attempts to supervise its own programs. "You can't just dump a bunch of things in a lady's hand and say, here take them," one FDA official said.

HEW officials deny that a physician has any direct responsibility to HEW to submit a report on adverse drug reactions. Lee sees the problem as a jurisdictional one. He feels, in effect, responsibility for monitoring medical practices belongs to the American Medical Association; Lee, a physician, says HEW must rely on the built-in systems of peer review to ensure that physicians practice medicine responsibly. Others feel this is an uncertain means of ensuring safety, particularly in governmented-supported family planning. There are still many unknowns about the pill. It has been linked speculatively to a higher incidence of blood clots among users, and some physicians feel that if may cause cancer of the breast and cervix or increase the rate of growth of such cancers. It is still not known to what extent the pill may deter bone growth in physically immature women, or may mask menopause in the middle-aged.

Recently, two doctors at the National Institutes of Health, Robert E. Markush and Daniel Seigel, linked the pill to a higher incidence of death from vascular diseases among users. Indiscriminate distribution may be equally hazardous. Patients with known or suspected cancer of the breast or cervix, a history of blood clots, liver disfunctions, epilepsy, severe heart disease, or other disorders should not be given the pill. A woman who is pregnant may endanger the health of her child if she takes oral contraceptives. A woman who has not had adequate counseling may fail to take precautions to keep the pill out of the hands of her children. (FDA has reported that the pill causes almost as many deaths among children as aspirin does.)

PROCEEDING WITH CAUTION

Recognizing these dangers, an FDA advisory committee on obstetrics and gynecology in 1966 established guidelines for dispensing the oral contraceptive; these were similar to international guidelines established by the World Health Organization. FDA recommended that, before a woman is given the pill, her medical history should be taken; she should be given a complete physical examination, with special attention to the breasts and pelvis; and she should be warned of the possible side effects of the pill. She should have follow-up examinations at intervals of 6 to 12 months. FDA recommended that an obstetrician or gynecologist, rather than a general practitioner, prescribe the pill. The agency also warned that physicians should use caution in prescribing the pill for young women whose bone growth is incomplete.

In addition, last spring FDA changed the label on the oral contraceptive, calling further attention to the possible side effects and requesting that all physicians monitor adverse reactions to the pill. Unfortunately, FDA has no authority over the dissemination of contraceptives; it inspects pharmacies and rules that the pills cannot be sold without a doctor's prescription, but it cannot regulate what a private physician or a public health official does in his own office or clinic.

HEW became deeply involved in family-planning services after its activity in this area was criticized as inadequate by Senator Ernest Gruening (D-Alaska) in 1966. At a meeting called by John W. Gardner, then Secretary of HEW, an interagency family-planning ad hoc committee was established to explore HEW's role in providing services to the poor. But Theodore Cron, an FDA commissioner of public information at the time of the meeting, who has since resigned from FDA, said that HEW gave little attention at that time to exploring the medical risks involved in programs for distributing birth control information and contraceptives. Cron, who is not a physician, recently commented to *Science* about the meetings: "FDA's input was minimal. We were barely in on the discussions and they treated us as if we were irrelevant."

HEW-supported family-planning programs face many difficulties. HEW officials concede that a great problem may be that HEW administers only some of its family-planning programs directly. The indirectly supported programs operate under grants that fall into two categories, formula grants and project grants. The quality of the HEW programs that operate under the project grants—such as the maternal and infant care program—is supposed to be guaranteed by HEW's selection process; grant recipients are chosen on the