Commissioner Aims to Open FDA's 'Black Box'

BY JOYCE FRIEDEN

In one of her first public acts at the Food and Drug Administration, new commissioner Margaret Hamburg announced that the agency aims to be more transparent about its daily work and decision-making process.

"Over the years, complaints have been made about FDA's lack of transparency," Dr. Hamburg said in June in announcing the launch of a transparency task force.

"The agency has been referred to as a 'black box' that makes important decisions without disclosing them. The agency can and should communicate in a way that provides more transparency, not less," she added. The commissioner said it was her goal that the public looks first to FDA for trustworthy and useful information about drugs and devices.

"On President Obama's first day in office, he pledged to strengthen democracy . . . by creating an unprecedented level of openness" in government, noted Dr. Hamburg, who took over at FDA on May 22. "This will be an agency-wide effort charged with figuring out how to make the FDA and its processes more transparent to the public."

The transparency task force will include the directors of all FDA centers as well as the agency's associate commissioner for regulatory affairs, its chief counsel, and its chief scientist. All meetings will be open to the public. The task force "expects to submit a written report to the commissioner about 6 months from now," according to FDA principal deputy commissioner and task force chair Joshua Sharfstein.

Being clearer about why the agency decides things a certain way is one area of interest for Dr. Sharfstein. "People don't understand why the FDA may have done something or not done something," he said. "In many cases, the agency has an explanation, but you don't necessarily hear that explanation very clearly."

Dr. Hamburg said she expects that a wide range of recommendations could emerge from the task force's work. Some recommendations "will be in areas that we can implement swiftly, but there may be other types of information that will take more time, and there may be some area where we have limitations within the current law and need to examine whether appropriate changes can and should be made," she said.

Both Dr. Hamburg and Dr. Sharfstein emphasized, however, that a balance will need to be struck between providing more information and the appropriate use of confidentiality.

Another balancing act will come in terms of clinical trials, Dr. Sharfstein continued. "What is the argument for different amounts of data [being disclosed] at different points in the drug development process, and on the other side, what are the confidentiality concerns and the reasons for them?"

The call for transparency comes at a time when FDA already has a backlog of requests under the Freedom of Information Act.

Asked how she planned to handle personnel needs at a time when the agency is behind in its work, Dr. Hamburg said, "When the recommendations come in, I will work with the task force and others on implementation. Some activity may result in more work, and some may result in decreased work. If we make more information available, there may be fewer Freedom of Information Act requests and citizen petitions." ■

The Federal Register notice announcing the task force's formation is available online at www.federalregister.gov.

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As physicians, Baby Boomers—a generation of optimists and workaholics—'have done nothing in medicine to improve social justice.'

Dr. Lawrence G. Smith, on the generational shift occurring in medicine, p. 40