

The Promise and Consequences of Translational Research:

**THE ETHICAL IMPLICATIONS OF USING PETS AS
RESEARCH SUBJECTS IN COMPARATIVE MEDICINE**

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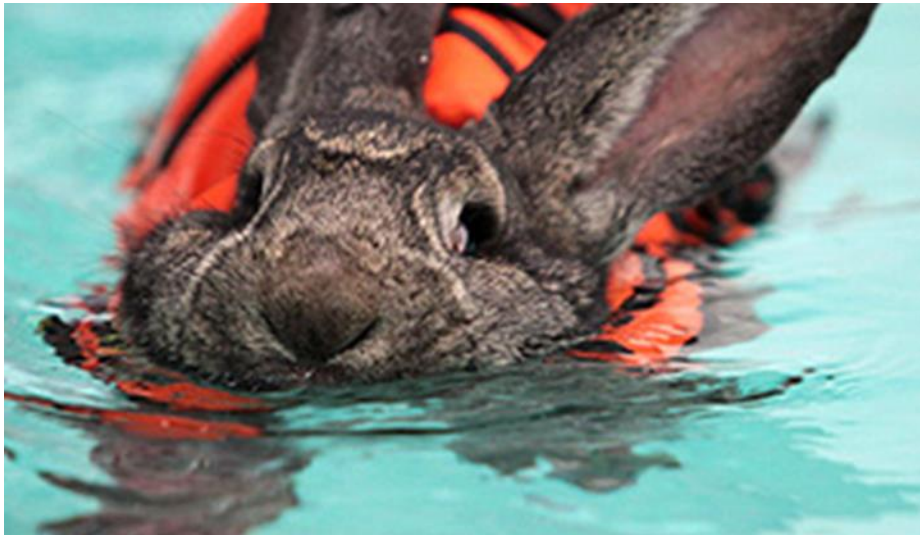
Center for Bioethics, Harvard Medical School

Massachusetts Society for the Prevention of
Cruelty to Animals-Angell Animal Medical Center

Yale Interdisciplinary Center for Bioethics

Why is a veterinarian presenting Ethics Grand Rounds?

- First off, contemporary veterinary medicine may not be what you think it is.....



Picture: Heidi Reich, VMU Wien



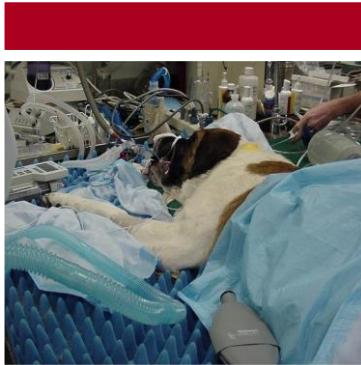
Do Non-Human Animals Deserve Moral Consideration?

- Arguably, they already have it
- External Reasons to Treat Animals Ethically:
 - Utilitarian arguments, Rights based arguments, Religious tenants, etc.
- Internal Reasons to Treat Animals Ethically:
 - Virtue Ethics: “Using animals in ways that are harmful or destructive to them, we display moral failings that reflect poorly on us as ethical agents”
 - Animals make moral claims on us because we are moral agents
 - Our relationships with animals, particularly domestic animals have moral value

(Adapted from Gruen 2011)



