

FDA's Woodcock: What to expect in the next 25 years of medicine

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How has the biopharma industry evolved over the last 25 years, and what can we expect from the industry in the next two and a half decades? Those were questions CDER director Janet Woodcock set out to answer at the 25th annual AAPS meeting in Washington, D.C., on Sunday. In honor of the organization's 25th anniversary, Woodcock, who's been with the FDA since 1986, reflected on the industry's past and on trends she believes will play a major role in shaping biotech and pharma in the coming years.

The drug industry was very different when AAPS was founded in 1986, Woodcock said. The issue of the day was drug lag--that is, concern that new molecular entities were being approved and reaching patients in other parts of the world sooner than in the U.S. Many industry watchers believed the FDA review process was too slow to keep up with advances in medicine. From this era came the first Prescription Drug User Fee Act, which was instituted in 1992 and gave the agency funding necessary to process NDAs more quickly. A decade and a half later, the pendulum moved in the other direction. Those who had been clamoring for new drugs had become concerned that innovative medicines were not tested carefully enough, and drug safety became a major issue. Woodcock said the early 2000s presented a cautionary tale for the agency. "Society has rolling expectations," she warned.

The HIV epidemic emerged around the same time as the agency was wrestling with concerns about slow drug approval. "Suddenly there was an incredible sense of urgency all around to do something about this," Woodcock said. The industry, she said, did a great job rising to the challenge, while the FDA did its part with accelerated approval. As a result, HIV has gone from a death sentence to a manageable disease.

The rise of the biotech industry began in the 1980s. "Today, biotech has a tremendous role in the innovative medicines approved each year," Woodcock said. "It has taken a lot of time for the technology to mature and be used the way it is now."

So what are the major issues that will shape the industry over the next 25 years? The worldwide economic crisis will surely be one, Woodcock noted. "It's the macro trend of all macro trends, in my mind," she said. The FDA expects to see decreased staffing and resources due to government-wide cuts, although the CDER director hopes her agency won't be hit as hard as others in the U.S. No matter how the chips fall with future budgets, Woodcock said she expects the FDA to increasingly rely on PDUFA for support. The industry's productivity has also gotten a lot of attention over the last several years. "Can we keep this engine going that brings new medicines to patients? Is it worth the return on investment?" Woodcock asked. Productivity will likely continue to be a concern as Big Pharma attempts to limit the cost and complexity of developing new drugs.

Emerging markets have been a major target of the industry, and Woodcock believes that trend will continue to blossom. In 25 years, she said, the U.S., EU and Japan will likely become members of a larger group of regulators dedicated to enforcing worldwide standards of drug efficacy and safety. "I

think we have to move toward...international standards in the future," she said. "We can choose to drive toward worldwide harmonization, particularly in manufacturing." Failing to do so will result in regional rivalries and varying expectations from country to country--a system that she believes no country or company could sustain.

Here are more specific trends Woodcock thinks will play formative roles in the industry in the next 25 years:

- Right now, manufacturing experts from the 1950s would easily recognize the manufacturing processes of today. Woodcock predicts that will change in the next 25 years as current manufacturing practices are abandoned in favor of cleaner, flexible, more efficient **continuous manufacturing**.
- In the same way that biotech emerged from the 1980s, we are on the cusp of the **molecular medicine** revolution. "Our understanding of disease at a molecular level will revolutionize treatment," predicts Woodcock. "I think molecular medicine is going to be extremely powerful." New approaches to medicine will be necessary to address another disturbing trend: the rise of chronic diseases like obesity, hypertension and type II diabetes. There will be a "clamor for effective drug intervention that will reverse this societal trend," though it is not yet clear if it will be possible to use medicine or medical intervention to resolve these metabolic diseases.
- In the U.S., Woodcock wonders what role **political turmoil** will play in the approval of new drugs. "FDA is really suffering under the politicalization of regulatory decisions," she says, adding that advances in science and technology could resolve some of the conflicts we experience today.
- The CDER director believes **drug regulation will grow less intrusive and less complex** in the next 25 years. Current regulation is formulated to deal with uncertainties in manufacturing, safety and efficacy around drugs. Says Woodcock: "The more we can make those predictable, the less regulation we will need." One of the most turbulent sectors in the coming years will be toxicology and risk prediction; improving those aspects of clinical trials would reduce the time spent testing and the money spent monitoring trials. Between electronic health records (EHRs) and clinical trial networks, Woodcock says we will get to a much more efficient, reliable clinical trials system worldwide.
- With a laugh, Woodcock said she believes EHRs will *finally* be standard in 25 years. "When that happens," she says, "networks like the Sentinel Initiative and other vigilance networks will be able to find out what's happening with medicines in the real world," allowing regulators and companies to quickly respond to reported drug problems. Adds Woodcock, "I predict we'll look back in horror at how we managed **drug safety** in the early 2000s."

Woodcock's final thought on drug development: "It is always a wild ride, but it's always interesting."