Warp Speed, the Right to Try, Real World Evidence and the Future of the Ethics of Clinical Research

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After witnessing extraordinary scientific and regulatory efforts to speed development of and access to new COVID-19 interventions, patients facing other serious diseases have begun to ask “where’s our Operation Warp Speed?” and “why isn’t Emergency Use Authorization an option for our health crises?” Although this pandemic bears a number of unique features, the response to COVID-19 offers translatable lessons, in both its successes and failures, for non-pandemic diseases. These include the importance of collaborating across sectors, supporting the highest-priority research efforts, adopting rigorous and innovative trail designs, and sharing reliable information quickly. But, the regulatory response to the pandemic demonstrates that lowering standards for marketing authorization can result in increased safety concerns, missed opportunities for research and treatment and risky delays in determining what works.

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Currently the Drs. William F and Virginia Connolly Mitty Professor and founding head of the Division of Medical Ethics at NYU School of Medicine in New York City. Dr. Caplan was the Sidney D. Caplan Professor of Bioethics at the University of Pennsylvania Perelman School of Medicine in Philadelphia, where he created the Center for Bioethics and the Department of Medical Ethics. Dr. Caplan is the author or editor of thirty-five books and over 850 papers in peer reviewed journals. His most recent books are Vaccination Ethics and Policy, with Jason Schwartz and, Getting to Good: Research Integrity in Biomedicine with Barbara Redman. He has served as the chair of the National Cancer Institute Biobanking Ethics Working Group. He has also served on the Special Advisory Panel to the National Institutes of Mental Health on Human Experimentation on Vulnerable Subjects and as the co-director of the Joint Council of Europe/United Nations Study on Trafficking in Organs and Body Parts. Dr. Caplan is a regular commentator on bioethics and health care issues for WebMD/Medscape, WGBH radio in Boston, WOR radio in New York City, Hearst Media Group, Connecticut and CNN. Dr. Caplan is the recipient of many awards and honors including the McGovern Medal of the American Medical Writers Association and the Franklin Award from the City of Philadelphia. He was a USA Today 2001 “Person of the Year and was described as one of the ten most influential people in science by Discover magazine. He holds seven honorary degrees from colleges and medical schools.