Review of proposed FDA regulation reveals the extent of financial ties to industry

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Credit: University of Oxford

The findings come from a cross-sectional study, published in *BMJ Open*, of the comments submitted to the US Food and Drug Administration (FDA) "Proposed Regulatory Framework for Modifications to Artificial

Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)—Discussion Paper and Request for Feedback."

Artificial intelligence (AI) and machine learning (ML) technologies have the potential to transform health care, continually incorporating insights from the vast amount of data generated every day during the delivery of health care. Many such devices must have regulatory approval or clearance before being available for clinical practice, and in the US that regulation falls to the FDA.

The suitability of traditional medical device regulatory pathways for AI/ML have been called into question because the nature of the technology means it is continually evolving and adapting to improve performance. Under the current framework it would mean that as devices evolved they would require further review and approval, which could be time consuming and may affect patient safety and interests. The FDA has therefore proposed a new regulatory framework for modifications to AI/ML and has asked for feedback from the public to refine the regulations.

"The process for developing regulations is, roughly, to get feedback from the public on its initial proposal, make changes and draft regulations or guidance, get more feedback, and eventually finalize," said James Smith, Postdoctoral Scientist at the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford and lead author of the report. "Anyone can comment but at present there is no requirement, or even recommendation, to disclose any conflicts of interest. Also, the FDA states that it looks for 'good science' in comments but it is not a requirement to incorporate it. Our goal was to look at the extent and disclosure of financial ties to industry and the use of scientific evidence."

The team analyzed all 125 publicly available comments on the FDA

proposal between 2 April 2019 to 8 August 2019 and found that 79 (63%) comments came from parties with financial ties to industry in the sector. For a further 29% of comments the presence or absence of financial ties could not be confirmed. The vast majority of submitted comments (86%) did not cite any scientific literature, with only 4% citing a systematic review or meta-analysis.

James said: "What concerns us about these findings is that we don't have a good idea of the impact of these ties and whether they might lead to bias in this specific context. Whether these observations about prevalence of ties hold true in the development of other regulations, we don't yet know, but there is a growing body of evidence showing the influence of industry throughout the medical research enterprise, and this paper adds to that. I hope it will highlight the need for greater transparency."

Gary Collins, Professor of Medical Statistics and a co-author of the study, added: "We were also concerned by the lack of scientific evidence used in comments, and the dominance of industry over academic commenters, despite AI/ML being a very active area of research. But we hope our findings will bring the FDA proposal to the attention of academics and encourage more of them to participate in the next round of feedback on the framework, and other regulatory frameworks, where academic input could be valuable."

More information: James Andrew Smith et al, Industry ties and evidence in public comments on the FDA framework for modifications to artificial intelligence/machine learning-based medical devices: a cross sectional study, *BMJ Open* (2020). DOI: 10.1136/bmjopen-2020-039969

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