

**The Biomarkers Consortium**  
*Advancing Medical Science*

**What Leaders and Experts Say**

**Edward Abrahams, Ph.D., Executive Director, Personalized Medicine Coalition**

“The search for new biomarkers points in the direction of a more promising medical future based on targeted therapies. The Personalized Medicine Coalition, a broad based group representing academic, industrial, patient, provider, and payer communities, applauds this new public-private initiative that joins together government, academia and industry efforts to unlock the potential of personalized medicine by concentrating attention at a key inflection point in the drug discovery and development process.”

**Deborah Banker, Ph.D., Vice-President, Research Communications, The Leukemia & Lymphoma Society**

“Precisely defining biomarkers is critical to distinguishing blood cancer subtypes, and planning and monitoring a patients’ therapy. The Society is excited to be part of this collaborative effort to discover and qualify biomarkers. Some day biomarkers may even be used to help prevent cancer.”

**Scott Campbell, Ph.D., Vice-President of Research, American Diabetes Association (ADA)**

"The ADA applauds the efforts of the NIH to explore development of new biomarkers for pre-diabetes and diabetes. If successful, we believe this will improve the diagnosis of pre-diabetes, important in prevention of diabetes, and perhaps lead to better treatment for those already diagnosed with diabetes."

**Declan Doogan, M.D., Head of Development, Pfizer Inc**

“This is the only way forward to address the huge challenge of bringing greater precision to product development and tackling the unacceptable levels of compound attrition.”

**Mike Fitzpatrick, M.S.W., Executive Director, National Alliance on Mental Illness (NAMI)**

"The 210,000 members and 1,200 affiliates of the National Alliance on Mental Illness would like to congratulate The Biomarkers Consortium for forming this important public-private partnership. NAMI is extremely pleased that the consortium will include an initial focus on depression. It is extremely important that government, industry, academia and patient organizations come together to uncover the biomarkers behind this devastating illness so that newer more effective treatments can be developed."

**Robert Goldstein, M.D., Ph.D., Chief Scientific Officer, Juvenile Diabetes Research Foundation International (JDRF)**

“The identification of more accurate biomarkers impacts both basic research and clinical practice. Type 1 diabetes would especially benefit from new markers that signify therapeutic effect. The Juvenile Diabetes Research Foundation recognizes that achieving this goal requires coordination of resources, and applauds the public-private partnership that is The Biomarkers Consortium. The entire scientific community should benefit from access to the data from this research.”

**Jim Greenwood, President and CEO, Biotechnology Industry Organization (BIO)**

“Identifying new biomarkers will improve the process of drug development in several important ways. Biomarkers can help researchers shorten development time, identify potential safety concerns earlier, and advance the growth of personalized medicine, which allows treatments to be tailored to individual patients. As leaders in the development of innovative safe and effective therapies, BIO members look forward to contributing to the success of The Biomarkers Consortium.”

**Thomas Insel, M.D., Director, National Institute of Mental Health**

“This consortium is an exciting new public-private partnership that will accelerate the development of diagnostic tests and other markers to improve clinical care. In my field, the treatment of mental disorders, developing biomarkers is one of our highest priorities.”

**Jonathan Knowles, Ph.D., Global Head of Research, F. Hoffmann-La Roche**

"Roche has a fundamental and longstanding commitment to innovation in healthcare through the creation of differentiated medicines and focuses on personalized health care based on clearly defined biomarker strategies. We therefore strongly endorse and support the aims of the new consortium. We believe that this will enhance and unite efforts to generate and expand knowledge about novel biomarkers and so aid the discovery of safer and more effective therapies in the future."

**Mike Leavitt, Health and Human Services Secretary**

“Today’s announcement of The Biomarkers Consortium is an important landmark. It represents a new step in sharing both the burdens and the fruits of fundamental scientific work and can help identify areas of opportunity, clarify responsibilities, and make important new findings openly available,” said Health and Human Services Secretary Mike Leavitt.

**Garry Neil, M.D., Group President, Johnson & Johnson Pharmaceutical Research & Development L.L.C.**

"We are proud and honored to be part of this extremely important consortium. We know that biomarkers can unlock important predictive information that will improve the accuracy and speed of drug development and help us reach the ultimate endpoint of our work —providing patients with better, safer and more cost effective medicines much faster than we have been able to do in the past.”

**Perry Nisen, M.D., Ph.D., Senior Vice-President Clinical Pharmacology and Discovery Medicine, GlaxoSmithKline**

"We expect that this consortium between the NIH, FDA, and biopharmaceutical companies will set a groundbreaking standard for effective public-private partnerships. Only by working together can we leverage sufficient resources and knowledge to bring advances in biomarkers to useful application against human disease."

**John Patterson, M.D., Executive Director, Global Drug Development, AstraZeneca**

"We are extremely proud to join this important collaboration. By working together on biomarkers we can bring future medicines to the right patients. Biomarkers offer a real opportunity to make sure that we deliver the right medicines to the right patients and we have embraced this philosophy for all of our new medicines. However, unless the markers are rightly tested and accepted by the clinical and regulatory communities it will be impossible to use them as a basis for the registration and commercialization of new medicines. We look forward to being able to facilitate the use of biomarkers through the activities of the consortium."

