cians would not attempt on private patients or persons in a private hospital. Would you comment on that?

Dr. LEY. I can only comment to the extent that the words used in that article are obviously the opinions of the writer. I would like to state that the peer review approach which the Public Health Service has been utilizing for its research grants and these regulations on informed consent have done much within the past 2 years to modify this circumstance.

I would also like to go emphatically on the record, because FDA was responsible for one study in the District of Columbia Village complex, that one study was conducted with full regard to patients' consent and informed consent was obtained with every subject in that particular study. That was the only study that FDA had direct responsibility for.

(The articles referred to follow:)

[From the Washington Daily News, June 24, 1968]

OLD STANDARDS AND NEW THINKING ON TESTING—CLINICAL RESEARCH ON HUMANS: INEFFECTIVE LAWS

(By Nicholas Horrock)

In 1963, Welfare Department physicians tested two new drugs on 67 elderly patients at the city's D.C. Village facility.

The tests were part of what The Washington Daily News has found to be a pattern of clinical research with humans, but possibly more important, they may depict the impotence of regulations in this field.

The trials with the drugs were conducted nearly 16 years after an international tribunal had set the norm that humans must volunteer to take part in medical experiments and months after this norm was codified by the United States, yet Welfare Department physicians did not seek individual consent from the patients involved.

Tho both drugs were new and not approved for public sale, the Welfare Department's Research and Education Committee did not first review the projects and doctors neither sought nor received individual permission from the patients to conduct the tests.

EXPLANATION

Welfare Medical Director Dr. Jack Kleh claims the drug tests did not undergo the department's review policies because they were "controlled by the Food and Drug Administration and was therefore not within the score of responsibility of the Research Committee."

Yet an FDA spokesman claims that it only "monitors" such tests and the burden of obtaining releases from patients is placed squarely on the drug company involved and the physicians it engages to conduct the test. Dr. Kleh reports these two trials were handled by Welfare Department doctors.

One of the two drugs, a pain killer produced by Squibb Company, has never been cleared for public sale. Dr. Kleh suggests it may have been withheld because it caused gastric disturbances in patients.

But he strongly argues that neither of the two drugs was dangerous nor had "serious adverse effetcs."

(The other drug tested was a psychotrophic agent used to control "agitated" senile patients. Developed by Wallace Laboratories, it was later approved for public sale.)

OUR PROBE

During the course of a two month investigation, The Washington Daily News has found a series of tests such as the 1963–D.C. Village experiments, a pattern that includes trials of such concoctions as a diet pill, a patent medicine, a shampoo and an acne treatment.

In a number of the tests it was difficult to discover any logical benefit to the patients involved, in others it was impossible. Subjects for these experiments included juvenile delinquents, retarded children and retarded adults.