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FDA'S ROLE IN PROTECTING THE PUBLIC HEALTH: EXAMINING FDA'S REVIEW OF SAFETY AND EFFICACY CONCERNS IN ANTI-DEPRESSANT USE BY CHILDREN

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HEARING

before the

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

of the

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Mr. Laughren. They were looked at in the routine ways. Adverse events were reported, and the item data were collected. Again, a signal did emerge in the Zoloft data later on with the two pediatric trials in depression, but even that wasn't recognized until--actually, Dr. Mosholder was the medical officer who reviewed that supplement initially. He did not observe a signal for suicidality. it is only when he went back during the summer of 2003 and looked at--relooked at the same data that a weak signal emerged.

Mr. Walden. Dr. Temple, did you have the authority to ask the companies to look at this, to keep better data so you could, in your written request to them?

Mr. Temple. Let me be clear. You always measure the standard suicide scores, and we have the capacity to look at those. That is what you do in all these studies. It is how you measure improvement.

So every time you do these studies, you get a suicidality score, and we look at it. There isn't anything the company has to do except give us the data. What we could have thought--what we conceivably could have asked but didn't know to ask was a better, more structured, more careful look at events that might or might not represented suicidality, but we didn't know to do that.

Mr. Walden. But didn't Dr. Laughren say that in the depression trials you should look more critically?

Mr. Temple. We were looking at the items in the Ham-D score, and nobody saw anything. It shouldn't surprise us that we didn't see it, because in the very data that have created the signal we are worried about now, you don't see any increase in the pediatric version of a Ham-D. That is not where it shows up, for some reason.

Mr. Walden. I guess, as I have listened to this, and I have sat through these hearings a long time, the picture that begins to emerge in my mind isn't a pretty one, because it is one that says you are worried less about suicidality than in continuing to allow physicians to prescribe a drug that most studies show at best has no effect in treating depression in kids and adults.

Mr. Temple. I don't agree that that is our conclusion. We spent tremendous resources and devoted tremendous effort to evaluate the suicidality question.

Mr. Walden. Well, when Dr. Mosholder does the review and says I am spotting something here that is very troubling, when you are dealing with drugs in kids that virtually every trial shows have no effect and Dr. Mosholder is finding some link to suicide, you--well, it seems to me, my opinion is you ended up on the side of let them prescribe it, because they might be okay; we don't necessarily agree Mosholder has got this right; we are going to go run it out somewhere else and see, and take that risk.

Mr. Temple. We didn't think we were letting them prescribe it or not letting them prescribe it. The question we were trying to face was do we have enough information to say there is increased suicidality in children given these drugs. That is what we were grappling with.

Mr. Walden. You have said earlier today that you didn't want to discourage the prescribing of these off-label, because they may work in some people.

Mr. Temple. That is a different question. We thought that it was very important to get the right answer on this question. That is correct.

Mr. Walden. Well, I will tell you, I guess that is where we are just going to agree to disagree maybe, but if I had to err.