The Birth of Conspiracy

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This is the first in a series on Birth Control, compiled and presented with the aid of the Women's News Co-op.

In less than 10 years there has been a staggering increase in the availability of contraceptive devices. The most talked about of these has been the pill. The media, drug companies and medical establishment have advanced and profited from the myth that the pill has led to the sexual liberation of women. But nothing of the sort has happened. Women are still denied complete self-expression in this society, are still the second sex—looked at by men primarily as sex-objects. The contraceptive explosion has not extended their possible life choices in many important ways. Families may be smaller but the woman's place is still in the home. Furthermore, the continuing disclosures of many of the pill's possible side-effects makes it abundantly clear that whatever "freedom" the pill has given is greatly diminished by the risks and uncertainties involved in taking it.

The public's right to know was virtually ignored until this January, when Senator Nelson's Business Monopoly Subcommittee began calling people to the witness stand. There was ample testimony that oral contraceptives have widespread metabolic effects. Dr,__ Louis Hellman, til recently Chairman of the Food and Drug Administration's (FDA) Advisory Committee on Obstetrics-Gynecology, and one of the pill's most ardent advocates, testified that the scope of these effects was indeed "surprising." Citing these widespread effects, several witnesses agreed with Dr. Hugh Davis of Johns Hopkins, who testified that he doubted the medical soundness of giving healthy women "such powerful hormones to achieve birth control objectives that can be reached by simple means of greater safety." There was general agreement among the doctors that the oral contraceptive is still in the experimental stages and that much more research was needed. There was also agreement among the witnesses that to date, the FDA and the drug companies have largely failed in keeping women and doctors alerted to all the possible dangers of the pill.

All indications of possible dangerous side-effects—even when scientifically substantiated—came under the heading of "classified" information. It took a woman, Barbara Seaman, to reveal 50 possible side-effects of oral contraceptives in her recent book, THE DOCTORS CASE AGAINST THE PILL. These include sterility, heart disease, skin discoloration, nausea, depression, eye disease, urinary infections, cancer of the breast and cervix, liver disease and thrombophlebitis. An increased tendency to blood-clotting—thrombophlebitis was the first serious side-effect which came to light, breaking the spell which the drug companies and the media had created around "The Golden Pill." It is one of the few side-effects where a strong correlation with pill-taking has been scientifically determined. Another possible and especially frightening side-effect which will take years to determine is the possibility of genetic changes in the descendants of women using the pill.

Once the information leaked out, it didn't take long for women to respond. A recent Gallup poll published in NEWSWEEK reflected more than a little disillusionment and concern: 87% of the women polled had heard of the hearings—according to the poll, an amazingly high percentage of awareness on a public issue. 18% of the women polled stated that they had recently stopped taking the pill—one-third of these in response to the hearings. Another 23% of current pill-takers said they were giving "serious consideration" to stopping.

Until the recent hearings it was practically impossible for the average woman to obtain information about the pill. Patient pamphlets distributed by the drug companies were simplistic and slick, completely omitting poten-

tial risks. Media coverage of the pill was favorable, almost to the complete exclusion of negative research. When unfavorable studies were reported, the coverage was sensationalistic and non-specific. FDA and drug companies' response to such reports was that they were "non-conclusive." Everywhere we were deluged with statements from the experts (?)—Guttmacher, president of Worldwide Planned Parenthood, Hellman of the FDA, Dr. John Rock, co-discoverer of the pill—affirming the pill's absolute safety. After only a few years on the market, the pill had gained what Dr. David Clark of the University of Kentucky has called "a diplomatic immunity" from criticism. "In general," wrote Dr. Herbert Ratner in the spring 1968 issue of CHILD & FAMILY, "Favorable findings of drug companies'-subsidized physicians, promoters of the pill and naive physicians have been encouraged, widely distributed, scientifically inflated, maximized and extolled, whereas unfavorable findings have either been ignored, suppressed, rationalized, minimized or ridiculed."

