

Senator McINTYRE. Proceed, Doctor.

Dr. KASSOUF. To go back to this for a moment, "Evidence of their safety and effectiveness has been continuously confirmed."

I will put the safety issue aside for the moment. The reader may ask if what the pamphlet said was so, why have drug dosages been frequently revised. The original pill had its dosage revised generally downward on two occasions after release to the public.

The last revision was upward in the estrogen content. It is clear that the minimum effective dose had not been established and therefore overdosage resulted. The last revision on estrogen is contrary to recent press reports of British research which states estrogen is best reduced. The safety issue seems to grow while minimal ideal dosage seems yet to be established.

In answer to a question, can the pill cause cancer in women, the answer was, "To date, no causal relationship between the use of oral contraceptives and cancer has been established." The last FDA conclusion states its answer in more complete form, i.e., "potential carcinogenicity of the oral contraceptives can be neither affirmed nor excluded at this time."

The Parke-Davis pamphlet dated June 1969 answers a question about clotting. The answer:

Although such disorders are rare and may be experienced by any woman, studies in Great Britain indicate they may occur more often in women using these drugs.

Four years of British research undone by one word. The British stated the pills do cause clotting and then gave the numbers.

Lastly, a pamphlet entitled "After Your Doctor Prescribes Ortho-Novum", copyright 1968, admits to the vascular problem on page 16 and gives some generally good advice. On page 18 it is all undone. The question, "Can any woman take Ortho-Novum tablets?" The answer was, "Any woman who is in good health and not pregnant will find Ortho-Novum safe and effective when taken as directed."

This is enough to demonstrate known hazards are denied and distorted. Major concerns are casually treated or ignored. Some of the pamphlets mislead and misinform, others are frankly dangerous, but all have one thing in common—they all seem to disparage the reader's right to know.

Encouraged by the pamphlets and the silence of organized medicine and Government, the drug companies extended their corporate reach. On January 2, 1969, Christopher Lehman-Haupt of New York Times reviewed negatively, "The Doctor's Case Against The Pill," by Barbara Seaman. He concluded his review with, "One wonders why the drug companies have been so exercised by it. In a way, their attempts to warn book reviewers against it are more disturbing than the book itself." Mr. Lehman-Haupt has performed a public service in exposing the drug companies' attempts.

The cross currents of information to the physician are bewildering. FDA cautioned about British data in 1968, but did not warn in regard to the manufacturers' policy statement. That appeared in the Journal of the American Medical Association. In 1969, the FDA confirmed the British findings of risk and, at the same time, found the manufacturers' statement wanting.