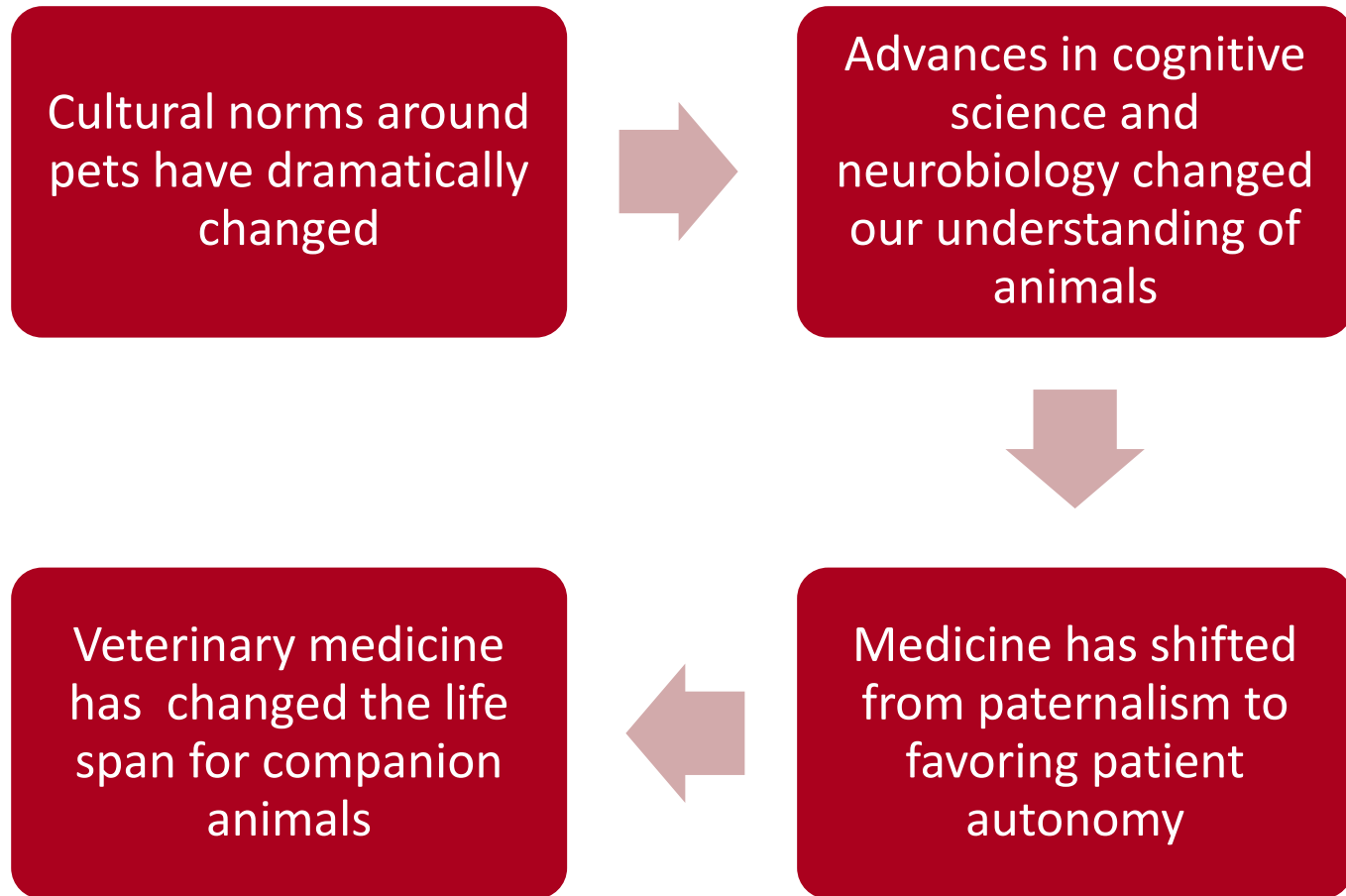
Contemporary Veterinary Medicine looks a lot like care for people....



.....WHY??



Linked observations on shifts in culture and medicine

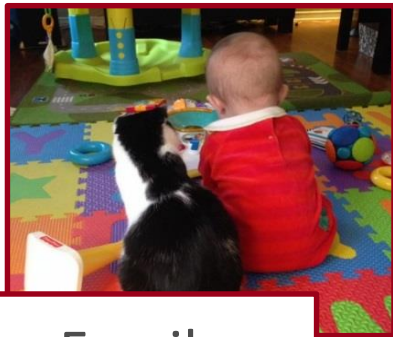


Animals as family members

- Emotional attachment to animals is not new
- New cultural acceptance of animals fully sharing daily life with humans
- Increased number of first time adult pet owners?



