Bodies of Evidence

Activists, Patients, and the FDA Regulation of Depo-Provera

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In January 1983, the FDA held one of only two scientific "Public Boards of Inquiry" in the history of the administration to determine whether to approve Depo-Provera for use as a contraceptive in the United States. At the hearing, ideas about gender and power played a central role in negotiations between scientists, doctors, patients, and women's health activists. The nature of the Depo-Provera Public Board of Inquiry lends itself to analysis of the interaction between and among these groups, each of which had a vested interest in the outcome of the FDA decision. The stories and strategies emerging from the actors involved in the Public Board of Inquiry reveal the enormous complexity of regulating reproduction in the late twentieth century.

At 9:22 a.m. on 10 January 1983, Dr. Judith Weisz called the crowd inside the Hubert Humphrey Building in downtown Washington DC to order. As chair of the U.S. Food and Drug Administration Public Board of Inquiry (PBI) on Depo-Provera, she became the first woman and only the second scientist to officiate at an FDA hearing. "What I didn't know and I soon became aware of," she noted, "was what a political hot potato this really was."[1] Seated to her left was Dr. Paul Stolley, a professor in the Department of Research Medicine at the University of Pennsylvania, and to her right, Dr. Griff Ross, associate dean at the University of Texas Medical School in Houston. Behind her, scrambling to take his position, was FDA attorney Jess Stribling. "For Judith, it was a very memorable and special event that she felt and still feels very keenly about," remembers Stribling.[2] Weisz's task at the hearing was to determine whether Depo-Provera—trade name for Depomedroxyprogresterone acetate—was safe for general marketing as a contraceptive in the United States. The FDA had already rejected the pharmaceuticals manufacturer Upjohn Company's application twice in this regard due to lack of evidence that the drug was safe (in 1974 and 1978), and Upjohn was now appealing the agency's latest decision. "Everybody kept telling me why are you spending this much time on this? It won't make any difference. Well, it kept the damn thing off the market for eight years," she said, revealing only years later her distaste for the drug.[3]

The Depo-Provera Board of Inquiry, the subject of this article, proved to be a definitive chapter in the history of women's health and reproductive politics. Its investigation centered on the safety of one of the most contro-

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versial forms of birth control, injected intramuscularly every ninety days to suppress ovulation. Although highly effective in preventing pregnancy, Depo-Provera's availability to and higher use among poor and minority patient populations before FDA approval led many activists to view the drug as a dangerous tool for reproductive containment, rather than as a new form of voluntary birth control. Journalists reported women in developing countries lining up by the thousands for injections of the contraceptive, funded by international family planning organizations. One Namibian physician noted that during the 1980s, injections were "simply banged into black and colored women, without discussion, explanation or even permission."[4] These reports led to concern about racist population control policies, and also drew attention to poor scientific research methods. Clinical trials failed to follow up with patients who discontinued use of the drug and inadequately documented the risks and side effects, ranging from weight gain to heavy bleeding to cancer. As a result, the FDA repeatedly turned down Upjohn's attempts to market Depo as a contraceptive in the United States in the 1970s and 1980s. Not until 1992, after a long-term study by the World Health Organization suggested the overall risk of cancer to be minimal, would the FDA approve the drug for such marketing. Nonetheless, during these decades thousands of American women received Depo injections to prevent pregnancy, either through clinical trials or through off-label use, as the drug was already FDA-approved for the treatment of endometrial cancer.

Depo's widespread availability and use in the United States as a contraceptive before FDA approval triggered feminist indignation. "It is time for all of us to speak out," announced Belita Cowan, director of the National Women's Health Network (NWHN) in 1979, "to expose the horrors of this drug, and Upjohn's role in promoting suffering and disease."[5] The NWHN, a DC-based lobbying group formed in 1975, created a Depo-Provera patient registry, generating media attention and consumer concern over the drug's safety and possible misuse. By the time of the 1983 FDA hearings, the network had galvanized consumers and public interest groups, who were increasingly receptive to the idea that women's personal experiences should revolutionize a flawed healthcare system. NWHN members were particularly attuned to the importance of racial diversity within their organization, working with activists of color to increase awareness of how institutionalized racism affected reproductive health. They recognized that race and class affected a woman's ability to make decisions about fertility and exercise reproductive control, and this awareness shaped how they approached the FDA hearings.[6]

The Board of Inquiry thus served as a significant steppingstone for women's health advocates, who now found themselves in a more powerful

position than they had in previous legislative debates regarding reproductive health. As a result, birth control marketers have had to contend with a new feminist political force.[7] Yet these negotiations also served as an ideological stumbling block, as feminists were forced to abandon their body politics—in particular the privileging of female experience over scientific data, at least in the scientific arena.[8] Wary of being cast as too "emotional" in their approach when testifying on a scientific panel, they began to replace stories with statistics, ultimately compromising their position as outside agitators.

This article is part of a broader intellectual conversation regarding the contested nature of drug regulation and medicine in American culture.[9] In the context of the women's health movement and the regulation of birth control, ideas about gender and race played a central role in negotiations between scientists, doctors, patients, activists, and pharmaceutical corporations. Female activists and patients confronted a regulatory structure reluctant to incorporate individual stories—particularly *women's* stories—into a scientifically rigorous risk-benefit analysis. As a result, they limited their personal testimonials to press conferences and women's health newsletters; in the scientific arena, they attempted to confront scientists on their own terms, yet still place women's bodies squarely at the center of the debate. Beginning with the formation of the historic Depo-Provera Public Board of Inquiry, this article then addresses the experiences of patients (those who filled out registries for the NWHN), the strategies of women's health activists who desired to testify at the hearing, and the controversial trials conducted primarily on women of color at the Grady Clinic in Atlanta, Georgia. Taken together, these stories and strategies reveal the enormous complexity of regulating reproduction in the late twentieth century and thereby help to explain why, despite huge gains, the women's health movement was not ultimately more successful in revolutionizing reproductive healthcare.

The Public Board of Inquiry

Judith Weisz fondly remembers being asked to chair the Public Board of Inquiry. "It was just wonderful that [FDA commissioner] Art Hayes appointed me," she recalls. "And I said to him, 'You appointed me because I'm a woman.' And he said 'No.' I said, 'Does it help?' and he said, 'Maybe.'"[10] In truth, Hayes appointed her out of respect for her science, she says. Weisz was professor and head of the Division of Reproductive Biology in the Department of Obstetrics and Gynecology at the Hershey Medical Center at Pennsylvania State University, where Hayes had previously worked. Regardless of his reasoning, she accepted the honorable role.

