Symposium on Human Insulin of Recombinant DNA Origin

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Introduction

The usual events in the development of a new drug are the discovery of a novel compound, its synthesis (or extraction), pharmacologic and toxicologic testing in animals, and finally the clinical testing. This developmental path was followed with human insulin (recombinant DNA) as well. However, with human insulin the novelty of the invention is its production by the very new recombinant technology. While the synthesis of organic compounds can indeed be quite problematical and the scale-up to production mode difficult, with human insulin a totally new production procedure had to be developed in the laboratory and then transmuted into a feasible manufacturing process. Given these difficulties, the increase in production from micro- and milligram quantities to production lots of many kilograms has been miraculous.

While the clinical trial program is intended to measure pharmacologic action as well as adverse effects, in this case we also desired to see how human insulin was different from or the same as animal insulin. Specifically, we had to establish that the final product was free of harmful noninsulin materials unique to the fermentation process.

This symposium summarizes the results of the extensive clinical testing that has occurred in Europe and the United States. The enormous contribution by the participants in these trials is attested to by the quality and quantity of data that were generated in just 2 yr and the fact that human insulin will be registered in several countries before the end of 1982. We at Eli Lilly and Company are grateful for the interest shown by our investigators and their staffs in human insulin and the priority they have given to the completion of the studies necessary to answer the questions we have asked. This volume is dedicated to all those who have been directly involved in the studies as well as to those who have assembled and analyzed the information and promulgated it to the medical community.

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