now

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[15] U.S. Food and Drug Administration (FDA), "Use of Approved Drugs for Unlabeled Indications," *Drug Bulletin* (1982): 4-5.
[16] Patricia Sullivan, "Felicia H. Stewart; Fostered Debut of 'Morning-After Pill'," *The Washington Post*, April 16, 2006.

thoroughly entrenched as a common coalition for reform. Taking a cue from the "success" of the HIV/AIDS movement in the 1980s, women activists were especially triumphant in uniting with the medical profession to advocate for a renewed interest in breast cancer research.[17] As Sheryl Burt Ruzek and Julie Becker explain, the women's health movement by this point had evolved from its more radical beginnings in the 1970s to a sort of "professionalization" of health activism.[18] In this regard, Stewart was but one of many to take on an activist role as both a feminist and a physician.[19]

After graduating from medical school, Stewart went into private practice as a gynecologist and shortly thereafter, she became the Associate Medical Director for Planned Parenthood of Sacramento Valley, California. Stewart was dedicated to educating both patients and physicians about reproduction and all available options in birth control and had been teaching her patients about emergency contraception since the 1970s. In 1969, she, along with several colleagues, began publishing *Contraceptive Technology*, a comprehensive book that explained all available birth control methods. The book has subsequently been updated every two years and is currently

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[17] I employ scare quotes with regards to the success of the AIDS movement because recent scholarship has reflected the ways in which lay health activists in this campaign championed an AIDS therapy that ultimately turned out to be ineffective. See Steven Epstein, "Activism, Drug Regulation, and the Politics of Therapeutic Evaluation in the AIDS Era," *Social Studies of Science*, 27 (1995): 691-726. For more on the breast cancer movement, see Shobita Parthasarathy, *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care* (Cambridge and London: The MIT Press, 2007).

[18] Sheryl Burt Ruzek and Julie Becker, "The Women's Health Movement in the United States: From Grassroots Activism to Professional Agendas," *Journal of the American Medical Women's Association* 54 (1999): 4-8.

[19] In the story of emergency contraception activism, there have been numerous actors of all backgrounds, genders, and classes. I focus here on Felicia Stewart's story because she was a pioneer for the movement from its inception.

in its 19th edition; it has long been regarded as the best medical guide on the subject.[20] A few years after the Yuzpe method was introduced, Stewart included a chapter entitled "Morning-After Birth Control" in her 1979 book, *My Body My Health: The Concerned Woman's Guide to Gynecology*. The chapter explained that the FDA was currently considering the possibility of using high doses of diethylstilbestrol (DES), as a morning-after contraceptive.[21] In addition to *My Body My Health*, Stewart in 1987 coauthored a monumental 899-page guide entitled *Understanding Your Body: Everywoman's Guide to a Lifetime of Health*, where, as the name implies, the authors offered advice on such topics as "insuring a successful working relationship with your clinician," "surviving a pelvic exam," "factors to consider as you choose an abortion clinic," and "do-it-yourself PMS care." The book also includes a chapter entitled "Morning-After Birth Control," in which the authors, having now discarded DES as a possible therapy (reflecting the recent discovery of the drug's teratagonic effects), and explains how to use a specific brand of oral contraceptives, Ovral, as emergency contraception.[22] Stewart was evidently a firm believer that educating patients about their bodies was an important component of women's health.

A Movement for Change

Stewart grew increasingly frustrated that, for the most part, neither women nor their physicians were aware that oral contraceptives could be used as post-coital

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[20] Sullivan, "Felicia H. Stewart."
[21] Felicia Stewart et al, *My Body, My Health: The Concerned Woman's Guide to Gynecology* (New York: John Wiley & Sons, Inc, 1979).
[22] Felicia Stewart et al, *Understanding Your Body: Every Woman's Guide to a Lifetime of Health* (Toronto and New York: Bantam Books, 1987).

emergency contraception (EC). The need for some sort of awareness campaign was clear; a 1994 Kaiser Family Foundation study revealed that only about one-third of American women had ever heard of emergency contraception, and only 1% had ever used the method.[23] Stewart became committed to educating the public on the existence of EC. In 1992, she and Dr. James Trussell, an economics professor and Director of the Office of Population Research at Princeton University, as well as a fellow emergency contraception activist, published two articles which appeared an issue of the journal *Family Planning Perspectives*. The publication of these articles has been widely cited as having sparked the first full-fledged activist campaign for emergency contraception awareness.[24] The first article, "The Effectiveness of Postcoital Hormonal Contraception," was in essence a literature review of all clinical trials that had been conducted to test the safety and efficacy of emergency contraception.[25] In the second article, "Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies," the authors introduced the term "emergency contraceptive pills"[26] and argued that increased access to EC would ultimately decrease the number of abortions women sought.[27] To increase access,

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[23] As qtd by Delbanco et al, "Are We Making Progress With Emergency Contraception? Recent Findings on American Adults and Health Professionals," *Journal of the American Medical Women's Association (JAMWA)* 53 (1998): 242-46.
[24] Francine Coeytaux and Barbara Pillsbury, "Bringing Emergency Contraception to American Women: The History and Remaining Challenges," *Women's Health Issues* 11 (2001): 80-86; James Trussell et al, "Call 1-888-NOT-2-LATE: Promoting Emergency Contraception in the United States," *JAMWA* 53 (1998): 247-250; Sullivan, "Felicia H. Stewart."
[25] James Trussell and Felicia Stewart, "The Effectiveness of Postcoital Hormonal Contraception," *Family Planning Perspectives* 24 (1992): 262-4.
[26] Previously, the method had been known as "morning-after contraception," a term that incorrectly implied the method was ineffective unless used immediately after sex—recall that EC had been proven to be up to 89% effective if taken within 72 hours after unprotected sex.
[27] The argument that emergency contraception ultimately helps prevent abortions is useful for gaining support for the drug from antiabortionists. This rhetoric is ultimately quite damaging for

the authors recommended: that physicians provide their patients with a pack of oral contraceptives along with directions on proper dosages to be stored in case of an incidence of unplanned, unprotected sex, and, importantly, that the FDA consider making oral contraceptives available as an over-the-counter (OTC) product instead of prescription-only.[28] The authors evidently did not yet believe that there was a need for a single dedicated product, and instead focused on promoting oral contraceptives for off-label use as emergency contraception. That same year, Stewart partnered with the nonprofit group Reproductive Health Technologies Project (RHTP) to lead a task force in determining ways to better educate the public about the existence of EC.[29] From this task force emerged poster and literature campaigns with titles such as "Back up your Birth Control" and "After the Fact, After the Act."[30] In 1995, Trussell, Stewart and several other authors published the phone numbers and addresses of 1,477 willing emergency contraceptive providers in the U.S., and in 1996, a national hotline was launched (1-888-NOT-2-LATE) that a woman could call to find the information of the closest EC providers to her zip code.[31]

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the pro-choice movement, however, as it implies that abortion is itself an undesirable or shameful procedure.