At just over five feet tall, Weisz probably did not cut an imposing figure at the PBI. But she was resolute, a quality that emerged early in her dramatic life. Having fled Hungary three weeks before the start of World War II, she says that "the Holocaust and the reality of what we can do as human beings is very real, very close to me. . . . You must go on pushing what you believe in." After the war, as a young student at Cambridge University, she had a seminal encounter with a Hitler supporter whose opinion she was unable to change. "I said to myself at that point, 'I will not cease to try to explain and make my position clear. However, I recognize this exists and I will not let it deter me'. . . And I think this is what I carry with me."[11]

In preparation for the hearing, she and her assistant "really analyzed everything that we could lay our hands on and tried to do it as scientifically as possible," she recalls. The more she read, the more horrified she was at what she believed to be an inappropriate use of Depo-Provera. But perhaps most upsetting was the manipulation of evidence. "I was appalled at the poor, poor science and the way that science was being used for political or emotional positions that the investigators had," she says. "There were no good studies. And it taught me something. . . . The potential of special interest. . . distorts the science; it is not the best possible science."[12] Weisz became determined to resolve the controversy surrounding the drug by "evaluating the scientific validity of the information available."[13] In her introductory remarks on that first morning of the hearing, 10 January 1983, she noted, "We realize this is a complex and emotional issue on which people have taken certain viewpoints and have taken them strongly."[14] But, she stressed, the objective of the hearing was to weigh scientific evidence, not to determine the implications of that science.

That task would turn out to be nearly impossible. Though Weisz's desire was to focus solely on scientific evidence to determine the future of Depo-Provera, she was keenly aware of the difficulty of separating the science from the society that produced it. The room was filled with special interest groups that had a vested interest in shaping the outcome of the hearing. Upjohn, the company that produced Depo-Provera, had appealed the FDA in 1978 in the hopes that a PBI would prevent consumer and feminist activists from participating in the hearing. The company hoped that the board would limit its attention to "expert witnesses": research scientists and clinicians who had studied the effects of the drug on animal and human subjects. "Upjohn believes it is essential that the issues in this proceeding be reviewed and decided by a panel of scientists, rather than a lay person," it explained. "The issues . . . are technically complex, require an understanding of sophisticated scientific concepts, and necessitate the comprehension and evaluation of a large body of scientific literature and other data."[15]

FDA commissioner Donald Kennedy granted Upjohn's request to hold a PBI. He believed that the use of qualified experts would "add another dimension to the analysis of the questions presented at the hearing." He also disagreed with the notion that a PBI should avoid controversial matters, explaining, "Determining whether a drug is 'safe' always involves a risk-benefit judgment . . . . I do not believe that the use of a PBI should be confined to proceedings in which there is no need to resolve a risk-benefit issue."[16] He did not realize in 1978 that it would take another five years of preparation to carry out Upjohn's request.

By the morning of 10 January 1983, all interested parties had had ample time to practice their lines and gather their props. The well prepared included Dr. Weisz herself, who knew that her objectivity was under question. "And this is one of the reasons," she explained, "that I insisted that we bring in, I don't know how many files. We had a whole big filing cabinet behind, as a backdrop."[17] For Weisz, appearance was nearly as important as actual preparation.

Women's health activists affiliated with the National Women's Health Network also arrived at the PBI armed with evidence. They demanded that Depo-Provera be analyzed within the larger context of contraceptive marketing and regulation, drawing attention to other controversial methods that had harmed women, such as the birth control pill. To document this additional "massive experiment," the NWHN had created a registry of women using the drug, so that it could track the damages incurred. By the time of the hearing, the group had accrued 529 registrants and hundreds of additional letters, the majority of which attested to the suffering of users who were not prepared for the crippling side effects of the drug. Seated in the room that morning listening to Dr. Weisz's introduction was health activist and NWHN witness Judy Norsigian, who had taken the train down from Boston, her infant in one arm, a large box of these testimonials in the other.

There were no emotional testimonials presented that morning, nor would there be over the next four days of the hearing; they were presented only outside the hearing, at a televised press conference. Yet there was certainly an awareness that media coverage might undermine the appearance of scientific objectivity in the proceedings. When a documentary filmmaker, Karen Branan, requested videotaping the hearing, the Upjohn Company balked. "The constant presence of cameras with the intended purpose of producing edited materials for a documentary film would turn a scientific forum into a media-based event," the company's spokesman declared. Branan had a bias, Upjohn believed, because she was a member of the NWHN, and was producing the documentary to "encourage women to organize around the

Depo-Provera issue." It felt that her position put the company at an obvious disadvantage in that "the film would undoubtedly emphasize emotional statements and evidence." Furthermore, Upjohn argued, certain witnesses might refuse to testify under such conditions, thus forcing the company to find last-minute replacements. Videotaping would also negatively impact the entire hearing because it "could have a chilling effect on the gathering of necessary evidence." In its statement, Upjohn articulated what was to be the biggest challenge for everyone involved—from the chairperson herself, to scientists, to corporate figures, to women's health activists: to leave emotion out of the proceedings. File cabinets and boxes of registry documents surely assisted participants in maintaining such professional demeanor, but, according to Upjohn, cameras might expose a more complex scenario. "The presence of cameras for the purpose of producing such a film might encourage theatrics or emotional statements rather than the objective scientific testimony intended by the panel. As a result, the Public Board of Inquiry could be depicted in a manner that would emphasize the emotional rather than the scientific nature of the proceedings."[18] In this gendered analysis, "emotional" was equated with the women's health agenda, and thereby fundamentally unscientific.

Weisz initially concurred and prohibited any videotaping of the PBI. "I do this reluctantly," she acknowledged two weeks before the hearing, "because I am not unmindful of the policy and obligation of the Federal Government . . . to conduct its public business as openly as possible." But she believed the taping would prevent the PBI from "fulfilling its purpose." The NWHN and Ralph Nader's Health Research Group immediately appealed her decision. Their appeal was undoubtedly strengthened by a letter to FDA commissioner Arthur Hayes from the Bureau Chief of CNN. "We cannot recall any occasion in which the FDA has discriminated against the television media," Larry La Motte wrote. "While such a decision may soothe some pharmaceutical manufacturers—it opens up a big can of worms with the television news industry and the general public it represents." La Motte's final sentence reveals the emotion with which he couched his appeal. "I *implore* you to give careful consideration to our point of view and to take note of our vigorous objections."[19] Such strong language undoubtedly led Weisz to realize what a "political hot potato," in her words, the hearing would become.

