CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Brooke Allocco, MD, Vice President, CRM Clinical Communications and Education, Boston Scientific Corporation

Brooke Allocco, MD, Vice President, CRM Clinical Communications and Education, Boston Scientific Corporation
Brooke Allocco is the Vice President of Clinical Communications and Education for the Cardiac Rhythm Management and Electrophysiology Divisions of Boston Scientific. In this role, she has responsibility for medical education, physician training, investigator sponsored research, and medical affairs. Prior to assuming this role in 2012, she spent several years in a variety of Marketing and Strategy roles within Boston Scientific, most recently leading the global marketing team for ICDs and CRT-Ds. Before joining Boston Scientific, she was a Manager in the Boston office of the Boston Consulting Group, where she advised large healthcare companies on strategic initiatives. Dr. Allocco holds a MD and MBA from Duke University and an AB in Economics from Harvard University.

Colin Anderson-Smits, B.A, B.S.H.S, MPH, Epidemiologist, FDA/OMPT/CDRH/OSB/DEPI

Colin Anderson-Smits has several years of experience in women's health. During graduate school his research and work experience was focused on female S.T.I' s among HIV infected women and emerging sexual pathogens, and has published several articles on this subject. Since joining the FDA Colin is the lead Epidemiologist for OB/GYN and Urological devices and serves as a Principal Investigator for ongoing research studies related to female sterilization and surgical mesh used in pelvic organ prolapse repair.

Sharon Andrews, Biomedical Engineer, FDA/CDRH/ODE/DRGUD/OGDB

I am a biomedical engineer/lead reviewer in the Obstetrics and Gynecology Device Branch in the Office of Device Evaluation in CDRH. My review work has primarily focused on contraceptive devices, vaginal products, adhesion barriers, and urogynecologic surgical mesh.

Leonardo Angelone, PhD, Staff Fellow, Division of Physics, Office of Science and Engineering Laboratories, U.S. Food and Drug Administration, Center for Devices and Radiological Health

Leonardo Angelone graduated "summa cum Laude" and received the title of "Doctor in Electronic Engineering" from the University of Rome "La Sapienza" (Rome, Italy). He has completed a PhD in Biomedical Engineering from Tufts University (Medford, MA), a research fellowship at the Department of Radiology of the Massachusetts General Hospital, Harvard Medical School (Boston, MA), and a post-doctoral fellowship at the Department of Research and Development of Cytyc Surgical Products. Leonardo Angelone joined the Division of Physics, Office of Science and Engineering Laboratories of FDA/CDRH as Staff Fellow in 2009.
Dr. Angelone's research focuses on safety and effectiveness of medical devices in relation to electromagnetic energy. The research combines anatomically precise computational models and experimental measurements to study several areas of clinical significance, including a) electromagnetic fields in human subjects with implanted and external medical devices; and b) radiofrequency heating in pregnant women and fetuses during MRI.

(Dr. Angelone continued)
The ongoing research has a direct impact to the regulatory mission of the Center of Devices and Radiological Health, since anatomically precise numerical models are used by industry in pre-market evaluation of safety and effectiveness of their medical devices. The accuracy of these models and the validation methods are often fundamental issues in the ongoing regulatory evaluation. The results of these projects will allow advancing the knowledge on the complex interactions between electromagnetic fields and human body, supporting CDRH regulatory and guidance role for the industry.

Suzanne J. Baron, MD, Medical Staff Fellow, FDA

Dr. Suzanne Baron is currently participating in the Medical Device Fellowship Program with the FDA in the Division of Cardiovascular Devices, where she has spent the last year working on the pre-market approval process for interventional cardiac devices. Prior to her work with the FDA, she completed her internal medicine residency, cardiovascular disease fellowship and interventional cardiology fellowship at Massachusetts General Hospital. Her research interests are focused on the prediction of clinical outcomes after implantation of new cardiac devices. In July of 2013, she will return to Massachusetts General Hospital for a structural heart disease fellowship to learn interventional techniques to treat congenital anomalies and valvular disease.

Manuel Bayona, M.D., M.S., Ph.D., Epidemiologist, Division of Epidemiology, Center for Devices and Radiological Health, FDA

I have work in academia teaching and conducting research for more than 25 years. I have over 60 publications and more than 100 oral and poster presentations in different fields of medicine and epidemiology including infectious diseases, asthma, cancer, gender health disparities (AIDS survival, asthma incidence, and obesity in children), and orthopedics. I have been working on patient reported outcomes (PRO) and minimal important difference MID for orthopedic surgery for the last year with Dr. Faisal Mirza, Orthopedic Surgeon, including two research projects as a co-principal investigator. I have also participated as a moderator in a Workshop held last year at the FDA Headquarters to review and synthetize preliminary findings about the use and evaluation of PRO and MID used in orthopedic surgery, and I am now a principal investigator of the project entitled "Gender Expression in Patient-Reported Outcomes and the Minimum Important Difference in Orthopedic Surgery".

Elaine Blyskun, BScEng, Supervisory Biomedical Engineer/Chief, Obstetrics and Gynecology Devices Branch,
FDA/CDRH

I am currently the Chief of the Obstetrics and Gynecology Devices Branch at FDA. I oversee the regulation of medical devices related to women's health. Previous to this position, I was a reviewer in the Obstetrics and Gynecology Devices Branch, where I conducted premarket reviews of ob/gyn device applications.

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Cornelia (Cory) M. Borkhoff, PhD, Scientist, Women's College Research Institute, Women's College Hospital, Toronto, Ontario, CANADA and Assistant Professor, Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, Ontario, CANADA

Dr. Cornelia (Cory) Borkhoff is a Scientist at Women's College Research Institute at Women's College Hospital and an Assistant Professor in the Institute of Health Policy, Management and Evaluation, University of Toronto.

Dr. Borkhoff completed the first study to demonstrate that patient gender influences physicians' treatment recommendations and interpersonal behavior in actual clinical practice, using standardized or "mystery" patients. She found that physicians were less likely to recommend total knee arthroplasty (TKA) surgery when the patient was a woman compared to a man, raising the possibility that physician bias, whether conscious or unconscious, may be at least partially responsible for the gender disparity in TKA utilization. The findings of this study appeared in the March 11 2008 issue of the Canadian Medical Association Journal (Borkhoff CM, Hawker GA, Kreder HJ, Glazier RH, Mahomed NN, Wright JG. The effect of patients' sex on physicians' recommendations for total knee arthroplasty. CMAJ 2008; 178:681-7). Furthermore, shared decision making (SDM) was more problematic for women with physicians including fewer SDM elements when the patient was a woman compared to a man (Borkhoff et al. The influence of patients' gender on physicians' interpersonal behavior regarding total knee arthroplasty: what if your physician doesn't ask you to dance? Arthritis Care & Research, Accepted manuscript online: 11 FEB 2013 | DOI: 10.1002/acr.21970.) This study provides some of the most conclusive evidence to date of a significant physician contribution to gender disparity in TKA.

Her work received recognition as one of the Top 10 success stories in the 10th Anniversary special issue of Intersections, the newsletter of the CIHR's Institute of Gender and Health.
http://www.cihr-irsc.gc.ca/e/documents/IGH_Intersections_Fall_2010_en.pdf

---

Daniel Caños, PHD, MPH, Acting Associate Director, FDA/OMPT/CDRH/OSB/DEPI

I am an Acting Associate Director within the Division of Epidemiology. I have designed and analyzed FDA condition of approval post-approval studies examining the medical device performance by gender. My doctoral work involved the study of habitual betaine and choline intake and risk of cardiovascular disease within the Women's Health Initiative (n~160,000). I serve as the Principle Investigator on FDA Office of Women's Health sponsored studies of gender differences in medical devices for Swan Ganz and CRT-D.

I am an Acting Associate Director within the Division of Epidemiology. I have designed and analyzed FDA condition of approval post-approval studies examining the medical device performance by gender. My doctoral work involved the study of habitual betaine and choline intake and risk of cardiovascular disease within the Women's Health Initiative (n~160,000). I serve as the Principle Investigator on FDA Office of Women's Health sponsored studies of gender differences in medical devices for Swan Ganz and CRT-D.