[28] James Trussell and Felicia Stewart, "Emergency Contraceptive Pills: A Simple Proposal to Reduce Unintended Pregnancies," *Family Planning Perspectives* 24 (1992): 269-273.

[29] RHTP was established in 1988 to promote FDA approval of mifepristone, a reproductive technology that induces an abortion in women up to nine weeks after conception.

[30] For more on these campaigns, see James Trussell et al, "Call 1-888-NOT-2-LATE."

[31] James Trussell et al, *Emergency Contraception: The Nation's Best Kept Secret.* It soon became clear that this book would require constant updating if it were to remain relevant. To remedy this, a website (www.not-2-late.com) was launched where a woman could enter her zip code and receive directions to the closest EC providers. The site, which as of this writing is still active, also includes literature and educational materials about emergency contraception. It is peer-reviewed by various physicians and academics including James Trussell and, until her death, Felicia Stewart.

The State and the Profession Respond

Activists in the movement soon began to lobby the state directly in their quest to increase access to emergency contraception. In November 1994, the Center for Reproductive Law and Policy (a US-based nonprofit that later became known as the Center for Reproductive Rights) filed a citizen petition to the FDA asking the agency to modify the labeling of packages of oral contraceptives to include instructions on how to use the pills for emergency contraception. The FDA denied the petition (why it was initially denied is unclear) but asked the Advisory Committee for Reproductive Health Drugs to convene and review the safety and efficacy of oral contraceptives when used as emergency contraception (EC). The committee, after reviewing the extensive literature and clinical trials on EC (including studies written by Felicia Stewart and James Trussell), unanimously concluded in June 1996 that oral contraceptives were indeed both safe and effective for EC use. Then-FDA Commissioner David Kessler agreed with the committee's conclusions, but maintained that this use of hormones actually constituted a new drug, rather than a new use of oral contraceptives.[32] Thus, rather than modify the labeling, Kessler decided that emergency contraception could not be FDA-approved until another

[32] Kessler was probably working from prior precedent in this decision. When DES was first noted as an effective emergency contraceptive, the FDA in 1971 allowed manufacturers to change the labeling to reflect the drug's EC-capability, so long as the labeling included a warning that the therapy was only for use in "extreme" cases like rape or incest. Evidently this warning was not heeded, however, as explanations on how to use the drug for post-coital contraception began appearing in several gynecology self-help guides and in college health center pamphlets. In response, the FDA announced two years later that if manufacturers wanted to market DES as a general post-coital contraceptive, the companies would need to submit new packaging and labeling applications for the drug. See FDA, "Diethylstilbestrol as Posticoital Oral Contraceptive; Patient Labeling," *Federal Register* 40 (1971): 5451-5.

new drug application had been submitted (NDA) for a drug explicitly labeled and marketed as an emergency contraceptive. This did not end the FDA's interest in emergency contraception. Indeed, in a February 25, 1997 issue of the *Federal Register* (FR),[33] the FDA called for new drug applications (NDAs) from pharmaceutical companies, saying, "this notice is intended to encourage manufacturers to make this additional contraceptive option available."[34] The notice went on to explain the findings of the FDA Advisory Committee, and cited numerous studies that had properly evaluated the safety and efficacy of various oral contraceptives. It concluded by providing a list of various brands of available oral contraceptives and their proper drug regimens for emergency contraception, as Figure 1 shows:

Figure 1: *Federal Register* List of Oral Contraceptive Brands and EC Doses

Brand Name	Pill Color	Number of pills to swallow within 72 hours after unprotected sex	Number of pills to swallow 12 hours later
Ovral	white	2	2
Lo/Ovral	white	4	4
Nordette	light orange	4	4
Levlen	light orange	4	4
Triphasil	yellow	4	4
Tri-Levlen	yellow	4	4

Source: Food and Drug Administration (FDA), "Prescription Drug Products: Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception," *Federal Register* 62 (1997): 8612.

Despite the FDA's refusal to change the labeling of oral contraceptive, this FR was still a landmark event, as it was published as a result of petitioning on the part of the general public, not pharmaceutical companies. Furthermore, this FR indicated that

[33] *Federal Register* is a daily publication that chronicles all proposed changed in government agencies.
[34] US Food and Drug Administration (FDA), " Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception," *Federal Register* 62 (1997): 8610-2.

manufacturers of oral contraceptives would not be required to submit any additional clinical research before the FDA would approve it for emergency contraceptive use.[35] In effect the FDA was granting approval for a drug that did not exist yet as a dedicated product.

