

Competitive Compliance: Why Uniform Screening Standards Support Innovation and Thwart Regulatory Capture



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EXECUTIVE SUMMARY

Gene synthesis screening is an effective tool to prevent dangerous pathogens from moving from digital design to physical reality. Mandatory screening will likely provide substantial benefits at modest cost. A UK-focused analysis found screening delivers approximately £3.50 in security benefits for every £1 spent, and we would expect broadly similar findings in the US. The availability of free, open-source screening tools alongside commercial options has significantly reduced compliance costs. Beyond security benefits, mandatory screening would level the playing field for providers, ensure clear and uniform standards, and create a demand signal for

screening technology innovation. Mandatory screening would not create a significant new requirement for companies that service recipients of federal research dollars, who already must screen their orders to comply with [President Trump's May 2025 Executive Order](#). Lastly, concerns that mandating screening could create regulatory capture issues are largely unpersuasive, owing to the competitive and fragmented state of the gene synthesis market, availability of low-cost screening tools, and the opportunity to tailor compliance standards to a variety of business models.

BACKGROUND

Gene synthesis, the ability to produce custom DNA sequences on demand, has become essential to modern biotechnology. The U.S. DNA synthesis market was valued at [\\$1.60 billion in 2024](#) and is projected to reach \$9.30 billion by 2034, driven by researchers developing new medicines, engineering improved crops, and advancing our understanding of biological systems. The U.S. maintains predominant market share across the industry ([55% worldwide](#)) and specializes in high-end, high-complexity applications. In contrast, the Chinese biotechnology industry as a whole has tended to [imitate Western firms](#) and gain a foothold in the low-cost market before transitioning to more technologically sophisticated manufacturing. Interviews with several scientists suggest that the Chinese gene synthesis industry has followed this broader pattern.

This rapid growth and increasing global accessibility of this technology create both opportunities and risks. As gene synthesis becomes cheaper and AI tools lower technical barriers, the pool of people capable of engineering dangerous pathogens continues to grow. MIT Professor Kevin Esvelt estimates [approximately 30,000 people](#) worldwide now have the skills to assemble a pandemic-capable virus from scratch, a number that could increase dramatically in coming years [as technologies advance](#). Without adequate safeguards, gene synthesis could be exploited to build and release pathogens that cause a deadly pandemic.

Screening orders at the point of synthesis offers a key opportunity to prevent dangerous sequences from entering the physical world. Currently, many major synthesis companies voluntarily choose to screen incoming orders for potentially dangerous sequences. The [International Gene Synthesis Consortium](#), an industry trade association representing the majority of gene synthesis capacity worldwide, has published a Harmonized Screening Protocol, which members commit to following. These recommendations closely mirror voluntary guidance from the [U.S. Department of Health and Human Services](#).

Many members of industry are in favor of mandatory gene synthesis screening¹ and already engage in it voluntarily. The expansion of screening practices among synthesis companies has been facilitated by the availability of low-cost tools. Several free and open-source screening tools are available ([IBBIS' Common Mechanism](#), [Secure DNA](#), and [SeqScreen Nano](#)), as well as a range of commercial tools that allow synthesis

¹ Based on interviews with gene synthesis companies and scientists who have spoken out in favor of gene synthesis screening legislation.

companies to opt in to different levels of cost and engagement. Although [bipartisan members of Congress](#) and the [Biden](#) and [Trump](#) administrations have indicated a strong desire to mandate screening across the gene synthesis industry, there is currently no universal screening requirement. However, both administrations have required recipients of federal research dollars to purchase from gene synthesis companies that screen. Whether voluntary or due to engagement with the federal research market, it is encouraging to see many companies screening, but experts estimate that [20% of synthetic DNA orders](#) still go unscreened, and the industry lacks any formal oversight to ensure that screening practices are sufficiently rigorous across providers and keep pace with emerging threats such as AI-designed sequences.

Screening has two major parts: customer and sequence screening. Customer screening focuses primarily on the individual or institution purchasing a given sequence, while sequence screening checks the orders for suspicious sequences. Some screening providers offer “compliance in a box,” allowing synthesis companies to essentially outsource the entirety of customer and sequence screening, while other companies prefer to conduct portions of this process in-house. In either approach, the cost of using screening tools is generally [fairly low](#), while human review (generally requiring highly-skilled labor) of flagged or ambiguous sequences can be [more costly](#). New screening technologies, including those leveraging modern AI methods, which can reduce the need for human review.

