September 7, 2023

Hon. Rob Bonta
Attorney General
1300 I Street, 17th Floor
Sacramento, California 95814

Attention: Ms. Anabel Renteria
Initiative Coordinator

Dear Attorney General Bonta:

Pursuant to Elections Code Section 9005, we have reviewed the proposed measure (A.G. File No. 23-0013, Amendment #1) that would authorize $5 billion in state general obligation bonds for mental health-related research and therapies involving certain psychedelic substances.

Background

Research and Development (R&D) Process Has Three Key Stages. The first stage in the R&D process usually entails "basic research," which is theoretical in nature, focusing on discovering new knowledge in a field. The second stage typically entails "applied research," which takes what is known and applies it to solving a specific problem. The third stage, "development," occurs when a promising idea for a product (such as a medical treatment) emerges from applied research. R&D is conducted mainly by businesses (including pharmaceutical companies), research institutes, and universities. Whereas businesses tend to focus on the latter stages of the R&D process, research institutes and universities tend to focus on the earlier stages.

Medical R&D Often Involves Clinical Trials. In the medical field, the development stage typically includes animal and human clinical trials to assess the effectiveness and side effects of new drugs. The federal Food and Drug Administration (FDA) approves pharmaceutical drugs that have been found safe and effective through clinical trials. The time line from research in a field to clinical trials to manufacturing a new, related drug can stretch across many years.

R&D Involving Certain Substances Must Follow Heightened Safety Protocols. Research studies and clinical trials are regulated, meaning they must follow certain protocols to promote the safety of participants. Multiple agencies are involved in setting regulations and reviewing proposed studies and clinical trials. Certain substances—those that generally are illegal, have not yet been shown to have medical value, and are at high risk of abuse—have the most regulatory restrictions. Currently, these heightened regulatory restrictions generally apply to psychedelic substances. At the

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federal level, the FDA and the Drug Enforcement Agency, among other agencies, are involved in the regulatory and review process. In addition, at the state level, the Research Advisory Panel of California, housed within the Department of Justice, reviews studies involving certain substances, including psychedelic substances.

R&D Often Involves Intellectual Property Agreements. These agreements establish who owns and controls any new resulting research discoveries, such as a new drug. If a new drug emerges from the R&D process and is approved by the FDA, the creators can seek to patent (or own) it. Those who own patents, in turn, can generate revenue from licenses and royalty payments. Licenses allow others specified access to a new drug (or other intellectual property), typically for a one-time, upfront fee. Royalty payments allow the creators to receive a share of the ongoing profit derived from usage of the new drug.

Some R&D Focuses on the Effects of Psychedelic Substances. Psychedelic substances can impact a person's brain and central nervous system and produce changes in perception, mood, and cognitive processes. Some psychedelic substances are found in nature (including certain herbs, seeds, and mushrooms), whereas others are created in laboratories. Researchers continue to study the impact of specific psychedelic substances. Some of this work focuses on the impact of these substances on certain mental health issues, including trauma, depression, anxiety, and addiction. To date, the FDA has approved one psychedelic drug (a nasal spray involving esketamine) for mental health purposes.

R&D Is Funded by a Few Main Sources. Both the private and public sectors fund R&D. Private businesses collectively contribute the greatest amount toward R&D. In 2021, businesses collectively contributed nearly 75 percent of the estimated $792 billion in R&D funding nationally. The federal government is by far the largest source of public funding for R&D—accounting for 19 percent of all R&D funding in 2021.The federal government provides funding for its own R&D centers, universities, and in partnership with businesses. Nationally, other government funding sources accounted for 1 percent of R&D funding, with higher education institutions and nonprofit organizations accounting for the remainder.

California Supports Some R&D Directly. Though a relatively small fund source, California state government also provides some R&D support. About half of the state's support involves tax credits to encourage businesses to conduct R&D, with the other half of state support generally provided as direct R&D grants. The state allocates grant funding to several agencies, including the University of California—its public research university system. Other agencies, including the California Institute for Regenerative Medicine (CIRM) and California Energy Commission, also receive state support for certain R&D activities.

State Can Sell Bonds to Finance Some Activities. The state collects tax revenue to fund many of its government services and facilities. It deposits most tax revenue into its General Fund, which it in turn uses to pay for education, prisons, health care, and other public services (including some research). It also uses General Fund revenue to make many of its debt payments. The state can borrow funds for purposes such as constructing facilities, which have high upfront costs but provide benefits over several decades. In these cases, the state issues bonds, which investors buy. The state uses the bond funds to build the facility, then repays investors, typically over a 30-year period. The state's associated debt payments entail paying back the principal (the amount initially borrowed) as well as paying interest costs on the bonds. General obligation bonds—a common type of state bond—require voter approval. In addition to borrowing for the purpose of constructing facilities,

voters approved general obligation bonds for stem cell research administered by CIRM in 2004 and 2020.

