ALCHEMIZING THE BAR: AN EXAMINATION OF GLOBAL ETHICAL CONSIDERATIONS FOR USING ALTERNATIVES TO ANIMALS IN RESEARCH, TESTING, AND EDUCATION

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Countries regulate scientific research in various ways. Such structures are the result of input from scientists, attorneys, physicians, advocates, and others. These schemes may also derive from outcomes of the research itself. Some countries do not incorporate or require the ethical use of an animal—or an alternative to the use of an animal—to be considered. Others do incorporate, and even require, the ethical use of animals in research. In alignment with The Three Rs—replacement, reduction, and refinement of animals used in science—technological capabilities now allow scientists to increasingly use alternatives, such as microphysiological systems, rather than animal models. This Article (1) discusses ethical codes and systems for using animals in research, testing, and education, (2) surveys whether any countries incorporate ethical considerations of the use of animals in science, and (3) describes potential ways to advance the law in alignment with The Three Rs. As such, advocates become alchemists who do more than continue to 'raise the bar' for animals in science; rather, they alchemize the bar, so that transformational and systemic outcomes for people and animals are realized.

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I. INTRODUCTION

When we strive to become better than we are, everything around us becomes better, too.

—Paulo Coelho, *The Alchemist*[1]

Brazilian author Paulo Coelho's allegorical novel *The Alchemist* tells the story of a traveling quest of a shepherd boy named Santiago who, with the *counsel* of an alchemist, learns to realize his dreams.[2] An alchemist helps Santiago to transform and become who he is.[3] After all, an alchemist's raison d'être radiates in transformation.

An etymological definition of the word alchemy derives from medieval chemistry and the science of "transmutation of baser metals into gold."[4] Alchemy may refer not only to changing physical processes but also to changing philosophical, psychological, spiritual, metaphysical, and methodological approaches and examinations too.[5]

Swiss psychiatrist and psychoanalyst Carl Jung writes in his work *Psychology and Alchemy* about alchemy of the self.[6] He demonstrates the importance of self-knowledge and how one's self-transformation can illuminate something novel or unknown.[7] If applied to the law and science, such methods of change can rouse new systems, practices, and processes. This transformation can alchemize legal and scientific

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1 PAULO COELHO, THE ALCHEMIST 155 (Alan R. Clarke trans., HarperCollins Publishers 2014) (1988).

2 Coelho, *supra* note 1, at *passim*.

3 *Id.*

4 *See Alchemy - Etymology*, OXFORD ENG. DICTIONARY, https://www.oed.com/dictionary/alchemy_n?tl=true&tab=etymology (accessed Feb. 25, 2024) (discussing the origin of the word alchemy).

5 *Id*.

6 CARL JUNG, PSYCHOLOGY AND ALCHEMY *passim* (Gerhard Adler, et al. eds., R.F.C. Hull, trans., Princeton Univ. Press 1980) (2d ed.1944).

7 *Id.* at *passim*.

professions, so that law and science support—and even require—the use of alternatives to animals in science.[8]

Law and science can do more than simply 'raise the bar' for animals; these professional callings can alchemize the bar for animals. This Article[9] reveals that an advocate who wants to help animals can work as a modern-day alchemist by working to transform law and policy in support of scientific systems that rely on alternatives—and not animals—for scientific research. Attorney-led groups, such as bar associations, organizations, and law firms might do this too, either in a supportive role or more directly.

Part II of this Article discusses professional ethical codes and systems. Part III identifies locations where the ethical use of alternatives to animals in research may be deliberated. Finally, Part IV looks forward. It reviews how the law can alchemize science. Given the impact that science has on human and animal lives, this topic deserves urgency and respect.

II. ETHICS

The ethical use of animals has been and continues to be deliberated by scientists and philosophers. Scientific inquiry has evolved from a review of humans noticing animals' "gross anatomical features, including bones, body cavities, musculature, and internal organs"[10] in a non-linear way to a more refined—yet still non-linear—exploration of body systems, cells, and tissues. Much of the knowledge and technologies that scientists have today are based off of these early experiments.[11]

Modern animal-involved science is done for a variety of purposes or goals. The use of animals may be preferred.[12] It may be considered

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[8] Throughout this Article the phrase, "research, testing, and education" is used to encompass varied scientific work that is done using animals. However, "animal research" or similar language may be used too. The use of "animal research" and other terms is not intended to exclude categories of research or distinguish one of any from the other, unless so stated.

[9] For context, the author originates from and is located in the United States. Thus, the author acknowledges that unintended biases, language barriers, and research access obstacles may impact the framing and understanding of approaches, information, viewpoints, and interpretations about this subject. Please note that it remains the author's earnest intention to be sensitive to the perspectives and nuances that exist within many nations, cultures, and communities within a global ecology. You must seek an attorney or other appropriate professional in the specific area of interest and location for guidance. This Article is not legal, ethical, or any other professional advice or guidance.

[10] Lewis B. Kinter, et al., *A Brief History of Use of Animals in Biomedical Research and Perspective on Non-Animal Alternatives*, 62 ILAR J. 7, 7 (2021).

[11] *Id.* at 14.

[12] *See Animal Testing and Experiments FAQ*, HUMANE SOC'Y U.S., https://www.humanesociety.org/resources/animals-used-experiments-faq#end (accessed Feb. 9, 2024) (for example, animals may continue to be used because "government agencies often seem to prefer that companies carry out animal tests to assess the toxicity or efficacy of products such as industrial chemicals, pesticides, medical devices and medicines.").

to "help researchers understand important biological and physiological processes."[13] Modern animal-involved science may also incorporate The Three Rs, which are the Replacement, Reduction, and Refinement of animals used in research.[14] With the publication of the book, *The Principles of Humane Experimental Technique*, Dr. William Russell—a zoologist, psychologist, and scholar—and Dr. Rex Burch—a microbiologist—established The Three Rs.[15] An ethical review of alternatives to animal-involved research is an outcome that The Three Rs may envision.

Scientist Arthur Schopenhauer wrote in his book, *Parerga and Paralipomena*, that he opposes vivisection.[16] Philosopher Jeremy Bentham famously pronounced, "[t]he question is not, can they reason, nor can they talk, but can they suffer?"[17] Philosopher Jean-Jacques Rousseau wrote about the sentience of animals;[18] modern-day philosophers such as Peter Singer and Tom Regan analyze animal ethics.[19]

This section is not a comprehensive review about the morality of using animals in research. Rather, the following examines professional ethical codes and standards in some professions, especially those used when animals are involved.

A. ETHICAL CODES

There are ethical codes for many professions. For example, physicians are governed by local, state, national, and global codes of ethics. One such guidepost is the Belmont Report, which was developed by a legislatively created commission in the United States; it establishes basic ethical principles for the protection of humans, and supports principles such as "do no harm" and "informed consent."[20] Another ethical code—it is for physicians—is from the World Medical Association; it consists of many provisions, such as a "physician must support sound

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[13] *Why Animals are Used in Research*, NATIONAL INST. OF HEALTH, https://grants.nih.gov/grants/policy/air/why.htm# (accessed Mar. 7, 2024).

[14] WILLIAM RUSSELL & REX BURCH, THE PRINCIPLES OF HUMANE EXPERIMENTAL TECHNIQUE *passim* (1959).

[15] *Id.* at 64; The Three Rs are also named the "3Rs" or the "3R alternatives" and this Article uses "Three Rs" for consistency.

