



## Is the Coronavirus Pandemic Accelerating Bioethics Nationalism?

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The global crisis created by the coronavirus pandemic and the rush to create and distribute a vaccine widely hoped to be a “silver bullet” that can facilitate a return to “normalcy” threatens to upend seven decades of assumptions about bioethical norms. Those norms are products of what political scientists call the post-World War II liberal international order (LIO), typified by documents like the Nuremberg Code, the Declaration of Helsinki, and the Universal Declaration of Bioethics and Human Rights. These documents and others established a rough but clear consensus that gave priority to human dignity and human rights, insisting on persuasive justification for violations of those values, specifically in the field of health care and the life sciences.

The coronavirus pandemic emerged at a time when the LIO was already under unprecedented stress. Embodied in entities like the United Nations, the International Monetary Fund, and the World Trade Organization, the LIO fostered a modicum of global stability and material progress, including improvements in health and nutrition. Even the Cold War and accusations of U.S. exploitation of the international system in which it was the dominant partner did not undermine the LIO as gravely as the emergence of strongmen that represent right-leaning illiberalism and intensified nationalism. Phenomena like Brexit and a newly assertive China are representative of challenges to a familiar if occasionally fractious order dominated by the United States and Europe. The pandemic has accelerated trends that are widely perceived as de-globalizing, though in fact the interdependence of 21<sup>st</sup> century economies creates a far more complicated picture. These complexities—a discourse of deglobalization against a deeply integrated background of commerce and communications—pose special problems for bioethical norms founded on assumptions within the LIO.

Recent reports of rapid mass vaccination campaigns in China and Russia using vaccines without documented safety and efficacy typify the problem. Beyond the lack of publicly available evidence that could warrant confidence in these products, there are questions about their recipients that create concerns about adherence to ethical standards. China is said to have approved use of the vaccine for members of the military without clear information about consent and risk disclosure, while Russia has announced widespread vaccination to begin this fall after phase II and III trials that are notably foreshortened. These processes will pose challenges for ultimate licensure of the vaccines, in terms of the ethics of both pre-approval subject selection and distribution.

National prestige and financial reward are uniquely and powerfully combined in a global pandemic that threatens to revise history. If ever international bioethics norms could be compromised this is the time, a public health crisis that presents existential risks of geopolitical destabilization. Perhaps, however, expedience should rule the day. It could be argued that this is precisely the situation that justifies deviations from norms, just as mandatory vaccination has been justified for some infectious diseases though it limits freedom of choice. But abridging the ground rules for vaccine testing and distribution is harder to justify when so many other candidate vaccines are under expeditious development while also adhering to widely recognized ethical and methodological standards.

Are the actions of these countries a form of “bioethics nationalism,” in which distinct bioethics standards are formally proclaimed as a matter of right by a sovereign state? The moral relevance of local values and preferences has long been recognized in clinical trials. When institutional review boards consider protocols that involve underrepresented groups, or when they take place in the developing world, they are encouraged to include regular or ad hoc members who can address local concerns. A few Latin American bioethicists would go further. They have long argued that, acting through the National Institutes of Health and the Food and Drug Administration, the U.S. exerts a kind of bioethical hegemony over clinical trials in the global south that are inherently exploitive and in the service of the pharmaceutical industry. This “hard bioethics” should be resisted and substituted with a set of standards more appropriate to the countries and cultures themselves.

Do the Chinese and Russian actions amount to a form of bioethics nationalism? I think the answer is: not quite. Nothing reported so far indicates that the two countries will not in the final analysis be guided by internationally recognized drug development standards. Rather China appears to be relying on one view of military medical ethics that exempts members of armed forces from consent requirements for a nonvalidated product if commanders believe it is needed for force readiness. (Apparently this approval is strictly limited to the Chinese military for one year. So far there has been no reporting of illicit vaccine testing on the notoriously oppressed Uighur population, for example). Russia’s rush to later phase trials may be pushing the methodological envelope, but it remains to be seen if the aggressive schedule will prove to have been warranted.

What one can conclude so far in this story—with the emphasis on “so far”—is that the global bioethical rules of drug development are strained by the pandemic but not torn. Whether bioethics will be an exception to the process of deglobalization now widely believed to have been accelerated by the pandemic remains to be seen.

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