

Date of Hearing: April 30, 2024

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 2841 (Waldron) – As Amended April 18, 2024

SUBJECT: Controlled substances: Research Advisory Panel: meetings.

SUMMARY: Permits the Research Advisory Panel (RAPC) to hold closed sessions for the purpose of discussing, reviewing, and approving research projects concerning cannabis and hallucinogenic drugs in California, as specified. Specifically, **this bill:**

- 1) Permits the RAPC to hold closed sessions for the purpose of discussing, reviewing, and approving research projects concerning cannabis and hallucinogenic drugs in California that require the sharing of trade secrets, potential intellectual property, or proprietary information in its possession, the public disclosure of which is prohibited by law.
- 2) Makes findings and declarations regarding RAPC's need to quickly review and approve studies in a manner that protects the privacy of subjects and maintains the confidentiality of information that may be proprietary or of which disclosure is prohibited by state or federal law.

EXISTING LAW:

- 1) Establishes the Bagley-Keene Open Meeting Act (Bagley-Keene Act), which requires state bodies to conduct their business in open public meetings, except as provided by the Bagley-Keene Act, and establishes requirements and procedures for such meetings. [Government Code (GOV) §11120, *et seq.*]
- 2) 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 sections 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]
- 3) Establishes the 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 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 & Safety Code (HSC) §11480, 11481]

- 4) Requires RAPC to annually and in the manner determined by RAPC, report to the Legislature and the Governor those research projects approved by RAPC, the nature of each research project, and where available, the conclusions of the research project. [HSC §11480, 11481]

COMMENTS:

- 1) **PURPOSE OF THIS BILL.** According to the author, the RAPC has worked in closed sessions for 50 years, considering studies and research on Schedule I and II drugs. The author continues that although the Bagley-Keene Act provides significant transparency for the public, it is in direct conflict with Evidence and Government Code protections for confidential materials and trade secrets submitted by researchers. The author argues this conflict has directly halted progress of research surrounding new treatments, therefore halting progress for Californians and people across the country. The author concludes that this bill will ensure that RAPC can move forward with the authorization of studies that have been on hold for far too long.
- 2) **BACKGROUND.** The Legislature created the RAPC in 1972 to ensure that addiction research and studies using certain controlled substances are tracked by the State and proceed safely and in accordance with best medical practices and California law. California law requires proposed research studies using certain opioid, stimulant, and hallucinogenic drugs to be reviewed and authorized by the RAPC.
 - a) **RAPC's Purpose and Process.** Research entities seeking to conduct drug trials 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 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 Federal 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.

- b) **Public Meeting Laws.** The California Constitution enshrines the rights of the people to instruct their representatives and to access information concerning the conduct of government, and requires the meetings of public bodies to be accessible for public scrutiny. To that end, the Bagley-Keene Act, the Gloria Romero Act, and the Brown Act provide guidelines and requirements for how state and local bodies must guarantee open and public access to their meetings.

The Bagley-Keene Act covers all state boards and commissions and generally requires these bodies to publicly notice their meetings, prepare agendas, accept public testimony, and conduct their meetings in public unless specifically authorized by the Bagley-Keene Act to meet in closed session.

- c) **Conflict with the Bagley-Keene Act.** Experimental research data is generally protected as a trade secret and is therefore protected from disclosure under existing law. IRBs, the FDA, and the DEA all conduct their meetings confidentially to avoid release of proprietary information, thus researchers expect and rely upon confidentiality for their research applications.

For 50 years RAPC also met in closed meetings. However, it was recently determined that RAPC falls under the Bagley-Keene Act, meaning they are required to meet, deliberate, and approve research proposals in public meetings. Open meeting requirements are in direct conflict with laws protecting the confidentiality of trade secrets and proprietary information. Due to this, the RAPC has been unable to meet and review and approve research proposals.

The current standstill of research in California has broad implications, costing researchers money in expired grants and contingent grants, shortened patents on new drugs, lost wages for research personnel, lost talent, and lost costs of research drugs for human use that will expire before use. This bill aims to rectify this situation by permitting RAPC to hold closed meetings and continue their work without violating the law.

