CONCURRENCE IN SENATE AMENDMENTS
AB 1103 (Ward)
As Amended September 3, 2025
Majority vote

## SUMMARY

Authorizes, until January 1, 2028, the Research Advisory Panel (RAPC) to expedite review of projects that have sought or received certain federal approvals and have proof of independent peer review of the study. Authorizes the chairperson of RAPC to assign two or more panel members to conduct an expedited review of eligible research applications and approve them on behalf of the panel, and authorizes individual panel members to communicate and consult asynchronously with other individual panel members with complementary core competencies outside of full panel meetings to conduct their individual reviews. Extends RAPC's existing exemption from the Bagley-Keene Open Meeting Act to January 1, 2028. *Makes Legislative findings about the need to limit public access to the meetings of RAPC.*

**Senate Amendments**

1) Exempt individual RAPC panel members assigned to review and approve a research project from the Bagley-Keene Open Meeting Act until January 1, 2028.

2) Remove the 10-day minimum from the reasonable period of time that RAPC is required to provide to a research project after communicating concerns and proposing withdrawal of approval.

3) Specify that, in order to be eligible for expedited review, applications for research projects should be completed and timely.

4) Make other technical changes to conform with AB 1170 (Dixon), Chapter 67, Statutes of 2025.

## COMMENTS

*RAPC.* Research entities seeking to conduct research projects concerning cannabis or hallucinogenic drugs in California must submit their research proposals to the 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, the Department of Public Health, the State Board of Pharmacy, the University of California, a statewide professional medical society, a private medical university, and the Attorney General (AG). The California Department of Justice (DOJ) provides administrative and legal support to the RAPC. RAPC's work complements a regulatory approval process that includes Institutional Review Boards (IRBs), the Food and Drug Administration (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, IRBs are institutional entities registered with the FDA and charged with providing ethical oversight of research involving human subjects.

*Bagley-Keene.* The Bagley-Keene Open Meeting Act 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 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.

*RAPC meetings halt because of interpretation of Bagley-Keene.* A January 2024 article in the *San Francisco Chronicle* noted that a group of more than 70 leading addiction researchers and advocates sent 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 *San Francisco Chronicle* story states this extra regulatory step delays trials by five to 10 months, costing taxpayers hundreds of thousands of dollars and leading some study funders to abandon California entirely. RAPC traditionally meets bimonthly, but it had not held a meeting from August 2023 to July 2024. 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 that it was supposed to fall under Bagley-Keene. The story states that holding those meetings in public raised alarm about exposing trade secrets and other sensitive information, so RAPC stopped meeting at all. The result was a ballooning backlog which, according to the author's office, has been completely addressed after AB 2841 (Waldron), Chapter 156, Statutes of 2024, gave RAPC an exemption to Bagley-Keene in order to address one barrier to them meeting.

*Scientific review of research proposals.* Research proposals are reviewed by several entities before they are ultimately approved. The steps in this approval process can vary based on the subject of the research. Human subjects, animal subjects, and In-Vitro studies dealing with Schedule I and II controlled substances in California are all approved by their funder, the DEA, and RAPC at a minimum. Research on human subjects must also be approved by an IRB. In practice, all of these approvals and reviews happen before the proposal is reviewed by RAPC. Following RAPC approval, the study is then subject to continuous monitoring by the IRB, DEA, FDA, and RAPC.

*FDA.* For clinical drug trials, the FDA requires an Investigational New Drug (IND) application, which is a request for authorization from the FDA to administer an investigational drug or biological product to humans. The FDA defines a clinical investigation as any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. An experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. The sponsor is any person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual of a pharmaceutical company, government agency, academic institution, private organization, or other organization.

The FDA is responsible for reviewing the pre-clinical pharmacology and toxicology, chemistry and manufacturing, and previous human data (if available) under an IND application. The FDA has two primary objectives in reviewing an IND: 1) to assure the safety and rights of subjects in all phases of an investigation, and 2) to help assure that the quality of the scientific evaluation of the drug is adequate to permit an evaluation of the drug's effectiveness and safety in phases two and three studies.

*DEA.* For pharmaceutical controlled substances, the DEA's responsibility is twofold: to prevent diversion and abuse of these substances while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. The DEA works closely with state and local authorities and other federal agencies to carry out this responsibility. According to the DEA, there are two separate categories for researcher registration which are based on controlled substance schedules: a schedule I researcher and a schedule II-V researcher. If a researcher wishes to conduct research in schedules I and schedules II-V, they must obtain two separate registrations. The DEA may require a state license to conduct research and/or a state controlled substance registration, if applicable, to be obtained before issuing a federal registration.

