

**iGIANT HEALTH Roundtable 1**  
**July 15, 2015**  
**1:00-4:00 PM**  
**HHH Building, CR 425A**

Rapporteurs:

Adrienne Phenix-ORISE Fellow, DHHS Office on Women's Health  
Aaron Polacek-ORISE Fellow, DHHS Office on Women's Health

**Nancy Lee**, HHS – Office on Women's Health

- Welcome and introductions

**Saralyn Mark** – SolaMed Solutions/OSTP

- Introductions/Agenda/Background
- Developed the iGIANT program while working as a Senior Policy Advisor in the White House OSTP to facilitate discussion/collaboration among diverse stakeholders
- Informal survey conducted to assess the impact of gender/sex on innovation and novel technologies
- There have been significant achievements in health sector
- Promising developments in other sectors including transportation, IT and retail, but the scientific basis has not been well defined and explored
- Partnered with OWH to encourage active discussion and broad outreach
- Creation of ambassador program to foster partnerships and alliances to promote innovation (First Class of Ambassadors)

**BRIEF PRESENTATIONS**

**Marjorie Jenkins**-FDA OWH

- OWH is located within the Office of the Commissioner and works across all divisions of the FDA
- The office was congressionally mandated in 1994 and has no regulatory authority
- The goal of the office is inclusion and diversity in clinical trials
- Educates clinicians and researchers through workshops and meetings
- Developing an upcoming campaign to increase the enrollment of women from diverse backgrounds into clinical trials:
  - The campaign will educate clinical research coordinators around the nation to include women in research trials for diseases which are lacking appropriate female representation such as cardiovascular diseases, diabetes, HIV, COPD, depression and anxiety

**British Robinson**--Women's Heart Alliance

- The NGO was established 9 years ago
- Goal is to raise awareness for women to alert them of heart disease being a leading killer

U.S. Department of Health and Human Services  
200 Independence Avenue, SW, Room 712E, Washington, DC 20201

[www.womenshealth.gov](http://www.womenshealth.gov) | 800-994-9662



- Prevention campaign to raise public awareness to decrease morbidity and mortality
- Joined with Clinton Health Matters Initiative to target college-aged women to educate them about the health effects of their lifestyles and nutrition
- Secondary targets were families and health providers
- Partnered with California State University, Los Angeles (60% women) for baseline screening and discussions about risk factors
- Encouraging students to develop app for women to inform them about cardiovascular disease, reminders of appointments, and training for clinicians

#### **Alyson McGregor-Brown University**

- Brown University is focusing on the translation of sex and gender differences to bedside and emergency care and has taken a responsibility to create cutting edge research on health care delivery and decisions that include gender/sex
- Established women's health in Emergency Care Division, which is now being called "SGEM" (Sex/Gender in Emergency Medicine)
- SGEM's mission is to address how sex and gender impacts emergency treatment and care
- SGEM has developed 125 scientific publications and a 2-year fellowship program
  - Created agenda for what are research questions to ask in emergency rooms
  - 9-minute videos designed to update information
  - Engaged patients through posters in hospital dialogue
- Releasing book on sex and gender in acute care medicine in 2016
- Forming national interest group to continue the conversations on sex and gender in emergency care
  - Projects long-lasting impact through focusing on acute care

#### **QUESTIONS FOR ABOVE PRESENTERS:**

##### **Do you have a case-study or example of how sex/gender is important in ER? (To Allyson McGregor)**

- "A lot of health disparities are emerging, for example, why women wait to call 911, higher mortality and less clusters for strokes. Research is figuring out why women have longer QT intervals. Medications can prolong this so we teach at the bedside to look at this before you give those meds."

##### **CVD risk calculators are developed for men, is anyone doing anything to focus on women only data?**

- "Yes, for example, there is a conference for millennial women on immune conditions and preeclampsia."

