

the timeliness, frequency, quality, and efficiency of interactions with and written feedback from FDA; (c) participant satisfaction with the timeliness, frequency, quality, and efficiency of voluntary interactions with non-FDA stakeholders facilitated by FDA (if utilized); and (d) an overall assessment of the outcomes of the Pilot and opportunities for improvement (Ref. 1).

## II. Request for Comments

FDA understands that to make this program the most effective, we will need additional feedback and suggestions from industry and other stakeholders. FDA encourages all stakeholders to comment on the TAP Pilot generally. The Agency is particularly interested in feedback on the following topics:

1. TAP Pilot participation will expand to include additional Offices of Health Technology (OHTs) in FY 2024 through FY 2027. In what order do you believe additional OHTs should be included in the TAP Pilot? Please provide the reasons/rationale/justification to support your recommendations in your response.

2. The TAP Pilot is intended to facilitate improved strategic decision-making and better align expectations regarding evidence generation during device development, including through facilitating interactions between TAP participants and stakeholders, such as patients, providers, and payers. These interactions are voluntary and may, for example, help provide a better understanding of the current treatment options used to treat or manage a given condition, which outcomes are most important to patients and providers, how a new technology may fit into clinical care paradigms and patient lives, how patients and providers consider tradeoffs between anticipated benefits and risks, and the evidence that may help support clinical adoption and coverage.

(1) What additional questions or topics could patients, providers, and/or payers address that could help inform sponsors' strategic decision-making?

(2) Are there specific patient, provider, or payer organizations whose members may be well-suited and willing to provide insights regarding evidence generation strategies to sponsors who wish to obtain such input?

## III. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information. These collections of information are subject to review by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information regarding Q-Submissions have been approved under OMB control number 0910–0756.

## IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. U.S. Food and Drug Administration, "MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027," available at <https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v>.
2. U.S. Food and Drug Administration, "Breakthrough Devices Program," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program>.
3. U.S. Food and Drug Administration, "Safer Technologies Program for Medical Devices," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices>.
4. U.S. Food and Drug Administration, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>.
5. U.S. Food and Drug Administration, "Total Product Life Cycle Advisory Program (TAP)," available at <https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap/>.

Dated: October 3, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 National Advisory Child Health and Human Development Council Stillbirth Working Group.

The meeting will be open to the public as indicated below. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The session will be videocast and can be accessed from the NIH Videocasting website (<http://videocast.nih.gov/>).

*Name of Committee:* National Advisory Child Health and Human Development Council; Stillbirth Working Group.

*Date:* October 20, 2022.

*Time:* 1:30 p.m. to 5 p.m.

*Agenda:* The NICHD Stillbirth Working Group of Council (Working Group) is charged with providing a report to the National Advisory Child Health and Human Development Council focusing on the current barriers to collecting data on stillbirths throughout the United States, communities at higher risk of stillbirth, the psychological impact and treatment for mothers following stillbirth, and known risk factors for stillbirth.

*Place:* Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892–7510 (Virtual Meeting).

*Contact Person:* Dr. Natasha H. Williams, Branch Chief, Office of Legislation and Public Policy, *Eunice Kennedy Shriver National Institute of Child Health and Human Development*, NIH, 6710B Rockledge Drive, [natasha.williams2@nih.gov](mailto:natasha.williams2@nih.gov), Bethesda, MD 20892–7510, (240) 551–4985.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <https://www.nichd.nih.gov/about/advisory>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS.)

Dated: October 5, 2022.

**David W. Freeman,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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