Around the same time, groups within the medical profession also took on assessments of emergency contraception. In October 1996 (several months after the FDA advisory committee had issued its assessment of EC) the American College of Obstetricians and Gynecologists (ACOG) issued a Practice Pattern that explained in detail how to properly prescribe oral contraceptives for EC use (providing a list that was identical to that which appeared in the *Federal Register*).[36] It also explained the possible side effects, the efficacy rates, and other relevant information for physicians to provide to their patients when prescribing the method.[37] Pharmaceutical companies, having now received approval from the FDA, responded quickly; the first EC, Preven, produced by Gynétics, was approved for prescription use in September 1998. Preven was about 75% effective in preventing pregnancy up to 72 hours after intercourse.[38] In 1999, the FDA also approved the progestin-only EC known as Plan B.[39]

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[35] Suzanne Delbanco et al, "Little Knowledge and Limited Practice."
[36] A Practice Pattern is a statement issued by an organized medical group (such as ACOG) to inform its clinicians of changes in clinical practice based on new scientific research or technological advancements.
[37] American College of Obstetrics and Gynecology (ACOG), "Emergency Oral Contraception Practice Pattern," *International Journal of Gynecology and Obstetrics* 56 (1997): 203-210.
[38] L.L. Wynn and James Trussell, "The Social Life of Emergency Contraception in the United States: Disciplining Pharmaceutical Use, Disciplining Sexuality, and Constructing Zygotic Bodies," *Medical Anthropology Quarterly* 20 (2006): 297-320.
[39] Barr Laboratories later acquired the rights to both Preven and Plan B, and took Preven off the market, as Plan B had a higher efficacy rate and lower incidence of side effects. The noted side effects of emergency contraception included headaches, nausea, and vomitimg. As of this

Impediments to Plan B Efficacy

While the introduction and FDA approval of these products was a major achievement for the emergency contraception movement, the drug's prescription-only status posed several issues, since there was a time factor involved in the efficacy of the drug. First, there was the problem of what a woman should do if she needed the drug after normal business hours. According to the American Medical Women's Association (AMWA), 50% of women who sought emergency contraception did so either on a weekend or after 6pm, when "it may have been difficult to contact their regular reproductive health care provider."[40] Women who did not have ready access to a physician also encountered issues accessing the drug; according to the AMWA, 18% of these women seeking Plan B after business hours did not have a primary care provider to begin with. Finally, on ideological grounds, some pharmacies, including Wal Mart, refused to stock the drug, thus limiting the sources where a woman could obtain the drug even after seeking out a prescription.[41]

In light of these barriers, activists soon shifted their focus to finding a mode of distribution that would decrease the amount of time that a woman needed to wait before she could access the drug (thus maximizing efficacy). Several proposals were explored including: (1) pre-emptive provision of a prescription on the part of a health care provider during routine exams, (2) a national hotline where physicians could call

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writing, no potentially fatal side effects such as thromboembolism or cancers have been discovered.

[40] American Medical Women's Association (AMWA), "Emergency Contraception Position Paper," 1996.

[41] Ibid.

in a prescription to the nearest pharmacy after speaking with a woman, and (3) training pharmacists to properly prescribe EC without a doctor's prescription. While the feasibility of all these proposals was assessed at least once in various studies, the idea that seemed the most promising was the proposal to make EC available over-the-counter (OTC), removing the need to first seek out a prescription or any other medical intervention.[42] Making Plan B available without a prescription would have the greatest impact for *all* women, not just those who could afford a visit to a physician's office.

In February 2001, the Center for Reproductive Law and Policy submitted another citizen petition to the FDA, now requesting that the status of both Preven and Plan B be changed to over-the-counter. Among the co-signers of the FDA citizen petition were American Medical Women's Association, the American Academy of Pediatrics, the American Public Health Association and Planned Parenthood Federation of America.[43] In April 2003, Women's Capital Corporation, the manufacturer of Plan B, formally submitted a supplemental new drug application (SNDA) making this same request. Three years later, in August 2006, the FDA approved Plan B as an over-the-counter drug for women aged 18 and older; women under the age of 18 would still only be able to access the drug with a doctor's prescription.

The Approval Process Becomes Politicized

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[42] For an explanation of each of these pilot projects, see Coeytaux and Pillsbury, "Bringing Emergency Contraception to American Women."
[43] For the full list of co-signers, see Appendix A.

To understand how the FDA arrived at this seemingly peculiar decision to allow women aged 18 and older to access Plan B over-the-counter—while still maintaining the drug's prescription-only status for those under 18, we must examine the various events that occurred between the time when Women's Capital Corporation's submitted the SNDA in 2003 and the FDA's 2006 decision. I will first explain the standard chain of events that occurs when the FDA receives an application to change a drug from prescription-only to over-the-counter (OTC).

The FDA outlined the process by which a drug can be considered for OTC status in the 1951 Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act. The amendment also outlined the criteria for a drug to be made available over-the-counter. To be made OTC, the FDA must determine:

> …if the product has an acceptable safety margin…whether it has low misuse and abuse potential, a reasonable therapeutic index of safety, whether the condition it is being used for can be adequately self-recognized and self-treated, and when the product is used under nonprescription conditions, is it safe and effective?[44]

To request a status change for a "first-in-a-class" drug (which Plan B was designated), the drug's manufacturer must submit a supplemental new drug application (SNDA) to the Center for Drug Evaluation and Research (CDER).[45] There are six offices in the CDER, and the application is reviewed by two of these six; the Office of Drug Evaluation V (responsible for reviewing all OTC status applications) and one other office whose members have "relevant expertise on the

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[44] As qtd by Curtis Rosebraugh, Joint Meeting of the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs, U.S. Food and Drug Administration (FDA), December 16, 2003.

[45] A "first-in-a-class" drug is the first drug, within a class of drugs of similar chemical ingredients, to be reviewed for OTC status.

particular drug."[46] In the case of Plan B, the SNDA went to Office of Drug Evaluation III, which includes the Division of Reproductive and Urologic Drug Products. The CDER can also request a joint hearing of relevant FDA advisory committees that is open to the public "for the purpose of providing expert scientific advice and recommendations."[47] For Plan B, a meeting between the Nonprescription Drugs Advisory Committee (NDAC) and the Advisory Committee for Reproductive Health Drugs (ACRHD) was convened.

After the hearing has convened, the two reviewing offices take the committees' recommendation under consideration in their respective reviews of the application, and make a decision. If the two offices are in accordance, an action letter is issued. The letter can say one of three things. It can deem the OTC application as "approvable," and the drug is effectively made available as an OTC drug. The offices can also issue a conditionally "approvable" letter that promises OTC status if certain minor changes are made (usually pertaining to the labeling of the drug). Finally, the offices can issue a "not-approvable" letter, denying the status change. If the two drug evaluation offices arrive at divergent recommendations, the application is sent to the Director of the Office of New Drugs, who makes the ultimate decision on the status change. It should be noted that, if the Director of the Center for Drug Evaluation and Research (CDER) chooses, she may overrule the

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[46] Government Accountability Office (GAO) Report, "FDA Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual," 1.