Companion animals occupy a complex and conflicted place in society.



Family members?

Working partners?



Powerless victims?

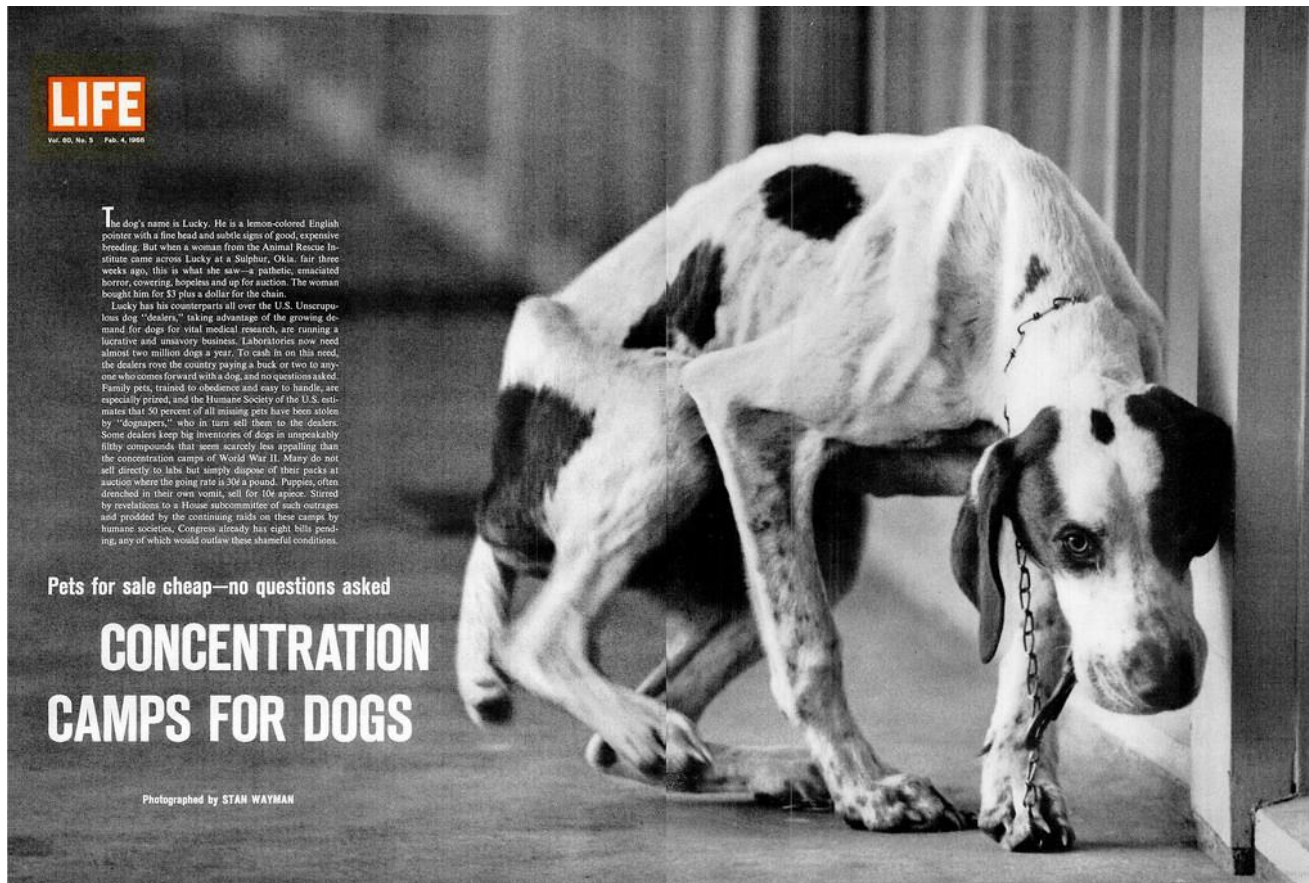


Pet are in legal limbo but have a high social value:

- Large majority consider pets family
- Legally “property”
- Protected from neglect/cruelty and in some states from “pound seizure”
- AWA covers pets, sort of....

