Date of Hearing: April 21, 2026

ASSEMBLY COMMITTEE ON JUDICIARY
Ash Kalra, Chair
AB 1864 (Berman) – As Introduced February 11, 2026

SUBJECT: GENE SYNTHESIS EQUIPMENT MANUFACTURERS AND PROVIDERS

KEY ISSUE: SHOULD THE STATE REQUIRE MANUFACTURERS AND PROVIDERS OF GENE SYNTHESIS PRODUCTS AND EQUIPMENT TO ADHERE TO A SCREENING FRAMEWORK TO PREVENT THE POTENTIAL MISUSE OF THESE PRODUCTS?

SYNOPSIS

Globally, biosecurity experts have long recognized the potential for misuse of gene synthesis, which is the artificial process of using chemicals and specialized equipment to build DNA or RNA sequences (or nucleic acid sequences). Though the benefits of gene synthesis are widely recognized, there are concerns that specific nucleic acid sequences can be used to create dangerous pathogens that could then be weaponized and used as biological weapons. To address these concerns, numerous institutions have developed guidance on screening mechanisms that providers of gene synthesis products can implement to ensure their products are being provided to customers with legitimate, rather than nefarious purposes. However, none of the existing guidance is mandatory for providers, leaving no mechanism for enforcement, and no true guard against these threats.

This bill addresses this gap in enforcement by requiring manufacturers of benchtop nucleic acid synthesis equipment and providers of specific synthetic nucleic acids to adhere to a previously adopted federal Framework for Nucleic Acid Synthesis Screening and imposes civil penalties for failure to adhere to the framework.

This bill enjoys the support of various organizations, especially those concerned with technology and artificial intelligence. In support of the bill, these groups generally contend that AB 1864 will reduce biosecurity risks to Californians by requiring basic screening of synthetic nucleic acids. This bill is also opposed unless amended by Biocom California, who asserts that this bill grants the California Department of Public Health with sweeping authority to regulate the DNA/RNA synthesis technologies without the requisite expertise, and contends that certain technical requirements are difficult to implement for industry stakeholders, among other things. This bill was unanimously passed out of the Assembly Health Committee.

SUMMARY: Prohibits the production, sale, or delivery of "benchtop nucleic acid synthesis equipment," and "synthetic nucleic acids subject to screening" unless a manufacturer or provider of those items 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, or equivalent regulations adopted by the California Department of Public Health (CDPH), if the department chooses to adopt such regulations. Specifically, **this bill**:

1) Makes the following findings and declarations:

a) 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 acids synthesized by benchtop 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.

b) In 2023, the Director of the White House Office of Science and Technology Policy 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 the State Department of Public Health deems to be equally or more protective of the residents of California from relevant biohazards.

2) Prohibits a manufacturer from producing benchtop nucleic acid synthesis equipment in this state or sell or deliver 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.

3) 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.

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

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

6) Specifies that a provider or manufacturer that violates this bill is 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.

7) Specifies that the civil penalty discussed in 6) can only be recovered in a civil action brought by the Attorney General.

8) 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 2024, unless the California Department of Public Health (CDPH) adopts regulations pursuant to this bill.

9) Authorizes CDPH to adopt regulations that define the "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 CDPH 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 the department, unreasonable burdens on manufacturers or providers.

10) Provides that CDPH may adopt definitions of the terms in 13) as part of the adoption of the regulations described in 9).

11) Requires, no later than one year after the adoption of any regulation adopted pursuant to this bill, CDPH 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.

12) Makes the provisions of this bill severable.