[47] As qtd by Greg Kaebnick, "Sneaking in Ethics at the FDA," Hastings Center, *Bioethics Forum*, 09/29/06 http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=284&blogid=140 (Accessed 4/10/2010).

recommendations of the two drug evaluation offices, even if both offices concur, but, this exception aside, she is otherwise not a direct part of the decision process.[48]

On December 16, 2003, nearly a year after Women's Capital Corporation submitted the SNDA, the two FDA advisory committees held a joint public hearing to discuss the OTC application. At the hearing, the committees heard from various medical experts as well as members of the lay public. After opening remarks, a representative from Barr Laboratories (who had purchased the marketing rights to Plan B from Women's Capital Corporation during the interim) spoke first and explained the mechanics of Plan B. Next, Vivian Dickerson, then president-elect of the American College of Obstetricians and Gynecologists (ACOG), also spoke in favor of the OTC switch. As Dickerson noted at the hearing, it is quite a rare event for ACOG to publicly testify in favor of a specific pharmaceutical product.[49] Even more importantly, by advocating for OTC status, ACOG was endorsing a decision that would ultimately decrease member clinicians' medical authority, as it meant women no longer needed to seek their services before obtaining the drug.

Representatives from both reviewing Offices of Drug Evaluation and various other FDA offices also spoke at the hearing, all in favor of the OTC change. In addition, Felicia Stewart, representatives from Planned Parenthood Federation of America (PPFA) and the National Family Planning and Reproductive Health Association (NFPRHA), and various reproductive health non-profit organizations were allotted time to speak on behalf of Plan B as an OTC drug. Several laywomen who were affiliated with the National Organization of Women (NOW), a feminist

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[48] For a detailed flow-chart of these events, see Appendix B.
[49] Vivian Dickerson, Statement at the Joint Meeting, December 16, 2003.

organization established during the 1970s, also spoke candidly and presented personal difficulties in attempting to access Plan B as a prescription-only drug. These various figures and groups comprised a new coalition in support of expanded birth control access. Now, women's rights activists, the medical community, and the state (as represented by the FDA) were in concert in their demand for expanded, uninhibited access to emergency contraceptives. Those who spoke against the status change largely represented antiabortion activist organizations who were concerned about the drug's implications for promiscuity and conservative religious groups who believed Plan B to be an abortifacient. Carol Denner, a member of Concerned Women for America (CWA), a conservative women's public policy organization, stated:

> For the safety of American women and girls, I and the over half a million members of the Concerned Women for America of Virginia, the nation's largest public policy women's organization, ask and recommend that high dose hormone therapy after unprotected sex be available only by prescription by those capable of evaluating women for their health risks.[50]

Invoking similar fears about the removal of a physician's gatekeeper role over the drug, Hanna Klaus, a physician who described himself as an expert in "natural family planning and teen sexuality education," stated that he feared that Plan B would "make up for [a] lack of sexual responsibility."[51] Klaus also encouraged the FDA to label Plan B as a drug capable of preventing embryo implantation as a warning to those women who considered pregnancy to begin at conception, as did other speakers. Other speakers in opposition of the change invoked fears of an increased frequency of sexually transmitted diseases among young people, the potential for

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[50] Carole Denner, Statement at the Joint Meeting, December 16, 2003.
[51] Hanna Klaus, Statement at the Joint Meeting, December 16, 2003.

young women to "abuse" the drug or take it as a regular form of birth control, the possibility that it might enable "sexual predators" to take advantage of young girls, and the potential side effects the drug posed for children born to women who had taken Plan B after implantation. Ironically, Wendy Wright, President of Concerned Women for America, invoked the same concerns that feminist activists had raised several decades earlier over the Pill: that the true safety of the drug remained unknown. She also accused Women's Capital Corporation of having published misleading advertisements about the drug.[52]

The majority of the speakers, however, spoke positively about Plan B and at the end of the hearing, the committee voted 23-4 in favor of making Plan B available to women as an OTC drug.[53] Both reviewing Offices of Drug Evaluation formally recommended that an approval letter be issued. However, acting Director of the Center for Drug Evaluation and Research (CDER) Steven Galson overruled the recommendation and issued a "not-approvable" letter to Barr Pharmaceuticals on May 6, 2004.[54] Reiterating fears about the need to protect children, Galson explained in the letter that that Barr had not included enough research subjects aged 16 or younger to assess whether they could use Plan B correctly without first receiving instructions from a physician (of the 585 subjects, 29 were between 14 and 16 years

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[52] Wendy Wright, Statement at the Joint Meeting, December 16, 2003.

[53] According to L.L. Wynn and James Trussell, three of the four officials who voted against the change were pro-life practicing physicians and political appointees of President George W. Bush (a president with major ties to the Right to Life movement). They explain that the most extreme of these physicians, Joseph Stanford, "[did] not prescribe any hormonal contraceptives to his patients, whether married or not, because of the possibility that they might prevent implantation of what he [called] 'newly formed life.'" See "The Social Life of Emergency Contraception."

[54] A decision contrary to the recommendation of an advisory committee is not a common event at the FDA; in a later lawsuit over this decision, Judge Edward Korman noted that this was the first time in ten years that the FDA had not changed the status of a drug from prescription to OTC even after an advisory committee recommended the change.

of age, and none were younger 14). He expressed concern that it was "very difficult to extrapolate data on behavior from older to younger ages" because of the "large developmental differences" between adolescents differing only one or two years in age.[55] Galson concluded by saying that Barr was free to reapply for the status change if new trials that adequately represented this age group were conducted, or if the company included an age stipulation in the OTC status, making it available as such only for women ages 16 and older.[56]

Emergency contraction activists, members of the medical community, Congressmen and even some figures within the FDA responded to this decision with outrage. The American College of Obstetricians and Gynecologists (ACOG), American Medical Women's Association (AMWA) and the American Medical Association (AMA) all issued statements criticizing the decision, and forty members of Congress petitioned the FDA to reverse its decision.[57] Many were especially surprised at Galson's reasoning, as officials within the FDA had worked with Women's Capital Corporation (WCC) before it had formally submitted the SNDA to discuss how to execute studies that would adequately asses women's ability to properly use the drug OTC. The issue of adolescent use was specifically addressed,

