

D. Cardiovascular and Renal Drugs Advisory Committee

Reviews and evaluates available data on the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders.

E. Dermatologic and Ophthalmic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

F. Drug Safety and Risk Management Advisory Committee

Reviews and evaluates information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use.

G. Endocrinologic and Metabolic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders.

H. Gastrointestinal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases.

I. Medical Imaging Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

J. Nonprescription Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

K. Obstetrics, Reproductive and Urologic Drugs Advisory Committee (Formerly Bone, Reproductive and Urologic Drugs Advisory Committee)

Reviews and evaluates available data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of

obstetrics, gynecology, urology and related specialties.

L. Oncologic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer.

M. Peripheral and Central Nervous System Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

N. Pharmaceutical Science and Clinical Pharmacology Advisory Committee

Reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases.

O. Pharmacy Compounding Advisory Committee

Provides advice on scientific, technical, and medical issues concerning drug compounding.

P. Psychopharmacologic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

Q. Pulmonary-Allergy Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations and a list of all nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the

receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

FDA seeks to include the views of women, and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0198]

Mark Moffett; Conviction Reversal; Final Order Withdrawing Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), withdrawing its January 25, 2023, order debarring Mark Moffett from providing services in any capacity to a person with an approved or pending drug product

application. FDA is issuing this order because the U.S. Court of Appeals for the First Circuit vacated Mr. Moffett's convictions and sentence.

DATES: The order is applicable July 14, 2023.

FOR FURTHER INFORMATION CONTACT:

Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on January 25, 2023 (88 FR 4826), Mark Moffett was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262). The debarment was based on FDA's finding, under section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)), that Mr. Moffett had been convicted of a felony under Federal law for conduct relating to the regulation of any drug product.

Mr. Moffett appealed the judgment of the District Court, and on November 18, 2022, the U.S. Court of Appeals for the First Circuit issued a judgment vacating Mr. Moffett's convictions as to all counts. On January 26, 2023, Mr. Moffett petitioned FDA for withdrawal of his debarment, citing section 306(d)(3)(B)(i) of the FD&C Act. Pursuant to section 306(d)(3)(B)(i) of the FD&C Act, "If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) . . . is reversed, the Secretary shall withdraw the order of debarment."

FDA has concluded that because the U.S. Court of Appeals for the First Circuit vacated Mr. Moffett's convictions, the order of debarment must be withdrawn. Accordingly, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(d)(3)(B)(i) of the FD&C Act, under authority delegated to the Assistant Commissioner, is issuing this order withdrawing the order that permanently debarred Mark Moffett from providing services in any capacity to a person with an approved or pending drug product application.

Dated: July 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-14929 Filed 7-13-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) scheduled a public meeting to be held Thursday, August 10, 2023, and Friday, August 11, 2023. Information about ACHDNC and the agenda for this meeting can be found on ACHDNC's website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

DATES: Thursday, August 10, 2023, from 10:00 a.m. to 3:00 p.m. Eastern Time (ET) and Friday, August 11, 2023, from 10:00 a.m. to 2:00 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required. Persons wishing to register to attend the meeting can do so via this link: <https://achdncmeetings.org/registration/>. Registration closes at 12:00 p.m. ET on August 9, 2023. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT:

Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301-443-0721; or ACHDNC@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of

additional conditions for screening on the Recommended Uniform Screening Panel (RUSP), following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

During the August 10-11, 2023, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

- A presentation on health equity and newborn screening;
- An update on the Duchenne muscular dystrophy condition nomination and a potential vote on whether to move it forward to full evidence-based review, which, depending on the strength of the evidence, could lead to a future recommendation to add this condition to the RUSP;
- A presentation, discussion, and vote on an ACHDNC expedited review process for resubmitted condition nomination packages; and
- A potential presentation and vote on whether to consider Krabbe disease through the ACHDNC expedited review process described above.

The agenda for this meeting includes a potential vote on whether to recommend a nominated condition (Duchenne muscular dystrophy) to full evidence-based review. In addition, as noted in the agenda items, the Committee may hold a vote on whether to recommend a nominated condition (Krabbe disease) be considered through the ACHDNC expedited review process described above. Both votes may lead to a recommendation to add or not add these conditions to the RUSP at a future time.

Agenda items are subject to change as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website listed above.

Members of the public will have an opportunity to provide comments on any or all of the above agenda items. Public participants may request to