In Reply  We studied the US Food and Drug Administration’s (FDA’s) oversight and management of an industry-funded prescriber education program aimed at improving prescriber practices and reducing adverse events from use of prescription opioids.1 Five years into the Risk Evaluation and Mitigation Strategy (REMS) program governing extended release/long-acting (ER/LA) opioids, the FDA was unable to evaluate the effect of the REMS on prescribing behavior or safety outcomes.

In their letter, Auth and colleagues from the FDA’s Division of Risk Management state that the agency has not abandoned the idea of such an evaluation, citing ongoing conversations with manufacturers and plans for “broader stakeholder input” on an evaluation. They also reference ongoing collection of surveillance data, but in the Supplement of our article, we report that the FDA itself has noted that “ongoing surveillance...is necessary to inform regulatory decisions related to these products and this REMS, but the goal of the surveillance data is not to assess the impact of the REMS itself, due to the many secular trends and concurrent interventions that will inevitably confound this assessment surveillance data.”

We agree that surveillance alone is insufficient for evaluation, which is why we suggested alternate designs for the agency to consider. The agency appears to still be searching for the best path forward; settling on a plan quickly should be a high priority. It is past time for the agency—and clinicians, patients, and the general public—to know whether this major clinical education effort is working as intended.

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Conflict of Interest Disclosures: Dr Alexander is past chair of the US Food and Drug Administration’s Peripheral and Central Nervous System Drugs Advisory Committee; has served as a paid advisor to IQVIA; is a cofounding principal and equity holder in Monument Analytics, a health care consultancy whose clients include the life sciences industry as well as plaintiffs in opioid litigation; and is a member of OptumRx’s National P&T Committee. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. Dr Sharfstein was the principal deputy commissioner of the US Food and Drug Administration from March 2009 to January 2011 and has served as an unpaid expert witness to the city of Baltimore in its lawsuit against opioid manufacturers. No other disclosures are reported.


CORRECTION

Omitted Disclaimer: In the Viewpoint titled “Investing in the Health of American Indians and Alaska Natives,”1 published online March 16, 2020, a disclaimer was omitted from the Article Information section. The following statement should have been included: “Disclaimer: The opinions and assertions contained herein are those of the authors and do not reflect any official or unofficial view or opinion of the Indian Health Service.” This article was corrected online.