Introduction

*The Odyssey of Depo-Provera*

The Pill, the IUD, and Norplant have dominated public awareness and debate over contraceptive technologies. Depo-Provera, a three-month injectable drug, held out the promise that it could also play a leading role in the contraceptive revolution, but it has not received much more than episodic public attention. Still, the drug has raised difficult questions about its experimental, contraceptive, and criminal justice uses. After the FDA approved The Upjohn Company’s application to test Depo-Provera as a female contraceptive in 1963, the drug was administered to 11,400 women at the Grady Memorial Hospital’s Family Planning Clinic in Atlanta, the drug’s major domestic clinical trial. The drug was also administered to convicted male sex offenders at the Johns Hopkins Hospital in Baltimore, but without the FDA’s experimental authorization. Neither at Grady nor at Johns Hopkins did the men and women involved in these studies give their informed consent. Depo-Provera’s approval for other medical purposes as early as 1960 meant that for thirty-two years prior to its FDA contraceptive approval in 1992, physicians were able to prescribe the drug as a contraceptive and state trial court judges were able to impose it as a probation condition for sex offenders. Depo-Provera’s FDA contraceptive approval has made little difference in the drug’s contraceptive and criminal justice uses. Physician prescribing practices and judicial use of the drug continue to raise serious ethical and legal issues. Female patients and male defendants are still injected with the drug without being informed of Depo-Provera’s short- and long-term side effects.

The odyssey of Depo-Provera is a study of the politics of contraceptive drug risk management. According to the conventional two-stage model of risk management, risk assessment, the first stage, “is the use of the factual base to define the health effects of exposure of individuals
or populations to hazardous materials or situations.” Risk acceptability, the second stage, “is the process of . . . integrating the results of risk assessment . . . with social, economic, and political concerns to reach a decision.” This model allows us to identify the risk assessment and risk acceptability elements of a regulatory decision, but it cannot explain the controversy over the assessment of the drug’s risk and the determination of its acceptability, because the model assumes a separation of fact and value. This study adopts an alternative view: the strict separation of facts and values cannot be maintained in practice, because the scientific basis of risk assessment is often incomplete and policies based on that information become enmeshed in larger debates. In the case of Depo-Provera, those debates concern issues such as pharmaceutical innovation, human experimentation, and the FDA’s marketing authority; population control, reproductive health, and state medical malpractice and products liability law; and deviant sexual behavior, alternative criminal punishments, and defendants’ constitutional rights.

Depo-Provera has received only occasional attention as a twenty-five year national struggle over Upjohn’s FDA application to license it as a contraceptive drug. Rarely has its story been linked to state medical malpractice and products liability issues raised by its contraceptive use or to the criminal justice issues raised by its use as a sentencing alternative. To tell the story of contraceptive drug risk, this study turns to Judith Weisz, a reproductive biologist who evaluated Upjohn’s Depo-Provera research, to Anne MacMurdo, a college student who received the drug for contraception, and to Roger Gauntlett, an Upjohn heir, who was ordered to take the drug as a probation condition. Together they tell a collective story of Depo-Provera’s fifty-year odyssey, which connects the national controversy over its FDA approval to the state civil and criminal legal issues raised by the use of the drug.

Depo-Provera and Contraceptive Risk

This introduction presents the principal participants; identifies the leading ethical, scientific, and political issues; defines the administrative, civil, and criminal legal risk management arenas; and establishes the criteria to evaluate contraceptive risk in terms of the stories told by Judith Weisz, Anne MacMurdo, and Roger Gauntlett. Their stories
portray contraceptive drug risk management as a fragmented activity structured by the Federal Food, Drug, and Cosmetic Act, state negligence and products liability law, state probation and parole law, and the federal Constitution. Their stories have been framed by the FDA’s marketing decisions, state medical malpractice and products liability law, and state criminal sentencing law and practice, and have been driven by the competing values of pharmaceutical innovation and profits, professional medical autonomy, population control and women’s reproductive health, and civil and criminal justice. In sum, the odyssey of Depo-Provera is a study in the politics of contraceptive risk.

Three Stories of Contraceptive Risk

**JUDITH WEISZ’S STORY**

Judith Weisz’s story views the odyssey of Depo-Provera as a study in the politics of risk management. Why choose Dr. Judith Weisz, a reproductive biologist at the University of Pennsylvania’s Hershey Medical Center, from among all the people involved in the drug’s administrative controversy? As chair of the FDA’s Depo-Provera Public Board of Inquiry, a scientific court established by the agency to analyze the drug’s medical research, she studied the scientific evidence, heard testimony from all interested parties, and wrote a report recommending that the FDA not grant Upjohn a license to market Depo-Provera. Her scientific impartiality, objectivity, and expertise provide a vantage point for examining the FDA’s risk assessments of the drug’s research, the agency’s policy judgments about the drug’s health risk acceptability, and the scientific and political scrutiny of its drug marketing decisions by Upjohn, by health, women’s, and population control organizations, and by members of Congress. She provides the same vantage point for understanding the state medical malpractice and products liability lawsuits brought by women to recover for their injuries from the drug’s use and the state criminal justice use of the drug as a probation and parole condition for sex offenders.

**ANNE MACMURDO’S STORY**

Anne MacMurdo’s story examines Depo-Provera’s contraceptive use. She and thousands of American women received “the Shot.” Some of these