January 18, 2024

To: The Honorable Governor Gavin Newsom, Attorney General Rob Bonta, and California State Legislators

Re: Dissolution of the Research Advisory Panel of California (RAPC)

From: Consortium for Urgently-needed Research in California (CURC)

Dear Governor Newsom, AG Bonta, and all California Legislators:

We urgently call for the dissolution of the Research Advisory Panel of California (RAPC) which was formed to "encourage research into marijuana and hallucinogens" based on California Health and Safety Codes §11213, §11392, §11480, §11481, §11603, §11604 created from 1965-1972.

As you know, RAPC has authority over research using any schedule I or II controlled substance as the primary or comparator drug, and any pharmacotherapy research into addiction to controlled substances (including methamphetamine, cocaine, opioids, and others). This legislation was passed over 50 years ago when research lacked oversight. Since then, research has fallen under the purview of multiple regulatory authorities, including well-developed Institutional Review Boards (IRBs; human subject review committees), Data and Safety Monitoring Boards (DSMBs), and closer regulation by the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and funders such as the National Institutes of Health (NIH). In addition, when the committee was formed, trials usually took five years to complete, while trials are now often expected to be completed in 1-2 years.

Currently, a submission to RAPC should be initiated when all other regulatory and start-up efforts are complete. The submission must be made 2 months prior to the meeting and a response is expected 3 months after the meeting. In practice, this means a research study that has already been vetted by the funder, FDA, DEA, DSMB, and IRB, and is ready to start, must wait a minimum of 5 additional months for RAPC approval. The feedback from RAPC in our experience is not helpful, often re-adjudicating study design decisions made by scientists and regulators over the preceding, extended approval processes. For example, RAPC often requests changes to the informed consent that conflict with University of California IRB guidelines, leading to further delays without benefit to the science or study participants.

The cost of these RAPC delays is immense, entirely unique to California, and limiting the State's capacity to respond to health crises **tightly intertwined with homelessness**. For each study that undergoes RAPC review, we estimate a cost – usually taxpayer monies – of $100,000 to $250,000 in unnecessary staff expenditures. Furthermore, many research

projects studying controlled substances, as well as critical addiction research responding to the crisis of substance use disorders California faces, have opted to abandon California research centers and pursue such research in other states specifically due to the delays caused by RAPC review. The NIH's National Drug Abuse Treatment Clinical Trials Network has begun abandoning California sites from its trials due to the untenable delay caused by RAPC review. Multiple studies of controlled substances, including sponsors of multi-center Phase 2 and Phase 3 clinical trials, have also abandoned California due to these delays or are in the process of partnering with centers in other states. Companies have backed out of plans to invest in research centers in California because of the RAPC. This problem has created a loss of job opportunities in California, threatened many existing jobs that can't be maintained during RAPC delays, penalized California residents who may have benefited from early access to emerging treatments for mental health and substance use disorders, limited the ability of new therapeutics to be aligned with the unique characteristics of California's population or to address co-occurring issues such as homelessness, and slowed the overall development of therapeutics by excluding some of the nation's top mental health and addiction research centers.

We represent a broad swath of over 70 scientific investigators across the state, including many within the University of California system, as well as other public and private universities and research institutes, who have been adversely affected by RAPC, with no perceived benefit to us, the research, or our study participants. We strongly urge legislation to dissolve RAPC as a redundant and nonviable obstruction to essential research and public health activities in California. In the interim, we urge Governor Newsom and Attorney General Bonta to have RAPC automatically approve all studies that have appropriate IRB approvals in place. Finally, RAPC meetings have been on hold since August of 2023, preventing dozens of studies from proceeding; we strongly urge the Governor and Attorney General to instruct the Department of Justice to have RAPC urgently approve all pending studies.

A proposed draft bill is provided below. We look forward to working with interested legislators to refine and sponsor such a bill to help resolve this critically important and timely healthcare research issue for the citizens of California.

Thank you for your consideration.

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Proposed draft legislation to dissolve Research Advisory Panel of California (RAPC)

The Research Advisory Panel of California (RAPC) was formed based on legislation from 1965-1972, involving **California Health and Safety Codes §11213, §11392, §11480, §11481, §11603, §11604**. The RAP-C is run from the Attorney General's office and meets six times per year. Per the Attorney General, investigators or sponsors must submit applications to the panel for any research projects planned to be conducted in California where:

- A Schedule I or Schedule II controlled substance is the main study drug or a comparison drug for human studies.
- A Schedule I controlled substance is used in non-human studies.
- Any controlled substance use disorder treatment research employs any scheduled or non-scheduled medication.

