FDA Commissioners—Their Function and Operation

Over the past eighteen years, we have witnessed a virtual procession of people serve as FDA Commissioners. In addition, there have been many other periods—some quite lengthy—during which various Acting Commissioners have bridged the gap between the departure of one Commissioner and the arrival of the next.

George P. Larrick was the last FDA Commissioner to "rise through the ranks" and follow the traditional promotion and selection process that had been used for the agency since its predecessor department was initially established at the turn of the century. In breaking with the past, a Public Health Service physician-administrator, James L. Goddard, was selected to head the FDA. Supposedly, this would transform the agency's enforcement and regulatory philosophy—which was attributed to the inspector background of Larrick and his immediate predecessors—into one with a more scientific and medical orientation associated with Goddard and his background.

Although Goddard and every subsequent occupant of the Commissioner's office have been medical or health care scientists, the overall orientation has changed relatively little—at least until the recent government-wide deregulation emphasis espoused by the Reagan Administration. And given the fact that FDA's primary mission is to protect and safeguard the public relative to foods, drugs, and cosmetics, it hardly could be otherwise. Simply put, FDA's major mission is neither research nor education—although both of these elements are highly important to it and to the public in FDA's ability to fulfill its regulatory role in the most efficient and effective manner possible.

However, in departing from the promotion from within practice, something did happen. The office became "political" rather than "career." In practical terms, this made the revolving-door syndrome one natural result; it also led to the instability and insecurity that has characterized the position for almost the past two decades; and it has contributed to certain rivalries between the FDA Commissioner and his or her boss, the Secretary of the U.S. Department of Health and Human Services (formerly, U.S. Department of Health, Education, and Welfare).

Without exception, each of the FDA Commissioners since Larrick has been competent, qualified, and has discharged his duties with skill and dedication. However, their individual personalities and operating styles have differed as greatly as night and day. This diversity began immediately with Goddard, whose authoritative rule, high management profile, and dominating personality earned him the nickname of "Dr. God."

But at the same time, these various FDA heads were obliged to mold their individual operating styles and their public images to "fit" with their respective bosses—namely, the person who happened to be HHS or HEW Secretary at that particular point in time.

And again, the personality and operating style of the respective HHS/HEW Secretaries has been every bit as broad and different as the FDA Commissioners. To this, add the fact that their relative interest in FDA and in FDA matters has been equally varied, and we have had situations ranging from one extreme to the other.

At no time was that phenomenon more evident than during the tenure of Arthur Hull Hayes. During the first portion of Hayes' term in office, Richard S. Schweiker was his boss—and Schweiker took such a strong personal interest in FDA matters that he virtually appeared to emasculate the Commissioner's office. Indeed, it was widely mentioned in Washington political circles that Schweiker served "as his own FDA Commissioner." This was the case despite the fact that both Hayes and Schweiker repeatedly claimed that they enjoyed a close, harmonious working relationship.

Then, when Schweiker resigned and Margaret M. Heckler was named Secretary, Hayes found himself in a profoundly different situation. No longer was the Secretary trying to run the FDA. Indeed, Heckler adopted and followed such an extreme "hands off" policy that when Hayes himself resigned many months later, it was reported that he had never once had a meeting with her during his entire term in office.

All of this makes interesting recounting for us and, we hope, interesting reading for our subscribers. But that is not our real purpose in reviewing this past history.

Rather, we wish to suggest that it may be appropriate to review the relationship that exists between the two offices involved; namely, HHS Secretary and FDA Commissioner. If so, such an examination and review would appear to be especially timely now with the FDA Commissionership currently vacant.

Former FDA Commissioner Alexander M. Schmidt wrote a guest commentary that appeared in the January 1983 issue of *Pharmaceutical Technology*. His editorial, written when Hayes and Schweiker were both still in office, was extremely tactful and diplomatic. But, in spite of his careful choice of words and phraseology, Schmidt clearly delineated what he saw as the respective roles of the two positions, as well as the hazard inherent in having the Secretary intrude too far into the realm of the Commissioner.

"It was my strongly held view as Commissioner," wrote Schmidt, "that the Secretary's job was to establish policy to govern the functioning of the agency. It was the Commissioner's job to be certain that the agency responded to the policy and was well run.

"The Commissioner, for his part, had to subscribe to the mandated policy or leave. The Secretary had to be fully satisfied with the Commissioner and his performance or replace him, but should never become involved with the operation of the agency or assume the Commissioner's function. I always insisted," continued Schmidt, "that one Commissioner of Food and Drugs was enough!"

Schmidt then went on to detail various managerial and pragmatic reasons why he felt such a clean division of responsibility should be established and followed. He summed up by saying, "There is a much more important reason for the Commissioner to run the agency, however, and that is simply that the higher FDA's decisions go in the administrative hierarchy, the more political and less scientific the decisions are likely to be . . . Good science certainly protects the public interest and in the long run, also protects the interests of industry and FDA."

Well said, Dr. Schmidt! We earnestly hope that your words of advice will have a positive influence in shaping the future roles and interrelationships between these two highly important government offices.

—EDWARD G. FELDMANN
American Pharmaceutical Association
Washinton, DC 20037

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