##### **Is the FDA OWH looking for ways to encourage companies to look at data by gender? (To Marjorie Jenkins)**

- "Encouragement and awareness are important topics at FDA, for example, there are stake holder meeting in 6 months. In December 2014, FDA started snapshots

of trials approved on how many women and minorities are included which can be used to determine clinical relevance. Snapshots provide data transparency.”

- **What do they do with that data?**
- “We hope that FDA will do a lot more publicity so women will look at it and force pharmaceutical companies to do a better job. A challenge is that information is provided by the company. We also hope that women will start to ask questions about their medications.”

\*Saralyn Mark moves to hold all questions until the end of all presentations instead of taking questions between presenters due to time constraints.\*

#### **Kjersten Bunker-Whittington-NIH ORWH**

- NIH released a commentary last year addressing female animals and cells in preclinical research stating intention to create policy to include sex and gender analyses
- Last year a committee was formed to draft policy to develop mechanisms to address the gap for use of female animal cells in preclinical research
- In September and October 2014, ORWH received feedback from the scientific community regarding language to be inserted in grant applications to include female cells in research
- Pending OMB clearance, the policy to include language in grant application will be required in ORWH grant applications

#### **Connie Tyne--Texas Tech University Health Science Center/Laura Bush Institute for Women's Health**

- Laura Bush Institute for Women's Health was established in 2007 as one of Texas Tech University Health Science Center's four institutes
- The institute developed a focus on recognizing that there are deficits in sex and gender-based care and having physicians recognize these issues
- Created task force of Physicians, Deans of Nursing, and the Schools of Allied Health and Pharmacy to focus on educating students to recognize sex and gender-based differences
  - The task force developed ideas to encourage students to think that about this from the start and be trained to implement this in their practice
- The institute is building a curriculum of interactive modules to increase awareness of sex and gender-based differences
  - Professors can choose slides from the slide library to make it part of their lectures- references materials are included on the slides
  - Developed a CME series of interactive modules which give credits to physicians and healthcare providers
  - Calling on assistance from specialists to help build a slide module

#### **Denise Castetter-Foundation for Men's Health**

- Men die earlier than women and suffer more from chronic conditions, and experience higher mortality rates. In spite of statistics, little is known about the causes of these differences

- There is a general lack of awareness of health amongst men that feeds into more neglect, avoidance of preventive services and health screenings
- This is a growing health care issue that impacts the whole family and society in general
- Health behaviors that are developed as boys continue into adulthood, and as a result we all pay the price
- Created a benchmark public poll to look at differences in age, household income, etc. and how health care is approached:
  - Want to launch poll this year and are looking for support and funding, mostly using grants
- Developing ideas to educate students on college campuses on what it means to be a healthy male using an app.

**Bette Siegel-- NASA Human Exploration Operations**

- “The Impact of Sex and Gender on Adaption to Space: Executive Summary” in *Journal of Women’s Health*, was published November 2014
  - Article describes treatment and protocols to protect health in space
  - Compilation of over 60 scientists and academics reviewing studies on how men and women respond in six areas:
    - cardiovascular, immunological, neurosensory, musculoskeletal, reproductive, and behavioral health
  - Compare results to health expectations while on Earth
- Urges further studies are necessary as more women participate in space exploration
- 

**Elizabeth Richard- NASA Human Health and Performance Center (NHHPC)**

- Established 5 years ago to facilitate collaboration among government and industry to enhance human performance
- Developed workshops, e-newsletters, etc. to enhance collaboration across industry
- Next workshop on precision medicine will be held on April 20, 2016 and is hosted by Rice University- [nhhpc.nasa.gov](http://nhhpc.nasa.gov)

**Phyllis Greenberger-- Society for Women’s Health Research (SWHR)**

- Founded in 1990 to transform women’s health through science, advocacy, and education
- Medical and scientific research has exclusively included men, creating biases and disparities in treatment and health care for women and minorities
- SWHR has led the way for women and minorities to be included in research exploring biological sex differences, resulting in policy changes at NIH and FDA
- Working with FDA to include sex differences in medical curricula
- Publishing book to chronicle the history of women’s health

