PARTNERSHIP FOR PUBLIC SERVICE

2014 LEADERSHIP IN ACTION AWARD

Presented by the Partnership for Public Service and the Senior Fellows Board

Winner: Drug Quality and Risk Communication Initiative

Sarah Pope Miksinski, Division Director, Office of New Drug Quality Assessment, Food and Drug Administration (FDA)

Achievement: Transformed how FDA communicates about the quality of new drugs to pharmaceutical companies and internal stakeholders and instituted a new team review process for assessing the quality of new medicines

Sarah Pope Miksinski, a division director in the Food and Drug Administration's (FDA) Office of New Drug Quality Assessment (ONDQA), is transforming the way the agency reviews the quality of new drugs and communicates associated risks to pharmaceutical companies and internal stakeholders.

ONDQA's job is to evaluate the quality of each new drug—defined by potency, purity, strength and identity—and to ensure patient safety by flagging risks that might make a new drug unsuitable for marketing. Miksinski's office was effective in finding risks to drug quality, but often struggled to communicate these risks in a manner that related directly to patient health.

While in the 2011-2012 *Excellence in Government Fellows* (EIG) program, Miksinski learned from a classmate how the Federal Emergency Management Agency (FEMA) assesses how people may be affected by natural disasters and communicates risk accordingly. Though FEMA's mission is different, the agencies share the goals of effectively communicating risk and protecting people from harm.

Miksinski realized that, in many cases, her office was placing too much emphasis on the technical facts and forgetting what was important to the patients.

"Previously, we had a highly technical process of identifying certain factors that might keep a drug from being approved without really focusing on communicating why we should be concerned about such factors," said Miksinski. "We needed to do a better job of really considering the voice of the patient."

Miksinski took her ideas to her executive leaders, who gave her the task of redesigning the review process. Teams are now encouraged and expected to identify risks related to drug quality earlier in the process and to engage in conversations about what is most important to the patients, while translating the technical findings in understandable terms.

Miksinski also instituted another big change in the risk assessment process.

When her office received an application for a new drug approval in the past, one person was given the responsibility of assessing the various quality aspects. For “clinically urgent” applications, the office often struggled to process the applications in a timely manner.

Based on a need for increased efficiency to expedite clinically urgent products, Miksinski designed and implemented a team-based review process in which multiple reviewers would assess the same drug application within their specific area of expertise, a change that quickly led to more thorough and faster quality reviews.

“Any time that you have a number of dedicated and highly-trained professionals working together in a highly effective team, you will get a better decision,” said Miksinski.

In 2013, the FDA approved 35 novel medicines, including a groundbreaking treatment for a form of cystic fibrosis and the first drug to treat advanced basal cell carcinoma, which FDA reviewed in three and a half months and five months, respectively. Thanks in part to the efforts of Miksinski and ONDQA, ninety-seven percent of new drug applications were reviewed by their target dates, including these two drugs with targets of six months.

“Sarah has taken the lead in shaping the future of the organization,” said Christine Moore, office director of ONDQA.