BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

James C. Greenwood
President & CEO

June 30, 2010

Gene Dodaro, Acting Comptroller General
Government Accountability Office
441 G Street, NW
Washington, DC 20548

Re: Patient Centered Outcomes Research Institute
Board of Governors nominees
Attention: National Health Care Workforce Commission Nominations

Dear Mr. Dodaro:

The Biotechnology Industry Organization (BIO) is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we appreciate the opportunity to submit this letter of nomination for the Patient-Centered Outcomes Research Institute (PCORI) Board of Governors.

As a representative of an industry committed to discovering new cures and ensuring patient access to them, BIO strongly supports efforts to increase the availability of accurate, scientific evidence to inform clinical decision-making. BIO was pleased to see that the Patient Protection and Affordable Care Act (PPACA) established the PCORI to conduct comparative effectiveness research. When appropriately applied, comparative effectiveness information is a valuable tool that, together with a variety of other types of medical evidence, can contribute to improving health care delivery.

BIO continues to engage in efforts to better understand the implications of comparative effectiveness research, and is working to ensure that effectiveness studies are conducted in a way that takes into consideration the specific patient populations that our members treat, such as rare disease groups, as well as patients battling severe and

progressive diseases. BIO supports initiatives to expand the use of comparative effectiveness research, and wants to see the PCORI succeed in its goal of improving the quality and delivery of health care.

In order to assist GAO in the nomination process, BIO solicited names for consideration for the pharmaceutical and diagnostic representatives to the PCORI Board of Governors. BIO strongly stands behind the following nominees, and based on the Board's role and function as described in PPACA, we believe that these individuals are the best qualified in the industry to serve as the pharmaceutical representative on the PCORI Board of Governors:

- Freda Lewis-Hall, M.D.
- Joshua J. Ofman, M.D., MPH, MSHS
- Michael Rosenblatt, M.D.
- Charles A. Sanders, M.D.
- Jay P. Siegel, M.D.
- Ellen Strahlman, M.D., MHSc

For your reference, we have enclosed the biographies and the *curriculum vitae* of each of these six nominees. Each nominee has extensive experience within our innovative industry, with expertise from research and development through to post-approval, and perhaps most critically, the clinical training to know how treatment decisions are made between patients and their physicians. Further, each nominee values the utility of comparative effectiveness research in informing patient care. We believe these traits will enable each candidate to appropriately and fairly represent the biotechnology industry, and ensure the PCORI may meet its mission.

Please feel free to contact me at (202) 962-9200 if you have any questions, or if you would like further information on the qualifications of BIO's nominees. Thank you for your attention to this very important matter. We look forward to working with you as you move forward with the PCORI nomination process.

Respectfully submitted,

James C. Greenwood

Attachments

- Appendix I: Nominee Biographies
- Appendix II: Nominee *curriculum vitae*

APPENDIX I: BIOGRAPHIES

Freda Lewis-Hall, M.D.
Chief Medical Officer
Pfizer

Dr. Freda Lewis-Hall is the Chief Medical Officer of Pfizer, the world's largest biotherapeutics company. Dr. Lewis-Hall is also a corporate Senior Vice President and a member of the company's summit decision-making body, the Executive Leadership Team. She reports to Pfizer's Chairman, Jeff Kindler, and leads a 2,400-person division, Pfizer Medical, responsible for the safe, effective and appropriate use of every Pfizer medicine and vaccine from its first day of use by a clinical trial volunteer to its final day of patient use anywhere in the world. She has overall accountability for patient safety, regulatory affairs, good clinical practice, pharmacovigilance, medicines quality assurance, external medical affairs, and external medical communications. She also chairs a cross functional board responsible for promoting innovation in clinical practice and research policy for Pfizer, which manages the world's largest privately funded biomedical research organization.

She joined Pfizer in 2009 from Vertex Pharmaceuticals where she was Chief Medical Officer and EVP of Medicines Development. Prior to Vertex, she worked for five years with Bristol-Myers Squibb as head of medical affairs for its U.S. operations, with responsibility for regulatory compliance, patient safety, and pharmacovigilance, among other responsibilities.

She began her work with pharmaceutical companies by joining Eli Lilly in 1994, where she founded the Lilly Center for Women's Health, one of the world's first centers of excellence devoted to the health needs of women and specifically, to exploring gender-based differences biomedical treatment through scientific research. She spent eight years with Lilly, beginning as a Clinical Research Physician in neuroscience programs and ending as Team Leader for the global development of women's health care therapies.

