



January 18, 2024

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

Marta Sokolowska, Ph.D.  
Deputy Center Director for Substance Use and Behavioral Health  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20903

*Via email*

Subject: RADARS Data, Docket No. FDA-2023-N-3595

Dear Dr. Califf and Dr. Sokolowska:

We are writing in response to the letter submitted by Physicians for Responsible Opioid Prescribing (PROP, an anti-opioid, anti-pharma activist group) to Docket No. FDA-2023-N-3595 on December 14, 2023. The letter asks FDA to consider alternative sources for surveillance data on the misuse of pharmaceutical products instead of relying on the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) System.

The Center for U.S. Policy supports FDA's funding of the evaluation and improvement of RADARS surveillance data. Our organization's dual commitment to individualized health care and responsible controlled-medication prescribing, both of which must be informed by credible evidence, compels us to refute PROP's arguments against FDA's funding for and use of RADARS surveillance data.

PROP's letter contended that RADARS lacks independence. The RADARS System is the property of Denver Health and Hospital Authority, a political subdivision created by the Colorado legislature.<sup>1</sup> The Authority is governed by an eleven-member independent Board of Directors. RADARS is guided by an external Scientific Advisory Board (SAB), consisting of some of the best minds in substance misuse research. The SAB offers *guidance* on RADARS program development, result interpretation, and the future development of the surveillance system while the independent board of directors controls the Denver Health and Hospital Authority and its programs, including RADARS.<sup>2</sup>

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<sup>1</sup> RADARS System, *RADARS System Experts*, <https://www.radars.org/what-is-the-radars-system/radars-system-experts.html>; Denver Health, *About Us*, <https://www.denverhealth.org/about-denver-health>.

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

The anti-pharma group's letter also decried the RADARS System's receipt of subscription revenue from pharmaceutical manufacturers. Industry purchases of data and support for scientific research and evaluation are common practices in the medical-scientific community. As evidenced by the FDA's user fee system supporting the FDA's review of new drug applications, it is possible for a scientific evaluator to receive industry funding without being influenced into an improper *quid pro quo* arrangement. Industry-funded research is routinely subjected to rigorous scrutiny and oversight to ensure objectivity.

To that end, the scientific community relies on the peer-review process to maintain the credibility and validity of research outcomes and reports. The unbiased nature of research conducted by RADARS scientists is evident in the numerous RADARS articles published in peer-reviewed journals. Discrediting RADARS undermines the credibility of the journals accepting its research, casts doubt on the commitment of peer reviewers to uphold quality standards, and challenges the integrity of medical-scientific literature and evidence utilized by institutions like the FDA and CDC.

Our organization recognizes the substantial value that the RADARS System has contributed over the past two decades. Its extensive publications highlight its dedication to the exploration and examination of public health data. RADARS has consistently been at the forefront of identifying trends related to drug diversion, substance misuse, and addiction, preceding other research entities. This timely and pertinent information has proven instrumental in shaping public health policies, as well as prescriber and patient interventions.

In conclusion, the FDA should disregard PROP's feverish criticism of one of the most important sources of data in addressing substance misuse, substance use disorders, and drug poisonings. We thank you for acknowledging the integrity and valuing the contributions of independent, objective organizations, such as the Denver Health and Hospital Authority's RADARS System, which are essential to the advancement of public health research. We welcome the opportunity for further dialogue on this important issue.

Sincerely,

*Lynn Webster*

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