**Steven Paul, M.D., Executive Vice-President, Science and Technology and President, Lilly Research Laboratories & FNIH Board member**

"The Biomarker Consortium addresses one of the most pressing needs in our quest to effectively diagnose and treat disease - the discovery and validation of disease biomarkers and surrogates. Such work is best done collaboratively—leveraging the scientific strengths and resources of both the public and private sectors."

**Charles Sanders, M.D., Chairman of the FNIH board of directors and of The Biomarkers Consortium Executive Committee**

"Rapid realization of the aims of The Biomarkers Consortium is beyond the capacity of any single-sector of our nation's health enterprise, much less the single-institution, or single-investigator, science research approach. This initiative is large-scale and complex. It requires the expertise of all stakeholders—government, industry, patient groups, academia, and other private groups. This partnership epitomizes the aim Congress had in mind when it established the Foundation for the National Institutes of Health to support the mission of NIH."

**Ellen Sigal, Ph.D., Chairperson, Friends of Cancer Research**

"The Biomarkers Consortium is a seminal public-private partnership that is bringing together multiple sectors of the health enterprise as never before to work together on the development and qualification of biomarkers. The financial and logistical challenges of this work require a truly multi-sector approach that includes all relevant stakeholders, including government, private industry, and advocacy and non-profit organizations. This collaboration will accelerate the scientific discovery of new technologies, medicines and therapies that can be used to better detect, diagnose, and treat disease. The public health impact of this consortium will be enormous."

**Lawrence Tabak, D.D.S., Ph.D., Director, National Institute of Dental and Craniofacial Research**

“The Biomarkers Consortium represents a unique partnership among the FNIH, the government and the private sector to help accelerate our ability to detect disease at its earliest stages and to find new treatments for disease.”

**Billy Tauzin, President and CEO, The Pharmaceutical Research and Manufacturers of America (PhRMA)**

"This is a pioneering effort by America's pharmaceutical companies to partner with the other health research sectors. This effort will advance biomarker research and development as never before. This research is critically important to the development of new cures, treatments, and diagnostics addressing the most pressing diseases facing patients today.”

**William Thies, Ph.D., Vice-President for Medical & Scientific Relations, Alzheimer’s Association**

“The Alzheimer’s Association is committed to advancing the development of effective interventions for diagnosing, treating and preventing Alzheimer’s disease and for that reason we enthusiastically support this important and innovative coalition. Biomarkers hold great promise for improving early diagnosis, expediting clinical trials and speeding progress in the development and testing of new therapies. This new coalition complements the work of the Alzheimer’s Disease Neuroimaging Initiative, which is a consortium of government and private organizations, including the Alzheimer’s Association, to improve the diagnosis and treatment of Alzheimer’s.”

**Regina Vidaver, Ph.D., Executive Director., National Lung Cancer Partnership**

"This is very important research. Knowing whether a treatment is actually working - and what works best —will be life-saving for many lung cancer patients. Physicians will be able to track progress, adjust or change drugs and collect data that will tell us what works against specific tumors, at different stages and, potentially, even in women versus men or within various ethnic groups."

**Andrew C. von Eschenbach, M.D., Acting Commissioner of Food and Drugs, FDA**

“One of our most pressing goals under the FDA's Critical Path Initiative is to improve developmental science and technology to deliver better diagnostics and more personalized treatments to patients more quickly and ultimately improve outcomes. We believe the identification and use of biomarkers in drug development can have a catalytic impact on this mission."

**Stephen Williams, M.D., Head, Global Clinical Technology, Pfizer Inc**

“The Biomarker Consortium represents an important and unique response to key obstacles in biomarker utilization. It provides a forum for sharing the substantial burden between government and industry of proving that markers are [or are not] fit for their purpose and therefore "valid". It provides a place where regulators can shape the research programs so that the biomarkers will meet their requirements for performance in drug development. It provides a place where senior scientists from academia and industry can

meet with regulators and payers to define strategic needs in biomarkers that will meet public health demands. This is a universal "win" for patients, academic science, drug regulators and industry.”

**Mary Woolley, M.A., President, Research!America**

“The Biomarkers Consortium is an important public-private initiative to accelerate research for health. From more than a decade of Research!America public opinion polls, we know Americans believe in the potential of research and want it to succeed. By communicating the role of biomarkers in detecting disease and assessing overall health, the Consortium will play a vital role in gaining public acceptance and understanding of this important field of research.”

**Elias Zerhouni, M.D., Director, National Institutes of Health**

"Biomarker research already has developed biological indicators that have had immense impact in prevention and treatment of disease. For example, blood pressure and cholesterol biomarkers have enabled diagnostics and therapies which have led to a 50 percent decrease in cardiovascular mortality in the U.S. over the last 30 years. The identification of biomarkers is an essential element for the new era of predictive, preemptive, personalized medicine."

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