Prior to joining the research-based pharmaceutical industry, she was a Special Advisor at the National Institutes of Health, Office of Special Populations, where she was instrumental in creating a national strategy for outreach for minority Americans affected by mental illness. She also founded the Howard University College of Medicine's Anxiety Disorders Treatment and Research Center, the first such center with special competencies in the treatment of anxiety disorders among minority patients, when she was Vice Chair and Associate Professor at the medical school.

She earned her M.D. from Howard University College of Medicine and completed a psychiatric residency there. She earned her B.S. from Johns Hopkins. She has published extensively, with a focus on women's health issues. She edited the landmark book, Psychiatric Illness in Women: Emerging Treatments and Research, in 2002.

In 2010, she was named among the nation's Most Powerful Women in Business by Black Enterprise magazine. She was also named that year as one of the 25 Most Influential African-Americans in Healthcare by Black Health magazine.

Joshua J. Ofman, M.D., MPH, MSHS
Vice President of Global Coverage & Reimbursement
Vice President and Head of Global Health Economics, Global Development
Amgen

Joshua J. Ofman, M.D., MPH, MSHS is the Vice President of Global Coverage & Reimbursement, Global Government Affairs and Vice President and Head of Global Health Economics, Global Development.

Dr. Ofman completed his undergraduate degree in the history and philosophy of science at University of California, Berkeley before completing his medical education at UC Irvine School of Medicine. He then completed his internship and residency in internal medicine at UCLA Medical Center. Following his residency, Dr. Ofman completed a two-year VA/UCLA/RAND fellowship in health services research, during which time he received his Masters of Science in Health Services (MSHS) degree from the UCLA School of Public Health. Dr. Ofman also completed a fellowship in gastroenterology at the UCLA integrated training program in digestive diseases. His research interests include health economics and technology assessment, program evaluation and health policy analysis, and he is widely published in these disciplines.

Dr. Ofman has served on several advisory boards for the American Gastroenterological Association, the American College of Physicians Clinical Efficacy Assessment Subcommittee, and is on the editorial board of the American Journal of Managed Care.

Prior to joining Amgen in 2003 as head of US Health Economics and Outcomes Research, Dr. Ofman was a member of the academic faculty in the Department of Medicine, UCLA School of Medicine, Cedars-Sinai Medical Center. Dr. Ofman also served as the Senior Vice President of Zynx Health Inc., a consulting company focused on evidence-based clinical information for quality improvement, and reimbursement and health economics strategy for life sciences companies.

Michael Rosenblatt, M.D.
Executive Vice President and Chief Medical Officer
Merck & Co

Dr. Rosenblatt is Executive Vice President and Chief Medical Officer of Merck & Co., Inc. He is the first person to serve in this role for Merck. Previously he served as Dean of Tufts University School of Medicine. Prior to that, he held the appointment of George R. Minot Professor of Medicine at Harvard Medical School and Chief of the Division of Bone and Mineral Metabolism Research at Beth Israel Deaconess Medical Center (BIDMC). He served as the President of BIDMC from 1999-2001. Previously, he was the Harvard Faculty Dean and Senior Vice President for Academic Programs at CareGroup and BIDMC and a founder of the Carl J. Shapiro Institute for Education and Research at Harvard Medical School and BIDMC, a joint venture whose mission is to manage the academic enterprise and promote academic innovation.

Prior to that, he served as Director of the Harvard-MIT Division of Health Sciences and Technology, during which time he led a medical education organization for M.D., Ph.D., and M.D. -Ph.D. training jointly sponsored by Harvard and MIT. And earlier, he was Senior Vice President for Research at

Merck Sharp & Dohme Research Laboratories where he co-led the worldwide development team for alendronate (FOSAMAX), Merck's bisphosphonate for osteoporosis and bone disorders. In addition, he directed drug discovery efforts in molecular biology, bone biology and calcium metabolism, virology, cancer research, lipid metabolism, and cardiovascular research in the United States, Japan, and Italy. In leading most of Merck's international research efforts, he established two major basic research institutes, one in Tsukuba, Japan, and one near Rome, Italy. He also headed Merck Research's worldwide University and Industry Relations Department.

He is the recipient of the Fuller Albright Award for his work on parathyroid hormone and the Vincent du Vigneaud Award in peptide chemistry and biology, and the Chairman's Award from Merck. His research is in the field of hormonal regulation of calcium metabolism, osteoporosis, and cancer metastasis to bone. His major research projects are in the design of peptide hormone antagonists for parathyroid hormone and the tumor-secreted parathyroid hormone-like protein, isolation/characterization of receptors and mapping hormone—receptor interactions, elucidating the mechanisms by which breast cancer "homes" to bone, and osteoporosis and bone biology.