13) Defines all of the following to have the same meaning as defined in the framework, except as otherwise provided by the regulations adopted pursuant to 9) above:

    a) "Benchtop nucleic acid synthesis equipment" means benchtop nucleic acid synthesis equipment sold by manufacturers that is intended to be used to synthesize nucleic acids for use within a research laboratory or within an institution. While this nucleic acid synthesis equipment may not be small enough to be placed on a benchtop (e.g., it sits on the laboratory floor), it is still considered benchtop equipment if it is sold with the intent that it will be used by researchers individually or in a core facility in an institution.

    b) "Customer" means the individual or entity (such as an institution) that orders or requests synthetic nucleic acids from a provider, or that purchases nucleic acid synthesis equipment from a manufacturer.

    c) "Manufacturer" means an entity that produces and distributes benchtop equipment for synthesizing nucleic acids. Manufacturers may provide equipment to a customer or third-party vendor.

    d) "Provider" means an entity that synthesizes and distributes synthetic nucleic acids. Providers may provide nucleic acids to a customer or third-party vendor. A provider is understood to be synthesizing and distributing nucleic acids as a transactional service, rather than as a research scientist collaborating with a colleague.

    e) "Synthetic nucleic acids subject to screening" means at a minimum, DNA or RNA, single- or double-stranded, 200 nucleotides (including the corresponding amino acid sequence, if applicable) or longer. As of October 13, 2026, this screening window will be decreased to 50 nucleotides.

EXISTING LAW:

1) Defines "gene synthesis equipment" to mean equipment needed to produce gene synthesis products that is not readily used for any other purpose. (Education Code 66360 (a).)

2) Defines "gene synthesis product" to include double-stranded DNA; double-stranded nucleic acids, RNA, or oligonucleotides, designed and created without an existing DNA template. (Education Code 66360 (b).)

3) 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. (Education Code 66360 (c).)

4) Requires the California State University to develop systemwide guidance for purchasing gene synthesis equipment or gene synthesis product for the entity's own use. Requires the California State University to consider including International Gene Synthesis Consortium criteria in their guidance. (Education Code 66361 (a) – (b).)

5) Requests the University of California to develop systemwide guidance for purchasing gene synthesis equipment or gene synthesis product for the entity's own use. Requests the University of California to consider including International Gene Synthesis Consortium criteria in their guidance. (Education Code 66361 (a) – (b).)

FISCAL EFFECT: As currently in print this bill is keyed fiscal.

COMMENTS: Biosecurity scholars and experts have long recognized there is a great potential for misuse of synthetic biological techniques, including gene synthesis or the artificial process of using chemicals and specialized equipment to build DNA or RNA sequences, rather than copying them from a living organism. Though the benefits of synthetic biology and gene synthesis are widely recognized, there are concerns that specific nucleic acid sequences (or sequences of concern) can be used to create dangerous pathogens that could then be weaponized and used as biological weapons. (*See* Trump et al., Emerging Threats of Synthetic Biology and Biotechnology (2021) p. 2.)

In response to those concerns, this bill requires providers and manufacturers of specified gene synthesis technologies to screen and vet purchase orders, potential customers, and even third-party users to ensure that these products are used for legitimate purposes. In support of the bill, the author submits:

> 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. AB 1864 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. This bill is a commonsense approach to require federally recognized best practices in order to keep Californians safe and defend against biological threats.

This bill requires manufacturers of benchtop nucleic acid synthesis equipment and providers of synthetic gene synthesis products subject to screening to adhere to the federal Framework for Nucleic Acid Synthesis Screening (the framework) 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 CDPH adopts regulations to create an equivalent framework.

The adoption of this framework was spurred in part by an October 2023 Executive Order by former President Biden, which emphasized the need to reduce the risk of misuse of synthetic nucleic acids, which could be substantially increased by the capabilities of artificial intelligence. In response to that order, the White House Office of Science and Technology Policy issued a revised framework on screening of synthetic nucleic acid purchases in 2024.

According to the framework, providers and manufacturers should take the following six actions to adhere to the framework:

1) 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;

2) Screen purchase orders for synthetic nucleic acids to identify so-called "sequences of concern" (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;

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

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

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

6) Take steps to ensure cybersecurity and information security.

Given the current gap in enforcement and the risks imposed by gene synthesis technology, requiring manufacturers to take the six steps above seems like a reasonable intermediate step, until and if CDPH or a federal Administration develops another enforceable alternative.

