Dear Colleagues:

In the last two days 1,087 AADA members responded to our grassroots call to action imploring the FDA to help address the crisis with the iPLEDGE system and sharing our frustration with the numerous issues we have encountered including being completely being shut out of the program, losing access to patient data, and outrageously long wait times with the call center.

Our voices have been heard loud and clear.

Today, I along with colleagues Ilona Frieden, MD, FAAD, chair of the AADA IPLEDGE Workgroup, and workgroup member John Barbieri, MD, FAAD, participated in a meeting with HHS Assistant Secretary of Health Admiral Rachel L. Levine, MD, and Patrizia Cavazzoni, MD, FDA director, Center for Drug Evaluation and Research as well as representatives from the National Association of Chain Drug Stores, and the isotretinoin manufacturers responsible for the iPLEDGE program. Admiral Levine and Dr. Cavazzoni made it clear that they have heard our calls for action, want a solution that safely restores access for our patients, and would like to see a dialogue established between all parties that resolves longstanding issues with the program. FDA and HHS agree that the solution is to be found with dermatologists and pharmacists who are on the ground, living the program day to day.

In the meeting we:

- Outlined the severe impact on patient access to treatment this is having, which worsens every day this situation continues.
- Reiterated our call for a temporary pause to the program while stakeholders work to resolve the urgent issues with the platform.
- Suggested suspension of those in the “cannot become pregnant” category. The purpose of the program is to prevent fetal exposures, but attestation requirements are the same for those who can and cannot become pregnant. Eliminating those who cannot become pregnant would restore access to thousands of patients quickly.
- Proposed instituting a temporary workflow outside of the current platform to conduct, document, and confirm safe practices on the use of isotretinoin for patients who can become pregnant.

- Repeated requests made prior to launch of the new platform for an accessible paper option.

While we did not receive a specific timeline for resolution, it was very clear the FDA understands this is an urgent issue that needs to be fixed, and we are hopeful that a resolution is at hand. Admiral Levine included in her remarks a call for a group of stakeholders to convene to address the issues. The AADA continues to engage all stakeholders pressuring them to find a solution as soon as possible.

Thank you to all AADA members who have shared your experiences and perspectives. We are hopeful that the “voices of the many” have helped turn the corner, and will continue to keep you updated on developments as we hear them.

Sincerely,

Bruce Brod, MD, MHCI, FAAD
Chair, AADA Council on Government Affairs and Health Policy