including these double-blind studies, is 131 studies now ongoing in the various indications.

We have 26 in rheumatoid arthritis, 21 in osteoarthritis, two in osteoarthritis of the hip, 22 in musculoskeletal disorders, and 60 others which involve the investigation of the drug as an analgesic and antipyretic for thrombophlebitis and so forth.

Senator HATFIELD. What is the span of time in which these are continuing? What is your general control period?

Dr. LAWRASON. The general control period extends, for each study, anywhere from 2 weeks to 3 months.

Senator HATFIELD. But what about beyond that point? What if someone has been on some kind of drug for, let us say, 3 years, 2 years, or 5 years? Are there not effects, as has happened in the past, that did not show up maybe in the first few weeks or the first few months, or the first year, or the first 2 years?

Dr. LAWRASON. We have a great deal of evidence for long-term study and treatment in patients. As a matter of fact, each of the two other physicians appearing today before the committee has had long-term studies going in patients for up to 5 years or more.

Senator HATFIELD. Do you use primate centers to any degree in the long-term studies?

Dr. LAWRASON. Only in toxicity. We have our major toxicity effort within our own group, within our own research laboratory.

Senator HATFIELD. Have you thought about the possibility of utilizing these primate centers to a greater extent on the basis of contract?

Dr. LAWRASON. Yes.

Senator HATFIELD. Because here you have a controlled situation. In many of these long-term effects, you cannot have a human control situation, but you can have an animal control situation in these primate centers.

Dr. LAWRASON. You are very right, and we are considering it. As a matter of fact, we have had preliminary discussions with the primate center just outside of New Orleans.

Senator HATFIELD. Let me ask you one other question. What kind of program or system is there for reporting side effects from the use of drugs? Every once in a while, I see something about a side effect, but I read it as something as a result of some individual having had some ill effects and having to initiate the reporting of that, and some physician more or less identifying the cause of it. Is there a system of reporting side effects by the drug manufacturers to the FDA and they in turn to the public, or what does exist in that way?

Dr. LAWRASON. The system involves reporting of both side effects and adverse effects during the investigational stage of a new drug and after the New Drug Application has been approved. During the investigational stage, we anticipate certain side effects even before we go into the clinic as a result of the preclinical information and laboratory data that has been acquired.

Anticipating these, we also watch for anything that is extraordinary. If it is extraordinary to the degree in which it is potentially life-threatening, we report it directly to the FDA. Once the application has been approved, any adverse effects that occur which are not cited in the package circular, or any that are extraordinary and new or of a serious nature, we send this information in directly to the Food and