The appeal was upheld, and the hearing opened with one camera stationed in the room for its duration. Any witness, however, had the right to refuse being videotaped. Notably, on the first day of the proceedings, which were devoted to Upjohn, seven of the ten witnesses declined to be on camera, some more vocally than others. "Madam Chairman," stated Dr

Roy Hertz, research professor at the George Washington Medical Center, "I have declined to be videotaped because I think it detracts from the objectivity and scientific environment in which this very difficult matter is being evaluated."[20] Jess Stribling, the FDA attorney, recalls that the possibility of videotaping was "shocking and even abhorrent to three very gifted and able medical researchers who were not accustomed to doing their work in front of the camera." In his assessment, they were "afraid that it was going to turn into a grand mess, and become a sideshow."[21] Those most likely to cause a scene, they feared, were the feminist health activists.

The irony is that according to Weisz, the only witness who "introduced an element of partisanship" into the proceedings was a supporter of Depo-Provera who opposed being videotaped. He introduced "a kind of pugilistic perspective," she remembers. "You know for him this was a game, in a way. And for me it wasn't a game. It couldn't be." She and the other members of the PBI felt strongly that they had to keep emotional outbursts under control. "I wanted the scientists to speak, to feel obliged to keep to the science, which we could critique. I can't critique all other things."[22]

Regulatory Revolution at the FDA

The last-minute debate over videotaping underscored the challenges of incorporating outsiders into FDA regulatory decisions, a significant issue for the FDA in the 1970s. Under the direction of Commissioner Charles Edwards and General Counsel Peter Hutt, the FDA grew dramatically in power and influence.[23] It also found itself much more susceptible to public interest, largely because of new legislation (such as the Freedom of Information Act) that opened up 90 percent of its files to the public.[24] Consumer activists and organizations such as the Health Research Group demanded information about the safety of products on the market. They also, as in the case of the Depo-Provera PBI, generated media attention as a way of drawing the public's attention to safety and regulatory decisions. They demanded not only greater access to information, but more involvement in making the decisions that affected public safety.

But greater public accessibility was not the only concern that Commissioner Edwards addressed in the 1970s. He recognized that the FDA "needed to upgrade its scientific capabilities and draw upon the expertise of the nation's community of scientists and physicians."[25] He developed a system of advisory committees in order to make use of expert scientific opinion. "I think it is all terribly important," he explained "because the complexity of the decisions, both scientific and technological, that we make everyday are only as strong as the science behind them. A regulatory agency like FDA must have scientific credibility."[26]

Commissioner Edwards appointed Peter Hutt, a lawyer for Covington and Burling, as FDA General Counsel. Hutt was determined to make information available to all interested parties, something previously unknown to the FDA. He offered a window into the formerly secretive world of food and drug regulation. As a lawyer, he wanted everything to be clearly structured and standardized.

The challenge was to incorporate this style of enforcement into a scientific setting. Hutt wanted definitive yes or no answers to his questions regarding drug safety. FDA counsel Jess Stribling (a Hutt appointee), heard that Hutt once met with the scientists at the FDA's Cancer Research Center and asked, "On all of the questions of safety I will have only one question for you and I want a yes or no—does it or does it not cause cancer?" Hutt may have wanted clear-cut answers, but "scientists of their very nature always want more data, and they should. They are looking for truth . . . and so they tend to be exhaustive and color what they say with all kinds of conditions."[27] The end result of this difference in perspective was a giant discrepancy in how to define "good science." Despite Hutt's desire for a definitive answer, determining whether or not a drug should be allowed on the market was not a black and white issue. Instead, FDA regulators applied a risk-benefit assessment in order to evaluate whether a drug's benefit outweighed its risks. Consumers learned that drugs were "not merely 'safe' or 'unsafe,' but that they have benefits that may be offset by particular risks."[28]

But it raised new questions. Who was qualified to make such an assessment? What factors should be included when determining a risk/benefit ratio? By the 1970s, special interest groups demanded a role in regulatory decision making. Determining a drug's safety and efficacy became a negotiation between different actors who interpreted evidence in drastically different ways. Consumer representatives frequently remarked that they recognized the difference between having the opportunity to voice their opinion and actually effecting change. They were aware of the fact that industry, scientific, and pharmaceutical professionals viewed them as outsiders. Among them, women's health activists involved in the Depo-Provera PBI learned that cultivating a more professional, insider perspective was crucial to keeping the drug off the birth control market.

The Burden of Birth Control

The debate over Depo-Provera tapped into an already explosive political issue. Reproductive politics, as historian Rickie Solinger has argued, "has been and remains one of the most fiercely contested and most complicated subjects about power in American society."[29] Whether fertility is controlled

externally, by coercive measures, or voluntarily, by individual choice and access to safe and reliable methods, radically alters individual meaning and experience. Poor women and women of color have had to negotiate economic and institutional constraints that blur the boundary between voluntary and coercive. As activist and scholar Loretta Ross explains, "our ability to control what happens to our bodies is constantly challenged by poverty, racism, environmental degradation, sexism, homophobia, and injustice in the United States."[30] Documented cases of sterilization abuse and unsafe testing procedures on women of color led many to see that what may constitute reproductive freedom for some women "is reproductive tyranny for others."[31]

The Depo-Provera controversy can only be understood within the history of hormonal contraceptives and the introduction of the birth control pill. Emerging at the dawn of the sexual revolution, the Pill raised expectations that women were sexually available without the threat of unwanted pregnancy. By 1965, over six million women had taken oral contraceptives. Planned Parenthood noted that 70 percent of all clients using its services for birth control chose to get a prescription for the Pill.[32] This form of contraception offered many advantages over barrier method: it was highly effective, convenient, and entirely separated from the act of intercourse. It also did not require the consent or even awareness of a male sexual partner. Both physicians and female patients initially expressed enthusiasm for this new form of birth control.

Yet by the end of the 1960s, many had lost confidence in the Pill. Initial clinical trials were conducted on poor women in Haiti and Puerto Rico with funding from population control institutions, underscoring the racist agenda of some of the pill's promoters.[33] The first pill, Enovid, contained approximately ten times the amount of progesterone and four times the amount of estrogen used in later doses. Many women suffered from severe side effects, including blood clots and heart attacks. Working as a columnist for the *Ladies' Home Journal*, Barbara Seaman (a founder of the National Women's Health Network) began receiving letters from her readers who were concerned about the risks of using the Pill. "I started finding out very early on that the patients taking the pill didn't agree with the doctors that it was perfectly safe and simple and wonderful," she wrote.[34] She followed up by interviewing other users, along with physicians and other health professionals, revealing a more widespread concern about the effects of the hormonal contraceptive. The resulting book, *The Doctors' Case against the Pill*, inspired Senator Gaylord Nelson to hold congressional hearings on the safety of oral contraceptives in 1970.