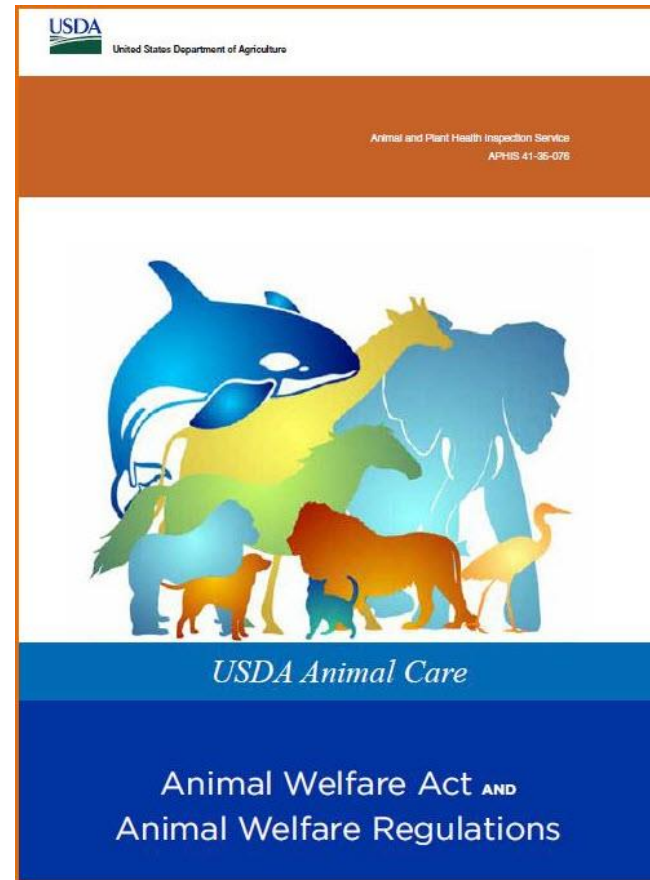


Pepper's Law 1965 and The Animal Welfare Act 1966



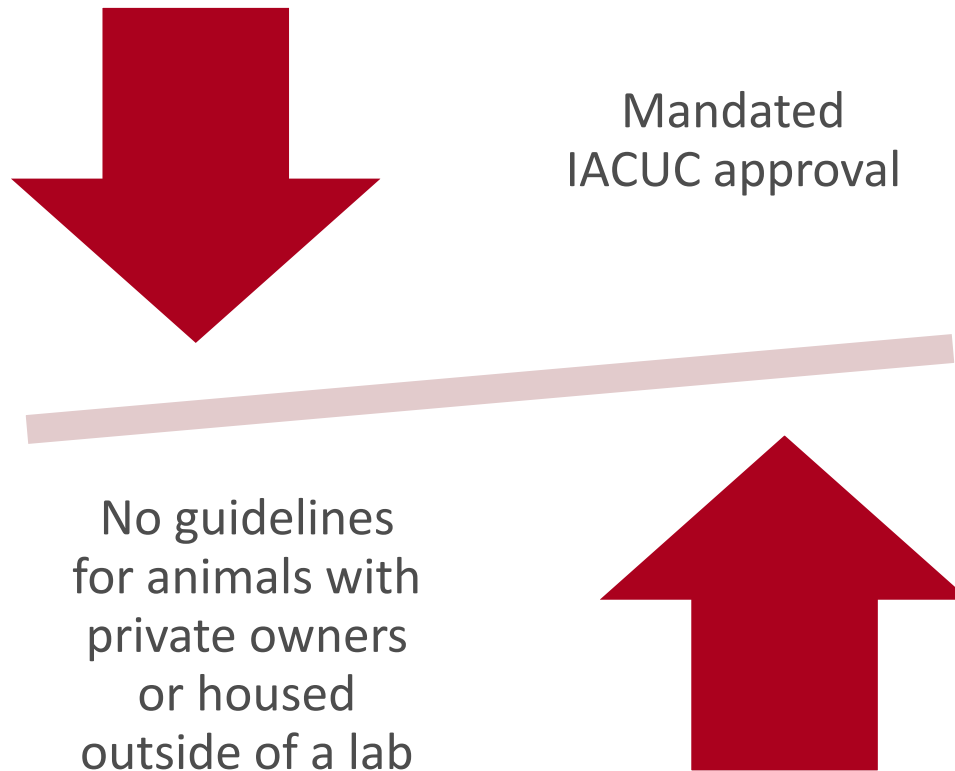
Are pet dogs and cats protected by the AWA????

