FDA leadership picks may stress safety over swift approval

Industry leaders and consumer advocates anticipate a shift in the focus of the US Food and Drug Administration (FDA) under the leadership of Margaret Hamburg as commissioner of the agency.

Hamburg was nominated by US President Barack Obama on 14 March, but as *Nature Medicine* went to press, she was still awaiting Senate confirmation. In the interim, Joshua Sharfstein, whom Obama appointed as deputy FDA commissioner, took the temporary position of the agency's acting head on 30 March.

Associated Press

Outspoken about safety: Margaret Hamburg

Both Hamburg and Sharfstein are former health commissioners of large cities (New York and Baltimore, respectively) and therefore "understand public health issues from the street level—how policy impacts people," says Peter Pitts, a former FDA associate commissioner for external affairs who currently serves as president of the New York-based Center for Medicine in the Public Interest, which receives biopharmaceutical industry funding.

The new FDA leaders are likely to put more emphasis on ensuring the safety of all medical products, rather than focusing on approving as many new medical products for use as soon as possible, as the FDA has been doing for the last few years, says Diana Zuckerman, president of the National Research Center for Women & Families in Washington, DC.

According to Jerry Avorn of Harvard Medical School, Hamburg and Sharfstein have the advantage of joining the agency after the enactment of the Food and Drug Administration Amendments Act of 2007, which gives the agency expanded authority to require post-marketing studies and clinical trials. Avorn predicts the legislation will give the new leaders clout when it comes to tracking the safety of approved drugs.

Some pharmaceutical insiders have voiced concerns in news articles that Sharfstein, who worked under drug industry critic Representative Henry Waxman, will crack down on the industry.

And John Calfee, a resident scholar at the American Enterprise Institute based in Washington, DC who has consulted for the drug industry, argues emphasizing safety too much could substantially hinder the approval of useful drugs.

Kirsten Dorans, New York

Profit-hungry pharma sees some biotechs as ripe for the picking

In late March, pharmaceutical giant Roche completed its takeover of Genentech, the company credited with founding the biotech industry more than three decades ago. The deal cost Roche nearly $47 billion. That may seem like a lot of money to pony up in these tough economic times, but drugs are a relatively recession-proof product, according to some experts. The pharmaceutical industry isn't hurting for cash so much as it's hurting for new drugs.

As the patents on many blockbuster medications near their expiration dates, pharmaceutical companies are becoming increasingly desperate to replenish their pipelines. "When a generic product comes to market, it could take away 80% to 90% of the sales," says Jason Napodano, a senior biotech analyst with Zacks Investment Research, a Chicago-based firm. "It takes a lot to replace that," he adds. Many companies see buying biotech firms as an attractive fix: not only do they get revenue from the products the biotech has already developed, but also they get the promise of a steady stream of new drugs—perhaps even the next blockbuster.

An added draw is that most biotechs are designing expensive drugs called biologics, which are derived from living cells. Because the development process is so complicated, such drugs are less likely to be replaced by generic versions even after their patents run out, says Ziad Bakri, an analyst at Cowen and Company, a New York–based provider of investment banking and equity research.

But pharmaceutical giants such as Eli Lilly or Sanofi Aventis aren't looking to pick up just any biotech firm.

"Pharmaceutical companies are very risk averse," Napodono says. So they're likely to bid on the dozen or so medium to large biotech firms that already have drugs on the market or in late-stage development. Although smaller companies are cheaper to acquire, they are typically too far away from being profitable to be appealing.

Last fall, Eli Lilly paid $6 billion for ImClone Systems, a mid-size biotech with a colorectal cancer therapy called Erbitux. According to the *Wall Street Journal*, the company is already looking to pick up another biotech in the $5 billion to $15 billion range—perhaps because the patent for Lilly's antipsychotic Zyprexa, which reportedly accounts for 22% of the company's net sales, expires in 2011.

No one can predict which biotech will be acquired next, but Celgene, Genzyme and Biogen Idec top many analysts' lists. Celgene develops therapies for cancer and other severe inflammatory conditions, Genzyme targets rare diseases and Biogen Idec's products address diseases such as lymphoma, multiple sclerosis and rheumatoid arthritis. Biogen Idec put itself up for sale in 2007, but there were no takers. Today, however, buyout rumors are rampant.

Roche's takeover of Genentech was hostile, but other biotech firms may welcome a buyout. Investors aren't as easy to come by as they once were. And pharmaceutical companies have valuable experience in manufacturing and selling drugs that biotechs may not have.

For the smaller biotech companies, in particular, prospects appear bleak. Funding has fallen off dramatically. Some small biotechs will die off, some will be acquired by larger biotech firms and some will save themselves through restructuring and layoffs. Still, those that survive may eventually succeed. And among the small biotechs struggling today, Napodano says, "there's a diamond in the rough."

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