

So much for animals. Now let's go on briefly to the real issue—the question of the induction of cancer in humans by oral contraceptives. I would like to say at the beginning that I do not know the answer to this question, and I strongly believe that *no one* knows the answer. For this reason, I believe the entire subject should be treated not with exaggerated headlines and publicity but with a certain degree of circumspection. Unfortunately, this has not been the case. As I mentioned previously, these Hearings have also accomplished dissemination of an unproved fact: that pills are producing cancer. The Hearings have also apparently publicized an accusation that there is a vast conspiracy between drug companies, the American Medical Association, clinical investigators, and possibly practicing physicians, to conceal from the general public and from other physicians the fact that the pills are causing cancer. For example, early in these Hearings there was considerable press coverage of remarks suggesting that a clinical study emanating from a group of Planned Parenthood clinics in New York City and Memorial Hospital had been suppressed in the medical literature. It was suggested that suppression of the report of this study was instigated by the pharmaceutical companies, who because of their vested interests, were afraid that the publicity would result in a considerable drop in sales of birth control pills. As something of an “insider” in this matter, I would like to set the record straight.

First of all, studies designed to prove or disprove a relationship between any agent and cancer are extremely difficult to perform and sometimes virtually impossible. With use of tobacco dating back hundreds of years, it was only very recently that the United States Public Health Service felt that it had enough conclusive information to relate cigarette smoking with cancer. (It is my personal opinion that these Hearings might have served a far greater public service by concentrating on cigarettes and cancer, which is a problem of far greater magnitude than concentrating on the subject matter which has been before this committee the past several weeks—but that's a different story!) As far as the New York oral contraceptive study is concerned, this investigation was under the direction of Doctors Maleded and Dubrow. If there were any attempts to suppress publication of their report, this undoubtedly came from scientific areas and not from commercial interests. About two years ago these investigators accumulated data as a result of collaborative efforts in New York Planned Parenthood clinics. The reliability of the data depended to a certain extent on the veracity of women who were attending these clinics, the records of the clinics, the adequacy of patients' visits to the clinics, as well as adequacy of comparisons between pill users and non-pill users. Maleded and Dubrow reported their data at various local medical meetings (I believe in the New York area) and, as is usually the case, word got around that there had been an investigation completed which proved that the birth control pills were causing cancer of the cervix. Naturally, this information also reached the U.S. Food and Drug Administration, a federal agency which has often been unjustly maligned, and one which I believe has really done a remarkable job considering the limitations of its finances, as well as staff. The FDA promptly requested its Advisory Committee, led by Dr. Louis Hellman, who testified at these Hearings, to hold a meeting in Washington, inviting several groups of investigators who have had long-term experience with oral contraceptives in the hope that they would bring their data relative to the pills and carcinoma of the cervix. My understanding is that four groups of investigators were invited: the Maleded and Dubrow group which had the study in New York; those representing the Puerto Rico study, the first one done anywhere; a group led by an eminent pathologist, Dr. George Wied in Chicago; and our own group from Los Angeles, which has a study dating back to 1956—the longest in the United States per se, and one which started a short time after the Pincus, Rock and Garcia study in Puerto Rico. All were invited to present their data at the Advisory Committee meeting in the FDA offices in Washington. The only ones who came with data were Doctor Maleded with the material that he had been reporting and Doctor Moyer and me with our data. Present at the meeting were most of the members of the Advisory Committee along with FDA Commissioner Herbert Ley, as well as several members of his staff. Dr. Maleded presented his data and suggested that the information implied that women using birth control pills had a substantially increased risk of developing cancer of the cervix. We presented our data and after prior consultation with a number of statisticians as well as with members of the