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PASSING THE BATON AT FDA

This editorial is being written prior to the U.S. presidential election, although it will not be published and read until after the results are in. Consequently, at this writing, there are much discussion and conjecture about what changes will soon take place on the Washington scene—and particularly within the top echelons of executive branch agencies—depending upon the outcome of the national elections.

Some cynics have asserted that it really doesn't matter who wins the Presidency and who the President appoints to Cabinet positions because the various bureaucratic machines will relentlessly continue to ramble along irrespective of personnel changes that may occur in the offices of the pertinent Secretary. Indeed, a number of presidential appointees have resigned in anguish during recent administrations, expressing frustration at their inability to have any dramatic impact on the course of operation of the very agencies which they were assigned to run.

Although speculation may be currently rife with respect to many top government posts, even at this writing it is known that one post will become vacant at the end of this year regardless of whom the voters may choose. We refer to the annoucement by FDA Commissioner Alexander M. Schmidt that he is resigning from FDA to return to the academic life at the University of Illinois.

Dr. Schmidt's resignation makes this an appropriate time to review the modern-day history of FDA and to do so particularly from the standpoint of what impact recent Commissioners have had on the agency.

From its establishment on through the World War II period, the FDA was principally oriented toward enforcement *via* on-site inspection procedures; moreover, it appeared to concentrate its efforts primarily in the food area. The entire line of FDA Commissioners had traditionally come up through the ranks, with a heavy orientation in the inspection field. The agency appeared, therefore, to be ill prepared for the dramatic post-World War II pharmaceutical boom which culminated at the legislative level with the enactment of the 1962 Drug Amendments. Despite a dedicated and well-intentioned group of administrators, FDA leadership of the early 1960's was simply unprepared for this rapid turn of events in the drug field. To draw an analogy from the military world, they were old line cavalry generals suddenly facing an enemy equipped with tanks, armored vehicles, and aircraft. FDA went into a state of virtual paralysis, and it was evident that some major change was necessary.

Early in 1966, change did occur—and quickly and dramatically—with President Johnson's appointment of James L. Goddard to the Commissionership. As a starter, for the first time in the agency's history, its leader was drawn from outside the career staff. "Dr. God," as many of his critics referred to him in private, was accused of being unduly impulsive, shooting from the hip, and operating in a disorganized, helter-skelter fashion. There may have been some truth to these criticisms but, nonetheless, there is no disputing the fact that this vigorous Commissioner breathed new life into the agency, gave it a sense of purpose, and effectively divorced it from the regulated industries. For better or for worse, FDA would never again be the same.

Dr. Goddard's successor, Herbert L. Ley, during his relatively brief tenure as Commissioner, primarily attempted to digest and integrate the radical changes initiated by his predecessor—changes that had had a traumatic effect upon the agency staff.

Despite Dr. Ley's efforts, however, the need for a major reorganization of the FDA operating structure was clearly evident. In early 1970, Charles C. Edwards was appointed to succeed Dr. Ley and brought in a background of managerial and administrative skills which he translated into an effective system of operations. For the first time, FDA operation began to show at least some organizational resemblance to the modern and efficient business operations in the industries that it regulated and dealt with on a daily basis.

In 1973, when Dr. Edwards' managerial skills were further tapped by promoting him to the position of HEW Assistant Secretary of Health, he was succeeded by Dr. Schmidt. In turn, it appears that Dr. Schmidt's major contributions during his tenure of office were (*a*) to reestablish meaningful communications with the health professions, the industry, and the public through pragmatic diplomacy, and (*b*) to imbue the agency with an aura of honesty, fair-dealing, and integrity, which he himself personally exemplified.

Hence, each of these modern-era FDA Commissioners has left his own mark on the agnecy and has, in fact, had some sort of meaningful influence on its course and direction. Despite this, however, the FDA remains part of that peculiar institution known as "the Washington bureaucracy." Consequently, just as in the case of Cabinet officials, there has been only so much that these respective FDA Commissioners were able to achieve in a quantitative sense.

Hopefully, Dr. Schmidt's successor will have the capacity, ability, and persistence to move the agency forward in each of those areas in which his recent predecessors have made notable starts. As the slang expression goes in the field of sports and in the entertainment world, FDA now needs someone at the helm "who can get it all together!"

—EGF