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Lily Cappelletti, Associate Director Research Partnerships, Michael J. Fox Foundation

Lily joined the Michael J. Fox Foundation in 2012. In her current role, she is responsible for engaging members of the PD community in clinical research and leads the strategic development and expansion of Fox Trial Finder.

Prior to joining MJFF, Lily managed strategic partnerships and public affairs at MTV Networks where oversaw the development and implementation of social action campaigns for the network. In this capacity she aligned coalitions of public and private partners to generate public awareness, consumer engagement and social impact. Lily also worked as a Senior Account Executive at Edelman where she helped fortune 500 companies to develop and implement corporate social responsibility strategies.

Lily graduated with an MPA from New York University and holds a BA in International Relations from Bucknell University.

Christine Lee Carter, Ph.D., M.P.H., Vice President for Scientific Affairs, The Society for Women's Health Research

Dr Carter has thirty three years of progressively responsible professional experience in providing leadership and scientific resources for governmental agencies, academic institutions, non-profit research organizations and corporate institutions in health-related scientific research and contract management. Areas of expertise include infrastructure development for research programs, interdisciplinary collaborations, research methodology, and all aspects of building and maintaining a successful, funded, research program. Specific skills include executive leadership, project management, research ethics (institutional review board (IRB) submissions and reviews), contract negotiations, etc., related to medical, scientific, policy and public health concerns. Additional interests, background and skills include human subjects' research, research networks, conference planning, scientific/research integrity, and medical and science education.

Janine Clayton, MD, NIH/ORWH

Janine Austin Clayton, M.D., is the Director of the Office of Research on Women's Health, National Institutes of Health (NIH), and Associate Director for Research on Women's Health, NIH, in the NIH Office of the Director.

She is the author of over 80 scientific publications, journal articles, and book chapters. Prior to joining the Office of Research on Women's Health, she was the Deputy Clinical Director of the National Eye Institute (NEI), NIH. A board certified ophthalmologist, Dr. Clayton's research interests include autoimmune ocular diseases and the role of sex and gender in health and disease. Dr. Clayton has a particular interest in ocular surface disease and discovered a novel form of disease associated with premature ovarian insufficiency which affects young women.

A native Washingtonian, Dr. Clayton received her undergraduate degree with Honors from the Johns Hopkins University, and her medical degree from Howard University College of Medicine. She completed a residency in ophthalmology at the Medical College of Virginia and fellowship training in Cornea and External Disease at the Wilmer Eye Institute at Johns Hopkins Hospital, and in Uveitis and Ocular Immunology at NEI. Dr. Clayton has been an attending physician and clinical investigator in cornea and uveitis at the NEI since 1996, conducting research on inflammatory diseases of the anterior segment. Her clinical research has ranged from randomized controlled trials of novel therapies for immune mediated ocular diseases to studies on the development of digital imaging techniques for the anterior segment.

(Dr. Clayton continued)
Dr. Clayton is a Fellow of the New York Academy of Medicine. She currently serves on the FDA Advisory Panel for Ophthalmic Devices; the medical and scientific advisory board of Tissue Banks International; and the editorial board of The Ocular Surface. She was selected as a Silver Fellow by the Association for Research in Vision and Ophthalmology and a recipient of the Senior Achievement Award from the American Academy of Ophthalmology. Dr. Clayton has received several awards from her NIH peers in recognition of her leadership. She co-chairs the NIH Working Group on Women in Biomedical Careers with the NIH Director.

James Coburn, ScB, ScM, Mechanical Engineer, US Food and Drug Administration

Over the past decade, orthopedic research has been my primary focus - specifically, using imaging and motion analysis to investigate phenomena related to devices. My work has been published in orthopedic journals and presented at biomechanics conferences. (e.g. ORS) The current work builds on ongoing research in the FDA's Functional Performance and Device Use Laboratory.

Patrice Desvigne-Nickens, MD, NIH/NLBI

Dr. Nickens is a medical officer in the Heart Failure and Arrhythmias Branch in the Division of Cardiovascular Science in the National Heart, Lung and Blood Institute. Dr. Nickens is responsible for the scientific development and fiscal management of relevant research programs focused on prevention, recognition and treatment in cardiovascular medicine. Her research portfolio includes many mechanisms of research: investigator-initiated projects, center grants, contract and grant solicitations, small business and conference grants to support basic and clinical investigations including clinical trials which address many aspects of heart failure and arrhythmia research. Dr. Nickens is responsible for initiative development, coordination of workshops and meetings and all reports within these scientific areas prepared for the Division and Institute Directors. Dr. Nickens serves as project officer on various trials and is a liaison to the American Heart Association Executive Council on Clinical Cardiology.

Dr. Nickens received a Bachelor Degree in Chemical Engineering from the Massachusetts Institute of Technology and Medical Doctorate from the University Of Pennsylvania School Of Medicine. She began an Internal Medicine residency at the Thomas Jefferson University Medical Center and completed her training in Internal Medicine as a NHLBI medical staff fellow at the Clinical Center of NIH. Dr Nickens is board certified in Internal Medicine. Dr Nickens joined NHLBI in 1982 and was project officer for the TIMI trial. In 1987 Dr Nickens left NIH to serve as primary care physician in Detroit and in 1988 in Baltimore. Dr Nickens rejoined NHLBI in 1991 and was responsible for research initiatives that investigated coronary disease in for underserved populations including women and African Americans. Dr. Nickens interests include training, the practice of medicine and public health policy and its impact on cardiovascular health disparities and their effect on women and minorities.

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Joel J Gagnier, BA, ND, MSc, PhD, Assistant Professor, Department of Orthopaedic Surgery, Department of Epidemiology, School of Public Health, University of Michigan

I have expertise in clinical epidemiology, clinical research methods, systematic reviews and meta-analyses and biostatistics. I have been working on understanding and advancing these methods for some time. I have given workshops at the Cochrane meetings on the general topic of investigating heterogeneity in systematic reviews and more specifically on clinical and methodological heterogeneity. Also, I teach several graduate level courses on systematic reviews and meta-analyses that devote much time to the topic of heterogeneity. I have published several papers and abstracts on these topics as well. Specifically, I completed a systematic methodologic review of the types of recommendations in the literature for dealing with heterogeneity. Next, we performed an empirical test of a statistical method called permutation based resampling for investigating covariates in meta-regression. Finally, we received funding from the National Library of Medicine, and completed a project in which we created a set of consensus and empirically based guidelines for investigating clinical heterogeneity in systematic reviews. We are currently applying these recommendations to a pool of systematic reviews to determine where improvements in these methods are needed.

Nieca Goldberg M.D., Medical Director of the NYU Langone, Joan H. Tisch Center for Women's Health

Dr. Nieca Goldberg is a cardiologist and a nationally recognized pioneer in women's heart health. She is the Medical Director of the NYU Langone Joan H. Tisch Center for Women's Health, the Clinical Associate Professor of Medicine at the NYU School of Medicine, the Co-Medical Director of the 92nd Street Y's Cardiac Rehabilitation Center, and a national spokesperson for the American Heart Association's "Go Red" campaign – an association where she has volunteered for over 15 years and has been a board member in NYC.

Dr. Goldberg is the author of **DR. NIECA GOLDBERG'S COMPLETE GUIDE TO WOMEN'S HEALTH.** She has also authored the award winning and highly acclaimed book WOMEN ARE NOT SMALL MEN which was updated and titled THE WOMEN'S HEALTHY HEART PROGRAM – Lifesaving Strategies for Preventing and Healing Heart Disease published by Ballantine Books.

A graduate of Barnard College and SUNY Downstate Medical Center, Brooklyn, she completed her medical residency at St. Luke's-Roosevelt Hospital Center and a cardiology fellowship at SUNY Downstate.

Dr. Goldberg's research and medical publications focus on cardiovascular disease in women, exercise imaging and exercise. She is often asked by the media for her expert interpretation of current studies and medical news. Dr. Goldberg has made numerous appearances on programs such as, The Today Show, The View, Good Morning America, The Early Show, and CBS Evening News. In addition, she has been featured and interviewed by reporters from The Wall Street Journal, The New York Times, The New York Post, The New York Daily News, Fitness Magazine, More, Glamour, Good Housekeeping and many others discussing woman's health and heart disease. She serves on the Woman's Day Editorial Advisory Board. Since 2008, Dr. Goldberg has been hosting a weekly radio show on SiriusXM Doctor Radio for Women's Health called Beyond the Heart.

