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EVERY FIVE YEARS

A current series on public affairs television is titled "Every Four Years." The series examines various aspects of the presidency of the United States, and specifically the changing style of those who have sought and reached the office as well as the evolving impact those changes have had on the office itself. The title, of course, refers to the presidential term, and the timing of the series is most appropriate with national elections coming up again this fall.

But even sooner, in fact this April, a process will repeat itself, which used to occur every ten years since 1820, but more recently has been taking place at five-year intervals.

We refer to the United States Pharmacopeial Convention, the members of which will be gathering in Washington, D.C., from April 17 through April 19, immediately preceding the APhA Annual Meeting.

As provided for in the USPC Bylaws, a call goes out "*every five years*" to all the recognized organizations in medicine, pharmacy, and several related areas for each of them to appoint delegates who will then convene at the USPC's quinquennial meeting. These delegates are responsible for (*a*) electing a Board of Trustees to oversee the operation, (*b*) selecting a Committee of Revision to undertake the assigned tasks of developing and updating the standards to go into the next edition of the compendia, and (*c*) adopting a series of resolutions to serve as the expression of the will of the assembled convention concerning what particular subjects should be addressed, or what particular tasks should be undertaken, during the upcoming five-year period until the next convention. The delegates also deal with certain other matters such as extending recognition to additional organizations and proposed amendments to the USPC Bylaws.

But the task of broadly laying out the master plan which will point the direction for the coming revision period is a function that should not be taken casually. All too often, organizations fail to recognize ominous signs which suggest the need for corrective action.

In the case of the USPC, we see certain strong indications that the federal government is moving in the direction of impinging on traditional compendia turf. Although there have been a number of such intrusions over the years—such as the antibiotic certification amendments and the authority to establish nonproprietary drug names—the movement was given substantial impetus with the Office of Technology Assessment's Drug Bioequivalence Study Panel report in mid-1974. That report called for the replacement of the USP and NF with a new standards-setting organization.

Changes that occurred in 1975 served to buy some additional time for the official compendia to undertake and complete the job of developing standards and specifications that would pass the scrutiny of discerning critics including the OTA panel. There is, however, some question as to how well the USPC has responded to date in fully satisfying that challenge.

Whatever might be said along that line, the fact remains that significant compendia-related activity has been recently stirring within Food and Drug Administration circles. Indeed, these activities have caused some compendia-watchers to be concerned that the FDA could be laying the groundwork for an Afghanistan-style take-over. Whether or not the FDA may have such designs, we truly don't know.

However, at least two speeches by FDA officials, during recent months, point in the direction of a future turf-battle.

First, the staff director of FDA's new Compendial Monograph Evaluation and Development Program, speaking at the APhA Academy of Pharmaceutical Sciences' November meeting in Kansas City, told the audience that the agency expects his program to produce a "new generation of compendial standards which are highly reflective of both the market and the state-of-the-art." Begun only in late 1978, this program has two professed objectives: (*a*) to evaluate existing selected compendial monographs and to develop or improve analytical testing methods to assure that they will be suitable for regulatory purposes, and (*b*) to develop monographs where none currently exist in order to establish adequate public standards.

Second, the executive director of FDA's regional operations, appearing as a panelist during the Food and Drug Law Institute's annual conference in Washington last December, informed the audience of programs initiated by his department within the past year. One such program he mentioned is a critical review of USP/NF monographs with a view toward developing new and improved test and assay procedures at the various FDA regional laboratories.

Clearly, therefore, in FDA's eyes there is significant room for improvement in the compendial monographs. And how far FDA plans to pursue these projects of "improvement" remains to be seen.

But if the agency were ever to mount a take-over effort, this would clearly be the wisest strategy to follow in initiating such tactics. Consequently, the delegates who soon will be assembling for the USP Convention should be conscious of this possibility and lay out the best possible defense to meet that threat—namely, a program that will produce a new edition of the compendia that is so improved in the standards and specifications area as to approach a level of perfection that it will defy FDA challenges to "improve" it.

In conclusion, we feel it would be tragic if this country ever were to lose the present system whereby drug standards are established within the private sector under legal sanction and recognition. The 1980 USP Convention will have the prime challenge of producing a workable, no-frills blueprint to see that such a loss is not allowed to occur through oversight or neglect.

—EGF