- 3) **SUPPORT.** Veterans Exploring Treatment Solutions (VETS) supports this bill, stating that researchers are advancing studies that can provide life-saving treatments of depression, anxiety, post-traumatic stress disorder, suicidal ideation, and substance use disorders. VETS continues that this bill will address the current halt in RAPC's ability to meet and will allow urgently needed research to proceed, offering the promise of healthier lives for all California, including our thousands of combat veterans who suffer severe mental illness as a result of their service to the United States.
- 4) **SUPPORT IF AMENDED.** California NORML has a support if amended position on this bill. California NORML does not believe this bill goes far enough, arguing that RAPC is an unnecessary and dysfunctional agency with a long record of delaying and obstructing drug research, and should be abolished instead. California NORML cites complaints from researchers who say their projects have been unnecessarily obstructed or delayed by the requirement for RAPC approval – and not on account of public disclosure concerns.

The University of California also has a support if amended position on this bill, requesting amendments to ensure the studies currently pending before RAPC be reviewed prior to the end of the year.

5) PREVIOUS LEGISLATION.

- a) SB 544 (Laird), Chapter 216, Statutes of 2023, revises, until January 1, 2026, certain teleconference requirements under the Bagley-Keene Act. Allows a multimember state advisory body to hold an open meeting by teleconference, where members can participate from a location without posting physical addresses, as described.
- b) AB 361 (Robert Rivas), Chapter 165, Statutes of 2021, allowed until January 1, 2024, local agencies to use teleconferencing without complying with specified Ralph. M Brown Act restrictions in certain state emergencies, and provided similar authorizations, until January 31, 2022, for state agencies subject to the Bagley-Keene Act and legislative bodies subject to the Gloria Romero Open Meetings Act of 2000.
- c) SB 53 (Wilk) of 2019 would have modified the definition of "state body" so that standing committees, even if composed of less than three members, are a "state body" under the Bagley-Keene Act. SB 53 was held on the Assembly Appropriations suspense file.
- d) AB 2958 (Quirk), Chapter 881, Statutes of 2018. Provided specified exemptions from Bagley-Keene for advisory state bodies that conduct meetings via teleconference.

- 6) POLICY COMMENT.** This bill aims to resolve a backlog in controlled substance studies by permitting the RAPC to hold closed meetings, averting the current conflict between the Bagley-Keene Act and legal requirements to keep proprietary information confidential. Some stakeholders suggest that this proposal does not go far enough, and that the RAPC should be dissolved altogether given that research is already reviewed by IRBs, the FDA, or the DEA.

It's true that RAPC's review works in tandem with those of IRBs, the FDA, and the DEA. However it's important to note that RAPC's review is completely independent, and in the case of private research studies, which pay for their own IRBs, RAPC review may be the only independent review of the study. RAPC review is also the only one which ensures that studies conducted in California comply with state law.

Additionally, RAPC has a record of providing an extra level of protection, which is important given the volume of controlled substance research that occurs in California. According to data provided by DOJ, RAPC regularly catches missed drug interactions (46% of studies in 2022), inappropriate inclusion and exclusion criteria for a particular drug or indication (77% of studies in 2022), inadequate consent forms with important safety or privacy information omitted (73% of studies in 2022), drug safety issues (46% of studies in 2022), missed reproductive risks (27% of studies in 2022), poorly designed studies, and other issues.

The Legislature must consider if it's in the best interest of the public to defer research oversight to IRBs, which may not act independently, or the federal government, whose priorities will change with each administration.

- 7) PROPOSED AMENDMENT.** To ensure RAPC can resume meetings to review and approve research proposals as swiftly as possible, the author has gained approval from the Assembly Rules Committee to add an urgency clause to this bill.

REGISTERED SUPPORT / OPPOSITION:

Support

Veterans Exploring Treatment Solutions

Opposition

None on file.

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