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[55] As qtd by Judge Edward Korman, *Annie Tummino et al v. Frank Torti, Acting Commissioner of the Food and Drug Administration*, 2009 No. 05-CV-336 (ERK) (VVP).
[56] See Appendix II: Not-Approvable Letter for the Prescription-to-OTC Switch Application of Plan B, May 6, 2004, Government Accountability Office (GAO), "FDA Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B was Unusual," 2005.
[57] Ameican College of Obstetricians and Gynecologists (ACOG), "Medical Group Sets the Record Straight on Emergency Contraception," May 4, 2004, http://www.acog.org/from_home/publications/press_releases/nr05-04-04-3.cfm (Accessed 04/10/10); Brian Vastag, "Plan B for 'Plan B'?: FDA Denies OTC Sales of Emergency Contraceptive," *JAMA* 291 (2004): 2805-6.

and WCC was told that, "trials in the adult population could be extrapolated to the postmenarcheal pediatric population."[58]

A 2005 US Government Accountability Office (GAO) report found the issuance of a "not-approvable" letter to be "unusual" for four reasons. First, Galson's decision was contrary to both Offices of Drug Evaluation and the Director of the Office of New Drugs' recommendation, something that had never happened in the review of any other OTC applications in the history of the FDA. Second, GAO noted that high-level FDA management had been more involved in the decision than is normally expected. Third, there were some questions raised as to whether the decision to deny OTC status had been made far *before* any advisory committees convened. And lastly, the GAO noted that Galson's reason for denying to OTC status change was "novel," since the differences in the cognitive abilities of adolescents versus adults had never been noted in any other status change decisions.[59]

In July 2004, Barr amended its SNDA, now asking the FDA to make Plan B available without a prescription only for women aged 16 or older as Galson's letter had suggested. Women younger than this would still be required to obtain a prescription for the drug. Now instead of being considered "over-the-counter," Plan B would be stored in the pharmacy among other prescription-only drugs, and the pharmacists would provide the product only after a woman presented a form of identification to verify her age. This would make Plan B technically a "behind-the-counter" (BTC) drug rather than OTC. The FDA stalled in making a decision on

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[58] As qtd by Edward Korman, *Tummino v. Torti*, 2009.
[59] US Government Accountability Office (GAO), "FDA Decision Process was Unusual."

this revised application until July 2006 (two years later), when it informed Barr that, while enough data had been provided showing that 17-year-olds could competently use the drug, due to "enforcement issues" with this age limit, it could not approve the application. It asked Barr to resubmit an application to allow 18-year-olds OTC access.[60] After over two years of political stalling and the symbolic resignation of a high-level FDA official in protest of the purposely-delayed decisions, Barr resubmitted still another application to make Plan B OTC for women 18 and older at the request of the FDA. This application was finally approved on August 23, 2006.

Federal Court Intervention

Meanwhile, the Center for Reproductive Rights (which had submitted the initial 2001 citizen petition asking for Plan B to be made available OTC), had filed a lawsuit in 2005 against then-acting FDA Commissioner Lester Crawford. Technically, the Center sued the FDA for not issuing a decision on Plan B within the timeline stipulated by the Administrative Procedure Act.[61] The Center claimed that the FDA had intentionally stalled the decision-making process for political reasons and that the decisions it handed down were "arbitrary and capricious."[62] The Center made the following claims in their lawsuit:

> The denial of the over-the-counter switch for women of all ages and the imposition of the BTC regime (1) is arbitrary, capricious, and otherwise

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[60] As qtd by Edward Korman, *Tummino v. Torti,* 2009.
[61] The Administrative Procedure Act is a federal law that stipulates time frames for the decision-making process of various administrative agencies.
[62] *Tummino v. Torti,* 2009. This ruling found that the OTC decision had been highly politicized as a result of strategic political appointments of high-level FDA officials in order to influence the decision on the part of then-US President George W. Bush, who had strong ties with the Right to Life lobby.

> contrary to the law, (2) exceeds the FDA's statutory authority, (3) violates women's rights to privacy, (4) discriminates against women and those persons wishing to exercise their right to privacy in violation of the Fifth Amendment's Equal Protection Clause, and (5) violates women's rights to informational privacy. Plaintiffs seek an injunction requiring the FDA to approve the OTC switch without age or point-of-sale restrictions and a declaratory judgment that the FDA's actions violate the [Administrative Procedure Act] and the Constitution.[63]

After several years of hearings and depositions, Judge Korman ruled in favor of the plaintiffs, writing in his 2009 ruling: "The FDA repeatedly and unreasonably delayed issuing a decision on Plan B for suspect reasons and, on two occasions, only took action on Plan B to facilitate confirmation proceedings of acting FDA Commissioners, whose confirmation hearings had been held up due to these repeated delays."[64] Judge Korman ordered that Plan B be made available as a BTC drug for women ages 17 and older, lowering the current age limit by one year. He did not recommend that the age limit be completely removed because "…a decision whether Plan B…may be used safely without a prescription by children as young as 11 or 12 is best left to the expertise of the FDA."[65] Why Korman did not lower the age limit to 16 as Barr had originally asked, however, remains unclear. Nevertheless Korman had in essence ruled that the FDA's decision-making process had been fraught with "political considerations, delays, and implausible justifications."[66] In an April 22, 2009 press release, the FDA announced that it would not appeal the decision, and with that, Plan B was made available as a behind-the-counter product

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[63] *Tummino v. Torti,* 2009.
[64] Ibid. Senators Hilary Clinton and Patty Murray had blocked the confirmation of two FDA Directors until they promised to make a decision on the Plan B OTC application.
[65] Ibid.
[66] Ibid.

for all women aged 17 and older, its most easily and broadest accessible form to date.[67]

Conclusion

Plan B's availability without a prescription (to women 17 and older, as of this writing) constitutes a milestone in the history of birth control; women no longer need to seek out the help of her physician before obtaining an effective contraceptive technology. Its current status as "behind-the-counter" (in which a woman must present a form of identification to verify her age to a pharmacist before she can purchase the drug), however, is not how the original OTC petitioners envisioned Plan B. While some had gone as far as to advocate that Plan B be made available in vending machines in order to further remove barriers, most activists hoped that Plan B would be available on the shelves of pharmacies, next to condoms, pregnancy tests, and other family planning products. I am confident, however, that the FDA will soon repeal these age restrictions, making Plan B available over-the-counter for all women.

