Activity Outline
FDA Grand Rounds: Development and Testing of Warnings for Tobacco Products: Scientific and Regulatory Considerations
January 13, 2022
Virtual

Activity Coordinator:
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Series Description

The FDA Grand Rounds is webcast monthly to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Lecture Description
Warnings inform consumers about risks and are required on many FDA-regulated products. They are especially important for products which have inherent and unavoidable risks associated with their use, such as tobacco products. This presentation will discuss the current regulatory landscape of tobacco product warnings through CTP's authority. We will examine the development and testing of warnings for cigarettes that resulted in the March 2020 final rule "Required Warnings for Cigarette Packages and Advertisements" with a focus on the scientific and regulatory considerations that went into that research and development plan for those warnings.

References

- Pepper JK, Zarndt AN, Eggers ME, Nonnemaker JM, Portnoy DB. Impact of Pictorial Cigarette Warnings Compared With Surgeon General's Warnings on Understanding of the Negative Health Consequences of Smoking. Nicotine Tob Res. 2020; 22: 1795-1804.
- Pepper JK, Zarndt AN, Eggers ME, Nonnemaker JM, Portnoy DB. Influence of Warning Statements on Understanding of the Negative Health Consequences of Smoking. Nicotine Tob Res. 2020; 22: 1805-1815.
- Strahan EJ, White K, Fong GT, et al. Enhancing the Effectiveness of Tobacco Package Warning Labels: A Social Psychological Perspective. Tob Control. 2002;11(3):183-190

Series Objectives

- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

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

- Recognize the scientific and regulatory issues considered by the FDA in developing new cigarette health warnings.
- Discuss the steps in the research process used to develop, test, and refine the new cigarette health warnings.
- Examine the requirements for the new cigarette health warnings final rule and its current status.

Target Audience
This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 January 13, 2022

Time	Topic	Speaker
12:00 - 1:00 PM	Development and Testing of Warnings for Tobacco Products: Scientific and Regulatory Considerations	David Portnoy, PhD, MPH

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 UAN JA0002895-0000-22-006-L04-P for 1.00 contact hour(s).

CNE

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

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, 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.

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

- Portnoy, David, PhD, MPH, Branch Chief, CTP - *nothing to disclose*

Planning Committee

- Dinatale, Miriam, Team Leader, Food and Drug Administration - *nothing to disclose*
- Pfundt, Tiffany, PharmD, Senior Advisor, HHS/ASPR - *nothing to disclose*
- Wheelock, Leslie, RN, MS, Director, OSPD, FDA, OC, OCS, OSPD - *nothing to disclose*

CE Consultation and Accreditation Team

- Bueide, Rachel E., MPhil, Training Specialist, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

All of the relevant financial relationships listed for these individuals have been mitigated.

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