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July 21, 2016

U.S. GAO
Attn: PCORI Board Appointments
441 G Street, NW
Washington, DC 20548

Via email: PCORI@gao.gov

Re: Request for Nominations for Board of Governors of the Patient-Centered Outcomes Research Institute (PCORI)

Dear Sir or Madam:

The Advanced Medical Technology Association (AdvaMed) would like to nominate the following individuals for membership on the Board of Governors of the Patient-Centered Outcomes Research Institute (PCORI).

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies.

According to PCORI's authorizing statute, members of the Board must represent "a broad range of perspectives and collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics." These individuals have impressive backgrounds and are excellent candidates for the Board positions.

Eve Ross, JD

Eve Ross, JD, heads Public Policy and Strategic Initiatives for W.L. Gore and Associates, Inc.'s (Gore) Medical Products Division. Gore is a privately held, globally diversified manufacturing enterprise; the Medical Division is a market leader in long term implantable cardiovascular and general surgical products in over 70 countries worldwide. Prior to this role, she was lead healthcare counsel for the corporation. Her practice focused on FDA regulatory and legal issues including product development and approval, and expanded to include CMS related issues of market access, coverage and payment in domestic and international markets. In addition, her responsibilities included corporate governance and

compliance, real property, business transactions, and fraud and abuse matters for the corporation.

As a colon cancer survivor, and a current cancer patient following European methods of medical management as opposed to the American approach of instant surgery, Ms. Ross can attest to the need for well designed, well executed studies on a very personal level. For this reason, she has served as a patient reviewer for two PCORI grant cycles, most recently the just-completed spring 2016 cycle. Additionally, as an industry representative, she understands PCORI's role as a leader in defining "value" to patients, health care providers and health systems, which the industry will adopt over time.

Ms. Ross is a former Chairperson of the AdvaMed Technology and Regulation Steering Committee, a patient merit reviewer for the Patient Centered Outcomes Research Institute (PCORI) (two cycles), serves on the MDEpinet National Medical Device Registry Task Force and the International Medical Device Regulator's Task Force on the same issue (appointed by FDA). As a result of her combined FDA/CMS knowledge and experience, she is a frequent speaker at industry events in the USA and abroad. Additionally, she is a member of the Arizona BioScience Board of Directors, the Flinn-Brown Civic Leadership Academy's Board of Advisors, and the Flinn Foundation's BioScience Roadmap Steering Committee, and was founding Chairperson, Northern Arizona Technology and Business Incubator (now NACET). She serves on Governor Ducey's (Arizona) Trade and Transportation Corridor Alliance and on the Board of Directors for Senestech LLC, an ag-bio startup. Eve Ross received her B.A. from Hamilton College, Clinton, NY and her J.D. from Arizona State University, Tempe, AZ.

Richard A. Frank, MD, PhD

Richard A. Frank, MD, PhD, is currently the Chief Medical Officer for Siemens Healthineers North America and a member of AdvaMed's CMO Committee, which focuses on the role for innovative devices in clinical care pathways. Dr. Frank has more than three decades' experience in regulatory labeling, public and private payment, and clinical adoption of therapeutic and diagnostic drugs and medical devices. He has provided expert testimony to advisory committees of both the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA), and he represents Siemens on a number of policy councils. Dr. Frank currently serves as the Industry Representative, representing imaging innovators, on FDA's Medical Imaging Drugs Advisory Committee. Dr. Frank has convened consensus conferences on coverage policy and commissioned health economic assessments by the most reputable actuaries for publication in peer-reviewed journals.

Dr. Frank also has broad experience with registries, ranging from having helped organize the Alzheimer's Disease Neuroimaging Initiative (ADNI) to working with CMS on Coverage with Evidence Development (CED) for lung cancer screening.

In prior roles, Dr. Frank has worked with Ministers of Health as well as private and public payers in a number of countries for the purpose of building innovation into their healthcare

delivery systems with clinical efficiency. This experience is particularly relevant to today's healthcare delivery environment in the US.

Dr. Frank trained in Internal Medicine at Strong Memorial Hospital in Rochester, NY, earning a license in the State of New York to practice medicine and surgery. He earned his PhD in Pharmacology from the University of Tennessee-Memphis. In addition, he holds two Bachelor of Arts degrees in Chemistry and Biology (Honors), with a minor in Mathematics, and was elected to Phi Beta Kappa at Cornell College in Mount Vernon, IA.

His personal interests include volunteering for humanitarian medical efforts, having served in Kyrgyzstan, Colombia, and Myanmar as well as domestic locations such as Philadelphia.

Attached please find curriculum vitae for each of these candidates. AdvaMed submits these candidates for your consideration based on their credentials and strong academic and professional backgrounds, as well as their ability to make significant and valuable contributions to the PCORI Board of Governors.

Thank you for your review and consideration. Should you have any questions, please contact Chandra Branham, JD, Vice President for Payment and Health Care Delivery Policy at (202) 434-7239.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald May", with a long horizontal flourish extending to the right.

Donald L. May
Executive Vice President
Payment & Health Care Delivery Policy