

From: [Aracely Campa](#)
To: [CityCouncil-List](#)
Subject: [EXTERNAL] CA Life Sciences response to proposed amends received 5-6
Date: Tuesday, May 7, 2024 7:02:09 PM
Attachments: [image001.png](#)
[CLS - Response to proposed amends 5-7.pdf](#)

Honorable Council Members and staff, apologies for the late letter but we were made aware of the last-minute amendment suggested yesterday evening. Please find attached CLS' response to the language.

Kind Regards,

ARACELY CAMPA RAMIREZ
Senior Director, State Government Relations
1201 K Street, Suite 1010
Sacramento, CA 95814
M 916.508.7115
califesciences.org



May 7th, 2024

Alameda City Council
City Hall
2263 Santa Clara Avenue
Alameda, CA 94501

RE: Life Science Animal Testing Ordinance – Agenda Item 5R (in response to proposed amendments received on May 6th via correspondence)

Dear Mayor Ashcraft and City Council Members,

On behalf of the life sciences community, **we oppose the new proposed amendments to Alameda’s animal testing restrictions** because they would pose a critical problem for life-saving drug development and life sciences research.

California Life Sciences wishes to express profound gratitude at Alameda’s city council for working to ensure that its proposed animal testing restrictions did not threaten the vital life sciences research that Alameda is home to. The **proposed language that the city council previously arrived at struck the ideal balance** between protecting animals and ensuring that Alameda continues to host life-saving biotechnology research. California Life Sciences supports this prior language and the efforts the city council made to perfect it.

However, California Life Sciences **opposes the two new proposed amendments to Alameda’s animal testing restrictions**. By striking the phrase “...anticipated or...” from the language, the first proposed amendment would fail to account for the time it takes to acquire regulatory approval – creating a logistical impossibility for researchers. This logistical impossibility would be further compounded by the second proposed amendment – which would force researchers to provide specific documentation that could breach intellectual property law, and furthermore, these documents may not exist in the explicit terms the language proposes. It is not unreasonable for the FDA to require animal testing for new medical treatments and devices. **However,**

SACRAMENTO

1201 K Street, Suite 1010
Sacramento, CA 95814
P 916 226 9957

SAN DIEGO

4242 Campus Point Court, Suite 110
San Diego, CA 92121
P 858 551 6677

SOUTH SAN FRANCISCO

685 Gateway Blvd. Suite 100
South San Francisco, CA 94080
P 650 871 3250

LOS ANGELES

4130 Overland Ave.
Culver City, CA 90230
P 858 551 6677

WASHINGTON, DC

1100 H Street, NW, Suite 540
Washington, DC 20005
P 202 743 7566

it is unreasonable to expect the FDA to know in advance what type of testing is required for every new medical innovation.

They cannot anticipate every innovation and how it works, and they cannot know what standard of testing best balances safety with life-saving advances until they see the results of initial experiments. The FDA is not equipped to respond to every intermediate step in the development of medical treatments in a timely fashion. Similarly, it is not unreasonable for scientists and researchers to submit innovative medical treatments to the FDA for regulatory approval. **But, it is unreasonable to require scientists and researchers to seek approval for every experiment required on the way to the next scientific breakthrough.** Scientific breakthroughs, especially in the Life Sciences, require hundreds if not thousands of experiments on isolated variables and incremental improvements to prove efficacy and safety. Requiring each of these experiments to be reviewed in advance would not only be unfeasible, it would cause delays in the development of potentially life saving therapies.

Testing standards, like science itself, are constantly evolving to meet the technologies of the moment. The FDA is designed to evaluate data from the scientific community after the data has been generated, and then take action to ensure public safety. They have the power to deny or approve applications entirely, but most often, they will require corrective action or additional testing before issuing approval. FDA guidance does not spell out the exact details required for animal testing. They are not static, because the FDA recognizes that the data required to prove safety and efficacy of medical innovations shifts over time, and is dependent on myriad factors flowing from the nature of the innovation itself and the realities of carrying out the scientific method each day. The proposed language change to the animal testing ban is based on a misguided belief that the scientific method can be predicted and circumscribed in advance – that explorers must draw the map before setting sail. Any working scientist will tell you that such a view profoundly misunderstands the daily reality of their work, and would make it impossible.

The use of animal testing for drugs, medical devices, vaccines, and chemical development products has been heavily discussed and is a critical component of Research and Development for the life sciences sector. For decades, our industry has worked to significantly reduce or replace animal

use in new therapies whenever possible and refine the methods and treatment of animals. Although new technologies have emerged, there are still Federal regulatory requirements our industry must meet.

