

Q & A
Kathy Hudson, Ph.D.

MS. AU: Because Dr. Hudson was so speedy, we can take one or two questions. Kevin.

DR. FITZGERALD: You have to have quick hands around here.

[Laughter.]

DR. FITZGERALD: Thank you, Kathy. Again, as always, very thought-provoking, so I have a question. You mentioned in the statement that you were one of the authors of that safety should come first. You also mentioned that there is a great deal of evidence we need to have in order to make decisions that we don't yet have. Is it then logical to conclude that much of what is going on now you think shouldn't be going on because we don't have the evidence to decide what is safe and what isn't?

DR. HUDSON: I think it is hard to know. The actual answer is it is hard to know. If you look at some tests that are being offered, you can't tell what the gene is, you can't tell what the variant is, you can't find any publications. In some cases, the disorder that is being tested for doesn't exist in the scientific literature. It is just very difficult to know because we are not demanding the kind of transparency that we really need.

DR. FITZGERALD: Right. If you are saying safety first and we don't know, does that mean don't do anything?

DR. HUDSON: There are a couple of interesting models. One is, we could put in place this genetic testing registry tomorrow. It is not that complicated. I think we need to move ahead expeditiously with putting that in place.

Secondly, I think that we could have tests on the market where we either haven't had a chance to evaluate them or we don't yet quite have all the evidence and collect evidence as we go forward. It is approval with additional evidence collection. There are ways where we could address the pursuit of the perfect not denying us some of the good tests that are available out there.

I should say there is a whole slew of tests that have been out in clinical practice and validated for a very long time that we need to figure out some mechanism of just grandfathering those in. We know what they do, we know how they behave, and we know the molecular biology and cell biology underlying them.

MS. AU: Thank you, Dr. Hudson. I'm sure we will see you back here again.

[Laughter.]

MS. AU: Back to Steve.

DR. TEUTSCH: Great. Thanks, Kathy. Thanks, Sylvia, to you for organizing this session.

[Applause.]

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DR. TEUTSCH: Obviously, a stimulating and important area. We will be talking more about it later this afternoon.

For now, since you and Kathy graciously got us done by 10 to one, let's plan to meet back here at 1:20. We will have a half hour. There is a cafeteria down the hall for those of you who don't have a boxed lunch. Then we will take up the public comments. Thanks, all.