THE COST-BENEFIT CASE FOR MANDATORY SCREENING

Pandemics carry staggering economic costs. COVID-19 alone cost the U.S. economy [trillions of dollars](#) in lost output, federal spending, and long-term health impacts. As novel technologies, such as synthetic nucleic acids, increase the risk of man-made outbreaks, implementing effective safeguards is increasingly important. While synthesis screening is already cost-effective enough that many companies screen voluntarily, making it mandatory would likely improve cost-effectiveness further by leveling the playing field and enabling economies of scale. A [recent economic analysis](#) of mandatory gene synthesis screening in the UK context provides a useful benchmark for the United States.

That analysis, which followed standard government cost-benefit methodology, found that for every £1 spent on mandatory screening, the economy would gain £3.50 in security benefits—derived from reduced likelihood of pandemics, toxin releases, and other biological incidents. Even under conservative assumptions about how much screening reduces risk, the expected value math strongly favors intervention: screening costs are modest and ongoing, while the cost of a single successful attack or accidental release would be catastrophic and irreversible.

The analysis found that mandating screening for synthetic nucleic acids over 50 base pairs would deliver clear value for money under most reasonable assumptions. Few factors in the model are UK-specific, and screening may actually be more cost-effective in the United States, where larger companies can spread fixed costs across

higher order volumes. Moreover, because the US controls a substantially larger share of the global market, a US mandate would increase pressure on other nations to follow suit. Since pandemics do not respect borders, moving the world toward a tipping point where screening becomes the international standard would multiply security and economic benefits to Americans.

MANDATORY SYNTHESIS SCREENING REWARDS COMPANIES COMMITTED TO U.S. BIOSECURITY STANDARDS

Gene synthesis screening requirements have the potential to bolster the U.S. gene synthesis industry against lower-cost but less secure overseas competitors. The U.S. nucleic acid synthesis industry is currently quite vibrant thanks both to the presence of highly-trusted industry pioneers like Twist Biosciences and Thermo Fisher, and to the emergence of innovative startups, which often focus on specialized nucleic acid sequences optimized for cutting-edge biotech applications. However, a number of researchers we interviewed stated that an increasing amount of low-cost bulk gene synthesis for the U.S. biotechnology industry is outsourced to China. Currently, only a single [Chinese gene synthesis company](#) has self-attested to complying with the U.S. government's [voluntary sequence screening framework](#). Although there are Chinese synthesis providers that are [members of the IGSC](#) and state that they screen orders, the U.S. government currently has little visibility into the Chinese gene synthesis ecosystem or whether U.S. orders are supporting companies that may not follow biosecurity best practices. By implementing standardized screening requirements for gene synthesis companies doing business in the U.S., and by mandating that companies and researchers receiving federal funding purchase synthetic DNA only from companies that follow adequate screening procedures, the U.S. government can ensure that only companies willing to cooperate meaningfully with U.S. biosecurity standards get the benefit of U.S. business. This policy requires that Chinese companies that wish to sell synthetic DNA to U.S. customers comply with U.S. federal screening requirements, including conformity assessments to ensure the adequacy of their screening protocols. Either U.S. business will be redirected away from Chinese gene synthesis companies, or else these companies will need to work with the government to prove that they meet U.S. biosecurity standards.

DRIVING DOWN THE COST OF COMPLIANCE

As described above, the cost of gene synthesis screening has been rapidly declining thanks to the mixture of free, open-source tools and commercial solutions. By implementing a gene synthesis screening mandate, the U.S. government could further minimize the costs of synthesis screening compliance.

First and foremost, universal, rigorous standards for sequence screening and know-your-customer screening would provide a level of certainty that the biotech community currently lacks. We conducted multiple interviews with DNA synthesis providers and with scientists who purchase synthetic DNA, and nearly all of them stated that the biggest cost of screening currently comes from the uncertainty of what “good enough” screening looks like. Synthesis companies are uncertain how much to invest in screening tools and procedures, and whether they are overinvesting compared to their competitors. Scientists who purchase synthetic DNA describe the lack of clarity around what sequences might be flagged by different synthesis companies, and if an order is flagged, what actions and documentation are necessary to prove the legitimacy of their order. This uncertainty delays their work and requires staff time to navigate. By adopting a gene synthesis screening mandate with clear compliance criteria, the US government can level the playing field for gene synthesis providers, provide welcome clarity to scientists, and give screening providers the information necessary to further optimize their products and streamline the screening process.

