Date of Hearing: March 24, 2026

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1864 (Berman) – As Introduced February 11, 2026

SUBJECT: Gene synthesis equipment manufacturers and providers.

SUMMARY: Prohibits a manufacturer from producing, selling, or delivering benchtop nucleic acid synthesis equipment and prohibits a provider from producing, selling, or delivering synthetic nucleic acids subject to screening unless the provider adheres to the Framework for Nucleic Acid Synthesis Screening issued by the Fast Track Action Committee on Synthetic Nucleic Acid Procurement Screening of the National Science and Technology Council as revised in September 2024 (the framework), unless the Department of Public Health (DPH) adopts regulations pursuant to this bill, in which case they must adhere to DPH's regulations. Specifically, **this bill**:

1) Prohibits a manufacturer from producing benchtop nucleic acid synthesis equipment in this state or selling or delivering benchtop nucleic acid synthesis equipment to a customer in this state unless the manufacturer adheres to the framework with respect to the produced, sold or delivered equipment.

2) Prohibits a provider from producing synthetic nucleic acids subject to screening in this state or sell or deliver synthetic nucleic acids subject to screening to a customer in this state unless the provider adheres to the framework with respect to the produced, sold, or delivered nucleic acids.

3) Specifies, for purposes of this bill, if the framework uses the term "should" it is a requirement for a provider or manufacturer.

4) Specifies, for purposes of this section, if the framework uses the term "encouraged," it is a recommendation, but not a requirement, for a provider or manufacturer.

5) Makes a provider or manufacturer that violates this bill subject to a civil penalty in an amount dependent on the severity of the violation that does not exceed one thousand dollars ($1,000) per day that the violation continues.

6) Requires a civil penalty assessed pursuant to this bill to be recovered in a civil action brought only by the Attorney General (AG).

7) Defines "framework" to mean the Framework for Nucleic Acid Synthesis Screening issued by the Fast Track Action Committee on Synthetic Nucleic Acid Procurement Screening of the National Science and Technology Council, as revised in September 2024, unless DPH adopts regulations pursuant to 9) below. States that if DPH adopts regulations pursuant to this bill, "framework" has the same meaning as defined in the regulations.

8) Except as otherwise provided in regulations adopted pursuant to this bill, the following terms have the following meaning:

a) "Benchtop nucleic acid synthesis equipment" has the same meaning in the framework (which is equipment intended to be used to synthesize nucleic acids for use within a research laboratory or institution, regardless of whether it is small enough to be placed on a benchtop).

b) "Customer" has the same meaning as defined in the framework (which is the individual or entity, such as an institution, that orders or requests synthetic nucleic acids from a provider or purchases nucleic acid synthesis equipment from a manufacturer).

c) "Manufacturer" has the same meaning as defined in the framework (which is an entity that produces and distributes benchtop nucleic acid synthesis equipment).

d) "Provider" has the same meaning as defined in the framework (which is an entity that synthesizes and distributes synthetic nucleic acids and which may provide synthetic nucleic acids to a customer or third-party vendor as a transactional service, rather than as a research scientist collaborating with a colleague).

e) "Synthetic nucleic acids subject to screening" has the same meaning as defined in the framework (which at the time of the September 2024 framework's issuance, states that at a minimum, DNA or RNA, single- or double-stranded, 200 nucleotides (including the corresponding amino acid sequence, if applicable) or longer should be screened for sequences of concern. As of October 13, 2026, this screening window will be decreased to 50 nucleotides).

9) Authorizes DPH to adopt regulations that define "framework" for the purposes of this bill, to have the same meaning as one or more, either in combination or in the alternative, federal law, regulation, or guidance document if DPH determines that the regulations would result in an equal or greater degree of protection for the residents of California from relevant biohazards and would not impose, in the judgment of DPH, unreasonable burdens on manufacturers or providers.

10) Authorizes, as part of the adoption of regulations, DPH to adopt definitions of the terms in 8) above.

11) Authorizes, if DPH adopts regulations and the law, regulation, or guidance document contains a definition of a term that is different from, but functionally equivalent to the definition in 8) above, DPH's regulations to specify which term is a functional equivalent of a term defined in 8) above.

