demonstrate that it is both safe and effective. Critical judgment gained through experience and knowledge of conditions for which the drug product is indicated is essential for a proper evaluation upon which will be based a decision to proceed with the extensive and expensive clinical trials required for the eventual submission of the New Drug Application.

This monitoring of the investigation of an entirely new chemical for use in medicine demands the attention of a physician who possesses scientific curiosity, an in-depth knowledge of the clinical condition for which the drug product is being investigated, and clinical judgment in respect to the therapeutic agents already available to the practicing physician for the treatment or control of the clinical condition under investigation.

An additional responsibility is an administrative chore, for it involves the constant attention to the details of drug supply and preparation of progress reports to the FDA showing the continuing toxicological, teratological, and carcinogenic investigations are being correlated and integrated with the studies in man. Indeed, it is a complex exercise not to be undertaken by the inexperienced or uninformed.

Senator NELSON. May I interrupt for a moment? In this first full paragraph on the page you refer to the qualifications of the physician to monitor such an investigation. Are you referring to the doctor who does the experimenting?

Dr. VAN RIPER. I was referring in that instance to the physician employed by the pharmaceutical company.

Senator NELSON. What qualifications do you seek for the performance of clinical tests done pending approval of your application?

Dr. VAN RIPER. You try to pick out individuals who have, through scientific qualification, established a reputation in a particular field. If you are investigating an analgesic, you certainly go to someone in the field. If you are investigating a drug in cardiology, you go to a cardiologist. It is a highly selective process.

Senator NELSON. Is that a requirement of the law?

Dr. VAN RIPER. It is not a requirement of the law. But it is essential to good clinical investigation.

Senator NELSON. Does the FDA require, along with the submission of your accumulated clinical testing, submission of the qualifications of the doctor?

Dr. VAN RIPER. Those are submitted before you ever are permitted to begin the investigation.

Senator NELSON. They approve your proposal and the physicians who are to participate prior to your starting a clinical test?

Dr. VAN RIPER. Mr. Chairman, they don't actually give you written approval. But it does give them an opportunity—for instance, should they see you are using an investigator in whom they would have some doubts as to his qualifications, it provides them an opportunity to at least warn you that they think you have made a bad choice.

Senator NELSON. But it is a practice in the industry to seek physicians who have expertise in the disease area with which the drug is concerned?

Dr. VAN RIPER. That is right.