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Patient-funded trials may do more harm than good, ethicists warn

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In the era of launching Kickstarter campaigns to pay for just about anything, Carnegie Mellon University ethicists warn that the trend of patients funding their own clinical trials may do more harm than good.

CMU's Danielle Wenner and Alex John London and McGill University's Jonathan Kimmelman co-wrote a column in *Cell Stem Cell* outlining how patient-funded trials may seem like a beneficial new way to involve more patients in research and establish new funding opportunities, but instead they threaten scientific rigor, relevance, efficiency and fairness.

"Patient-funded trials look like they could be a boon to science by attracting previously untapped resources to research," said Wenner, the lead author and assistant professor of philosophy in the Dietrich College of Humanities and Social Sciences. "The problem with this model is that it lacks mechanisms to ensure that research is grounded in good science. Rather than increasing the pace of biomedical progress, it may delay innovation through the diversion of resources, and ultimately harm the very people it is intended to help."

Wenner, London and Kimmelman believe that crowdfunding trials are gaining popularity partially due to limited funding from the National Institutes of Health (NIH) and other agencies. People also are more willing to explore alternate funding models.

"Patients with diseases that do not have effective treatments and interventions are desperate to see the pace of science move more quickly

or get fast access to something that will help them immediately. Similarly, researchers who can't get NIH funding are turning to crowdfunding," said London, professor of philosophy and director of CMU's Center for Ethics and Policy.

But, patient-funded trials often attract people who are seriously ill and therefore willing to take large risks. They also allow clinics to pop-up that are clearly motivated by profit under the guise of offering new interventions, some of which do not have sufficient basic science findings to support them.

"Many patients and patient advocacy groups think the current funding system is too conservative," London said. "But, it's a system that directs the individual interests of various parties toward one goal. For example, drug companies can't make money until their intervention passes requirements set by the FDA to ensure that it actually works. Patient-funding trials sidestep such mechanisms."

Wenner, London and Kimmelman suggest incentives are needed to align patient-funded trials and clinics with the production of solid research. They believe this could be done through large-scale policies that provide scientific and ethical oversight and by mandates from a variety of different parties, such as academic medical centers requiring peer review of all research trials. Another option is the implementation of accreditation requirements for health care facilities to encourage them to use appropriate methods for scientific review and ethical considerations.

"The bottom line is that patient-funded models are a novel funding model, but they threaten to de-stabilize a system that ensures high quality results," London said.

Provided by Carnegie Mellon University