December 24, 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 Dr. Cavazzoni:

Earlier this week, the undersigned organizations (American Academy of Dermatology Association (AADA) and the National Association of Chain Drug Stores (NACDS)), met to discuss temporary solutions to the most pressing problems within the iPLEDGE system. We appreciate the FDA listening to our concerns, acknowledging our issues, and coordinating efforts with the program administrators to quickly identify solutions. We are, however, now going on two weeks since the launch, and there are still issues that have contributed to major disruptions in patient care. We understand that since the December 13 update, prescriptions dispensed are approximately one-third of expected amount from the FDA. This means that at least 50% of patients who take isotretinoin may be in critical danger of not receiving their medicine by the end of the month. Most concerning, we are hearing from patients, pharmacists, and prescribers that they are feeling hostage to a system that is not working. We offer the following recommendations to help alleviate these concerns.

Recommendations:

Coordinate Stakeholder Meetings and Communication Pathways

The FDA should hold a cadence of meetings scheduled with all the relevant stakeholders facilitated in order for the necessary collaboration to occur to implement short term interim solutions and to track the timing of when the process will be working as designed to help ensure patient access to care. This collaborative effort should also include identification of key contacts from each stakeholder group, including IPMG, to facilitate the needed communication, training, and action items. Without direct communication with the FDA and stakeholders, the system may ultimately undermine patient access.

Disable Patient Attestation as a Short-Term Solution

The FDA should consider waiving the current system and allow modification by directing the IPMG to have the vendor temporarily disable the patient attestation requirement of the program. While prescribers are increasingly able to access the system, many patients remain locked out and are experiencing difficulties troubleshooting given the understaffed call center. Temporary removal of the patient attestation component could remove a major barrier by permitting pharmacies to get the RMA number with just the prescriber component. Together, credentialed pharmacies and the completed prescriber information can allow for an RMA to be generated, which can then be made available to the pharmacy and allow the prescription to be filled. This temporary waiver could enable the process to be

complete at the pharmacy end without any major adjustments to their systems and provide a significant step forward in a timely solution while longer term remedies are explored.

Direct RMA Administrator to Provide Fax and Call Center Solutions
The FDA could also consider directing the RMA Administrator to implement a fax process between the prescriber and the REMS Administrator, which could allow prescribers who are unable to access the REMS portal to provide the required patient and clinical information. The FDA could also direct the REMS Administrator to dedicate call center resources to support patients and pharmacies who are unable to access the portal. The FDA could then direct the REMS Administrator to use the combined fax and call center solutions to manually enter the applicable patient detail in the portal so that when a pharmacy accesses the portal, the RMA process will be available.

This solution keeps all the detail in the portal where it belongs and avoids compliance and liability risks that may be more present in a fax process between the prescriber and the pharmacy. Importantly, requiring the REMS Administrator to support the alternative fax option with the necessary call center support can help the FDA better understand where the gaps are to develop the necessary electronic solutions in a more timely manner.

Provide Blanket "Amnesty" to Avoid Lock-out Periods for Individuals Who Can Become Pregnant
We recommend FDA implement a policy of "amnesty" to patients who can become pregnant but have, or are threatened to have, a one-month lock-out from receiving medication through no fault of their own. Patients on the medication who have a negative pregnancy test are required to both be confirmed in the iPLEDGE system *and* to pick up their isotretinoin within 7 days. If not, they are locked-out from receiving the medication for one month. Because of the dysfunction of the system, many patients may have missed this window and many more may do so in the next few weeks. We urge the FDA to consider that it is unfair for these patients to be forced to stop their medication for 1 month. The FDA should consider solutions that do not penalize patients for the failings of an online portal. Specifically, the FDA should consider solutions for patients to continue to be qualified to receive medication, using already established standard criteria for avoidance of fetal exposure.

Open Dedicated Call-Center Phone Lines for Each Stakeholder Component
Finally, we urge FDA to direct the IPMG to institute call-center lines specifically dedicated to each stakeholder component: prescribers, patients, and pharmacies. This could help ensure that each stakeholder component is able to reach call-center assistance staffed by individuals that are specifically trained to resolve the unique challenges facing each stakeholder component group.

Establish Forward-Leaning FDA Support
We understand that FDA is collecting contact information so that interested stakeholders may work directly with the IPMG. Although we appreciate FDA's doing this on behalf of stakeholders, we ask the FDA for additional support because prescribers and pharmacies rely on the authority of FDA when implementing any temporary solutions that may require the waiver of one or more elements of the REMS. We ask the FDA to exercise its authority to require the responsible parties, whether that be the IPMG or the REMS administrator, to resolve the ongoing dysfunctions.

We have heard and believe that the FDA understands the utmost urgency of the situation, and appreciate the efforts and collaboration to date. We respectfully ask the FDA to consider the above recommendations identified by the prescriber and pharmacy stakeholders who are on the front lines to help ensure patient safety and patient access to care.

Sincerely,

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

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores