

Date of Hearing: April 21, 2026

ASSEMBLY COMMITTEE ON JUDICIARY
Ash Kalra, Chair
AB 2442 (Patterson) – As Amended April 15, 2026

PROPOSED CONSENT

SUBJECT: PEPTIDES

KEY ISSUE: SHOULD THE LEGISLATURE AUTHORIZE THE STATE TO CONVENE A WORKING GROUP TO STUDY AND MAKE RECOMMENDATIONS REGARDING THE CREATION OF A STATE-AUTHORIZED RESEARCH AND INVESTIGATIONAL FRAMEWORK?

SYNOPSIS

According to the author, gray markets have emerged with online retailers marketing peptides for “health benefits,” while containing numerous disclaimers that suggest such peptides may not be suitable for human consumption. The author further contends that existing law does not provide a clear or defined regulatory framework for the research, testing, or medical use of investigational peptides and novel compounds, leaving uncertainty for patients, providers and researchers without safe, standardized pathways to access or study these treatments.

To address these concerns, this bill requires the California Department of Public Health to convene a working group to study and make recommendations regarding the creation of a state-authorized research and investigational therapeutic framework that complements the existing federal regulatory structure while expanding opportunities for scientific research and investigational therapeutic access. Among other things, the bill requires this working group to study the potential uses of investigational and novel compounds, the safety and efficacy of these compounds, and the public health implications of such compounds. As part of this work, the group would also be required to submit a report to the Legislature regarding its findings and recommendations.

This bill is author-sponsored and has no registered support or opposition on file. Since its introduction, the bill has been substantially amended to remove most of the statutory language that triggered its initial referral to this Committee. The bill previously passed the Committee on Health on consent.

SUMMARY: Requires the California Department of Public Health to convene a working group for the purpose of studying and making recommendations on the creation of a state-authorized research and investigational therapeutic framework that complements the existing federal regulatory structure while expanding opportunities for scientific research and medically supervised investigational therapeutic access. Specifically, **this bill:**

- 1) Requires the California Department of Public Health to convene a working group to study and make recommendations regarding the creation of a state-authorized research and investigational therapeutic framework that complements existing federal regulatory structures while expanding opportunities for scientific research and medically supervised investigational therapeutic access.

- 2) Requires the State Public Health Officer or their designee to chair the working group.
- 3) Specifies that the working group must include all of the following among its members, without limitation:
 - a) A biomedical researcher.
 - b) A licensed physician.
 - c) A pharmacologist.
 - d) A toxicologist.
 - e) A community representative.
- 4) Allows the working group to contract with outside entities, including public or private universities for research assistance.
- 5) Requires the working group to study all of the following, without limitation:
 - a) Potential uses of investigational therapeutic compounds and novel peptide compounds.
 - b) The available research on the public health implications of investigational therapeutic compounds and novel compounds.
 - c) The available research on the safety and efficacy of investigational therapeutic compounds and novel compounds to support rare disease research, healthy aging and longevity science, veteran therapeutic innovation, obesity and metabolic disease treatment, and neurodegenerative disease research.
 - d) The feasibility of establishing a state-authorized research and investigational therapeutic framework that complements existing federal regulatory structures while expanding opportunities for scientific research and medically supervised investigational therapeutic access.
 - e) Impacts of the existing use of investigational therapeutic compounds and novel compounds.
- 6) Requires the working group to develop policy recommendations regarding all of the following without limitation:
 - a) The content and scope of educational campaigns and accurate public health approaches regarding use, effect, and risk reduction for novel investigational therapeutic compounds and novel compounds.
 - b) The authorization of various investigational therapeutic compounds and novel compounds for regulated uses.
 - c) The appropriate regulation of the investigational therapeutic compounds and novel compounds for regulated uses.

- 7) Requires the working group to submit a report to the Legislature detailing its findings and recommendations in compliance with existing law, no later than January 1, 2029.
- 8) Defines all of the following, for the purpose of this bill:
 - a) “Investigational therapeutic compound” means a peptide or novel compound that meets all of the following:
 - i. Is not currently approved for marketing by the United States Food and Drug Administration (FDA) with active patent or exclusivity protections.
 - ii. Is manufactured and tested under institutional standards established pursuant to this bill.
 - iii. Is dispensed only under supervision of a licensed health care practitioner within a bona fide practitioner-patient relationship.
 - b) “Novel compound” means a synthetically produced small-molecule compound that meets all of the following:
 - i. Is not scheduled under state or federal controlled substances law.
 - ii. Is not approved for marketing by the FDA under the Federal Food, Drug, and Cosmetics Act, unless patent and regulatory exclusivity protections have expired and a generic version is lawfully marketed in the United States.
 - iii. Is not currently in Phase II or Phase III clinical trials for which a manufacturer or sponsor continues to actively pursue full FDA approval.
 - c) “Peptide” means a compound consisting of two or more amino acid linked by peptide bonds and includes synthetic peptides, recombinant peptides, modified peptides, conjugated peptides, and peptide analogs intended for research or investigational therapeutic use.
- 9) Sunsets the provisions of this bill on January 1, 2030.