[16] 2 ARTHUR SCHOPENHAUER, *On Religion*, *in* PARERGA AND PARALIPOMENA 324, 375 (E. F. J. Payne trans., Oxford Univ. Press rev. ed. 2000) (1851); *See also* ARTHUR SCHOPENHAUER, ON THE BASIS OF MORALITY (Arthur Brodrick Bullock trans., 1903) (1840) (writing that animals have moral rights).

[17] JEREMY BENTHAM, AN INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION 245 (Oxford: Clarendon Press 1907) (1823) (writing in support of the moral interests of animals).

[18] JEAN-JACQUES ROUSSEAU, DISCOURSE ON THE ORIGIN AND THE FOUNDATION OF INEQUALITY AMONG MEN 14 (Donald A. Kress trans., Hackett Publishing Co. 1992) (1754).

[19] PETER SINGER, ANIMAL LIBERATION NOW *passim* (Diversion Books 2023) (writing about animal rights); TOM REGAN, THE CASE FOR ANIMAL RIGHTS *passim* (1983) (writing that animals have intrinsic moral worth).

[20] OFFICE OF THE SEC'Y, DEP'T OF HEALTH, EDUC., & WELFARE., THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979).

medical scientific research."[21] The Declaration of Helsinki is another international ethics code that was adopted in 1964 by the World Medical Association.[22] It provides that "[m]edical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, *as appropriate*, animal experimentation."[23]

The Nuremberg Code[24] was created in response to the horrific atrocities inflicted upon human beings.[25] Although it is not an official law in any nation, the Nuremberg Code provides ten points; two of the points state that experiments should "yield fruitful results for the good of society" that are "*based on* the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study."[26]

The legal profession abides by ethical codes too. These codes may be state, national, or international; and may be required or permissive. At the national level, the American Bar Association publishes its Model Rules of Professional Conduct to guide attorneys in the United States.[27] These rules serve as a template for individual states to adopt, in full or in part, their own codes. For example, American Bar Association Model Rule 2.1 provides that attorneys must exercise independent

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21 *WMA International Code of Medical Ethics*, WORLD MED. ASS'N, https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/ (accessed Feb. 9, 2024).

22 *WMA Declaration of Helsinki–Ethical Principles for Medical Research Involving Human Subjects*, WORLD MED. ASS'N (1964), https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (accessed Feb. 9, 2024).

23 *Id.* (emphasis added).

24 *Nuremberg Code*, UNIV. OF N.C. RSCH., https://research.unc.edu/human-research-ethics/resources/ccm3_019064/ (accessed Feb. 9, 2024).

25 *See generally* Gilly Griffin and Paul Locke, *Comparison of the Canadian and US Laws, Regulations, Policies, and Systems of Oversight for Animals in Research*, 57 ILAR J., 271, 272 (2016), https://doi:10.1093/ilar/ilw037 (accessed Feb. 9, 2024) (discussing a brief history of animal-involved research).

26 UNIV. OF N.C. RSCH., *supra* note 24 (emphasis added). Some may allege that because the Nuremberg Code states that scientific experiments must be "based on the results of animal experimentation" that the practice of animal-involved experiments must continue. However, advocates should note that the Nuremberg Code does not necessarily require the continuing use of animals in experiments; the Code can be interpreted to indicate that current experiments that use alternatives and not animals are *based on* animal experiments; as history reveals, scientific endeavors and experiments build upon themselves and are based on animals as once-utilized foundational starting points; *see generally* Aldric Hama, *The Nuts, Bolts and Ethics of Animal Research in the Global Search for Cures*, JAPANFORWARD (Mar. 27, 2023), https://japan-forward.com/the-nuts-bolts-and-ethics-of-animal-research-in-the-global-search-for-cures/ (accessed Feb. 9, 2024) (writing about history of animal research in the EU, the U.S., and Japan).

27 *Model Rules of Professional Conduct*, AM. BAR ASS'N, https://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/ (accessed Feb. 10, 2024).

professional judgment in representing a client.[28] When providing advice, "a lawyer may refer not only to law but to other considerations such as moral, economic, social and political factors, that may be relevant to the client's situation."[29] Thus, it is possible that absent any other rule, law, or concern, an attorney in the United States may include moral or ethical factors about the use of animals in science when advising and representing a client. At a global level, the International Bar Association has a code of ethics and provides that a lawyer must "maintain the highest standards of honesty, integrity and fairness toward […] those with whom the lawyer comes into professional conduct."[30]

B. ETHICAL SYSTEMS

Outside of the aforementioned generally applicable ethical codes and practices, there is no global ethical system pertaining to animals used in research.[31] That is, there is no global legal establishment that provides oversight of animals; there is no legal treaty requiring or encouraging alternatives to animals in research.[32] What one country defines as ethical might not be another country's definition of ethical. Even some non-profit organizations that are incorporated to protect animals might have different approaches about the ways to help animals used in research; or might not work to try to protect animals used in research at all. Also, some organizations may be quite small to provide the impact that is needed. For example, the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) has an accreditation and assessment program; however the AAALAC is voluntary and carries a modest membership.[33] The AAALAC accredits only approximately "1,100 companies, universities, hospitals, government agencies[,] and other research institutions in 50 countries/regions."[34]

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[28] *Rule 2.1: Advisor*, AM. BAR ASS'N, https://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/rule_2_1_advisor/ (accessed Feb. 9, 2024).

[29] *Id.*

[30] INT'L BAR ASS'N, INTERNATIONAL PRINCIPLES ON CONDUCT FOR THE LEGAL PROFESSION 5 (2011), https://www.icj.org/wp-content/uploads/2014/10/IBA_International_Principles_on_Conduct_for_the_legal_prof.pdf (accessed Feb. 9, 2024).

[31] Kiani et al., *Ethical Considerations Regarding Animal Experimentation*, 63 J. PREVENTATIVE MED. HYGIENE E255, E258-259 (2022); International Standards for the Care and Use of Laboratory Animals, KENT SCI.CORP. (June 24, 2019), https://www.kentscientific.com/blog/international-standards-for-the-care-and-use-of-laboratory-animals/ (accessed Feb. 29, 2024).

[32] International Standards for the Care and Use of Laboratory Animals, *supra* note 31.

[33] *What is AAALAC?,* ASS'N FOR ASSESSMENT & ACCREDITATION LAB'Y ANIMAL CARE, https://www.aaalac.org/about/what-is-aaalac/ (accessed Feb. 13, 2024) ("AAALAC endorses the use of animals to advance medicine and science when there are no non-animal alternatives, and when it is done in an ethical and humane way.").

[34] *Id.*

In the European Union and the United Kingdom, the ethical review of alternatives to animal research is considered.[35] In the United States, 'ethics committees' exist and are called Institutional Animal Care and Use Committees (IACUCs).[36] The characterization of an IACUC as an animal-forward *ethics committee* is disingenuous though. IACUCs in the United States do not typically make ethical determinations about whether an experiment involving animals can move forward pursuant to any standard of moral rightness. IACUCs do not decide whether animals can be used.

However, in the United States, a regulation under the Animal Welfare Act provides that "nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility."[37] As such, an IACUC could, if directed by its facility, elect to set its own ethical standards or ethical review process.[38]9 C.F.R. § 2.31(a) prohibits an IACUC from "prescrib[ing] methods or set[ting] standards for the design, performance, or conduct of actual research or experimentation";[39] *it does not prohibit the research facility* from setting its own ethical standards for itself or the IACUC. Also, the law does not prohibit an IACUC from prescribing methods or setting standards—including ethical methods or standards—that are *outside* the design, performance, or conduct of actual research or experimentation.[40]

III. LOCATIONS

Countries regulate scientific research based on input from scientists, attorneys, physicians, advocates, companies, and outcomes from research itself. Some countries do not require ethical review or consideration of alternatives. Others do incorporate, and even require, ethical considerations for using animals in research.

