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A PROBLEM AND A SOLUTION

In the federal bureaucracy where the number of problems awaiting resolution seems almost limitless, we sometimes encounter the ironic situation of having solutions for problems that no longer exist. The difficulty in terminating pertinent government committees once such problems have been resolved is the genesis of the proposals for so-called "sunset legislation."

More often, however, rather than an overabundance of solutions, we in the health-care field are faced with problems ranging from runaway costs to mal-distribution of practitioners. Most of these problems are difficult at best and even appear to defy solution.

Hence, it is a welcome, if rare, relief when a solution appears on the horizon at the same time when one is grappling with a difficult problem. In our view, this situation appears to exist in one aspect of the blockbuster drug bill, S.2755, appropriately titled the "Drug Regulation Reform Act of 1978."

This omnibus bill has a host of features, many of which are good and some of which are bad, but in this column we are going to address only one aspect—a facet that has drawn relatively little attention from any other quarter.

Over the years, drugs have been approved for marketing under current federal law based on certain specified uses as spelled out in the pertinent drug's official labeling. Later on, certain drugs have accidently been found to be useful in treating some other condition not included among the uses listed in the approved labeling. Such discoveries are generally made by practitioners in the course of their daily routine. These practitioners often will pass along the information informally *via* corridor discussion with colleagues, or at most, *via* the letters column in some medical journal.

However, these testimonials clearly do not constitute the necessary scientific data sufficient to document the value of the drug for the particular alternative use. Consequently, the Food and Drug Administration cannot authorize expanding the indications for use stated in the labeling for the drug until data from suitable scientific studies have been made available that will support such claims. And, in our view, this stand is entirely proper.

On the other hand, the drug manufacturer usually has little incentive to undertake the costly studies to develop such documentation. After all, the drug is already approved for marketing, and the extra expense of developing these additional data will probably not be recouped through extra sales demand for the product.

But some of these so-called "unapproved uses of approved drugs" may represent important applications of considerable value in medical treatment. For example, years ago, the local anesthetic agent lidocaine was found to be useful in treatment of cardiac arrhythmia. Indeed, its use for this purpose was credited with saving any number of lives. But, for any number of reasons, if a drug does have a valid and justified ancillary use, that fact should be stated on the label; and, in turn, that means that someone has to see that those scientific studies are performed that were mentioned in the preceding paragraphs.

A tentative answer to this dilemma is advanced in Section 108 (h) (2) of S.2755. This subsection provides for inclusion in the drug entity monograph of a requirement that, in order to obtain a license to manufacture a drug product under that monograph, any person might be compelled to conduct scientific investigations relating to other uses of the drug—even uses that the manufacturer may not wish to endorse. On both moral and economic grounds, we find it difficult to agree with this approach.

Later on, however, under Section 201, the bill provides for the establishment of a National Center for Clinical Pharmacology. This new Center would fulfill a variety of research and training functions.

The language in the bill specifically states that either *"upon request or on its own initiative, the Center may conduct and support research in clinical pharmacology and clinical pharmacy, including investigations (1) of the safety and effectiveness of existing and new uses of drug products, ..."* The bill goes on to list several other meaningful roles that the Center would serve. But it is this first-stated purpose that is pertinent to this discussion. Note that its mandate specifically covers research on new uses for drugs to establish their safety and effectiveness for such purposes.

Expenditure of public funds to fulfill this need appears justified and in the best interest of all parties concerned: the government, the drug industry, the health care professions, and the general public. Not only is the problem evident, but so too is its solution.