The drug industry objected, contending that the leaflet overemphasized dangers and minimized benefits from oral contraceptives.

The revised draft leaflet has this to say about the pill's dangers:

"As with all effective drugs, they may cause side effects in some cases and should not be taken at all by some. Rare instances of blood clotting are the most important known complications of the oral contraceptives."

The original wording was much sharper on clots. It said:

"There is a definite association between blood clotting disorders and the use of contraceptives. The risk of this complication is six times higher for users than for nonusers."

The original warning offered signpost symptoms requiring immediate medical attention. It also said:

"Your doctor has taken your medical history and has given you a careful physical examination."

The revised draft said the contraceptives "should be taken only under the supervision of a physician," and users should have "periodic examinations at intervals set by your doctors."

[Press Release, March 23, 1970]

(From the Office of U.S. Senator Thomas J. McIntyre)

WASHINGTON, D.C.—Senator Thomas J. McIntyre (D–N.H.) today made the following statement concerning news stories that the Food and Drug Administration has watered down its proposed consumer label warning on known and potential dangers of birth control pills:

"I am deeply disturbed by press stories indicating that the Food and Drug Administration has watered down the consumer labeling for birth control pills which the agency proposed before the Monopoly Subcommittee on Small Business earlier this month.

"As a member of the subcommittee I had been concerned that women who might be considering use of the Pill were not being provided the necessary information concerning its known and potential dangers to enable them to make an informed and rational decision as to whether they wanted to use the Pill or some other method of contraception. I thought that the labeling proposed by Commissioner Edwards at the hearings went a long way toward answering this need. I anticipated that it would be published in essentially the same form in the Federal Register so that all interested parties would have opportunity to comment before the order was finalized.

"Needless to say, I was amazed to hear that the agency had shortened the label statement from 600 words to 96 words, and if the text carried in press accounts is accurate, deleted much of the essential information, even before the order was published.

"It is my understanding that since the story broke in the press, FDA is again re-writing the label statement to put some of the original information back in. I hope that this is true and I shall look forward to reviewing the final version when it is printed."

[From The Washington Post, April 6, 1970]

PILL ADVICE STILL UNCLEAR AS FDA SPURNS NEW WORDING—AGENCY PREFERS SHORT WARNING, DESPITE PROTESTS

(By Morton Mintz)

An entirely new warning to users of the Pill has been recommended to the Food and Drug Administration by its outside advisers on birth control.

At least temporarily, however, the FDA is rejecting the recommendation in favor of a proposal of its own.

Thus it was still unclear yesterday what advice an estimated 8.5 million women eventually will get with each package of oral contraceptive pills.

The recommended new warning resulted from a hitherto undisclosed development last Wednesday—the invasion by two members of the Women's Liberation Movement of a closed meeting of the Advisory Committee on Obstetrics and Gynecology at FDA headquarters in Rockville.