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35 *See* Section III.B (discussing animal research in the European Union and United Kingdom).

36 *See generally* Animal Welfare Act, 7 U.S.C. §§ 2132, 2143, 2144, 2157; 9 C.F.R. §§ 2.31, 2.37 (providing information about IACUCs in the United States).

37 9 C.F.R. § 2.31(a).

38 *See id.* (describing the authority of an IACUC).

39 *Id.*

40 *Id.*

A. NORTH AMERICA: UNITED STATES, CANADA,[41] MEXICO[42]

This section discusses whether the United States, Canada, and Mexico require ethical considerations for using alternatives to animals used in research.

The United States does not explicitly mandate the ethical review of alternatives, but it does support The Three Rs.[43] In the legislative history of the 1985 amendment to the Animal Welfare Act, the U.S. Congress noted that "methods of testing that do not use animals are being and continue to be developed which are faster, less expensive, and more accurate than traditional animal experiments for some purposes and further opportunities exist for the development of these methods of testing."[44]

Animal research in the United States is largely governed by two federal laws and state laws, as applicable.[45] The largest of these two federal laws is the Animal Welfare Act which provides minimum standards for the treatment of some animals used in research.[46]

The Animal Welfare Act envisions change toward alternatives in subtle ways. Members of IACUCs at research facilities "represent society's concerns regarding the welfare of animal subjects used at such facility" and the focus on the welfare of animals may mean that fewer animals are used.[47] IACUCs generally do not make ethical determinations about whether an experiment can move forward pursuant to any determination of moral rightness. However, a member of an IACUC must provide "representation for general community interests in the

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41 The author expresses gratitude to Camille Labchuk, Executive Director of Animal Justice, for contributing to this section about Canada by providing information about Canadian animal research.

42 The author expresses gratitude to Elizabeth E. Téllez Ballesteros, DVM, MSc, PhD; Claudia T. Edwards P., DVM, PhD; Aviva Vetter; and Brenda Cortés for contributing to this section about Mexico by providing information about Mexican animal research.

43 *See* Lisa Levin & Louis Muglia, Alternative Thinking about Animals in Research, NAT'L ACAD. MED. (Nov. 14, 2022), https://nam.edu/alternative-thinking-about-animals-in-research/ (accessed Feb. 10, 2024) ("The imperative to consider alternatives to animal use in the U.S.'s federal Animal Welfare Act, which subtextually recommends consideration of the 3Rs….").

44 Food Security Act of 1985, Pub. L. No. 99-198, § 1751(2), 99 Stat. 1354, 1645.

45 Gilly Griffin & Paul Locke, Comparison of the Canadian and US Laws, Regulations, Policies, and Systems of Oversight for Animals in Research, 57 INST. FOR LAB'Y ANIMAL RSCH. J. 271, 274 (2016).

46 Originally called the Laboratory Animal Welfare Act of 1966, the Animal Welfare Act was amended in 1970, 1976, 1985, 1990, 2002, 2007, 2008, 2013, and 2019 (some of these amendments relate to other animals not used in research). *Animal Welfare Act Timeline*, NAT'L AGRIC. LIBRARY U.S. DEP'T OF AGRIC., https://www.nal.usda.gov/collections/exhibits/awahistory/list (accessed Feb. 7, 2024); *see generally* 7 U.S.C. § 2151 (quoting that the USDA may "promulgate such rules, regulations, and orders as [it] may deem necessary in order to effectuate the purposes" of the AWA).

47 7 U.S.C. § 2143(b)(1).

proper care and treatment" of animals, thus IACUC members can work to ensure proper welfare and treatment of animals.[48]

The Animal Welfare Act also envisions change toward alternatives via its requirement that the principal investigator of an experiment consider alternatives to animals.[49] At a practical level, this consideration usually involves a literature search of alternatives.[50] The principal investigator does not actually need to use the alternatives; only the consideration of alternatives is required.[51]

The other major federal law that governs animal research is the Health Research Extension Act.[52] Enacted in 1985, the Health Research Extension Act requires the Secretary of the U.S. Department of Health and Human Services, through the Director of the National Institutes of Health (NIH), to establish guidelines about "(1) [t]he proper care of animals to be used in biomedical and behavioral research. (2) [t]he proper treatment of animals while being used in such research…" and "(3) [t]he organization and operation of animal care committees."[53] These guidelines of the NIH Office of Laboratory Welfare are called the Public Health Service Policy on Humane Care and Use of Laboratory Animals ("PHS Guidelines").[54] The PHS Guidelines incorporate the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training*.[55] These principles consist of nine key guideposts, several of which relate to the ethical use of animals.[56] The PHS Guidelines also contain the *Guide for the Care and Use of Laboratory Animals*.[57] The PHS Guidelines is a policy document, and is published and supported by a federal agency.[58]

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48 7 U.S.C. § 2143(b)(1)(B)(iii).

49 7 U.S.C. § 2143(a)(3)(B).

50 *Literature Searching: How to Find Animal Use Alternatives*, NAT'L AGRIC. LIBRARY U.S. DEP'T OF AGRIC., https://www.nal.usda.gov/services/literature-searching-animal-use-alternatives#toc-research-planning-and-publishing-guidelines (accessed Feb. 7, 2024).

51 *Id*.

52 Health Research Extension Act of 1985, Pub. L. 99-158 § 495, 99 Stat. 820 (1985).

53 Health Research Extension Act of 1985, 42 U.S.C. § 289d(a)(1)-(3) (2022) (stating that "[the] guidelines shall not be construed to prescribe methods of research").

54 U.S. DEP'T OF HEALTH & HUM. SERVICES & OFFICE OF LAB. ANIMAL WELFARE NAT'L INST. OF HEALTH, NO. 15-8013, PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS 1 (2015).

55 *Id.* at Preface.

56 *Id.* at 4-5.

57 *Id.* at Preface.

58 *Id*. at Preface.

States can and have enacted laws prohibiting pound seizure,[59] supporting adoption after research,[60] and most recently, requiring funding for non-animal research.[61] Another recent update related to drug development and animal research in the United States is that federal law now explicitly permits non-animal technologies to be used instead of animals (however, applications for drugs are subject to approval by the U.S. Federal Food and Drug Administration).[62]

Canada does not explicitly maintain a system for ethical review of alternatives to animals in science.[63] However, Canada has a voluntary oversight entity called the Canadian Council on Animal Care (CCAC).[64] The CCAC creates voluntary standards and issues certificates for institutions that it believes are in compliance with CCAC standards.[65] The CCAC also recognizes The Three Rs.[66]

Canada's system for regulating the use of animals in research is primarily maintained by the laws of each province.[67] For example, Ontario has the Animals for Research Act, which provides minimal protections and mandates inspections.[68] Also, Alberta has the Animal Protection Act, which mandates compliance with CCAC standards.[69]

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[59] *See generally* MASS. GEN. LAW. ch. 140 § 151 (prohibiting the transfer of animals to U.S. Department of Agriculture licensees, or to a business or institution licensed or registered as a research facility or animal dealer). Compare with 7 U.S.C. § 2158(a)(2) (providing that the Animal Welfare Act does not prohibit the following entities to sell animals into research: a state, county, or city owned and operated pound or shelter; private entity established for the purpose of caring for animals, such as a humane society, or other organization that is under contract with a state, county, or city that operates as a pound or shelter and that releases animals on a voluntary basis; and each research facility licensed by the USDA.).

