Date of Hearing: April 5, 2022

ASSEMBLY COMMITTEE ON HIGHER EDUCATION
Jose Medina, Chair
AB 1963 (Salas) – As Amended March 28, 2022

SUBJECT: California State University and University of California: gene synthesis providers.

SUMMARY: Requires, any California State University (CSU) campus, and requests any University of California (UC) campus, beginning January 1, 2023, to only purchase gene synthesis products (GSP) from a gene synthesis provider, and gene synthesis equipment from a manufacturer of gene synthesis equipment, that is a current member of the International Gene Synthesis Consortium (IGSC), as specified. Specifically, **this bill**:

1) Requires, beginning January 1, 2023, any CSU campus, and requests, beginning January 1, 2023, any UC campus, to only purchase GSP from a gene synthesis provider, and gene synthesis equipment from a manufacturer of gene synthesis equipment, that is a current member of the IGSC, as defined.

2) Requires each campus of the CSU that purchases gene synthesis products or gene synthesis equipment to appoint the appropriate campus committee to ensure that gene synthesis products and gene synthesis equipment is only purchased from a current member of the IGSC, as defined.

3) Requests each campus of the UC that purchases gene synthesis products or gene synthesis equipment to appoint the appropriate campus committee to ensure that gene synthesis products and gene synthesis equipment is only purchased from a current member of the IGSC, as defined.

4) Defines for purposes of this measure, the following definitions:

    a) "Current member" means a current member of the IGSC who is a certified member of that organization and includes voting members, small company members, and nonprofit members. It does not include provisional associate members or any other membership tier where the entity does not implement an IGSC tested and approved screening system;

    b) "Gene synthesis equipment" means equipment needed to produce gene synthesis products that is not readily used for any other purpose;

    c) "Gene synthesis product" is double-stranded DNA (dsDNA), double-stranded nucleic acids, RNA, or oligonucleotides, designed and created without an existing DNA template;

    d) "Gene synthesis provider" means an entity that does any of the following:

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

        ii) 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; and,

iii) 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.

e) "Gene synthesis provider" does not include 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 entity's own use.

EXISTING LAW:

Federal law.

1) Establishes the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, setting forth the requirements for the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety, to animal health, or to animal products (Code of Federal Regulations (CFR) Title 42, Section 73.2).

2) Prohibits, unless subject to an exemption, any individual or entity from possessing, using, or transferring any select agent or toxin, as defined, without a certificate of registration issued by the Health and Human Services Secretary (CFR Title 42, Section 73.7).

State law.

1) Establishes the UC as a public trust to be administered by the Regents of the UC; and, grants the Regents full powers of organization and government, subject only to such legislative control as may be necessary to insure security of its funds, compliance with the terms of its endowments, statutory requirements around competitive bidding and contracts, sales of property and the purchase of materials, goods and services (Article IX, Section (9)(a) of the California Constitution).

2) Establishes the CSU administered by the Board of Trustees, and provides that the Trustees shall have the full power over the construction and development of any CSU campus and any buildings or other facilities or improvements (Education Code Section 89030, et seq.).

FISCAL EFFECT: Unknown

COMMENTS: What is *gene synthesis*? According to a peer reviewed journal article published in *Health Security* (Volume 17, Number 6, 2019), *Strengthening Security for Gene Synthesis: Recommendations for Governance,* by Amanda Kobokovich, et al., gene synthesis is the process of designing and synthesizing sequences of dsDNA. Gene synthesis allows researchers to design and create a gene "from scratch," without an existing DNA template. That is to say, gene synthesis is the method of creating or engineering artificial genes in a laboratory setting.

The article finds that since the inception of gene synthesis technologies (circa 1970s), there have been concerns about possible misuse of gene synthesis, pathogens – particularly small viruses – which may be assembled "from scratch" in the laboratory, evading the regulatory provisions many nations have enacted in order to control unauthorized access to dangerous pathogens.

