



Openness, Transparency and Accountability: A Policy and Legal Perspective on Societal Expectations Regarding the Care and Use of Research Animals

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Overview

1. Openness, transparency and accountability – development under US federal law
2. Evolution of animal rights, animal welfare, researcher responsibilities
3. Current societal expectations regarding scientific research that uses animals
4. Potential implications of these expectations

1. Openness, Transparency, Accountability

Definitions

- Openness
- Transparency
- Accountability
 - Responsibility for action(s)
 - Metrics/measures to assess accountability
 - Reporting

Key US federal statutes today

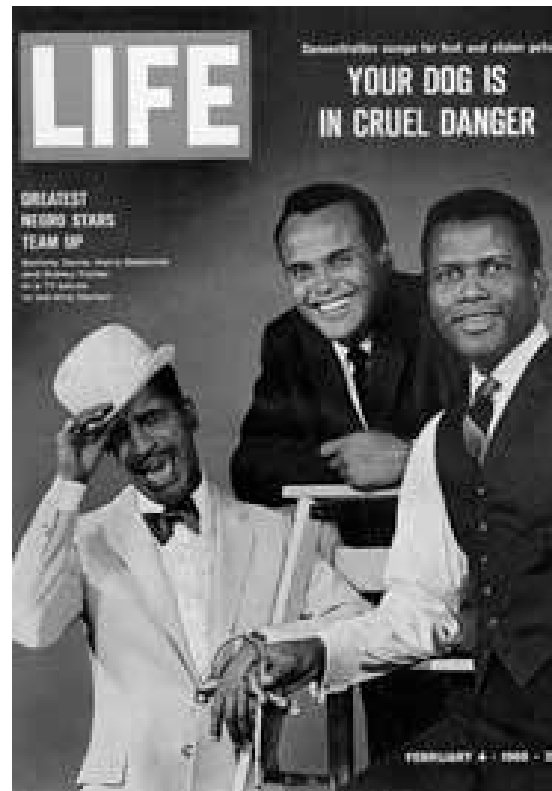
- Animal Welfare Act, 7 USC section 2131 et seq. (“**AWA**”)
- Public Health Service Act (as amended by Public Law 99-158, November 20, 1985 (the Health Research Extension Act), codified at 42 USC section 289d et seq. (“PHS Act” or “Health Research Extension Act or **HREA**”))

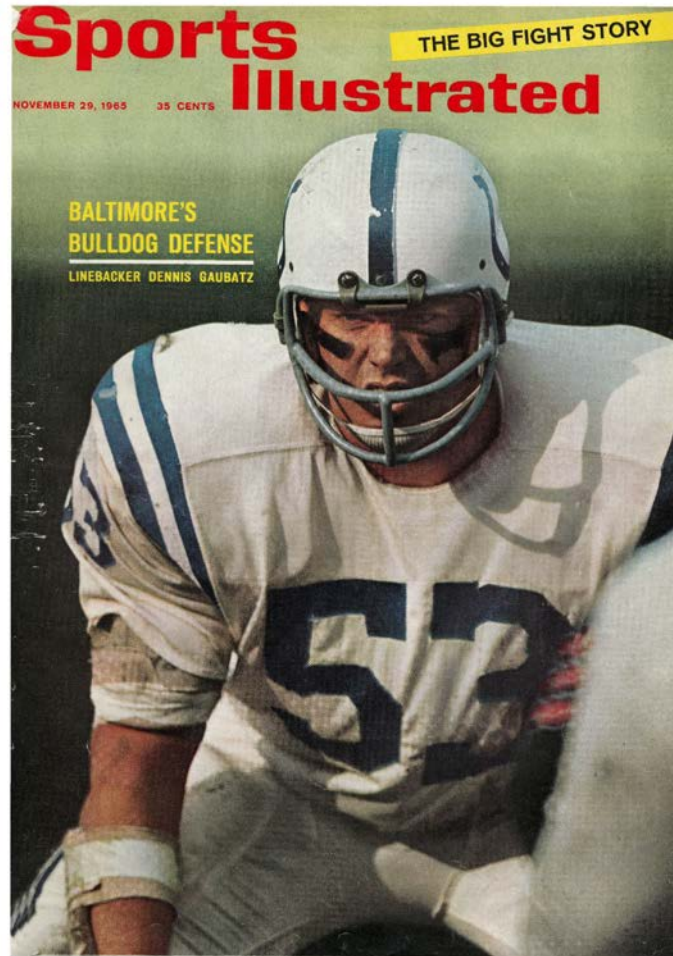
19th Century -- Laboratory animal legislation