[60] At least 15 states within the United States have "Beagle Freedom" laws which require research dogs to be released for adoption when they are no longer needed for research. *Map of Beagle Freedom Laws*, ANIMAL LEGAL & HIST. CTR., https://www.animallaw.info/content/map-beagle-freedom-laws (accessed Feb. 14, 2024).

[61] Maryland is the first jurisdiction that requires laboratories that use animals to contribute money to non-animal research. S.B. 560, Gen. Assemb., 445th Sess. (Md. 2023); See also Kitty Block, Maryland Becomes First State to Require Animal Testing Labs to Contribute Money to Non-animal Research, THE HUMANE SOC'Y OF THE U.S. (May 9, 2023), https://www.humanesociety.org/blog/maryland-becomes-first-state-require-animal-testing-labs-contribute-money-non-animal-research (accessed Feb. 14, 2024).

[62] Consolidated Appropriations Act, H.R. 2617, 117th Cong. (2023).

[63] *Canadian Legislation and Policies*, CANADIAN COUNCIL ON ANIMAL CARE, https://ccac.ca/en/animals-used-in-science/canadian-legislation-and-policies/ (accessed Feb. 29, 2024).

[64] *Id*.

[65] *Certification Process*, CANADIAN COUNCIL ON ANIMAL CARE, https://ccac.ca/en/certification/certification-process/ (accessed Feb. 15, 2024).

[66] *Replacement, Reduction, Refinement,* CANADIAN COUNCIL ON ANIMAL CARE, https://ccac.ca/en/three-rs/replacement-reduction-refinement.html (accessed Feb. 15, 2024).

[67] *Provincial Information,* CANADIAN COUNCIL ON ANIMAL CARE, https://ccac.ca/en/animals-used-in-science/canadian-legislation-and-policies/provincial-information.html (accessed Feb. 15, 2024).

[68] Animals for Research Act, R.S.O. 1990, c. A.22 (Can.).

[69] Animal Protection Regulation, Alta. Reg. 203/2005 (Can.).

The federal government's criminal code protects animals from cruelty, abuse, and neglect.[70]

Mexico does not explicitly require the ethical review of alternatives to animals in science.[71] However, Mexico does not permit animal testing for cosmetics and prohibits the import, manufacture, and marketing of cosmetics that have been tested on animals.[72] Mexico is a member of the World Organization for Animal Health.[73]

In 1999, Mexico enacted, at the federal level, technical specifications for the "production, care and use of laboratory animals."[74] Mexico also has a general health regulation for animal research[75] and a federal animal health law with a brief mention about reduction.[76] At the state level, some but not all states conduct their own regulatory scheme of animal-involved research.[77]

B. EUROPE: EUROPEAN UNION,[78] UNITED KINGDOM

This section discusses information about European Union and United Kingdom standards for animal-involved science and the ethical review of alternatives.

The European Union (EU) has a legal system in place that requires the ethical review of alternatives.[79] "…EU legislation is unique as it sets a final goal of full replacement of all animals used for scientific and educational purposes and is taking concrete action towards that goal."[80]

Member nations of the EU follow Directives and Regulations. The first Directive for the protection of animals used in science was adopted

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70 Criminal Code, R.S.C. 1985, c. C-46 (Can.).

71 *See Mexico,* WORLD ANIMAL PROTECTION, https://api.worldanimalprotection.org/country/mexico (accessed Feb. 9, 2024) (discussing scientific animal-involved research in Mexico).

72 Kitty Block & Sara Amundson, *In Major Win for Animals, Mexico Bans Animal Testing for Cosmetics,* THE HUMANE SOC'Y OF THE U.S. (Sept. 7, 2021), https://www.humanesociety.org/blog/major-win-animals-mexico-bans-animal-testing-cosmetics (accessed Feb 7, 2024).

73 *Members,* WORLD ORG. FOR ANIMAL HEALTH, https://www.woah.org/en/who-we-are/members/ (accessed Feb. 7, 2024).

74 Especificaciones técnicas para la producción, cuidado, y uso de los animales de laboratorio, NOM-062-ZOO-1999, Diario Oficial de la Federación [DOF] 22-08-2001 (Mex.).

75 Reglamento de la Ley General de Salud en Materia de Investigación para la Salud, Titulo Septimo, Diario Oficial de la Federación [DOF] 06-01-1987, últimas reformas DOF 02-04-2014 (Mex.).

76 Ley Federal de Sanidad Animal, Título Tercero, Capítulo I, Artículo 20(II), Diario Oficial de la Federación [DOF] 25-07-2007, últimas reformas DOF 05-11-2022 (Mex.).

77 *Mexico supra* note 71.

78 The author expresses gratitude to Catherine Morrow, Chairperson, Irish Anti-Vivisection Society for contributing to this section about Ireland by providing information about Irish animal research.

79 *Alternatives to Animal Testing,* EUROPEAN FOOD SAFETY AUTH., https://www.efsa.europa.eu/en/topics/topic/alternatives-animal-testing (accessed Feb. 16, 2024).

80 *Animals in science,* EUROPEAN COMM'N, https://environment.ec.europa.eu/topics/chemicals/animals-science_en (accessed Feb. 9, 2024).

in 1986 but has since been replaced.[81] The current Directive, along with its implementing regulation "establishes measures for the protection of animals used for scientific or education purposes."[82] The Directive applies to live non-human vertebrate animals.[83] The EU's directive adopting The Three Rs states in relevant part:

> [W]herever possible, a scientifically satisfactory method or testing strategy, *not entailing the use of live animals*, shall be used instead of a procedure […]; ensure that the number of animals used in projects is *reduced to a minimum* without compromising the objectives of the project […]; ensure *refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm* to the animals[…]; [and that this Article 4 must be] implemented in accordance with Article 13.[84]

The EU "Choice of methods" section of the Directive states that "[w]ithout prejudice to national legislation prohibiting certain types of methods […]" member states must "ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under" EU legislation.[85] Methods of research must be the most likely to provide satisfactory results; use the minimum number of animals; involve animals with the lowest capacity to experience pain, suffering, distress, or lasting harm; and cause the least pain, suffering, distress, or lasting harm.[86] Members of the EU may include additional standards within their countries as well. For example, Ireland further regulates animal-involved research with its Health Products Regulation Authority (HPRA),[87] which operates under EU Directive 2010/63/EU and was incorporated into Irish law in 2013 through its Animal Health and Welfare Act.[88]

The United Kingdom (UK) has an ethical system in place and requires the ethical review of alternatives. The UK adopts EU Directive

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81 *Id.*

82 Directive 2010/63/EU of the European Parliament and of the Council of Sept. 22, 2010, on the protection of animals used for scientific purposes, 2010 O.J. (L 276) 33, 38 [hereinafter Directive 2010/63].

83 *Id.* at 39.

84 *Id.* at 39-40 (emphasis added).

85 Directive 2010/63, *supra* note 82, at 85.

86 *Id.*

87 *See generally*, *About us*, HEALTH PROD. REGUL. AUTH., https://www.hpra.ie/homepage/about-us (accessed Feb. 4, 2024) (describing the purpose of HPRA). *See* Viola Galligioni et al., *The Case for Modernizing Biomedical Research in Ireland through the Creation of an Irish 3Rs Centre*, 12 ANIMAL 1078, 1080-81 (referencing the relationship between Directive 2010/63 and HPRA).

