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ANTIBIOTIC CERTIFICATION—OBSOLETE AND ARCHAIC

All too often laws and regulations, once enacted or finalized, go on *ad infinitum*. Various observers have commented that they become "chiseled in stone" or "fixed in concrete." However they are described, the point is that such rules or legislation may have been appropriate and valid at one time but now have outlived their usefulness. As such, they ought to be reexamined and the continued need for them should be reassessed in the context of the contemporary situation.

Although many examples might be mentioned, building codes are frequently cited as illustrations of this phenomenon. A local community may have adopted standards and specifications for plumbing installations fifty years ago when cast-iron, threaded pipe was the only reliable system. Subsequently, copper tubing with soldered joints for water service and polyethylene or polypropylene plastic pipe for waste drains were developed and now offer more reliability as well as greater simplicity in installation. But the building code calling for cast-iron pipe remains virtually frozen, and only through lengthy and laborious processes is it modified and changed to take into account the advances in plumbing technology.

So it is in other regulatory areas, including drug quality monitoring and surveillance.

In particular, we were reminded of this situation when APhA Academy of Pharmaceutical Sciences former president George Schneller, speaking at the November meeting of the subdivision, addressed the subject of Food and Drug Administration routine batch certification of antibiotics.

Dr. Schneller labeled this federal requirement as *"obsolete and archaic, and increases the cost of these medicines to the public while contributing nothing to public safety or health."*

He further charged that it is an example of *"oppressive regulation which is a substantive cause of inflation."* To correct the matter, he recommended that the rule be deleted, and in its place "*. . . a much more rational and economical alternative would be to control the quality of antibiotic products by the same machinery as other drugs—namely, through the publication of appropriate tests and standards in the USP and through the FDA's regular enforcement activities directed to assuring compliance with those standards.*"

For our part, we completely agree with Dr. Schneller's views. In fact, we commented along this line [see *J. Am. Pharm. Assoc.*, NS2, p. 640 (Nov. 1962)] in the final days of enactment of the Kefauver–Harris Drug Amendments. That article argued the very same scientific points that Dr. Schneller just recently reiterated and reemphasized; namely, that when the initial antibiotic agents were first marketed in the 1940s, *"they were extremely crude concentrates of extractives from microbial culture media. Conventional methods of drug analysis were not applicable to them and would not assure a true measure of their potency.* [But subsequent] *rapid advances in the manufacturing processes of production, synthesis, and purification soon made it possible to produce these antibiotics as essentially pure, crystalline substances with a degree of purity comparable to other fine chemicals."*

The article went on to state that these advances in technology eliminated the original justification for batch certification of antibiotics; and, furthermore, the result made it illogical to treat antibiotics any differently than all other potent medicinal agents on the market.

However, as in the case of the long outdated local plumbing code which refuses to recognize or accept comparable improvements in the plumbing field, current federal drug regulation continues to prescribe testing requirements for antibiotics which Dr. Schneller has properly labeled as "obsolete and archaic."

The limited resources available to FDA in terms of both scientific personnel and test facilities could be put to much better use in many other areas of drug monitoring and surveillance.