and ethicists, is developing international, consensus-based guidelines for use by researchers and patient partners in preparing ethics submissions and for use by research ethics committees and institutional review boards in the assessment of PRO research. The guidelines will focus specifically on ethical considerations of PRO research and data collection in clinical practice, using methodological guideline development of the EQUATOR (Enhancing Quality and Transparency of Health Research) Network[10]. The development process will include a literature review, a modified Delphi exercise and an international consensus meeting involving members of research ethics committees, experts in research ethics, patient partners, trialists and PRO researchers. Given the dearth of guidance currently available, the authors plan to hold the Delphi exercise and consensus meeting with a view to publishing the guideline in 2021. ❐

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S.C.R. and M.J.C. conceived of the idea; S.C.R. developed the first draft; and all authors made substantial revisions and approved the final manuscript.

Competing interests

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Check for updates

Do not sell regulatory science short

To the Editor—A recent federal notice[1] proposes to permanently remove oversight by the US Food and Drug Administration (FDA) over 91 medical devices, including several devices that apply artificial intelligence and those under temporary COVID-19 waiver. Public needs during a response to an unprecedented public-health emergency aside, the federal notice sends an alarming message—that regulatory science and applying its principles during regulatory review are unnecessary.

The evidence for removal is the lack of adverse events reported in an FDA database[2]. Assuming that all relevant adverse events are accurately identified in the 'real world', and further assuming that all of those adverse events are accurately reported in the FDA database, then the absence of adverse events would indicate that the screened devices are safe and are of 'low risk'. However, even with those arguably unproven assumptions, the cause for the absence of adverse events has many attributable factors, including the FDA review process itself, which is now subject to removal —simply put, the safety of the current devices driving the removal might be in part attributable to those devices having undergone independent, scientifically sound FDA review. The proposed permanent changes thereby represent a manifestation of the principle that 'nobody ever gets credit for fixing problems that never happened'[3]; however, it is exactly in this context that regulatory science, with its diverse tools, standards and approaches, is necessary to ensure safety, efficacy, quality and performance to help prevent adverse events[4].

After decades of public funding and numerous strategic governmental initiatives[5], regulatory science today is a firmly established hard science recognized and championed by the FDA. Regulatory science is, however, not restricted to the FDA—numerous scientists contribute continuously via methods, tools and standards to facilitate and inform regulatory decision-making. The partnership between science and the 'regulatory ecosystem' have brought stakeholders together[6] to begin to tackle very difficult problems, including how to regulate continuously learning artificial-intelligence tools or generative adversarial networks. There are numerous unanswered questions that represent an opportunity for all stakeholders to come together and drive development toward a comprehensive and agile regulatory framework[7]. In other words, the federal notice highlights the exact purposes for which regulatory science exists—namely, that rigorous review of passive event-reporting systems and long-term monitoring to elucidate causal relationships of adverse events is necessary.

Accelerating medical innovation requires the collaborative generation of logically

sound oversight, founded in valid scientific evidence and generated inside and outside the FDA. It is paramount that the intrinsic complexities of medical devices be delineated via established regulatory science tools and scientific evidence to help create the best future regulatory frameworks. Regulatory science has concrete patient-care, societal and economic consequences. Estimating the unintended and potentially costly consequences of this federal notice and its elimination of applied regulatory science requires more than commenting or lobbying. It requires science—regulatory science. ❐

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Competing interests

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