88 *See* Animal Health & Welfare Act 2013 (Act No. 15/2013) (Ir.), https://www.irishstatutebook.ie/eli/2013/act/15/enacted/en/html (accessed Feb. 29, 2024) (incorporating concepts from the Directive 2010/63 into the laws of Ireland).

2010/63/EU and recognizes The Three Rs.[89] The primary law in the UK that regulates the use of animals in research is the Animals (Scientific Procedures) Act 1986 (ASPA).[90] This law defines an animal generally as "a protected animal" that is "any living vertebrate other than man."[91] The UK prohibits the use of an animal in an experiment if an alternative non-animal method is available and expected benefits from the research outweigh any possible animal suffering.[92]

The ASPA provides that the Secretary of State must support the development of alternative strategies; take steps to encourage research of alternatives; and ensure the promotion and dissemination of information about alternative strategies.[93] Licenses for medical, veterinary, scientific, and environmental research must be obtained from the government before an experiment that uses animals occurs.[94]

C. SOUTH AMERICA: BRAZIL,[95] URUGUAY, PERU[96]

This section is an exploration of the ethical review of alternatives for Brazil, Uruguay, and Peru.

Brazil supports The Three Rs.[97] In 1934, Brazil enacted an early law[98] that excluded scientific interests from its definition of animal mistreatment.[99] The Constitution of the Federative Republic of Brazil prohibits practices that subject animals to cruelty.[100] Brazilian law provides that painful or cruel experiments on living animals are crimes

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89 *See* Animals (Scientific Procedures) Act 1986, c. 14, § 1, (UK) (the act to make new provisions for the protection of animals used for experimental or other scientific purposes) [hereinafter ASPA]; *The law, licences, and the three 'Rs'*, Univ. of Stirling, https://www.stir.ac.uk/research/research-ethics-and-integrity/animal-research-at-the-university-of-stirling/the-law-licences-and-the-three-rs/ (accessed Feb. 4, 2024); *European Directive 2010/63*, Understanding Animal Rsch., https://www.understandinganimalresearch.org.uk/regulation/european-directive (accessed Feb 17., 2024).

90 Alexandra Palmer et al., *Animal Research Beyond the Laboratory: Report from a Workshop on Places Other than Licensed Establishments (POLEs) in the UK*, Animals, Oct. 2020, at 1–2; ASPA, *supra* note 89, at 1.

91 ASPA, *supra* note 89, at *Preliminary* (also stating that the regulations to this statute include any living cephalopod).

92 ASPA at *Preliminary.*

93 ASPA at *Preliminary.*

94 ASPA at *Preliminary.*

95 The author expresses gratitude to Bianca Marigliani, PhD for contributing to this section about Brazil by providing information about Brazilian animal research.

96 The author expresses gratitude to Marcia Condoy Truyenque, Director of Derecho Animal en Peru for contributing to this section about Peru by providing information about Peruvian animal research.

97 Kathryn Bayne, et al.; *The Evolution of Animal Welfare and the 3Rs in Brazil, China, and India*, 54 J. of Am. Ass'n for Lab'y Animal Sci. 181, 182-183 (2015).

98 Decreto No. 24.645, de 10 de Julho de 1934, Diário Oficial do Rio de Janeiro [D.O.E.R.J.] de 10.7.1934 (Braz.).

99 *Id.*

100 Constituição Federal [C.F.] [Constitution] art. 225 (Braz.) (1988).

when alternatives exist; this applies to educational and scientific experiments.[101]

In 2009, Brazil enacted a law about the use of animals in science.[102] The law includes many provisions for the use of vertebrates in scientific research and education, which is restricted to higher educational purposes, such as for biomedical school; the creation of a National Council on the Control of Animal Experiments (CONCEA); institutions must have an Animal Ethical Committee; and the registration and licensing of institutions that breed, maintain, or use experimental animals is required."[103]

Brazilian law provides that CONCEA is responsible for monitoring and evaluating the introduction of alternative techniques that replace the use of animals in education or scientific research.[104] Alternative methods per Brazilian law "do not use animals; use species from lower orders; employ fewer animals; use ex vivo organic systems; or reduce or eliminate discomfort."[105]

CONCEA has published four normative resolutions that recognize 41 alternative methods for several outcomes.[106] Each normative resolution establishes a five-year deadline for the mandatory replacement of the traditional method by the alternative (aimed to reduce, refine, or replace the traditional method).[107] Published in 2015, CONCEA Normative Resolution 25 includes the *Brazilian Guide for the Production, Maintenance or Use of Animals for Education or Scientific Research* ("Brazilian Guide").[108] The Brazilian Guide provides guidance about the use of animals in research.[109]

According to CONCEA Normative Resolution 52, "[t]he use of animals in education or scientific research implies the absence of a validated alternative method in vitro or ex vivo to replace the animal

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101 Lei No. 9.605, de 12 de Fevereiro de 1998, Diário Oficial da União [D.O.U.] de 13.2.1998 (Braz.).

102 Lei No. 11.794, de 8 de Outubro de 2008, Diário Oficial da União [D.O.U.] de 9.10.2008 (Braz.).

103 *Id.*; E. Rivera, et al., *Laboratory Animal Legislation in Latin America*, 57 ILAR J. 293, 295 (2016).

104 Lei No. 11.794, de 8 de Outubro de 2008, Diário Oficial da União [D.O.U.] de 9.10.2008 (Braz.).

105 Decreto No. 6.899, de 15 de Julho de 2009, Diário Oficial da União [D.O.U.] de 7.16.2009 (Braz.).

106 Resolução Normativa No. 18, de 24 de Setembro de 2014, Diário Oficial da União [D.O.U.] de 9.25.2014 (Braz.); Resolução Normativa No. 31, de 18 de Agosto de 2016, Diário Oficial da União [D.O.U.] de 8.19.2016 (Braz.); Resolução Normativa No. 45, de 22 de Outubro de 2019, Diário Oficial da União [D.O.U.] de 10.25.2019 (Braz.); Resolução Normativa No. 56, de 5 de Outubro de 2022, Diário Oficial da União [D.O.U.] de 10.07.2022 (Braz.).

107 Resolução Normativa CONCEA No. 54, de 1 de Outubro de 2022, Diário Oficial da União [D.O.U.] de 1.17.2022 (Braz.).

108 Resolução Normativa No. 25, de 29 de Setembro de 2015, Diário Oficial da União [D.O.U.] de 06.10.2015 (Braz.).

109 *Id.*

model."[110] Annex 1 of the Normative Resolution 52 states that it should "be clear that the potential benefits of activities involving animals in research or education outweigh the negative consequences of animal experimentation."[111] Brazil has a robust legal system that supports The Three Rs and the development of alternatives to animals in science. However, there is no law enforcement system implemented in this field and no publicly available data on animal use for such purposes, which makes it difficult to measure the impact of these laws and resolutions.

In 2000, Uruguay advanced regulations about animals used in research titled, the University of the Republic (UdelaR) Regulations: Use of Animals in Testing, Research, and Education.[112] This is the first law in Uruguay to explicitly govern the use of animals in research with a concern for animal welfare.[113] The law mandates the creation and oversight of an ethics committee.[114] No legislation requires the use of alternatives.[115]

Uruguay has established a National Commission for Animal Experimentation (CNEA), charged with overseeing registered facilities that use animals in research.[116] This Commission requires facilities to adhere to The Three Rs.[117] Although the Uruguayan regulations about animals used in research are fairly new, the commitment to The Three Rs offers promise for the development of further protection for animals used in science.

