

The Chief Scientist has considered Dr. Fleming's arguments, as well as the proposal to deny Dr. Fleming's application for termination of debarment and concludes that there is no genuine and substantial issue of fact requiring a hearing. Further, the Chief Scientist finds that Dr. Fleming's application does not satisfy the grounds for terminating debarment.

II. Arguments

In his response to ORA's proposal to deny his request for termination, Dr. Fleming concedes that the convictions underlying his debarment pursuant to section 306(b)(2)(B)(ii)(I) of the FD&C Act have not been reversed. FDA could therefore only terminate his debarment under section 306(d)(3)(B) if the Agency determined that such termination would serve the interests of justice and adequately protect the integrity of the drug approval process. In the application to terminate his debarment, Dr. Fleming presented three reasons for terminating his debarment: (1) that he was effectively debarred in the period between when he was convicted of the two felony offenses on which his debarment was based and when FDA finalized his debarment; (2) that he has taken training courses related to billing and ethics; and (3) that he has taken steps to prevent future mistakes in billing and collecting data.

In proposing to deny Dr. Fleming's application to terminate his debarment, ORA weighed the seriousness and nature of the offenses that led to his debarment, including his culpability, against his statements regarding other mitigating factors. After accounting for his assertions that he had effectively been debarred since his original convictions, ORA found that Dr. Fleming had not established that terminating his debarment would serve the interests of justice or adequately protect the integrity of the drug approval process. In his request for a hearing on ORA's proposal, Dr. Fleming repeats some of the arguments from his application for termination of debarment and provides some additional context related to his own views on drug regulation, the criminal justice system, and other ethical considerations. He further clarifies some of the corrective actions he has implemented with respect to patient billing.

As a preliminary matter, the Chief Scientist notes Dr. Fleming's request in his application for termination of debarment that FDA consider the time starting from when he was convicted in 2009 as "time served." Dr. Fleming contended that, because he was

convicted in 2009, "the effective period of debarment has been 12+ years." While Dr. Fleming does not renew this argument in his request for a hearing on ORA's proposal, the timing of when he was convicted, when ORA proposed his debarment, and when FDA finalized his debarment is not in dispute. Notwithstanding his arguments to the contrary, FDA did not debar Dr. Fleming until the Agency issued the final order debarring him in September 2018. Neither his convictions nor ORA's proposal to debar him started his debarment period pursuant to the Agency's authority under section 306(b)(2)(B)(ii)(I) of the FD&C Act. He thus cannot now argue that his ultimate debarment in September 2018 had any effect whatsoever on him before that time. The Chief Scientist therefore agrees with ORA that terminating his debarment on that basis would not serve the interests of justice or adequately protect the integrity of the drug approval process.

The Chief Scientist further agrees with ORA that Dr. Fleming has not shown that terminating his debarment would serve the interests of justice or adequately protect the drug approval process—even in light of the additional assertions and arguments proffered in support of his hearing request on ORA's proposal. Both offenses underlying his debarment are felony fraud convictions related to the regulation of drugs. As noted in ORA's proposal to deny Dr. Fleming's application for termination, the pattern of fraudulent conduct on which his convictions were based calls into question his ability to comply with the FD&C Act and indicates that he poses a threat to the drug approval process if he were allowed to participate in it. In light of the conduct underlying the convictions on which Dr. Fleming's debarment was based, his assertions that he has taken some courses and adopted corrective measures relative to billing patients and collecting data do not come close to showing that terminating his debarment would serve the interests of justice and adequately protect the drug approval process in the sense contemplated by section 306(d)(3)(B)(ii). Dr. Fleming has thus presented no material factual dispute for a hearing on ORA's proposal to deny the application to terminate his debarment.

III. Conclusion

Therefore, the Chief Scientist, under authority delegated to her, denies Dr. Fleming's application for termination of debarment under section 306(d) of the FD&C Act. A hearing on this request is not necessary because there are no

genuine and substantial issues of fact (see § 12.24(b)).

Any person with an approved or pending drug product application who knowingly uses the services of Dr. Fleming, in any capacity during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Fleming provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Fleming during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: February 22, 2023.

Namandjé N. Bumpus,

Chief Scientist.