Enforcement considerations. Under the bill, the Attorney General's office would be the sole entity allowed to bring a civil cause of action for a violation of this bill. If and until CDPH adopts regulations under this bill, the Attorney General's office will need to determine whether a manufacturer or provider is adhering to the federal framework described above.

The bill states that if the framework uses the term "should," it is a requirement for a provider or a manufacturer, and if the framework uses the word "encouraged," it is a recommendation, but not a requirement. As part of each of the six requirements described in the framework above, the framework states that a provider or a manufacturer "should" do a multitude of things as part of complying with a given requirement. For example, as part of requirement 3), providers "should develop and implement a process to assess the legitimacy of orders for their equipment, such as through verified user accounts," among other things.

A manufacturer or provider that does not meet one of these requirements may be subject to a civil penalty of $1,000 per day that the violation continues. To the extent that the framework is ambiguous as to what mechanisms, procedures, or processes a provider or manufacturer should be implementing to adhere to the framework, the provisions of this bill may be difficult to enforce. *To that end, the author may wish to consider more prescriptive and clear language to lessen the potential for ambiguity in enforcement.*

***ARGUMENTS IN SUPPORT**:* Collectively, the Encode AI, the Secure AI project, American Nurses Association California, California Initiative for Technology & Democracy, a Project of California Common Cause, and Kapor Center Advocacy, argue that gene synthesis screening has been recognized as a primary defense against misuse. They note that while there have been efforts to establish guidelines and best practices for screening gene synthesis products, each of these efforts relies on voluntary compliance, which leaves a gap for bad actors to exploit. In support of the bill, they further submit:

> AB 1864 would mandate compliance with the federal government's 2024 Framework. Gene synthesis providers would need to screen orders against a database of dangerous pathogen sequences and conduct follow-up screening to verify customer legitimacy if a match is found. It would extend similar requirements to manufacturers of benchtop nucleic acid synthesis machines, which can produce DNA on-site. The 2024 Framework incorporated extensive input from industry, academia, and national security experts — many firms already adhere to it, and it imposes minimal burdens on legitimate research.
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> Under AB 1864, companies would need to have a process for reporting orders to law enforcement if concerns about legitimacy cannot be resolved, and they would need to take steps to protect proprietary and other sensitive information. The bill would give the California Department of Public Health limited rulemaking authority to adopt future federal screening guidelines in place of the 2024 Framework, helping avoid conflicting requirements and navigate a changing threat landscape. By empowering the Attorney General to seek civil penalties, AB 1864 would create real enforcement that levels the playing field for responsible firms. This would not only safeguard Californians from severe public health threats, but also protect industry against incidents that could jeopardize public trust and result in backlash.

***ARGUMENTS IN OPPOSITION**:* Biocom California, a life science organization representing biotechnology, pharmaceutical, medical device, genomics, and diagnostics companies, and various research institutions, has registered an oppose unless amended position on the bill. Among other things, Biocom is concerned that the bill provides CDPH "with sweeping authority to regulate the life sciences industry with respect to DNA/RNA synthesis technologies." Specifically, they note that CDPH does not have the specialized expertise to address biosecurity risk mitigation strategy and contend that biosecurity oversight is best addressed through a federal framework.

Additionally, Biocom takes issue with several of technical requirements of the bill, including the following:

> These include the reduction of the sequence screening window from 200 nucleotides to 50 nucleotides, requirements that providers detect potential assembly of shorter fragments into sequences of concern across multiple orders, expanded screening for sequences beyond federally regulated lists, and mandates requiring benchtop synthesis equipment to incorporate built-in screening and real-time tamper detection capabilities. Collectively, these requirements would increase compliance burdens, impose substantial costs on manufacturers, research institutions, and small biotechnology companies, and potentially slow the pace of scientific discovery while offering uncertain biosecurity benefits.

REGISTERED SUPPORT / OPPOSITION:

Support

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

Opposition

Biocom California (unless amended)

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