

comparing, say, a pill-using group with a non-pill-using group; in other words, people who use other forms of contraception—and merely studying other rates of incidence of mental illness in the entire group. The other is a more retrospective thing. That is comparing rates of psychosis in hospitalized patients who have used drugs for a long period of time; in other words, an *expose facto* type of study.

I think probably there are people—I have not been involved with studies of this kind and I am sure you could get better experts than I from, say, the National Institutes of Mental Health to give you information on this.

Senator HATFIELD. Let's take your study. Has the prospective study been based upon what you would call a sufficiently broad patient population?

Dr. KANE. Probably not. The two Swedish studies were excellent.

Senator HATFIELD. You do not feel, then, that your study actually had sufficient numbers to make their application—

Dr. KANE. Their numbers are not important. Their randomness is the critical factor. Mine was not an entirely random population.

Senator HATFIELD. As a layman, may I interrupt? Correct me if I am mistaken. We are told by certain experts, according to the testimony in this hearing, that, taking breast cancer as an example, we have a Corfman-Siegel report that indicated that in order to get an accurate projection of a twofold increase, let's say, in breast cancer, they would have to have a number of 80,000 cases or 80,000 people. There is a relationship here between numbers and validity of study or what you can draw as conclusions from such a study.

Now, going back to your study, what's the number or what's the basis upon which we can draw certain conclusions from your study?

Dr. KANE. There are two things here. I think perhaps psychosis is similar to cancer. We have symptoms here, for instance—you can draw conclusions from 10 patients, studied very carefully, about acutely occurring symptoms. In other words, if you give them a medicine or a blank and compare their reaction on this, you will then be able to gauge their reaction to the medicine for even a 1 month period. We have done this. They are balanced studies.

Senator HATFIELD. You can draw a medical fact from that?

Dr. KANE. Oh, yes, you can, for certain kinds of things, certain kinds of acute symptoms. If you give, for example, LSD, the changes you would expect from LSD, at least behaviorally, would be mainly occurring within a 2- to 4-hour period from certain doses. I think you can have that study.

Then you can have the longer term study for, say, effects of hormones on genes over a longer period of time.

Senator HATFIELD. Let's come back to your study again. Do you feel that your study and the conclusions that you have drawn have incorporated sufficient numbers of people that we can draw a medical fact from them?

Dr. KANE. Yes, with regard to the more acute changes, I think so. With regard to the risks for development of psychosis, I think there is much less information. I think that is in the same ballpark as the figures for cancers. You must have large numbers.