**Dorit Donoviel-National Space and Biomedical Research Institute (NSBRI)**

- Non-profit entity that works closely with NASA on health issues for astronauts and has a policy on the inclusion of gender/sex in research studies
- Explores if Space is a model for accelerated aging:

- Health and aging are accelerated in the Space environment, and what we are learning about Space can be applied on earth
- Allows for the application of medicine in non-traditional settings
- Focusing funding on non-invasive surgical techniques and devices
  - For example, astronauts are found to be susceptible to kidney stones. NSBRI developed a ultrasound based technology that can visualize the stone and move the stone without invasive surgery with ultrasound technology.

**Nancy Lee--Office on Women's Health (OWH)**

- OWH is within the Office of the Assistant Secretary for Health at the Department of Health and Human Services
- Coordinates and collaborates women's health across the Department and serves as experts on women's health for the Secretary
- Websites for women and girls to target consumers, as well as parents and teachers
- Conducts work in four areas – policy, social media, continuing education, and model programs
- Policy work is in accordance with Secretary's priority areas
- Social media on Facebook and Twitter to push federal messages and lead consumers to website
- Continuing education conducted for clinicians to inform them about how to treat women's unique health needs
- Create and distribute knowledge of model programs as applied research on issues such as interpersonal violence, preventing sexual assault on college campuses, breastfeeding encouragement, and caregiving

**Kathryn Sandberg-Georgetown Center for Sex Differences**

- Interested in research, similar to NIH ORWH, on increasing the number of studies conducted in female animal models and disease
- Realized that publications report on single sex studies (5:1 male to female) in animals
- Utilizing metrics is critical for progress
- Change is at the policy level:
  - It can't come from a basic scientist
  - We need a model for female animals and must develop models specific to isolating females subjects

**Stephen Shaya -J and B Medical Supplies- unable to attend due to medical emergency  
(Presented by Saralyn Mark)**

Asked patients questions about their perception on gender-specific products:

- Are their needs being met by their products?
- Do the products need to be gender-specific?
- 82 patients said they would benefit from gender-specific products
- Contacted 3 manufacturers to ask about their gender-specific offerings and if it would help?

- Manufacturers responded that they would create gender-specific products, but economies did not incentivize such products.

**Ranna Parekh-- American Psychiatric Association (APA)**

- APA constituents are its psychiatrists who treat patients and conduct research
- Work continues to de-stigmatize mental health
- For ADHD, goal is to get individuals to functioning status
- Girls are more likely to have inattention than hyperactivity; therefore, girls are underdiagnosed or diagnosed too late
- One effect is that girls not complete their education
- Additional health education is necessary for clinicians to know health differences across racial groups as well as gender

**Katie O'Callaghan--FDA CDRH**

- Regulates 5000 types of medical devices from simple to robotic surgical systems, therapeutic devices, joint replacements, and diagnostic devices (MRI & x-rays)
- Looks at sex specificity:
  - Is it safe and effective?
  - Do the benefits outweigh risks in a population?
  - Should all research consider sex/gender differences?
- Looks at effectiveness of sex specificity:
  - differences in treatment effects (pacemaker in heart failure patients) in women
- Looking to partner with professional organizations to expand research
- FDA has become more active in regulatory science and evaluating effectiveness in medical products
- There is growth in the use of patient-reported outcome measures
- Increasing sense of awareness and development of sex/gender awareness into ideation phase:
  - Pair with industries to uncover unique challenges to include women in clinical trials and utilizing ambassadors to spread the word
- Need more research and innovation, more communication (2 way), increased knowledge and awareness of how differences in sex/gender impact treatment and care

