
Q & A

DR. WILLIAMS: This is for Jeff and relates to the last slide. We have certainly seen in other circumstances where "voluntary" things have become ersatz regulatory issues. Look at the NCQA, the Joint Commission, and others. In some sense, if you tie this to data that will be used by payers and other reimbursers, the people that control the purse strings, they may say, we are not going to reimburse any tests that haven't gone through this process. Then you have a de facto regulatory system.

While I think this is really important and this is definitely the direction that things need to be going, I would ask you to respond to that issue.

DR. COSSMAN: I don't know if everybody heard the question. Maybe I can paraphrase it. This could end up becoming too successful in the sense that even though it is not a regulatory body and there is no federal mandate that you have to go through this, it still may be something that everybody wants because the reimbursers, the payers, may require this certification or this process before they pay. It would then become a de facto regulatory body.

That is a real problem. I can't tell you I have a glib answer how to solve something like that. What we would like to do is start very small with single bites and look at one area and see the pattern that emerges in terms of the reflex of the payers.

First of all, we have to start small because there is no way that you could start with all diagnostics all at once. You are looking at the entire agency so far. We are 2.5 FTEs.

[Laughter.]

DR. COSSMAN: So it is going to be hard to handle all of diagnostics right when we open the door. We are looking for one. One of the criteria would be that exact issue. We have heard that same question from others, that we would be swamped and wouldn't have the bandwidth to be able to manage this and it would become a second FDA. We don't want to be a second FDA. We have no interest in doing that. If that becomes a non-starter, then this won't happen.

But we think that this is so valuable to do, from what we have been hearing from people, that we need to find a solution to that. I'm open to people who have ideas and are creative and innovative here. We need to be problem-solving. But we don't want to create more of a problem than already exists.

DR. TEUTSCH: Andrea.

DR. FERREIRA-GONZALEZ: To take the next step on that question of becoming a de facto regulator, how do you envision not going that route? What I see is that people start using it and third-party payers get hold of this information. Then you can require an academic laboratory or any other laboratory to send the data to this place in order to be reimbursed by any of the third-party payers.

DR. COSSMAN: I think it is a similar issue. How do we not become a regulatory body. That is in terms of payers. Is that what you are asking? If payers would require it, then you would become a de facto regulatory body. I think it is a similar point.

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We don't have the solution for that. What we are saying is we would start small, with a single example, move out from there, and see what emerges in terms of the pattern from payers. We are just starting our discussions with payers to see how they would react to this.

In fact, the very first one I talked to -- and I won't say what company, but it is a very large insurance company -- said, we at the insurance company don't have the bandwidth to be able to determine which test someone ran. We just pay a CPT code. We don't know if they ran the test that worked well or the test that worked medium well or the test that doesn't work at all. We don't have an inspection method to be able to determine that. So right now, they wouldn't even be able to use this information. Even that hasn't happened yet.

DR. FERREIRA-GONZALEZ: They don't have the means today of identifying this, but they can ask that. If you are going to be submitting claims to particular third-party payers, then you submit information that you have been cleared.

DR. COSSMAN: They could.

DR. FERREIRA-GONZALEZ: We already have regulatory bodies to look at the quality of the testing. It seems to me that it could be, in the future, another hurdle to this.

DR. COSSMAN: Exactly. If this looks like it is an insoluble problem and is another hurdle, that is a deal-stopper. What we want to do is be innovative and creative here and find solutions for getting through this so that we can find ways around it. I don't have the answer here today, but if people have ideas, we are open to suggestions. I would be happy to talk to people in the insurance industry and CMS and see if there are ways that we can do this so that it works in a way that doesn't open up a floodgate of problems but rather is problem-solving.

DR. TEUTSCH: Great. I know we would like to have some more discussion. Thank you very much, Dr. Cossman. We appreciate that and your initiative in addressing this important topic.