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The Bogeyman Narrative Undermines U.S. Pharmaceutical Innovation (Part 1 of 2)

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While I share former FDA Commissioner Gottlieb's passionate advocacy for safeguarding America's biomedical edge (1), characterizing China's rapid ascent in pharmaceutical innovation as a geopolitical threat is not only reductive, it is a disservice to our patients and strategically self-defeating. It is somewhat reminiscent of the Cold War era, when the Soviet Union's served as a bogeyman to galvanize the U.S. space program.

Dr. Gottlieb notes that "showing that a drug is safe and effective through rigorous clinical studies, conducted under the FDA's oversight, gives the US a competitive edge that China cannot match" and "the data from their later-stage, human trials are still viewed skeptically by US regulators and drug companies". I agree with this assessment. Chinese pharmaceutical companies continue to face challenges in securing timely market access in the United States, largely due to FDA concerns regarding data integrity and regulatory compliance. In addition, US regulation 21 CFR 314.106(b) requires, among other things that foreign data be applicable to the U.S. population and medical practice for a drug to be approved based solely on foreign evidence and that data be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, it is able to validate the data through an on-site inspection or other appropriate means (2). However, these barriers echo earlier temporary hurdles faced by other countries and will undoubtedly be inadequate to protect US dominance in the long term.

In the past decade, China's regulator, the National Medical Products Administration (NMPA) joined the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) whose respective mandates are to develop and register medicines in the most resource-efficient manner and to harmonize inspection procedures through common standards for good manufacturing practices (GMP). Over the past 5 years, Chinese biotechnology companies have developed over 600 first-in-class drug candidates (3). A report from report from the National Medical Products Administration (NMPA), China's drug regulatory authority indicates that it approved 48 first-in-class drugs across about 20 therapeutic areas, some ostensibly superior to products originating from the US, EU and Japan (4).

In truth, China's rise is a wake-up call, not a red flag and global interdependence is the new

reality. We do not need China as a rhetorical foil to identify the real challenges confronting U.S. pharmaceutical innovation—nor to pursue the thoughtful solutions so clearly articulated by Dr. Gottlieb. The failure of our policymakers to wield a scalpel rather than an axe in trimming the NIH budget is a historic misstep that risks dismantling our strategic research infrastructure and derailing the careers of emerging scientific talent. Protecting NIH funding is not merely a fiscal decision—it is a strategic imperative for sustaining America's competitive edge in biomedical innovation for decades to come (5).

The Bogeyman Narrative Undermines U.S. Pharmaceutical Innovation (Part 2 of 2)

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