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'Bad Science Moves Quickly': Rushed Papers, Expanded Access Requests Threaten Research

By Theresa Defino

The COVID-19 pandemic is leaving its mark on the design and conduct of studies, including in ways that benefit subjects and patients, particularly through telemedicine. But two ethicists warn that developments such as the increasing use of unproven medications outside of clinical trials and the rise of publishing platforms less rigorous than peer-reviewed journals are shaking the research enterprise in profound, lingering and negative ways.

A "huge fight about rebuilding standard clinical trials" will need to be waged once the pandemic is better controlled and efforts made to strengthen prepublication peer reviews in light of growing numbers of retractions, predicted Art Caplan of New York University (NYU). Caplan also offered a dose of reality, warning that the United States is "not going to vaccinate our way out of this pandemic."

Alison Bateman-House, also with NYU, drew attention to "pandemic exceptionalism" and the "skyrocketing" increase in expanded access requests, as well as the "perfect storm" leading to clinician uncertainty in selecting treatments for COVID-19 patients. Research compliance officials support different types of studies, so the details Caplan and Bateman-House provided on drug development and approval also will likely prove enlightening.

Caplan, professor of bioethics at the NYU Grossman School of Medicine and director of the Division of Medical Ethics, and Bateman-House, an assistant professor of medical ethics, made their remarks during the recent webinar, "COVID-19 Ethics: Looking at Scientific Data Dissemination, Vaccine Development and Access to New Therapies Through an Ethical Lens," sponsored by WCG Clinical Inc.[1]

Caplan began by discussing the usual process for the development of vaccines, including the use of "challenge" studies in which people are intentionally infected with a virus.[2]

His caution that vaccinations will not end the pandemic, at least for years, stems from the myriad challenges in both creation and distribution. Vaccines will "be a big help, but they're unlikely to be effective enough, cheap enough, desired enough, or last long enough for us to get away from…heavy reliance on behavior modification," said Caplan. And, he warned, "We're going to have some big [political] fights about who goes first when vaccines start to appear."

Typically, vaccine (and other) studies are first performed using animals. Depending on their success, a trial would move on to Phase I, which tests safety and typically only enrolls "20 to 50" individuals. Phase II trials may enroll "maybe a hundred or more subjects," he explained.