Office of Senate Floor Analyses
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THIRD READING

Bill No: AB 1103
Author: Ward (D)
Amended: 7/10/25 in Senate
Vote: 21

SENATE HEALTH COMMITTEE: 11-0, 6/25/25
AYES: Menjivar, Valladares, Durazo, Gonzalez, Grove, Limón, Padilla, Richardson, Rubio, Weber Pierson, Wiener

SENATE JUDICIARY COMMITTEE: 12-0, 7/8/25
AYES: Umberg, Niello, Allen, Arreguín, Ashby, Durazo, Laird, Stern, Valladares, Wahab, Weber Pierson, Wiener
NO VOTE RECORDED: Caballero

ASSEMBLY FLOOR: 75-0, 5/19/25 - See last page for vote

SUBJECT: Controlled substances: research

SOURCE: Veterans Exploring Treatment Solutions

DIGEST: This bill codifies processes for the review of research projects by the Research Advisory Panel of California (RAPC) in an expedited manner, and its general review of applications for research projects that do not meet the expedited criteria. Extends RAPC's exemption that allows for holding closed sessions by one year, until January 1, 2028.

ANALYSIS:

Existing law:

1) Establishes RAPC as an independent panel to encourage further research into the nature and effects of cannabis and hallucinogenic drugs and to coordinate research efforts on such subjects. Permits RAPC to hold hearings and approve research projects, which have been registered by the California Attorney General (AG), concerning cannabis or hallucinogenic drugs, or the treatment of

abuse of controlled substances in the state. Permits RAPC to withdraw approval of a research project at any time. [Health and Safety Code (HSC) §11480 and §11481]

2) Permits persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, to lawfully obtain and use substances as are defined as controlled substances, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by RAPC. [HSC §11213]

3) Requires RAPC, annually and in a manner it determines, to report to the Legislature and the Governor those research projects it approved, the nature of each research project, and the conclusions of the research project, where available. [HSC §11480 and §11481]

4) Establishes the Bagley-Keene Open Meeting Act (Bagley-Keene), which requires state bodies to conduct their business in open public meetings, with some exceptions, and establishes requirements and procedures for such meetings. [Government Code (GOV) §11120, et seq.]

5) Prohibits Bagley-Keene from being construed to prevent various state bodies from holding closed sessions for specified purposes, including RAPC until January 1, 2027, to discuss, review, and approve research projects containing specified sensitive and confidential information, like trade secrets and/or intellectual property. [GOV §11126(c)(20)]

6) Defines a "state body" as each of the following:

   a) Every state board, or commission, or similar multimember body of the state that is created by statute or required by law to conduct official meetings and every commission created by executive order;
   b) A board, commission, committee, or similar multimember body that exercises any authority of a state body delegated to it by that state body;
   c) An advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body of a state body, if created by formal action of the state body or of any member of the state body, and if the advisory body so created consists of three or more persons; or,
   d) A board, commission, committee, or similar multimember body on which a member of a body that is a state body pursuant to this section serves in his or her official capacity as a representative of that state body and that is

supported, in whole or in part, by funds provided by the state body, whether the multimember body is organized and operated by the state body or by a private corporation. [GOV §11121]

7) Specifies that certain state agencies and other entities conducting specified duties do not fall within the meaning of "state body." [GOV §11121.1]

This bill:

1) Codifies RAPC's expedited review process of applications, until January 1, 2028, for research projects as follows, with the review and criteria for expedited review to be published on RAPC's website:

   a) Requires RAPC, in order to ensure compliance with state law and public policy protecting the rights of human subjects and the welfare of animal subjects in medical and scientific research, to review research projects that would require the administration of Schedule I or Schedule II controlled substances to research subjects;
   b) Requires RAPC to inform the AG of the head of the approved research projects that are entitled to receive quantities of cannabis;
   c) Permits RAPC to expedite the review of applications for research projects involving the administration of Schedule I, Schedule II, or both, controlled substances that include such things as:

      i. Proof of independent peer review of the study for all research projects;
      ii. A letter indicating federal approval for an investigational new drug, or a letter indicating federal agreement that the study may proceed, and a specified approval letter from an institutional review board for projects involving human subjects;
      iii. Documentation that a required 30-day period allowing for federal response to a proposed project has occurred; and,
      iv. Processes and required documentation for projects involving animal subjects.

2) Codifies RAPC's general review of applications for research projects that do not meet the expedited criteria.

