Activity Outline
FDA Drug Topics: Across the Regulatory, Research, and Clinical Care Environments: Sex and Gender Influences
April 23, 2019
FDA/webinar

Activity Coordinator
Lesley Navin
Lesley.Navin@fda.hhs.gov

Series Description

This series of educational webinars is designed to aid physicians, physician assistants, nurses, pharmacists, pharmacy technicians, students, and other healthcare professionals, to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety.

Lecture Description
This webinar will provide an overview of current regulatory practice regarding the consideration of sex differences, the importance of the Sex as a Biological Variable (SABV) initiative, and future opportunities to further integrate SABV through collaboration in regulatory, research, and clinical care environments. A brief overview of the regulatory history of the inclusion of women in research activities and clinical trials will be provided.

References

- Ouyang, Pamela et al. “Strategies and methods to study female-specific cardiovascular health and disease: a guide for clinical scientists” Biology of sex differences vol. 7 19. 31 Mar. 2016, doi:10.1186/s13293-016-0073-y
- Institute of Medicine (US) Committee on Understanding the Biology of Sex and Gender Differences; Wizemann TM, Pardue ML, editors. Exploring the Biological Contributions to Human Health: Does Sex Matter? Washington (DC): National Academies Press (US); 2001. Available from: https://www.ncbi.nlm.nih.gov/books/NBK222288/ doi: 10.17226/10028
- Participation of Women in Clinical Trials Supporting FDA Approval of Cardiovascular Drugs Pamela E. Scott, Ellis F. Unger, Marjorie R. Jenkins, Mary Ross Southworth, Tzu-Yun McDowell, Ruth J. Geller, Merina Elahi, Robert J. Temple, Janet Woodcock Journal of the American College of Cardiology May 2018, 71 (18) 1960-1969; DOI: 10.1016/j.jacc.2018.02.070

Series Objectives

- Explain how to utilize FDA's Drug Information, medication safety resources, and regulatory guidances to improve delivery of patient care and optimize outcomes.
- Describe and inform health care providers of recent labeling, policy and regulatory changes which would impact prescribing and medication management to optimize patient care.

Learning Objectives After completion of this activity, the participant will be able to:

- Review the role of the Office of Women’s Health internal and external to FDA
- Recognize the integration of SABV into and its role within the regulatory environment
- Identify future areas for collaboration and funding opportunities to expand and disseminate SABV

Target Audience
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, and students other healthcare professionals.

Agenda

Lecture 1 April 23, 2019

Time	Topic	Speaker
1:00 - 2:00 PM	Across the Regulatory, Research, and Clinical Care Environments: Sex and Gender Influences	Erin South, PharmD MAJORIE JENKINS, MD MEdHP

Continuing Education Accreditation

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-19-020-L04-P, and ACPE Universal Activity Number JA0002895-0000-19-020-L04-T for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

AAPA

PA AAPA CATEGORY 1 CME

This activity is designated for 1.00 AAPA Category 1 CME credits. FDA Center for Drug Evaluation and Research has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. PAs should only claim credit commensurate with the extent of their participation.

CPH

Up to 1.00 CPH Recertification Credits may be earned at this event.

Requirements for Receiving CE Credit

Physicians, physician assistants, pharmacists, nurses, pharmacist techs, and those claiming non-physician CME:participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians, physician assistants, and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- JENKINS, MAJORIE, MD MEdHP, Director of Medical Initiatives, US FDA OWH - nothing to disclose
- South, Erin, PharmD, Pharmacist, FDA *My spouse and I received Salary from CVS Health for a role as Employee. My spouse received Stocks from CVS Health for a role as Employee.*

Planning Committee

- Burke, Kara, PharmD, Team Leader/Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- Cao, Christian, MPAS, PA-C, Safety Evaluator Team Leader, FDA/CDER/OSE/DPV - nothing to disclose
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Navin, Lesley, RN, MSN, Consumer Safety Officer, FDA/CDER/DDI - nothing to disclose
- Weinstein, Edward, M.D., Ph.D., Medical Officer, CDER FDA *My spouse received Salary from EndoCentre of Baltimore for a role as Employee.*

CE Consultation and Accreditation Team

- Lisa Thompson, MSHA, MBA, CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.