In 2012 Dr. Goldberg was celebrated, yet again, on New York Magazine's "Best Doctors" list, a recognition she also received in 2011, 2010, 2009, 2008, 2007, 2006, 2005, 2004, 2001, and 2000. In 1999, she was the only woman in their top ten "Hall of Fame of Physicians". The recipient of numerous awards for her advocacy for women's heart health, she received the American Heart Association's "Dr. With Heart" award, Woman's Day magazine's "Red Dress" award, Jewish Women International's "Women to Watch" award and The Women at Heart 2006 Honoree Award from the Links Greater New York Chapter.

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Sharonne N. Hayes MD, FACC, FAHA, Professor of Medicine and Cardiovascular Diseases, Founder, Mayo Clinic Women's Heart Clinic, Director, Diversity and Inclusion

Dr. Sharonne N. Hayes is Professor of Medicine and Cardiovascular Diseases at Mayo Clinic in Rochester, MN. She founded and maintains an active clinical practice in the Women's Heart Clinic and serves as Mayo Clinic's Director of Diversity and Inclusion. She has long advocated for the advancement of women's health and sex-based medicine within the field of cardiology and across all areas that affect women's health and well-being and provided education, strategic planning, and program development for improvement of health care and reduction of health disparities. She is active with the NHLBI's Heart Truth ("Red Dress") campaign, and AHA's Go Red Campaign and serves on the Board of Directors for WomenHeart: The National Coalition for Women with Heart Disease

Her research interests include sex and gender-based cardiology, cardiovascular conditions affecting primarily women, spontaneous coronary artery dissection (SCAD), fibromuscular dysplasia, health equity, and the utility and optimal role of social media in clinical practice, medical research and health education. Dr. Hayes received her medical degree from Northwestern University in Chicago and pursued fellowships in Internal Medicine, Cardiovascular Research, and Cardiovascular Diseases at Mayo Clinic Rochester, joining the Mayo staff in 1990.

Dipti Itchhaporia, MD, FACC, Immediate Past Chair, Board of Governors, American College of Cardiology(ACC), Robert and Georgia Roth Chair for Excellence, American College of Cardiology, Hoag Memorial Hospital, Newport Beach,CA

Dipti Itchhaporia, M.D. , F.A.C.C. is immediate past Secretary and Chair of the Board of Governors for the American College of Cardiology (ACC) and is on the Executive committee and the Board of Trustees for the ACC. She serves on the Life Long Learning Oversight committee and is part of the Curriculum Development Workgroup for the ACC. She is active in the ACC's global initiatives. She serves on the Physician Advisory Group on the California Physician Performance Initiative and is a member of the oversight committee for the State of California's elective PCI without surgical oversight pilot project. She has been part of the faculty leading the Society of Cardiac Angiography and Intervention's Women in Innovation and the ACC Gender Data Forums that have examined women specific data in Interventional trials.

Dr. Itchhaporia is the Robert and Georgia Roth Chair of Cardiac Excellence and the medical director of disease management at the Hoag Heart and Vascular Institute

She has also held many other leadership positions including being on the board of the Western Affiliates Board of the American Heart Association (AHA) and was the past president of the Orange County Chapter of the AHA. She has also served on the National American Heart Association Professional Educational Committee.

Dr Itchhaporia received her medical degree from St. Louis University School of Medicine and completed her residency in internal medicine at Stanford University Medical Center. Subsequently, she joined the General Medicine Faculty at the University of California, San Francisco (UCSF) as assistant clinical professor and then went on to do a cardiology fellowship at Georgetown University and an interventional cardiology fellowship at Stanford University.

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Karl J. Jepsen, PhD, Professor / Associate Chair Research, The University of Michigan, Department of Orthopaedic Surgery

The primary objective of my research program is to understand how complex physiological systems establish function during growth and maintain function during aging. Having a better understanding of how complex systems work will benefit efforts to reduce fracture risk by identifying the genetic and environmental factors that impair (or promote) specific components of the functional adaptation process and that compromise (or improve) musculoskeletal health.

For the skeletal system, a major impediment to developing advanced diagnostics that can be used to identify at-risk individuals earlier in life and to treat these individuals based on their personal biological needs is that we have not adequately incorporated the adaptive nature of bone into clinical and experimental studies. The skeletal system, like many physiological systems, establishes function by adapting to genetic and/or environmental perturbations. We showed that the skeletal system compensates for the natural variation in robustness by simultaneously coordinating multiple morphological and tissue-quality traits. This coordination occurs during growth and results in each person acquiring a set of traits that is specifically adapted to their genetic background and life history. When viewed at the population level, this functional adaptation process results in a situation where variable compensatory traits are superimposed on the natural variation in skeletal robustness. This situation poses significant scientific challenges for identifying the biological factors regulating the functional adaptation process, as well as translational-challenges for identifying traits that have practical clinical value as advanced diagnostic measures of future fracture risk.

We identified a pattern in the way individuals coordinate their traits. This pattern or network of trait interactions has experimental value in that genetic factors regulating each component of the network can be teased out and studied. The network also has tremendous clinical value because it means we can estimate a person's fracture risk and provide insight into potential therapies by first evaluating their particular set of acquired traits and determining how their trait set relates to bone strength and fracture resistance. Evaluating acquired trait sets provides a more flexible, personalized approach to identifying novel biomechanical and biological pathways contributing to bone fragility.

Jerri Anne Johnson, M.Ed., Abbott Vascular

Jerri Anne Johnson is the Director of the Women's Heart Health Initiative at Abbott Vascular. In this role, she works with patient groups, medical societies, health care providers, and other organizations to promote awareness of heart disease, the number one killer of women. Key areas of focus for the Women's Heart Health Initiative include building partnerships with cardiologists and OB/GYNs to drive screening and cardiovascular disease risk factor management in women and creating programs to drive awareness and screening of high risk and underserved populations. In her 24 years with Abbott, Jerri Anne has championed disease state education in the areas of cardiology, chronic kidney disease, and pain management/prescription drug abuse prevention. Prior to joining Abbott, she was a public school teacher in Lancaster, Pennsylvania. She holds a B.S. and a M.Ed. in education from Millersville University where she proudly serves as President of the Millersville University Alumni Association and a mentor to disadvantaged students. She is a wife, mother of 7, and grandmother to two.

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Tony M. Keaveny, PhD, Professor of Mechanical Engineering and Bioengineering; Director, Berkeley Orthopaedic Biomechanics Laboratory, UC Berkeley

An expert in bone biomechanics, osteoporosis, finite element modeling, and the biomechanics of bone-implant systems, Dr. Keaveny has published over 120 full-length articles in such journals as the Journal of Bone and Mineral Research, Bone, Spine, Journal of Orthopaedic Research, Journal of Biomechanics, Journal of Biomechanical Engineering, and is co-author of the textbook "Orthopaedic Biomechanics: Mechanics and Design in Musculoskeletal Systems". Dr. Keaveny has served as Principal Investigator on numerous grants funded by NIH, NSF, The Whitaker Foundation, and various industrial entities, and is the recipient of the Y.C. Fung Young Investigator Award and the Van C. Mow Medal, both from the ASME Bioengineering Division. A keen advocate of translational research, in 2004 Dr. Keaveny founded O.N. Diagnostics in Berkeley, California, to translate some of his laboratory research at UC Berkeley into clinical practice. In particular, he has been a leader in development of finite element analysis of clinical CT scans for bone strength assessment, both for the hip and spine, and for monitoring of treatment.