That the debate over a medical technology became such a politicized matter, and that so many lay actors became embroiled in what could only ultimately ever be a discussion about the safety and efficacy of a drug (as this is the only regulatory power the FDA holds) is symptomatic of a greater trend in the late 20th century that Steven Epstein calls the "politicization of science;" that is, the spilling over of heated

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[67] Food and Drug Administration (FDA),"Updated FDA Action on Plan B (levonorgestrel) Tablets."http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149568.htm (Accessed March 3, 2010).

political debates into issues of science and technology to the point where the politics dictate the direction of the field.[68] This is indeed what happened in the case of Plan B. Because of political influences, access to the drug was limited for young women despite dubious scientific reasoning. The FDA became center stage between feminists, physicians, and social conservatives for a referendum on morality, promiscuity and cultural values.

More troubling about these debates, however, is what *wasn't* said rather than what was. As I shall explain shortly, while actors on all sides raised several weighty hypothetical situations to convey a particular argument, no one raised the questions that is, to me, represent most pressing issues this debate: What options did (and does) the state provide to women who choose not to take Plan B, and instead choose to become a mother? Feminists wanted Plan B as a means of allowing women to control her own reproduction and choose *not* to become pregnant. Opponents wanted to restrict access to prevent children from becoming promiscuous and thus potentially encountering an unwanted pregnancy. But the dialogue never moved beyond these two archetypes to ask about the woman who chooses *not* to use Plan B (or for whom Plan B has failed). As I shall argue in the following section, this omission in the discourse on motherhood and morality is a problem not unique to debates over Plan B, but rather is widespread within American discourse today.

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[68] Steven Epstein, *Impure Science: AIDS, Activism and the Politics of Knowledge* (Berkeley and London: University of California Press, 1998) 6.

Conclusion:
Birth Control, Motherhood, and the Neoliberal State

We have just traced the evolution of birth control through three historical episodes and examined its shifting status in the United States: first as a nonmedical entity, then reaching a peak of medicalization with the development of the Pill, and finally in its most recent shift in which women were invited to exercise authority over the practice. In Chapter 1, we saw how Margaret Sanger lobbied the medical community to extend its authority over contraception. After several key judicial rulings, in which the medical profession was continually encouraged to expand the instances in which they would prescribe birth control to a woman, Sanger finally found success in 1937, when the American Medical Association (AMA) issued a report stating that the organization would work to "make clear to physicians their legal rights in relation to the use of contraceptives," and would encourage medical schools to actively instruct their students on the various forms of contraception.[1] In the aftermath of this report, American women saw a steady influx of physicians who were trained in contraception and willing to prescribe it to their female patients.

We then turned our attention to another episode of birth control history—that of oral contraceptives in the 1960s—and examined a technology that revolutionized contraception in several ways. Now, marketed by "ethical" pharmaceutical companies, and prescribed by family practitioners, oral contraception became the most popular form of birth control among American women almost

[1] "Report of Reference Committee on Executive Session," *Journal of the American Medical Association*, 108 (1937): 2217-18

immediately after its introduction on the market. The Pill was the watershed moment for the medicalization of birth control; without a doctor's prescription, a woman could not obtain it. What's more, oral contraceptives marked the entrance of a new actor in the politics of birth control: the US Food and Drug Administration (FDA). While the FDA at first reinforced this medicalization (as it did and does with all drugs, ceding prescribing power to physicians), the controversy over the Pill's side effects led the agency to encroach on this medical authority through the patient package insert (PPI). The PPI, the first of its kind in the history of drug regulation, was instituted in a move to convey information about the risks of the Pill directly to women rather than continue to rely upon physicians to do so. While the PPI may retrospectively seem like a meager resolution to the problem of the Pill's safety, that the medical profession lobbied so strongly against it for nearly a decade after it was initially mandated illustrates the profound implications the insert held for medical authority over birth control. The PPI was the state's means of enabling a woman to privately make an "intelligent, personal decision" about whether or not the drug was safe for her.

In the last chapter, we examined the development of the Plan B pill in the late 20th century. In this episode, feminists and physicians united in a movement to expand access to this form of birth control and the FDA, in the interests of maximizing the efficacy of the drug, made Plan B available over-the-counter (OTC), thus granting women more control over their ability to access contraception. Opposition to this change arose among those who feared the moral implications of removing doctors (previously the gatekeepers to the drug), from mediating access to

birth control. Despite their objections, Plan B was ultimately made available over-the-counter for women ages 18 and older, and, after a significant court intervention, this age limit was lowered to 17. I am confident that we will soon see the complete removal of this age restriction and Plan B will be made available OTC to all women in the near future.

I would like to further situate Plan B historically and examine it through the lens of the history of welfare policy in the United States. In the Progressive Era, motherhood was incentivized through various measures that served to support full-time caregivers; what Theda Skocpol has called "maternal welfare reform."[2] These measures, while valorizing motherhood, ultimately served to prevent women from moving beyond maternity and thus insulated the prevailing social hierarchy.