When the industry cannot eliminate the use of all animals in research, it adheres to rigorous ethical guidelines governing the use of laboratory animals – including a review of all activities by an Institutional Animal Care and Use Committee (IACUC), as mandated by the Public Health Service (PHS) Policy, USDA Regulations, and voluntary accreditation bodies such as the Association for Assessment and Accreditation of Laboratory Animal Care.

Alameda's life sciences industry is invested in this community. Many of these companies are "born" here, and they want to remain committed, thoughtful leaders and be a company this community is proud to have in its neighborhood. Although initially, a company may not conduct animal testing, it is critically important to be available as an option, if required, as a condition of Federal approval.

This industry improves lives with its cutting-edge, innovative, life-saving therapies. To ensure this sector can thrive in this community, we respectfully ask the Council to maintain the language passed in the initial version of the ordinance. There are already very clear regulations in place, and such unrealistic constraints would serve only to discourage Life Sciences companies from seeking out Alameda as a home for their life saving work.

If you have any additional questions, please feel free to contact me at schung@califesciences.org.

Sincerely,



Sam Chung
Vice President, State Government Relations
California Life Sciences

cc: Members, Alameda City Council

From: [Reyla Graber](#)
To: [Marilyn Ezzy Ashcraft](#); [Tony Daysog](#); [Malia Vella](#); [Tracy Jensen](#); [Trish Spencer](#)
Cc: [Lara Weisiger](#)
Subject: [EXTERNAL] 5/7/24 CC meeting Agenda Item 5R-2nd reading of Animal Testing Ban ordinance
Date: Tuesday, May 7, 2024 4:01:16 PM

Dear Mayor and City Council Members,
Alamedans' who support prohibiting animal testing on City properties were truly dismayed by the 4/16 amended ordinance. If, as is, it passes on 2nd reading tonight, it will do nothing to diminish animal testing in Alameda. As written it is simply an empty gesture and we, as a community are back to where we started.

However, you do have an opportunity to give some life to this ordinance by considering the additional sentence recommended by Ryan Merkley of PCRM in his email to the Council sent yesterday.

If you do add the one sentence, as suggested it will show that our City is for positive change and we desire companies to act as ethically as possible when it comes to animal testing. This sentence will remind companies of their ethical obligation to do alternatives to animal testing whenever it's legal to do so.

Additionally we think the word "anticipate" should be removed as suggested.

We heartily endorse the 2 proposed changes, and urge the Council to vote for them, thereby giving meaning to this ordinance.

Thank you for your serious consideration on this matter.

Sincerely,

We the undersigned Alameda residents:

Reyla Graber
Pat Gannon
Mary Tigh
Judy Jacobs
Geraldyn Gulseth
Janet Davis
Francesca
Joe Cloren
Cole Cloren
Ann Richter
Paul Foreman
Rajiv Mathur
Sue MacDonald

From: [Ryan Merkley](#)
To: [Marilyn Ezzy Ashcraft](#); [Tony Daysog](#); [Tracy Jensen](#); [Trish Spencer](#); [Malia Vella](#)
Cc: [City Clerk](#)
Subject: [EXTERNAL] RE: FDA and animal testing
Date: Monday, May 6, 2024 5:15:59 PM

Dear Councilmembers,

I am writing to propose two small changes to the “animal testing ban” you will vote on tomorrow evening. These changes will ensure that the ordinance meaningfully reflects its original intent.

First, we recommend striking the phrase “...anticipated or...” since it allows any company to claim that it is working toward regulatory approval without providing to you or city residents any such evidence of a requirement.

Secondly, immediately following the sentence that ends in “...devices and parasiticides.”, we propose that you insert these sentences:

“Any person wishing to conduct animal testing or experimentation on property owned or controlled by the City of Alameda must provide documentation from a federal or state regulatory agency stating that animals are required for the specific therapeutic, vaccine, device, or parasiticide being developed or tested. Such documentation must be in the form of a current federal or state statute, regulation, or agency guidance document or explicit correspondence from the federal or state agency.”

We hope you will make these changes in order to ensure the ordinance for which so many Alameda residents voiced their support is rendered useful.

Please also see my previous correspondence on this issue below.

Thank you for your time and attention to this issue.

Very truly,

Ryan Merkley, Director of Research Advocacy
Physicians Committee for Responsible Medicine
5100 Wisconsin Ave. NW, Suite 400, Washington, DC 20016
Phone: (202) 527-7336
Email: rmerkley@pcrm.org

From: Ryan Merkley <RMerkley@pcrm.org>
Sent: Wednesday, March 13, 2024 1:56 PM
To: mezzyashcraft@alamedaca.gov; tdaysog@alamedaca.gov; tjensen@alamedaca.gov; tspencer@alamedaca.gov; mvella@alamedaca.gov
Subject: FDA and animal testing

Dear Alameda City Council Members,

As you consider the ordinance to prohibit the use of animals in experiments on city controlled property, I hope you'll keep in mind the quickly changing landscape of drug testing – away from unreplicable animal models.

