



FOR IMMEDIATE RELEASE
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**Medical Leaders form Coalition for 21st Century
Medicine -- Advocate on Behalf of Diagnostic
Innovators, Patients and Doctors**
*Plans to Work with FDA and Congress to Ensure All Voices are
Heard*

Washington, DC – A group of key medical stakeholders, including innovative diagnostic technology companies, clinical laboratories, venture capitalists, and patient advocacy groups, announced today they have formed the **Coalition for 21st Century Medicine** (www.twentyfirstcenturymedicine.org). The Coalition is dedicated to improving the quality of healthcare and of personalized and preventive medicine by encouraging the research, development and commercialization of innovative new diagnostic technologies.

Howard Birndorf, Coalition for 21st Century Medicine co-chair and Chairman and Chief Executive Officer of Nanogen, Inc. said, “The Coalition for 21st Century Medicine believes innovation is the key to predictive and preventive personalized medicine. Access to advanced diagnostic products and services is vital to the future, quality, and affordability of personalized healthcare.”

This announcement comes on the same day that the Food and Drug Administration (FDA) holds a public forum on its draft guidance entitled “Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays (IVDMIA).” In this document, FDA outlines their proposed approach to IVDMIA regulation. The outcome of this discussion could profoundly impact the future of the diagnostics industry and the future of personalized medicine.

The Coalition believes there is a need to carefully consider the regulatory issues in light of unintended consequences such as the potential impact on innovation. The Coalition is concerned that if FDA’s IVDMIA guidance is implemented as drafted, vital medical tests may become unavailable, innovation and improvements could be impeded, the cost of research and development could rise, and insurance coverage for laboratory tests could erode or disappear.

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Presenting on behalf of the Coalition for 21st Century Medicine Tom Tsakeris, President of Devices and Diagnostics Consulting Group and former Director of the FDA's Division of Clinical Laboratory Devices, said: "Labs have been a significant source of innovation for decades. Laboratory developed tests, including tests and services that would be considered IVDMIA's under the draft guidance, are an essential part of public health and are the future of personalized medicine. To preserve this future, FDA should go through formal rulemaking procedures and carefully consider the alternatives."

Paul Radensky, M.D., an adviser to the Coalition, said: "We look forward to working cooperatively with FDA to make sure doctors and patients have timely and transparent access to the most innovative and effective diagnostic products in the world."

"We believe a formal FDA notice and comment rulemaking process is the best way to ensure complete, on-the-record input from all affected parties. We urge FDA to pursue a process in which doctors, patients, and innovators can add their experience and voice to this important proceeding."

For more information about the Coalition for 21st Century Medicine please visit www.twentyfirstcenturymedicine.org.

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Coalition members are: 20/20 GeneSystems, Inc.; Asuragen, Inc.; Aureon Laboratories, Inc.; Avicara Dx, Inc.; Bio-Rad; Burrill & Company; CardioDx, Inc.; CIPHERgen; Clariant, Inc.; Combimatrix Molecular Diagnostics, Inc.; Expression Analysis, Inc.; Fisher Healthcare; Genetic Alliance; Genomic Health; Kleiner, Perkins, Caufield & Byers; Luminex Corporation; Millipore; Mohr Davidow Ventures; Nanogen, Inc.; Prometheus; RedPath Integrated Pathology, Inc.; Sequenom, Inc.; Target Discovery; Tm Bioscience; Ventana Medical Systems, Inc.; XDx, Inc.; YgeneX (Coalition in formation)

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