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Race Against the Clock: Federal Agencies Issue Their Six-Month Updates on AI Activities in Accordance With President Biden's Executive Order on AI

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Since President Biden issued his sweeping Executive Order on the Safe, Secure and Trustworthy Development of AI on October 30 of last year (EO), federal agencies have been operating in high gear to meet the deadlines and expectations outlined therein. As was the case for the deadlines that have already passed, we saw a flurry of activity and agency announcements earlier this week as we hit the 180-day mark since the EO was issued, and President Biden's office published an overview of those actions on the White House website. While many of these actions are generally applicable, below, we focus on a few of the updates of interest to those operating in the health and life sciences industry.

The U.S. Department of Commerce Issues Draft Guidance and Seeks Public Comment on AI

The U.S. Department of Commerce issued several announcements relating to its 180-day initiatives outlined in the EO, including announcements from the National Institute of Standards and Technology (NIST) and the U.S. Patent and Trademark Office (USPTO), two offices the Department of Commerce oversees:

- NIST released four draft publications on April 29 designed to "help improve the safety, security and trustworthiness of artificial intelligence (AI) systems." The draft guidance documents, which seek input from

stakeholders and the public, address several aspects of AI technology, including the risks and mitigation strategies for generative AI technology, the reduction of threats to data that is used to train AI systems, the promotion of transparency in digital content that AI is capable of altering, and the development of global AI standards. Once finalized, these documents will provide additional guidance that builds off of the AI Risk Management Framework previously issued by NIST, which offers a broad framework to manage AI risks.

- The USPTO published a request for public comment on April 30 seeking feedback on the impact of "the proliferation of artificial intelligence on prior art, the knowledge of a person having ordinary skill in the art (PHOSITA), and determinations of patentability made in view of the foregoing." The USPTO issued this request for comment as part of its goal to incentivize and encourage investment in innovations that are made possible through the use of AI. The scope of the request considers how AI might affect the USPTO's evaluations of "ordinary skills in the art" to determine if an invention is patentable under U.S. law.

The U.S. Department of Health and Human Services Pre-Announces a New AI-Related Rule

The U.S. Department of Health and Human Service's Office of Civil Rights issued a statement on April 26 preannouncing issuance of the final version of a new rule under Section 1557 of the Patient Protection and Affordable Care Act. The rule, which is expected to be officially issued sometime next week, is designed to strengthen nondiscrimination protections and advance civil rights in health care, including through the application of technology. The rule clarifies that the requirement for nondiscrimination in health programs and activities "continues to apply to the use of AI, clinical algorithms, predictive analytics, and other tools," a clarification that the HHS considers a "key pillar[]" of its response to the EO. One main focus of the new rule is the application of Section 1557's nondiscrimination principles to the use of patient care decision support tools in clinical care, including how covered entities will identify and mitigate discrimination in the context of that use

With numerous additional forthcoming deadlines outlined in the EO, the health and life sciences industry can expect the next 180 days (and beyond) to be just as busy as these last 180 days. Faegre Drinker's AI-X team is keeping a close eye on those updates — stay tuned for more!

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