Reviving the FDA: NEJM perspective

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In a Perspective piece published online today in the *New England Journal of Medicine*, Georgetown University School of Medicine family medicine physician Susan Okie gives a comprehensive overview of change, and planned change, within the Food and Drug Administration (FDA). The review comes as the FDA's commissioner, Margaret Hamburg, completes her first year as the agency's leader.

Okie writes that the FDA's priorities over the past year have included "finding ways to make the FDA more nimble and proactive, restoring its credibility and refocusing staff on its public health mission, persuading Congress to boost funding for its expanding portfolio of responsibilities, [and] sharpening its ability to deal with new science and globalization…"

To that end, Hamburg reportedly has spent hundreds of hours meeting with interest groups and meeting with key members of Congress to build alliances.

As Okie outlines, Hamburg and the deputy commissioner, Joshua Sharfstein, have already undertaken several changes at the agency. The two leaders have met with FDA employees to understand hurdles they encounter because of legal and regulatory requirements. Such discussions have prompted new measures to accelerate responses to urgent health threats. In nonemergency situations, changes that have been described as "nuanced" actions often achieve desired results, Sharfstein says.

Hamburg, Sharfstein and internal task forces have been "reexamining

the processes for making decisions" about the safety and effectiveness of drugs and medical devices. Okie says the agency is awaiting reports next year by Institute of Medicine panels that are likely to recommend reforms. The leadership anticipates decisions that could lead to lasting changes at the agency.

Finally, Hamburg's longer-term priorities include regulatory science and globalization. The Commissioner tells Okie that in addition to advocating for increased funding, the agency hopes to collaborate with scientists in academia and industry, as well as other federal health agencies, on research and training in areas such as biomarker, bioimaging, clinical-trial analytics and pharmacoepidemiology.

As for globalization, Okie reports that the agency is introducing a risk-based strategy for targeting priority inspections in order to "grapple with the expanding task of ensuring the safety of products… made overseas."

Hamburg says despite the criticism of her agency and the growing pains within "...overseas, the FDA is still considered the gold standard for a regulatory agency," while here at home she says, "I have encountered a sense of real eagerness... to support the FDA in its mission."

Provided by Georgetown University Medical Center