Gene synthesis screening requirements also create a demand signal that can encourage the growth of a fledgling biotech sub-industry: gene synthesis screening providers. In addition to three established organizations — Battelle, Aclid, and RTX BBN — that offer commercial screening solutions, a number of [researchers](#) are piloting new screening methodologies, often leveraging recent advances in AI, to build screening tools that are more [resistant to obfuscation](#) and more cost-effective. Interviews with several of these researchers indicated that they are interested in commercializing these solutions, but that uncertainty about future synthesis screening requirements makes it harder to secure startup funding and business partnership commitments. A clear demand signal from the government would spur more researchers and private funders to enter the gene synthesis screening space—accelerating research, encouraging new startups, and driving down costs through competition.

In addition, agencies could make small initial investments to further decrease compliance costs for companies. For example, the government could work with industry groups to create a secure way to share the list of institutions registered to work with pathogens or toxins on the Health and Human Services Select Agents list, and provide this list to approved gene synthesis screening companies or nonprofits. This would allow screening providers to create a “TSA precheck program for DNA synthesis,” exempting researchers who have already demonstrated a legitimate reason to work with dangerous sequences from future screening.

ADDRESSING REGULATORY CAPTURE CONCERNS

Although few experts consider regulatory capture a [serious risk](#) in gene synthesis screening, some policymakers have raised this concern. The argument is that companies encouraging governments to create an industry-wide screening standard might raise the cost of doing business for new entrants, thereby entrenching the market share of established players. While this concern may be legitimate in other contexts, several factors make it unlikely to apply to the gene synthesis industry.

- **Market Fragmentation and Competition** - The gene synthesis industry is highly competitive, with companies competing primarily on quality, price, and turnaround time. While a significant portion of the bulk DNA synthesis market is controlled by ~4 companies (IDT, Twist, GenScript, and ThermoFisher), dozens of smaller players currently focus on more specialized markets such as [long DNA sequences](#) or sequences with [complex structure](#). In the bulk market, manufacturing innovations that exploit economies of scale give industry leaders a significant [comparative advantage](#). This has so far proven to be the most significant [barrier to new entrants](#), rather than the cost of screening. In the more specialized gene synthesis industry, products tend to be longer-stranded, harder to write, and/or higher-fidelity, creating distinct (and expensive) technical challenges. These challenges make sequence screening a relatively small percentage of operating costs, which creates a market in which screening efficiency is not a significant determinant of success. This fragmented and highly competitive market structure would make it challenging for any individual company or group to perform regulatory capture. Each of the four major players is well-equipped to handle screening compliance costs, so fierce competition among them would continue, while smaller players would remain focused on specialized markets where they compete primarily on novel capabilities.
- **Low Cost of Screening and Open Source Tools** - As previously discussed, the cost of mandatory screening is relatively modest (especially relative to the benefits), and free and open-source screening tools are available. For mandatory screening to serve as an effective tool for regulatory capture, it would need to be expensive and/or difficult to conduct without specialized knowledge or tools. Clarifying the standards that companies should adhere to—a key goal of mandatory screening—will lower the cost of compliance and reduce any burden on new entrants. Lastly, many companies already service recipients of federal research dollars, who must purchase from companies that screen, meaning that the marginal burden of universal screening would be minimal.
- **Screening Compliance That Fits Company Business Models** - U.S. federal implementation of screening standards will be done in collaboration with the scientific community and biotech industry, and can ensure that compliance requirements are appropriate for different companies' sizes and business models. While large gene synthesis providers need automated systems, smaller startups often use “built-in screening” because their business model naturally leads them to develop close collaborations with their customers to iterate on and optimize specialized orders. Compliance standards can reflect this, allowing fledgling companies that have not yet scaled up production to provide lightweight documentation of this built-in process.

Experts have also [noted](#) that the reputational consequences of failing to require screening could be devastating for the entire industry. Industry representatives have [expressed](#) the view that a worst-case outcome is plausible even without an actual biosecurity incident—a public perception that the gene synthesis industry contributed to a near-miss could be equally damaging. In this respect, requiring screening across industry ensures that safety does not become a competitive disadvantage.

CONCLUSION

The case for mandatory gene synthesis screening is strong. Economic analysis suggests screening delivers substantial security benefits relative to its modest costs. Beyond the direct security benefits, mandatory screening would level the playing field for providers already screening voluntarily, provide much-needed clarity on compliance standards, and create a demand signal that encourages innovation in screening technology. It would also ensure that companies doing business in the US—including overseas competitors—adhere to rigorous biosecurity standards. Concerns about regulatory capture are largely unpersuasive given the competitive and fragmented nature of the gene synthesis market, the availability of free and open-source screening tools, and the flexibility to tailor compliance requirements to different business models. By implementing a clear federal mandate, the US can reduce industry uncertainty, maintain its leadership in biotechnology, and help prevent the catastrophic risks of a man-made pandemic.