Mitchell W. Krucoff MD, Duke University Medical Center

Dr. Mitchell W. Krucoff graduated Yale University magna cum laude with a BA in religious studies in 1976. He attended medical school and did his medical residency at George Washington University in Washington D.C. where he was elected to the AOA Medical Honor Society. In 1988 Dr. Krucoff joined the cardiology faculty at Duke University Medical Center where he remains to this date. He is an interventional cardiologist, tenured Professor of Medicine/Cardiology and Director of the Cardiovascular Devices Unit at the Duke Clinical Research Institute (DCRI). He is a special government employee of the United States FDA, and received a Distinguished Service Award from FDA in 2007 for his tenure as a member of the Circulatory Devices Panel, Center for Devices and Radiological Health. He holds the memo of understanding between Duke and FDA a Director, Cardiac Safety Critical Path Cardiac Safety Research Consortium. Internationally he is the co-Director of the Japan-USA Harmonization By Doing international regulatory affairs group. Dr. Krucoff is also the founder and Director DCRI eECG Core Laboratories, the largest academic electronic ECG Core Laboratory in the world. In 2008 he was awarded the honorary Hein JJ Wellens Professorship by the University of Maastricht in the Netherlands.

Exploring new healing paradigms Dr. Krucoff is past Editor In Chief of Alternative Therapies in Health and Medicine, is currently Executive Editor of the peer review Journal of Alternative and Complementary Medicine, and co-authored the American College of Cardiology Consensus Statement on complementary therapy and cardiovascular care.

Dr. Krucoff has published more than 200 peer review articles and numerous book chapters elective and acute coronary revascularization, diagnosis and interventions in acute coronary syndromes, silent and symptomatic myocardial ischemia and complementary therapies and spirituality applications in high tech cardiovascular care.

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Amy L. Ladd MD, Professor & Chief, Robert A. Chase Hand Center, Department of Orthopaedic Surgery, Stanford University Medical Center

Dr. Ladd is the Chief of the Robert A. Chase Hand & Upper Limb Center at Stanford University, and is Professor of Orthopaedic Surgery, and by Courtesy, Plastic Surgery and Rheumatology. She has practiced hand and upper limb surgery, including pediatric surgery, at Stanford since 1990.

Her research focuses on kinematics of the upper limb, with an emphasis on the pathomechanics of thumb carpometacarpal arthritis, the subject of a current NIH RO1 grant with Brown University. The creator of a successful Stanford project based course for undergraduates entitled "Anatomy of Movement," she continues to work closely with team members of different ages and backgrounds on medical education technology. Most recently she is developing iPad applications for patient education.

Dr. Ladd graduated from Dartmouth College with an AB in History, her MD from SUNY Upstate Medical University, Orthopaedic Residency from the University of Rochester, and the Harvard Combined Hand Surgery Fellowship. She was a fellow at L'Institut de la Main in Paris, France. In her Stanford career she has mentored over 150 medical students and residents, many of whom are women who have pursued musculoskeletal medicine as their career pathway.

Alexandra Lansky, MD, Yale School of Medicine

Dr. Lansky's research has made the leap from bench to bedside by helping providers and women with heart disease receive prevention and treatment specific to women. Her career commitment to a gender based approach to diagnosis, prevention, treatment and education will result in improved heart health for all women.

Alexandra J. Lansky, MD, FESC, FACC, Associate Professor of Medicine at Yale University School of Medicine, is Director of Cardiovascular Research and Co-Director of the Yale Valve Program, and a practicing cardiologist at Yale-New Haven Hospital. Under her leadership, Yale pursues interventional cardiovascular research in a broad range of therapeutic and device related areas including ischemic heart disease, structural heart disease, peripheral disease and diagnostics. Since joining Yale in 2010, Dr Lansky continues to pursue her career-long interest in gender-based research and education in cardiovascular diagnostics, lesser invasive interventional therapies and prevention. Dr. Lansky founded and serves as the Medical Director of HeartHealthyWomen.org, a Department of Health and Human Services-sponsored educational Web site for the treatment of women with cardiovascular diseases. (www.hearthealthywomen.org). Throughout her career, she has served as the principle investigator of numerous pivotal interventional device imaging studies. She has published over 300 manuscripts including numerous gender based reports in peer-reviewed journals and is the lead author of the American Heart Association Statement on Interventional Cardiology in Women.

Prior to joining Yale, , Dr. Lansky was Associate Professor of Clinical Medicine and Director of Clinical Services at the Center for Interventional Vascular Therapy at Columbia University College of Physicians and

Surgeons. Dr. Lansky was the Joint Chief Scientific Officer of the Clinical Trials Center and Director of the Women's Cardiovascular Health Initiative at the Cardiovascular Research Foundation in New York. Dr Lansky is board certified in cardiovascular medicine, she is a graduate of the Medical College of Virginia, and received her internal medicine residency, cardiology and Interventional cardiology fellowship training at the Washington Hospital Center, Washington DC. Dr Lansky is a Fellow of the European Society of Cardiology, the American College of Cardiology and the American Heart Association.

Dr. Nancy C. Lee, Director, Office on Women's Health/Office of the Secretary/HHS

Nancy C. Lee, M.D., is the Deputy Assistant Secretary of Women's Health, and Director, of the Office on Women's Health at the Department of Health and Human Services, a position she has held since April 2011. For most of her career, she was employed at the CDC where her research and public health efforts focused on cancer screening, the epidemiology of reproductive system cancers, safety of contraceptive methods, and HIV infection among American women. She has extensive experience in women's health, cancer prevention and control, and surveillance systems and has published over 95 articles in scientific journals. Dr. Lee has consulted with the National Cancer Institute, the Food and Drug Administration, the American Cancer Society, the Institute of Medicine, Planned Parenthood Federation of America, the World Health Organization, and the Agency for International Development. She participated in research projects in Africa, China, Central America, and Southeast Asia. From 1999-2004, she was Director of CDC's Division of Cancer Prevention and Control, a division with more than 130 staff and an annual budget of $280 million. She left that position in 2004 to work as a private consultant. Dr. Lee is board-certified in internal medicine.

Nilsa Loyo-Berrios, PhD, MSc, Associate Director Post-Approval Studies Program, FDA/CDRH/OSB/DEPI

Dr. Loyo-Berrios obtained an Epidemiology master's degree in 1994, and has acquired experience in the field, first at the Puerto Rico Department of Health (PRDH) as Director of the Risk Assessment Division. Then in 1997, she pursued a doctorate degree in Epidemiology at the Johns Hopkins University, Bloomberg School of Public Health. During her years in the doctoral program, she also worked as a consultant for the Pan-American Health Organization (PAHO) in Washington DC and maintained some services as consultant to the PRDH. In 2004, she obtained her PhD in Epidemiology and stayed home with a new born baby, until 2005, when she joined what then was the Epidemiology Branch at the Division of Postmarket Surveillance (DPS), Office of Surveillance and Biometrics (OSB), Center for Medical Devices and Radiological Health (CDRH). For two years, she worked as an epidemiology reviewer and was responsible for reviewing clinical data in premarket applications (PMA), with focus on identifying potential postmarket issues, making recommendations on the most appropriate study methodologies and was also responsible for working with sponsors to develop study protocols. Once devices were approved for market distribution, she was responsible for monitoring study implementation, ensuring studies were conducted as per approved protocol and that conditions of approval were fulfilled. The device areas that she was involved with included: cardiovascular, ObGyn, urology, gastroenterology and respiratory medicine.

Dr. Loyo-Berrios continued to work with the epidemiology group at CDRH and acquired experienced as a Team Leader, later as Branch Chief, and now as the Associate Director for the Post-Approval Studies Program. Throughout her years of working at CDRH/OSB/DEPI, she has been involved with regulatory review work in the following areas: reproductive, gastrointestinal, urology, anesthesiology, general surgery, infection control, cardiovascular, in-vitro diagnostics, ophthalmic, neurology, orthopedics and restorative devices. Dr. Loyo-Berrios has special interest in women health issues and currently works in several projects including the development of the National Breast Implants Registry, the PROFILE Registry and overseeing reviews for

mandated studies for devices including: permanent birth control occlusion devices, endometrial devices, and mesh. She is also PI for a Comparative effectiveness study on treatment options for uterine fibroids.

