# PUBLICATION

## Executive Orders on Domestic Production of Critical Medicines and Biological Research Security

**Authors: Michael J. Halaiko, Alexandra P. Moylan**
**May 08, 2025**

### What Happened?

The President signed two companion Executive Orders (EO) on May 5, 2025 that collectively signal a significant federal pivot toward (i) accelerating the domestic manufacture of pharmaceuticals deemed "critical" to the national interest and (ii) tightening the biosafety and biosecurity framework that governs academic, industrial, and government-sponsored life-science research. The first EO – Regulatory Relief To Promote Domestic Production of Critical Medicines – directs the U.S. Department of Health and Human Services (HHS), in coordination with the Food and Drug Administration (FDA), the Department of Defense (DoD), the Environmental protection Agency (EPA) and other agencies, to identify essential medicines, streamline or waive certain regulatory requirements impeding domestic manufacture, leverage the Defense Production Act to expand domestic capacity, and prioritize federal procurement toward U.S.-based sources. It requires the FDA to reconsider its system for review of foreign manufacturing facilities, which will be funded by increased fees on foreign manufacturing facilities. The second EO – Improving the Safety and Security of Biological Research – focuses on gain-of-function research, which involves altering pathogens to enhance certain properties. It ends all current and future funding of Gain-of-function research conducted in "countries of concern" like China and Iran. It pauses federally funded research in the United States involving infectious pathogens and toxins that may pose a danger to Americans until safer, more comprehensive oversight policies are developed and implemented.

### Who Will Feel the Impact?

Although the EOs are directed to federal agencies, their practical reach extends to any entity that (a) manufactures, imports, distributes, or dispenses prescription or over-the-counter drugs, active pharmaceutical ingredients, or key excipients; (b) conducts, sponsors, or funds laboratory work involving select agents, recombinant DNA, or potentially pandemic pathogens; or (c) supplies equipment, raw materials, or contract services to such entities. This includes – but is not limited to – branded and generic drug manufacturers, contract development and manufacturing organizations (CDMOs), academic medical centers, clinical research organizations, biotechnology startups, research institutions, and venture investors with exposure to life-science portfolios.

### Why Should Entities Involved in Drug Research, Development, and Manufacturing Take Note?

The Regulatory Relief Order is poised to reorder supply-chain economics by making federal purchasing power contingent on domestic content thresholds that will be specified in forthcoming HHS guidance. Organizations that rely heavily on offshore active pharmaceutical ingredients or finished-dose manufacturing may face material revenue erosion in the federal market unless they rebalance production footprints toward the United States. Simultaneously, the EO empowers FDA to grant expedited review of facility supplement submissions, site transfers, and prior-approval supplements aimed at repatriating manufacturing lines, thereby offering an administrative fast-track for companies that are willing to absorb near-term capital expenditure. The EO notes that current timelines for building new drug manufacturing capacity of 5-10 years are "unacceptable." It tasks the FDA with increasing inspection fees for foreign manufacturing plants and conducting more unannounced inspections abroad, bringing foreign oversight in line with domestic oversight. It is a preview of potential tariff modifications or import disincentives on imported pharmaceuticals.

The Biological Research Security EO materially raises the compliance bar for federally funded work involving genetically modified organisms, viral vector platforms, and synthetic biology. It portends mandatory risk assessments aligned with the National Institutes of Health (NIH) Guidelines, codification of the existing dual use research framework into binding regulation, and expanded criminal and civil penalties for non-compliance. Grant recipients will need formalized biorisk management plans, third-party auditing, and incident reporting pathways that parallel those set forth in OSHA's laboratory safety rules, all of which are likely to increase overhead costs, extend project timelines, and implicate directors' and officers' fiduciary oversight obligations.

### Key Takeaways for Drug Research, Development, and Manufacturing Businesses

First, life-science companies and CDMOs contemplating green-field or brown-field manufacturing investments in the United States should move quickly to engage with HHS, FDA, and DoD to position their facilities for "critical medicine" designation and to capitalize on expedited regulatory pathways. Second, entities that cannot feasibly onshore manufacturing may need to develop contingency strategies – such as strategic collaborations with domestic CDMOs or technology transfer to U.S. subsidiaries – to preserve eligibility for federal procurement contracts. Third, research institutions should begin mapping existing and planned studies against the anticipated DURC and PPP categories, updating Institutional Biosafety Committee charters, and budgeting for external audits, as non-compliant work may become categorically ineligible for federal funding. Fourth, boards of directors should treat both EOs as catalysts for enhanced enterprise risk management: the domestic-production mandate introduces supply-chain concentration risk, while the biosafety mandate elevates the regulatory enforcement environment. Finally, while the EOs take immediate legal effect, their most impactful provisions depend on agency rulemakings and guidance that will roll out over the next 6–12 months; interested stakeholders should monitor the Federal Register and consider submitting comments to shape the contours of forthcoming regulations.

For more information or assistance on this topic, please contact Michael J. Halaiko, Alexandra P. Moylan, or another member of Baker Donelson's Health Law team.