Who was responsible for this colossal cover-up? Much of the responsibility must fall on the many doctors who failed to fully inform their patients of the pill's possible risks. Even after many unfavorable reports had seeped through drug company barricades, many doctors continued to prescribe the pill without warning their patients of possible complications. And all too often, women who questioned the pill's safety were told, as Nicholas von Hoffman puts it in a WASHINGTON POST article, "to run along and not worry about it."

When it comes down to it, the doctor is concerned with keeping up the image that he not only knows best—he knows everything. In the words of Morton Mintz, a journalist who has carefully documented the reckless marketing and promotion of the oral contraceptive in his recent book, THE PILL, the doctor-patient relationship is largely "built on the presumption that in medical matters the doctor knows best—that he would not prescribe the pill (or any drug) unless he had good reason to judge that doing so was relatively safe." Furthermore, this idea that "doctor knows best" is especially important if the patient is a woman and, more especially, if she is poor, non-white or young and unmarried. Consequently, any questions which a woman patient might raise about the pill's safety challenge the doctor's sense that he knows best in medical matters—the basis for his sense of himself as a professional.

Just such a portrait of the "professional" doctor emerged recently when a woman took a pill manufacturer to court to sue for personal injuries incurred by pill use. Dr. Robert Kistner of Harvard Medical School (one of the most ardent defenders of the pill at the congressional hearings) was a star witness for the defendant, G.D. Searle, makers of Enovid. Later, partial transcripts of his testimony were read at the subcommittee hearing. When asked by counsel for the plaintiff to what extent he went over the information contained in the Enovid pamphlet for doctors with a patient, Kistner replied: "I don't relate the package insert to the patient. The Package insert is related to me." When asked more specifically if he discussed the blood-clotting risk with his patients, Kistner replied that he did, if the patient herself initiated the discussion. He would not, he testified, initiate the discussion himself. When counsel for the plaintiff asked him why he didn't tell his patients of the potential risks involved in oral contraceptives use, Dr. Kistner replied:

"Well, if you tell them they might get headaches, they will get headaches."

Doctors explained their nonchalance about the pill on the basis of the (supposed) excellent medical supervision of the pill-takers. In October, 1969, Dr. Herbert Ley, Commissioner of the FDA was asked if he thought that women should be better informed of the pill's known and suspected risks. Dr. Ley replied that this was unnecessary since "sufficient medical supervision is exercised." But can there be "sufficient medical supervision" in the administration of a drug about which so much is still unknown? Advocates of the pill pushed the notion that prior to a prescribing of the pill, a complete physical examination was "sufficient medical supervision." But how could it be? As Mortin Mintz points out, even "the most careful and perceptive diagnostician could not on the basis of a favorable history and examination determine" if a particular woman was predisposed to blood-clotting; "neither could he detect a cancer in the breast."

In its heyday, the pill was given to practically any woman who asked for it. Very few women—private patients as well as clinic patients—received a thorough examination before they were put on the pills. Again, the advocates of the pill promoted the belief that after the pill was being taken, sufficient medical supervision meant a biannual checkup. And yet millions of women have their prescriptions automatically refilled every six months without even this superficial checkup. A Public Health official recently stated in an interview: "It is common practice for a woman to be given a bag of pills and told to come back in six months and then not be seen for a year. Under these circumstances it is impossible for the detailed instructions in the labeling to be followed."

(Dr. Ley resigned abruptly from the FDA in December, the day after the news of the British study implicating the high estrogen pills in a greater clotting risk reached this country. He has since expressed the opinion that a pamphlet describing the known and suspected complications of oral contraceptives in non-technical language should be included in every pack of pills.)

A very large share of the responsibility for the cover-up job that has surrounded the pill from the start must be laid squarely on the shoulders of the drug companies. It would be difficult to conceive the amount of promotion and publicity which the drug industry undertook to sell the pill to doctors. The Prescription Task Force of HEW estimated in 1968 that the drug industry spent $4500 per physician per year on advertising and promotion of all drugs. Plainly, this kind of money is persuasive. Furthermore, the drug industry is consistently one of the nation's most profitable. A recent article in FORBES magazine gives a partial explanation: "The drug industry has something most companies can just dream of: customers who are willing to pay almost any price for their products." In 1967, six million women took $90 million worth of birth control pills; in 1968, the amount was well over $100 million. Last year total sales of oral contraceptives amounted to $120 million. Whatever doubts may exist about the pill, there is no doubt that it is extremely lucrative.