**Noel Bairey Merz, Cedars Sinai (via British Robinson)**

- “Sex Differences in Cardiovascular Disease Biomarkers: Research Ready for Incorporation into National Reference Standards for Diagnosis of Heart Attack to Improve Cardiovascular Outcomes in Women”
- Failure to use biomarkers contributes to mortality gaps between men and women
- Physicians are less likely to diagnose cardiovascular disease in women than in men
- Urges physicians to recognize new biomarkers

BREAK

## GENERAL DISCUSSION

### **Establishing a Common Lexicon: Does it Matter to Speak the Same Language?**

- “Gender” matters to consumers and “sex” is for scientists to build evidence
- We need to be clear where we are at in our current knowledge and understanding
- When evaluating evidence, it’s important to correctly use “sex” and “gender”
- It is important to define “sex” and “gender” and how it will be used
- What is best for public messaging? It is possible to lose the audience when proper language is not used
- This is an opportunity to teach appropriate terminology
- Very important to know your audience before sharing message
- Encouragement for breaking the barrier about correct usage
- Keep an open mind knowing sex and gender change; both are influenced by the environment
- When using terms, be up front with your clarification
- Begin using with applicable data
- Sometimes we need to use both terms as there is an overlap and an interaction between science and behavior
- If using “sex/gender” it may be read that the slash implies interchangeability and they have the same definition

### **Other Challenges?**

- Sex differences in health outcomes are not only disease specific but also permeate to multiple aspects of life
- Need to engage health insurance entities to consider sex/gender differences in diagnosis and treatment
- Knowledge of sex differences is not the way medicine is currently taught and practiced-must work to change curriculum
- Women should ask if the drugs they are being prescribed have been studied effectively for women’s health
- IOM should provide more validation that women’s health needs are unique
- Men’s health voice is not overbearing-it’s just the way medical environment works
- Women need to keep advocating and seeking means to educate clinicians to improve outcomes
- National Practitioner Database can allow for clinician to indicate he/she has obtained CME credits on sex differences in health

### **In working with small companies and start-ups in healthcare, what are the concerns and what drives innovation?**

- Funding is always an issue. There needs to be a way to spread the message of value proposition to the companies developing products. That message needs to be clear and something that drives them to invest time into doing what needs to be done.
- We can force or legislate, but that takes time

- We can focus on benefits of these efforts

#### **Has the economic return on investment case been made?**

- It probably varies in different industries
- The FDA snapshots will make the case if people know they exist and pressure the companies to act
- Side effects of medications and ripple effects of side effects- economic impact is far beyond the 10 drugs that were pulled from the market. The impact is on the health insurers not the pharmaceutical companies. Concern is also about generics-they are not always the same
- There is potential to unveil differences masked by bias. When gender is not included as an indicator, there is no difference. But there is a clear and pronounced difference when gender included
- Worked with insurers to look at side effects in databases and found it difficult to answer their questions
- Engage CLIA in terms of getting sex and gender differences into lab testing:
  - In molecular diagnostics, it's easier to get labs to change behavior
- There is power in defining metrics: think about changes in practice guidelines and metrics incorporating sex/gender -specific measures
- Insurers are the key and consumers can be driving force as well-consider the Red Dress and Breast Cancer Awareness campaigns

#### **Charge and action steps from Saralyn Mark:**

- This is the start of a new initiative and there are more roundtables being planned:
  - September 29, 2015-Stanford University-IT Roundtable
  - October 21, 2015-J and B Medical Supply in Detroit with Auto Assn-Transportation Roundtable
  - November, 2015-Texas Tech University/Laura Bush Institute-Retail/Ergonomic Roundtable

“Roundtable participants are iGIANT ambassadors. As an iGIANT ambassador think about hosting a roundtable of your own. It doesn't have to be too labor intensive or expensive. It's a working meeting and can be small- 8-12 participant is a good number. Include industry, insurance partners and private sector organizations. Personal face to-face time is valuable as opposed to virtual meetings. Think about where you want to go with health, IT, retail, and transportation sectors. Think about potential partnerships. Be creative and go beyond what you've been doing. There may be a summit in early 2016, an announcement of iGIANT prizes and a briefing at the White House. We can improve our world by working together.”