While Seaman's book had not initially garnered much attention, the hearings received "intense media coverage."[35] Nelson used many of the

same doctors that Seaman had interviewed as expert witnesses for the hearing. But he did not ask Seaman—or any Pill users—to testify. For this he experienced the wrath of feminists who at one point interrupted testimony, shouting from the audience: "Why is it that scientists and drug companies are perfectly willing to use women as guinea pigs?" and "Why have you assured the drug companies that they could testify?. . .They're not taking the pills, we are!"[36] They were promptly dismissed from the room, but their outburst appeared on the evening news. This vivid scene was undoubtedly on the minds of Upjohn officials thirteen years later when they feared the presence of cameras at the Depo-Provera PBI.

Depo-Provera Testimonials

By the time of the PBI, health activists involved in the National Women's Health Network had become far more astute in recruiting patients' stories to illustrate what they believed to be the harmful qualities of the drug. They had also raised greater awareness and funds for women's health activism. The idea of creating such a network emerged in 1974, a brainstorm of Barbara Seaman and Belita Cowan, who believed that women's health should have a lobbying presence in Washington DC.[37] The organization was incorporated in 1976 with a twelve-member board of directors, and members consisted of both individuals and women's health organizations. The Network's budget, which was about $22,000 when the PBI hearings were first announced in 1979, was nearly $500,000 by the time they were held in 1983. During those same years, individual membership grew from under 3,000 to about 13,000.[38]

Through the NWHN newsletter and advertisements in women's magazines, the network solicited over 800 responses from Depo-Provera users interested in joining its patient registry in the 1980s. Though these responses are not necessarily representative of the larger patient population receiving Depo-Provera injections (with a clear bias toward those who were dissatisfied with the drug), they provide crucial evidence of how concerned women chose to interpret the drug's effects on their minds and bodies.[39] Sheryll, for example, wrote the NWHN in 1984, "This letter is written to register myself as one of the Depo-Provera guinea humans," suggesting that she saw herself as an unwitting subject. Her biggest concern, she explained in her letter, was that she had to watch her daughter face the same difficult choices about birth control that she had dealt with more than a decade earlier. Her daughter could not tolerate an IUD, failed with the diaphragm, and was currently taking birth control pills. "This is not progress," she wrote. "This is not the purpose of the FDA. . . . I think we are facing a national disgrace."[40]

Three weeks after having a hysterectomy to stop severe bleeding after a Depo-Provera injection, twenty-two year old Sara read about the NWHN patient registry in *Ms*. Though her anger was "clouding [her] senses," she vowed that her story was true. "Thank you for caring about this and me," she wrote from Buffalo, New York.[41] Nancy picked up the same issue of *Ms*. and decided to contact the network. "My experience you might not be interested in," she wrote from Delray Beach, Florida, "but I'd like to add my name to your list of unfortunate women who also received this drug." She proceeded to tell her story over four handwritten pages, documenting more than ten years of physical discomfort from endometriosis and her disillusionment with the medical profession. "I just want my story told to let other women know that if you need the help keep searching. There is someone out there who will believe in you and help you. . . Thank you for letting me tell my story."[42]

Some described Depo-Provera as having taken an enormous toll on their emotions and personal life. Kay, for example, sought legal advice about the drug after experiencing severe side effects. She recalled that she was not given any warning about these risks and did not sign any consent forms. She experienced heavy bleeding from her 250-mg dosage and told her doctor she did not want to receive any more injections, but he suggested increasing the dosage to 400 mg instead. "Since I have received these shots," she declared in an affidavit, "I have experienced such spells of weakness that I felt like my body was encased in a huge block of cement, and I could hardly drag it around." When trying to retrieve a piece of paper that had fallen under her bed, she claimed that she could not get back up off the floor for half an hour, due to weakness. She also experienced depression, vision problems, painful intercourse, and weight gain, though she did not initially connect these effects to the drug. "Then I discovered the truth about Depo-Provera, and all of my mysterious symptoms fell into place," she wrote.[43]

This notion of "discovering the truth"—or the belief that the drug's actual effects were finally coming to light as a result of the women's health movement—influenced many women who chose to join the NWHN registry. Several discussed their frustration with a doctor or clinician who made them feel like it was "all in their head." One recalled, "I was so uncomfortable—even miserable—on this medication that I pleaded with the dr. to tell me if certain symptoms could be related to the drug. I would say 'does this medication cause nervousness or depression?; he'd say—always ' 'do you feel nervous or depressed? Are you sure you're not just feeling overly emotional about your failure to get pregnant?" so I'd drop it. Or he'd relate any symptom to my being overweight only."[44] Another remembered, "When I began having very severe pain in my breasts and hot spots I mentioned

this to the doctor and he replied 'all you women are alike. You all think you have cancer. Just keep up with the injections'."[45] One presented her theory as to why patients encountered this phenomenon. "I'm sure you and other women in your group have run into the 'I can't find out what's wrong—so it must be in your head' syndrome so many physicians suffer from," she wrote. "It's easier and less ego-damaging than saying 'I don't know what's causing the problem.'"[46]

Most of those who chose to participate in the NWHN patient registry indicated that they were not aware that Depo-Provera had not been approved by the FDA for contraceptive use, or that it had potential side effects. For example, only 16 out of 322 women who filled out one particular version of the registry checked that they were satisfied with the drug. As a result, many presented themselves as unwitting subjects of an experiment, rather than as informed patients. Many compared themselves to test animals. Janice remarked, "I feel like a lab rat," after one injection of Depo-Provera was followed by crippling leg pain, weight gain, and depression. "It pains me to think that before this happened I was a normal 30-year-old single woman working on my college degree at the University of Texas," she continued.[47] Renee wrote, "I can't believe that on top of everything else that happened to me they would give me a drug that had not been fully tested or approved. I feel like a human guinea pig."[48] Celestine, who was diabetic, received two injections of the drug at the Grady clinic in Atlanta and experienced "overwhelming symptoms . . . . I think I was just a guinea pig."[49] She added that she had kept the drug in her refrigerator as a reminder. Though she did not specify what she wanted to be reminded of, we can assume that it was Depo-Provera's misuse. Patricia, diagnosed with endometriosis, expressed anger that she had trusted the doctor and was not told about side effects. "The only positive result of the experience was that I began to be greatly concerned about the medical/pharmaceutical world's use of women as guinea pigs."[50]