As is often the case with US manufactured death-dealing devices, the pill was tested in a distant colony of the mother country. Not only were the lives of impoverished third world women viewed as unimportant, but any unfortunate accidents resulting from the drug could more easily be covered up. Enovid, the first oral contraceptive marketed in the US, was given a trial run in Puerto Rico in 1956. Of the 811 women in this study, 556 had dropped out by the end of the first year; by the end of the third not one of the original women remained. Five women in this group died from "Heart attacks;" no autopsies were done. Searle spokesmen said the deaths were unrelated to Enovid. At the subcommittee hearings Dr. Edmond Kassouf testified that the possibility of blood-clotting should have been investigated in the sudden death of three of these women. He said that the Searle "handling" of this study could-explain why the British were able to document the blood-clotting risk two years before the US.

By May 1960 the FDA concluded that "the evidence establishes the safety of Enovid tablets" and marketing of the pill began by the end of the year. The nature of the "evidence" was not disclosed. In 1963 Senate hearings into the FDA's handling of oral contraceptives were conducted. It was discovered that the entire basis for the safety decision on Enovid was data collected on 132 women who had taken the pill for one to three years; 66 who had taken it for 12 to 21 consecutive cycles and 66 for 24 to 38 cycles. On the basis of this study, undertaken primarily to test efficacy, not safety, the pill was made available to millions of women who would take it for up to thirty years. It is estimated that 132 women is fewer than the number of women who will die in 1970 from blood-clotting caused by the pill.

One of the most frequent criticisms of the drug companies expressed at the hearings was their complete failure to warn women of the pill's possible dangers. Dr. Kassouf was one of the most outspoken critics in this respect. He testified that patient pamphlets distort or deny known risks and completely omit many suspected ones. He stated that there are still patient pamphlets in circulation which say nothing of the blood clotting risk. (Once the FDA has compelled a change of wording in a pamphlet, it has no legal authority to demand the recall of the offending pamphlet.) These pamphlets have, as Mintz puts it, "a simple, seductive theme: The way for you to harmonize your life is to hormonize it." Take, for example, Meade-Johnson's pamphlet, "So close to nature," which claims: "Unlike others available for the same purpose, this preparation follows the principles and systems of Nature herself. Its actions closely resemble those of your natural menstrual patterns and works without upsetting the delicate-balance of your normal body function."

Another major area of drug company cover-up was in investigating doctors' reports of complications arising during pill use. In the first place, such reports were not solicited by the drug companies—nor the FDA. Furthermore, doctors were led to believe that when complications were reported, thorough follow-ups were undertaken. This was simply not the case. Often there was no investigation at all. In 1961 Dr. Kassouf notified G.D. Searle of a patient who had developed phlebitis while taking Enovid. He was simply told that there was "no evidence to implicate the pill." When follow-ups were undertaken, they were often very cursory. In 1966 Dr. Schuyler G. Kohl made a report to the FDA Committee on Obstetrics-Gynecology on the methods of drug company investigations. He reported that these investigations were often superficial and "reflected considerable concern over the company's image with the physician. He cannot be irritated—it's bad for our business relationships!"

While covering-up unfavorable reports about the pill, the drug companies promoted some myths of their own to the effect that the use of the pill was not only completely safe, but actually beneficial. Perhaps the most outrageous of these myths was contained in a book called FOREVER FEMININE, published in January 1966. It was written by Dr. Robert Wilson, a Brooklyn gynecologist. It advanced the theory that the pill could prevent menopause and make a woman youthful, sexy and able to enjoy sex, "regardless of age.—Wilson described his "crash program" preparing a 72-year-old woman for her marriage night. In 1964, the Wilson foundation had received $17,000 from the Searle Foundation. In June 1966, the National Cancer Society of New York announced that studies conducted by its medical director, Dr. J. Ernest Ayre, had shown that Enovid could not cause, and might even inhibit, cancer of the cervix. From 1963, G.D. Searle had given annual grants to Dr. Ayre.