ADJOURN



## iGIANT HEALTH Roundtable 2

July 16, 2015

1:00-4:00 PM

HHH Building, CR 405A

Rapporteurs:

Taylor Kimbel- ORISE Fellow, DHHS Office on Women's Health

Stephen Hayes- ORISE Fellow, DHHS Office on Women's Health

**Nancy Lee**, HHS – Office on Women's Health

- Welcome and introductions

**Saralyn Mark**– SolaMed Solutions/OSTP

- Introductions/Agenda/Background
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BRIEF PRESENTATION:

**Susan Kornstein** – VCU Institute for Women's Health/Journal of Women's Health

- VCU – Institute for Women's Health established in 1999 and designated a National Center of Excellence in Women's Health in 2003
- Clinical Area – multidisciplinary including primary care and OB-GYN to provide less fragmented and more coordinated care; developed through input of advisory committee
- Support interdisciplinary research in women's health
- Provide a range of services such as grant development and administration, etc.
- Bring together researchers from all across the country; research development groups
- Annual Women's Health Research Day at VCU encourages collaboration
- Awards – building bridges in women's health research
- Partnerships across university and community-funded seed grants
- Focus on global women's health including as a Gates Foundation grantee to support service learning abroad
- Disseminate women's health research in a variety of formats: Women's Health Annual Congress, clinically focused Journal of Women's Health, research and government sponsored reports
- Academy of Women's Health-focus on dissemination of translational research and evidence-based practices

**Eliza Chin** - American Medical Women's Association

- Celebrating centennial this year
- AMWA was an early supporter of sex and gender issues –
- An advocate for women's health and child health since the 1920's
- Publish Journal of the American Medical Women's Association (JAMWA)
- Development of research and materials, educational campaigns with sex/gender focus
- Founding member of Advancing Women's Health Research, now Sex and Gender Women's Health Collaborative
- Organizing member of the Sex and Gender Medical Education Summit, along with the Laura Bush Institute, Mayo Clinic and Society for Women's Health Research-Summit date: October 18-19, 2015
- Work to develop sex and gender-based medical competencies with a goal to integrate these competencies into medical school curricula

**Pamela Scott** - FDA Office of Women's Health

- Focus on policy, science and outreach
- Establishes partnerships and collaborations for outreach
- Research program has funded over 300 programs, including projects to inform regulatory processes
- Collaborates with NIH OWH
- Hosts continuing education opportunities, online education course such as pharmacy and women's health curriculum
- Hosts panels and workshops
- Creates communications and outreach tools to promote FDA activities related to women's health
- Currently conducting 5 year review of 300 projects – evaluating where to improve, success and failures
- Working on the development of women's health roadmap to guide strategic thinking and planning, improve clinical trials design and identify where to focus with emerging technologies

**Ana Nunez** - Drexel University College of Medicine

- Founded Women's Health Education Program in 1993 to include sex and gender issues across all levels of training
- Designated an OWH Center of Excellence in Women's Health in 1996
- Ujima Initiative – Mind Body Spirit Health Grant, 5 organizations to start – now 26
- Conduct participatory research - Coalition for a Healthier Community (CHC) grantee
- Collaboration with Drexel – goal to engage university to focus on technological innovation

- Oversee pipeline programs, focus on social media, hosting 4<sup>th</sup> annual social media leadership institute; mentorship program focused on working with youth to create projects

