

There's A Lot To Like About Hamburg's Legacy At The FDA

Law360, New York (February 09, 2015, 12:30 PM ET) --

U.S. Food and Drug Administration Commissioner Margaret Hamburg will retire at the end of March. Educated at Harvard Medical School, Dr. Hamburg brought a diverse experience portfolio to the FDA as commissioner. Before joining the FDA, Dr. Hamburg conducted research in neuroscience and AIDS, worked to reduce public safety threats from nuclear, chemical and biological weapons at the Nuclear Threat Initiative and served as commissioner of the New York City Department of Health and Mental Hygiene, where she is credited with reducing the city's tuberculosis rate.

Dr. Hamburg's FDA Track Record

Dr. Hamburg is one of the longest-serving FDA commissioners. FDA morale was low when Dr. Hamburg became commissioner in 2009. The FDA had been criticized for drug safety lapses, which included undisclosed drug side effects and drug supply chain problems resulting in contaminated medications. Dr. Hamburg thus prioritized improving drug safety. Other priorities of Dr. Hamburg's were science-driven decision-making and meeting unmet patient needs by accelerating the new drug and medical device approval processes without compromising patient safety.

Dr. Hamburg's influence on the FDA resulted in many positive developments, including improved agency morale, increased numbers of drug approvals, record numbers of orphan drug approvals, decreased drug approval times, implementation of a biosimilar approval process, strengthening the security of the nation's drug supply chain, a 30 percent reduction in medical device approval times, implementing modernization of the U.S. food safety system, ushering in the era of personalized medicine, implementing the Family Smoking Prevention and Tobacco Control Act to cut down on retail tobacco sales to minors and reduce youth smoking, spurring desperately needed antibiotic development through implementation of the Generating Antibiotic Incentives Now Act, and encouraging the development of combination drugs for diseases like AIDS, hepatitis and cancer by interpreting the law to grant five years of exclusivity for certain fixed dosage combination drugs.

However, Dr. Hamburg's tenure — as with any FDA commissioner — was not without controversy. The FDA was accused of failing in its oversight of compounding pharmacies, resulting in a 2012 fungal meningitis outbreak which is blamed for the deaths of over 60 people. Dr. Hamburg received criticism



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for allegedly lax oversight of advisory panel personnel conflict of interest rules as a perceived tradeoff to attract qualified panelists. The FDA was also criticized for being tone deaf to increasing rates of opioid addiction as manifested through its approving a nontamper resistant opioid formulation. Dr. Hamburg engaged in, and ultimately won, a political battle with then U.S. Department of Health and Human Services Secretary Kathleen Sebelius for approving the over-the-counter sales of the Plan B emergency contraceptive. Finally, the FDA's proposed regulation of laboratory developed tests remains contentious and unfinished.

Desired Qualities of the New FDA Commissioner

Dr. Hamburg leaves the FDA at a critical time. The FDA, by some estimates, regulates 25 percent of the nation's gross domestic product. Personalized medicine is becoming increasingly important as evidenced by President Obama's recent call for a new personalized medicine initiative — and the FDA's regulation of LDTs will have far-reaching impact on this burgeoning area of medicine. There are significant unmet medical needs with vocal patient advocates and a continuing push to accelerate translational medicine. 21st Century Cures, a sweeping law making its way through Congress, may have significant effects on medical product regulation. And, the FDA is in the middle of implementing a number of important regulatory schemes, including ongoing food safety modernization.

With this as background, desirable qualities of Dr. Hamburg's successor include someone who is medically trained, scientifically oriented and a clear thinker (e.g., someone who has practiced medicine and led a large health care program or facility), understands the economics of health care and the costs of bringing new technology to market, acknowledges the need for America to continue leading the world in health care innovation and drug development, demonstrates the ability to focus resources where risks are the greatest, understands the regulatory paradigm of risks and benefits as well as the cost to industry and society of overregulation, solicits and integrates patient input into the regulatory process, recognizes the need to find new ways to provide patients having incurable diseases with timely access to new and experimental drugs and devices and continues to build on the successful programs of prior FDA commissioners.

Stephen Ostroff, a medical doctor and the FDA's chief scientist, will temporarily replace Dr. Hamburg until Congress approves a new commissioner. As such, it is possible that Dr. Ostroff may transition from acting commissioner to FDA commissioner.

Alternatively, it has been speculated that Duke cardiologist Robert Califf, who was recently appointed by Dr. Hamburg as FDA Deputy Commissioner for Medical Products and Tobacco, may replace Dr. Hamburg. Dr. Califf has an impressive track record and would appear to have many, if not all, of the above-listed desirable qualities. Dr. Califf was the founding director of the Duke Clinical Research Institute, ran the Duke Translational Medicine Institute, spearheaded Merck's ZETIA six-year IMPROVE-IT study and served on the board biotech startup Portola Pharmaceuticals.

Conclusion

Dr. Hamburg leaves a positive legacy of accomplishments that benefited the FDA, industry and the people of the U.S. Her successor assumes the FDA's helm at a critical juncture. The choice of the new FDA commissioner should be carefully considered, taking into account training, experience, mindset and the key challenges the agency will face in the coming years.

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