Nancy Lynch, MD, Advisorthopaedics Incorporated

Dr. Lynch has over 25 years of experience in the clinical and business elements of orthopedics. She is a Board-certified orthopedic surgeon and a Fellow of the American Academy of Orthopædic Surgeons. She earned a medical degree from the Washington University School of Medicine in St. Louis, then completed a residency in orthopedic surgery at the Mayo Clinic and a fellowship in hand and microvascular surgery at the Indiana Hand Center. She practiced full-time for 8 years, then pursued an MBA at Duke University's Fuqua School of Business, following which she worked in the venture capital industry in Silicon Valley.

Dr. Lynch's firm, Advisorthopædics Incorporated, which is focused exclusively on innovation in orthopedics, provides consultation services to a range of entities developing products for musculoskeletal care. Facilitating the translation of clinical needs into viable solutions with commercial potential is the company's aim. Clients include private and public companies, contract research organizations and investors. She is a member of the American Society for Surgery of the Hand's Commercial Support Committee, Innovation Park at Notre Dame's Private Sector Advisory Committee and the University of Notre Dame's Gigot Center for Entrepreneurship Advisory Board.

Dr. Danica Marinac-Dabic is Director, Division of Epidemiology, and Office of Surveillance & Biometrics, Center for Devices and Radiological Health (CDRH), FDA

Dr. Danica Marinac-Dabic served as a Chief of Epidemiology in the Division of Postmarket Surveillance at CDRH. A physician and epidemiologist by training Dr. Marinac-Dabic leads the CDRH Post-Approval Studies Program in charge of oversight of all FDA mandated postmarket studies of medical devices. Dr. Marinac-Dabic also oversees the CDRH Epidemiologic Research Program charged with advancing the methods and infrastructure for evidence development and appraisal with application to medical device regulatory science. Under her leadership FDA Medical Device (MDEpiNet) Initiative was launched in 2010 to identify evidence gaps and questions, datasets, and approaches for conducting robust analytic studies to improve understanding of clinical outcomes and performance of medical devices through strategic consortium with academic centers. Dr. Marinac-Dabic also leads FDA International Consortium of Orthopedic Registries (ICOR) Initiative, focusing on advancing methods and infrastructure for regulatory science and surveillance for orthopedic medical devices. Dr. Marinac-Dabic is author of several book chapters, manuscripts and presentations on various topics of medical device epidemiology and surveillance.

Joan A. McGowan, Director of Musculoskeletal Diseases Division, National Institute of Health – National Institute of Arthritis Musculoskeletal and Skin Diseases

Dr. McGowan is the Director of the Musculoskeletal Diseases Division at the National Institute of Arthritis and Musculoskeletal and Skin Diseases, leading a program of research on basic muscle and skeletal biology, orthopaedics, osteoarthritis,

bioengineering, tissue engineering and regenerative medicine, muscle physiology and muscle diseases, and, osteoporosis and related bone diseases.

Before joining NIH, Dr. McGowan was a faculty member at the Harvard Medical School and Massachusetts General Hospital. She received training at Cornell University (Master in Nutritional Science) and Brown University (Ph.D. in Biomedical Science).

Dr. McGowan has been very active in osteoporosis and women's health activities at NIH including serving as a Project Officer in the NIH Women's Health Initiative, a clinical trial and observational study that was designed to test promising interventions in cardiovascular disease, breast and colon cancer and osteoporosis.

(Dr. McGowan continued)
Dr. McGowan has also served as a member of the Advisory Board of the Canadian Institute of Musculoskeletal Health and Arthritis. She serves as the NIH liaison to the United States Bone and Joint Initiative.

Dr. McGowan co-chairs the Federal Working Group on Bone Diseases whose members represent all of the U.S. federal agencies with activities in osteoporosis and related bone diseases. This group serves to develop and foster collaborative activities among the government agencies in bone diseases. She was the NIH organizer of a Consensus Development Conference on Optimal Calcium Intake in 1994 and one on Osteoporosis held in March, 2000. She served as the Senior Scientific Editor of **Bone Health and Osteoporosis: A Report of the Surgeon General** published in October 2004. Dr. McGowan serves as the NIH Liaison to the National Bone Health Alliance.

Michelle McMurry-Heath, MD, PhD, Associate Director for Science, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health

Dr. McMurry-Heath is the Associate Director for Science of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration. In that capacity she helps manages the regulatory science programmatic portfolio for the Center which includes research scientists in the Office of Science and Engineering Laboratories and the Office of Surveillance and Biometrics. Her science cluster team includes the standards, pediatrics, medical countermeasure, external expertise and partnership programs. Together these programs tackle many of the cross Center scientific and engineering issues.

Prior to joining the FDA, she was the founding director of the Health, Biomedical Science, and Society Initiative at the Aspen Institute and Adjunct Assistant Professor of Health Policy at George Washington University. Her Aspen Institute team focused on creating new policy strategies for stimulating biomedical research, disseminating emerging healthcare technologies, and reducing healthcare disparities domestically and internationally. Her science diplomacy work has included projects from Rwanda to Cambodia. From 2001-2004, she oversaw health and social policy issues for Senator Joseph Lieberman and was the senior health policy advisor for the Lieberman for President Campaign. While on the Hill, she worked on homeland security, health disparities, healthcare quality, and translational research bills, including the American Center for Cures initiative and legislation (later enacted as the Cures Acceleration Network). After studying biochemistry at Harvard, Dr. McMurry-Heath went on to become the first African-American to receive both MD and PhD degrees from Duke University. She trained in pediatrics and molecular immunology.

Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI
Professor of Medicine (Cardiology) and Health Evidence Policy
Director of Interventional Cardiovascular Research and Clinical Trials, Mount Sinai School of Medicine, New York

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI is a professor of medicine (cardiology) and health evidence and policy and director of interventional cardiovascular research and clinical trials at The Zena and Michael A. Weiner Cardiovascular Institute at The Icahn School of Medicine at Mount Sinai, New York, NY. Dr. Mehran completed her training in internal medicine at the University of Connecticut, where she also served as chief medical resident before continuing with fellowships in both cardiovascular disease and interventional cardiology at Mount Sinai Medical Center.

Dr. Mehran is internationally recognized for her work in multicenter, multinational clinical trials, specializing in complex data analyses. She has developed several risk scores for bleeding and acute kidney injury to identify patients at risk for these complications. Previously (2004-2010), Dr. Mehran was an associate professor of medicine and director of

(Dr. Mehran continued)
outcomes research, data coordinating and analysis at the Center of Interventional Vascular Therapies at Columbia University, where she led a variety of projects focused on outcomes of patients undergoing percutaneous coronary intervention (PCI). She is renowned for her vast experience working with regulatory agencies to design and conduct clinical trials. Currently, she is one of several lead investigators who collaborate with the FDA to develop standard definitions for clinical trials in cardiovascular disease. Her research interests extend from mechanisms of restenosis to treatment and prevention of acute kidney injury in cardiac patients, outcomes research, as well as the advancement of pharmacologic and interventional treatments for acute coronary syndromes and acute myocardial infarction. In addition to founding a highly regarded academic research organization at the Cardiovascular Research Foundation, where she has served as the chief scientific officer for the past 12 years, she is widely published and frequently invited to speak at both national and international scientific conferences. She has also served as the course co-director of the annual Transcatheter Cardiovascular Therapeutics (TCT) meeting for the last 15 years and is a member of the editorial boards of multiple peer reviewed journals, including Journal of the American College of Cardiology, Circulation, Circulation Research, and Catheterization and Cardiovascular Interventions. She has served on the board of trustees of the Society of Cardiovascular Angiography and Interventions (SCAI), the program committee of the American Heart Association (AHA) Scientific Sessions, as well as the writing committee of the ACC/AHA PCI guidelines. She is currently on the ACC National Cardiovascular Data Registry (NCDR) research and publications subcommittee, is a member of the board of directors for Harboring Hearts, and is the Medical Director of the Health Disparities Research Consortium (HDRC). She is also the founder of the SCAI-Women in Innovations (WIN) Initiative. During her time as SCAI WIN chair she organized two data forums focused on analysis of sex specific data from major international cardiovascular trials. She also spearheaded a national OB/GYN patient screening project aimed at increasing early detection, diagnosis and treatment of heart disease.