[FR Doc. 2023-04003 Filed 2-27-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

The meeting will be open to the public for virtual viewing via NIH Videocast. Advanced registration is recommended. Individuals who plan to attend the meeting virtually and need special assistance or other reasonable accommodations to virtually view the meeting should notify the Contact Person listed below at least seven (7) business days in advance of the meeting. The open session can be accessed from the NIH Videocast website (<http://videocast.nih.gov/>).

Name of Committee: Interagency Autism Coordinating Committee.

Date: April 4, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Meeting Access: <https://videocast.nih.gov/watch=49068>.

Agenda: To discuss business, updates, and issues related to ASD research and services activities.

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (www.iacc.hhs.gov) prior to the meeting. Pre-registration is recommended.

Deadlines: Written/Virtual Public Comment Due *Date:* Wednesday, March 22,

2023, by 5:00 p.m. ET Public Comment Guidelines.

For public comment instructions, see below.

Contact Person: Ms. Rebecca Martin, Office of Autism Research Coordination, National Institute of Mental Health, NIH, Phone: 301-435-0886, *Email:* IACCPublicInquiries@mail.nih.gov.

Public Comments

The IACC welcomes written and oral public comments from members of the autism community and asks the community to review and adhere to its Public Comment Guidelines. In the 2016–2017 IACC Strategic Plan, the IACC listed the “Spirit of Collaboration” as one of its core values, stating that, “We will treat others with respect, listen with open minds to the diverse views of people on the autism spectrum and their families, thoughtfully consider community input, and foster discussions where participants can comfortably offer opposing opinions.” In keeping with this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also adhere to this core value.

A limited number of slots are available for individuals to provide a ~3-minute summary or excerpt of their written comment to the Committee during the meeting. For those interested in that opportunity, please indicate “Interested in providing oral comment” in your written submission, along with your name, address, email, phone number, and professional/organizational affiliation so that OARC staff can contact you if a slot is available for you to provide a summary or excerpt of your comment during the meeting.

For any given meeting, priority for comment slots will be given to individuals and organizations that have not previously provided comments in the current calendar year. This will help ensure that as many individuals and organizations as possible have an opportunity to share comments. Commenters going over their allotted 3-minute slot may be asked to conclude immediately in order to allow other comments and the rest of the meeting to proceed on schedule.

Public comment submissions received by 5:00 p.m. ET on Wednesday, March 22, 2023, will be provided to the Committee prior to the meeting for their consideration. Any written comments received after 5:00 p.m. ET, Wednesday, March 22, 2023, may be provided to the Committee either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. The Committee is not able to respond individually to comments. All public comments become part of the public record. Attachments of copyrighted publications are not permitted, but web links or citations for any copyrighted works cited may be provided. For public comment guidelines, see: <https://iacc.hhs.gov/meetings/public-comments/guidelines/>.

Technical Issues

If you experience any technical problems with the webcast, please email IACCPublicInquiries@mail.nih.gov.

Disability Accommodations

All IACC Full Committee Meetings provide Closed Captioning through the NIH videocast website. Individuals whose full participation in the meeting will require special accommodations (e.g., sign language or interpreting services, etc.) must submit a request to the Contact Person listed on the notice at least seven (7) business days prior to the meeting. Such requests should include a detailed description of the accommodation needed and a way for the IACC to contact the requester if more information is needed to fill the request. Special requests should be made at least seven (7) business days prior to the meeting; last-minute requests may be made but may not be possible to accommodate.

Additional Information

Information about the IACC is available on the website: <http://www.iacc.hhs.gov>.

Dated: February 22, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-04060 Filed 2-27-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; AD/ADRD Digital Neuropathological Platforms for Advanced Analytics (U24) Review.

Date: March 17, 2023.

Time: 11:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Mir Ahamed Hossain, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, mirahamed.hossain@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: February 22, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-04062 Filed 2-27-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Molecular Dynamics of HIV (R01 Clinical Trial Not Allowed).

Date: April 6–7, 2023.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G34, Rockville, MD 20892, (Virtual Meeting).

Contact Person: Vishakha Sharma, Ph.D., Scientific Review Officer, Scientific Review Program Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G34, Rockville, MD 20852, 301-761-7036, vishakha.sharma@nih.gov.