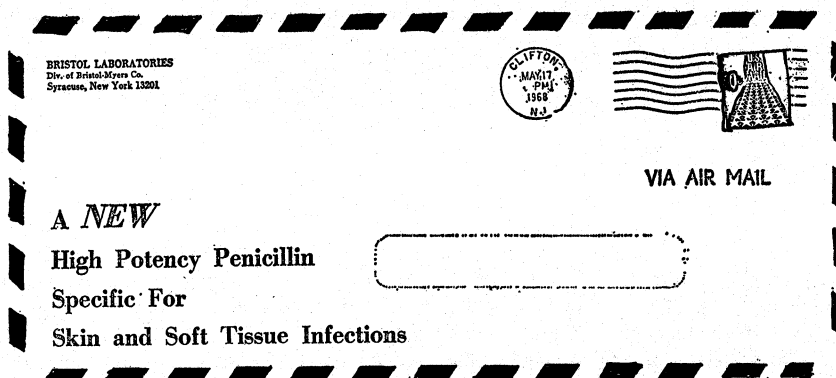


EXHIBIT D



Dr. MINCHEW. When we received a copy of the Dynapen promotional letter, on May 20, 1968, it was seen immediately that the letter was naming the drug for uses beyond the intent of the labeling. I asked that our Division of Medical Advertising evaluate the letter and other features of Bristol's initial advertising campaign in medical journals on the basis of the approved labeling. About the same time, an Arlington, Va., physician was given a detail piece which will be discussed.

We regarded the promotional letter announcing Dynapen as seriously misleading in a number of respects. For example:

1. The too-general main theme, "* * * penicillin for Skin and Soft Tissue Infections," invited uncritical use of Dynapen as an "everyday" penicillin when, in fact, the approved labeling restricts use of this drug to treating infections that are due to penicillin G-resistant staph.

2. The letter stated that Dynapen is a "specific useful in a broad range of skin and soft tissue infections." The implication given by "broad range" in the promotional letter was that Dynapen is indicated for infections caused by a wide variety of bacterial organisms. This is inconsistent with the limitations of use in the approved labeling.

Senator NELSON. Does Dynapen have the effectiveness on various bacteria that no other drug does? Is there any such case?

Dr. MINCHEW. Only in the area of penicillin G resistant staphylococci is it particularly valuable, but even here there are other drugs which may well work against the penicillinase producing staph. There are no bacteria for which no other drugs are effective and these are.

Senator NELSON. Is it more effective, these other drugs, than any other drugs available on the market?

Dr. MINCHEW. For the penicillinase producing staph or the others?

Senator NELSON. For the others, not the penicillinase?

Dr. MINCHEW. No, sir.

Senator NELSON. So that to implement the position of FDA on this, it ought to be solely limited to the use of penicillinase-resistant staph?

Dr. MINCHEW. Our position is that it should be limited to the treatment of penicillin-resistant staph infections or in initiating therapy when such an infection is suspected. You don't often know the resistance pattern of the staphylococcus when you first start therapy.