Virginia M. Miller, Ph.D., Professor of Surgery and Physiology, Mayo Clinic, Rochester, Minnesota

Virginia M. Miller, Ph.D. Professor of Surgery and Physiology, Mayo Clinic, Rochester, Minnesota

Virginia is Professor of Surgery and Physiology in the College of Medicine, Mayo Clinic. A native of Pittsburgh PA she earned her Ph.D. in physiology from the University of Missouri in Columbia MO. She has held professional positions at the University of Virginia and the University of Delaware before coming to the Mayo Clinic. She received her Master of Business Administration from the Carlson School of Management at the University of Minnesota. Dr. Miller served as director for the Office of Women's Health at Mayo from 2001-2005. She is the principal investigator for Mayo Clinic's Specialized Center of Research on Sex Differences and Research Director of the Mayo Clinic training program Building Interdisciplinary Research Careers in Women's Health. She has authored over 200 original publications and reviews several of which have focused on content of medical curricula and scientific editorial policy. In addition to service on various grant review panels and editorial boards for scientific journals, she served as a member of the governing council for the

American Physiological Society (APS) and as President of the Organization for the Study of Sex Differences (OSSD).

Faisal M Mirza, MD, FRCSC, Medical Director, Global Development Bone Therapeutics Area, Amgen

I am an orthopaedic surgeon scientist with research and clinical experience in biomechanical and clinical outcomes research. I am Principal Investigator on a device-related outcomes research grant through the Critical Path Initiative and have identified gender differences as part of that research.

Bone quality and strength is particularly relevant for musculoskeletal health as it pertains directly to the interface between medical devices and patients. Women have different bone characteristics than men.

Braxton D. Mitchell, MPH, PhD, University of Maryland School of Medicine

Dr. Mitchell is a genetic epidemiologist whose research focuses on a variety of age-related diseases, including type 2 diabetes mellitus, cardiovascular disease, stroke, osteoporosis, osteoarthritis, and obesity. He has worked with many population studies, including the Old Order Amish community of Lancaster County, PA, in which he has carried out research for over 15 years. He participates in numerous gene mapping studies, many of which involve collaborations with clinicians, geneticists, and basic scientists with the shared goal of identifying and characterizing genetic determinants of complex diseases and traits, and then assessing the impact of identified variants at the population level. Relevant to this talk, he has directed the San Antonio Family Osteoporosis Study and helped lead the Amish Family Osteoporosis Study as well as the genomics studies in the Osteoarthritis Initiative. He has authored over 300 scientific papers, and served on numerous NIH study sections.

Tina Morrison, PhD, FDA/CDRH

Dr. Tina Morrison is a mechanical engineer who studied Cardiovascular Biomechanics for two years as a post-doctoral fellow at Stanford University. Her research focused on quantifying the in vivo deformations of the thoracic aorta from CT imaging. She continues her research efforts at the Food and Drug Administration at the Center for Devices and Radiological Health (CDRH) in the Office of Device Evaluation (ODE). Currently she is the Chief Advisor of Computational Modeling for the ODE and is leading the Regulatory Review of Computational Modeling working group at CDRH. She is energetic about advancing regulatory science through modeling and simulation because she believes the future of medical device design and evaluation, and thus enhanced patient care, lies with computation and enhanced visualization.

She has been a scientific reviewer, principal investigator on two projects, and a technical expert on another since 2008. She is a co-principal investigator on a Critical Path Initiative (CPI)-funded project titled "Leveraging the Simulation-Based Engineering and Medical Imaging Technology Revolutions for Medical Devices", where she continues to interact with industry and academic experts through workshops on Computer Methods for Medical Devices. Additionally, she is the principal investigator on a CPI project titled "Characterization of Human Aortic Anatomy Project (CHAP)", a large multicenter national study investigating the gender differences in anatomy of more than 10,000 diseased aortas, and the gender disparities in available endovascular treatment options. She also provides technical expertise regarding finite element analysis and medical imaging for another CPI project titled "Assessment of plaque composition, dynamic biomechanics, and therapeutic outcomes in subjects implanted with endovascular devices (ASPECT)". She received her Ph.D. in Theoretical and Applied Mechanics from Cornell University in 2006 and her Masters in Mechanical Engineering in 2002 from the University of Connecticut.

Martha Nolan, JD, Vice President, Public Policy, Society for Women's Health Research (SWHR)

Martha Nolan, Vice President, Public Policy is responsible for the development and implementation of all SWHR's government relations activities and public policy programs and statements. In this capacity, she provides advice and counsel to SWHR's president on public policy goals and strategies and directs the advocacy of SWHR's mission and priorities not only before Congress, but the Administration and its Agencies as well.

Ms. Nolan joined SWHR in September 2003 after nearly eighteen years of experience working for the health insurance industry as a lawyer and a lobbyist. Her most recent experience was as Assistant Vice President of Federal Affairs at MetLife, a provider of insurance and other financial services to individual and institutional customers, where she was responsible for lobbying on all legislative and regulatory health issues, including nonmedical health products such as dental, long-term care and disability income insurance. In her capacity at MetLife, Ms. Nolan lobbied for the successful passage of the Federal Employee Long Term Care Insurance Act of 2001, the first benefit addition to federal employees in a very long time. Ms. Nolan also chaired the Disability Insurance Industry Technical Advisory Group before the Social Security Administration and co-chaired the Disability Discussion Group, a broad based forum created to discuss disability issues in Washington.

Prior to joining MetLife, Nolan was Senior Counsel for State Affairs for United Health Group (UHG). There she oversaw lobbying, coordinated advocacy and managed state legislative and regulatory issues for over half the country. Prior to UHG, Ms. Nolan managed State Affairs health lobbying for all 50 states for MetLife. She also worked for CIGNA and HIAA prior to her employment with MetLife.

A lawyer by profession, Nolan earned her Juris Doctorate at Suffolk University Law School. She received a Bachelor's degree in American History from Harvard University.

Mary I. O'Connor, MD, Professor and Chair, Department of Orthopedic Surgery Mayo Clinic in Florida

Mary I. O'Connor, MD, is Professor and Chair of the Department of Orthopaedic Surgery at the Mayo Clinic in Jacksonville, FL. She is the Medical Director for the Office of Integrity and Enterprise Risk Management at Mayo Foundation, an Associate Medical Director for Development and member of the Executive Operations Team at Mayo Clinic Florida.

Dr. O'Connor received her MD from the Medical College of Pennsylvania and completed her residency in orthopedic surgery and fellowship in orthopedic oncology at Mayo Clinic. Honors include the Mayo Distinguished Clinician Award and the Jacksonville Business

Journal "Woman of Influence" distinction. She is the PI of a multicenter study supported by the Society for Women's Health Research to investigate potential sex difference in knee osteoarthritis.

Dr. O'Connor was the first female member of the Musculoskeletal Tumor Society (MSTS), the American Association of Hip and Knee Surgeons (AAHKS) and The Knee Society. She is Past President of the Association of Bone and Joint Surgeons, AAHKS, the International Society of Limb Salvage, MSTS, the Ruth Jackson Orthopaedic Society and past Chair of the American Academy of Orthopaedic Surgeons Women's Health Issues Advisory Board. She is deeply committed to promoting women in orthopaedics and advancing the care of women's musculoskeletal health.

Ellen Pinnow, MSc, OMPT/CDRH/ODE

Ellen Pinnow is currently in the Investigation Device Exemption (IDE) Office in the Center for Devices and Radiologic Health (CDRH) at the Food and Drug Administration (FDA). She has been with FDA for nine years. She was previous a Branch Chief in the Division of Epidemiology in the Office of Surveillance and Biometrics and worked in the Office of Women's Health. Previously, she worked at the Medstar Research Institute at the Washington Hospital Center for 15 years in the Division of Cardiology as an Epidemiologist and the Manager of the Cardiovascular Research Institute Data Coordinating Center.

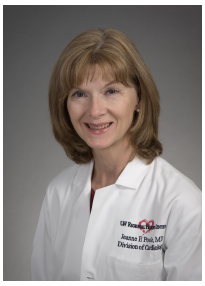
Ms. Pinnow is a co-author on more than 90 peer-review manuscripts. She has presented and published on research evaluating obstacles and opportunities for recruitment and retention in clinical research. Additionally, she has conducted research on the participation of women in clinical research. This includes evaluation of women's participation in clinical trials for new drugs approved by the FDA, early phase drug trials, and post-approval studies for medical devices.