- Regulating the use of animals in research and science has been of long-standing concern
 - In 1880 a bill aimed at regulating animal experimentation was introduced for the District of Columbia
 - Provisions were roughly similar to the 1876 British Cruelty to Animals Act
 - Scientists opposed it and it was easily defeated
- State anti-cruelty laws routinely exempted research animals (and still do)

20th Century (pre-1966) -- Laboratory animal legislation

- Animal welfare of considerable concern
 - In the 1960s, US Congress received more mail about animal care issues than about civil rights and the war in Vietnam combined
- Lab animal bill introduced in 1960 to require US federal grant recipients to treat animals humanely
 - 106 Cong. Rec., Part 9, pp. 1192 – 93 (1960); S. 3570, 86th Cong., 2d Sess. (1960)
- Legislation finally enacted in 1966





THE LOST PETS THAT STRAY TO THE LABS

By **Coles Phinizy**

Science's need for experimental animals is very real but is often filled by unscrupulous and cruel professional dognappers

29 November 1965

The AWA - brief overview

- The major piece of federal legislation that defines the relationship of between biomedical researchers and animals in research settings.
- Strives to balance welfare of animals with necessity of biomedical research
 - Regulate humane handling, care, treatment, and transportation of animals; BUT
 - Cannot regulate design, outlines, guidelines of actual research or experimentation

42 USC §2143(a)(1) & (6)

1966 legislation

- “Laboratory Animal Welfare Act”
 - USDA assigned responsibility for administration
 - Regulations authorized for:
 - the humane care and treatment (research, exhibition, companionship, transportation)
 - Owner protection from theft and sale into research
 - Feeding, watering, sanitation and veterinary care
- Applicable to research facilities (and others)

