Senator NELSON. You heard the testimony of Dr. Dameshek in which he expressed his concern about the need to find some method to control the use of the drug, or at least of assuring that this drug wouldn't continue to be overprescribed.

Is it your view that the situation is so serious that some method ought to be developed?

Dr. LEPPER. Yes, I think it clearly is, as I made recommendation to restrict it to hospitals because when we have introduced some new drugs in recent years they have been originally restricted to hospitals. It has been fairly easy to prevent them, then, from becoming used for any more than some specific indications. We have never, to my knowledge, gone the other direction to restrict an old drug back to the use in the hospital.

However, this would certainly get around the massive overuse in respiratory infections in the community and the massive overuse in urinary tract infections in the community, which happen to be the two most common infections in the community.

It would also then allow us, as I say, to develop control mechanisms within the hospital as to what is a reasonable level of utilization such as we have for caesarian sections or therapeutic abortions, or other kinds of controversial procedures. In these the hospitals have very similar rates, and if some hopsital has excessive use, it becomes quite apparent to the accreditators that there is something different going on here.

Senator NELSON. You mentioned that some drugs have been restricted to hospital use. Which drugs were you referring to?

Dr. LEPPER. Well, I think vancomycin was one such drug that was introduced for the staphylococcal problem, which was marketed only to the hospital pharmacists. It was not put on the general market.

Senator NELSON. Was that a result of a regulation by FDA or was that a self-imposed restriction on the part of the manufacturer?

Dr. LEPPER. I believe this was an era, sir—I am not awfully sure of the legal aspects—I believe there was an era in which new drugs were released sequentially by FDA for hospital use, followed by general community use, and some of the drug got as far as hospital use and were never released further for several reasons.

Vancomycin specifically could only be given intravenously, and therefore was not a very competitive drug in the community, and I don't believe it then got past being released for use outside the hospital.

I believe, however, FDA did have that legal authority of approving drugs for use at one point along the way. I do know there has been a tremendous body of literature, talking about restricting drugs to hospitals on a voluntary basis, and this was done successfully in Australia with erythromycin when the staphylococccal problem was so bad and they wanted to try to keep an overuse of this drug from occurring. That is, try to limit it to staphylococcal diseases so you wouldn't lose its effectiveness.

This was somewhat successful in Australia for a period of about 2 years in the midfifties. In this country there was some talk about doing the same thing with erythromycin. It never happened on a voluntary basis.