# MEDICAL INNOVATION: ORAL CONTRACEPTIVES (MEDICAL INNOVATION: SMALL MOLECULE)

Physician: Gregory Pincus, Carl Djerassi, Frank Colton Industry: G. D. Searle

#### Situation

#### Millions of unwanted pregnancies, with a cost in the billions

Until the second half of the twentieth century, women's options for family planning and preventing unwanted pregnancies were extremely limited, and were in most cases ineffective and even harmful to women's health. Condoms and diaphragms were only adopted in America in the early part of the twentieth century, and both were far from reliable. As a result, <u>millions of unwanted children were born, and millions more aborted, from the lack of a reliable</u> contraceptive. The cost of unwanted pregnancies in America alone was billions more than it is today.

With the rapid development of the pharmaceutical industry in the early part of the twentieth century, <u>the idea of a developing a reliable oral contraceptive became a dream for some, but</u> was also deemed controversial by others. Just talking about preventing unwanted pregnancies was illegal in many jurisdictions, and in the late 19th century the federal government and several states adopted so-called "Comstock Laws" that, among other restrictions, prevented the distribution or promotion of contraceptive devices.

# **Physician-Industry Collaboration**

## A pioneer and activist team up with a renowned biologist

After the Second World War, Margaret Sanger, a pioneer and activist on the issue of contraceptives who had been imprisoned in the early twentieth century for distributing diaphragms and literature promoting family planning, teamed up with a wealthy friend, Katherine McCormick, to push for the development of an oral birth control pill. In 1953, they approached a physician and biologist named Gregory Pincus, who was an expert in hormonal biology, with the idea of discovering a way to use synthetic hormones to mimic the way real estrogen and progestin works in a woman's body to prevent ovulation.

Encouraged by the recent work of Carl Djerassi in Mexico on the creation of synthetic progesterone, McCormick offered to fund Pincus's research. Pincus in turn sought out the pharmaceutical company G.D. Searle with the concept. <u>Searle was reluctant, as contraception remained a controversial -- and, in some states, even illegal -- subject in American society</u>. However, Pincus was allowed to push forward with McCormick's funding.

Working with two colleagues, Min Chueh Chang and John Rock, Pincus built off of the work of Frank Colton at Searle, who had previously developed an experimental type of contraceptive that remained untested. Pincus was given samples of the drug for his research and in 1960, the dream was realized: it gained FDA approval as a contraceptive, Enovid. Within two years of government approval, 1.2 million American women used it every day. It was a giant boon to Searle, who enjoyed a monopoly on the drug. The Pill, the contraceptive that no company initially wanted produce, turned out to be Searle's best selling product for years.

## **Innovation Benefits**

## One of the 10 greatest public-health accomplishments of the 20th century

Although it was approved by the FDA, The Pill was not without side effects, mostly from the high dosage in which it was prescribed. Many women who used it suffered from nausea, blurred vision, bloating, weight gain, depression, blood clots, and strokes. In the 1980s, the dosage was changed and it became much better tolerated. <u>Today, oral contraceptives come in dozens of brands and many contain as little as one milligram of progesterone -- around one tenth that found in the earliest versions of the Pill.</u>

Originally a topic of great controversy, the development of oral contraceptives is now hailed as one of the 10 greatest public-health accomplishments of the 20th century. It allowed women to choose if and when they would have children, and giving them much greater freedom to pursue activities and careers outside of their homes and families. In 2002, 11.6 million American women were using the pill, according to a government-sponsored study. Today, it has been taken by more than 80 percent of all American women. In addition to preventing pregnancy, the birth control pill helps women to regulate their menstrual cycles and control acne as well.

# **Patient Benefits**

# "What it gave to me was the sense of ownership of myself"

The ability of women to avail themselves of a reliable and convenient contraceptive has literally transformed millions of lives, and Silvia Clark is among them. Speaking in the PBS production "<u>American Experience: The Pill</u>," Clark spoke of how it empowered her to take control of her life and career:

"The pill for me didn't immediately fix anything in terms of my relationship with my husband, or improve it in that sense. What it gave to me was the sense of ownership of myself, which at that point in my life was very, very important. I could foresee at the age of twenty-three having another baby and another baby and another baby. And I was very disturbed, myself, about the loss of who I was.

"The loss of the investment that I'd made in my education, any future for me. Now that was considered a selfish motive at that time but that's how I felt. And so the idea that I could do something that would give part of me back to me was very important. And my husband was quite happy for me to use the pill, it wasn't a secret at all, and I think he was probably relieved because it took that burden away.

"So all in all, I think it was very, very positive."