- Regulates sourcing for use in research and commercial businesses
- Sets minimum standards for care and housing in these settings *only*
- Doesn't supersede pet owner's property rights



Does the AWA protect owned pets?

That depends upon your definition of protection



Using Pets in Clinical Research

- Owned pets fall through an oversight gap when enrolled in clinical research
- Also gap in protections for international field trials on healthy owned or free-roaming domestic animals
- Can bypasses costs, limitations, and regulations that govern the use of laboratory animals, even when they are the same species.
- Pets are being used and proposed as good subjects for *pre-clinical* human trials



Using Pets in Clinical Research

- Parallel system of drug development for the veterinary market
- Pets can be recruited at the vet hospital or via direct marketing to owners by a third-party contract research organization
- It is becoming more common for veterinarians to be both the care provider and the clinical investigator
- **There are no specific guidelines for ethical use of pets in clinical research**



Current Efforts to Create Ethical Guidelines for Pets in Clinical Trials

- Creation of a few, hybrid IRB-IACUC committees
- Creation of Independent Ethical Guidelines



Ethical Decision-Making in Innovation for Animal Welfare

Think Tank
February 15-17, 2017
Denver, CO

The Michelson Prize & Grants

The \$75 million challenge to find a nonsurgical sterilization method for cats and dogs

Imagine a product that would vastly reduce the number of animals entering and being euthanized in US shelters. The Michelson Prize & Grants is looking for scientists from a wide range of fields to develop a safe and effective way to spay and neuter cats and dogs without the need for surgery.

Join us in taking on this challenge.



