of drugs, and (5) false and misleading advertising. I shall discuss these problems in order.

As I stated in my opening statement on April 23, the FDA does not engage in the clinical testing of drugs. It approves new drugs solely on the basis of information supplied by the pharmaceutical industry. This raises the question of whether it is sound practice for a firm which has a financial interest in marketing a drug, to direct, arrange, and finance its evaluation. It also raises the question of whether it is possible for an evaluator to maintain objectivity when he is dependent on funds from the company.

Is it a good idea for a physician who is testing a drug to send his data to the company for a statistical analysis while at the same time asking for additional financial support?

Is it a good idea to send a rough draft of proposed results to the firm while at the same time asking for additional money?

Wouldn't it be rather difficult to tell a firm that its product is unsatisfactory especially when a grant for your department at your medical school has been suggested? These are actual cases and I am placing into the record several letters which illustrate the points raised here.

(The letters follow:)

STATE UNIVERSITY OF IOWA,
Iowa City, Iowa, April 18, 1963.

NELSON H. REAVEY CANTWELL, M.D., Ph. D.,
Merck Sharp & Dohme Research Laboratories,
West Point, Pa.

DEAR DR. CANTWELL: I received your letter this morning and want to thank you for suggesting a grant for the rheumatology section at the University of Iowa.

Since you were here, we have started a number of new patients on indomethacin (the LX capsules). At least three of the patients complained of severe epigastric distress within 30 minutes after taking the capsule. Therefore, in the next few subjects we started them out on 1 capsule twice a day increasing 1 capsule daily until they reached the maximum 6 capsules and believe it or not we encountered no distress. This is the method we will follow for the time being, with our fingers crossed.

The fifteen year old patient with generalized psoriasis and psoriatic arthritis returned for a check-up and is under excellent control on a total dose of 150 mg. per day. She goes to school daily and is able to walk much better than she has at any time during the past year. Another woman (age 45) was admitted with generalized psoriasis and psoriatic arthritis. Before she was admitted to the hospital she was started on terrific doses of steroids which did not control either the painful hands or the skin eruption. The dermatologist started her on 42 mg. Triamcinelone and a few days later we began the indomethacin, 2 tablets at first then increasing daily until she reached the maximum of 300 mg. By the time that we reached the maximum dose she had little or no pain in her hands, was able to make a partial fist and began to feel much better. This morning we have her down to 16 mg. Triamcinelone. She is able to be up and about, has no fever, the skin lesion is receding rapidly and she can actually close her fingers and grasp objects. We started another psoriatic arthritic who has been on steroids for over five years to determine whether or not we can reduce the steroid dose.

Under separate cover I am sending you another batch of the monthly Bulletins in case you need some of these. I have had several calls from Iowa physicians asking me about the drug and two of them have sent patients to us so that we could evaluate them and give them indomethacin.

Again I want to thank you for your kindness and will see you in June.

Sincerely yours,

W. D. PAUL, M.D.

PAUL J. BILKA, M.D.,
Minneapolis, Minn., May 8, 1963.

NELSON H. REAVEY CANTWELL, M.D.,
Merck Sharp & Dohme Laboratories,
West Point, Pa.

DEAR NELSON: I have decided to make a preliminary analysis of the patients on the Indocin tablets. Since I started the higher dosage schedule, beginning last summer, there are 63 patients who have been treated from up to eight months, and it certainly looks like we are getting a better result using the minimum dosage