

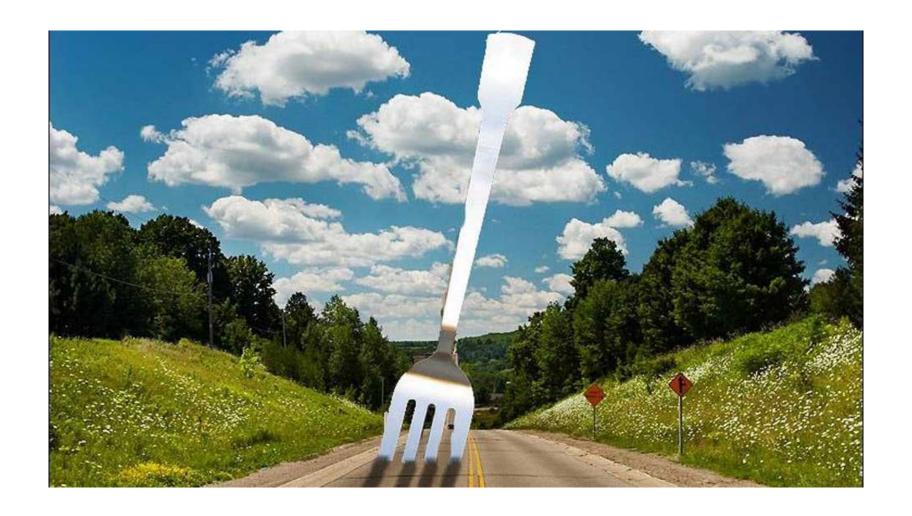
Advancing Research Together



Have We Reached the Proverbial Fork in the Road for Animal Research?



I Don't Mean This.



I Mean This.



The Future of Medical Research is at Risk.

We must choose wisely which path is taken.



Leading Indicators cont'd.

- Society continues to place a higher premium on animal welfare over science.
- When Dr. Anthony Fauci becomes a pariah due to animal research, what does that say about the future of medical research?
- Congressional Appropriators now "legislating" how the research enterprise is managed.
 - Banning of "Teachable Moments"
 - NHP report to Congress
 - Canine research ban coming?
- Administrative burden on investigators shows no real signs of abatement.
 - 21st Century Cures Act hasn't done much to reduce
 - Law directs agencies to reduce burden on investigators



Leading Indicators

- Zero-tolerance environment by regulators means institutions are constantly under the gun to be perfect. If imperfect, you are a target. Are human hospitals held to this standard?
 - USDA Compliance a growing issue
 - IES has entered the room
- Legal challenges abound, i.e. 'personhood' lawsuits and half-baked criminal charges.
- Weaponizing FOIA: Open records laws are used as a blunt instrument against research institutions. An IACUC must sue its own university to get protection.



Leading Indicators cont'd.

Institutions are losing access to resources...

NHPs and canine models are most at risk currently.



First Principles Question:

Are Animal Models Still Necessary?

YES



First Principles Question:

Are Nonhuman Primates Still Necessary?



Preponderance of the Evidence:

Nonhuman Primates are Still Necessary

- Examples abound in the literature
- 2017 Pathogens and Immunity: The Critical Role of Nonhuman Primates in Medical Research
- 2018 -Foundation for Biomedical Research: Understanding the Leidos Reports https://fbresearch.org/medical-advances/whyprimates/



Another First Principles Question:

Do Researchers Have the Resources Necessary to Complete their Jobs?

In many cases, the answer is no.



What's Your Evidence?

The Atlantic

"America Is Running Low on a Crucial Resource for COVID-19 Vaccines," The Atlantic, Aug. 31, 2020

Bloomberg

"Airlines Accused of Discrimination for Banning Lab Monkeys,"
Bloomberg, Dec. 5, 2018

The New York Times

"Future Vaccines Depend on Test Subjects in Short Supply: Monkeys," The New York Times, Feb. 23, 2021

Mother Jones

"A Plane of Monkeys, a Pandemic, and a Botched Deal: Inside the Science Crisis You've Never Heard Of Experts say there's a dire shortage of primates for biomedical research—and it's putting human lives at risk." Mother Jones, June 23, 2022



WHY NOT?

- Special interest groups have pressured most major airlines out of transporting NHPs for research
- At the onset of pandemic China halted all exports of NHPs
- NIH reprioritized NHP research to focus on COVID

Cause and Effect

- Global supply chains interrupted, costs fluctuate wildly
- Research institutions forced to seek other sources
- Some projects halted, some may never restart
- Major biopharma never tested COVID treatment due to lack of NHP availability at BSL-3 facilities



Will canine research continue in the U.S.? Envigo / Inotiv VA facility



Opinion by Melanie D.G. Kaplan Updated 8:48 PM EDT, Wed July 27, 2022









LOCAL

USDA cites dog-breeding facility in Virginia for mistreating animals

By <u>Dana Hedgpeth</u>
Updated December 26, 2021 at 3:05 p.m. EST | Published December 26, 2021 at 9:29 a.m. EST



Dogs at a breeding facility in Cumberland, Va. The facility is owned by Envigo, an Indianapolis-based firm that provides research-related service for the pharmaceutical and biotechnology industries. (People for the Ethical Treatment of Animals)

Envigo / Inotiv VA facility and the future of canine research

- On May 19, 2022 the U.S. Attorney General filed a civil complaint in the U.S. District Court for the Western District of Virginia against Envigo / Inotiv's dog breeding facility in Cumberland, Va for violations of the Animal Welfare Act.
- The court issued an injunction preventing the facility from breeding or selling any more dogs and ordered some dogs to be removed from the facility.
- On July 15, W.D. Va. Judge Moon ordered Envigo / Inotiv to transfer out all remaining dogs to be placed in rescues across the country for adoption within 60 days. He also ordered the shut down of the facility.
- The incident garnered unprecedented news coverage.



Envigo / Inotiv VA facility: Unprecedented news coverage

- Notable national news coverage so far:
 - Associated Press (5 articles)
 - CBS News
 - CNN (2 stories)
 - FOX News (3 stories)
 - Good Morning America (3 stories)
 - National Geographic
 - NBC News
 - New York Times (2 articles)
 - People magazine (4 articles)
 - Reuters
 - The Today Show
 - USA Today (2 articles)
 - Yahoo News



























 Local news coverage so far in 40 states



Have We Reached the Proverbial Fork in the Road?



In the interest of American public health, American competitiveness, and national security we *must* consider options to bolster support for research on U.S. soil...

Doing so requires government support.

Choosing NO path is also an option...

But it will drive research to more accommodating countries.



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China bets big on brain research with massive cash infusion and openness to monkey studies

Ambitious \$746 million program aims to complement big neuroscience projects in Europe and the United States

20 SEP 2022 · 5:10 PM · BY DENNIS NORMIL











Thank You

info@nabr.org
info@fbresearch.org

202-857-0540