In Peru, it is against the law to cause unnecessary suffering, injury, or death to a live animal used in research or an experiment.[118] Research can only be conducted by universities and specialized centers[119] and not by other education or technical institutes.[120]

The Ministry of Agriculture must establish regulations for the welfare of animals used in research; but to date, no such regulations have been promulgated.[121] Nevertheless, facilities that use animals in research are required to have an Animal Welfare Ethics Committee that is charged with ensuring animals do not experience unnecessary suffering.[122] Further, some of these facilities adopt The Three Rs.[123]

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110 Resolução Normativa CONCEA No. 52, de 19 de Maio de 2021, Diário Oficial da União [D.O.U.] de 5.24.2021 (Braz.).

111 *Id.*

112 Rivera, *supra* note 103, at 296.

113 *Id.*

114 Law No. 18611, Chp. II, Oct. 21, 2009.

115 Rivera, *supra* note 103.

116 *Evaluation of Practices and Procedures Related to Scientific Experimentation with Animals in Uruguay*, MINISTRY OF EDUC. AND CULTURE (Aug. 3, 2023), https://www.gub.uy/ministerio-educacion-cultura/comunicacion/noticias/actividad-monitoreo-CNEA.

117 *Id*.

118 Ley de Protección y Bienestar Animal, (Ley No. 30407/2016) (Peru).

119 *Id*. at 574727.

120 *Id.* at 574728.

121 *Id.* at 574726.

122 *Peru*, ANIMAL PROT. INDEX, https://api.worldanimalprotection.org/country/peru (accessed Mar. 29, 2024).

123 *Id*.

D. NEW ZEALAND[124] AND AUSTRALIA

New Zealand and Australia support The Three Rs as ethical standards to strive toward.[125] New Zealand's Animal Welfare Act mentions The Three Rs as a recommended guideline, but this recommendation of The Three Rs is not enforced.[126] New Zealand has animal ethics committees that consider whether a research project has adequately assessed the suitability of using non-animal and alternative methods, but this is not monitored by the government.[127] New Zealand prohibits the consideration of data from animal tests that are conducted in the country for assessing the safety of psychoactive products.[128] New Zealand prohibits the use of gorillas, chimpanzees, bonobos, and orangutans (non-human hominids) unless approved by the Director-General.[129] Further, Australia prohibits the use of animals for developing, making, or testing a cosmetic with exceptions.[130] Australia only allows animals to be used when it is justified as ethically acceptable; there is a balancing of effects on animals and the potential benefits.[131] Australia prohibits the use of animals for cosmetics testing.[132]

E. ASIA: CHINA, INDIA, JAPAN,[133] SOUTH KOREA[134]

This section discusses ethical considerations for using animals in research for China, India, Japan, and South Korea.

China has two long standing laws that govern animal research.[135] First, the Regulations for the Administration of Laboratory Animals

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124 The author expresses gratitude to Tara Jackson of the New Zealand Anti-Vivisection Society (NZAVS) for contributing to this section about New Zealand by providing information about New Zealand animal research.

125 *Animals in Research, Testing, and Teaching*, MINISTRY FOR PRIMARY INDUS. https://www.mpi.govt.nz/animals/animal-welfare/animals-research-testing-teaching/ (accessed Feb. 10, 2024); AUSTRALIAN RSCH. COUNCIL, AUSTRALIAN CODE FOR THE CARE AND USE OF ANIMALS FOR SCI. PURPOSES, 11-12 (2013).

126 *See* Animal Welfare Act 1999, S 6 (N.Z.) (stating that the purpose of the law is to promote The Three Rs, but not to require them).

127 *Id*. *See also, Animals in Research, Testing, and Teaching*, *supra* note 125 (listing the member requirements for animal ethics committees, which does not include any government officials.).

128 The Psychoactive Substances Act 2013, S 1 (N.Z.).

129 Animal Welfare Act 1999, S 6 (N.Z.).

130 *Id.*

131 AUSTRALIAN RSCH. COUNCIL, *supra* note 125, at 9.

132 *Id.* at 87.

133 The author expresses gratitude to Satoko Wazaki, Head of the Secretariat of the Japan Anti-Vivisection Association for contributing to this section about Japan by providing information about Japanese animal research.

134 The author expresses gratitude to Borami Seo for contributing to this section about South Korea by providing information about South Korean animal research.

135 Bryan E Ogden, *Laboratory Animal Laws, Regulations, Guidelines and Standards in China Mainland, Japan, and Korea*, 57 ILAR J. 301, 301-302 (2017).

was passed in 1988.[136] This law requires laboratory animals to be treated according to certain welfare standards.[137]Second, the Guidelines for the Humane Treatment of Laboratory Animals[138] expands on the requirements of the Regulations for the Administration of Laboratory Animals.[139] China's Guidelines for the Ethical Review of Laboratory Animal Welfare require the ethical review board to consider The Three Rs.[140] In 2018, China began to require the ethical review of animals used in science during transport and use.[141]

These guidelines promote the use of alternatives as well, although the strongest language is limited to where the animal models under consideration are seen as engaged.[142] Although the country explicitly encourages the use of alternatives in training laboratory personnel,[143] the country's Guidelines are not as strong when encouraging general use of alternatives.[144]

China was once a nation that required animal testing on cosmetic products. However, the country gradually relaxed these requirements, and in 2019 announced a policy stating a preference for non-animal-involved toxicology tests for cosmetics effective January 1, 2020.[145] Although animal testing is permitted in China, it is no longer required.[146]

India strives toward ethical standards, but does not require the ethical review of alternatives.[147] India regulates animal research under its 1960 Prevention of Cruelty to Animals Act[148] which is implemented through its Committee for the Purpose of Control & Supervision of Experiments on Animals (CPCSEA).[149] Further, India prohibits the test-

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136 *Id*. at 302.

137 *Id*.; see also *China*, Animal Prot. Index, https://api.worldanimalprotection.org/country/china (accessed Mar. 29, 2024).

138 *Id.*

139 *China*, Animal Prot. Index, https://api.worldanimalprotection.org/country/china (accessed Mar. 29, 2024).

140 Judy A. MacArthur Clark, *Guidelines for the Ethical Review of Laboratory Animal Welfare People's Republic of China National Standard GB / T 35892-2018, 5.2*, Wiley, Feb. 6, 2018, https://www.ufaw.org.uk/downloads/guidelines-for-the-ethical-review-of-laboratory-animal-welfare-gbt-358922018.pdf (accessed Mar. 29, 2024).

141 *Id*. at 110.

142 *Id*. at 109.

143 *Id*. at 107.

144 *Id*. at 109-110.

145 *China's Acceptance of Certain Non-Animal Testing Methods for the Regulation of Cosmetics*, Inst. for In Vitro Sci. (Apr. 3, 2019), https://iivs.org/2019/04/03/china-accepts-new-alternative-methods-for-cosmetics/.

146 *Id*.

147 Guidivada Mani, et al., *A Review on Ethical Issues of Animal Experimentation in India*, Tejasvi Astitva (August 7, 2020), https://www.tejasviastitva.com/10547-2/ (accessed Feb. 24, 2020) (recommending that India uses alternative methods to animal testing when available, indicating the use of alternatives is not mandatory.).

