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**Comments for the FDA Meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee July 27-28, 2022**

The American Society for Dermatologic Surgery Association (ASDSA) statement of the use of automated Artificial Intelligence (AI) systems and other computerized algorithms for the evaluation of skin lesions, including skin cancers:

- (1) Such devices and algorithms should be used by a board-certified dermatologist who is also concurrently examining the patient live and in-person. When the device use is deemed appropriate, outputs of devices and algorithms may be considered in combination with physical findings, elicited patient history, and other factors deemed germane by the examining board-certified dermatologist, who will then arrive at a diagnostic decision. The in-person skin examination by a board-certified dermatologist is an indispensable element of skin lesion assessment, particularly when precancerous lesions, cancerous tumors, or lesions of unknown or suspicious behavior are being evaluated.
- (2) When devices and algorithms are developed for use by board-certified dermatologists in combination with an in-person skin examination, these devices are part of the E/M service provided and should not be separately billed to the insurer or patient. Additionally, such devices or algorithms should be designed to meet a set of quality benchmarks, and should be tested on a range of patient groups, including underserved minorities and those with unusually high or low risk of disease.
- (3) We do not support patient self-examination with these devices and algorithms for self-evaluation of skin lesions, including those suspicious for skin cancer. Such devices and algorithms are not highly regulated and remain unproven. They may result in wrong diagnoses, missed diagnoses, or over- or under-diagnosis. Both patients at low risk and those at high risk are better served by scheduling an in-person examination with a board-certified dermatologist, who can also help them determine the appropriate future skin screening schedule that is most appropriate for them.
- (4) To the extent that algorithms and devices for patient self-diagnosis of skin lesions are already widely available, they should be required to include detailed disclaimers that include that they are for entertainment and educational purposes and not a diagnostic device, that they are not approved by dermatologists or a recognized medical regulatory authority for self-diagnosis, that an in-person skin examination by a board certified dermatologist is the gold standard for lesion assessment, and that anyone concerned about a suspicious mole or lesion should contact the office of a local board-certified dermatologist to schedule a skin examination. ASDSA and other medical professional societies of dermatologists provide referral information that would help patients identify a board-certified dermatologist in their area.
- (5) The appropriate minimum thresholds for sensitivity and specificity for devices and algorithms for computerized or AI-based evaluation of skin lesions, including those being evaluated for skin

cancer, should be determined by panels of expert dermatologists and other physicians who care for skin cancer patients.

- (6) The development, dissemination, and marketing of stand-alone devices or algorithms for diagnosis of skin lesions should be prohibited. Makers of such devices are engaging in the practice of medicine and are not licensed by any state to practice medicine. Importantly, such makers have no fiduciary responsibility to patients, but do have fiduciary responsibility to their owners and stockholders.
- (7) At this time, ASDSA does not believe there is sufficient data to warrant the reclassification of approved computer-aided melanoma detection class III devices.

The American Society for Dermatologic Surgery Association (ASDSA) has over 6,400+ board certified dermatologists as its members. physicians, ASDSA is a 501(c) (6) association, dedicated to patient safety, education and advocacy on behalf of dermatologic surgery.

For questions, please contact Kristin Hellquist, Director of Advocacy & Practice Affairs at [khellquist@asds.net](mailto:khellquist@asds.net) and for additional information please visit [asds.net/ASDSA](http://asds.net/ASDSA)