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INFORMATION RELEASE: RAW DATA OR SUMMARY?

Regular readers of this column know that it is not too often that we come down squarely on the same side as the drug industry in commenting on controversial issues.

We do, however, find that this is pretty much the case regarding the current legislative proposals on the subject of disclosure of data developed and used to support the approval of a new drug.

The Drug Regulation Reform Act of 1978 (S.2755; H.R. 11611) includes provisions for the "Disclosure of Reports Contained in a Petition." The "petition" referred to is part of the proposed system for bringing new drugs onto the market; a manufacturer would petition the FDA for establishment of a drug "monograph," the existence of which would be the critical determining factor in approving a drug for marketing. As such, this revised system would replace the present New Drug Application (NDA) procedure.

Under another heading, the legislation specifies that three separate reports—a summary report, a detailed compilation, and "a full report of all data and information from each such investigation"—must be submitted to support the petition. Pundits have labeled the three types of reports as "the one-inch high report, the one-foot high report, and the one-mile high report," respectively.

At any rate, the section dealing with disclosure of reports spells out that the entire content of all these reports would be subject to virtually unrestricted public inspection and review. And that is the proposition with which we find fault.

Over the years, no one has championed the cause of disclosure of drug information more vigorously than APhA. In our own speeches and editorials we have repeatedly urged the drug industry to be more open and informative in revealing pertinent product information for the benefit of practitioners and the patients they serve.

In recent years, there has been a growing trend among a significant number of manufacturers to divulge technical, scientific, and clinical information relating to their products. Some firms have done far better than others in this regard, and, regrettably, there are still some who continue to "stone-wall" on the issue. Consequently, some sort of legislative requirement probably is necessary to bring the laggards into line and to assure that every company will meet at least an acceptable minimum level in releasing pertinent information. For clarification, what we are talking about relates specifically to data supporting the safety and effectiveness of a drug and not to economic, marketing, or "trade secret" information in the normally accepted sense.

The drug industry, and the Pharmaceutical Manufacturers Association in particular, has been screaming that the drug bill goes completely overboard in this regard. They point out that every minute detail of every study would be subject to open examination. Among other things, it is claimed that this would provide a "road map" to competitors both in this country and abroad. Furthermore, it is stated that the privacy of test subjects would be destroyed, and incentives for drug research would be lost.

On the other side, skeptics point out that the drug industry has a notoriously poor record in giving out any more information than the required minimum, that drugs deserve to be treated differently than other commodities of commerce, and that only through scrutiny of the details can one detect either biased conclusions or falsified data.

We have attempted to be objective in our analysis of this issue. Frankly, we aren't able to judge with certainty that release of all test data will result in the rights of test subjects being trampled upon or in the wheels of research coming to a screeching halt.

But more importantly, we are not persuaded that the release of the complete detailed data will serve any public interest purpose. The Food and Drug Administration will have the complete file for its review in verifying that conclusions are supported adequately and that there has been no hanky-panky with regard to what research has in fact been performed.

The information that practitioners—or those to whom they look for guidance such as their professional societies—need in order to make independent judgments concerning the relative merits, usefulness, and limitations of a drug can be fully satisfied from a detailed summary of the sort envisioned in the second, or even the first, report called for in the drug bill.

The PMA has proposed in its testimony on the drug bill that the data disclosure provision be amended to mandate only the release of an appropriately detailed summary. If such information is prepared by the drug sponsor, approved by the FDA, and released prior to the marketing of a new drug, we feel that the needs of the public and the health professions will be adequately served. A broad range of health scientists have already expressed similar views in Congressional testimony. It is our hope, therefore, that this is one point on which cool heads will prevail and this reasonable compromise will be accepted by the bill's proponents. —EGF