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October 11, 2024

Sean Delehanty
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
Department of Commerce

Delivered via electronic submission.

Re: Docket No. 2024-20529 - Establishment of Reporting Requirements for the Development of Advanced Artificial Intelligence (AI)

Dear Mr. Delehanty;

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed's member companies range from the largest to the smallest medical product innovators and manufacturers. AdvaMed's member companies produce innovations that transform health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

The AdvaMed Medical Imaging Division represents the manufacturers of medical imaging equipment, including, magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Our members have introduced innovative medical imaging technologies for use by healthcare providers, and they play an essential role in health care infrastructure and the care pathways of screening, staging, evaluating, managing, and effectively treating patients with cancer, heart disease, neurological degeneration, COVID-19, and numerous other medical conditions.

We respectfully request that AI-based medical devices already regulated by the FDA be exempt from the proposed rule. The FDA's current regulatory framework ensures the safety and effectiveness of AI/ML-driven medical devices. Requiring these devices to comply with additional

reporting requirements would only create unnecessary redundancy and could delay patient access to critical medical innovations.

The FDA has established a robust regulatory framework for AI/ML-enabled medical devices, which has been in place for over 20 years. This framework includes both premarket review processes and post-market surveillance requirements that ensure the safety and efficacy of AI-driven medical devices. Medical Device Manufacturers (MDMs) are subject to ongoing FDA oversight, including compliance with the Quality System Regulation (QSR) and adherence to post-market surveillance mechanisms, adverse event reporting, and continuous product improvement based on real-world evidence.

Introducing additional reporting requirements specifically for AI-based medical devices would create duplicative regulatory burdens which could lead to confusion and inefficiencies. The FDA's current premarket submission and post-market surveillance requirements already provide the necessary transparency, safety, and accountability for AI-enabled devices. Creating new reporting obligations would result in unnecessary delays for innovations reaching patients and overburden product developers, particularly small businesses and startups, which could stifle innovation in critical healthcare technologies.

FDA's regulatory processes are tailored specifically to address the risks and benefits of AI-based medical devices. This regulatory oversight is not only rigorous but also flexible enough to adapt to the rapid advancements in AI technology. The FDA regulatory framework also allows for a Predetermined Change Control Plan (PCCP), which further enhances this flexibility by allowing manufacturers to make controlled updates to AI models without requiring a new premarket submission. This ensures that AI devices continue to evolve safely without imposing undue delays on improvements.

The current FDA framework also addresses concerns related to discrimination and patient safety, which the proposed rule aims to mitigate. MDMs are required to perform testing to ensure their AI devices are safe and effective for the intended population. These devices adhere to international standards, such as ISO 14971 and ISO 13485, which provide a foundation for risk management and quality assurance. Existing FDA oversight mechanisms already mandate the evaluation of bias, privacy considerations, and the continuous monitoring of AI performance.

The FDA's current regulatory framework ensures the safety and effectiveness of AI/ML-driven medical devices. Requiring these devices to comply with additional reporting requirements would only create unnecessary redundancy and could delay patient access to critical medical innovations. We urge the agency to exempt regulated AI-based medical devices from the proposed rule.

Thank you for your consideration of our comments. We welcome the opportunity to work with the agency to ensure that the regulatory environment continues to foster innovation while protecting patient safety.

Sincerely,

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