The Improved Standards for Laboratory Animals Act of 1985

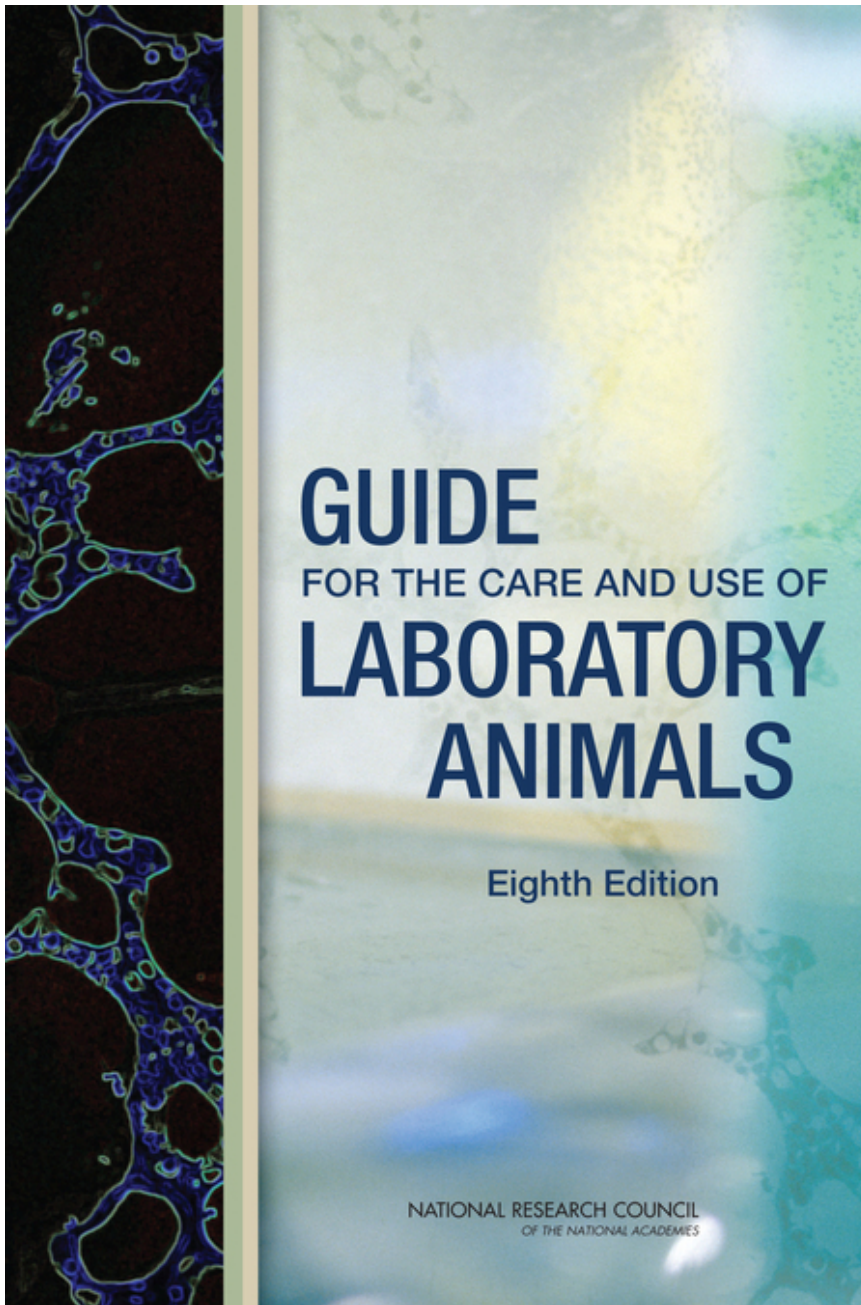
- Authorized USDA to promulgate rules that affected animals during experimentation
- Key provisions:
 - Minimizing pain and distress during experimentation (unless the experiment required otherwise)
 - Establishing an Institutional Animal Care and Use Committee (IACUC)
 - Training animal care personnel, including principal investigators
 - Requiring that principal investigators consider alternatives to any procedures likely to produce pain and distress
 - USDA yearly inspection
- USDA cannot regulate research
 - Statutory language now found at 7 USC §§ 2143(a)(3)(E) and (a)(6)(A)
 - Researcher still has “keys to the laboratory door”

HREA or PHS Act

- Not regulatory – guidance/policy driven
- Applicable to any person or entity that receives funds from the Department of Health and Human Services
 - NIH, CDC, FDA, and other agencies
 - Administered by the Office of Laboratory Animal Welfare (OLAW)
- Contractual mechanism – to submit application for funding, applicant must assure that it will meet guidelines and that training is available

US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training

1. Transportation – follow AWA rules
 2. Procedures must have value to human/animal health, societal good
 3. Use appropriate number of animals and correct species, given research; consider in vitro alternatives
 4. It is imperative to avoid or minimize pain, distress and discomfort
 5. Use analgesics and pain killers if procedure will cause even momentary pain
 6. Implement humane euthanasia
 7. Housing and husbandry must be appropriate and normally under veterinary supervision
 8. All personnel shall have appropriate training
 9. IACUCs, not investigators, should review and approve exceptions
- ** The Guide should be followed to implement these principles **



- The Guide is intended to be used by institutions and principal investigators to assist them in caring for and using animals in a scientifically and technically appropriate, and humane way
- Use of Guide is required by the PHS Policy and should form the basis for a comprehensive animal care and use program
- Guide is based on performance standards

Guide for the Care and Use of Laboratory Animals (8th Edition 2011)

- “This edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) strongly affirms the principle that **all who care for, use, or produce animals for research, testing, or teaching must assume responsibility** for their well-being.” (1)
- “Both researchers and institutions have **affirmative duties of humane care and use** that are supported by practical, ethical, and scientific principles.” (1)
- “Throughout the *Guide*, scientists and institutions are encouraged to **give careful and deliberate thought to the decision to use animals**, taking into consideration the contribution that such use will make to new knowledge, ethical concerns, and the availability of alternatives to animal use. [citation omitted] (3)
- “**Using animals in research is a privilege granted by society to the research community** with the expectation that such use will provide either significant new knowledge or lead to improvement in human and/or animal well-being.” [citations omitted] (4)
- “The *Guide* endorses the **responsibilities of investigators** as stated in the *U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*. These principles direct the research community **to accept responsibility for the care and use of animals during all phases of the research effort.**” [citations omitted] (4)

2. Animal rights, animal welfare, researcher responsibilities

Defining animal rights

The term “animal rights” means that animals are “entitled to be protected against the state and the majority even where a price is paid by the general welfare.”