EXISTING LAW:

- 1) Establishes the state Sherman Food, Drug, and Cosmetic Law, administered by the California Department of Public Health, which provides for the regulation of the processing, labeling, advertising, and sale of food, drugs, and cosmetics, including dietary supplements. (Health & Safety Code Section 109875 *et seq.*)
- 2) Establishes the Right to Try Act, which permits a manufacturer of an investigational drug, biological product, or device to make available an investigational drug, biological product, or device to an eligible patient, as defined. (Health & Safety Code Section 111548 *et seq.*)
- 3) Requires the compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state to be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. Specifies that the California Board of

Pharmacy may adopt regulations to impose additional standards for compounding drug preparations. (Business & Professions Code Section 4126.8.)

- 4) Establishes the federal Food, Drug and Cosmetic Act which provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics, including dietary supplements, enforced by the FDA. (21 U.S.C. Section 301 *et seq.*)
- 5) Prohibits a person from introducing or delivering for introduction into interstate commerce any new drug, unless an approval of a new drug application or abbreviated new drug is effective with respect to such drug. (21 U.S.C. Section 355.)
- 6) Defines “drug” to mean:
 - a) Articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;
 - b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
 - c) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and,
 - d) Articles intended for use as a component of a) b) or c) above. (21 U.S.C. Section 321 (g)(1).)
- 7) Provides that a drug product may be compounded if a licensed pharmacist or licensed physician compounds the drug product using the bulk drug substances, as defined in federal regulations that:
 - a) Comply with an applicable USP or National Formulary (NF) monograph if one exists, and the USP chapter on pharmacy compounding;
 - b) Are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or
 - c) Appear on FDA’s list of bulk drug substances that can be used in compounding (the 503A bulks list) if such a monograph does not exist and the substance is not a component of an FDA-approved drug product. (21 U.S.C. 353a.)

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

COMMENTS: According to the author, “gray” markets for peptides have emerged with online retailers marketing peptides for “health benefits,” while adding disclaimers for research, chemical use, or for strict research use and not for human consumption. Following regulatory changes restricting compounding pharmacies from producing peptides, adopted in 2023, the author states that several unapproved peptides started being sold online as “research chemicals.” The author further submits that these restrictions have led consumers to turn to unregulated markets for access to widely desired peptides. As such, the author introduced the bill to study

and make recommendations regarding the creation of a state-authorized research and investigational therapeutic framework, while expanding opportunities for scientific research and investigational therapeutic access to investigational and novel peptide compounds.

Peptides, Compounding & the FDA. Peptides are short strings of amino acids which play an essential role in numerous physiological processes. There are several well-known naturally occurring and synthetic peptides, such as Insulin, and glucagon-like peptide 1 (or GLP-1s) that are approved by the FDA for use.

In 2023, the Biden Administration identified a list of peptides that posed potential safety risks and prohibited compounding, which is generally the practice in which a licensed practitioner combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient, of these peptides. While the FDA does not specifically approve compounded drugs, existing law can and does limit what drugs may be compounded. (*See* 21 U.S.C. 353a.) Since the FDA's prohibition, there have been reports of individuals buying peptides from online sellers with dubious claims regarding health benefits. (Sarah Boden, *Influencers are promoting peptides for better health. What does the science say?*, NPR, (Feb. 23, 2026) available at: <https://www.npr.org/2026/02/23/nx-s1-5716162/peptides-science-muscle-growth-longevity-wellness>.) Additionally, experts suggest that these products could contain toxic contaminants and are often not tested in human clinical trials. (*Id.*) Recently, the current federal administration has indicated that it will weigh lifting these restrictions, potentially making access to various compounded peptides more widespread. (Nathaniel Weixel, *FDA to weigh lifting restrictions on some MAHA-favored peptides*, The Hill, (Apr. 15, 2026) <https://thehill.com/policy/healthcare/5832457-fda-considers-peptide-access/>.)

To that end, the author contends that existing law does not provide a clear or defined regulatory framework for the research, testing, or medical use of investigational peptides and novel compounds.

This bill requires the California Department of Public Health to convene a working group that will study, among other things, various aspects of investigational therapeutic and novel peptide compounds. Specifically, the bill requires the working group to study the potential uses, the safety and efficacy, the public health implications, and the impacts of the existing use of investigational therapeutic and novel peptide compounds. The bill also requires the working group to study the feasibility of establishing a state-authorized research and investigational therapeutic framework that complements existing federal regulatory structures while expanding opportunities for scientific research and medically supervised investigational therapeutic access.

Additionally, the bill calls for the working group to make policy recommendations regarding: 1) the educational campaigns and accurate public health approaches regarding use, effect, and risk reduction for novel investigational therapeutic compounds and novel compounds; 2) the authorization of various investigational therapeutic compounds and novel compounds for regulated uses; and 3) the appropriate regulation of the investigational therapeutic compounds and novel compounds for regulated uses.

Lastly, the bill then requires the working group to submit a report to the Legislature regarding its findings and recommendations by January 1, 2029, and prescribes the makeup of the members of the group, and other logistical matters.

To the extent that there are concerns about the uses of peptide compounds in California, this bill attempts to address those concerns by, among other things, studying and making recommendations regarding the creation of a state-authorized research “framework.” The bill does not clarify what such a framework could look like; however, the bill provides the working group with wide discretion to determine the potential boundaries of such a framework and the feasibility of doing so.

REGISTERED SUPPORT / OPPOSITION:**Support**

None on file

Opposition

None on file

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