12) Authorizes, if DPH adopts regulations and the law, regulation, or guidance document does not define a term defined in 8) above, the regulations to specify that a term has the same definition as in a prior version of the framework.

13) Requires, no later than one year after the adoption of any regulation adopted pursuant to this bill, DPH to submit a report to the Legislature assessing whether the regulations have maintained or enhanced the protection of the residents of California from relevant biohazards.

14) Makes the provisions of this bill severable. If any provision of this bill or its application is held invalid, prohibits the invalidity from affecting other provisions or applications that can be given effect without the invalid provision or application.

15) Finds and declares that the state has a strong interest in protecting the residents of California from biohazards caused by reckless or malicious individuals with access to dangerous nucleic acid synthesis equipment or ordered from commercial gene synthesis providers, and providers and manufacturers must take due care in order to avoid creating unreasonable risks of serious injury.

16) Finds and declares that in 2023, the Director of the White House Office of Science and Technology Policy (OSTP) initiated an interagency process for the development of a framework "to encourage providers of synthetic nucleic acid sequences to implement comprehensive, scalable, and verifiable synthetic nucleic acid procurement screening mechanisms, including standards and recommended incentives, resulting in the issuance by the National science and Technology Council's Fast Track Action Committee on Synthetic Nucleic Acid Procurement Screening of the Framework for Nucleic Acid Synthesis Screening, revised as of September 2024 (the framework). It is in the interest of all Californians that all synthesis providers and manufacturers operating in the state adhere to the framework or a future framework or standards promulgated by the federal government that DPH to be equally or more protective of the residents of California from relevant biohazards.

EXISTING LAW:

1) Requires DPH to establish an advisory committee to advise the Legislature and the Governor on human cloning and other issues relating to human biotechnology. [Health and Safety Code (HSC) § 24186]

2) Requires the California State University (CSU), and requests the University of California (UC), to develop systemwide guidance for purchasing gene synthesis equipment or gene synthesis products from gene synthesis providers who prevent the misuse of synthetic genes and safeguard the benefits of gene synthesis technology while minimizing risk and consider including International Gene Synthesis Consortium (IGSC) criteria in their guidance. [Education Code (EDC) § 66361]

3) Defines "gene synthesis equipment" to mean equipment needed to produce gene synthesis products that are not readily used for any other purpose. [EDC § 66360]

4) Defines "gene synthesis product" as double-stranded deoxyribonucleic acid (DNA), double-stranded nucleic acids, ribonucleic acid (RNA), or oligonucleotides, designed and created without an existing DNA template. [EDC § 66360]

5) Defines "gene synthesis provider" to mean an entity that does any of the following:

    a) An entity that creates gene synthesis products for delivery to a customer;

    b) A distributor of gene synthesis products, including, but not limited to, entities who manufacture gene synthesis products for use by other parties, both inside and outside of the entity;

c) A third-party entity that is not the end user of a gene synthesis product and does not make gene synthesis products, but otherwise fills, completes, modifies, or purifies gene synthesis products; and,

d) Excludes from the definition of "gene synthesis provider" a research scientist making gene synthesis products for the research scientist's own use or for use by another research scientist or an entity that manufactures gene synthesis products for the entities own use. [EDC § 66360]

FISCAL EFFECT: Unknown. This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, from Silicon Valley to Biotech Beach, California is the undisputed cradle of innovation, which has led to great technological advancements and the development of lifesaving vaccines and treatments. However, innovation cannot come at the expense of protecting public health and we must implement enforceable guardrails to ensure that gene synthesis technology is not misused to create dangerous bioweapons. The author states that this bill would protect Californians against the misuse of gene synthesis technology by requiring providers of synthetic genes and manufacturers of gene synthesis equipment to screen customer orders for dangerous pathogen sequences and confirm the legitimacy of customers. The author concludes that this bill is a commonsense approach to standardize federally recognized best practices in order to keep Californians safe and defend against biological threats.