Steven K, Pollack, BS, PhD, Director, Office of Science and Engineering Laboratories, Center for devices and Radiological Health, Office of Medical Products and Tobacco, Food and Drug Administration

Dr. Pollack is the Director of the Office of Science and Engineering Laboratories (OSEL), the applied research arm of the FDA's Center for Devices and Radiological Health. Prior to this, he held the position of Director of the Division of Chemistry and Materials Science within OSEL. He obtained his Ph.D. in physical organic chemistry at the University of California, Irvine and his BS in chemistry from the State University of New York at Albany. He has held research and management positions at American Hospital Supply Corporation, Allergan Pharmaceuticals and Springborn Laboratories before returning to academia for a postdoctoral fellowship at the University of Massachusetts at Amherst. He has held faculty positions at the University of Cincinnati in Materials Science and Engineering and at Howard University, where he was Professor of Chemistry. His academic work included polymer physics, polymer synthesis and molecular modeling. Immediately prior to coming to FDA, he was a research chemist and a Deputy Laboratory Head in the Center for Bio/Molecular Science and Engineering at the U.S. Naval Research Laboratory where he worked in the areas of molecular electronics, nanotechnology and biothreat detection. Dr. Pollack is also holds an adjunct Professorship at University of Maryland in the Dept. of Bioengineering. He is author of over 75 papers, 3 patents, and 2 book chapters in the areas of computational chemistry, polymer science and nanotechnology.

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Jeanne E. Poole, BS, MD, FACC, FHRS, Professor, Department of Medicine, Division of Cardiology; Director, Electrophysiology/Arrhythmia Service, University of Washington



Dr. Poole is Professor of Medicine at the University of Washington, Seattle, WA. She is the Section Head for the Electrophysiology Service and Program Director for the Clinical Cardiac Electrophysiology Fellowship Program. Her career has focused on the treatment and prevention of life threatening ventricular arrhythmias and use of implantable cardiac defibrillators and cardiac resynchronization devices.

She has participated in many clinical trials of implantable device therapy, as the P.I. of NHLBI clinical trials Core Labs, such as the SCD-HeFT ICD-Electrogram (EGM) Core Lab, the HAT study ECG AED-EGM Core Lab and the ECG-Rhythm Core Lab for the on-going CABANA study. She was also the national PI for The REPLACE Registry Study.

Andrea L. Pusic MD MHS FRCSC, Associate Attending Surgeon, Memorial Sloan-Kettering Cancer Center

Dr. Pusic is a plastic surgeon at Memorial Sloan-Kettering Cancer Center in New York City. She completed a Master's degree in Epidemiology at Johns Hopkins University and Plastic Surgery residency at McGill University.

Her research focus is measurement of patient-reported outcomes. With grant support from the Plastic Surgery Foundation, she and a team of international collaborators developed the BREAST-Q. This questionnaire, created using state of the art psychometric methods, evaluates satisfaction and quality of life outcomes among breast surgery patients. As a measurement tool, it is designed to facilitate regulatory efforts, support advocacy and encourage an evidence-based approach to the management of breast surgery patients. As an example of its application, the UK National Health Service is currently using the questionnaire as the primary outcome measure in a national prospective survey of 8,000 breast surgery patients. In 2007, she was awarded the Clinical Research Recognition Award by the American Society of Plastic Surgery. Currently, she is Chair of the Clinical Trial Committee of the American Society of Plastic Surgeon, co-PI of the National Breast Implant Registry and co-PI of the Mastectomy Reconstruction Outcome Consortium study (R01 CA-152192-01-A1).

Kate Rumrill, Vice President, Global Clinical Affairs, Covidien

Kate serves as Vice President of Global Clinical Affairs for Covidien's Peripheral Vascular (PV) Division. Kate joined Covidien in November 2011. She leads the PV clinical team in establishing and implementing a successful clinical strategy across the portfolio.

Kate has over 23 years of industry experience in pharmaceutical and medical device development, including leadership positions with Sterling Winthrop/Sanofi, Eli Lilly and more recently Aspect Medical Systems and NeoSync, Inc.

Kate holds a bachelor's degree in Biology with a second major in Psychology from the State University of New York. She also holds an MBA in Healthcare Management from the University of Phoenix.

Kim A. Selzman MD MPH FHRS FACC, Associate Professor of Medicine, University of Utah, Salt Lake City VA Hospital

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Dr. Selzman is an Associate Professor of Medicine at the University of Utah in the Department of Medicine and the Director of Cardiac Electrophysiology at the Salt Lake City VA Hospital. She also is a part-time medical officer for FDA in the Division of Cardiovascular Devices and works mainly in the Implantable Electrical Devices Branch. She practiced clinical cardiac EP at the University of North Carolina in Chapel Hill for 5 years prior to joining FDA and relocating to Salt Lake City. She was raised in Philadelphia, PA and attended Temple University for Medical School. She later received her Masters in Public Health from UNC in Chapel Hill in 2008. She was the medical officer representing FDA for the MADIT CRT and REVERSE/RAFT panel meetings which both focused on expanding indications for Cardiac Resynchronization Therapy. She is a member of the Heart Rhythm Society (HRS) and is one of the HRS representatives to the NCDR Publications committee. She is married with two children, 6 and 8 years old.

Jeffrey Shuren, MD, JD, Director, CDRH, FDA

JEFFREY SHUREN, MD, JD is the Director of the Center for Devices and Radiological Health (CDRH) at FDA. He previously served as Acting Center Director. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, Dr. Shuren joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. Dr. Shuren returned to FDA as the Assistant Commissioner for Policy in 2003, and assumed his current position in September 2009. He received both his BS and MD degrees from Northwestern University under its Honors Program in Medical Education and his JD from the University of Michigan Law School.

John Spertus MD MPH. Lauer/Missouri Endowed Chair and Tenured Professor, University of Missouri – Kansas City, Saint Luke's Mid America Heart Institute/UMKC

John Spertus is a cardiologist and the Lauer/Missouri Endowed Chair and Professor of Medicine at the University of Missouri-Kansas City, where he serves as Clinical Director of Outcomes Research at Saint Luke's Mid America Heart Institute. Dr. Spertus' research focus on methods for assessing patients' health outcomes, measuring healthcare quality, and the use of information technology to guide medical decision-making based on risk-prediction models so that treatment can be safer, more cost-effective, evidence-based and patient-centered. He developed the Seattle Angina Questionnaire (SAQ), and the Kansas City Cardiomyopathy Questionnaire (KCCQ), which have both been translated into over 50 languages and are emerging as the gold standards for measuring patients' symptoms, function and quality of life in coronary artery disease and heart failure. Most recently, Dr. Spertus has extended his translational research to illuminate the prognostic significance of genetic and other biomarkers on cardiovascular outcomes and to support the execution of multivariable risk models in clinical care to provide personalized estimates of outcomes as a foundation for shared decision-making and the implementation of care that is evidence-based, efficient, equitable, safer and more patient-centered.

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Stephen Thomas, PhD, Director of the University of Maryland Center for Health Equity, University of Maryland School of Public Health

Stephen B. Thomas, PhD, is professor in the Department of Health Services Administration in the School of Public Health and Director of the Maryland Center for Health Equity at the University of Maryland in College Park. One of the nation's leading scholars on community engaged research to eliminate racial and ethnic health disparities, Dr. Thomas has applied his expertise to address a variety of conditions, including cardiovascular disease, diabetes, obesity and HIV/AIDS. He is principal investigator, with Dr. Sandra C. Quinn, of an NIH designated Research Center of Excellence on Race, Ethnicity and Health Disparities, funded by the National Institute on Minority Health and Health Disparities. From 2009-2012 he was also principal investigator, with Dr. Sandra Quinn, of the NIH National Bioethics Infrastructure Initiative: Building Trust Between Minorities and Researchers..