148 Prevention of Cruelty to Animals Act, 1960, §§14-17.

149 Ministry of Environment, Forest and Climate Change Government of India, Compendium of CPCSEA (Issued in 2018).

ing of animals for cosmetics, as well as the import of products that were tested on animals.[150]

Japan's self-governing system does not require the ethical review of alternatives.[151] An Institutional Animal Care and Use Committee (IACUC) is not legally required.[152] However, most companies and schools have IACUCs that can support The Three Rs.[153] Also, Japan's Act on Welfare and Management of Animals mandates self-regulation and has an article that describes The Three Rs.[154] The Act is philosophical, however, and there is no penalty for violating it.[155] The Japanese Association for Laboratory Animal Science is supposed to conduct surveys every three years to determine the number of animals that are used for scientific purposes.[156] Japan has made strides toward the ethical review of alternatives, even if the system is self-governing.

South Korea does not require an ethical review of alternatives, but it does require that alternatives be considered.[157] The primary law in South Korea that addresses this topic is the Animal Protection Act.[158] This Act considers, among other things, what animals can be used in science. For example, the Act provides that no one can conduct a test on a lost, abandoned, or service animal.[159] Like other nations, South Korea has IACUCs.[160] South Korea also provides that the testing of animals must consider human welfare and the dignity of animal life; however, alternative methods must be considered before a test on an animal is conducted.[161]

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150 *India: No Import of Cosmetics Tested on Animals*, LIBR. OF CONG., https://www.loc.gov/item/global-legal-monitor/2014-10-17/india-no-import-of-cosmetics-tested-on-animals/ (accessed Feb. 10, 2024).

151 Ogden, *supra* note 135, at 305.

152 NAOKO KAGIYAMA & TATSUJI NOMURA, NAT'L RSCH. COUNCIL INST. FOR LAB'Y ANIMAL RSCH., THE DEVELOPMENT OF SCIENCE-BASED GUIDELINES FOR LAB'Y ANIMAL CARE: PROCEEDINGS OF THE NOVEMBER 2003 INTERNATIONAL WORKSHOP, JAPANESE REGULATIONS ON ANIMAL EXPERIMENTS: CURRENT STATUS AND PERSPECTIVES (National Academies Press ed., 2004).

153 *Id.*

154 Shōwa yon jū hachi nen hōritsu dai hyaku gogō [Act on Animal Welfare and Management], Act No. 105 of 1973, art. 41, para. 1-2, *translated in* (Japanese Law Translation [JLT DS]), https://www.japaneselawtranslation.go.jp/en/laws/view/3798/en#je_ch5at2 (Japan) (accessed Feb. 7, 2024).

155 *See id.* art. 41-50 (delineating penal provisions of the Act on Animal Welfare and Management that do not list any penalties for violation of Article 1).

156 KAGIYAMA & NOMURA, *supra* note 152; (at the time of this Article's publication in 2024, it had been more than ten years since the Japanese Society of Laboratory Animal Science last conducted such a survey).

157 Dongmulbohobeob, [Animal Protection Act] art. 47 (S. Kor.) *translated in* Korean Legislative Research Institute's online database, https://elaw.klri.re.kr/eng_service/main.do (search required) (accessed Feb. 24, 2024).

158 *Id*.

159 *Id.* art. 49.

160 *Id.* art. 51.

161 *Id.* art. 47.

F. AFRICA AND MIDDLE EAST: ZIMBABWE,[162] SOUTH AFRICA,[163] PAKISTAN[164]

This section discusses whether Zimbabwe, South Africa, and Pakistan require ethical considerations for using animals in science.

Zimbabwe regulates animal-involved research primarily through the county's Scientific Experiments on Animals Act.[165] This law works in connection with the Animal Health (National Animal Research Ethics Committee) Regulations of 2021 and the Animal Health Act[166] by prohibiting animal research done by people who are unlicensed.[167]

The National Animal Research Ethics Committee is mandated to regulate animal-involved research.[168] The Committee must conduct inspections to monitor compliance of research.[169] The Committee also reviews applications for research proposals and issues ethics certificates where appropriate.[170] No licensee in Zimbabwe can perform any experiment on any animal that is likely to cause pain to attain a manual skill.[171] Also, the animals should be provided an anesthetic to prevent pain.[172] The mitigation of pain in animals for scientific research and higher education is important.[173] Although The Three Rs are not explicitly included in the law,[174] research facilities may include The Three Rs into the research.[175]

South Africa does not have a law that explicitly requires ethical review of alternatives to animals.[176] The country recognizes The Three Rs and has added "Responsibility" as a fourth "R."[177] When a review of

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[162] The author expresses gratitude to Yvonne Gurira, Esq. for contributing to this section about Zimbabwe by providing information about Zimbabwean animal research.

[163] The author expresses gratitude to the Animal Ethics Unit of the National Council of SPCAs for contributing to this section about South Africa by providing information about South African animal research.

[164] The author expresses gratitude to Hira Jaleel, LL.B, LLM for contributing to this section about Pakistan by providing information about Pakistani animal research.

[165] Scientific Experiments on Animals Act, c. 19:12 (1963) (Zim.).

[166] Animal Health Act, c. 19:01 (1961) (Zim.); Animal Health (National Research Ethics Committee) Regulations, SI 246 (2021) (Zim.).

[167] Scientific Experiments on Animals Act, c. 19:12, § 3(2) (1963) (Zim.).

[168] Animal Health (National Animal Research Ethics Committee) Regulations, *supra* note 166, at § 4.

[169] *Id.*

[170] *Id.*

[171] Scientific Experiments on Animals Act, c. 19:12, § 5(1) (1963) (Zim.).

[172] *Id.* at §5(2).

[173] *Id*.

[174] *See id.* (the statute makes no mention of The Three Rs).

[175] Email from Yvonne Gurira, Esq. (Oct. 2023, 03:42 PST) (on file with ALR).

[176] *South Africa*, WORLD ANIMAL PROT., https://api.worldanimalprotection.org/country/south-africa (accessed Feb.13, 2024) (stating that South Africa has no laws recognizing animal sentience or preventing animal cruelty).

[177] *Animals in Research*, NATIONAL COUNCIL OF SPCAs, https://nspca.co.za/animals-in-research/ (accessed Feb.13, 2024).

a research application is conducted, The Three Rs analysis is conducted to make decisions about the welfare of animals used in research.[178]

Ethics committees that govern the use of animals in scientific settings exist.[179] Also, a National Health Research Ethics Council provides direction about ethical issues about health.[180] The National Health Research Ethics Council develops guidelines pertaining to the conduct of research that involving humans and animals.[181] Animal welfare inspections occur in all laboratory animal facilities.[182]

Although technically in South Asia, the country of Pakistan is also a part of the Middle East region.[183] Pakistan does not explicitly regulate the ethics of animal-involved research, but there is an anti-cruelty law[184]—and other criminal laws—which may include cruelty of animals used in research.[185]

While there is no country-wide law in Pakistan that governs the use or welfare of laboratory animals, the capital of Pakistan—Islamabad—criminalized animal testing on live animals in "veterinary schools and industrial complexes."[186] This prohibition was spurred by the rise of viral videos allegedly showing extreme animal cruelty by veterinary students.[187] Although additional welfare laws have been discussed for laboratory animals, such laws have yet to be enacted.[188]

IV. MOVING FORWARD: THE ROLE OF LAW

There are many ways that people can work to try to transform law, policy, and science. One can work to achieve ethical systems that rely

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178 *Id.*

179 *Id.*

180 *National Health Research Ethics Council*, DEP'T OF HEALTH REPUBLIC OF SOUTH AFRICA, https://www.health.gov.za/nhrec-home/ (accessed Feb.13, 2024).

