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IN THE NAME OF LIBERTY

A student of history, taking note of the crusades in the middle ages—as well as of the many other "holy wars" past and present—once observed that more wars are claimed to be waged and more blood is professed to be shed in the name of the Almighty than for all other causes combined.

We were recently reminded of this comment as we noted the many advertising stunts, promotional campaigns, and various other gimmicks which have been cloaked with some reference to the nation's Bicentennial celebration, in an effort to dignify them. The words "liberty," "freedom," and "self-determination," among others, have been widely used in association with all sorts of proposals, positions, and causes, most of which—when stripped of their Bicentennial puffery—are propositions of dubious value at best.

These comments are prompted by a recent request to us from a physician asking that we lend support to a bill (H.R. 12573) introduced this spring in the U.S. Congress. The bill is appealingly entitled the "Medical Freedom of Choice Act," and its descriptive summary states that it is intended: "*To expand the medical freedom of choice of consumers by amending the Federal Food, Drug, and Cosmetic Act to provide that drugs will be regulated under that Act solely to assure their safety.*" Specifically, the purpose of the bill is to revoke the provisions of the 1962 Drug Amendments which require that, as a condition of approval for marketing, a new drug must be demonstrated to be effective, as well as safe, for the claims made in its labeling. H.R. 12573 has the active support of at least two physician-members of the House of Representatives.

The proposition that the need to demonstrate effectiveness should no longer be required for new drugs appears to be gathering support, particularly from among those physicians and medical organizations with a politically conservative stance. The most notable example is the American Medical Association which, about a year ago, adopted a resolution in its House of Delegates calling for repeal of the effectiveness requirement in the Federal law.

We have already expressed our own view that the effectiveness requirement is a necessary provision if we are to avoid a return to the era of quackery and nostrums. The editorial in the October 1975 issue of this Journal specifically dealt with this point. These present comments are intended to review the subject from a slightly different perspective.

A sizable segment of the medical profession has been noted for its fiercely independent beliefs and attitudes. Any law or regulation which serves to establish boundaries or restrictions—no matter how logical and justifiable such limits may be—is met at least with suspicion, generally with hostility, and often with outright resistance by this segment of medicine. In the case at hand, such physicians feel that their bounds to prescribe and use drugs in the treatment of patients should be limitless and without restriction. In their view, this represents a "freedom" which physicians have a right to enjoy.

It strikes us that those who hold such views probably have not stopped to consider where the extension of such a line of thinking will ultimately lead. For example, is not the prescription legend category of drugs a comparable restriction on freedom for the general public? American citizens could readily argue the position that their personal freedom is restricted by the legal requirement that many drugs may be obtained only on the prescription of a duly authorized prescriber.

Moreover, are not the medical practice acts—which limit the practice of medicine to individuals who have fulfilled certain requirements pertaining to education, experience, examination, and licensure—restrictions on the liberty of other citizens who might wish to offer their services in the field of medicine without having fulfilled such requirements? As absurd as these questions may seem—particularly to the medical profession—they are directly equatable to the suggestion that the effectiveness requirement be eliminated for new drug approval.

If the Food and Drug Administration has been dragging its feet in processing new drug applications, or if the drug industry has been negligent in submitting adequate proof to demonstrate effectiveness, these are problems of mechanics for which other, more specific remedies should be sought and considered. It should be recognized that the basic system is sound, and this fact must be clearly distinguished from any faults in its implementation or operation. —EGF