Antibiotic Certification—An Anachronism

All too often it is human nature to continue to operate in a certain way or to do a certain thing, even though the reasons for performing that action have long ceased to exist. Moreover, in government and bureaucratic circles, the propensity for such behavior is all the more pronounced.

For these reasons, the Food and Drug Administration's current proposal to phase-out its antibiotic certification program comes as a refreshing change. Many of us on the Washington scene have become skeptics because we usually see "business as usual" from the federal government despite campaign promises to the contrary from politicians when they are running for office.

For those readers not familiar with the history of this certification program, a brief review would be appropriate.

When the first several antibiotic drugs initially were marketed in the 1940s, they were extremely crude concentrates of extracts obtained from microbial culture media. At that time, conventional chemical or instrumental methods of drug analysis were not applicable to them; in particular, those analytical procedures could not provide a true measure of the biological potency of the antibiotic test samples.

To meet this immediate problem, between 1945 and 1948, Congress passed legislation providing for the batch certification of the five antibiotics then available. The certification program was conducted by a laboratory within the Food and Drug Administration, and it used microbiological test procedures to measure growth inhibition of various organisms when tested against a relatively purified, standard reference sample of the crude antibiotic.

However, rapid advances in the manufacturing processes of production, synthesis, and purification soon made it possible to produce these antibiotics as essentially pure, homogeneous, crystalline substances with a degree of purity comparable to other fine chemicals.

In light of these modernized production procedures—along with the development of many new analytical techniques—it was not considered necessary to add to the certification program any of the dozens of newer antibiotics which subsequently came onto the market during the 1950s and very early 1960s. Indeed, because of these developments, by 1962 it was difficult to rationalize the continuation of the antibiotic certification program in any form, much less its wholesale expansion to cover all antibiotics as provided for in the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act.

Both APhA and the Pharmaceutical Manufacturers Association—as well as several other groups including the United States Pharmacopeia—testified in opposition to the antibiotic certification provision during 1959–1962 Congressional hearings conducted by Senator Kefauver and Representative Cellar. However, drug industry opposition suddenly evaporated, apparently as the result of a closed-door political compromise in which the industry agreed to accept antibiotic certification as a trade-off for having Congress not disturb the exclusivity of drug patents. At any rate, the bill passed by Congress and signed into law by President Kennedy in October 1962 included the section extending certification to all antibiotics.

Over the years, experience convincingly showed the antibiotic certification program to be a needless and costly exercise, because batch after batch was found to be well within compliance.

In light of this track record, in the late 1970s, the FDA began to exempt certain antibiotic dosage forms from the certification requirement. Then, in a somewhat surprise action, FDA Commissioner Arthur Hull Hayes, Jr., published a sweeping proposal in the Federal Register of May 7, 1982, calling for the elimination of the entire certification program for all antibiotic drugs. In essence, Dr. Hayes was saying that, rather than go through the lengthy and unnecessary process of a gradual phase-out, decisive action was clearly preferable. In our personal view, this action is both administratively logical and scientifically sound. Moreover, it will greatly minimize paperwork and procedural processing.

As an aside, one might properly wonder how the FDA is able to nullify or revoke a program enacted by Congress. It is because of the unique construction of the language used in the Act as it relates to the certification program. Specifically, FDA has the authority to grant exemptions from certification, and any antibiotic drugs so exempted no longer are subject to section 507 of the Act (the special category of antibiotic drugs), but are then automatically covered by section 505 of the Act (the so-called "new drugs" provision which covers drugs generally).

In concert with the FDA's proposed decertification action, the USP is actively preparing and promulgating revised monographs to ensure the continued existence of public standards of quality for these pharmaceutical products. Consequently, even in the absence of the FDA certification program, the combination of (*a*) compendial standards, (*b*) manufacturers' quality control testing, and (*c*) FDA market surveillance and enforcement will ensure the continued high quality of antibiotics in exactly the same manner as with all other pharmaceutical products (except for insulin and biologicals).

In a way, this FDA action makes such good sense that one is inclined simply to say, "fine," and then dismiss it from his or her mind. However, as noted in our opening paragraphs, society generally, and the government in particular, very rarely halts an activity or discards a procedure simply because it has become obsolete and outdated.

Consequently, we feel that Dr. Hayes, the FDA, and the Administration should be commended for this bold and decisive action.

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