Others portrayed themselves as unwitting human subjects. "I was a Depo-Provera victim for one year in 1967–68," recalled Sarah, blaming the drug's side effects for ruining her marriage. "At the time I took the shot I was happily married. After one year of hating it when my husband touched me, and being depressed so chronically, so much damage had been done to our bonds of trust and love that we proceeded to get a divorce." Her anger stemmed from her sense of betrayal, and she portrayed herself as an unknowing subject. "To be part of a study and to be ignored when you are the one to report side effects is an unconscionable act by the drug companies pushing their wares."[51] Another wrote that although she believed her case was not "as serious as others," she felt "violated that I was used in negligent

medical practice."[52] One woman of color, who was fifteen when she had been given the shot as a contraceptive at the Grady clinic, felt in retrospect that she had been too young and naïve in her willingness to be injected with Depo-Provera. "If I knew then what I knew now I would have never taken the shot," she wrote on her registry form.[53] Underscoring the coercive use of the drug on some poor women of color, another Grady patient wrote that her welfare worker ordered her to take the drug. "She said that if I didn't take it my check would be cut off."[54]

The stories about Depo-Provera use that emerge from the majority of the NWHN registry forms (and attached letters) are filled with emotion—anger, frustration, fear, confusion, and determination. Most complained about an unexpected side effect—or a condition that they believed to be a side effect—of the drug. Many would not have thought about the effects of the drug if it were not for the "Stop Depo-Provera" campaign launched by the NWHN, or the media coverage it promoted (including special episodes on Phil Donahue's talk show and *Hour* magazine, to which many registrants referred). There is a feeling of injustice and outrage that a drug they now believed to be hazardous was used so freely on healthy women. The registrants also shared the assumption that since the FDA had not approved Depo-Provera as a contraceptive (which many claimed not to understand when they had agreed to the injections), it was unsafe.

Activist Strategies

These were precisely the images that the NWHN wanted to capture—indeed, helped to create—to draw attention to what they believed was reckless use of the drug. These were the testimonials that it wanted entered as evidence in the PBI. They did, in fact, submit a stack of letters and registry into the public record. And Judy Norsigian carried a box of these documents to the hearing, its weightiness a reminder of the many women negatively affected by the drug.

But because of the nature of the hearing—a scientific board of inquiry—the NWHN was discouraged from presenting this type of anecdotal, emotional evidence (in and of itself, of course, a gendered construct). As soon as the FDA commissioner granted Upjohn's request, the network sought legal counsel to investigate ways in which it could remain involved in the hearing, despite its scientific format. Its attorneys stressed that the hearings would be "extremely scientific," unlike congressional or legal proceedings "which tend to be imprecise and involve more sociological/political presentations." Instead, presentations and rebuttal would be very technical; speakers would be engaged in "complex scientific discourse."

They cautioned the NWHN to restrict witnesses to real experts—in order to be taken seriously. The group must put forth "hard scientific evidence" and "refrain from including presentations on the sociological, political or economic aspects of the problem."[55]

This warning—limited their presentation to "hard scientific evidence" and "expert witnesses"—forced these activists to confront problems with their ideology. If they truly believed that expertise is rooted in individual bodies, and that knowledge is experience-based, rather than acquired through advanced medical degrees, then this was a fruitless task. All women are experts, and it would be impossible to refrain from sociological aspects of the problem.

This resistance is apparent in some of the activists' preparations for the hearing. Most notably, activist Gena Corea, a strong-minded feminist activist and journalist who had published *The Hidden Malpractice: How American Medicine Mistreats Women* in 1977, struck a controversial chord in the first draft of her PBI testimony: "It is not often the voices of women are heard in such rooms as this and they may occasionally be loud for having been stifled so long. We will speak in a different voice. The words we choose may sound strange to the experts gathered here. We will not speak of 'therapeutic modalities' in referring to drugs which may cause cancer in our bodies or impair our ability to resist disease, nor will we describe that devastation to our bodies, to our very beings, as 'epidemiological fall-out,' a phrase which moves like fog across the mind to obscure tremendous female suffering."[56]

This draft elicited concern from other NWHN supporters planning to testify—one even threatening to withdraw unless the testimony was changed—because they believed such comments would only antagonize. "Gena's written testimony is an attempt to interject her own value judgments into a scientific setting and call it a scientific paper," declared Vicki Jones, MPH, whom the network had asked to testify. She found that most of Corea's paper consisted of assumptions, not facts. "I cannot follow a testimony that is unscientific, hostile, and inappropriate," she explained. "I feel this type of testimony will create a hostile and unreceptive atmosphere and will ultimately discredit those like myself who are qualified and trained to give scientific testimony in a professional manner." Instead, she believed that "the surest approach to get scientists to listen, rather than just to hear, is to fight expertise with expertise."[57]

The difference between the two approaches—one emotional, the other rational—speaks to the fundamental dilemma faced by feminist health activists by the 1980s. While the case of Depo-Provera exacerbated these tensions, activists in other areas, such as breast cancer and later, AIDS,

also confronted this conundrum as they sought to "democratize medical decision-making."[58] On one hand, they criticized science and scientific inquiry for ignoring women's experiences and perspectives. On the other, they wanted to influence scientific regulation and policy, which required playing by the rules—fighting "expertise with expertise." But in attempting to present themselves as both outsiders and insiders, they threatened their legitimacy in both groups. They sought to "reform science by exerting pressure from the outside," in the words of sociologist Steve Epstein, "but also to perform science by locating themselves on the inside."[59] At the PBI, this tension was apparent even before the hearing began, with the controversy over whether videotaping would "encourage theatrics or emotional statements rather than . . . objective scientific testimony," as Upjohn's attorney suggested it would—an obvious attack on feminist politics.[60]

Incorporating an evidenced-based approach to the Depo-Provera debate required outside counsel. The Washington DC firm of Steptoe & Johnson agreed to provide the NWHN with pro-bono legal representation in connection with the hearing by providing assistance on procedural matters. While the firm expected the NWHN to "take the lead in developing its position and contacting witnesses and formulating their testimony," it was "consulted concerning strategy and the general development of the Network's position." It also agreed to represent the group at the hearing.[61]

But most of the preparation work for the hearing was done by individual members of the NWHN—primarily Belita Cowan, Gena Corea, and Judy Norsigian. One of their intentions was to generate as much publicity on the case as possible, in order to educate women, especially women of color, about the side effects of Depo-Provera. They did this through network "Newsalerts" and advertisements in women's magazines and African American newspapers. Health activist Billye Avery, the only woman of color involved in the founding of the Gainesville Women's Health Center in 1974, also made important connections between the African American community and women's health activists. She joined the board of the National Women's Health Network in the mid-1970s and along with other women of color in the network, began to organize the first national conference on Black women's health, to be held at Spelman College in Atlanta in 1983. She moved to Atlanta in 1981, just as the Depo controversy was heating up. Atlanta was home to Grady Memorial Hospital, the site of controversial Depo-Provera trials.[62]

The Grady Trials

At the center of the political and scientific debate about the use of Depo-Provera as a contraceptive in the United States was a birth control clinic in

downtown Atlanta. The Grady Memorial Hospital Family Planning Clinic, founded in 1964, treated over 50,000 lower-income neighborhood women, primarily women of color, in its first few years.[63] From 1972 to 1978, lower-income women of color received injections at Grady as part of the largest U.S.-based clinical trials of Depo-Provera. Birth control advocate Dr. Robert Hatcher, known to his friends and family as "Captain Condom," oversaw the trials as director of the clinic and remains on the faculty at Emory University, in the Department of Gynecology & Obstetrics.[64] Approximately nine thousand women of color were injected with Depo-Provera as part of the study before it was terminated by the FDA in 1978. The Grady trials quickly became controversial. Supporters and opponents, policymakers, researchers, and activists debated whether Grady patients were victims of racist policies that endangered their health, or recipients of a "superb contraceptive," in Dr. Hatcher's words.[65] Much of the data later debated at the PBI centered on the controversial Grady studies.

