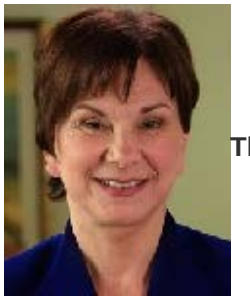
Biotech

Janet Woodcock - FDA

by *Damian Garde* |



The gatekeeper of biopharma's biggest market

Name: Janet Woodcock
Title: Director of the FDA's Center for Drug Evaluation and Research

FDA meetings have made for intriguing theater over the past year. Advocates chastise the agency for its perceived gender bias. Pharma execs squabble about safety data that happen to defend their multi-billion-dollar products. Parents of children with rare diseases read tearful entreaties for the agency to approve new drugs with debatable supporting evidence.

Each, wittingly or otherwise, is trying to get through to Janet Woodcock, a 20-plus-year FDA veteran who runs the agency's drug-approval arm and has the power to alter the course of the industry.

Woodcock is director of the FDA's Center for Drug Evaluation and Research, a division tasked with vetting new drug applications. Under her leadership, the agency is approving more and more new drugs each year--45 last year and 41 in 2014--all the while facing mounting criticism from critics who say the FDA is too close to the business it regulates, industry insiders who claim the process is still too slow, and patient advocates who argue the agency needs to rethink its approach to rare diseases.

Case in point: Duchenne muscular dystrophy.

Two companies, BioMarin Pharmaceuticals ($BMRN) and Sarepta Therapeutics ($SRPT), are petitioning the agency to approve treatments that could help about 13% of boys with the deadly, muscle-wasting disease. Each is armed with data from small studies in which their candidate drugs charted only intermittent efficacy, below the standard usually required to win FDA approval. There are no approved treatments for the disease, and parents of DMD patients are clamoring for anything that might improve and extend the lives of their children, even if it's a long shot.

The question facing Woodcock becomes: Should the FDA bend its standards in response to unmet need, or would relenting open up a loophole that biopharma companies could later exploit to the detriment of patients?

Woodcock always stays on-message in her public comments, sticking to the point that the agency makes its decisions based solely on safety and efficacy data. But the FDA, under her watch, has been increasingly flexible in the approval process.

CDER's cancer division, led by Richard Pazdur, has repeatedly approved new cancer medications with shallow efficacy records, clearing them to treat only the most desperate patients until companies come back with enough data to justify broader use. And the agency seemed to cave to public pressure last year when it approved Addyi, a twice-rejected female libido treatment whose scant effectiveness didn't outweigh its side effects in the eyes of many critics.

Each case boils down to the same fundamental issue: What makes a drug approvable? Woodcock, as gatekeeper of the world's biggest drug market, plays a sizable role answering that question, giving her the power to shift the dynamics of biopharma.

-- Damian Garde (email | **Twitter**)

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