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

INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

Attention: Ms. Anabel Renteria
Initiative Coordinator

Dear Attorney General Bonta:

Pursuant to Elections Code Section 9005, we have reviewed the proposed initiative on immunology and immunotherapy (A.G. File No. 25-0026, Amendment #1).

BACKGROUND

U.S. Medical Research and Development (R&D) Is a Multi-Stage Process. Basic research, which is mostly conducted by universities, focuses on discovering new scientific knowledge. Applied and clinical research, which is mostly conducted by industry, use that knowledge to develop and test treatments for specific medical conditions. The R&D process then continues through regulatory review and, finally, implementation—when new treatments reach patients. Many projects do not advance through all stages, as they may fail to meet safety, efficacy, or other regulatory standards along the way.

Private and Public Sources Fund U.S. Medical R&D. Approximately 65 percent of medical R&D funding in the United States comes from private industry. The federal government is the next largest contributor, accounting for about 25 percent of R&D funding. Universities and research institutes also contribute some of their own funding, while philanthropy and state governments play a much smaller role in R&D funding.

Immunology and Immunotherapy Are Areas of Medical R&D. Immunology is the study of the body's immune system and how it protects the body by detecting and destroying abnormal cells. When the body's immune system has problems, conditions such as autoimmune disorders and cancers can arise. (Common autoimmune disorders include Type 1 diabetes, rheumatoid arthritis, psoriasis, and hypothyroidism. Common cancers include breast, prostate, lung, and colorectal cancer.) Immunotherapy develops treatments that help the immune system fight


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diseases more effectively. For example, doctors use immunotherapy to boost the body's ability to treat some autoimmune conditions, kill cancer cells, and design new vaccines.

California Has Several Centers Conducting Research in This Field. At least ten research centers in California conduct work in the field of immunology and immunotherapy. Most are affiliated with University of California (UC) campuses or nonprofit, private universities. Most of the centers undertake a broad range of medical research, although at least three specialize in immunology and immunotherapy.

State Has Funded Medical Research Using Bonds. California voters have approved two measures giving the state authority to issue bonds for medical research. Bonds are a way that the state borrows money and then repays the money plus interest over time. Voters approved Proposition 71 (2004), which authorized \$3 billion in state bonds to fund stem cell research in California. Proposition 14 (2020) authorized an additional \$5.5 billion in state bonds for stem cell research. This additional funding enabled research to continue after the original Proposition 71 funds were depleted.

PROPOSAL

Authorizes State Bonds for Immunology and Immunotherapy R&D. The measure allows the state to sell up to \$8.4 billion in bonds to support R&D in immunology and immunotherapy. The measure requires that at least \$4.2 billion of the bond funds be used specifically for R&D on cancer, heart disease, and Alzheimer's disease. No more than 2 percent of total bond funds may be used for state administrative costs. Proceeds from the bonds—along with any future revenues from licenses, royalties, or other income generated by the funded research—are deposited into a newly created California Immunology and Immunotherapy Medical Research Fund.

Designates Half of Bond Funds for Research Institute. After paying for certain bond costs and administrative costs, half of the bond funds are allocated directly to an immunology and immunotherapy research institute selected by the California Department of Public Health (CDPH) based on eligibility criteria outlined in the measure. CDPH is required to review the agreement with the institute every five years for compliance purposes.

Designates Half of Bonds Funds for Competitive R&D Grants. The remaining bond funds are awarded through competitive grants to public and nonprofit universities and medical research institutions in California. The measure creates an Advisory and Accountability Research Council to set research priorities and establish grant selection criteria. The council has an executive committee consisting of seven UC campus chancellors. The executive committee is to appoint no fewer than 10 and no more than 15 other council members from nonprofit universities and research institutions. The council selects grants for funding, then CDPH enters into grant agreements with the awardees.

Requires 10 Percent of Revenue From Discoveries First Be Used to Repay the State. The measure requires the selected research institute, in consultation with CDPH, to develop a licensing program aimed at maximizing revenue from the discoveries of the funded research. The measure requires that 10 percent of any income generated from inventions, technologies, or discoveries arising from the funded research be used in specified ways. Resulting revenue is first

deposited into the state's General Fund until it equals the total cost of the bonds. Thereafter, resulting revenues are deposited into the California Immunology and Immunotherapy Medical Research Fund to support future research grants and activities.

Has Three Other Notable Provisions.

- ***Requires California Patient Discount.*** The measure requires that any technology, treatment, or drug developed through funded research be made available to California patients at a price discounted by 20 percent.
- ***Requires Purchases From In-State Suppliers.*** The measure requires that grant recipients purchase goods and services from California suppliers, with the goal of more than 50 percent of purchases coming from in-state suppliers.
- ***Sets Intellectual Property Requirements for Grantees.*** The measure requires that discoveries funded by the measure stay with the grantees and that any related intellectual property be licensed in a way that does not block the development or commercialization of new treatments.

FISCAL EFFECTS

Increased State Costs of About \$500 Million Each Year for 25 Years to Repay the Bond.

The estimated cost to repay the bond would be about \$500 million each year over a 25-year period. Payments would be made from the state General Fund. (The General Fund is the account the state uses to pay for most public services, including education, health care, and prisons.) The estimated annual costs would be less than one-half of 1 percent of the state's total General Fund budget. Since the state has to pay interest on the money it borrows, the total cost of the bond would be about 10 percent more (after adjusting for inflation) than if the state paid up front with money it already has.

Uncertain Amount of Revenue Resulting From Discoveries. The state could receive revenue generated by the R&D funded by the measure. The amount of revenue is uncertain but could be significant. The amount would depend on how many funded projects successfully progress through the R&D process, generate new treatments, and reach the market. How long it might take for this revenue to materialize and to offset the state's bond costs is uncertain but could be decades.

Potential Indirect Fiscal Effects. The measure could result in indirect effects on the state and local governments. If the measure leads to the development of new treatments, it could affect the costs of health care programs run by the state and local governments, such as Medi-Cal, California's program that provides health coverage to low-income residents. By providing new funding to medical research institutions in California and requiring that a substantial share of research-related goods and services be purchased from California suppliers, the measure could result in net gains in employment and taxable income. The net fiscal impact of the indirect effects of the measure is unknown at this time.

Summary of Fiscal Effects. We estimate that the measure would have the following major, direct fiscal effect:

- Increased state costs of about \$500 million annually for 25 years to repay the bonds. The state could recoup part or all of this cost in subsequent decades if the funded research leads to discoveries that generate revenue, though this is uncertain.

Sincerely,



for Gabriel Petek
Legislative Analyst



for Joe Stephenshaw
Director of Finance