May 5, 2025

Russell T. Vought
Director
Office of Management and Budget
725 17th Street NW,
Washington, DC 20503

Submitted electronically via https://www.regulations.gov/

RE: Request for Information: Deregulation [Docket No. OMB-2025-0003-0001]

Dear Director Vought,

The American Academy of Dermatology Association (AADA) writes to provide comments on the Office of Management and Budget's (OMB) request for information (RFI) titled, *Request for Information: Deregulation*.

As the leading society in dermatological care, representing nearly 17,500 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 dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of disease.

As the agency begins its process of reviewing regulations for potential repeal, reform, or recision, we urge OMB to consider the following regulatory issues:

I. Drug Shortages

Ongoing drug shortages continue to pose serious challenges for dermatology practices in the United States. Even routine, generic dermatologic drugs are affected by these shortages, including sodium bicarbonate and lidocaine with epinephrine. These local anesthetics are necessary for a range of office-based dermatologic procedures, including skin biopsy, excision, wound closure, tissue rearrangement, skin grafting, cauterization, non-ablative lasers, and ablative skin resurfacing.

Access to local anesthetics is critical to ensuring patient comfort and safety during dermatologic procedures. However, persistent national shortages of medications, like lidocaine, have forced dermatologists, especially those in solo and small group practices, to ration supplies or delay care. In fact, dermatologists practicing in underserved areas have reported limited to no supplies of lidocaine and

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lidocaine with epinephrine. Some are also facing shortages of sodium bicarbonate, which is often used to buffer lidocaine and reduce the pain of injection. These supply challenges are particularly burdensome for small and solo practices, as wholesalers tend to prioritize hospitals, health systems, and larger groups.

Although supply chain issues contribute to drug shortages, regulatory barriers are often a more significant factor. Delays in FDA approvals, limited transparency around manufacturing disruptions, and burdensome post-approval requirements reduce manufacturers' ability to respond to supply challenges. This is particularly true for commonly used dermatologic medications, such as sterile injectables, which are more complex to produce and less profitable, making them less attractive for sustained production. These regulatory challenges don't just impact manufacturers, they have direct clinical consequences. When essential medications are in limited supply, physicians may be forced to modify treatment plans, delay procedures, or adjust clinical workflows, all of which can impact the efficiency and delivery of high-quality care. Ongoing shortages of essential medications threaten patients' access to high-quality care and undermine the stability of clinical practice. Without regulatory reform, the drug supply will remain vulnerable to future disruptions.

To address drug shortages that disrupt patient care and practice, the AADA urges OMB to direct the FDA to undertake regulatory reforms that strengthen the drug supply chain, reduce administrative burden, and prevent drug shortages. Additionally, we urge the FDA to prioritize diversifying the generic drug manufacturing base by reducing reliance on single-site production, increasing redundancy, and ensuring a minimum number of manufacturers for essential medications. The AADA also urges the FDA to make facility inspection reports publicly available to help purchasers assess supply-chain risk, and to continue evaluating the use of buffer supply models to reduce shortages.

II. iPLEDGE REMS

The iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) program is designed to prevent fetal exposure to isotretinoin, the most effective medication used to treat severe acne, and the only medication that can result in long-term clearance[1]. Yet, in recent years, dermatologists have directly observed the challenges and burdens associated with the iPLEDGE program and its unintended impacts on patient care.

Over a year has passed since the FDA's November 30, 2023 letter mandating changes to the iPLEDGE program to minimize burdens on patients, prescribers, and pharmacies, while maintaining the safe use of isotretinoin. This required the Isotretinoin Product Manufacturers Group (IPMG) to submit a proposal to the FDA by May 30, 2023, and provided the agency with another six months to review the plan[2]. No finalized FDA plan has been communicated, and the continued lack of transparency on the implementation of the November 2023 modifications has created growing concern among patients and

[1] FDA, iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) Website (Accessed Apr. 2025). https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/ipledge-risk-evaluation-and-mitigation-strategy-rems?utm_medium=email&utm_source=govdelivery

[2] Letter from FDA to IPMG (Nov. 30, 2023). https://www.fda.gov/media/174325/download?attachment

prescribers regarding the status and timing of necessary reforms and removals of these burdensome requirements.

While the AADA appreciates the FDA's efforts to require isotretinoin manufacturers to make the following iPLEDGE program changes, these modifications have yet to be fully implemented[3]:

- **Remove** the requirement that pregnancy tests must be performed in a specially certified (i.e., Clinical Laboratory Improvement Amendments [CLIA]) laboratory
- **Allow** prescribers the option of using home pregnancy testing for their patients during and after isotretinoin treatment. Prescribers who rely on the patient to perform a home pregnancy test need to take steps to minimize patients falsifying the results of these tests. As of November 7, 2023, all pre-treatment pregnancy tests must be performed in a medical setting (e.g., office, laboratory).
- **Remove** the waiting period requirement (also referred to as the "19-day lockout") for patients if they do not obtain isotretinoin within the first 7-day prescription window. Before initiating isotretinoin treatment, a repeat confirmatory pregnancy test must be completed in a medical setting (as described above) without any required waiting period.
- **Revise** the pregnancy registry requirement to remove the objective to document the pregnancy and fetal outcomes (and associated data collection) for each pregnancy.
- **Revise** the requirement for prescribers to document patient counseling in patients who cannot become pregnant from monthly to only at enrollment.

Previous studies have shown that burdensome iPLEDGE requirements led to a 30% decrease in isotretinoin prescriptions, resulting in increased reliance on antibiotics, which can contribute to antibiotic resistance[4]. Research also indicates that onerous iPLEDGE requirements can result in financial hardship, with 55% of adult patients, 80% of caregivers, and 89% of children reporting missing school or work for medication-associated office visits[5]. These outcomes reinforce the need for timely implementation of the proposed iPLEDGE modifications to reduce burdensome administrative obstacles for both patients and prescribers.

To reduce the burdens of the iPLEDGE program on patients and prescribers, the AADA urges OMB to direct the FDA to finalize the mandated iPLEDGE updates and actively engage patient, physician, and pharmacist stakeholders in the next phase of the process.

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Thank you again for the opportunity to provide comments for OMB's deregulation efforts. We look forward to collaborating with you to improve the iPLEDGE program and strengthen the drug supply

[3] FDA, iPLEDGE Update (November 30, 2023). https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/ipledge-risk-evaluation-and-mitigation-strategy-rems

[4] Lee G, Wolf JR, Somers KE. Administrative Burden of iPLEDGE Deters Isotretinoin Prescriptions: Results From a Survey of Dermatologists. Cutis. 2022 Jul;110(1):44-47. https://pubmed.ncbi.nlm.nih.gov/36179224/

[5] Collins M-K, Moreau JF, Opel D, et al. Compliance with pregnancy prevention measures during isotretinoin therapy. J Am Acad Dermatol. 2014 Jan;70(1):55-59. https://pubmed.ncbi.nlm.nih.gov/24157382/

chain, ensuring that dermatologists and their patients have timely access to safe and effective treatments. Please do not hesitate to reach out to Nija Chappel, JD, MPH, Manager, Regulatory Policy, at nchappel@aad.org if you have any questions or need additional information. Thank you for your time and consideration.

Sincerely,

Susan C. Taylor, MD, FAAD
President, American Academy of Dermatology Association