Whether a pregnant woman would opt to take a screening test that could determine her risk of having preeclampsia and whether she would change her health care practices or care provider if she received a diagnosis or a clear determination of risk for preeclampsia from such a test are two big questions facing the research and development community.

The Preeclampsia Foundation is developing a survey of its members to understand the level of interest in diagnostic or screening testing. No such tests for preeclampsia and its related conditions are currently available, and the Foundation believes the U.S. Food and Drug Administration (FDA) should be more open to biomarker tests and encourage their safe production. In conversations with bio-pharmaceutical companies around the globe, there is a sense within these companies that the FDA has had a dampening effect on the development and eventual approval of these tests.

Biomarker and genetic testing were the topics of a June meeting in Washington, DC, sponsored by the National Organization for Rare Disorders. Representatives of the Preeclampsia Foundation were in attendance and had the opportunity to participate in a town hall-style

meeting with top officials and key personnel from the FDA Center for Device and Radiological Health (FDA-CDRH), including Dr. Jeffrey Shuren who leads the Center.

"It was very gratifying to hear firsthand from FDA leaders how keenly interested they are in preeclampsia, recognizing - as we do - the importance of accurate and timely diagnosis against our current far-from-perfect processes, as well as the ability to predict who will get it in order to guide management choices," said Julie Allen, government relations manager for the Foundation.

The Foundation also participated in breakout sessions with the FDA and nearly 40 patient advocacy organizations to specifically discuss the following: the accuracy and innovation of biomarker and genetic testing to date, and patient views about clinical risk as well as future FDA-CDRH efforts to incorporate patient perceptions and analysis of risk in their communications. The FDA-CDRH is in the process of developing guidance documents that will seek to regulate the organizations creating diagnostic tests, including clinical laboratories and companies. The agency is considering how to appropriately establish patient safety requirements in such a regulation to address the associated level of risk to the patient while ensuring that tests can move through the approval process and to market.

Representatives from the FDA expressed great interest in the Foundation's work and efforts to understand more about how patients may respond to testing options for preeclampsia.

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