181 *Id.*

182 Animals in Research, *supra* note 177.

183 *About Pakistan,* CONSULATE GENERAL OF PAKISTAN, https://pakconsulatela.org/about-pakistan/ (accessed Feb.13, 2024); Greta Scharnweber, *What and Where is the Middle East*, MIDDLE EAST POL'Y COUNCIL, https://csme.indiana.edu/documents/cirricula/MEPolicyCouncil_What-WhereMiddleEast.pdf. (accessed Feb.13, 2024).

184 The Prevention of Cruelty to Animals Act, No. XI of 1890 PAK. CODE (online), *amended by* the Prevention of Cruelty to Animals (Amendment) Act, No. XVI of 2018 PAK. CODE (online).

185 *See* Act XLV of 1860, PAK. PENAL CODE (providing that negligent conduct that harms an animal is punishable and not providing any exception for scientific research).

186 Charlotte Pointing, *Pakistan Announces 'Landmark' Animal Testing Reforms In Islamabad Capital Territory,* Plant Based News (July 6, 2022), https://plantbasednews.org/culture/law/pakistan-landmark-animal-testing-reforms/ (accessed Mar. 29, 2024). *See also Sana Jamal*, *Pakistan Announces Animal Welfare Reforms, Bans Animal Testing*, GULF NEWS (July 1, 2022), https://gulfnews.com/world/asia/pakistan/pakistan-announces-animal-welfare-reforms-bans-animal-testing-1.88983060 (accessed Mar. 29, 2024).

187 *Id*.

188 *Id.*

on alternatives-involved research. Bar associations, organizations, and firms should try to do this too.

An advocate can determine whether there are bar associations, veterinary associations, law schools, policy groups, animal-forward organizations, and others that lead or support steps toward change. Bar associations may have a process to adopt resolutions that governments can use. For example, in February 2024, the American Bar Association House of Delegates approved a resolution about animal testing.[189] Crafted by the Animal Law Committee of the American Bar Association Tort Trial & Insurance Practice Section, the resolution "urges national governments, the U.S. Congress, and U.S. federal agencies to promote the development and use of methods that aim to replace, reduce, and refine the use of animal models in research and testing; and [. . .] to remove barriers to, and create incentives for, the use of non-animal model research and testing methods in regulatory testing and federally sponsored research."[190]

An advocate can identify the laws and policies within a particular location and determine whether ethical review of animal-involved research is required, permitted, preferred, or limited. In other words, what are the laws or policies that regulate the use of animals in research? Also, an advocate can learn how a locale establishes its priorities and goals, which may be instructive. For example, in 2021, Queen Elizabeth announced that "[l]egislation will also be brought forward to ensure the United Kingdom has, and promotes, the highest standards of animal welfare."[191] This example of a nation's priorities at a particular point in time can lay the groundwork for momentum.

Advocates should lawfully work to encourage scientists to adopt—either by policy or otherwise—The Three Rs, especially the "Replacement" goal. Further, advocates should encourage researchers to want to conduct research with alternative technologies. This encouragement can be driven by economic incentives and cultural attitudes. Thus, advocates can work to advance initiatives that support the use and investment of technologies that enable researchers to do their work without the use of animals. It is important that governments and organizations provide financial investments of alternatives, so advocates should work to attain funding for alternatives. An advocate can explain the estimated or known costs of caring for animals and the health-related urgency that scientific progress requires. After all, much of the research conducted may be for the purpose of advancing human and animal health; technologies that provide efficiency, consistency,

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189 Anna Stolley Persky, *Incentivize Alternatives to Animal Research, ABA House Says*, AM. BAR ASS'N J. https://www.abajournal.com/web/article/resolution-502 (accessed Feb. 26, 2024).

190 *Resolution 502 Rev*, AM. BAR ASS'N, https://www.americanbar.org/content/dam/aba/administrative/news/2024/mym-hod-resolutions/502.pdf (accessed Feb. 26, 2024).

191 Queen's Speech 2021, GOV'T. DIGIT. SER. (May 11, 2021), https://www.gov.uk/government/speeches/queens-speech-2021 (accessed Feb. 13, 2024).

speed, and accuracy—look at the rapid interest and development of Artificial Intelligence technologies for example—may be better options than animal-involved methods. Advocates must explain that alternative technologies provide less variability and greater accuracy than the use of animal models. Animals provide too much variability.

Cultural viewpoints must shift too. These cultural shifts must occur within the scientific community and the public at-large. One way to influence cultural shifts at the scientific level is to support the creation of jobs that work toward finding solutions toward alternatives. Scientists and researchers work to solve problems and address curiosities. The use of animals is an issue that must be solved. Another way to inspire a cultural shift is to incorporate humane education lessons. Universities must provide training and education about alternatives in alignment with The Three Rs.

Depending on the jurisdiction, advocates can conduct public records requests to find information. This information can be helpful when advocating for particular policies or changes. Unfortunately, given that recordkeeping requirements pertaining to necessary information may be limited, the data needed might be received and reviewed on a smaller scale. For example, if a nation does not require sufficient recordkeeping of animals used in research, then an advocate can request information from known laboratories directly; some entities may provide the needed information, while many others may not.

Civil litigation or regulatory efforts may provide another path forward. Also, advocates may find it helpful to work directly with research institutions by writing letters and peacefully working to determine if any change—even a small change—might be incorporated. Advocates may wish to join IACUCs and advocate that IACUCs and their related institutions should be scientifically free to advocate for the ethical use of alternatives.

Advocates should work to bolster state laws to create changes for animals used in research. People working at a state legislative level should determine whether it is feasible to include morality in its reasons why the change should occur. One should identify whether the locality can enact laws that would encourage the use of alternatives to animals in research.

An additional way to change law and science is to work at an international level to develop a global treaty to move toward Global One Health which includes supporting, advocating for, and investing in alternatives for animals.[192] Advocates from each nation should

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[192] One Health, WORLD HEALTH ORG., (Oct. 2023) https://www.who.int/news-room/fact-sheets/detail/one-health (accessed Feb. 13, 2024); L. Syd M. Johnson et al., *How One Health Instrumentalizes Nonhuman Animals,* 26 AMA JOURNAL OF ETHICS 184, 186 (Feb. 2024), https://journalofethics.ama-assn.org/sites/joedb/files/2024-01/vwpt1-peer-2402_0.pdf (accessed Feb. 25, 2024) (describing how One Health's ideology involves considering animal and human interests holistically, and that animals have the right to evade abuse).

arrive together to discuss the issues, ultimately determining whether inclusive Global One Health efforts–that include the interests of animals such as an animal-forward treaty or similar agreement–could be adopted. Delegates from each nation can offer what they believe to be the most animal-forward ideas or practices. As such, alternative-focused research and goals toward achieving The Three Rs can be realized with ideas from people representing many nations.

Attorneys and bar associations have an important role in advancing alternatives and ethics for animals, too. While all jurisdictions are unique, it may be possible that one's attorney-member bar association can work to advance resolutions which may inspire change. If applicable, an advocate can show that the use of alternatives in science can positively impact people and animals, and that this topic is related to legal practice.

There are many uncovered pathways forward to alchemize the bar for animals. These pathways and this Article envision many changes that will soon advance law and science.

V. CONCLUSION

Animals have been used to find cures, test the safety and efficacy of products and chemicals, and educate scholars. While one can allege that the use of animals in research, testing, and education has contributed to advances in science—thus arguing in support of its continued practice—it is also possible that the use of animals has hindered—or now hinders—forward progression of science and humane treatment of animals. Countries should incorporate initiatives that support The Three Rs to replace, reduce, and refine animals in research. The Three Rs—especially "Replacement"—encourage nations to adopt laws and policies that require the ethical review of alternatives to animals. The time is now to do what is right for people and animals.