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HOW MUCH IS "ENOUGH"?

For the past year or two, articles, speeches, testimony, and assorted other means of communication have been rife with comment and opinion to the effect that either additional regulation is needed in the area of drug discovery and introduction or, conversely, that already drug discovery and introduction are subjected to excessive regulation.

On the one side, those who advocate additional legal controls present persuasive arguments based upon statistics showing significant toxicity, adverse reactions, and related harmful effects associated with a particular drug which often come to light only after its widespread or long-term use. On the other hand, opponents to further regulation present equally persuasive arguments that already drug innovation has been inhibited, a so-called "drug lag" has developed, and patients are presently being denied the benefit of important new drug discoveries, all due to what they regard as the excessively restrictive current regulations which delay or prevent new drug marketing approval.

It is, of course, just such differences of viewpoint which are said "to make a horse race." All of this reminds us of an anecdote which may or may not have basis in fact but certainly is pertinent. We were told that the river which ran through a small rural town was closed to swimming by the local health department on grounds that it was polluted and a menace to health. The town leaders went to extensive effort to correct the problem and to clean up their river. But when they then requested the health department to open the river to swimming, their request was again denied—this time with the explanation that the river constituted the source of the local drinking water supply and it would be unsanitary, therefore, to permit swimming!

Whether or not such an incident actually occurred, we do know for a fact that rather comparable incidents repeatedly have happened in the area of drug standards. For example, on many occasions, critics from the drug industry have alleged that official compendia specifications were insufficient to assure an aspect of drug quality whether it be potency, identity, bioavailability, stability, or some other related characteristic. Subsequently, the compendia proposed adoption of either a new or more stringent specification in order to remedy the alleged deficiency. Not uncommonly, such proposals then met with objection from the very same critics on grounds that such test requirements were excessive, or would contribute prohibitively to manufacturing costs, or even that the proposed requirements were too "severe" because their own products could not meet the new standard!

It is well to recognize that the genesis of any proposed new law or regulation generally can be traced back to some sort of abuse or problem. For example, the Good Laboratory Practice regulations which were discussed in our February editorial were the direct result of falsified test data submitted to FDA in support of certain New Drug Applications. Consequently, as a general observation, most disinterested parties would tend to feel that society and government must impose regulatory controls to avoid problems or to prevent repeated abuses.

Our view tends to concur but, at the same time, we also recognize that such regulations must be reasonable and properly tempered to avoid excessive restrictions which will unduly inhibit and discourage future research by destroying legitimate incentives. Drug regulation is particularly susceptible to "overkill," and care must be exercised to avoid a result which might be even more disastrous than the problem it is intended to control.

Edward G. Feldmann