3) Requires RAPC, effective January 1, 2028 (after the expedited provisions in this bill sunset), to review research projects (this process being considered RAPC's standard review) that would require the administration of Schedule I or

Schedule II controlled substances to research subjects, and inform the California Attorney General (AG) of the head of the approved research projects that are entitled to receive specified quantities of cannabis.

4) Provides a process for RAPC to withdraw approval of a research project for reasonable cause, requiring notice to the head of the research project within specified timeframes.

5) Extends RAPC's exemption, as described in 5) above of existing law, that allows for holding closed sessions by one year, until January 1, 2028.

6) Exempts panel members assigned by the chairperson of RAPC, who conduct the expedited reviews, from the definition of "state body," pursuant to 7) above of existing law, until January 1, 2028.

7) Requires the AG to continue to employ a RAPC executive officer and necessary employees, whose duties include, but are not limited to, coordinating with RAPC's chairperson to assign incoming research project applications for review or approval by individual panel members with relevant core competencies.

8) Revises and recasts the provision requiring RAPC to report to the Legislature and the Governor on all research projects so that it begins January 1, 2028, and includes the reporting element that tells whether a research project was approved under the expedited process, in addition to the information required in 3) above of existing law.

Comments

According to the author of this bill:

> This bill would expedite state review and approval of federally sanctioned drug trials and other clinical research projects that study the potential medical uses of Schedule I and II controlled substances conducted at California institutions. This includes clinical trials administering psychedelic compounds to treat opioid use disorders, other substance use disorders, traumatic brain injury (TBI), post-traumatic stress disorder (PTSD), major depressive disorder, generalized anxiety disorder, and other mental health conditions fueling the disproportionate incidence of suicide among California veterans and daily rates of suicide among Californians generally. According to a January 2025 report by the California Department of Public Health (CDPH) Office of Suicide Prevention, suicide is the leading cause of violent death in the state, and a major

preventable public health concern in California that can have both immediate- and long-term emotional and economic impacts on individuals, families, and entire communities. As these clinical trials are prerequisites to developing new and more effective Food and Drug Administration (FDA)-approved treatments for these conditions, eliminating any and all unnecessary delays in commencing such clinical research in California will expedite the availability of these treatments, and save lives that could otherwise be lost due to effective treatments arriving too late.

Background

RAPC's purpose and process. Research entities in California seeking to conduct projects concerning cannabis or hallucinogenic drugs, as well as other Schedule I and II controlled substances, must submit their research proposals to RAPC prior to receiving a federal Drug Enforcement Agency (DEA) license to use controlled substances in a research project. These researchers are affiliated with public and private research universities, as well as private pharmaceutical companies and drug manufacturers. RAPC evaluates the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of human subjects in California to the risk of the proposed controlled substance exposure. Members of the panel are experts in their fields, and are appointed by the Governor, CDPH, the State Board of Pharmacy, the University of California, a statewide professional medical society, a private medical university, and the AG. DOJ provides administrative and legal support to the RAPC whose work complements a regulatory approval process that includes Institutional Review Boards, the FDA, and DEA review of controlled substance research studies using Schedule I and II controlled substances, or that involve new treatments for misuse of substances, such as fentanyl and other opioids. While the FDA and DEA are government institutions, Institutional Review Boards are institutional entities registered with the FDA and charged with providing ethical oversight of research involving human subjects. This bill, in part, codifies RAPC's general review process, including the expedited review process by a subset of the group authorized to approve projects that meet all of the established criteria and present no extraordinary circumstances.

Bagley-Keene. Bagley-Keene applies to all state boards and commissions, and requires these entities to publicly notice their meetings, prepare agendas, accept public testimony, and conduct their meetings in public, unless authorized to meet in closed session. Bagley-Keene covers multimember bodies and advisory bodies. Examples of entities covered by the act are: state boards; commissions;

committees; panels; councils; advisory bodies created by the Legislature; and, advisory bodies having three or more members that are created by formal action of another body. The only gatherings of members of a body that are exempt from Bagley-Keene are social gatherings and conferences. Entities are required to provide notice of a meeting to any person who requests notice in writing, and are required to make the notice available on the Internet at least ten days in advance of the meeting. Notices are required to include the name, address, and telephone number of any person who can provide further information prior to the meeting and an agenda, including a brief description of the items of business to be transacted or discussed in either open or closed session, as specified. Upon request, entities are required to provide a person with notice for all meetings of a state body or for a specific meeting or meetings. Notices are required to be made available in appropriate alternative formats that comply with the Americans with Disabilities Act of 1990 and the relevant related federal rules and regulations, as specified.