In his own analysis, Hatcher found that Grady patients were enthusiastic about the drug, stressing its convenience and reliability during interviews he conducted in 1978. Unlike the angry testimonials describing terrible side effects collected by the NWHN, Hatcher's examples reveal that some women viewed Depo-Provera as a valid birth control option. "I want the 'shot,'" stated one. "I don't want to use the pill or anything else. I'd go crazy; I'd worry all the time about getting pregnant. . . It's the only thing I trust." Far from sounding like a victim, this patient clearly felt empowered by her ability to receive the injections. "The shot's the best for me," announced another Grady patient. "I've used it for two years; if they stopped it I'd go through the floor. . . It's our choice, not the Government's." Yet as the authors of *Undivided Rights* point out, "'choice' implies a marketplace of options in which women's right to determine what happens to their bodies is legally protected, ignoring the fact that for women of color, economic and institutional constraints often restrict their 'choices.'" Many of those opposed to the use of Depo-Provera believed that it was not a safe option, regardless of its reliability or effectiveness.[66]

Despite his enthusiasm for Depo-Provera as a contraceptive, Hatcher had to tread carefully in his testimony at the PBI. When he took the stand on 13 January, the fourth day of the hearing, his Grady trials had already come under attack. Some witnesses, including Dr. Robert Hoover, an epidemiologist from the National Cancer Institute, pointed out that there were major flaws with the study. There were no controls, nearly 50 percent of the patients were lost to follow-up, and most received minimal exposure to the drug (less than one year). "I think you would want a combination of both a prospective follow-up study and a series of case control studies," Hoover

explained, when asked to define what an adequate study would look like.[67] "It should be designed to include a substantial number of women who received meaningful doses or a number of years of use." His final words on the subject probably made Hatcher wince. "I guess I am a little surprised at the inadequacy of the case from the human side given the fact that there is an opportunity to do it."[68] Dr. Renate Kimbrough of the Center for Disease Control agreed. "I feel that this study, number one, is too short in duration. . . . You should follow patients at least for twenty years. . . . In addition to that, the number of patients is really quite small."[69]

On the defensive, Hatcher presented himself as a clinician whose time was consumed by running a large and much-needed family planning program. "I do minimal research and I am not a sophisticated epidemiologist," he explained.[70] He emphasized that Grady was a "service setting," one in which funds were consistently cut, which prevented the staff from doing "some things we might have liked."[71] After receiving some critical questions from PBI chair Judith Weisz, he noted, "To be very honest with you, we are not a research unit. I mean, it's not like a research unit. And when we have not had the funds to do something specific we haven't done it."[72]

Though Hatcher felt strongly that Depo-Provera should be approved by the FDA, he had to exercise caution in his appeal. Five years before the hearing, the FDA audited, then terminated, the Grady Clinic Depo-Provera study. In its report, the agency's Clinical Investigations Branch noted that "the contraceptive use of Depo-Provera at Grady Hospital Family Planning Clinic is routine in nature and is in no way investigational."[73] Complaints included poor record keeping ("No meaningful medical information is recorded and the form is apparently used primarily for billing purposes"), and lack of follow-up.[74] Members of the Clinical Investigations Branch committee learned from patient interviews that while most had signed a consent form, they were unaware that Depo-Provera was not FDA approved as a contraceptive. Based on their findings, the committee determined that "the use of Depo-Provera at Grady provides neither evidence of safety nor of effectiveness of the drug."[75] At the PBI, Weisz was well aware of these findings. "It's quite clear from the documents that you have admitted that the intent was excellent," she commented. "However, if one reads the report of the audit by the FDA in 1978 it is—it appears that there were some flaws in the translation of the intent into actual action."[76] Hatcher agreed. "I think it was a serious failure. But, however, I do not believe that it was detrimental to our patients."[77]

The NWHN members in attendance disagreed. Though deterred from providing anecdotal evidence at the PBI, they knew from the descriptions in the patient registry that Depo-Provera could be detrimental. Rather than

offer individual stories of suffering to the inquiry board, they raised questions about the assumed objectivity of the human studies. Dr. Helen Holmes, science and society scholar at Spelman College, expressed concern about the inadequacy of studies on Depo-Provera; particularly those that "purport to demonstrate absence of harmful effects. . . . Many tests are so designed and conducted that they cannot yield meaningful information about Depo-Provera."[78] Her first concern was with the inadequacy of follow-up. "Over the past few days we have been given some amazing figures about the numbers of women who have had Depo-Provera, millions of women, and each speaker doesn't seem to agree with the next. I'm concerned about these women: if so many of them have had Depo-Provera, where are they and why haven't they been followed?"[79] Such a question begs comparison with the 1970 Nelson pill hearings, during which feminists from D.C. Women's Liberation demanded to know why pill users were not allowed to testify. But this time around, the concern was being voiced by a participant in the hearings, not an outsider. As a scholar, Holmes could challenge the methodology of the studies, in a way that activists without advanced degrees previously could not.

But it was not just the absence of the women themselves from the data that disturbed Holmes. She also questioned the remarkable absence of reported side effects. "Depo-Provera users have complained of completely unpredictable spells of bleeding, of splitting headaches, of loss of sexual desire," she reminded the board. Why was this absent from the data? Holmes provided a sociological explanation, underscoring the critical divisions of gender, class, and race. "The user may be ashamed to describe any of these to a stranger, especially to one of a different social class or race. . . . She may have heard from her friends that their complaints were doubted and/or dismissed as not relevant. Even a normally assertive American woman may be intimidated by the power of the so-called medical mystique."[80] So perhaps the absence could be attributed to the reticence of patients. But another, perhaps more critical problem, Holmes maintained, was that doctors failed to ask about side effects in the first place, or failed to take those they heard about seriously. Was heavy bleeding or depression or migraines a minor issue? These were effects that "can completely ruin the quality of a person's life."[81]

Holmes' strategy—to offer possibilities for the absence of data—essentially brought the voices and stories from the NWHN patient registry into the hearing. She avoided anecdotal evidence, but still created a setting in which a listener could imagine an innocent woman debilitated by heavy bleeding or blinding headaches. Given that the board's task was to determine whether the benefits of the drug outweighed the risks, such testimony

could be interpreted as scientific, because it suggested that quality-of-life issues played a role in determining the risk/benefit ratio. This was thus a subtle yet powerful contribution to the hearing, because it paved the way for a more critical feminist assessment of scientific methods. To dismiss a woman's complaints as being "all in her head" was no longer just sexist—it was bad science.

