rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. This notice would not impose a mandate that will result in the expenditure by state, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $183 million in any 1 year.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This notice will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have federalism implications.

G. Congressional Review

This notice is subject to the Congressional Review Act and has been transmitted to the Congress and the Government Accountability Office's Comptroller General for review.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 31, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–26473 Filed 11–8–24; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4815]

Patient-Focused Drug Development: Workshop To Discuss Methodologic and Other Challenges Related to Patient Experience Data; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public workshop entitled ''Patient-Focused Drug Development: Workshop to Discuss Methodologic and Other Challenges Related to Patient Experience Data.'' The purpose of the public workshop is to discuss methodological challenges related to patient experience data, and other areas of greatest interest or concern to public stakeholders.

DATES: The public workshop will be held virtually on December 13, 2024, from 10 a.m. to 5 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by February 11, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom platform.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 11, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–4815 for ''Patient-Focused Drug Development: Workshop to Discuss Methodologic and Other Challenges Related to Patient Experience Data.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993, 301–796–8112, *Ethan.Gabbour@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Under the seventh iteration of the Prescription Drug User Fee Act, incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development and, as appropriate, regulatory decision making. This included issuing a Request for Information (RFI) available at *https://www.federalregister.gov/documents/2023/05/02/2023-09265/methodological-challenges-related-to-patient-experience-data-request-for-information-and-comments* to elicit public input on methodologic challenges related to patient experience data, and other areas of greatest interest or concern to public stakeholders.[1] The RFI was published on May 2, 2023, and the public comment period was open until July 3, 2023. A summary of the comments was published on December 12, 2023, and is available at *https://www.regulations.gov* by entering the following docket number: FDA–2023–N–1506. The input received in response to the RFI helped inform the topics for this public workshop. This public workshop together with the input received in response to the RFI will also help inform a subsequent workshop focused on methodological challenges and will help FDA identify priorities for future work.

II. Topics for Discussion at the Public Workshop

The purpose of this virtual public workshop is to highlight and discuss methodological issues related to patient experience data, including the submission and evaluation of patient experience data in the context of the benefit-risk assessment and product labeling, as well as other areas of greatest interest or concern to stakeholders. This workshop will explore the different types of patient experience data and how FDA utilizes such data for regulatory decision-making, along with considerations for submitting patient experience data to FDA. In addition, this workshop will feature presentations and panel discussions with experts on selected methodologies and the challenges and opportunities they present.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://fda.zoomgov.com/webinar/register/WN_Jb5xMhbVS1-wYhLn6fwMng#/registration*. Please provide complete contact information for each attendee, including name, organization, email, and affiliation.

Registration is free and persons interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact *Ethan.Gabbour@fda.hhs.gov* no later than December 6, 2024. Closed captioning will be available.

Dated: November 6, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26399 Filed 11–13–24; 8:45 am]

BILLING CODE 4164–01–P

[1] The Federal Food, Drug, and Cosmetic Act, as amended by the 21st Century Cures Act (Pub. L. 114–255) and the FDA Reauthorization Act of 2017 (Pub. L. 115–52), defines patient experience data as data that are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers and drug manufacturers) and are intended to provide information about patients' experiences with a disease or condition, including the impact (including physical and psychosocial impacts) of such disease or condition or a related therapy or clinical investigation and patient preferences with respect to treatment of the disease or condition.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for Licensing or Collaboration: Single Source-Detector Separation Approach To Calculate Tissue Oxygen Saturation

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Child Health and Human Development (NICHD), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of the licensing or collaboration opportunities for the inventions listed below, which are owned by an agency of the U.S. Government and are available for licensing and collaboration to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Inquiries related to these licensing or collaboration opportunities should be directed to: Zarpheen Jinnah, Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: *zarpheen.jinnah@nih.gov* or Phone: 240–620–0586.

SUPPLEMENTARY INFORMATION: Tissue oxygen saturation (StO2) is an important parameter to assess oxygen delivery and uptake. Hypoxia, a term used to indicate inadequate StO2, is often seen in patients with cardiac problems, respiratory infections or pulmonary diseases. Prolonged hypoxia can damage vital organs such as the brain, lungs, and heart and can be fatal. Currently available tissue oximeters to monitor StO2 are expensive and cumbersome.

NICHD has developed a novel method, which uses a single source-detector separation to calculate StO2. With this technique, a simple tissue oximeter can be made with just a LED and a photodetector, which enables the development of a miniaturized device. As a result, it can be used independently or implemented on existing technologies to measure StO2 without any hardware modifications. It can be applied in wearable devices, implantable medicines or endoscopies to measure tissue oxygenation in different tissues such as muscle, brain, spinal cord, internal organs, fetus and placenta.

This Notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404.

NIH Reference Number: E–037–2023–0.

Product Type: Device.

Therapeutic Area(s): Respiratory, Neurology or Cardiac.

Potential Commercial Applications:

- Miniaturized tissue oximeter for implantation or endoscopy.
- Measure tissue oxygen saturation.
- Multilayer tissue oximeter.

Competitive Advantages:

- Simpler and more compact as it only requires a single light source such as LED and a single photodetector such as a photodetector to build a tissue oximeter.
- Multilayer measurement.
- Implementation with existing technologies without any hardware modifications.

Publication: Nguyen, T., et al. Application of the Single Source—Detector Separation Algorithm in Wearable Neuroimaging Devices: A Step toward Miniaturized Biosensor for Hypoxia Detection. (*PMID 38671806*).