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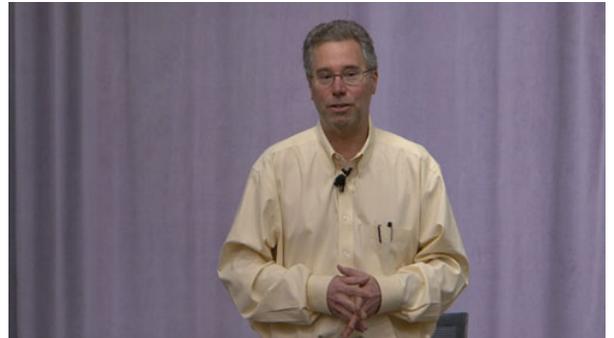
Ethical Issues in Drug Development

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Genentech Executive Vice President Richard Scheller discusses some of the thought-provoking ethical issues that arise in the drug development process. To illuminate the issue, Scheller describes the painful challenges of the clinical trial placebo process, often required by the Food and Drug Administration. He also articulates some of the ethical implications related to drug costs and insurance reimbursements.



Transcript

There are ethical issues everyday. There are a lot of ethical issues around the clinical trials. For example, you have a drug that you're pretty sure is going to work and we're required in a number of cases by the FDA to have a placebo group. And nobody wants to be in the placebo when we're doing a survival trial. Nobody wants to be in the placebo group, and one could question whether it's ethical to even have a placebo group or whether you should just put everyone on the drug and compare it to historical standards, which of course is not as good an experiment, that's for sure. But these are real folks that you're treating. So a lot of our issues around our clinical trials are basically determined by the FDA, where I tell us, "No placebo control, no approval, no drug for anybody." So we're required in a lot of cases and we often-often-we sometimes disagree with the FDA on whether it's ethical to have a placebo group. But in the end, they're the regulators and they would rather be really, really sure that you have a drug that makes a difference that you can then market to hundreds of thousands or million people than to... And maybe for some folks, not to get the drug early on and to be sure in the end that it's a good drug. So a lot of our ethical issues around our clinical trials are determined by the regulatory agencies and we basically just have to follow what they say.

Now, in terms of drugs and their use in the third world, we wouldn't, frankly, try and make a drug for a third world country disease because it's not profitable. And fortunately, there are groups like the Gates Foundation now that are putting that kind of money into those kinds of clinical development work, that are starting to think more about that. But we can't justify to the people that buy our stock everyday that we are going to spend \$1.5 billion and then give it away. Now that's for better or for worse, and that's not the way the rest of the world functions nowadays. If it's free enterprise, it's going to determine what drugs are made. And it's a growth hopefully driven business, I have to justify at the end that there's some return on the investment that I make. In the United States, for example though, it was really a bit of a fallacy that our health care system was so terrible. I mean, in terms of prescription drugs, if you have insurance, insurance pays. If you have insurance and you have to make a co-payment and sometimes on an expensive drug, the co-payment can be more money than someone will have. So if you couldn't afford the co-payment, we paid it.

And if you didn't have any insurance and you needed the drug, we just gave people the drug. So somebody want to do a... 60 Minutes wanted to do a story once on one of our expensive cancer drugs and to find somebody that was dying because they couldn't get the drug and make us look bad. But you know what, they couldn't find anyone who wasn't getting the drug. So that drug, we've given away, I don't remember what the number is, billion dollars worth of free drug. We spend a lot of money every year on co-payments for folks. So we believe that, least in the Western world where we operate, everybody has access to our drugs, even if we just give it to them for free.