During second-wave feminism of the 1970s, activists challenged the idea that "motherhood had to be women's primary identity," and demanded that the state take measures to guarantee women's right to move beyond motherhood and enter the workforce—to which the state again responded positively.[3] Various federal and state affirmative action measures, combined with the implementation in 1972 of Title IX of the Civil Rights Act, helped achieve the state's guarantee of "employment for all."[4]

But what are the implications of this "employment for all"? The rhetoric of the women's rights movement has shifted so far from its origins of protecting

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[2] Theda Skocpol, *Protecting Mothers and Soldiers: The Political Origins of Social Policy in the United States* (Cambridge and London: The Belknap Press of Harvard University Press, 1992).
[3] Linda Gordon, *The Moral Property of Women: A History of Birth Control Politics in America* (Urbana and Chicago: University of Illinois Press, 2002) 297.
[4] Ann Shola Orloff, "From Maternalism to 'Employment for All': State Policies to Promote Women's Employment across the Affluent Democracies," in *The State After Statism: New State Activities in the Age of Liberalization*, ed. Jonah D. Levy (Cambridge and London: Harvard University Press, 2006) 230.

motherhood that it has actually overlooked those women who do indeed decide to take on motherhood as a form of work. Indeed, as Kristin Luker has pointed out in the case of abortion, many women have joined the Right to Life movement because they see the issue as a "referendum" on the meaning of motherhood—and thus their own position in society.[5] These women embrace motherhood as their societal role, a value vehemently repudiated by second-wave feminism.

The state, too, has overlooked this group of women in its policy measures. Especially after the repeal of Aid to Families with Dependent Children (AFDC) in 1996 and its replacement with state-directed Temporary Assistance for Needy Families (TANF)—which requires recipients to be actively seeking employment while receiving funds—the state no longer recognizes motherhood as a form of labor deserving of the same protections as it does for women who choose to enter the workforce. Instead, the state asks women who choose motherhood as a profession to rely upon (male) breadwinners to support her work financially.

Nor does the state offer services like subsidized childcare or long-term maternity leaves for those women who choose to become mothers while still maintaining employment (as Social-Democratic states of Europe have implemented). In this case, the state largely relies upon market forces to provide women with alternative sources of care while they are away at work. This neoliberalism in childcare of course has severe implications for single mothers who cannot afford to pay for caregivers. For these women, and for middle-class women who choose to remain within the traditional social hierarchy of male breadwinner/female caregiver,

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[5] Kristin Luker, *Abortion and the Politics of Motherhood*, (Berkeley: University of California Press, 1984).

the state no longer provides much support in the way of policy. In short, the rhetoric of maternal reform has shifted so far from its roots in valorized motherhood that "making claims on the state for resources and recognition on the basis of motherhood, or care" has become "politically impossible."[6]

Making claims on the state on the basis of *children's* concerns, however, has gained new political currency in issues of reproductive rights. Nowhere has this rung more true than in the case of abortion. As of 2001, 17 states had implemented policies requiring a minor's parents give consent before she obtains an abortion; 14 have laws requiring that parents be notified that her daughter has sought the procedure.[7] Though it was never enacted, the Reagan Administration in 1983 tried to impose similar parental consent requirements on minors who sought a prescription for contraceptives from clinics receiving federal funds.[8] Also part of this debate is the issue of sex education in schools; those who propose to teach "abstinence-only" programs support their claim by invoking fears that teaching children about sex will only serve to encourage them to engage in promiscuity. The rhetoric of protecting children from immorality, a revival from Progressive Era politics, again appears to be pervasive in American thought.

It is in this framework that I place the Plan B pill. The debate around this technology, while framed as an issue of safety and efficacy, was in reality an example

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[6] Ibid, 232. I recognize that welfare policy is imbued with racial, gender, and class injustices and I do not mean to belittle these issues with my argument. I simply move here to point out that the rhetoric of women's rights has shifted to a point where those women who do indeed desire to take on motherhood as a profession have been overlooked in both women's reform demands and state policies.
[7] Gordon, *Moral Property of Women*, 311.
[8] Ibid 350.

of a misplaced discourse on morality, tradition, and the value of motherhood in the United States. Feminist supporters of Plan B made claims that women needed access to this technology in order to further guarantee their right to choose when to become mothers. For the state, Plan B represented a "magic bullet" of upholding a woman's right to choose, for affording women access required no new state policies (beyond the FDA's status change) but rather relied upon market forces to make the drug available. Opponents claimed that access to the Plan B needed to be restricted in order to protect the integrity of children. Nowhere in this debate did we find activists demanding for the rights of those women who choose *not* to take the Plan B pill and instead embrace motherhood.

To refocus the discourse, I move for a renewed emphasis on welfare policies that further guarantee a woman's right to choose. We must, through state policy, continue to allow women to access technologies that enable her to choose to delay or prevent motherhood. At the same time, there is a strong need to support those women who choose *not* to use these technologies and instead choose motherhood (either concurrent to employment or as a profession itself)—something the state has heretofore not done adequately. Rosalind Petchesky writes:

> Two essential ideas underlie a feminist view of reproductive freedom, ideas that have recurrently been implicit in all historical situations in which abortion, birth control, child care, maternity care, and the status of unmarried mothers and their children have become objects of political tension. On the broadest level, these two ideas reflect the long-standing tension in feminist theory between an emphasis on *equality* and an emphasis on women's *autonomy* (emphasis in original).[9]

[9] Rosalind Petchesky, "Reproductive Freedom: Beyond 'A Woman's Right to Choose'," *Signs* 5 (1980): 661-685, 662.