In the end, the Public Board of Inquiry agreed. On 26 October 1984, it submitted its final report and publicly announced its recommendation that the FDA not approve the drug. As a reporter for the journal *Science* noted, this was a "severe blow" to the Upjohn Company.[82] As Judith Weisz explained in the report, "The facts relating to the long-term consequences of the use of the drug are inadequate and insufficient to provide a basis for risk assessment. This is a serious deficiency in light of the specific questions that have been raised that the drug may have major adverse effects following its long-term use or that may become evident only after a latent period."[83]

Weisz was predominantly critical of how studies at the Grady Clinic had been conducted. "It is particularly unfortunate that the opportunity was missed to collect meaningful information at the Grady Clinic. . . . This was a setting in which, at least theoretically, resources might be expected to have been available for adequate collection of data relevant to the population in the United States."[84] In the absence of substantive data, many of the scientists pooled data to describe the number of "women-years" studied. Significantly, Weisz credited a health feminist with successfully challenging this methodology. "The fallacy of this approach has been stated most aptly by a witness for the Women's Health Network to the effect that while it takes nine months to produce a baby, nine women, each one contributing one month, cannot produce a baby."[85]

Despite Weisz's disdain for how the Depo-Provera studies had been conducted, she agonized over her final report. "I was up all night saying, you know, how am I going to summarize all this experience," she recalls. She knew the PBI's decision would have political and international ramifications. "But if science has anything to say about this, it has to be the best science possible."[86]

FDA commissioner Frank Young agreed, telling Weisz that she had "tackled a truly Herculean task in an exemplary manner." He was particularly impressed with what a thorough job she had done. "I know that you worked many nights and weekends wrestling with how to strike an appropriate balance among competing and conflicting concerns." As with Commissioner Edwards and General Counsel Hutt before him, Young supported the idea of professionalizing the FDA with the use of outside experts. Though neither he nor any of his followers would oversee another

PBI, Young found Weisz's role to be "an excellent model of how outside experts can improve public policy decision-making." Weisz had been invaluable, he concluded, "in helping to resolve a very important scientific and public health issue."[87]

Not all outsiders, however, were granted the same honor or authority as was Weisz. Health feminists had come a long way in terms of their political and professional roles in regulatory decisions. They participated in the hearing, and one was even quoted in Weisz's final report as most aptly criticizing the use of "women-years" as legitimate scientific evidence. But they were in a more complicated position than was Weisz (though she, too, calls herself a feminist).[88] They were torn between the experiential evidence provided by the bodies of individuals (the testimonials) and the scientific evidence of experts.

In the end, individual stories played only an indirect role in the hearing. Instead, activists chose to highlight particular women as victims in a proposed (but unsuccessful) class action lawsuit, at a separate press conference. Professionalism compromised their ability to use these stories, requiring different strategies. Instead, they turned to a more traditional type of expert—one whose credentials were listed after her name, not derived from any "authentic experience" as women. They provided more statistics than stories, touting evidence-based medicine over antimedicalization. This compromise resulted in a mixed legacy for women's health activism. On one hand, it allowed for greater recognition and potential impact within organized medicine, generating more legislation and regulation of women's health research and practice. On the other, it weakened the movement's ideological basis—albeit slippery to begin with—by undermining the notion that knowledge and power are rooted in the biological body.

NOTES

[1]Judith Weisz, interview with author, 4 March 2008.

[2]Jess Stribling, interview with author, 23 April 2008.

[3] Weisz interview, 4 March 2008.

[4]Quoted in Jenny Lindsay, "The Politics of Population Control in Namibia," in *Women and Health in Africa*, ed. Meredeth Turshen (Trenton, NJ: Africa World Press, 1991), 146.

[5]Belita Cowan, 29 April 1979, National Women's Health Network (NWHN) records (acc. no. 99s-33), box 10, folder "Old," [unprocessed collection], Sophia Smith Collection, Smith College Library, Northampton, MA, hereafter SCL.

[6]Jael Silliman et al., *Undivided Rights: Women of Color Organize for Reproductive Justice* (Cambridge, MA: South End Press, 2004), 35.

[7]Rosalind P. Petchesky, *Abortion and Woman's Choice: The State, Sexuality, and Reproductive Freedom*, rev. ed. (Boston, MA: Northeastern University Press, 1990), 177.

[8]See, for example, the early editions of *Our Bodies, Ourselves* (New York: Simon and Schuster, 1973, 1976, 1979, 1984).

[9]For an overview of recent scholarship on drug regulation, see Andrea Tone and Elizabeth Watkins, eds., introduction to *Medicating Modern America: Prescription Drugs in History* (New York: New York University Press, 2007), 1–14.

[10]Judith Weisz, interview with author, 22 April 2008.

[11]Ibid. At the age of eighty-one, she is still active in her community, protesting the development of an ethanol plant in her town, as well as continuing her research at Penn State.

[12]Judith Weisz, interview with author, 4 March 2008.

[13]Judith Weisz, Griff Ross, Paul Stollery, "Report of the Public Board of Inquiry on Depo-Provera" (1984), 5, NWHN records, SCL.

[14]U.S. Food and Drug Administration, *Official Transcript of Proceedings, Depo-Provera Public Board of Inquiry*, 10 January 1983, 1: 5, NWHN records, SCL.

[15]Upjohn Company, "Request for a Public Board of Inquiry," 25 August 1978, FDA docket no. 78-0124, supplement, 54. These records are stored on microform in the FDA Division of Dockets Management, Rockville, MD, hereafter FDA DDM.

[16]"Memorandum of Decision Granting Request for Public Board of Inquiry in the Matter of Depo-Provera Sterile Aqueous Suspension," FDA docket no. 78N-0124, 1: 103, FDA DDM.

[17]Weisz interview, 4 March 2008.

[18]Kenneth M. Cyrus letter to Jess Stribling, 9 December 1982, FDA docket no. 78-0124 207, 150–52, FDA DDM.

[19]Larry La Motte to Commissioner Hayes, 5 January 1983, FDA docket no. 78N-0124, 163, FDA DDM.

