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March 6, 2026

Martin Makary, MD, MPH
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, Maryland 20993

Submitted electronically to commissioner@fda.hhs.gov

RE: Comments on the recent FDA iPLEDGE changes

Dear Commissioner Makary,

The American Academy of Dermatology Association (AADA) writes to express our gratitude for the Food and Drug Administration's (FDA) approval of mandated modifications to the iPLEDGE REMS program.[1] **We greatly appreciate the FDA's decision, which will minimize burdens for patients, prescribers, and pharmacies while maintaining the safe use of isotretinoin. We urge the agency to collaborate with key stakeholders such as dermatologists, pharmacists, and patients to ensure that implementation of these modifications meaningfully improves safe access to isotretinoin. As part of this collaborative effort, the AADA also encourages the FDA to increase transparency regarding the outcomes and performance of the iPLEDGE REMS program by sharing program data and insights with stakeholders to help inform ongoing improvements.**

The AADA is the leading society in dermatological care, representing over 18,000 dermatologists nationwide. AADA is committed to excellence in the medical and surgical treatment of skin disease; advocating for high standards in clinical practice, education, and research in

[1] Center for Drug Evaluation and Research (CDER). iPLEDGE Update: FDA approves iPLEDGE REMS modification (February 9, 2026). U.S. Food and Drug Administration. Published 2026. Accessed March 6 2026. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/ipledge-risk-evaluation-and-mitigation-strategy-rems#292026

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dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of disease.

Encouraging Stakeholder Engagement
The AADA strongly encourages the FDA to engage in sustained, structured collaboration including regularly scheduled multi-stakeholder meetings, to ensure iPLEDGE reforms are implemented smoothly and effectively.
Isotretinoin is a prescription medication approved by the FDA to treat patients 12 years of age and older with severe acne, including deep, painful cysts and nodules. Treatment typically lasts about six months, though it may be shorter or longer depending on the patient. Dermatologists often refer to isotretinoin as the most effective treatment for severe acne because it can significantly diminish or completely clear breakouts, helping to prevent permanent scarring. It is also the only acne treatment capable of providing lasting remission.

Isotretinoin is highly teratogenic, so there is high risk of serious birth defects if pregnancy occurs while a patient is taking the medication. To prevent fetal exposure, the FDA mandates iPLEDGE, a program designed to prevent pregnancies among patients taking isotretinoin and to ensure that pregnant individuals do not use the drug.

Given that dermatologists are the primary prescribers of isotretinoin, their expertise and experience are necessary to ensure the iPLEDGE program functions effectively. The challenges associated with the 2021 rollout of the updated iPLEDGE system, during which nearly all patients and prescribers lost access for months, underscore the significant risks that can arise when key stakeholders such as dermatologists are not meaningfully and proactively engaged.
Accordingly, the AADA urges the FDA to require that IPMG work in close coordination with the AADA throughout implementation to proactively identify and mitigate potential complications and pitfalls.

Patients are best served when board-certified dermatologists work collaboratively with the FDA and IPMG to ensure the iPLEDGE REMS program is clinically appropriate and operationally feasible. We appreciate the efforts of the FDA and IPMG to implement these valuable reforms and continued collaboration is essential to refining the iPLEDGE REMS program and reducing unnecessary burdens that can negatively affect patient care. Priority areas for further modernization should include improving educational materials on long-acting contraception, expanding access to emergency contraception resources, and eliminating or reducing the 30-day waiting period for patients already using highly effective forms of contraception. Advancing these targeted improvements to the iPLEDGE REMS program in a

deliberate and transparent manner is critical to decreasing the risk of fetal exposure to isotretinoin and safeguarding patients' safe access to isotretinoin.

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The AADA appreciates the FDA's leadership in implementing these important modifications to the iPLEDGE REMS program and looks forward to working with the agency and IPMG as these changes are implemented. If you have any questions regarding this letter or to schedule a meeting, please contact Nija Chappel, JD, MPH, Manager, Regulatory Policy, nchappel@aad.org or at (202) 609-6313.

Sincerely,

Susan C. Taylor, MD, FAAD
President

CC:
Admiral Brian Christine, MD, Assistant Secretary of Health, U.S. Department of Health & Human Services
Tracy Beth Høeg, MD, PhD, Acting Director, Center for Drug Evaluation & Research, FDA