He has been an active participant in the biotechnology industry, serving on the board of directors and scientific advisory boards of several biotech companies. He was a scientific founder of ProScript, the company that discovered bortezomib (Velcade), now Millennium Pharmaceutical's drug for multiple myeloma and other malignancies. He was chair of the Board of Scientific Counselors of the National Institute of Diabetes and Digestive and Kidney Diseases of the NIH. He has been elected to the American Society of Clinical Investigation, the Association of American Physicians, to Fellowship in the American Association for the Advancement of Science and the American College of Physicians, and the presidency of the American Society of Bone and Mineral Research. He has testified before a Senate Hearing on U.S. biomedical research priorities in 1997.

From 1981 to 1984, he served as Chief of the Endocrine Unit, Massachusetts General Hospital. He received his undergraduate degree summa cum laude from Columbia and his M.D. magna cum laude from Harvard. His internship, residency, and endocrinology training were all at the Massachusetts General Hospital.

Charles A. Sanders, M.D.

Charles A. Sanders, M.D., is the former chairman and CEO of Glaxo Inc., as well as a former member of the board of Glaxo plc. He has a long and distinguished career in industry, with a diverse background in medicine, clinical development, and business. He is not currently employed by any particular company, but serves on the Board of Directors for the following companies: GlaxoSmithKline Foundation, LipoScience, Cephalon, Inc., Fisher Scientific International, Biodel, Inc., Reata Pharmaceuticals, Biocom, Cardioxyl Pharmaceuticals, Vertex Pharmaceuticals, Icagen, Inc. and BioCryst Pharmaceuticals. In addition, he serves on the Board of Directors of the UNC Health Care System. Dr. Sanders has an extensive background in the biotechnology industry and is very well qualified to represent the interests of the industry as a whole.

Before joining Glaxo Inc., Dr. Sanders spent eight years with Squibb Corp., where he held a number of posts, including the position of vice chairman. He also served as chief executive officer of the science

and technology group and chairman of the Science and Technology committee of the Board. Previously Dr. Sanders was general director of Massachusetts General Hospital and professor of medicine at Harvard Medical School. A native of Dallas, he is a graduate of Southwestern Medical College of the University of Texas.

Dr. Sanders is an expert on the therapeutic and surgical procedures for patients with complications following heart attacks and has conducted numerous studies on performance metrics and safety as well as the clinical benefits of medical devices designed to improve heart health and cardiac output. He has authored articles on clinical data that tracks pharmaceuticals and public policies that allow for continued pharmaceutical research and development to promote high quality health care. Dr. Sanders has also conducted studies on effective methods of diagnosing various heart conditions.

Dr. Sanders is past-chairman of the New York Academy of Sciences, The Commonwealth Fund, and the Overseers Committee to Visit the Harvard Medical School, and a past member of the President's Committee of Advisors on Science and Technology. He is currently a member of the Institute of Medicine of the National Academy of Sciences, a member of the CSIS Board of Trustees, chairman of Project HOPE, and chairman of the Foundation for the National Institutes of Health. In addition to his current board appointments, Dr. Sanders has also served on the boards of several multi-national corporations, including Merrill Lynch and Company, Morton International Inc, and Reynolds Metals Company.

Jay P. Siegel, M.D.
Chief Biotechnology Officer
Head, Global Regulatory Affairs, Pharmaceuticals
Johnson & Johnson

Jay Siegel, M.D., is the Chief Biotechnology Officer and the Head of Pharmaceutical Global Regulatory Affairs in Johnson & Johnson. As Chief Biotechnology Officer, he leads an organization responsible for expanding and applying the Company's extensive capabilities in the discovery and development of protein- and cell-based products, including pharmaceuticals, devices, and combination products. The Global Regulatory Affairs organization provides regulatory support for pharmaceutical products in over 100 countries and provides strategic support to product development. Dr Siegel serves on the R&D leadership councils for pharmaceuticals, for Medical Devices and Diagnostics, and for the entire J&J enterprise.

Dr. Siegel is actively engaged in policy development at the national and international levels in the regulatory, biotechnology, and clinical development arenas. He currently serves on the Board of Directors of the Biotechnology Industry Organization, the Executive Committee of the Clinical Trials Transformation Initiative, and an Institute of Medicine Expert Panel. Previously, while at FDA, he negotiated and signed 16 international agreements harmonizing clinical testing requirements, including one (ICH E10) setting standards for active controlled trials.

Dr. Siegel is widely recognized and sought as an expert speaker in various aspects of biotechnology and of clinical research, including comparative trials. Most recently (April, 2010), he was an invited expert panelist at a U. Penn. Conference on Comparative Effectiveness Research. While at FDA, he played a central role in development of FDA and international guidance and policy on comparative trials.

