American Academy of Dermatology Association

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December 15, 2021

Patrizia Cavazzoni, MD
Director, Center for Drug Evaluation and Research
Food and Drug Administration
25 New Hampshire Avenue
Silver Spring, Maryland 20903

Submitted electronically to Patrizia.Cavazzoni@fda.hhs.gov

Dear Director, Cavazzoni,

We thank the FDA for its response from Saturday Dec 11. Unfortunately, despite this response and assurances from Syneos, the iPLEDGE system roll-out on December 13 had major problems which caused many hardships for our physician members as well as for patients and is inhibiting access to isotretinoin. Thus, we reiterate our call to temporarily suspend the iPLEDGE program until the issues are resolved. We have heard from hundreds of prescribers who have reported major issues including:

- The iPLEDGE website repeatedly being inaccessible for prescribers and patients
- Existing patients missing from website for those (a minority) who have been able to login.
- Painstakingly slow ability to update patient categories for the minority of prescribers able to log in.
- Despite promises of increased staffing and improved call center, the hold times are still averaging over several hours for the call center and our members are reporting that after long waits on hold they are being dropped from the queue or cut off when they finally reach an operator
- The link to paper consent form is broken on website or is just a blank page.
- Pharmacies unable to receive approval codes to dispense.
- Issues with prescribers NPI being unrecognizable to the system.
- No link to accept transfers of patients previously enrolled by a different prescriber.

Dermatologists, who are the main prescribers of isotretinoin, were never consulted about the details of the system transition before the announcement in October. In anticipation of problems, we made many requests to work with the iPLEDGE manufacturers and the medication sponsors to avoid the exact type of systematic breakdown of the system that has occurred. The impact of this transition and the long-standing problems with iPLEDGE itself underscore the need for immediate action on the part of the FDA

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and – hopefully in the very near future - a public stakeholders meeting (e.g. advisory committee) dedicated to the topic of the iPLEDGE REMS program.

Again, temporarily suspend the iPLEDGE program until these major issues are resolved. Until then, we look forward to working more closely with representatives from the FDA, iPLEDGE program sponsors, and other interested parties to advance needed iPLEDGE changes and welcome the opportunity to continue our dialogue on this matter to reach resolution. AJ Custard, JD, Manager, Regulatory Policy, is our primary point of contact on this issue. He can be reached at (202) 230-6650 or ajcustard@aad.org.

Sincerely,

Kenneth J. Tomecki, MD, FAAD
President, American Academy of Dermatology Association