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Issues Facing the New FDA Commissioner

Louis Lasagna and Kenneth I. Kaitin

The new Food and Drug Administration (FDA) commissioner, Jane E. Henney, M.D., who received Senate confirmation on 21 October, will be facing a host of complex issues concerning agency policies and programs when she takes office. Her handling of these issues will be watched closely by scientists in academia, government, and industry. The greatest attention will be paid to the speed and efficiency of the agency's new drug approval process, but considerable importance will be attached to such matters as monitoring product safety, pediatric research, barriers to dissemination of data on new uses for marketed drugs, and the impact of genomics on drug development and use.

A recurring debate concerns the speed with which the FDA approves the marketing of new drugs and biopharmaceuticals. Recent withdrawals of several drugs from the market because of serious adverse reactions stirred the passions of those who believe that the public is best served by a slow, cautious, and demanding regulatory agency. In contrast, patients with diseases not well treated by currently marketed medicines want an FDA that efficiently evaluates data on drug safety and efficacy and grants approval as soon as the evidence suggests that the drug, when marketed, is likely to do more good than harm.

Henney will face many hurdles as she settles into her new role.

Another issue concerns the recent FDA Modernization Act of 1997 (FDAMA).* The act addresses the desirability of pediatric research before new drug approval when a drug is likely to be prescribed for children. The reward for such research is a 6-month prolongation of market exclusivity or patent life, seemingly an important benefit for sponsors. Pediatric research, however, ordinarily first requires evidence from adults that safety and efficacy requirements are met. If such research delays drug approval until the studies are completed, these delays may offset any prolongation of market protection granted.

Although FDAMA set out guidelines for allowing firms to circulate reprints of published articles describing new uses for marketed drugs, these guidelines have not diminished industry's long-standing frustration over the FDA's usual vetoing of such practices. However, the issue has been rendered moot by a recent court decision that this sort of censorship by the FDA deprives firms of their constitutional freedoms. The FDA will almost certainly appeal the decision. If it stands, the FDA's monitoring of reprint dissemination will be closely watched with regard to how the agency differentiates between persuasive scientific data and unjustifiable hype.

There is a discrepancy in how the agency regulates "direct-to-consumer" advertisements for "traditional" remedies such as St. John's wort and other botanicals and for pharmaceutical products. For traditional remedies, marketing firms are free to advertise their products as they deem appropriate, as long as they make no promise of therapeutic benefit and indicate clearly that the material has not been approved by the FDA for therapeutic use. This level of agency oversight is less stringent than for pharmaceutical compounds, whose health claims must be accompanied by full disclosure of side effects and risks associated with the use of the product. This incongruity is surrealistic and, with the public's growing interest in traditional therapies, may prove troublesome for the FDA.

Other controversial and politically contentious issues facing Henney include regulations dealing with human cloning experiments, tobacco, and the abortifacient RU486, as well as improvements in the agency's system for monitoring adverse drug reactions, the level of funding for internal agency research, and flexibility in the "substantial evidence" standards for drugs used to treat life-threatening illnesses. Another challenge will ensue from President Clinton's recent executive order establishing a high-level council to oversee the U.S. food supply in response to concerns about the frequent outbreaks of illness, some fatal, caused by such harmful food-borne substances as the 0157:H7 strain of *E. coli* bacteria.

Gaining Senate confirmation has been the first hurdle for Henney, but there will be many more as she settles into her new role.

*Available at http://fda.gov/opacom/7modact.html

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