Committee Staff understands that in 2010, the United States Department of Health and Human Services (HHS) published guidelines for commercial gene synthesis providers. The guidelines

include sequence screening of gene synthesis orders and screening of customers. However, in the decade plus since HHS released its guidelines, many changes in gene synthesis technologies and market conditions have occurred and, per the article, have reduced the efficacy of biosecurity protections.

Committee Staff understands that HHS is in the process of reviewing its current gene synthesis guidelines, but it is presently unclear as to when updated guidelines will be finalized.

The IGSC. The IGSC is an industry-led group of gene synthesis companies and organizations formed to design and apply a common protocol to screen both the sequences of synthetic gene orders and the customers who place them. Additionally, the consortium works with national and international government organizations and other interested parties to promote the beneficial application of gene synthesis technology while safeguarding biosecurity.

Formed in 2009, IGSC members screen synthetic gene orders to identify regulated pathogen sequences and other potentially dangerous sequences. By screening the sequences of ordered genes and vetting customers, IGSC members help to ensure that researchers and the synthetic biology community realize the many benefits of gene synthesis technology while minimizing risk.

Specifically, IGSC members screen the complete DNA and translated amino acid sequences of every double-stranded gene order against the IGSC's comprehensive curated Regulated Pathogen Database derived from international pathogen and toxin sequence databases.
Currently, the IGSC members together represent approximately 80% of commercial gene synthesis capacity worldwide.

Purpose of the measure. According to the author, "Synthetic genes and the ability to order customizable DNA from the internet is one of the most consequential public safety risks of our lifetime. While gene synthesis serves an important function for research, scientists have shown that it is possible to recreate deadly diseases like COVID-19 and smallpox with mail order DNA."

The author contends that, "California Universities conduct some of the most innovative research in the nation using these products. With the state's massive purchasing power and Californian's tax dollars being spent to support these institutions, it is important that we ensure that our schools are only purchasing GSP from companies who act responsibly and conduct public safety screenings of their customers and orders."

Further, the author argues that, "AB 1963 is necessary because it would require any CSU campus and request any UC campus to purchase GSP 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. This resolves the issue of potentially supporting irresponsible GSP companies because the IGSC membership is contingent upon a strict evaluation of companies' screening protocols."

Lastly, the author states that, "Enactment of this bill will make sure our Universities, as well as California tax payer dollars, are supporting research and companies who are taking the proper action to preserve safety and biosecurity, not only in California but throughout the global community."

Committee comments. According to the Johns Hopkins Center for Health Security, per a 2018 report from the National Academies of Sciences, the synthesis of known pathogens, particularly small viruses, is one of the most pressing biodefense risks in the nation. Committee Staff understands that the genetic sequence information for most pathogens, including COVID-19 and smallpox, are readily available online for free or low cost.

Currently, no standards exist that require gene synthesis companies to screen their customers or their DNA orders to ensure that they are not purchasing sequences that can be assembled into a deadly pathogen. Further, no requirements exist that mandate or encourage the CSU or UC purchase GSP from responsible companies who maintain public safety guidelines by using important screening practices.

Committee Staff understands that most, if not all, CSU and UC campuses that purchase GSP already order from IGSC companies; however, this measure will ensure that all campuses adhere to the strictest public safety screening guidelines by only purchasing GSP from IGSC member companies.

Prior legislation. AB 70 (Salas) of 2021, which was vetoed by the Governor, would have required, beginning January 1, 2025, a gene synthesis provider and manufacturer of gene synthesis equipment operating in California to either be current members of the IGSC or verified by the Department of Public Health (DPH) as entities adhering to proper screening protocols, as specified.

The Governor's veto message stated, "This bill would require the CDPH to establish a new state regulatory program to provide oversight over gene synthesis providers and manufacturers of gene synthesis operating equipment. The bill would also require gene synthesis businesses to demonstrate membership in a voluntary industry consortium or be verified by CDPH to use customer and sequence screening protocols that meet or exceed the protocols established by that consortium.

In order to fund the establishment of the program, the bill would authorize CDPH 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. For these reasons, I am returning this bill without my signature."

REGISTERED SUPPORT / OPPOSITION:

Support

John Hopkins Center for Health Security

Opposition

None on file.

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