2) **BACKGROUND.**

   a) **Gene synthesis.** Gene synthesis is the artificial construction of gene sequences from their chemical building blocks (nucleic acids), rather than copying them from a living organism. Gene synthesis is enabling experimentation and innovation in research, medicine and industrial applications.

   b) **Risks Associated with Synthetic Biology.** Although important for many beneficial applications, there are significant risks associated with the misuse of synthetic biology and related biotechnologies, including gene synthesis. The National Academy of Sciences released its report, "Biodefense in the Age of Synthetic Biology" in June 2018 in response to a request of the then Department of Defense for an assessment of the security concerns related to advances in synthetic biology. As the Senate Health Committee pointed out in its discussion of this report in its analysis of AB 1963 (Salas), Chapter 179, Statutes of 2022, (which requires the CSU and requests the UC to develop guidance for purchasing gene synthesis products from providers who prevent misuse, universities began requesting biosecurity attestations from gene synthesis providers), these capabilities make possible new modes of attack, some of which may not be detectable or treatable with current approaches to disease containment and biodefense mitigation. The age of synthetic biology also lowers some of the barriers to developing and using biological and chemical weapons, potentially putting such weapons within the reach of adversaries with relatively low expertise, financing, and access to scientific equipment and resources. The report notes how related developments such as gene therapy, nanotechnology, automation, additive manufacturing, and health informatics may converge with synthetic biology and help overcome current barriers to the development

or use of synthetic biology-enabled weapons. The report notes that to account for the broader capabilities enabled by synthetic biology, the U.S. government could, among other actions, evaluate existing infrastructure for disease surveillance and identification and consider strategies for preventing misuse of biology that manage emerging risk in addition to current approaches focused on restricting access to specific pathogens and toxins.

The risks associated with synthetic biology, including gene synthesis, are compounded by artificial intelligence (AI). The Nuclear Threat Initiative's 2023 report titled "The Convergence of Artificial Intelligence and the Life Sciences: Safeguarding Technology, Rethinking Governance, and Preventing Catastrophe" notes that AI tools and technologies that enable the engineering of living systems could be deliberately misused to cause significant harm, as they expand access to knowledge and capabilities for producing well-known toxins, pathogens, or other biological agents. The report warned that such misuse has the potential to cause a global biological catastrophe.

A June 2023 study published on Cornell University's website titled, "Can Large Language Models Democratize Access to Dual-Use Biotechnology?" found that non-scientist students, given just one hour with Large Language Model (LLM) chatbots, identified four potential pandemic pathogens, obtained reverse genetics protocols to turn synthetic DNA into live viruses, and received names of gene synthesis companies unlikely to screen orders.

c) **Screening and Introduction to the Framework.** Screening is a tool that can help to prevent synthetic nucleic acids from ending up in the hands of bad actors. In October 2023, President Biden issued an Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. The Executive Order directed the federal government to reduce the risks of misuse of synthetic nucleic acids and improve associated biosecurity measures. The Executive Order requires that OSTP develop a framework to encourage providers of synthetic nucleic acid sequences to implement comprehensive, scalable, and verifiable synthetic nucleic acid procurement screening mechanisms. The OSTP published its Framework for Nucleic Acid Synthesis Screening in April of 2024 and issued a revised version in September of 2024.

The framework outlines a unified process for screening purchases of synthetic nucleic acids and benchtop nucleic acid synthesis equipment, guiding providers of synthetic nucleic acids and manufacturers of benchtop nucleic acid synthesis equipment to screen purchase orders to identify sequences of concern (SOCs) and assess customer legitimacy.

The framework incorporates and supplements portions of the Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids, U.S. Department of Health and Human Services, October 2023, and its accompanying Companion Guide.

The framework states that federal funding agencies will, as appropriate and consistent with applicable law, require that procurement of synthetic nucleic acids and benchtop nucleic acid synthesis equipment using federal life sciences funding be conducted through providers and manufacturers that adhere to the framework.