A schedule I research protocol must include the name, address, and DEA registration number of the investigator, as well as their institution or company and their qualifications. The protocol must also include the purpose of the research project, the controlled substances involved, including the amount needed (with justification) and the source, a detailed description of the research procedures, the dosages to be administered, the method of administration, the location of the study, a statement of security provisions for handling the substances, and a manufacturing or import statement.

*IRB.* According to the University of California (UC), IRBs are administrative committees designated to provide ethical and regulatory oversight of research that involves human subjects. IRBs exist to protect the rights, safety, and welfare of human subjects involved in research projects, consistent with ethical principles and federal, state, and local regulations. IRBs are enacted under federal regulation (Title 45, Code of Federal Regulations, Section 46) and are regulated by the Office for Human Research Protections within the U.S. Department of Health & Human Services.

*Institutional Animal Care and Use Committee (IACUC).* An IACUC is required by federal regulations for most institutions that use animals in research, teaching, and testing. The IACUC has a key oversight role, including the review and approval of animal use activities, and inspection of animal facilities. The principal investigator or instructor, and their staff, are responsible for understanding and following the regulations, as well as institutional policies, governing animal care and use. Members of each IACUC are appointed by the chief executive of

the research facility, and must include at least one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility, and at least one member not affiliated in any way with the facility other than as a member of the IACUC, to provide representation for general community interests in the proper care and treatment of animals.

**According to the Author**
This bill would expedite the AG's mandatory review and required approval of substance use disorder research and other clinical research projects to be conducted at California institutions, including clinical trials administering Schedule I and II psychedelics (as well as other hallucinogens and cannabis) to treat opioid use disorders, traumatic brain injury, post-traumatic stress disorder, and other mental health conditions fueling the disproportionate incidence of suicide among California veterans. Eliminating any and all unnecessary delays in commencing such clinical research in California will save lives.

**Arguments in Support**
Veterans Exploring Treatment Solutions (VETS) is sponsoring this bill and states in support that it will maintain the proper safety and oversight function of RAPC while eliminating statutory burdens that slow the ability of the panel to approve research. VETS applauds the commitment of individual RAPC panel members to facilitate life-saving research, but recognizes existing statutory requirements that slow the work of RAPC, slow the approval of research, and ultimately slow the development of life-saving treatments for veterans experiencing suicidality and other mental health conditions. VETS argues that we desperately need to accelerate the development of more effective treatments for service-related injuries and mental health conditions fueling the disproportionate incidence of suicide among veterans.

Smart Justice also supports this bill arguing it comes at a critical time when the Trump Administration is making cuts to Medicaid and other federal programs that will impact treatment programs in California for mental health and substance use disorder. California must treat addiction and mental health treatment as a public health emergency. Smart Justice argues that removing burdensome administrative barriers from the ability to commence clinical research in California will expedite new and more effective FDA-approved treatments that will save lives that might otherwise be lost due to effective treatments arriving too late.

The California Pharmacists Association (CPhA) supports this bill stating that it streamlines and modernizes the oversight of critical medical and scientific research involving controlled substances while maintaining strong safety and ethical standards. By prioritizing and expediting the review of research already vetted by federal agencies and peer-reviewed institutions, it reduces unnecessary delays, supports scientific innovation, and accelerates the development of potentially life-saving treatments. At the same time, it preserves safeguards for human and animal subjects. CPhA argues that research delays have impacted studies focused on high-priority public health issues, such as substance use disorder, PTSD, and treatment-resistant mental health conditions, and have contributed to a broader loss of research funding and academic talent across the state.

**Arguments in Opposition**
The California Narcotics Officers' Association (CNOA) opposes this bill stating that the expedited review process bypasses broader deliberation and scrutiny that could identify potential risks or gaps in oversight, and the extension of the open meeting exemption further restricts

transparency around how decisions affecting controlled substances—an area of high law enforcement concern—are made. CNOA argues this bill undermines necessary transparency and checks on sensitive controlled substance research.

## FISCAL COMMENTS

*According to the Senate Appropriations Committee, pursuant to Senate Rule 28.8, negligible state costs.*

## VOTES:

**ASM HEALTH: 16-0-0**
**YES:** Bonta, Chen, Addis, Aguiar-Curry, Arambula, Carrillo, Flora, Mark González, Krell, Patel, Patterson, Celeste Rodriguez, Sanchez, Schiavo, Sharp-Collins, Stefani

**ASM APPROPRIATIONS: 15-0-0**
**YES:** Wicks, Sanchez, Arambula, Calderon, Caloza, Dixon, Elhawary, Fong, Mark González, Hart, Pacheco, Pellerin, Solache, Ta, Tangipa

**ASSEMBLY FLOOR: 75-0-4**
**YES:** 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
**ABS, ABST OR NV:** Dixon, Flora, Jeff Gonzalez, Papan

## UPDATED

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