

Ethics of Emergency: An Anatomy of Legal and Ethical Issues of Clinical Research and Emergency Use Authorization of COVID-19 Vaccines

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Abstract

Serving as one of the major pandemic prevention measures, the COVID-19 vaccines create a new paradigm of an unprecedentedly efficient research and development (R&D) and review process. However, the new paradigm also brings new regulatory and ethical issues. This article examines the regulatory and ethical challenges through the lens of public health ethics in emergency (PHEE). PHEE sets alleviating harms and protecting public health as the primary concerns, while it tolerates governmental interventions not necessarily least restrictive. PHEE also highlights the decision-making process to be transparent, inclusive and accountable. In addition, equity, justice, and preparation for returning to normalcy are also the core PHEE principles. PHEE coincides with legal and ethical practices in the COVID-19 R&D and review process. In terms of the clinical research of COVID-19 vaccines, international practices remain to consider human subjects protection as the priority, regardless of calls for a loosened ethical standard for the purpose of speeding up research during the pandemic. With regards to emergency use authorization (EUA), the US government took an “EUA plus” standard, in response to public doubts about safeness and effectiveness of the vaccines invented within a condensed timeline. Echoing with PHEE, the abovementioned issues concerning COVID-19 vaccine research and EUA indicate that the protection of individual health and life, due process, and accountability are

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irreparable even under public health emergency. The pandemic law of Taiwan has been deferential to medical and public health expertise, that is, the legislation grants blanket authorization to the executive branch. However, the R&D and EUA of domestic vaccines of Taiwan are not simple decisions based on scientific evidence, but involve complicated political judgements. The legal and policy suggestion based on PHEE is to strengthen transparency and accountability in the decision-making process. To conclude, while COVID-19 is likely to bring a new normal to public health and regulation, PHEE urges the obligation to adhere to the core of ethics.

Keywords: COVID-19, vaccine, public health ethics, public health emergency, clinical research ethics, human subjects ethics, emergency use authorization, J.Y. Interpretation No. 690, Pharmaceutical Affairs Act