

physician has developed confidence and faith in a particular drug and in the manufacturer over a period of time. Experience with a drug which consistently produces the desired effect results in confidence. No amount of advertising in journals, by mail, at conventions, or persuasion by the detailman can short circuit the process of developing confidence in a particular drug.

The pharmaceutical firms know that confidence on the part of the physician is essential for the existence of the company. As a result, these firms are constantly striving to produce quality medications and to improve their methods of production. A bad result with a drug or misleading information cutting corners, or a bad batch of a particular medication can be disastrous for a pharmaceutical firm. Each proprietary company is identified with every one of its brand-named drugs and puts its reputation on the line with each and every package that leaves the plant.

A generic drug is anonymous. By inspection there is no way of telling what the drug is, let alone the manufacturer. The generic drug firm if it so desires can cut corners and if a bad result occurs, the attention is not focused on the manufacturer. There is no need for the generic firms to gain the confidence of the medical profession because there is no way of identifying the drugs produced with the generic firm. Once there is product identification, the company is a brand-named firm and must have the confidence of the medical profession.

Senator NELSON. Let me ask a question here.

Again, what we seek to get in the evidence here—and we ask about this constantly—is what are the examples of adequacy or inadequacy of the generic drug versus brand name? We have been asking that for 2 years and really have not been getting any adequate answers. We get the assertion that you can't trust generics, you have to have confidence, you have to stick to the brand name company. But, we just do not get any real evidence that this is, in fact, so.

Dr. ALFANO. As I stated, I will send that report on oxytetracycline that has come out.

(Material not received.)

Senator NELSON. Committee counsel tells me that that would not quite fit the circumstance, because that drug is only produced by one company, Pfizer.

Dr. ALFANO. I do not have the report. I cannot go discussing it.

Senator NELSON. Is this Terramycin? If it is Terramycin, it is under patent to be produced by one company.

Dr. ALFANO. As I have said, I do not have it, and I could not come up with the answers.

But you could just, on chloramphenicol, have one product and show that—as far as I know, there has been evidence to show that the generic product was not therapeutically equivalent to the trade name product.

Senator NELSON. The FDA testified that that is not the case. I asked Dr. Ley who was here just last week. I asked him if FDA had any evidence that there was any difference in the therapeutic equivalency of the chloramphenicol they took off the market? He said there is no such evidence. They achieved a different blood level at a different period of time. That is all.

Dr. ALFANO. What was that period of time?