UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

OFFICE OF THE PRESIDENT

NELSON PEACOCK
Senior Vice President – Government Relations

Office of State Governmental Relations
1130 K Street, Suite 340
Sacramento, California 95814
(916) 445-9924
Steve Juarez, Associate Vice President and Director

September 12, 2016

The Honorable Edmund G. Brown
Governor, State of California
State Capitol
Sacramento, CA 95814

RE: AB 1823 (Bonilla) – REQUEST FOR SIGNATURE

Dear Governor Brown:

The University of California (UC) respectfully requests your signature on AB 1823, which would establish the California Cancer Clinical Trials Program at UC. This bill requests UC create and administer a grant program for organizations that will provide support for ancillary costs to cancer patients to help them participate in clinical trials and will be funded by private donations.

According to The Clinical Journal of Oncology, (http://jco.ascopubs.org/content/27/17/2758.full) projected cases of all invasive cancers in the United States are expected to increase by the year 2030. The increase in incidences of cancer will be highest in non-white populations. Diverse patient participation in a clinical trial depends, in part, on whether a participant can afford ancillary costs like transportation, childcare, or lodging during the course of his or her treatment. AB 1823 provides a mechanism to assist patients when they are most vulnerable and in need of assistance.

The participation rates of underserved communities in UC cancer center clinical trials far exceed the national rate of participation of three to four percent. For example, the UC Davis Comprehensive Cancer Center reports 13.8 percent African American, 15.0 Asian Pacific Islander, and 15.1% Latino participation rate in Cancer Clinical trials. Other UC cancer centers report similar rates of participation. Although UC participation rates are higher than national averages, UC believes more can be done to assist patients to connect to clinical trials.

In addition, this bill will provide more patients with cancer the opportunity at lifesaving and life extending treatments. While clinical trials are first and foremost research endeavors, patients who are enrolled in clinical trials live longer and receive better care than non-participants

This bill also helps bolster the University's ability to obtain federal approval to administer this program, which is necessary because UC is both a provider of healthcare and research institution that conducts medical research and clinical trials. This dual role requires UC to seek approval from the Office of Inspector General (OIG) for the US Dept. of Health and Human Services—which administers and interprets the laws at issue—to ensure it does not run afoul of implicated laws.

Specifically, the Federal anti-kickback statute makes it a criminal offense to knowingly offer, pay, solicit, or receive any remuneration to induce or reward referrals of items and services that may be payable by a federal health care program. [42 USC § 1320a-7b(b)]. A corresponding civil statute imposes civil monetary penalties on any offer or payment of "remuneration" (which includes anything of value, including waivers of beneficiary cost-sharing obligations) intended to induce a Federal health care beneficiary to order or receive any item or service from a particular provider [42 USC § 1320a-7a(a)(5)]. Collectively, these laws have been interpreted to limit the ability of research institutions, like UC, to pay or reimburse study participants in connection with the care they receive while enrolled in research studies—and the ability of sponsors to fund those expenses indirectly.

In order to provide clarity around the application of these laws to particular circumstances, OIG routinely issues "advisory opinions" about arrangements where the parties have asked OIG for guidance. UC will seek an advisory opinion concerning its role as administrator of the program, and OIG would be more likely to opine favorably on this arrangement if it is in furtherance of a State policy that has been ratified by the judgement of the Legislature and the Governor. Conversely, if we were to bring this arrangement to OIG without the imprimatur of approval by the State of California, it would be much easier for OIG to issue an unfavorable judgment because it would not be upsetting a State legislative scheme. It should be noted that if permission is granted, the entire state would benefit and others in the state would be able to administer similar programs. Conversely, an unfavorable opinion would prevent others in the state from establishing a similar program.

In conclusion, we believe AB 1823 will increase participation rates in cancer clinical trials for California patients, and we applaud the author's leadership on this issue. As always, we appreciate your consideration of our views. If you have any questions please do not hesitate to contact me at (916) 445-9924.

Sincerely,

Angela M. Gilliard

Angela M. Gilliard, JD
Legislative Director

cc: Assembly Member Susan Bonilla
President Janet Napolitano
Senior Vice President Nelson Peacock
Associate Vice President and Director Steve Juarez