Proposal

Creates a New State Institute. The proposed measure adds an article to the California Constitution as well as several statutory sections establishing the Treatments, Research, Education, Access, and Therapies (TREAT) Institute. The TREAT Institute would be governed by an independent board appointed by various state leaders. Board members would serve in the dual capacity of being executive officers of the Institute, with particular board members overseeing particular divisions of the Institute. The measure also creates two work groups (one focused on R&D and the other focused on care providers) that serve in an advisory capacity.

Focuses on R&D Related to Using Psychedelic Substances to Treat Mental Health Issues. The measure creates a state constitutional right to conduct research in California using all psychedelic substances (natural and synthetic), except for peyote. (The State Constitution currently is silent on this issue.) Substances that could be studied include psilocybin (magic mushrooms), ibogaine, LSD, MDMA (molly or ecstasy), ketamine, and cannabis. The measure specifies that the TREAT Institute is to award funding to support research, clinical trials, training, and education relating to the use of these substances for the treatment of mental health issues. The Institute is to support all stages of the R&D process and is to establish its own associated state regulatory standards and oversight.

Authorizes State Bonds to Fund R&D. The measure authorizes the state to sell a total of $5 billion in general obligation bonds to support TREAT activities. The state may issue no more than $500 million in bonds in any calendar year. The bond funds are intended primarily to support R&D, with no more than 6 percent of total bond funds allowed for administrative costs. The measure would provide the TREAT Institute with an initial $6 million General Fund loan so it could commence its operations, followed by annual General Fund loans of $150 million if the first bonds are not sold in the first fiscal year following passage of the initiative. The Institute would be required to repay these loans within 12 months after the sale of the first bonds. Besides these provisions, the measure specifies that bond proceeds are to cover all associated debt payments for the first five years.

Requires Award Recipients Be Subject to Intellectual Property Agreements. Businesses, universities, and others that receive awards from the TREAT Institute are to be subject to intellectual property agreements intended to balance the potential financial returns to the state with those conducting the R&D. To this end, TREAT award recipients generally must share a portion of the revenue they receive from any new discoveries they develop from R&D funded by the TREAT Institute. For the first 15 years of TREAT's existence, all associated royalty revenues are to be used for more R&D on psychedelic substances as well as TREAT's administrative costs. Beginning in year 16, 5 percent of royalty revenues are to be deposited into the General Fund for the broad benefit of the state. The share given to the state is to increase by 5 percentage points a year for each of the next four years—reaching 25 percent of royalty revenues by year 20. The remainder of royalty revenues are to continue being available for R&D and the TREAT Institute's administrative costs.

Fiscal Effects

Annual State Costs of $220 Million for 30 Years to Repay the Bonds. We estimate the cost to repay the bonds (both principal and interest) would average about $220 million General Fund each year for 30 years, with costs totaling $6.6 billion over the period. Given inflationary effects over the

30-year period, the total cost of the bonds is projected to be about 10 percent more expensive than if the state paid in cash. The annual payments would be less than 1 percent of state General Fund revenue. Assuming no other state bonds were enacted, the state's debt load would remain moderate according to various measures.

About $100 Million in Initial Bond Payments Paid by Bond Proceeds. We estimate a total of about $100 million in bond funds would be used to pay bond costs from 2025 through 2029. The total amount of bond funds available for the main activities of the initiative would be affected accordingly—reduced from $5 billion to an estimated $4.9 billion. During this initial five-year period, the state General Fund would not incur associated costs. The state's annual General Fund payments would commence in 2030.

State Could Receive Some Revenue From New Discoveries. If TREAT award recipients discover new drugs, the state would receive some associated revenue. Because the R&D process can be lengthy, the state likely would not derive such revenue in the initial few years after TREAT-funded R&D commenced. Moreover, the amount of revenue derived in this way is uncertain. Many times, R&D does not lead to new discoveries, but, in a few cases, new discoveries (such as a new drug) are very lucrative. The amount the state receives also will be affected by the specific terms of the intellectual property agreements that the TREAT Institute negotiates with TREAT award recipients.

Other Possible Fiscal Effects. The measure could result in indirect fiscal effects on state and local governments. For example, to the extent the measure results in new mental health treatments that are more cost-effective than existing treatments, state and local governments could experience savings in some programs such as Medi-Cal, the state's subsidized health care program for low-income people. Alternatively, government costs could increase if promising new treatments are more expensive or if more staff are needed to support their implementation. The magnitude and direction of these and other indirect effects are unknown.

Summary of Fiscal Effects. This initiative would have the following major, direct fiscal effect:

- Average state costs of about $220 million each year for 30 years, with costs totaling $6.6 billion over the period.

Sincerely,

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for Gabriel Petek
Legislative Analyst

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for Joe Stephenshaw
Director of Finance