Meetings halt because of interpretation of Bagley-Keene. A January 2024 article in the *San Francisco Chronicle* notes that a group of more than 70 addiction researchers and advocates penned a letter to Governor Newsom, California AG Rob Bonta, and state lawmakers requesting a dissolution of RAPC, which they called a nonviable obstruction to essential research and public health activities in California. The letter argued the cost of the RAPC delays is immense, entirely unique to California, and limiting the state's capacity to respond to health crises tightly intertwined with homelessness. The *Chronicle* story states this extra regulatory step delays trials by five to ten months, costing taxpayers hundreds of thousands of dollars and leading some study funders to abandon California entirely. RAPC is supposed to meet bimonthly, but at the time the January 2024 article had been written, RAPC had not held a meeting since August 2023. A story in the *Los Angeles Times* in May 2024 stated that RAPC had long met behind closed doors to make its decisions, but concerns arose in 2023 that it was supposed to fall under Bagley-Keene. The story states that if such meetings were open to the public, concerns would be raised about exposing trade secrets and other sensitive information, so RAPC stopped meeting at all. Meetings ordinarily scheduled for every other month had been canceled since October 2023. The result was a ballooning backlog: as of early May 2024, there were 42 new studies and 28 amendments to existing projects awaiting approval, according to state officials. AB 2841 (Waldron, Chapter 156, Statutes of 2024) provided RAPC an exemption to Bagley-Keene to allow for holding closed sessions in certain situations, such as to discuss, review, and approve research projects that contain sensitive and confidential information, including trade secrets, intellectual property, or proprietary information in its possession, until January 1, 2027, to assist in an

expedited review to address the backlog. This bill, among other things, seeks to extend that exemption until January 1, 2028, even though RAPC indicates that the backlog of applications has been largely addressed.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: No

Senate Rule 28.8

SUPPORT: (Verified 8/12/25)

Veterans Exploring Treatment Solutions (source)
Biocom California
California Civil Liberties Advocacy
California Life Sciences Association
California Medical Association
California NORML
California Pharmacists Association
City and County of San Francisco
Compassionate Veterans
Courage California
Drug Policy Alliance
Heroic Hearts Project
Navy SEAL Foundation
Smart Justice California
The American Legion

OPPOSITION: (Verified 8/12/25)

None received

ARGUMENTS IN SUPPORT: Veterans Exploring Treatment Solutions (VETS), as sponsor, and other supporters of this bill argue that eliminating unnecessary delays in research will accelerate the development of new and effective FDA-approved treatments for TBI, PTSD, treatment-resistant depression, generalized anxiety disorder, and substance use disorders. These conditions impact many vulnerable populations and drive rates of suicide in California, the third-largest veteran population in the U.S. (after Texas and Florida). VETS further states that while charities like theirs do as much as they can with scarce resources to turn the tide on veteran suicide, they simply cannot meet the growing demand from veterans for these treatments through private philanthropy alone. Ultimately, the only way to meet this demand is by expediting clinical research into psychedelics,

accelerating the availability of FDA-approved psychedelic treatments in the U.S., and making them accessible through the Veterans Health Administration, currently serving 9 million enrolled veterans each year.

ASSEMBLY FLOOR: 75-0, 5/19/25
AYES: Addis, Aguiar-Curry, Ahrens, Alanis, Alvarez, Arambula, Ávila Farías, Bains, Bauer-Kahan, Bennett, Berman, Boerner, Bonta, Bryan, Calderon, Caloza, Carrillo, Castillo, Chen, Connolly, Davies, DeMaio, Elhawary, Ellis, Fong, Gabriel, Gallagher, Garcia, Gipson, Mark González, Hadwick, Haney, Harabedian, Hart, Hoover, Irwin, Jackson, Kalra, Krell, Lackey, Lee, Lowenthal, Macedo, McKinnor, Muratsuchi, Nguyen, Ortega, Pacheco, Patel, Patterson, Pellerin, Petrie-Norris, Quirk-Silva, Ramos, Ransom, Celeste Rodriguez, Michelle Rodriguez, Rogers, Blanca Rubio, Sanchez, Schiavo, Schultz, Sharp-Collins, Solache, Soria, Stefani, Ta, Tangipa, Valencia, Wallis, Ward, Wicks, Wilson, Zbur, Rivas
NO VOTE RECORDED: Dixon, Flora, Jeff Gonzalez, Papan

Prepared by: Reyes Diaz / HEALTH / (916) 651-4111
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