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Making the FDA Great Again Requires Rebuilding the Rest of US Science

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Former FDA Commissioner Scott Gottlieb's recent JAMA Forum commentary correctly identifies a core vulnerability in the US Food and Drug Administration: the politicization of medical product center leadership. As he notes, "politicizing the centers risks surrendering the US position as the global regulator of reference just as China builds toward replacing the FDA's international role." This diagnosis is accurate but incomplete. The FDA's current fragility is not an isolated phenomenon. It reflects a broader, self inflicted weakening of US scientific and regulatory capacity across the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), USAID, and global health partnerships.

Over the past two years, large-scale workforce losses have disrupted the very institutions that supply the FDA with evidence, surveillance, and scientific legitimacy. As documented in recent analyses, "the dismissal of thousands of public health experts has weakened elements of that infrastructure," eroding institutional memory that cannot be quickly rebuilt" [1]. These departures have affected NIH-funded clinical trials, USAID-supported field sites, and global health programs that historically provided the FDA with trusted international data and collaborative networks. Rebuilding FDA leadership without restoring the surrounding ecosystem risks treating one organ while the rest of the system fails.

At the same time, China's rise in pharmaceutical innovation is not merely geopolitical positioning but a structural transformation. China's regulatory reforms, AI-enabled discovery platforms, and rapid out-licensing of high-value clinical assets have made it a central contributor to global pipelines. As recent analyses note, "China's ascent reflects regulatory reform, AI-enabled discovery, and the out-licensing of high-value clinical assets that increasingly shape multinational R&D pipelines" [2]. Gottlieb is right that US regulatory credibility matters, but credibility depends on more than FDA leadership. It requires stable NIH funding, robust CDC surveillance, and sustained global partnerships that allow US regulators to evaluate foreign data, participate in harmonization efforts, and maintain international trust.

A further missing dimension is institutional memory. Regulatory agencies do not function solely through formal rules; they rely on tacit knowledge accumulated over decades. As recent work has emphasized, "programs lose more than people; they lose operational bandwidth, practical records, know-how, and informal problem-solving practices" [1]. FDA's recent staff departures

mirror similar losses across NIH, USAID, and global NGOs, weakening the shared expertise that underpins US leadership in biomedical regulation.

Gottlieb is right to call for restoring career scientific leadership at FDA centers. But making the FDA “great again” requires rebuilding the broader scientific infrastructure that surrounds it. Without stable NIH investment, revitalized CDC and USAID capacity, and renewed global engagement through WHO and international regulatory networks, FDA reforms will be insufficient. The United States cannot maintain its role as the global regulator of reference if the institutions that support its scientific authority continue to erode.

Reforming FDA governance is necessary, but it must be part of a whole-of-system strategy to restore the scientific, regulatory, and global partnerships that once made US biomedical leadership possible.

References:

1. Babul et al. doi:10.7759/cureus.99372

2. Babul et al. doi:10.7759/cureus.105407