Francione, *Animal Rights and Animal Welfare*, 48 Rutgers L. Rev. 397, 398 (1996)

Campaigns

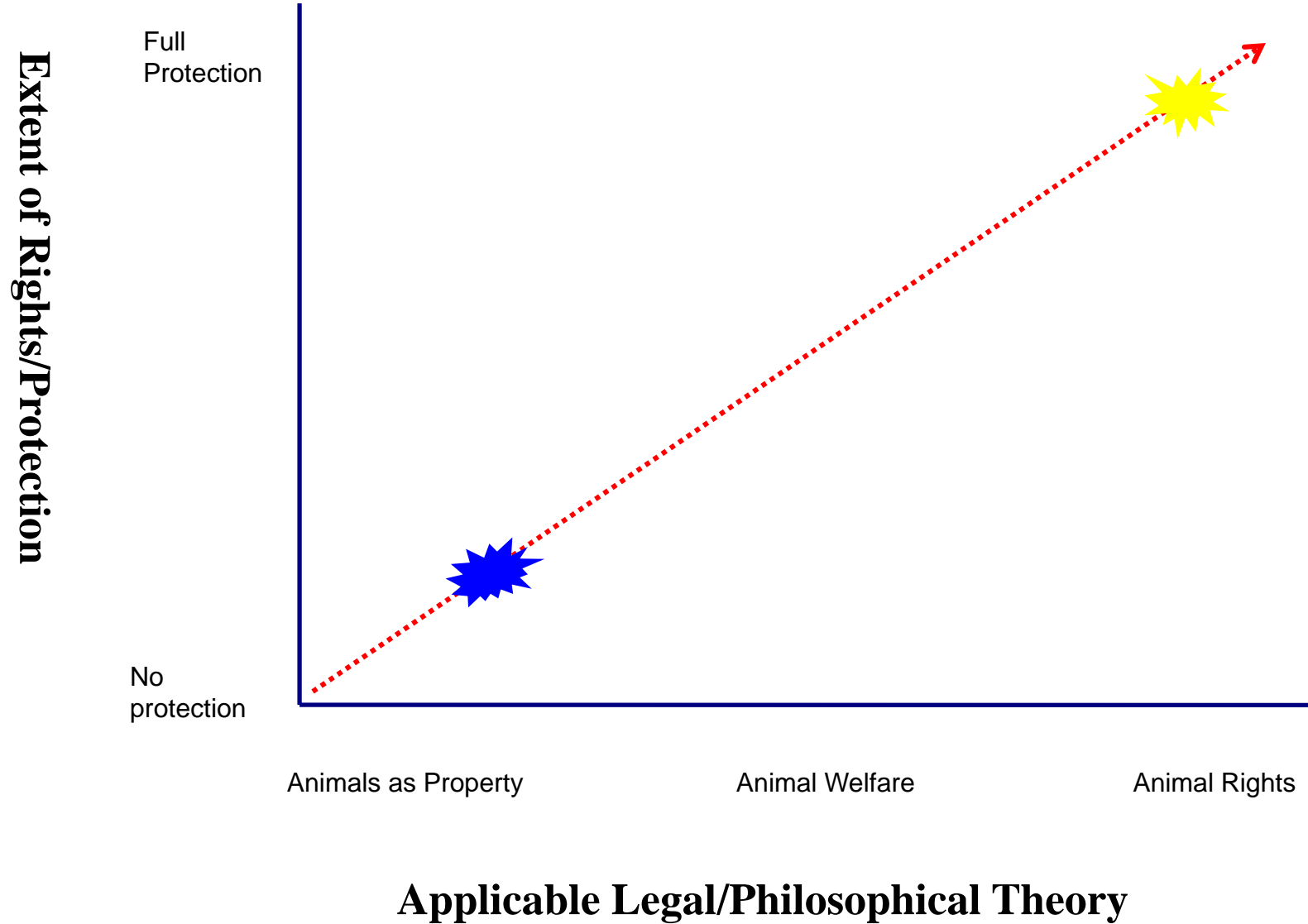
Use your voice to help secure
freedom and sanctuary for
nonhuman animals.

