The need to strengthen the US Food and Drug Administration: US cuts threaten health care at home and abroad

The administration of US President Donald Trump has taken a series of actions since January, 2025 that directly threaten the foundations of health care, for global and US citizens alike. What started as severe cuts to development aid, which have disrupted medicine supply chains and numerous health programmes in African and other low-income countries,[1] has evolved into a broader retrenchment of the USA's health infrastructure with substantial job losses across agencies, including the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health, all negatively impacting patients.[2,3] Additionally, a tariff war looms over the pharmaceutical sector amid the launch of a Section 232 investigation that would allow the US President to restrict medicine imports, impeding supplies of life-saving products.[4,5] And the Trump administration's announcement in May, 2025 to reference pharmaceutical prices globally further adds complications to the availability of medicines in the USA and worldwide.[6]

The implications of these reckless moves are particularly worrying when it comes to regulation. The FDA, arguably the most important and respected medicines regulator in the world, has been rocked by around 3500 job cuts[2,3,7] that will inevitably disrupt workflows and mean longer waiting times for regulatory processes, affecting product approvals and access to effective new treatments. The firing of some key senior staff has led to concerns that FDA decisions might in future be influenced by political rather than purely scientific considerations. Staffing pressures also bring a risk that inspections of pharmaceutical companies and manufacturing facilities will be delayed, or that there might be shortcuts in oversight, including important work to prevent and mitigate drug shortages.[8] The loss of more than 100 support staff at the FDA's Office of Inspections and Investigations[9] is likely to compromise its operational capabilities. This work is crucial for ensuring drug quality, product safety, and batch validation—an often overlooked but vital aspect of keeping substandard products off the market.

The FDA was struggling even before the cuts in 2025. As of 2024, about 42% of the 4700 plants producing medicines in the USA were overdue an inspection, with some uninspected for more than 5 years.[10] Furthermore, between 2018 and 2021 nearly half of drug manufacturers required to report significant quality problems with their products failed to do so.[11,12] High-profile cases in the USA such as the fatal contamination of over-the-counter eyedrops from uninspected foreign suppliers in 2023 are an example of what is at stake when inspections lapse.[13]

More broadly, loss of capacity at the FDA threatens the delicate ecosystem of innovation that is responsible for finding new medicines and bringing them to patients. The FDA has a central role in enabling research and development, particularly in complex, high-risk areas such as antimicrobial resistance, emerging infectious diseases, and pandemic preparedness. Under-resourcing this vital institution therefore jeopardises the research and development medicines pipeline that supports global health security.

There are already fewer and fewer companies active in areas such as infectious diseases, including finding replacement antibiotics for those that no longer work. The 2024 Access to Medicine Index highlighted this issue, with the number of research and development projects that target priority diseases such as malaria and tuberculosis decreasing from 367 to 253.[14] For emerging infectious diseases, the pipeline of products dropped from 80 to just 33, with no ongoing research and development at all in 12 of 16 priority emerging infectious diseases.[14] The 2024 Antimicrobial Resistance Benchmark, meanwhile, found only 19 experimental antibacterials targeting eight priority pathogens, with no research and development for the remaining six targets.[15] This shrinkage threatens the ability to manage both routine and catastrophic infections.

Without adaptive and timely regulatory guidance from the FDA, pharmaceutical companies will face increased costs and reduced commercial incentives to develop or adapt products for new health threats. Several biotechnology companies are planning studies outside the USA, signalling that the USA might not be the centre of innovation in the future.[16] The situation is already fragile with too few pharmaceutical companies

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operating in important therapeutic areas. With an estimated 50% chance of another pandemic of equal or greater severity than COVID-19 within the next 25 years,[17] more protection from present and future health threats is sorely needed.

The FDA has been vital in managing past global disease outbreaks, most recently during the COVID-19 pandemic when fast-track approval of vaccines under Emergency Use Authorization proved crucial in protecting citizens. Going forward, the FDA, alongside agencies such as the CDC, needs the capacity and workforce to act swiftly again in a crisis to prevent the collapse of public health systems.

The FDA is also integral to enabling new models for advancing access to and the affordability of medicines. Its assessments and approval timings are important—for example, to the functioning of US legislation such as the Pasteur Act of 2023,[18] which aims to fix the broken market for antibiotics by creating subscription-style payments, and the Inflation Reduction Act of 2022, designed to address affordability for all types of medicines.

Globally, the FDA has a key leadership role and it is generally seen as setting a gold standard for approvals. Although there are other important efforts to streamline access to medicines around the world, including WHO's prequalification system and work by the European Medicines Agency and the nascent African Medicines Agency, without a fully functioning FDA there are likely to be negative impacts on access to essential medicines in low-income and middle-income countries. The world could easily regress to the situation in pre-2000 when patients in low-income and middle-income countries faced waiting times of decades before getting access to life-saving treatments or did not have access to essential medicines.

Trump may aspire to make the USA self-sufficient by reshoring strategic industries, including pharmaceuticals, but bringing manufacturing back to the USA will not happen overnight. The USA is currently heavily dependent on overseas suppliers, especially when it comes to generic and biosimilar medicines, which account for about 90% of all US prescriptions.[19] These products are widely sourced from India and China and simply shedding this dependency is unrealistic in the short term. In the meantime, it falls to the FDA to ensure that medicines made overseas meet stringent quality standards.

The FDA's position as an indispensable institution in the international system of medicines regulation, approvals, and harmonisation to enable global availability is non-negotiable. Patients in the USA and around the globe need a strong, independent, and resilient FDA to support innovation and ensure continued access to effective, high-quality treatments. Chipping away at the regulatory foundations will only make the world a less safe and more unfair place.

I am the Chief Executive Officer of the independent non-profit Access to Medicine Foundation, which produces the biennial Access to Medicine Index, and declare no other competing interests.

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