**Beth Sefton (presenting for Teresa Woodruff)** – Northwestern

- Research to develop 3-D micro-dynamic models of the reproductive system to pave the way for important discoveries, such as the following:
- Engineering three dimensional culture platforms– reproductive track
- Better understanding sex-based differences in response to drugs and environmental exposures
- Improving fertility treatment, including oncofertility for reproductive issues related to cancer treatment
- Determining response to hormones and endocrine-disrupting chemicals, particularly for vulnerable populations
- Providing a human correlate for drug development, especially for medications given to pregnant women
- Advancing predictive toxicology and disease prevention
- Focusing on implications for precision medicine
- Female and male models FemKUBE and DudeKUBE; pregnancy model in development – PregoKUBE
- Developing reusable platforms to answer multiple scientific questions

**Janet Pregler** – UCLA/Iris Cantor UCLA Women’s Health Center

- Oversee comprehensive women’s health center; community outreach, working closely with LA County’s Office of Women’s Health – working on issues related to women’s health and the environment
- Also involved in financial education project partnering with the Federal Reserve
- Executive Advisory Board – Iris Cantor – UCLA Women’s Health Center established in 2004 through donor support
- Pilot research funding program, looking at gender differences in research
- Research needs to be done across the spectrum, basic concepts and above; research needs not recognized across the government
- Key issue: funding translational research, funding for basic questions – lack of funders
- Pilot projects- money raised from philanthropists, research funded across the spectrum
- Addressing traditional funding barriers- direct and indirect costs, fund salaries
- Attracted senior researchers and new professionals who are particularly interested in women’s health and sex/gender-based research

**Michelle Berlin** – Sex and Gender Women’s Health Collaborative

- Established to meet a need to understand sex and gender-based differences in health
- Host many resources on website including a practitioner database of professionals with a particular interest in sex and gender-based issues

- Organizing member of the Sex and Gender Medical Education Summit, along with the Laura Bush Institute, Mayo Clinic and Society for Women's Health Research
- Working to evaluate existing resources to develop a toolkit for incorporation of sex and gender competencies in research
- Exploring several socio-economic factors as they relate to the area of precision medicine

**Janine Clayton** – NIH, Office of Research of Women's Health

- New inclusion policy released June 2015 to focus on animal and pre-clinical studies
- History - office founded by the Congressional Women's Caucus and women's health advocacy community
- Over 50% of participants in NIH supported research are women
- Highlight transparency throughout the research process by enhancing reporting
- Sex/gender-based factors in research still being overlooked
- Focusing on women in science – looking at occupational barriers, norms
- Moving forward – focusing on a broad policy by working through interpretation of inclusion policy across the scientific community

**Paul Underwood** – Boston Scientific, Close the Gap

- Focusing on coronary artery diseases at Boston Scientific
- Boston Scientific's Close the Gap Initiative focuses on women and minorities with a broad cardiology focus
- Diversity is a core value of Boston Scientific
- Focusing efforts into three categories: Emerging Markets, Clinical Trials, Communication
- Emerging Markets: coronary artery disease prevalence model; coronary interventions may be over utilized, but underutilized in women; outreach related to cardiovascular disease, using research to inform community that women and men are treated differently
- Clinical Trials: lopsided participation for typical enrollment; move to have participation reflect consumer community; working to get a better mix of patients - looking specifically at women and minorities; collecting social and economic data to examine influence on care and geographic data exploring unique recruitment strategies to determine what can be done to enroll more women
- Communications: targeting diverse groups, working to disseminate information and improve outreach

**Nancy Lee** – HHS, Office on Women's Health

- Congressionally mandated office established in 1991, within the Office of the Secretary
- Provide expertise to the Secretary and the White House
- Collaborating across the Department of Health and Human Services and with other stakeholders to promote women's health
- Primary focus areas include: Policy, Education, Model Programs
- Policy-ocusing on federal and community policies

- Education of health professionals and women-host [Womenshealth.gov](http://Womenshealth.gov) which contains consumer health content, [Girlshealth.gov](http://Girlshealth.gov) which targets girls 16 and under, outreach through social media such as Twitter, Facebook, Pinterest to distribute government health resources; oversee ProfEd, evidence-based education
- Model Programs-supporting public health and community-based research, particular focus areas include violence against women and health issues across the lifespan

