Activity Outline
FDA Grand Rounds: Assessment of Safety and Efficacy of Fecal Microbiota for Transplantation products
December 10, 2020
Virtual

Activity Coordinator:
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Series Description

The FDA Grand Rounds is webcast every other month 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
Fecal Microbiota Transplantation (FMT) is a novel treatment being assessed for use in the treatment of many, highly diverse conditions ranging from infections to inflammatory bowel diseases and even neurological disorders. FMT has been well studied for the treatment of recurrent Clostridium difficile infections, however questions remain regarding the safety and efficacy of this therapy. This presentation will cover our efforts to advance our understanding of both safety of these products and the mechanisms of action of FMT against C. difficile and to identify novel markers of efficacy and potency for this class of biologics. Using a mouse model that exhibits significant resistance to C. difficile due to its microbiota composition, we have identified a genetic pathway that is potentially involved in protection against this infection. Additionally, we have been working to understand the impact of the COVID-19 pandemic on this class of products as SARS-CoV-2 viral RNA has been detected in stool. Detail of these efforts, including development and validation of a SARS-CoV-2 stool test, assessment of clinical stool samples and preliminary animal studies will be discussed along with the impact of this work and the pandemic overall on the safety and availability of FMT products.

References

- Microbiota of MR1 deficient mice confer resistance against Clostridium difficile infection - https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0223025
- Regulatory considerations for Fecal Microbiota Transplantation Products - https://www.sciencedirect.com/science/article/pii/S1931312820300573?via%3Dihub

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:

- Discuss the use of Fecal Microbiota Transplantation as treatment for various disorders
- Discuss FDA's efforts to advance safety and markers of efficacy for this class of biologics
- Discuss the development and validation of SARS-COV-2 stool test

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

Agenda

Lecture 1 December 10, 2020

Time	Topic	Speaker
12:00 - 1:00 PM	Assessment of Safety and Efficacy of Fecal Microbiota for Transplantation products	Paul Carlson, PhD

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 JA0002895-0000-20-022-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 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Carlson, Paul, PhD, Biologist/Principal Investigator, FDA/CBER - nothing to disclose

Planning Committee

- Dinatale, Miriam, Team Leader, Food and Drug Administration - nothing to disclose
- Pfundt, Tiffany, PharmD, Pharmacist, FDA - nothing to disclose
- Thomas, Devin, LCDR, MPH, CHES, Health Promotions Specialist, FDA/OC/OCS/OSPD - nothing to disclose
- Wheelock, Leslie, RN, MS, RN, Director, OSPD, FDA, OC, OCS, OSPD - nothing to disclose

CE Consultation and Accreditation Team

- Bryant, Traci, M.A.T., CE Consultant, 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.