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FIFTY MORE FDAs?

A great deal has been said and written on the subject of the purported cancer drug, laetrile or amygdalin. The substance has enjoyed an abundant share of both critics and advocates.

The critics have included the majority of what might be characterized as "the health care establishment"; namely, government health agencies, the major societies of practitioners in medicine and pharmacy, the scientific societies in the field of health-related research, and so on.

We, ourselves, commented on the subject in our October 1975 column when we disputed the editorial position of *The New York Times* that the public should not be denied "harmless, but ineffective, remedies." At that time we predicted that a public policy position embodying this concept would return us to the bygone days of nostrums and quack remedies.

The next August, we spoke out on a closely related subject—namely, legislation to overturn the effectiveness or efficacy provision of the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act. If such legislation were enacted, the result would be to permit marketing of unproved drugs without regard to claims made for them. In essence, physicians—if not the general public—would be able to prescribe, to obtain, and to administer "harmless, but ineffective, remedies." In our view, this latter situation would be equally unfortunate from the standpoint of the public health and welfare.

Inasmuch as laetrile has been opposed primarily on the grounds that it is ineffective as a cancer treatment, attention has primarily focused on the repercussions its approval would have on the integrity of the effectiveness requirement as a condition for drug approval and marketing.

However, another problem of potentially major proportions has now surfaced, and it is the purpose of this editorial to bring attention to this aspect.

Laetrile proponents, in failing to obtain permission for laetrile marketing and distribution on the federal level, have turned to the individual state legislatures in an effort to obtain enabling legislation. This strategy would permit manufacture and distribution intrastate—thereby circumventing the federal prohibition which only governs drugs or drug products that move in interstate commerce.

At last count, about a dozen states have already succumbed to the onslaught of lobbying efforts by the laetrile proponents. Various others will probably follow in the next round of state legislative sessions.

What is the effect of this action? Well, for one thing someone has to look after the questions of quality, purity, packaging, and labeling of the laetrile that will be manufactured and marketed within these states.

It is one thing to inject a patient with a costly, but harmless, placebo. It is quite another matter to inject that patient with a costly, contaminated placebo. Hence, comprehensive standards are necessary regarding the purity of the product. Freedom from microbiological contamination, absence of heavy metal impurities, stability of ingredients (which include cyanide precursors), proper labeling, protective packaging, directions for storage, instructions for safe administration, and so on are all the niceties which we take for granted in the case of drugs produced by conventional drug manufacturers and moving through the usual channels of federal Food and Drug Administration scrutiny, approval, and surveillance. But the FDA is inoperative with regard to laetrile; it has no jurisdiction or authority.

Indeed, if a laetrile product were to come before FDA in any manner that would bring it under FDA inspection or monitoring authority, then FDA would be obliged to seize that product because it is illegal under federal law; the statutes prohibit FDA from condoning the existence of such a product in channels of distribution.

The only alternative is for each of these individual states to establish its own mini-FDA. Each state-level mini-FDA would then perform, within the respective states, all of the functions with regard to laetrile that we normally associate with the federal agency for conventional drugs. Already one or more states are moving in this direction. And if anyone believes that once established and operational these state-level agencies will confine themselves to laetrile monitoring, that person is ignoring the clear lessons of history.

In only a short time, we anticipate that we shall have successfully replicated 50 of these mini-FDAs, each contributing its own huge dose of red tape, paperwork, and bureaucratic procedures to a broad spectrum of drugs. Beyond the hassle for the drug industry and the frustration for the health professions, the cost to taxpayers will be enormous.

Whatever the benefits and limitations of the present federal FDA, we suspect that neither its proponents or opponents relish the prospect of such a dual system. Consequently, if this outcome is to be avoided, the potential problem must be recognized, and appropriate action taken to avoid such a development from ensuing.

Edward G. Feldmann