In this all the AMA has been the handmaiden of the drug companies. Dr. Kassouf and others testified at the hearings that no doctor reading the AMA Journal could possibly be aware of much of the negative research on the pill. If published, he said, such research usually appeared in FDA reports or British medical journals. Approximately one half of the revenue of the AMA comes from drug company advertising in the AMA Journal. In 1967 Searle placed 77 pages of advertising in the Journal. It is no surprise then that the Journal should not be quick to publish reports of studies unfavorable to the pill and that it should, on the other hand, be quick to publish any study likely to please the manufacturers of oral contraceptives. In a letter to Dr. John Talbot, editor of the AMA Journal, Dr. Herbert Ratner criticized the "evolving double standard in which what favors the pill, including preliminary results, gets ready publication, but what is adverse gets delayed or no publication at all."

The best allies of the drug companies in promoting the pill have been the "population experts." In planning for women's parenthood, doctors have ardently pushed the pill because of its virtual 100% efficacy in preventing conception. For years, they made light of the growing list of suspected complications and lent their support to scientifically unproven theories about the pill's benefits. Planned Parenthood's Dr. Guttmacher, for several years, promoted the "fertility rebound" theory—that a woman who went off the pill would experience a period of increased fertility—until a report published in 1966 showed that the pill had caused sterility, temporary and permanent, in about 10% of the women studied. Dr. Rock insisted on a recent television interview, as he has done all along, that the pill is "completely safe."

The third and most avid population buff, Dr. Hellman, newly named HEW assistant deputy for population affairs, has always been nonchalant about possible complications of the pill. Asked about the possibility of cancer, he replied: "If there is going to be cancer, then it would take at least ten years to show up

That would be 1972 at the earliest, probably five years later. And I think we'll be well away from the present pill by then.- Furthermore, in "selling" the pill, these experts have consistently downgraded the reliability of other less effective (and less expensive) methods of contraception. Morton Mintz points out that Dr. Hellman always speaks of the diaphragm's 10% failure rate without explaining that this accounts for failure to use it properly or at all.

Looking at the history of how recklessly the pill was marketed-and promoted, the conclusion is inescapable that the pill has been, in the words of Dr. Hugh Davis, "a massive experiment with millions of healthy women." The avarice of the drug companies, the total ineptitude of the FDA and above all, the arrogance of the men doctors, population experts and manufacturers who promoted the pill are blatantly obvious.

By the time the Congressional hearings rolled around, many women had had enough: the time had come for women to put the pill and their right to live as liberated women—in fact, their right to live—in the right perspective. The 30 members of Washington Women's Liberation who interrupted the pill hearings several times raised issues of extreme importance which the subcommittee did not deal with at all. Chief among these is the relationship of the reckless marketing and promotion of the oral contraceptive to the secondary status of women in this society. "Would the pill have been so carefully marketed if it had been a male contraceptive?" the women asked. "Would it have been so recklessly promoted?" "Would side-effects have been so thoroughly squashed?"

An even more blatant issue which the women raised was the complete absence of women from the hearings. There were no women on the subcommittee; there were no women witnesses. Gaylord Nelson, chairman of the subcommittee, refused to respond to the women's request that they and other women be allowed to testify. Throughout the hearings Nelson said repeatedly that he would give "top priority" to any drug company that wished to testify. "Nothing," said one of the women, "makes the oppression of women more obvious than this hearing today." Perhaps the most important issue arising from the history of the pill and from the cover-up that has characterized it from

the start, which the women raised is: What right have men (doctors, drug manufacturers, experts, government officials) to exercise any control or influence over the most personal functions of a woman's body?

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