Specifically, we propose a bill that would eliminate California Health and Safety Codes §11213, §11392, §11480, §11481, §11603, §11604 thus ending the "Statutory Authority Concerning the Research Advisory Panel" for the following reasons:

- Given that since RAPC was created over 50 years ago, institutional review boards (IRBs), data and safety monitoring boards (DSMBs), and Food and Drug Administration (FDA) review have become required and standard elements of any research, and close monitoring by the Drug Enforcement Administration (DEA) and funders add to that regulatory milieu, making §11213, §11392, §11480, and §11481 entirely redundant to existing regulatory procedures;
- Given that the National Institutes of Health will issue a Certificate of Confidentiality (automatically for all federally funded research and upon request for non-federally funded studies), protecting research subjects from release of their personal information and study involvement for civil, criminal, administrative, legislative, or other proceedings, making §11603 and §11604 redundant and inferior to the federal level protections already available.
- Given that substance use disorders represent a crisis in California and across the United States, with substantial associated economic, social, and medical costs;
- Given that mental health disorders represent an additional crisis in California with substantial associated economic, social, and medical costs;
- Given that the crisis of homelessness in California is tightly intertwined with mental health and addiction;
- Given that research into treatments for substance use and mental health disorders is a high priority for the State of California and all efforts should be made to facilitate this research;
- Given that clinical trials into treatments for substance use and mental health disorders are considered urgent and often expected to be conducted in 12 to 18 months, thus making an additional 5–10-month delay for RAPC approval after multiple other regulatory approvals incompatible with successful research;
- Given that multiple research institutions, including the National Institutes of Health Clinical Trials Network for addiction research, have begun to abandon California research centers due to the untenable delay created by RAPC review;

- Given that the cost to academic and private research institutes is $100,000 to $250,000 per study to obtain RAPC approval;
- Given that funders abandoning California as a site for research into treatments for substance use and mental health disorders affects public and private research enterprises, availability of research jobs in California, the early availability of experimental treatments for California residents, and the ability of California to ensure new treatments are relevant to the State's population.

PROPOSED BILL WOULD ELIMINATE THESE CODES:

(From **Appendix E** of the 2022 RAPC *52nd Annual Report to the Governor and Legislature of California):* **STATUTORY AUTHORITY CONCERNING THE RESEARCH ADVISORY PANEL FROM THE CALIFORNIA HEALTH AND SAFETY CODE**

Health and Safety Code section 11213. ~~Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Section 11480 and Section 11481. Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.~~

Health and Safety Code section 11392. ~~(Authorized acquisition for use in bona fide research, instruction, or analysis.) Spores or mycelium capable of producing mushrooms or other material which contains psilocin or psilocybin may be lawfully obtained and used for bona fide research, instruction, or analysis, if not in violation of federal law, and if the research, instruction, or analysis is approved by the Research Advisory Panel established pursuant to Sections 11480 and 11481.~~

Health and Safety Code section 11480. ~~(a) The Legislature finds that there is a need to encourage further research into the nature and effects of cannabis and hallucinogenic drugs and to coordinate research efforts on such subjects.~~

~~(b)There is a Research Advisory Panel that consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, the State Public Health Officers, a representative of the Attorney General, a representative of the University of California who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a private university in this state who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a statewide professional medical society in this state who shall be engaged in the private practice of medicine and shall be experienced in treating controlled substance dependency, a representative appointed by and serving at the pleasure of the Governor who shall have experience in drug abuse, cancer, or controlled substance research and who is either a registered nurse, licensed pursuant to Chapter 6~~

~~(commencing with Section 2700) of Division 2 of the Business and Professions Code, or other health professional. The Governor shall annually designate the private university and the professional medical society represented on the panel. Members of the panel shall be appointed by the heads of the entities to be represented, and they shall serve at the pleasure of the appointing power.~~

~~(c)The Research Advisory Panel shall appoint two special members to the Research Advisory Panel, who shall serve at the pleasure of the Research Advisory Panel only during the period Article 6 (commencing with Section 11260) of Chapter 5 remains effective. The additional members shall be physicians and surgeons, and who are board certified in oncology, ophthalmology, or psychiatry.~~

~~(d)The panel shall annually select a chairperson from among its members.~~

~~(e)The panel may hold hearings on, and in other ways study, research projects concerning cannabis or hallucinogenic drugs in this state. Members of the panel shall serve without compensation, but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.~~

~~(f)The panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of cannabis or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of cannabis pursuant to Section 11478.~~

~~(g)The panel may withdraw approval of a research project at any time, and when approval is withdrawn shall notify the head of the research project to return any quantities of cannabis to the Attorney General.~~

~~(h)The panel shall report annually to the Legislature and the Governor those research projects approved by the panel, the nature of each research project, and, where available, the conclusions of the research project.~~

Health and Safety Code section 11481. ~~The Research Advisory Panel may hold hearings on, and in other ways study, research projects concerning the treatment of abuse of controlled substances.~~

~~The panel may approve research projects, which have been registered by the Attorney General, concerning the treatment of abuse of controlled substances and shall inform the chief of such approval. The panel may withdraw approval of a research project at any time and when approval is withdrawn shall so notify the chief.~~

~~The panel shall, annually and in the manner determined by the panel, report to the Legislature and the Governor those research projects approved by the panel, the nature of each research project, and where available, the conclusions of the research project.~~

Health and Safety Code section 11603. ~~The Attorney General, with the approval of the Research Advisory Panel, may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was obtained.~~

Health and Safety Code section 11604. ~~The Attorney General, with the approval of the Research Advisory Panel, may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.~~