decade. Also, none of the States which has such a statute or regulation has repealed it, and we count 39 at the present time.

In our opinion, the substitution concept of today is a far cry from that which we knew prior to 1950. Substitution, historically, referred to the substitution of a different therapeutic agent than that prescribed by the physician. However, the brand substitution concept is relatively new and is based on the premise that the substitution of one brand for another brand of the same drug is analogous to supplying a different therapeutic agent. This is largely a thesis that no one can seem to prove.

Mr. GORDON. Since the antisubstitution laws, as you say, are anachronistic, would you support their elimination?

Dr. APPLE. Mr. Gordon, 2 years ago, at our 1965 meeting, there was considerable discussion about this subject, and our house of delegates took the position that a special ad hoc committee should be appointed to study the entire issue, and such a committee was appointed and has met on several occasions and will continue to meet until it is ready to submit a report to our house of delegates.

Offhand I would say repeal does not seem to appear to be practical and may not even be desirable, but perhaps the antisubstitution laws can be made to serve a useful social purpose. I think later on here we indicate that.

Mr. GORDON. You are saying, I guess, that they do not serve a useful social purpose at the present time; is that correct?

Dr. APPLE. Well, this is a subject matter which our committee has been asked to come up with an opinion to pass on to the house of delegates, so that the association will have a definite position, and I am sure you can appreciate that this is a policy matter that the house of delegates is going to have to speak on before I can speak for it or against it.

Mr. GORDON. Let me ask you this: Who or what organizations were responsible for getting these laws on the books?

Dr. APPLE. Well, as I indicated, at times our own profession did through our own associations, but, as I recall the situation, it evolved in this way: I think others could, perhaps, give you a better accounting of it. The pharmaceutical industry created a special task force, a special organization called the National Pharmaceutical Council, which led the effort for the enactment of these antisubstitution laws.

Mr. GORDON. They worked through the State legislatures, I presume, on a State-by-State basis.

Dr. APPLE. Yes, sir.

Mr. GORDON. Please continue.

Dr. APPLE. We recognize that there are isolated examples of seemingly identical drug products which are not therapeutically equal. In some of these cases, the evidence is only the report of a single observation with no indication as to whether the result was due to some idiosyncrasy of the patient or the drug. In others, it is clear that the product involved should not have been on the market at all because it failed to meet the legal standards, due to poor manufacturing practices. And, because our knowledge about drug action in humans is still incomplete, a differential response may be identified but not explained.

Mr. GORDON. Dr. Apple, you quoted Commissioner Goddard on page 21 of your statement as saying that there are about 7,000 single