

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11949

I would point out again that approximately 75 percent of these reports have concerned products of well-known manufacturers. Since the products of such manufacturers hold the major share of the market, this is to be expected. But again, the data in this system do not reveal any clear differences between various segments of the prescription drug industry.

The Bioequivalence Issue

Let me now turn to bioequivalence, an issue that has stirred considerable public controversy.

New regulations relating to bioequivalence have been promised for some time by the FDA. However, because of the complex issues involved, their publication in the Federal Register has been delayed to provide for full consideration of these problems. I am pleased to report, however, that these regulations will be published in the near future as a proposal and will definitely appear before the MAC regulations are published as a final order.