

Dr. WILLIAMS. This is dated May 14, 1969. And a letter from G. D. Searle Co. to doctors in California:

"Dear Doctor"—this is dated June 25, 1969. This is a refutation of the Nettleship Company's advice to doctors to get signed consents. (The information follows:)

G. D. SEARLE & Co.,
Chicago, Ill., June 25, 1969.

DEAR DOCTOR: Recently certain organizations concerned with malpractice insurance have written to physicians with a suggestion that the patient for whom an oral contraceptive is prescribed sign a form. We have discussed this with a broker for malpractice insurance in California and we believe it will be of assistance to you for G. D. Searle & Co. to comment on this action. The form concerned purports to be an acknowledgement by the patient that she has been advised of the "serious reactions and complications" of using oral contraceptives. However, the use of such a form is probably no substitute for the insertion of careful notes on the patient's record showing the information given to her regarding the actions of this or any other medication that has been prescribed. These notes should be entered at the time of the conference with the patient.

As you know, only a physician may decide whether the patient should have an oral contraceptive and, if so, what she should be told concerning the contraceptive. This discretion must be exercised in accordance with the medical history that she supplies, the physician's determination of her physical condition, and the impact he feels such information will have on her well-being and her best interests. This requires explanations which vary for each patient, depending on the findings and expectations.

Consent to use OVULEN® or ENOVID® can best be obtained in this discussion between the physician and his patient. The evidence relating to this consent should be contained in the patient's record. It is questionable whether a signed form such as has been suggested adds anything to proof of such consent.

We are enclosing in this letter the prescribing literature on OVULEN and ENOVID (in this literature discussed in detail are all contraindications, warnings, precautions and side effects) and also the booklet, *Planning your Family*, which may be given to patients, if you desire. This booklet is made available for the purpose of assisting you, by presenting important information about OVULEN, including an effort to cover major contraindications, warnings and precautions in laymen's language. In the event you decide to present this booklet to your patients we suggest that you note this fact on their records and, along with anything else that was said to them regarding the drug. This practice has been discussed with the Nettleship Company and they heartily approve.

You may obtain additional complimentary copies of the booklet from your Searle representative or from G. D. Searle & Co.

Sincerely,

WILLIAM L. SEARLE,
Vice President, General Manager.

Dr. WILLIAMS. Then dated July 1969 is a special report of the California Medical Association News, and this document is in support of the G. D. Searle position that doctors do not need to get signed consents but they should pass out little leaflets which were being offered by the CMA to its members.

(The information follows:)

[From the California Medical Association News, July 1969]

SPECIAL REPORT—INFORMED CONSENT REGARDING "THE PILL" AND NEW DRUGS

In prescribing certain drugs, it is prudent for the physician to give the patient information on the advantages and disadvantages of the medication. This is especially true when patients request the oral contraceptive, popularly known as "the pill." Because of the sensational publicity relating to possible side effects from the pill, we know from past experience in other similar situations that serious patient questions may arise out of real or fancied effects from use of the pill.