Source: <https://www.nonhumanrights.org/campaigns/>

US federal laws today

- Animals are considered to be property
- Animals cannot be said to possess “rights” (although some commentators believe that they do)
- Animals enjoy certain protections (surrogate protections), especially from pain and distress in biomedical research
- **It is the responsibility of the researcher and research institution to assure these protections**

A Continuum of How Animals are Viewed in Biomedical Research



3. Societal Expectations

Gallup poll 2015

Americans' Concerns With Animal Treatment in Various Settings

In general, how concerned are you about the way each of the following types of animals is currently treated in the U.S. today -- very concerned, somewhat concerned, not too concerned or not at all concerned?

	Very concerned	Very/Somewhat concerned
	%	%
Animals in the circus	31	69
Animals used in competitive animal sports/contests	32	68
Animals used in research	33	67
Marine animals at amusement parks/aquariums	25	62
Animals in the zoo	21	57
Livestock and other animals raised for food	26	54
Household pets	22	46

May 6-10, 2015

Sorted by "% Very/Somewhat concerned"

GALLUP®

Source: <https://news.gallup.com/poll/183275/say-animals-rights-people.aspx>

Pew Research Center, August 2018

2009

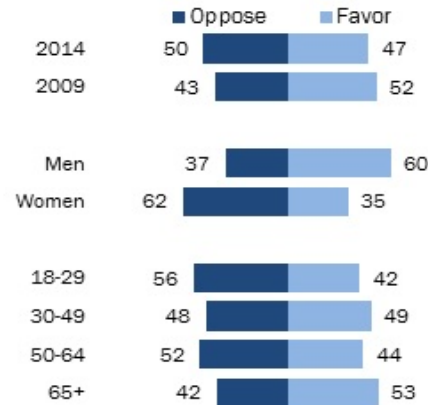
Gender Divide over Using Animals in Research		
	Favor %	Oppose %
Total public	52	43
Men	62	33
Women	42	52
18-29	39	58
30-49	55	38
50-64	52	44
65+	61	33
College grad+	59	36
Some college	49	46
HS or less	49	46
Republican	62	33
Democrat	48	48
Independent	51	44

Figures read across.

2015

Use of Animals in Scientific Research

% of U.S. adults saying they favor/oppose the use of animals in scientific research



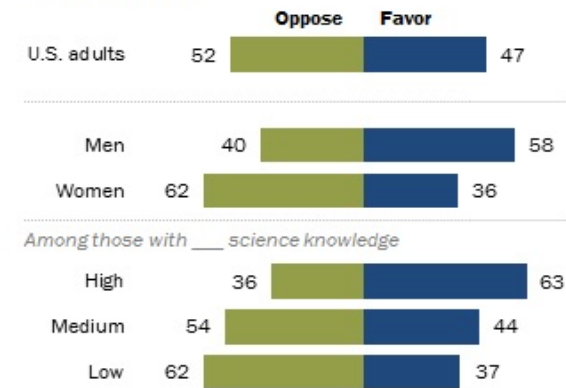
Survey of U.S. adults Aug. 15-25, 2014. Q24a. "Don't know" responses not shown. Whites and blacks include only non-Hispanics; Hispanics are of any race.