**Janet Rich-Edwards** – Harvard/Brigham and Women’s Hospital- Connor Center

- Improving the health of women by transforming their care through enhanced patient services and the education and support for leaders of change
- Policy focus evaluates how Massachusetts health care policy have affected health by gender
  - Stress the importance of the inclusion of women in research including the evaluation of factors in early life which affect women’s health
  - Explore connection between woman’s pregnancy history and the incidence of cardiovascular disease. *Heart Health for Moms* initiative was developed from input based on women’s experiences in the 1<sup>st</sup> post-partum year
    - A lifestyle modification program focused on women and their families that is web-based, includes mobile (texting and mobile-friendly website) component and community board
  - Women’s experiences of violence, both sexual and emotional, especially early in life are often predictive of classic chronic diseases
    - Working on app to engage women more with their primary healthcare providers by allowing them to disclose their life history of violence while deciding if they want to talk to a clinician and explore potential links with their other conditions

**Kim Templeton** – American Association for Orthopedic Surgeons

- Convened over 100 patient and professional organizations including medical schools to focus on pediatric and adult bone health and trauma requiring the use of data as a cornerstone for the project
- This led to the publication of *Burden of Musculoskeletal Conditions in the U.S.* which represents the first time sex and gender data has been collated in this fashion
- The sex and gender chapter in this report went live in May 2015, and it has more responses to it than any other chapter
  - Next steps include creating slide sets for each chapter to be used in medical schools and beyond, using the chapter as a platform to gain attention for sex and gender-based differences in the musculoskeletal realm, and identifying venues for publication and gaps in research

Saralyn Mark then shared comments from some industry participants who were unable to attend in person due to medical emergencies including information from a recent survey conducted by J and B Medical Supply (see submission).

## BREAK

Saralyn Mark reconvened the discussion by asking the following question: “How do we share and translate the accomplishments that we have just highlighted with the public to encourage more innovation?”

### Discussion:

- Several presenters described the difficulties surrounding the terms “sex” and “gender.” A majority felt that it was important to have those conversations, but that “gender is what gets you to the “operating table” while sex is what determines what is done on the “operating table”
  - Other speakers mentioned that delineating what is gender versus sex-based had become “an unnecessary roadblock”
  - Janine Clayton stressed the importance of using the same language among scientists and policy makers in the federal government
- Saralyn Mark then asked, “If the impact of gender/sex for precision medicine will make a difference for medical devices?”
  - Paul Underwood: “Yes, if you have something that fits the body of a woman it’s going to make a difference.”
  - Kim Templeton: “Anatomic characteristics of the knee make the difference, not the type of knee.”
    - Example: certain kinds of knees with angles that are different than those of conventional male-oriented knees are marketed directly and solely to women. Men with smaller dimensions might be able to benefit from having these knees, but the knees are not marketed to them.
    - Another example of the opposite: companies are trying to produce sex-specific hips; however, there is no sex-related difference between the hips of men and women
  - Janine Clayton commented that the iGIANT program may need to address whether something is legitimate or not in these particular situations. “It is important to explain when sex matters and when it does not because marketing ploys will unnecessarily harm women.”
    - Janet Pregler: “It s government’s job to say when sex-specific devices are beneficial and when they are not as you cannot expect consumers to know what knee is best for them.”
      - As an observation, Paul Underwood shared that in case of the knee example used by Kim Templeton, manufacturers could have just have easily labeled the knees “Knee A” and “Knee B” but chose to label one as made for women as a marketing tool
      - He also pointed out that we are a nation with poor scientific literacy which hinders discussion.

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Saralyn Mark outlined what roundtable participants can do as ambassadors to contribute to the iGIANT effort including hosting and participating in future roundtables, writing articles and blogs and speaking about the impact of gender/sex on innovation and novel technologies.

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