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POSTMARKETING DRUG SURVEILLANCE

After being approved for marketing, any number of useful drugs have subsequently been found to have serious side effects associated with their use. This situation occurs because clinical testing during investigational trials involves relatively small numbers of test subjects—usually a few hundred at most—and the principal objective is to determine the effectiveness of the new agent.

Consequently, side effects which are relatively rare, or which may show up only in certain patient populations, or which might be so unusual or bizarre that they are not associated with the therapy being administered, often will not be detected until the drug goes into general marketing and has been in wide scale distribution for some time.

Recognition of this problem has long troubled many people and groups with an interest in improved health care. Hence, various approaches to providing a solution have been tried and even more have been offered. Most observers have concluded that the only possible means of getting a handle on this problem is through some program of postmarketing drug surveillance.

Efforts made in the past have proven unsatisfactory, however, because they relied on voluntary reporting *via* poorly coordinated and inadequately publicized systems. Although both individuals and groups may have been well intended, this problem and the resulting programs hardly were "top priority" in terms of either resources or commitment. Understandably, therefore, the problem continued to grow as more drugs and more potent drugs were approved for marketing.

Finally, in early 1976, Senator Edward M. Kennedy laid down a challenge to the drug industry in a speech at the Annual Meeting of the Pharmaceutical Manufacturers Association.

The PMA responded to this challenge and invited half-a-dozen professional health societies to join with it in funding an expert commission to study and analyze the problem and to develop and propose a solution.

To the credit of the respective organizations, there was quick general support for the PMA proposal. In late November 1976 the Joint Commission on Prescription Drug Use was officially launched with due pomp and ceremony under the bright lights of television cameras in a major chamber of the U.S. Capitol building, with Senator Kennedy personally presiding.

It is fair to say that the Joint Commission has not enjoyed either a speedy or tranquil voyage during the three-year period that has ensued.

At the time of its establishment, the message was made loud and clear that the Commission was to complete its work within a maximum of three years and preferably less. Moreover, it was anticipated that progress would be such that the framework for a postmarketing system could begin to take shape in tandem during the latter half of this same three-year period. In this manner, the system could be operative shortly after the Commission completed its work.

But such was not to be, and for the purposes of this column it is unnecessary to delve into the reasons causing these delays. Similarly, it is unnecessary here to recount what has been a rather bumpy road for the Joint Commission to travel or the reasons for that bumpy ride.

Rather, our purpose is to call attention to the expected imminent release of the final report of findings, conclusions, and recommendations of the Joint Commission.

Reports from study commissions very often have a way of rapidly slipping into oblivion. This fate seems to be especially common in Washington because the commissions themselves are often created out of political expediency. It is a convenient and simple way to temporarily dispose of a controversial, emotionally charged issue. Then, by the time a few years have passed, and the commission issues its report, public interest has greatly diminished—if it has not disappeared altogether. When the issue is forgotten, it should hardly be surprising, then, that the report pertaining to that issue gets little and fleeting attention.

We hope, however, that this will not be the fate of whatever comes by way of a report from the Joint Commission on Prescription Drug Use. The need for an answer to postmarketing drug surveillance is as great, if not greater, today than it was in 1976. Moreover, much in the way of time, effort, and money has been spent during this three-year project.

As one of the sponsoring organizations, APhA has a special interest in seeing that the Joint Commission's report is given the careful examination and thoughtful scrutiny that it deserves. And, in particular, the fact that it is expected to deal with substantial scientific issues ought to make it of specific interest to the readers of this journal.

We urge that they, as well as all health care scientists and practitioners, give the report their close attention, and that they actively participate in whatever forums develop for discussion and debate regarding its proposals. —EGF