a) **Details of the Framework.** According to the framework, providers and manufacturers should take the following six actions for such procurement, consistent with the 2023

federal Department of Health and Human Services Guidance and the October 2023 Executive Order in order to adhere to the framework:

i) Attest to implementing this screening framework through a statement that either is posted on a public website or provided to the federally funded customer and federal funding agency upon request;

ii) Screen purchase orders for synthetic nucleic acids to identify SOCs, which at the time of the framework's issuance, includes a nucleotide sequence or its corresponding amino acid sequence that is a best match to a sequence of federally regulated agents, except when the sequence is also found in an unregulated organism or toxin. As of and after October 13, 2026, this definition will include sequences known to contribute to pathogenicity or toxicity, even when not derived from or encoding regulated biological agents;

iii) Screen customers submitting purchase orders of synthetic nucleic acids with SOCs, and purchase orders of benchtop nucleic acid synthesis equipment, to verify legitimacy;

iv) Report potentially illegitimate purchase orders of synthetic nucleic acids involving SOCs or of benchtop nucleic acid synthesis equipment;

v) Retain records relating to purchase orders for synthetic nucleic acids and benchtop nucleic acid synthesis equipment; and,

vi) Take steps to ensure cybersecurity and information security.

b) Current state of screening. President Trump's May 2025 Executive Order on "Improving the Safety and Security of Biological Research", which requires federal departments and agencies to revise or replace the 2024 framework within 90 days of the date of the Executive Order. At the time of this analysis' publication, a new framework has not been issued, and it is unclear whether the 2024 framework is still in place. The 2025 Executive Order does not explicitly rescind the 2024 framework, yet Pennsylvania State University's website states that it has been paused.

In 2009, an industry-led group of gene synthesis companies and organizations formed the International Gene Synthesis Consortium (IGSC) to design and apply a common protocol to screen both the sequences of synthetic gene orders and the customers who place them. Membership in the IGSC is voluntary. The third version of the IGSC's protocol was developed based on the 2024 framework and is substantially aligned with its requirements. According to information provided by the author and sponsors, compliance with the IGSC's Harmonized Screening Protocol is not independently verified.

In September 2024, the Johns Hopkins Center for Health Security (JHCHS) launched the Gene Synthesis Screening Hub dedicated to helping providers, manufacturers, and customers adhere to the framework. As part of its work, it maintains a list of firms that publicly attest to following the 2024 framework. JHCHS notes that they do not attempt to independently verify or categorize the types of providers or manufacturers listed and do not claim that the list is exhaustive.

c) What does the bill do? This bill requires manufacturers and providers to comply with the 2024 framework, unless DPH adopts regulations as described above. Second, this bill authorizes DPH to update regulations to adhere to future federal standards, regulations, or guidance documents, allowing California's requirements to stay current as biosecurity evolves. Further, this bill authorizes the AG to enforce the statute to seek civil penalties.

2) SUPPORT. This bill is sponsored by ENCODE AI and the Secure AI Project, who state in support that this bill would align California law with existing federal guidelines, safeguarding public health and protecting California's life sciences enterprise from misuse. The cosponsors state that the history of biological threats demonstrates the existence of malicious and irresponsible actors. The cosponsors note that in 2023, local authorities discovered an illegal biolab in Reedley, California, operating without proper containment or oversight, storing pathogens including human immunodeficiency virus, malaria, and SARS-CoV-2 (which is the virus that causes COVID-19). The cosponsors further state that in the 1990s, the Japanese cult Aum Shinrikyo attempted to acquire Ebola, cultivate anthrax, and produce botulinum toxin. Those efforts failed in part because the group needed to collect physical samples from nature. The cosponsors contend that gene synthesis removes that barrier: a bad actor with access to synthesis services or equipment no longer needs a physical sample to obtain a dangerous biological agent. Gene synthesis screening is the primary defense against misuse. Screening checks orders against databases of dangerous pathogen sequences and verifies that customers are legitimate researchers at known institutions. The cosponsors applaud efforts related to screening (including the creation of the IGSC, AB 1963, and the framework) and recognize that each of them relies on voluntary compliance and self-attestation with no independent verification. The cosponsors continue that voluntary compliance creates an uneven playing field that punishes responsible firms for doing the right thing and leaves a gap that bad actors can exploit. The cosponsors state this bill would make compliance with the federal government's 2024 Framework mandatory. The cosponsors conclude that this bill will not only safeguard Californians from severe public health threats, but also protect industry against incidents that could jeopardize public trust and result in backlash.

