From: Jean Sieper <siepers@comcast.net>
Sent: Wednesday, April 13, 2022 12:56 PM

To: Planning Commissioners <PlanningCommissioners@ci.brisbane.ca.us>; cholsteine@ci.brisbane.ca.us

Subject: Urgent: Please Reject Use Permit 2022-UP-2

Dear Members of the Planning Commission,

As a physician and scientist, we urge you to reject Use Permit 2022-UP-2 for Bristol-Myers Squibb (BMS), which is requesting to expand its animal experimentation facility to include minipigs. Approval of this permit would be a detriment to our community and an endorsement of the inhumane and flawed use of animals in the testing of pharmaceuticals.

While the Food & Drug Administration (FDA) requires that companies test pharmaceuticals in nonhuman animals, 95 percent of drugs that prove safe in animals fail in human clinical trials. To address this problem, Sen. Cory Booker, who represents a state heavy with pharmaceutical and biotech companies, and Sen. Rand Paul cosponsored the FDA Modernization Act. The bill, which is gaining steam in Congress, would help remove FDA's antiquated requirement for animal tests—a prerequisite that many pharmaceutical companies would like to see abolished.

One drug company, Vanda Pharmaceuticals, sued FDA in an effort to avoid unnecessarily testing its drug on beagles, pointing out that the test would not provide human-relevant data. While Vanda and others recognize the lack of scientific necessity when it comes to the use of animals, Bristol-Meyers Squibb is investing even more in the antiquated approach. FDA has even identified "Advancing Novel Technologies to Improve Predictivity of Non-clinical Studies and Replace, Reduce, and Refine Reliance on Animal Testing" as a priority area.

Brisbane should invest in organizations that are employing 21st century research methods. Further, high-paying jobs in science and research need not involve the use of animals. Many major pharmaceutical companies and private research labs have, in recent years, invested heavily in non-animal methods:

In 2013, Harvard University announced that it would close its New England Primate Research Center, choosing to instead focus on other areas of research.

In 2012, contract research company Covance announced that it was closing its animal testing facility in Chandler, Ariz., just 3 years after the local government had heavily aided its creation.

In comparison, labs entirely focused on non-animal methods or replacing animals in testing and research are more plentiful now than ever before. In Maryland, there is the Institute for In Vitro Sciences. Harvard now has the internationally recognized Wyss Institute, which is a leader in developing organs-on-a-chip, which allow for the testing of drugs and chemicals using human cells rather than

nonhuman animals.

One of the "Conditions of Approval" for the requested permit states that Bristol-Myers Squibb "shall comply with the requirements of the USDA, to ensure the welfare of the animals comply with USDA standards." However, this requirement is toothless.

Compassionate people would like the laws governing the use of animals in laboratories to forbid cruelty, but that is simply not the case. Research facilities like Bristol-Myers Squibb are subject to incredibly weak federal laws and rules. Under the Animal Welfare Act, no experiments are prohibited—including those that inflict pain. The law is primarily a husbandry statute that regulates the size of cages, cleanliness, and food and water. In addition, the USDA, which is supposed to enforce the Animal Welfare Act, was cited by its own inspector general for closing investigations involving grave violations, including animal deaths and serious repeat violations; failing to properly apply financial penalties, reducing fines by an average of 86 percent; and wasting resources by conducting inspections at facilities that did not house animals covered by the Animal Welfare Act. In February 2019, The Washington Post

reported: "USDA inspectors documented 60 percent fewer violations at animal facilities in 2018 from the previous year. ...The drop in citations is one illustration of a shift—or what critics call a gutting—in USDA's oversight of animal industries." In May 2021, Science reported that "USDA now only partially inspects some lab animal facilities, internal documents reveal," further revealing the agency's low standards.

We urge you to reject Use Permit 2022-UP-2 and stand up for modern science and the welfare of animals. If you have further questions about this issue, we urge you to contact the Physicians Committee for Responsible Medicine, a global nonprofit that is one of the world's preeminent sources of education on modern research and testing methods.

Thank you for your time and attention to this issue.

Very truly, William J. Sieper, D.O. and Jean M. Sieper, Ph.D. 475 Crestmont Dr. San Francisco, CA 94131-1018