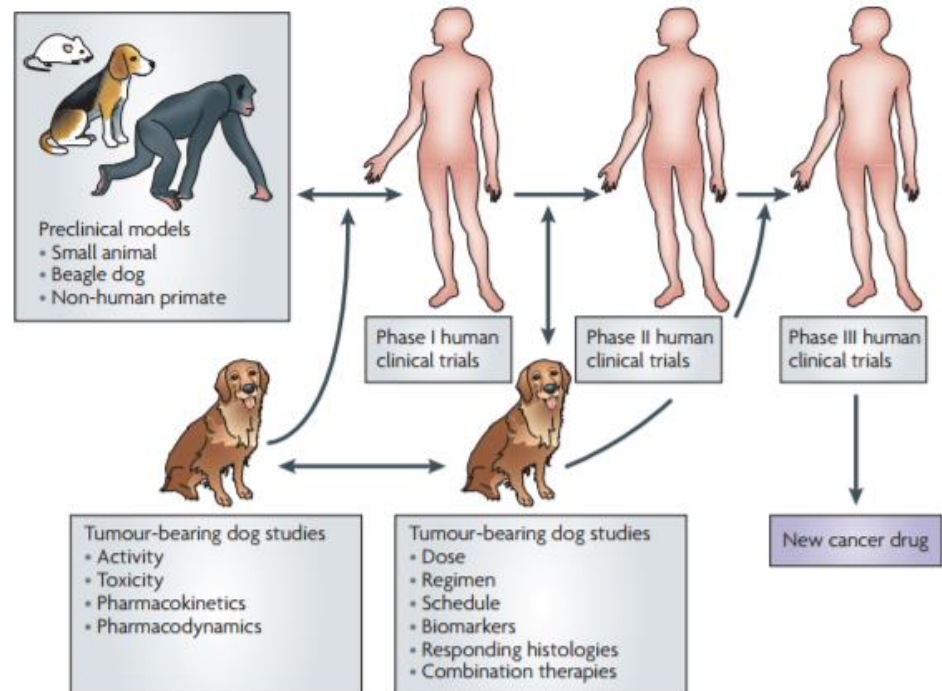
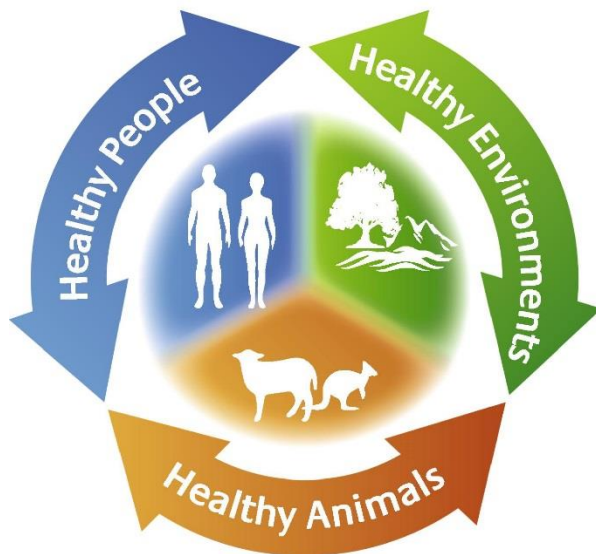
What's the problem with standard applied biomedical research?

- The time and cost of bringing a new, effective drug to market
- Enter “Translational Medicine”
- ~85% of drugs in development never make it to market. Why?
 - Translational and scale issues
 - Induced disease models vs. spontaneous models
- Options: Use “Phase 0” trials or.....



.....Answer the siren call of ONE HEALTH

The One Health Triad



[Nat Rev Cancer](#). 2008 Feb;8(2):147-56. doi: 10.1038/nrc2273.

Translation of new cancer treatments from pet dogs to humans.

[Paoloni M](#)¹, [Khanna C](#).



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PETS AS NEW PREDICTIVE MODELS OF HUMAN DISEASES : COMPARATIVE MEDICINE

Classical in vivo models have obvious translational limitations.

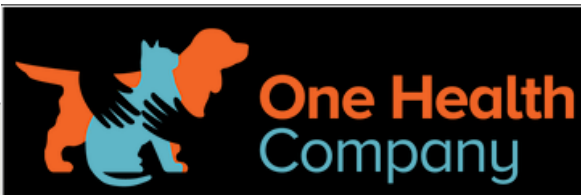
**Natural diseases in dogs and cats share
numerous features with human diseases.**

Why using dogs and cats models?

To establish a continuum between species in terms of
pharmacology, pharmacokinetics and toxicology
in order to reach clinical trials in humans with more reliability.



“One Health Company noted that pets remain with their families, diseases are never induced, and putting a pet down is never considered an option in any of their clinical trials.”



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(My) Ethical Concerns About Using Pets in Research

- Is the “Therapeutic Misconception” easily exploited when pets are research subjects?

“...patients—and investigators—may sometimes not clearly understand that research has purposes distinct from clinical care. Such a lack of understanding can compromise the objectives of informed agreement to participation in research.”

Ethical Conduct of Clinical Research Involving Children.

Institute of Medicine (US) Committee on Clinical Research Involving Children; Field MJ, Behrman RE, editors. Washington (DC): National Academies Press (US); 2004.



