"Dr. Egeberg thought it was too long," Acosta said.

The American Medical Association's role in influencing the changes was revealed by AMA President Gerald D. Dorman in a recent issue of the AMA News.

"What appeared in the press (after the Senate hearing) was an early draft that was being considered within FDA," Dr. Dorman said.

"We have reason to assume significant changes will be made before the final proposal will be published."

Dorman's statement is at variance with what Edwards told the Senate subcommittee when he released the original version, which he said would be published within 10 days in the Federal Register "so all interested parties will have an opportunity to comment on it."

The AMA, reportedly, is opposed to the warning because it might weaken the traditional doctor-patient relationship and lead to malpractice suits.

Drug companies thought the warning gave too much emphasis to the dangers of the pill and not enough to its benefits.

Agencies such as Planned Parenthood, concerned about the world population explosion, feared that the pill warning would lead to unwanted pregnancies.

[From The New York Times, March 24, 1970]

F.D.A. RESTRICTING WARNING ON PILL—A DRAFT REVISION INDICATES ORIGINAL IS TONED DOWN

WASHINGTON, March 23 (AP)—The Food and Drug Administration is toning down its announced package warning for 8.5 million users of oral contraceptives after pressure from physicians, drug manufacturers and high Government officials.

An F.D.A. spokesman and sources in the Department of Health, Education and Welfare confirmed today that the 600-word leaflet announced earlier this month was being extensively reworded.

The original leaflet referred to such serious possible reactions to the pill as blood clots, mental depression, swelling, skin rash, jaundice, high blood pressure, and elevation of blood sugar levels similar * * *.

One draft revision runs less than 100 words, mentions only a single specific danger from oral contraceptive use, and deletes detailed suggestions on when women using the pill should see a physician.

"Any similarity between this draft and what the F.D.A. proposed is purely coincidental," said one knowledgeable Senate source.

Dr. Charles C. Edwards, F.D.A. commissioner, to read to a Senate monopoly subcommittee on March 4 the leaflet's specific wording, which he said, "We are going to publish in The Federal Register so that all interested parties will have an opportunity to comment on it."

WARNING ON PACKAGES

The warning would be contained in all packages of oral contraceptives for the education of users.

It is not unusual for an agency to revise a proposed regulation after publication and after receipt of comments. But it is unusual, informed sources said, for the regulation to be drastically reworded before publication and before formal comment is received.

When asked about the revision, Dr. Edwards said today that the drafting process still was under way and the agency would require some kind of a warning leaflet—a first for prescription drugs.

He did not disavow the authenticity of one draft revision obtained by a reporter. Other F.D.A. officials said the draft had been ordered lengthened.

Sources in the office of the Assistant Secretary of Health, Education and Welfare said revision of the leaflet was necessary for "legal and professional acceptance."

Dr. Edwards ruffled bureaucratic feathers when he told the Senate subcommittee about the leaflet and its specific warning without first informing his superior, Dr. Roger O. Egeberg, Assistant Secretary of Health, Education, and Welfare.

COMPLAINT BY A.M.A.

The American Medical Association complained to Dr. Egeberg and the H.E.W. Secretary Robert H. Finch, that the leaflet would interfere with the doctor-patient relationship and possibly could lead to malpractice suits.