Dr. Thomas has been recognized at the national level for his professional accomplishments, receiving the 2010 Dorothy Nyswander Open Society Award from the Society for Public Health Education for his work on

(Dr. Thomas continued)

community health and social justice, the 2005 David Satcher Award from the Directors of Health Promotion and Education for his leadership in reducing health disparities through the improvement of health promotion and health education programs at the state and local levels and the 2004 Alonzo Smyth Yerby Award from the Harvard School of Public Health for his work with people suffering the health effects of poverty. In 1998, he received the K-01 NIH Mentored Research Science Award in Applied Research Ethics to explore strategies for overcoming the legacy on Tuskegee on willingness of African Americans to participate in medical and public health research. Over the years, his work is recognized as one of the scholarly contributions leading to the 1997 Presidential Apology to Survivors of the US Public Health Service Syphilis Study Done at Tuskegee.

Dr. Thomas has served on numerous national committees, including, but not limited to, the NIH State of the Science Committee on Tobacco Cessation, Prevention and Control; the National Research Council committee on Assessing Fitness for Military Enlistment: Physical, Medical and Mental Health Standards; the Institute of Medicine Committee on Reducing the Odds: Preventing Perinatal Transmission of HIV and the Centers for Disease Control and Preventions Agency Wide Research Agenda Collaborative. Dr. Thomas serves on the advisory board for the Mayo Clinic's Cancer Center and Mayo's Center for Translational Science Activities. He was a training site director for the Kellogg Health Scholars Post-Doctoral Program at the University of Pittsburgh's Graduate School of Public Health where he served as the Philip Hallen Professor of Community Health and Social Justice (2000-2009) and Associate Dean for Diversity (2009-2010) before founding the University of Maryland Center for Health Equity in 2010.. His work has been published in leading peer

reviewed journals such as the Annual Review of Public Health, Journal of the American Public Health Association, Social Science and Medicine, Health Promotion Practice and Archives of Internal Medicine.

After completing his undergraduate degree in school health education at TheOhio State University, Dr. Thomas went on to earn his master's degree in health education at Illinois State University and later earned his doctorate in community health education from Southern Illinois University in Carbondale.

Rachel B Wagman, MD, Amgen

Rachel B Wagman, MD is Global Development Leader in the Bone Therapeutic Area at Amgen. In this role, she focuses on developing and executing medical strategic plans. Her activities are centered on phase 3 and 4 clinical development/execution and life cycle management, providing scientific and medical leadership in cross-functional osteoporosis-

related issues, and contributing to product registration filing applications submitted to global regulatory authorities.
Prior to joining Amgen, Dr Wagman was a clinical research physician at Eli Lilly and Company in US Endocrinology, where she focused on clinical trials and medical initiatives in the treatment of osteoporosis.
Dr Wagman has published in several peer-reviewed journals and has given invited presentations throughout the United States on osteoporosis. She has completed training in both internal medicine and endocrinology, gerontology, and metabolism. Dr Wagman is a member of the American Society for Bone and Mineral Research, the Endocrine Society, American Association of Clinical Endocrinologists, and the American College of Physicians. She also has held faculty appointments in the Division of Endocrinology at Stanford University School of Medicine (2005-2010) and Indiana University (2002-2006).

Keith A. Wear, Ph.D., FDA/CDRH, Food and Drug Administration Center for Devices and Radiological Health

Keith Wear received his Ph.D. in Applied Physics from Stanford University. He is lead author on 36 papers published in peer-reviewed scientific journals, and has given 14 invited presentations at scientific conferences, on use of ultrasound to assess bone health. He is an Associate Editor of IEEE Transactions on Ultrasonics and an Associate Editor of the Journal of the Acoustical Society of America. He is on the editorial boards of the Ultrasonic Imaging and the Journal of the Acoustical Society of America. He is a Fellow of the American Institute of Ultrasound in Medicine, the Acoustical Society of America, and the American Institute of Medical and Biological Engineering.

Kimberly Wong Oleson, Medtronic, Inc.

Kimberly Wong Oleson is the Vice President of Global Clinical Operations for the Medtronic Clinical Research Institute and is responsible for the enterprise-wide strategy for Medtronic's global clinical research operations. Functions that comprise Clinical Operations include Clinical Quality, Safety, Monitoring, Data Management & IT, Contracts & Payments, Vendor Management, and Clinical Portfolio/Metrics.

Trained as a biostatistician, Kimberly has successfully held positions of increasing responsibility across multiple businesses within Medtronic which include: Senior Director of Clinical, Regulatory and Quality for the Ventures & New Therapies business; Institutional Official for the Medtronic Physiological Research Laboratories; and Senior Director of Clinical for Medtronic's Cardiac Rhythm Disease Management business.

With 25+ years of experience in the medical device industry, 8 peer-reviewed publications and 3 issued/filed patents, Kimberly's technical contributions have led to the commercialization of innovative medical therapies in the fields of drug delivery, neurology, cardiology, interventional radiology, and cardiac electrophysiology. For distinguished service, Kimberly is a recipient of Medtronic's Star of Excellence Award.

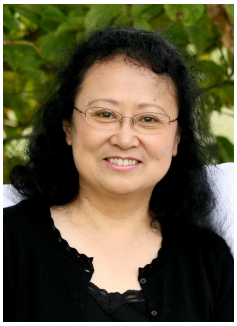
CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies

Yelizaveta (Lisa) Torosyan, MD, PhD, FDA/DEPI/OSB/CDRH/FDA

Dr. Torosyan is an MD/PhD scientist with clinical background, NIH postdoctoral experience, multidisciplinary research expertise, and skills in bioinformatics. A physician by training, she started her career as Assistant/Associate Professor at the Yerevan Medical University in Armenia. Her research was focused on Familial Mediterranean Fever, a major genetic syndrome with musculoskeletal manifestations. In 1997, she received the Fogarty International Award and joined the Inflammatory Biology team at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS, Bethesda, MD). While working at the NIAMS/NIH, she conducted research involving population genetics, epidemiology, and pathophysiology of genetic inflammatory syndromes. In 2003, Dr. Torosyan moved to the Uniformed Services University of the Health Sciences (Bethesda, MD). Serving as Research Assistant Professor, Dr. Torosyan expanded her expertise in bioinformatics applications and contributed to multidisciplinary research involving molecular signature identification and biomarker discovery. Throughout her career, Dr. Torosyan authored numerous peer-reviewed publications and presented at national and international meetings. In 2012, she joined the Division of Epidemiology at CDRH, where she is reviewing submissions on orthopedic medical devices and contributing to development of the Medical Device Epidemiological Network (MDEpiNet). Dr. Torosyan's regulatory research is focused on evidence synthesis

(Dr. Torosyan continued)
using biomarkers which can identify individual susceptibility to adverse events and thereby characterize device performance in different subpopulations. Using systems biology approach and skills in data meta-analysis and cross-validation, Dr. Torosyan is conducting research on the identification and potential applications for biomarkers and modifiers of the adverse events associated with arthroplastic and other medical devices.

Lilly Yue, PhD, Deputy Division Director, FDA/CDRH/OSB/DBS



Lilly Yue, Ph.D., is the Deputy Director for Premarket and Operations in the Division of Biostatistics, OSB/CDRH. She is the 2012 President of the FDA Statistical Association (FDASA), 2013 Program Chair of the Statistical Interest Group on Medical Devices and Diagnostics (SIGMEDD) of the American Statistical Association (ASA), and 2013 Co-Chair of the FDA/Industry Statistics Workshop. She has been an Associate Editor for the Journal of Biopharmaceutical Statistics (JBS) and Guest Editor of JBS Special Issues on Medical Device Clinical Studies. Her research interests include the application of propensity score methodology and regulatory statistics, and she has published a number of papers in peer reviewed scientific journals. Before joining the FDA, she worked for Eli Lilly and Company as a senior statistician.

Robbert Zusterzeel, MD, FDA

Dr. Zusterzeel obtained his medical degree from the University of Maastricht in the Netherlands and is currently a research fellow in the Center for Devices and Radiological Health. His PhD research focuses on the safety and efficacy of Cardiac Resynchronization Therapy (CRT).

CDRH Health of Women (HoW) Program Launch: ***"Educate, Enable, Enlist and Explore - HoW to Improve the Health of Women"*** Public Workshop
Speaker and Chairperson's Biographies