Activity Outline
Topics in Public Health: Demonstrating Substitutability Between Generic and Brand Narrow Therapeutic Index Drug Products
March 17, 2023

Activity Coordinators:
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Series Description
This series will educate PHS health professionals about topics that are pertinent to their roles within the various agencies within the Department of Health and Human Services and other Public Health Service agencies by presenting topics that directly relate to the HHS Strategic Plan, the Secretary's Strategic Initiatives, current topics for DHHS OPDIVs who utilize PHS health professionals, and/or other topics directly related to the advancement of public health.

Lecture Description
Two recently completed studies comprised of more than 51,000 patients demonstrate the comparability of treatment outcomes for generic vs. brand narrow therapeutic index (NTI) drug products, one in patients with hypothyroidism treated with generic and brand-name levothyroxine products and another in a senior population (≥65 years of age) treated with generic and brand warfarin. These studies provide real-world evidence to support public confidence in the generic NTI drugs and the FDA generic drug program.

References

- Brito JP, Ross JS, et al. Comparative Effectiveness of Generic vs Brand-Name Levothyroxine in Achieving Normal Thyrotropin Levels. JAMA Network Open. 2020;3(9):e2017645. doi:10.1001/jamanetworkopen.2020.17645
- Desai RJ, Gopalakrishnan C, et al. Comparative Outcomes of Treatment Initiation with Brand vs. Generic Warfarin in Older Patients. Clin. Pharmacol. Ther. 107, 1334 – 1342 (2020).
- CDER FY2020 GDUFA Science and Research Report: Patient Substitution of Generic Drugs. U.S. Food and Drug Administration. January 2021.

Series Objectives

- Increase awareness of current topics in public health
- Help improve patient/public health outcomes
- Help participants modify their practice within their job or deployments

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

- Evaluate substitutability of Narrow Therapeutic Index (NTI) generic drug products
- Examine clinical studies of substitution in patients and analyze medical informatics data
- Discuss patient and provider perceptions impacting generic substitution

Target Audience
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, This activity is intended for physicians, pharmacists, nurses, and other public health medical professionals interested in learning more about the initiatives other advances in public health..

Agenda

Lecture 1 March 17, 2023

Time	Topic	Speaker
2:00 - 3:00 PM EDT	Demonstrating Substitutability Between Generic and Brand Narrow Therapeutic Index Drug Products	Daniil Marchuk, PharmD, BCPS, PMP Trang Tran, PharmD, MBA, BCPS

Continuing Education Accreditation

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.

This activity was planned by and for the healthcare team, and learners will receive 1 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 JA0002895-0000-23-016-L99-P, and ACPE Universal Activity Number JA0002895-0000-23-016-L99-T for 1.00 contact hour(s).

CNE

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

CPH

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

Requirements for Receiving CE Credit
Physicians, 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 (https://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.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

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 and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Marchuk, Daniil, PharmD, BCPS, PMP, Senior Regulatory Project Manager, FDA - nothing to disclose
- Tran, Trang, PharmD, MBA, BCPS, Senior Regulatory Health Project Manager, FDA - nothing to disclose

Planning Committee

- BIRCH-SMITH, POSTELLE, PharmD, Lead CSO, FDA - nothing to disclose
- Brodhead, LeAnn, PharmD, Health Insurance Specialist, CMS - nothing to disclose
- Herber, Kari, RN, Regional Program Manager, Department of Homeland Security - nothing to disclose
- Janusziewicz, Ashlee, Pharm.D, Compounding Incidents Team Leader, FDA/CDER/OC/OUDLC - nothing to disclose
- La, Thang, PharmD, MPH, Central Triage Unit Manager, FDA/CDER/OSE/RSS - nothing to disclose
- McClain, Rena, PharmD, Health Insurance Specialist, CMS - nothing to disclose
- Nabavian, Sadaf, Senior Regulatory Project Manager, FDA - nothing to disclose
- Radden, Erica, MD, Medical Officer, USPHS/DHS/USCG - nothing to disclose

CE Consultation and Accreditation Team

- Catherine Harrison, CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Any relationship shown above in italics has been divested within the last 24 months and is therefore considered mitigated.
All relevant financial relationships have been mitigated.

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

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