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Changing the FDA Approval Process

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Susan Desmond-Hellmann, chancellor of UCSF, has a big idea to change the drug approval process at the Food and Drug Administration (FDA). The current process is binary, allowing for only a yes or no from the reviewer for drug approval. Desmond-Hellmann suggests that a variable approval process, that can change status as greater evidence comes in over time, will encourage more innovative products and even investment funding, based on product confidence.

Transcript

One of the biggest challenges in my opinion on making new innovative products in life sciences is the binary outcome of FDA approval. So put yourself in the shoes of an FDA Reviewer. So you're in charge of reviewing the new drug and you have two outcomes. Yes, this is safe and effective for obesity, and perhaps millions of patients are going to be exposed to that drug and if they do have an excess of heart attacks, it's your fault. How often are you going to say no? Always. There's no benefit to you to say yes, and all the risk is on you, because you've only got an answer of yes or no. Well, if you really follow product approvals and the course of product approvals and all of what's been in the paper about side effects, you'll know that life doesn't come in binary. It's a maybe. So maybe this drug is safe and effective after ten years and maybe not. The reality is we don't know at the time of product approval what the long-term consequences of new medicines are.

So my big idea is to give FDA and that poor reviewer, all of the onus on them to protect patients from side effects but also wanting to give therapeutic benefit, to treat it as a continuous variable rather than a dichotomous variable. A continuous variable would have a range of certainty, of confidence. And that confidence would come over time. So for example, the FDA could say no. "Four and a half pounds, that's not enough. That's not enough any side effects acceptable." On the other hand, let's say, it was ten pounds but you still have uncertainty. You could have an approval process that started out with a low level approval. You don't get a sales force, you can't promote that drug and you can't put TV ads on it. But you could sell it. Then you increase your confidence.

"We haven't seen any heart attacks after five years, Looking good. The ten pounds is really holding up and in fact, some of the patients as they stay on the drug longer, lost 15 pounds. OK, maybe you can have a sales force. Still no ads on TV." Then you gain more confidence, it gets to be eight years. Is there a system where we could, as we increase our confidence in safety and advocacy, allow for broader distribution and more promotion. Not a yes or a no answer. I think that could really change two things. One is, the odds in the business model would be more stacked in favor of investing in difficult things like obesity, type 2 diabetes, high blood pressure that were at risk for no innovations. And the other thing is we could improve how we communicate to the public. Instead of saying, "Yeah, I saw that on TV.

It must be perfect. You can't have side effects and put it on the nightly news." We're doing a lousy job of communicating to patients that all medicines have consequences. So, if instead of saying "We're 100% sure it's good for you and not bad for you" to communicate "Every medicine has a consequence. Every medicine has a side effect and this one we have a lot of confidence or poor confidence." So I think that would completely change things.