Dr. Siegel joined Johnson & Johnson in 2003 as president, Centocor Research & Development, Inc., a title he still holds, and, prior to entering his current role, he served in J&J as group president, Research and Development, Biotechnology, Immunology and Oncology. Previously, he was group president with oversight responsibility for Alza Corporation, TransForm Pharmaceuticals, R&D quality assurance, regulatory affairs, and pharmacovigilance.

Prior to joining Johnson & Johnson, Siegel spent 20 years at the FDA Center for Biologics Evaluation & Research in positions of increasing responsibility regulating the biotechnology industry. From 1995 to 2002, he served as head of the FDA Office of Therapeutics Research and Review, where he led a team overseeing the biopharmaceutical therapeutics industry.

Dr. Siegel received a B.S. in Biology from California Institute of Technology and an M.D. from Stanford University. He trained in Internal Medicine at the University of California, San Francisco, and in Infectious Diseases and Immunology at Stanford University.

Dr. Siegel is recipient of numerous honors including the U.S. Public Health Service's highest honor, the Distinguished Service Medal and, twice, the HHS Secretary's Award for Distinguished Service. He has been elected to fellowship in the American College of Physicians and the Society for Clinical Trials.

Dr. Siegel has authored numerous publications in the areas of clinical trial design, biotechnology, and immunology.

Ellen Strahlman, M.D., MHSc
Senior Vice President, Chief Medical Officer
GlaxoSmithKline

Ellen Strahlman, MD, MHSc, is Senior Vice President and Chief Medical Officer for GlaxoSmithKline (GSK), where she is responsible for all global medical, regulatory, safety, medical policy, and scientific communications functions for GSK and directly accountable for all matters of patient safety, general medical governance, ethics and integrity, medical information, and investigation involving human subjects relating to any GSK products (pharmaceuticals, biologics, and consumer healthcare medicinal products) in development or on the market.

Clinically trained in general surgery and ophthalmology, Dr. Strahlman has a particular interest in and strong commitment to evidence-based medicine, health outcomes research, and public health. She holds a Masters Degree in Health Sciences (Epidemiology & Statistics) from the Johns Hopkins Bloomberg School of Public Health, where she was a Carnegie-Mellon Fellow – the first ophthalmologist and first surgeon to receive this honor. While a Senior Medical Officer at the National Eye Institute, National Institutes of Health, and throughout her career in industry, she has been responsible for the design and conduct of epidemiological research and clinical trials and has served as principal investigator or co-investigator on numerous peer-reviewed, published studies, including comparative clinical effectiveness research. She also has experience in the design and conduct of pharmacoeconomic and health outcomes studies.

Prior to joining GSK in August 2008, Dr. Strahlman served in senior leadership positions at Pfizer Inc, Novartis AG, Virogen PLC (Chief Executive Officer), Bausch & Lomb Inc, and Merck & Co. in the United States, United Kingdom, Switzerland, and Germany. With nineteen years of industry experience, she has held key roles in regulatory and medical affairs, clinical research and development, outcomes research and pharmacoeconomics, and business development and has been responsible for the development of innovative prescription drugs and biologics, generic medicines, OTC products, and medical devices in ophthalmology, infectious disease, allergy, and other therapeutic areas.

Dr. Strahlman has extensive experience working closely with medical and scientific constituencies, as well as regulatory and other government authorities, in the United States, Europe, and Japan and has actively promoted multi-stakeholder collaborations for the advancement of knowledge and health outcomes. She represents the biopharmaceutical industry on the FDA Dermatologic & Ophthalmic Drug Advisory Committee, the Foundation of the American Academy of Ophthalmology, and the Columbia University Medical and Science Technology Council.

Throughout her career, Dr. Strahlman has been a champion and spokesperson for public health and world health issues, most notably in the areas of HIV and infectious blinding eye diseases such as trachoma and onchocerciasis (river blindness). She currently serves on the Board of Directors of ViiV Healthcare, a specialist HIV company established by GlaxoSmithKline and Pfizer to deliver advances in treatment and care for people living with HIV. She also has a particular interest in corporate social responsibility in the biopharmaceutical industry and has consulted and published on the subject.

Dr. Strahlman is a member of the BIO Board of Directors and the alternate GSK representative on the PhRMA Science & Regulatory Executive Committee.

Dr. Strahlman is a Phi Beta Kappa graduate of Harvard University (Biochemical Sciences and Applied Mathematics) and obtained her medical degree from the Johns Hopkins School of Medicine. She completed her residency in ophthalmology at The Wilmer Eye Institute at Johns Hopkins.