3) PREVIOUS LEGISLATION.

a) AB 1963 requires the CSU and requests the UC to develop guidance for purchasing gene synthesis products from providers who prevent misuse, universities began requesting biosecurity attestations from gene synthesis providers.

b) AB 70 (Salas) of 2021 would have required DPH to develop a verification process, with input from the IGSC and industry stakeholders, to verify that a gene synthesis provider and manufacturer of gene synthesis equipment to adhere to customer and sequence screening protocols that are equivalent to, or stronger than the IGSC's Harmonized Screening Protocol, including at a minimum a review of each entity's compliance every two years. Would have authorized DPH to charge a fee to establish and administer the verification process not to exceed DPH's reasonable costs. Would have required gene synthesis providers and manufacturers of gene synthesis equipment operating in California to be either current members of the IGSC or verified by DPH as having proper screening protocols, subject to a civil penalty of $1,000 per day that it is noncompliant. Would have required any entity that is a recipient of state resources to purchase gene synthesis products from a gene synthesis provider and gene synthesis equipment from a

manufacturer of gene synthesis equipment, only if they are a current member of the IGSC or are otherwise verified by DPH, whether or not the gene synthesis provider or manufacturer of gene synthesis equipment is operating in California, subject to revocation of all state resources for the duration of noncompliance. Would have required DPH to develop an appeals process (ensuring that appellants are provided with due process) for entities subject to civil penalty and state resource revocation. AB 70 was vetoed by the Governor who stated in part:

> "In order to fund the establishment of the program, AB 70 would authorize DPH to begin charging fees from the entities to be regulated before the program is established and before businesses are required to be in compliance. This structure is not implementable and General Fund resources needed to support the establishment of a new regulatory program should be considered in the annual budget process. Furthermore, consideration should be given to whether a patchwork of state and federal regulations on biosecurity is the most effective way to approach an issue of international magnitude."

c) AB 1986 (Salas) of 2019 would have required DPH to, with input from industry stakeholders, develop gene sequence and customer screening guidelines for gene synthesis providers and manufacturers of gene synthesis equipment on or before January 1, 2022. Would have required the guidelines to include a requirement that gene synthesis providers identify gene synthesis product orders that include dangerous pathogen sequences and other potentially dangerous sequences and, if a dangerous pathogen or other potentially dangerous sequence is identified, a requirement that the order be reviewed by a human and subject to additional screening. Would have required DPH to develop a process to certify that gene synthesis providers and manufacturers of gene synthesis equipment are in compliance with the guidelines developed pursuant to AB 1986. Would have required the certification process to include, at a minimum, a review of each entity's compliance biennially. Would have required, beginning January 1, 2023, gene synthesis providers and manufacturers of gene synthesis equipment operating in California to be certified pursuant to AB 1986. Would have subjected a gene synthesis provider or manufacturer of gene synthesis equipment that is not certified, or fails to maintain its certification, to a civil penalty of one thousand dollars ($1,000) per day that it is not certified. Would have required any entity that is the recipient of state resources to purchase gene synthesis products from a gene synthesis provider, and gene synthesis equipment from a manufacturer of gene synthesis equipment, that is certified pursuant to this bill subject to the revocation of all state resources for the duration of the noncompliance. Would have required DPH to develop an appeals process (ensuring that appellants are provided with due process) for entities subject to civil penalty and state resource revocation.

4) **DOUBLE REFERRAL.** This bill is double referred, upon passage of this committee, this bill will be referred to the Assembly Judiciary Committee.

5) **POLICY COMMENT.** This bill references the federal framework and states that if the framework uses the term "should", it is a requirement for a provider or manufacturer. The framework states that providers and manufacturers should "attest to implementing this screening framework through a statement that either is posted on a public website or provided to the federally funded customer and federal funding agency upon request." Given

that this bill is focused on California, the federally funded customer and federal funding agency would not be relevant. As this bill moves forward, the author may wish to consider amending the bill for clarity.

REGISTERED SUPPORT / OPPOSITION:

Support

Encode AI Corporation (co-sponsor)
Secure AI Project (co-sponsor)
California Initiative for Technology & Democracy, a Project of California Common CAUSE
CFT – a Union of Educators & Classified Professionals, AFT, AFL-CIO
Kapor Center Advocacy
Five Individuals

Opposition

None on file

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