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DESTRUCTIVE FALLOUT

Our initial reaction, after reading the Report of the Drug Bioequivalence Study Panel to the Office of Technology Assessment (OTA), was one of shock and dismay.

True, the Panel had done a fine job of answering the one question embodied in the charge given it by Senator Kennedy and the OTA. However, the Panel then went off wildly in all directions criticizing: (*a*) how the drug industry conducts in-process quality controls and adheres to good manufacturing practices; (*b*) how the official compendia operate and perform; and (*c*) how the Food and Drug Administration monitors the nation's drug supply. And then the Panel proceeded to make sweeping recommendations for changes in all of these areas.

In leveling their criticism, the severest and harshest blast was directed at the official compendia. The Panel did not like anything about how the compendia operate, how they are organized and financed, what analytical methodology they employ, the design of the test procedures, the specifications and tolerances, the attributes tested or not tested, the frequency of issuing revisions, and even the fact that the participants contribute their services without monetary compensation.

Well, having gone so completely off the deep end—with neither the background, experience, nor information to make valid judgements in these areas—it is not surprising that the resulting report is filled with errors of fact and interpretation. This is especially the case concerning the comments, conclusions, and recommendations of the Panel relative to the *United States Pharmacopeia* and the *National Formulary*. And we told Senator Kennedy as much, in just so many words, when we testified before his Senate Subcommittee on Health at its hearing on July 22.

But now that the dust has begun to settle just a bit, we ask ourselves: Why? Why did the Panel attack the official compendia with such a frenzy? Why did the Panel feel the need to be so vicious with particular respect to the official compendia?

At best, we can only speculate as to the answer. We suspect, however, that the reason lies in the assessment made by various persons, organizations, and groups—most notably the HEW Task Force on Prescription Drugs—to the effect that "lack of clinical equivalency among drug products meeting all the official compendia standards has been grossly exaggerated as a major hazard to the public health."

By attacking the official compendia and attempting to discredit their standards, one can indirectly undermine this general assessment of drug equivalency. Although the strategy itself was clever, its execution was inept. The Panel's criticisms were obviously unfounded; their lack of understanding of the compendia content, purpose, and coverage was embarrassingly apparent; and their suggestions and recommendations ranged from the impractical to the unlawful. And so, hopefully, the Panel's effort to destroy the compendia has failed.

But before dismissing this incident, we feel compelled to make an observation.

However correct the Panel may have thought it was—did the end justify the means? Over many years, countless scientists and practitioners from pharmacy, medicine, and the allied health fields have given an enormous amount of unselfish, dedicated effort to create, develop, maintain, and improve the official compendia. They did this primarily for two reasons: altruistic dedication to their profession and belief in a voluntary system whereby the professions themselves would function as the guardians of drug quality.

In one massive blow, the Panel sought to destroy this entire system. If they had succeeded, and if they were justified, then so be it. But if they had succeeded, *and they were not justified* in wiping out the system, then their action warrants severe condemnation. In our opinion, destroying the official compendia system would not only have been a disservice to the public, but it would have had the effect of destroying a small but important part of the health professions themselves.

—EGF