the agency could adopt established names in the interest of simplicity and usefulness. The step we took to implement that was to require soon after the passage of the law that each new drug application presented to us provide for an established name for the drug. Then, as Dr. Goddard said, last year we took a number of established names, adopted through this USAN committee, and adopted them as our own as simplified names. This is the only way those USAN names can be given legal effect, either by our adoption or by an adoption by the U.S. Pharmacopeia or the National Formulary.

Senator NELSON. Who has the authority to decide what the established name shall be?

Mr. GOODRICH. The ultimate authority rests in the agency. However, Congress did continue the practice of recognizing USP and National Formulary names as the established names unless we establish an established name as an agency name.

Senator NELSON. So the law historically was that the company that developed a drug provided the name which became the generic or established name; did it not?

Dr. GODDARD. That is correct.

Senator NELSON. Now, they still supply a generic or established name and it may or may not be accepted by USAN; is that correct?

Dr. GODDARD. That is correct. And it may or may not be accepted by FDA.

Mr. GOODRICH. And for us to make the USAN name binding, it would have to be adopted by the agency or by one of the official compendia.

Senator NELSON. You did not happen to bring along a list of generic names supplied by brand-name companies that are shorter than the brand names they created for themselves; did you?

Dr. GODDARD. That would be a very short list, Senator.

Senator NELSON. If company A gets its New Drug Application approved as submitted then it may license company B and several other companies. These other companies then just submit their New Drug Application and use the clinical evidence originally submitted by the licensing company, company A. That takes away several years of work?

Dr. GODDARD. Yes.

Senator NELSON. Maybe you could tell me how much of the 5 years that you say it takes from the beginning to the NDA approval really involves clinical testing on animals as against clinical testing on humans.

Now, we have the situation where company A might license 50 companies, some of them quite small. Each one of that 50, big or small, distinguished or unknown, may incorporate all of the experience of company A.

Along comes one of the biggest drug companies in America. Company A did not and will not license them. So they come in and produce a drug that meets all USP standards—dissolution rate, potency, purity, and so on. In fact, it meets them better than company A and all the others.

Yet it cannot put the drug on the market without going through that 5 years of research. Is there any evidence whatsoever to justify making this requirement of the large company and not of the other companies?