In December, Vanda Pharmaceuticals announced that the U.S. Food and Drug Administration approved the company's use of nonanimal methods to determine a drug's toxicity. This new method, using microphysiological systems (often called "tissue chips," which include human organ cells), will be done in place of a chronic nine-month study on dogs. The company's announcement stated: "Vanda believes that this is an important milestone in its multi-year effort to convince the FDA to move away from animal toxicology studies and instead adopt novel and advanced human-relevant technologies."

You can read Vanda's news release here: <https://vandapharmaceuticalsinc.gcs-web.com/node/15621/pdf>

Drug testing is changing fast, and we hope Alameda will stand on the right side of this change.

Sincerely,

Ryan Merkley, Director of Research Advocacy
Physicians Committee for Responsible Medicine
5100 Wisconsin Ave. NW, Suite 400, Washington, DC 20016
Phone: (202) 527-7336
Email: rmerkley@pcrm.org

From: [Richard Schwartz](#)
To: [CityCouncil-List](#)
Subject: [EXTERNAL] Fwd: The Big Myth About Animal Research that Holds Science Back
Date: Thursday, May 2, 2024 8:17:16 AM

Dear City Council Members,
I thought as this issue is still an issue with the citizens and neighbors of Alameda, this email addresses some of the latest findings of the inaccuracy of animal testing. Thank you all for continuing to examine the current and evolving issues.

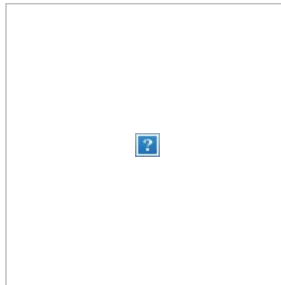
Sincerely,
Richard Schwartz, historian
--

Richard Schwartz
<http://www.RichardSchwartz.info>

Subscribe to my events email list,
<http://eepurl.com/o4ltf>

Begin forwarded message:

From: National Anti-Vivisection Society <navs@navs.org>
Subject: The Big Myth About Animal Research that Holds Science Back
Date: May 2, 2024 at 8:00:00 AM PDT
To: richard@richardschwartz.info



The Big Myth About Animal Research that Holds Back Science

Dear richard,

Every day, vital scientific progress is shadowed by outdated practices that cause needless suffering. Despite mounting evidence that non-animal research methods are more accurate, cost-effective, and humane, many in the scientific community continue to rely on animal experiments. It's time for change.

A Persistent Myth in Science

The belief that animal testing is necessary for effective science persists, fueled by substantial investments from entities like the National Institutes of Health, which spends \$15 billion annually on these practices. As a result, countless animals continue to suffer in laboratories.

At the National Anti-Vivisection Society (NAVS), we envision a future where science respects all life. Your partnership

is crucial in making this vision a reality. Today, we ask you to deepen your commitment and help us extend the reach of humane scientific methods.

Your Impact in Action

Your support empowers NAVS to educate upcoming scientists about non-animal research methods through collaborations with educational institutions and the International Foundation for Ethical Research (IFER). By introducing humane alternatives early in their education, we cultivate a new generation of scientists who prioritize ethical practices.

Thanks to the generosity of supporters like you, NAVS has provided over \$2 million in funding to forward-thinking researchers through IFER. These grants support projects that are refining science and reducing reliance on animal testing. Consider the work of Dr. Woojung Shin, a past grantee who now advocates for non-animal methods in her role as an assistant professor. Her story is a testament to the power of your contributions.

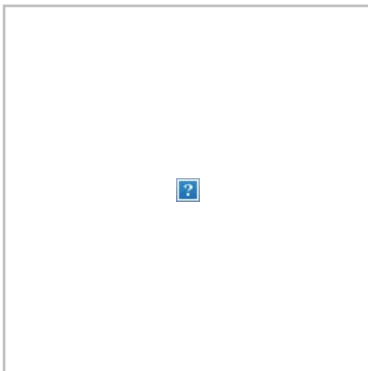
Act Now to Save Lives

With every day that passes, more animals face unnecessary suffering. By making a tax-deductible donation today, you can help open the cages and end animal experiments. Your gift supports the development of smart, humane research alternatives that do not compromise scientific integrity.

[Donate Now](#)

Thank you for your unwavering support. Together, we can dismantle outdated practices and champion a future where animal welfare and scientific innovation go hand in hand.

Warm regards,



Kenneth Kandas
Executive Director, NAVS

P.S. Your immediate action can change lives. Please consider making a gift today to support ethical science and help end cruel animal testing. Every donation brings us closer to a world where all beings are treated with respect and compassion. Thank you for your commitment to this vital cause.



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