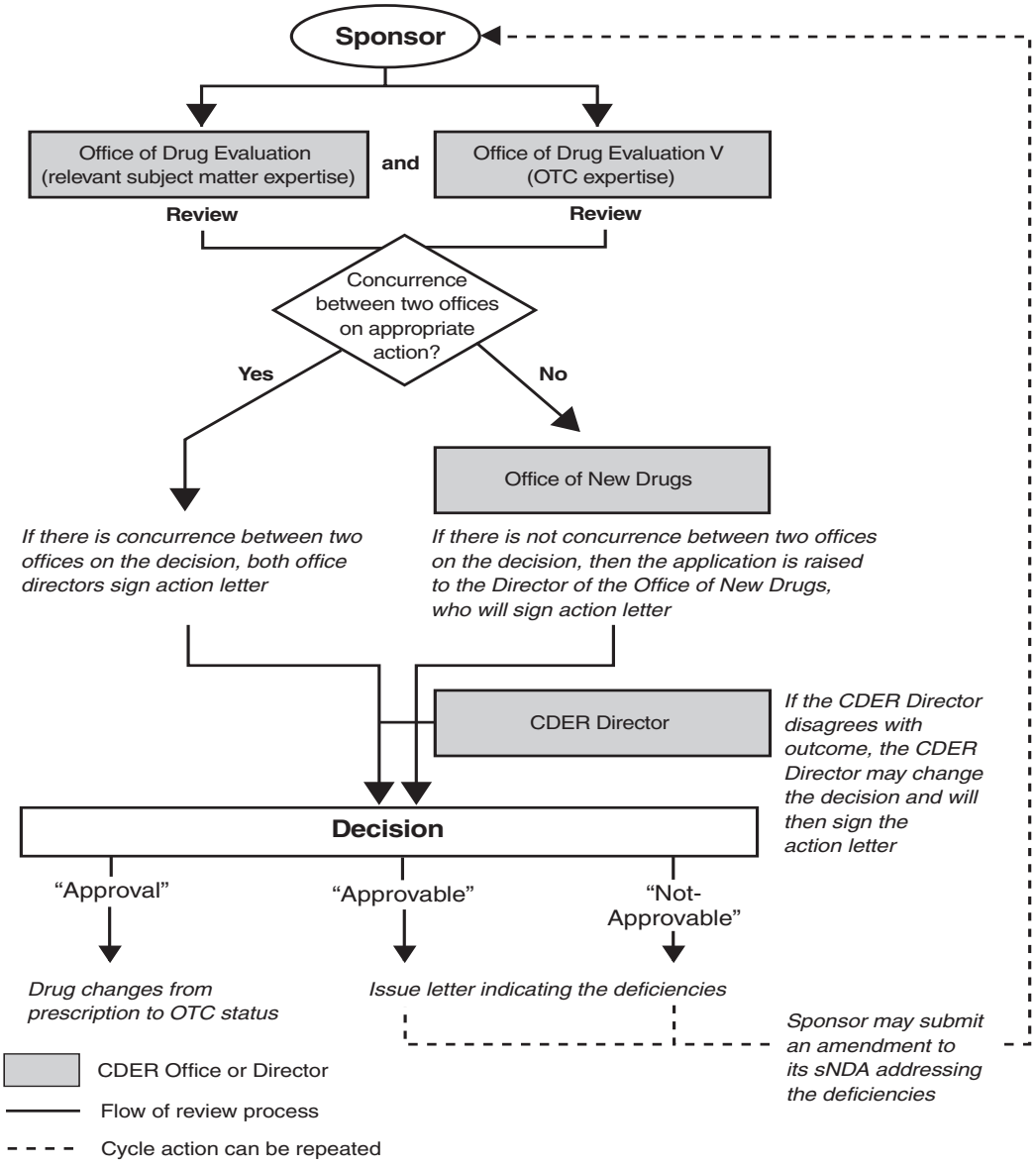
In this thesis, we have seen the ways in which the state has responded positively to demands in the name of protecting the rights of women. Let us again use the state as a tool to produce policies that afford women equal employment opportunities when entering the workforce *or* when entering motherhood. Let us "bring the state back in" to provide mothers the same protections we do for women in the traditional workforce. I thus move for a rethinking of the maternal welfare state to examine the ways in which these policies enabled women to fully embrace motherhood—while continuing to uphold the state's guarantee of "employment for all"—in a move to ensure that all forms of women's employment choices—whether they be in the workforce, motherhood, or both—are guaranteed and protected by the state.

Appendix A:
List of 2001 FDA Citizen's Petition Co-Signers

Advocates for Youth
The Alaska Emergency Contraceptive Project
American Association of University Women
American Academy of Pediatrics
American College of Nurse-Midwives
Americans for Democratic Action
American Medical Women's Association
The American Nurses Association
American Public Health Association
American Society for Emergency Contraception
American Society for Reproductive Medicine
Arizona Family Planning Council
Association of Reproductive Health Professionals
Beaverhead Family Planning Clinic
Center for Entrepreneurship in International Health and Development, School of Public Health,
University of California, Berkeley
Center for Women's Policy Studies
Choice USA
The Compton Foundation
The Consortium for Emergency Contraception
Family Health Care, Inc.
Family Health International
Family Planning Association of Northern Ohio, Inc.
Family Planning Council
Family Planning Councils of America
Family Planning Council of Iowa
Family Planning Association of Maine
Family Tree Clinic
Fargo Cass Public Health
Health Care of Southeast Massachusetts
Health Quarters
Ipas
Lake County Family Planning
Medical and Health Research Association of New York City, Inc
National Abortion Federation
National Abortion and Reproductive Rights Action League
    California Abortion and Reproductive Rights Action League
    Massachusetts Abortion and Reproductive Rights Action League
    Minnesota Abortion and Reproductive Rights Action League
    New York Abortion and Reproductive Rights Action League
National Asian Women's Health Organization

National Association of Nurse Practitioners in Women's Health
National Black Women's Health Project
National Coalition Against Domestic Violence
National Consumers League
National Family Planning and Reproductive Health Association
The National Organization for Women Legal Defense and Education Fund
The National Organization on Adolescent Pregnancy, Parenting & Prevention
National Partnership for Women and Families
Okanogan Family Planning
Oops- Emergency Contraception Hotline
Pacific Institute for Women's Health
Pathfinder International
Physicians for Reproductive Choice and Health
Planned Parenthood Federation of America and all Planned Parenthood Affiliates Nationwide
Planned Parenthood of Central Washington
Planned Parenthood/ Chicago Area
Planned Parenthood of Connecticut
Planned Parenthood Heart of Illinois
Planned Parenthood of Houston and Southeast Texas, Inc
Planned Parenthood Association of Lubbock
Planned Parenthood of Nassau County
Planned Parenthood of the Saint Louis Region
Planned Parenthood of Southern Arizona
Planned Parenthood of Stark County
Planned Parenthood of the Texas Capital Region
Planned Parenthood of Western Washington
The Population Council
Population Services International, U.S. Programs
Pro Choice Resource Center
Program for Appropriate Technology in Health
The Reproductive Health Technologies Project
The Sexuality Information and Education Council of the United States
Texas Family Planning Association
Tri City Health Center
Voters for Choice
Women's Health Center of West Virginia

Appendix B:
Flow Chart of OTC Review Process



Source: Government Accountability Office (GAO), "FDA Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraception Drug Plan B Was Unusual," November 2005.

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