Researchers challenge post-marketing trial practices

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Current research ethics focuses on protecting study participants, but according to bioethicists from Carnegie Mellon University and McGill University, these efforts fail to prevent problems that undermine the social value of research.

Published in *Science*, CMU's Alex John London, and McGill's Jonathan Kimmelman and Benjamin Carlisle argue that current research ethics frameworks do not flag drug trials that, while not putting patients at risk, produce biased evidence. As an example, they point to phase IV research — when pharmaceutical companies test drugs and devices that have been approved for marketing. They insist that without an adequate system of checks in place, phase IV trials will continue to be used by drug companies to market products without generating the information that clinicians and policy makers can use to improve care and maintain a more cost-effective health system.

"Medical care isn't like most consumer products where the consumer can assess the quality of the product from its performance and estimate its value for the money," said London, associate professor of philosophy and director of CMU's Center for Ethics and Policy. "In medicine we are forced to rely on what can at times be complex scientific studies for this information. So it is difficult to overstate the importance of preserving the integrity of this research."

London and Kimmelman point out how some phase IV studies have used questionable designs and have been used by drug companies for

producing "brand loyalty" among physicians conducting the study. Some of the practices that result in bias, like selective reporting of data, may be difficult for journal editors or clinicians to detect on their own.

Current review systems at drug regulatory agencies like the Federal Drug Administration (FDA) or at universities have little authority to police post-marketing trials for bias. To correct the problem, London and Kimmelman, who frequently collaborate on ways to improve clinical research, point to several policy options, including expanding the review authority of the FDA, academic medical centers and medical journals.

"Rigorously designed and executed research has a critical role in improving patient care and restraining ballooning health care costs," said Kimmelman, associate professor of biomedical ethics at McGill. "There is currently a push to streamline the ethical review of research. In this process, oversight systems should be empowered to separate scientific wheat from marketing chaff."

Provided by Carnegie Mellon University