[20]USFDA, *Official Transcript of Proceedings*, 1: 38.

[21]Jess Stribling, interview with author, 23 April 2008.

[22]Weisz interview 4 March 2008.

[23]Suzanne Junod, "Women over 35 Who Smoke: A Case Study in Risk Management and Risk Communications, 1960–69," in *Medicating Modern America*, 98.

[24]Barbara Resnick Troetel, "Three-Part Disharmony: The Transformation of the Food and Drug Administration in the 1970s" (PhD diss., City University of New York, 1996), 5.

[25]Ibid., 63.

[26]Ibid., 80.

[27]Stribling interview, 23 April 2008.

[28]Junod, "Women over 35," 98.

[29]Rickie Solinger, *Pregnancy and Power: A Short History of Reproductive Politics in America* (New York: New York University Press, 2005), 3.

[30]Ross quoted in Silliman et al, *Undivided Rights*, 4.

[31]Silliman et al, *Undivided Rights*, 11. See also Jennifer Nelson, *Women of Color and the Reproductive Rights Movement* (New York: New York University Press, 2003), Johanna Schoen, *Choice and Coercion: Birth Control, Sterilization, and Abortion in Public Health and Welfare* (Chapel Hill: University of North Carolina Press, 2005).

[32]Elizabeth Siegel Watkins, *On the Pill: A Social History of Oral Contraceptives, 1950–1970* (Baltimore, MD: Johns Hopkins University Press, 1998).

[33]Petchesky, *Abortion and Woman's Choice*, 171.

[34]Quoted in *Washington Post* obituary, 29 February 2008, B07.

[35]Watkins, *On the Pill*, 107.

[36]Ibid., 112.

[37]http://www.nwhn.org/about/index.cfm?content_id=30&section=About (accessed 11 November 2009).

[38]Suzanne Staggenborg, *The Pro-Choice Movement: Organization and Activism in the Abortion Conflict* (New York, 1991), 167–68.

[39]Copies of these registries are in the NWHN records, 99s-33, box 7, SCL. Copies of the letters are in 99s-33, box 8, SCL. The registries are difficult to compare and analyze, because two different types were used and the collection is unprocessed. I entered the answers into two different databases (DP1 and DP2) based on which form was used. In all, 167 registrants answered using the first form and 362 answered with the second.

[40]Letter attached to registry #51, DP2, NWHN records, box 7, SCL.

[41]Letter, 23 January 1980, DP2, NWHN records, box 8, SCL.

[42]Letter attached to registry #53, DP1, NWHN records, box 7, SCL.

[43]Letter, 25 July 1980, NWHN records, box 8, SCL.

[44]Registry #25, DP2, NWHN records, box 7, SCL.

[45]Registry #27, DP2, NWHN records, box 7, SCL.

[46]Letter attached to registry #114, DP2, NWHN records, box 7, SCL.

[47]Registry #39, DP2, NWHN records, box 7, SCL.

[48]Registry #156, DP2, NWHN records, box 7,SCL.

[49]Registry #262, DP2, NWHN records, box 7, SCL.

[50]Registry #58, DP1, NWHN records, box 7, SCL.

[51]Letter, 3 August 1979, NWHN records, box 7, SCL.

[52]Registry #34, DP2, NWHN records, box 7, SCL.

[53]Registry #277, DP2, NWHN records, box 7, SCL.

[54]Registry #294, DP2, NWHN records, box 7, SCL.

[55]Office member, 28 October 1980, NWHN records, 99s-33, box 10, SCL.

[56]Gena Corea, "Draft of NWHN Testimony before the FDA Board of Public Inquiry Hearing on Depo-Provera," 97s-5, box 16, SCL.

[57]Vicki Jones to Belita Cowan, 18 December 1982, NWHN records, 97-s, box 15, SCL.

[58]Barron H. Lerner, *The Breast Cancer Wars: Hope, Fear, and the Pursuit of a Cure in Twentieth-century America* (New York: Oxford University Press, 2001), 229.

[59]Steven Epstein, *Impure Science: AIDS, Activism, and the Politics of Knowledge* (Berkeley: University of California Press, 1996), 13. Epstein labels this process "expertification." While he makes a reasonable claim for the role of AIDS activists in transforming the production of scientific knowledge, it is important not to downplay the earlier contributions of women's health activists to this process.

[60] Cyrus to Stribling, 9 December 1982.

[61]Susan G. Esserman and Roger E. Warin to Sybil Shainwald, 3 December 1981, NWHN records, 99s-33 box 10, SCL.

[62]Silliman et al., *Undivided Rights*, 65, Sandra Morgen, *Into Our Own Hands: The Women's Health Movement in the United States, 1969–1990* (New Brunswick, NJ: Rutgers University Press, 2002), 45.

[63]Malcolm Potts, "Statement of Position," FDA docket no. 78N-0124, Boston Women's Health Book Collective Records, Rare Books Depository H MS c261, box 34, Francis A. Countway Library of Medicine, Harvard University, Boston, MA.

[64]http://www.webmd.com/robert-anthony-hatcher (accessed 11 November 2009).

[65]Statement of Robert A. Hatcher, "The Depo-Provera Debate," *Hearings before the U.S. House of Representatives Select Committee on Population, Ninety-fifth Congress, second session,* 8 August 1978, 213.

[66]Silliman et al., *Undivided Rights*, 5.

[67]USFDA, *Official Transcript of Proceedings*, 2: 198.

[68]Ibid., 2: 200.

[69]Ibid., 2: 230.

[70]Ibid., 4: 5.

[71]Ibid., 4: 28.

[72]Ibid., 4: 35.

[73]USFDA, memorandum from Clinical Investigations Branch, 23 February 1979, FDA files, 248: 168–72, FDA docket no. 78-0124, 5.

[74]Ibid., 2.

[75]Ibid., 5.

[76]USFDA, *Official Transcript of Proceedings*, 4: 26.

[77]Ibid., 4: 27.

[78]Ibid., 4: 185.

[79]Ibid., 4: 187.

[80]Ibid., 4: 189.

[81]Ibid., 4: 190.

[82]Marjorie Sun, "Panel Says Depo-Provera Not Proved Safe," *Science*, 23 November 1984, 950.

[83]Weisz, Report of the Public Board of Inquiry," 172.

[84]Ibid., 87.

[85]Ibid, 88.

[86] Weisz interview, 4 March 2008.

[87]Frank Young to Judith Weisz, 28 January 1987, FDA Administration Files, Upjohn Company, AF12-868, vol. 106, FDA. This is a a separate collection of records kept on pharmaceutical companies stored in the basement of the National Archives in College Park, MD, to which the author was granted special access.

[88]Weisz interview, 4 March 2008.

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