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COVER STORY

## Online Extra: Putting the FDA Out Front

Deputy Commissioner Dr. Janet Woodcock explains how the agency has led the drive for personalized medicine

In her 19 years at the Food & Drug Administration, Dr. Janet Woodcock has tackled some of the toughest issues facing the agency. She led the Center for Drug Evaluation & Research -- the FDA's drug-approval arm -- from 1994 to 2003. Since then, she has worked with industry on a "critical path" initiative designed to improve the process of drug development and also on an effort to understand how different people respond differently to drugs.

Now FDA Deputy Commissioner, Woodcock recently spoke with *BusinessWeek* Senior Correspondent [John Carey](#) about the promise of a more personalized type of medicine. Edited excerpts of their conversation follow:

### **What's your vision of how drugs can be used in better, more targeted ways?**

The overall vision is a medical vision: that we can get better outcomes for people and get a higher percentage of people who actually respond to any given treatment. Instead of your doctor telling you that 40% of the population responds to a drug, he can tell you that if you take this drug, you have a 90% chance of responding.

On the flip side, our vision is that there aren't bad drugs or good drugs. Instead, some drugs run into bad problems with a small subset of people. Instead of taking all those drugs off the market or putting warnings all over them, we need to make sure that people who are at high risk for a side effect don't get the drug in the first place.

The vision is that this will actually decrease the cost of health care. We know there is a tremendous burden from adverse events of drugs, and everyone agrees we can do a much better job.

### **How will this happen? Will doctors really use a diagnostic test before prescribing a drug to make sure they get the drug -- and the dose -- right?**

Our thought is that this is really hard for existing drugs like warfarin [a blood thinner], where there are established practice patterns. Doctors are very anecdotal. They say, "I've always done it this way, and it has worked for me and my patients. I'm not going to change."

But when you have a new therapy like herceptin [Genentech's ([DNA](#)) breast cancer drug], and you say it's only for people who have the receptor for the drug, then people follow the instructions [and use the test].

### **What's the FDA's role in moving toward personalized medicine?**

We did something very unusual, which was to get out in front of this. Part of the reason we did it is that we have a unique perspective. We see all the problems. We see every development program. No one else does.

And we could see that the pharmaceutical industry was using all this science [e.g. genomics] in the discovery process, but not in drug development because they were afraid of regulation.

So we had a meeting four years ago, the first meeting on pharmacogenomics, and all this got put on the table. It was a "call to light" kind of meeting. We looked at the promise [of personalized medicine], and then people in the industry stood up and said, "We are terrified."

### **Why?**

One of the companies wrote me a list of questions. One was: What if we find that our treatment turns on an oncogene [i.e. a naturally occurring gene that can cause cancer]?

It turns out that oncogenes are involved in many inflammatory and other processes. So it is no big deal [if a drug turns on an oncogene], and many approved drugs do. But since we didn't know much about it at the time, the industry worried that if they told us [that an oncogene was activated], we would put a clinical hold on their development programs.

Questions like this one had to be answered for the technology to move forward.

### **So are companies less fearful now?**

Yes, to a great extent. But problems still remain. The industry has a model of the blockbuster drug [where everyone gets the same drug], and it's a painful sociological transition [to a more personalized approach, where drugs would be used only in subsets of people]. But even if we don't move to personalized medicine, we still might not have blockbusters anymore. The industry is coming to grips with new business models.

### **So is industry beginning to sign on to the idea of studying genetic variations in patients in their clinical trials -- and using those genetic variations to identify groups of patients who either benefit most, or suffer the most side effects?**

We think there has been an upwelling [of interest by drugmakers]. We will see this technology moving into the clinic in the next year or so. Then we will have to bring the regulators in.

### **Where will we see the first results?**

I think the impact will be tremendous first in metabolism and in oncology. [For a cancer drug that now works only in 10% of people], we can make it a 100% response if we can figure out who the people are who should get the drug. Then the other 90% don't have to be exposed to the drug, and everyone is happy.

### **This depends upon having a diagnostic test to separate people who should get a drug from who shouldn't. Will companies develop those tests?**

We recognize that the big kahuna here is the development of diagnostics. The business models aren't very good. So at the FDA, we're trying to incentivize the development of diagnostic tests.

### **How many drugs would benefit from having a test and being used in a more targeted way?**

I think the estimate is that about one-quarter of existing drugs have polymorphism differences [i.e. genetic variations among people] that are clinically significant.

We don't want to burden the health-care system with a lot of tests. In a class of drugs where there are a lot of choices that are all relatively safe, if you try to introduce a new drug with a test, no one will use the test. [That's why the personalized approach] will be used more for unmet medical needs and serious conditions.

For example, diabetes is not well treated. If we had a new drug for Type 2 diabetes for which you needed some sort of metabolic test to determine what dose to take, people would probably do it. The same is true for a lot of other conditions that are poorly treated or untreated. The biggest challenge is getting really good diagnostics developed as commercial tests.

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