November 12, 2024

Robert M. Califf, MD
Commissioner
Food and Drug Administration
25 New Hampshire Avenue
Silver Spring, Maryland 20903

Re: Changes to the iPLEDGE REMS Program

Dear Commissioner Califf:

Almost a year has passed since the FDA's November 30, 2023, letter mandating changes to the iPLEDGE REMS Program, which required the Isotretinoin Products Manufacturer Group (IPMG) to submit a proposal to the FDA by May 30, 2024, and provided the agency another six months to review the plan. With a few weeks left until that deadline, the American Academy of Dermatology Association (AADA) is writing again because we believe stakeholder engagement is critical to guarantee patient safety and providing reliable and timely access to treatments. The challenges encountered during the 2021 rollout of the updated iPLEDGE website highlight the importance of engaging with key stakeholders, including dermatologists, to ensure a smooth and successful process. Unfortunately, for the past year, AADA's attempts to collaborate with the agency and the IPMG have been rejected and ignored.

On behalf of the 17,000 U.S.-based members of the AADA, we write again to request that the FDA and IPMG work collaboratively with the AADA to implement changes to the iPLEDGE Program. **In particular, we request a meeting with FDA subject matter experts; urge the FDA to require IPMG to meet with AADA and other stakeholders on a regular basis but not less than quarterly; and additionally encourage the agency to require the inclusion of AADA in the development, testing, and evaluation of changes to the iPLEDGE REMS program.**

The AADA appreciates the FDA's mandated changes to the iPLEDGE program and looks forward to their full implementation. However, we have not yet seen the IPMG proposal and have not been included in the development, testing, or evaluation of the proposed changes. We stress that an iterative feedback process that fully includes the participation of AADA will mitigate complications during implementation. Frustratingly, the lack of stakeholder engagement comes after a March 2023 joint Drug Safety and Risk

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Management Advisory Committee and Dermatologic and Ophthalmic Drugs Advisory Committee meeting during which many advisory committee members expressed significant concerns about the IPMG's lack of transparency and collaboration.

There is still time to engage stakeholders and avoid a repeat of the 2021 rollout experience – but only if FDA requires it. Again, AADA appreciates the FDA's leadership in requiring many significant modifications to the iPLEDGE program and we are willing to work with the FDA and IPMG to help implement the changes to achieve the best interests and safety of patients.

Thank you for taking these concerns into consideration. **We look forward to the opportunity to meet with you or a member of your team to discuss this issue in further detail.**

If you have any questions regarding this letter or to schedule a meeting, please contact Chad Appel, JD, Director, Regulatory & Payment Policy, at cappel@aad.org or (202) 712-2614.

Sincerely,

Seemal R. Desai MD FAAD

Seemal R. Desai, MD, FAAD
President

CC:
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