

December 18, 2023

Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

Re: Docket No. FDA-2023-N-3595

Dear Dr. Califf:

On behalf of Public Citizen and Public Citizen’s Health Research Group, I write to comment on a notice published in the *Federal Register* on October 18, 2023 entitled “Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification.”

The *Federal Register* notice states that the FDA is seeking comments on the proposed “collection of information” plan regarding its practicality, accuracy, quality, utility, clarity, and burden upon respondents. The notice further states that “FDA has a need for valid, high-quality surveillance data on the misuse of pharmaceutical products and other substances in the US.” Though the aim of enhancing the surveillance of substance misuse is worthy, the specifics of the notice are vague and concerning.

It is not clear what direct financial support is to flow from the FDA to the Researched Abuse, Diversion and Addiction-Related Surveillance program (RADARS), though the notice does state the effort is to be “FDA-funded” and further that the FDA will provide analytic expertise in support of the survey efforts. The notice also indicates that a contractor will conduct the proposed survey evaluations; however, it is not clear if this anticipated contractor refers to RADARS and its affiliates, or to non-conflicted third-party evaluators. Before this effort progresses further, these details should be publicly clarified.

We are concerned that the proposed data collection plan aims to use FDA resources to support RADARS, a drug abuse and dependence monitoring organization that has long been excessively influenced by Purdue Pharmaceuticals and other opioid manufacturers, at the expense of the public’s health. RADARS is an organization that was formed by Purdue Pharmaceuticals and has continued to support questionable lobbying efforts by the opioid industry.

RADARS is in Colorado. A complaint filed by the Colorado Attorney General against Purdue Pharmaceuticals and members of the Sackler family describes strong co-mingling between the organization's origins, governance and operations, and opioid manufacturer interests,¹ some of which remain evident today. For example, a review of the current RADARS eight-member scientific advisory board lists three medical doctors² all of whom received pharmaceutical payments exceeding \$1,100 in at least one year from 2016 through 2022.³ Two of those medical advisors each reported over \$580,000 in pharmaceutical industry financial support during that seven-year period.

We are concerned that RADARS seems to have been selected as a single-source beneficiary of this FDA research funding. Surprisingly, no other surveillance efforts are mentioned in the notice including those supported by the Substance Abuse and Mental Health Services Administration, National Institute of Drug Abuse, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality or the Drug Enforcement Administration.

Finally, the notice focuses narrowly on the collection of data from populations engaged in opioid treatment programs. This narrow focus ignores the reality that most people who need substance use disorder treatment do not receive it,⁴ and that many more people who otherwise have no history of abuse or dependence are exposed and sometimes poisoned by opioids.⁵ The narrow focus on those in opioid treatment draws directly from the cynical Purdue Pharmaceutical/Sackler family playbook.⁶ This playbook blames patients for their addiction and misuse, even though industry, the FDA and physicians share substantial responsibility for the iatrogenic origins of the opioid overdose epidemic.⁷

¹ State of Colorado v. Purdue Pharma et al. District Court, City and County of Denver Colorado. Filed: July 1, 2019. https://coag.gov/app/uploads/2019/07/2018CV33300_16_2019-08-20_FIRST_AMENDED_COMPLAINT_AND_JURY_DEMAND_5848790077512882290.pdf. Accessed December 17, 2023.

² RADARS System. About the Scientific Advisory Board. <https://www.radars.org/what-is-the-radars-system/about-the-scientific-advisory-board.html>. Accessed December 17, 2023.

³ Center for Medicare and Medicaid Services. Open Payments. <https://openpaymentsdata.cms.gov/>. Accessed December 17, 2023.

⁴ U.S. Department of Health and Human Services. Press Release: SAMHSA Announces National Survey on Drug Use and Health (NSDUH) Results Detailing Mental Illness and Substance Use Levels in 2021. January 4, 2023.

⁵ Kariisa M, Davis NL, Kumar S, et al. Vital signs: drug overdose deaths, by selected sociodemographic and social determinants of health characteristics - 25 states and the District of Columbia, 2019-2020. *MMWR Morb Mortal Wkly Rep*. 2022 Jul 22;71(29):940-947.

⁶ Posner G. "Pharma: Greed, lies and the poisoning of America." Avid Readers Press. New York, New York. 2020.

⁷ Agency for Healthcare Research and Quality. Opioid Safety. September 7, 2019.

<https://psnet.ahrq.gov/primer/opioid-safety#:~:text=Origins%20of%20the%20Opioid%20Epidemic&text=It%20now%20appears%20clear%20that,recognizing%20their%20potential%20for%20harm>. Accessed December 17, 2023.

We strongly encourage the FDA to publicly revise this research database development effort, so that there is no funding or direct collaboration with RADARS. Such industry engagement in this regulatory surveillance effort would be bad for public health.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael T. Abrams". The signature is fluid and cursive, with a large initial "M" and a long, sweeping tail.

Michael T. Abrams, M.P.H., Ph.D.
Senior Health Researcher
Public Citizen's Health Research Group