

'Nearer the bench than the Beltway': An appeal for thoughtful regulation of infectious disease research

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COVID-19 has killed close to 5 million people worldwide, and the crisis has given rise to uncertainties about both the origins of the virus and how



to respond to future pandemics. Much of the uncertainty swirls around responsibility and risk: How should scientists conduct infectious disease research now? Experts in a range of disciplines including political science, arms control, and biology have called for tighter regulation of the enterprise, with some calling for an end to certain areas—like "gain of function" investigations—altogether.

Others, however, are asking lawmakers to consider a more nuanced and thoughtful approach. In a commentary published this week in *mBio*, a pair of researchers with decades of experience in high-containment laboratories argue that any approach to new regulation should draw on existing practices, past experiences, and careful consideration of both the human and financial costs.

Most importantly, responsibility for the <u>safety</u> and security of running a lab should be entrusted not to government-level agents, but to the leaders of the research organization. "Near the bench rather than the Beltway," they wrote in the commentary.

"[Organizational leaders] should take responsibility for their own programs and people," said Dave Franz, D.V.M. Ph.D, former commander of the U.S. Army Medical Research Institute of Infectious Diseases in Frederick, Maryland. Franz co-authored the new commentary with James Le Duc, Ph.D, former director of the Galveston National Laboratory, in Texas, which includes several biosafety level 4 (BSL-4) laboratories. BSL-4 facilities investigate <u>infectious agents</u> that pose a high risk of life-threatening <u>disease</u>.

In the commentary, Franz and Le Duc noted that leaders of highcontainment labs have a long history of safely managing potentially dangerous research projects at their organizations without catastrophic outcomes. "If you're running a good operation with education and training, and you're focusing on safety, <u>transparency</u> and <u>ethics</u>, I believe



you can reduce accidents," Franz said.

"A lot of the people that think more regulation is the way ahead haven't run a high-containment lab," Franz said. Regulating BSL-3 and -4 labs in the same way as nuclear labs, for example, doesn't work because of the dramatically different nature of the subject material.

A lack of experience in biological labs, Franz said, could result in new rules that further burden the enterprise, rather than minimizing harm. "It's hard for government to be nuanced, but we need to think about the cost and benefit of regulations before we put them in place," Franz said. "They often don't think about the cost in dollars, or in time, or the cost of chasing young people away from the profession."

But a leader within an organization, Franz said, can establish an environment of trust and respect. "If you're working in a healthy organization, the boss has an open door, and you trust your leadership, that can reduce harm."

The scientists noted that they're not against regulation and rules that reduce risk, but at the same time urge <u>policymakers</u> be careful in their consideration of additional unnecessary or ineffective regulatory burdens. "I hope we're thoughtful going forward," Franz said.

More information: David R. Franz et al, Technology Advances, High-Risk Research, and a Safe Way Forward, *mBio* (2021). <u>DOI:</u> <u>10.1128/mBio.02373-21</u>

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