AMERICAN ACADEMY of DERMATOLOGY | ASSOCIATION

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December 26, 2019

Stephen Hahn, MD
Commissioner of Food and Drugs
US Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Draft Guidance for Clinical Decision Support Software [Docket No. 2017-D-6569]

Dear Commissioner Hahn,

On behalf of the American Academy of Dermatology Association (AADA), which represents more than 13,800 dermatologists across the country, we appreciate this opportunity to comment on the Food and Drug Administration (FDA) Draft Guidance on Clinical Decision Support Software (Draft Guidance). Clinical decision support (CDS) software has the potential to improve patient care and we appreciate the FDA issuing guidance that explains FDA's regulatory approach to CDS software functions. AADA is committed to excellence in medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology; and supporting and enhancing patient care to reduce the burden of disease. One in four Americans suffers from a skin disease. Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases, and many genetic disorders.

CDS, including augmented intelligence (AuI), has the potential to enhance the patient and population experience, reduce costs, and improve the potential fulfilment of care teams. Given its importance, the American Academy of Dermatology (AAD) adopted a position statement on Augmented Intelligence. We recognize that while the scope of this position statement is focused on augmented intelligence, the principles do generally apply to CDS software. For example, FDA must focus on safety, efficacy, and equity. All efforts should be made to ensure the data and outputs are free of as much bias as possible.

It is the position of the AADA that data used to train models must be of high quality and their source must be identifiable. Algorithms must be internally and externally validated and evaluated, and the methodology and results made transparent. We support transparency efforts in order for physicians and other health care providers (HCPs) to understand and evaluate the tools used to care for our patients. Like the American Medical Association (AMA), the AADA does not agree with FDA that CDS that utilizes certain AI systems and methods such as, but not limited to, machine learning or deep learning, fall outside of FDA oversight. The Draft Guidance states "that the complexity or proprietary nature of the algorithm is not the distinguishing factor as much as the ability of the healthcare provider to confirm the output independently, using the same inputs and basis."

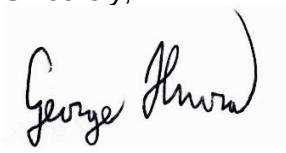
As stated in the Draft Guidance, "FDA intends to focus its regulatory oversight on device functions that do not meet the definition of Device CDS, as defined by the [21st Century] Cures Act and used in this guidance but are devices. FDA provides an example of: "Software that calculates the fractal dimension of a lesion and surrounding skin image and builds a structural map to provide diagnosis or identify whether the lesion is

malignant or benign. This software is a device function, because it is intended to analyze a medical image and to diagnose a disease or condition." The AADA agrees that the FDA should oversee this type of device. Prospective clinical trials with relevant clinical end points based on intended use should be performed in order to validate this type of AuI technology for patient care. Both clinical effectiveness and patient safety should be demonstrated before using this technology for clinical decision making. Care must be made in identifying potential bias which could arise in the design or deployment that could potentially exacerbate health care disparities, particularly among vulnerable populations. Data collected during model deployment can be used for model retraining and refinement. For this type of AuI tool, post-marketing surveillance must also be performed to ensure safety through routine evaluation after deployment. The technology should improve outcomes important to patients, clinicians, and other health system stakeholders, and efforts should be made to measure these outcomes. Outcomes may include quality, cost, and/or efficiency of care delivery. AuI tools should be safeguarded from cyber threats that could harm the integrity of the products.

The FDA proposes to exercise enforcement discretion for CDS functions used by healthcare professionals that inform clinical management of non-serious conditions when the user is unable to independently review the basis of the recommendation. While we do understand the FDA maintains enforcement authority, we have concerns about patient safety (e.g., harm resulting from inaccurate information). The same notion applies to software functions that help patients self-manage their disease or conditions without providing specific treatment or treatment suggestions. For example, a device CDS intended for patients that FDA describes on lines 609-11 states: "Software that assists patients with choosing OTC sunscreen (based on use, time, ingredients, etc.) as well as best practices for selection and application to prevent sunburn. We encourage the FDA to work with the Federal Trade Commission (FTC) to ensure that the information and guidance provided is accurate and that consumers should seek medical advice from a physician if needed.

Thank you for the opportunity to comment on the Draft Guidance. We appreciate the open doors of communication with FDA and look forward to continued collaboration. Please contact Natasha Pattanshetti, JD, MPH, manager, regulatory policy at (202) 712-2618 or npattanshetti@aad.org if you have any questions or if we can provide additional information.

Sincerely,



George J. Hruza, MD, MBA, FAAD
President, American Academy of Dermatology

cc: Irv Bomberger, Interim Executive Director
Barbara Greenan, Chief Advocacy and Policy Officer
Leslie Stein Lloyd, JD, CAE, Director, Regulatory and Payment Policy