PEW RESEARCH CENTER

2018

Americans divided over whether animals should be used in scientific research

% of U.S. adults who say they ___ the use of animals in scientific research



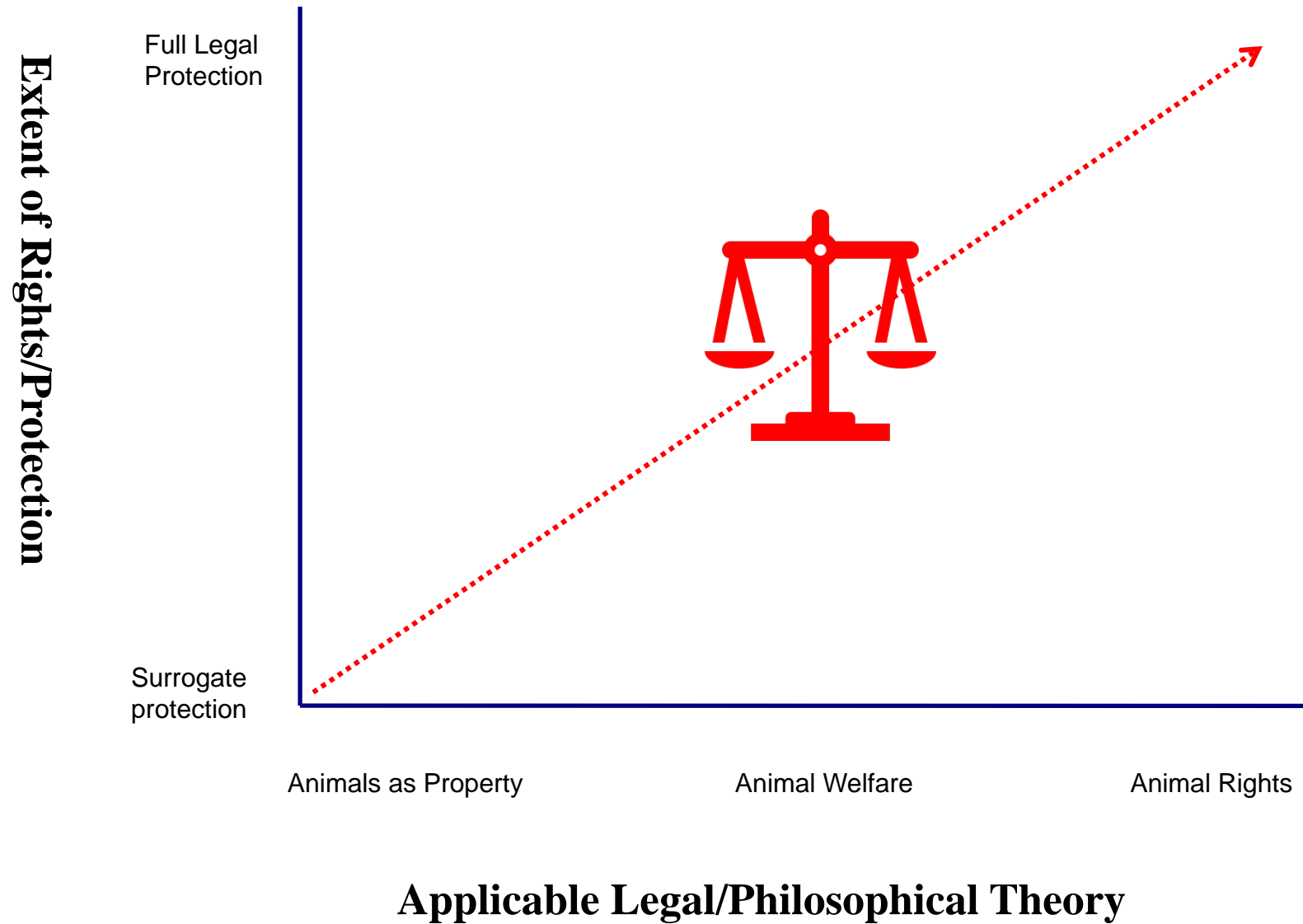
Note: Respondents who did not give an answer are not shown. Source: Survey conducted April 23-May 6, 2018. "Most Americans Accept Genetic Engineering of Animals That Benefits Human Health, but Many Oppose Other Uses"

PEW RESEARCH CENTER

"The latest survey results come at a time when the use of animals in scientific research continues to be a contentious issue that pits members of the scientific community against activists, and sometimes politician who say the practice is inhumane and unnecessary. "

4. Potential Implications

Animal Rights, Animal Welfare and Animals as Property



116TH CONGRESS
1ST SESSION

H. R. 1209

To amend the Public Health Service Act to ensure that non-animal methods are prioritized, where applicable and feasible, in proposals for all research to be conducted or supported by the National Institutes of Health, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2019

Ms. ROYBAL-ALLARD (for herself and Mr. CALVERT) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to ensure that non-animal methods are prioritized, where applicable and feasible, in proposals for all research to be conducted or supported by the National Institutes of Health, and for other purposes.



Thanks!