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Ethical Concerns About Using Pets in Research

- How do we obtain “consent”???
- Similar to children, we actually obtain *permission*, not consent
- Should we and how do we begin to respect the autonomy of pets as research subjects?
- Decision making in light of “kinship relationship” and substituted judgement



Ethical Concerns About Using Pets in Research

- Consider the convoluted role of money in veterinary medicine:
 - Are financial incentives for pet owners and veterinarians appropriate?
 - What are the conflicts of interest?
 - Are financial constraints to care tantamount to coercion?

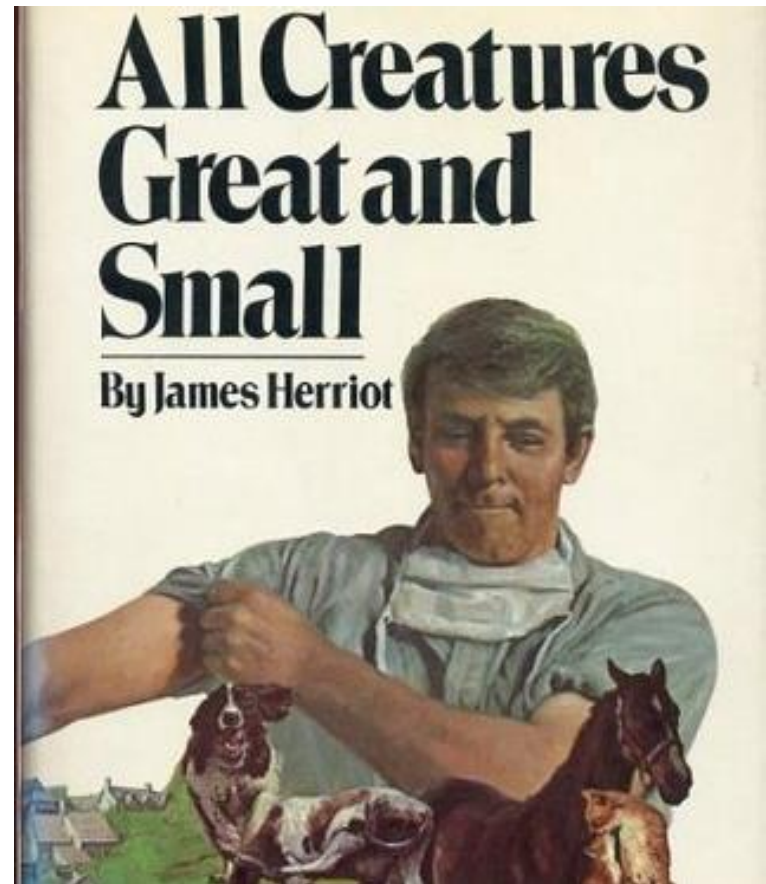


Veterinary medicine is no longer recognizable as the profession of “James Herriot”

Over 26,000 vet clinics in the US

At least 20% are owned by a large corporation, most by a consolidator

Vet business models have ethical implications in this story....for recruiting and enrolling



Ethical Concerns About Using Pets in Research

- For pre-clinical research:
 - Potentially riskier/ more chance of harming the subject
 - Is there deliberate or incidental deception to pet owners about the goals of dual purpose research?
- Can we justify using healthy pets for clinical (or pre-clinical) research?



The Ethical Implications of Using Pets in Research: Solutions and Considerations for Debate

- Basic minimal ethical guidelines be created and mandated
- Should owned pets be covered under the AWA?
 - **Yes**, pets should receive the same minimum standard of care and humane end point determination as lab animals
 - **No**, we need a different law that recognizes the importance of the human-animal bond and pets as having a different moral status



The Ethical Implications of Using Pets in Research: Solutions and Considerations for Debate

- Consider pets a “vulnerable population” as research subjects
 - Enrollment of pets in research should be similar to enrollment of other vulnerable populations
- Would a hybrid IACUC/IRB that focuses on ethical protocol serve the purpose of protecting pets?



Questions, Comments or Challenges?



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