

FDA's Four Principles

Joshua Sharfstein, M.D.
Principal Deputy Commissioner, U.S. FDA

FDA's Principal Deputy Commissioner Joshua Sharfstein outlined four principles that define FDA's role as a public health agency in a speech in mid-September.

The first principle of public health is prevention. He noted recent challenges in the pharmaceutical industry, including supply-chain management and the adulteration of drug products with contaminants such as diethylene glycol. "I think all of these things are amenable to a preventive approach," he said. "When one company falters because of a quality problem, it's their problem to fix and prevent. But when a problem occurs across the industry, when it causes the kind of quality-system problems...it's everyone's problem and it's FDA's problem to help think about solutions."

Sharfstein also brought up the quality trio guidelines finalized by the International Conference on Harmonization, ICH Q8, Q9, and Q10, as an example of how industry can prevent problems. "The goal of these efforts is to understand from the start what makes a product of high quality rather than waiting to discover a problem after the fact," he said. "FDA would like to foster more such productive collaboration that leads to concrete results in preventing problems."

The second principle of a public-health approach identified by Sharfstein during his talk is the "best available science." He noted that FDA is working to identify key projects that can help product quality, streamline approval pathways, and improve scientific training. "We'd like to see more guidance documents emerge out of these scientific efforts to provide a clear and transparent process to address long-standing quality issues and to help bring important products to the market."

Third, a public agency by definition involves the public, he said, pointing to the new transparency initiatives at FDA such as its website, public meetings, and blog. He encouraged industry to improve its transparency as well, noting that sometimes, companies are reluctant to issue a press release or conduct a recall when things go wrong.

"In the next decade, with speed of information only accelerating, it's a good assumption that product quality problems will eventually come to light. It's better for companies to develop effective and transparent communication systems now rather than stumble when others are providing key messages about your products for you," he said.

Sharfstein emphasized his point by stating, "When public health is at stake, FDA is going to take this basic position: You can explain this problem to the public or we will."

Fourth and finally, Sharfstein discussed the premise of public health as one in which the health of the public matters. "In evaluating product quality issues for 2020, I would

imagine there are many ways to resolve key challenges as you face them, however, I urge you to consider the health of the public as the North Pole for your compass.”

In some concluding remarks during a question-and-answer session, he added, “Let’s not be so risk-averse that we lose opportunities for really important innovation and progress.”