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LEGAL CONSIDERATION IN REGULATING ANIMAL USE IN BIOTECH AND PHARMACEUTICAL INDUSTRIES

ABSTRACT

The use of animals in pharmaceutical and biotechnology research has been the focus of regulatory scrutiny and ethical discussion. Given modern breakthroughs, it is imperative to guarantee the ethical treatment of animals while also promoting scientific research. The legal frameworks controlling the use of animals in various sectors are examined in this article, with particular attention paid to important rules and regulations, moral dilemmas, and new emerging trends.

HISTORICAL BACKGROUND

The use of animals in laboratories and the pharmaceutical industry has a complex history, evolving over centuries in response to scientific advancements, societal attitudes, and ethical considerations.

Ancient and Medieval Periods: the use of animals for medicinal purposes dates back to ancient civilizations. Ancient Egyptians, Greeks, and Romans used animals in various forms of medical experimentation and study. For instance, Hippocrates and Galen conducted dissections and observations on animals to understand anatomy and physiology. In many cultures, animals were used not only for medical experiments but also for ritualistic purposes. Observations of animal behavior and health were crucial for understanding diseases and their treatments.

Renaissance to 19th Century: A major shift occurred during the Renaissance, when empirical observation became more important. As anatomical studies proliferated, researchers like Andreas Vesalius started dissecting animals in great detail.

The emergence of experimental biology the scientific method was popular during the 18th and 19th centuries. The possibility of using animals in immunology was demonstrated by the use of animals (namely cows) by researchers such as Edward Jenner in the creation of the smallpox

vaccine. More methodical ways to drug testing were introduced with the development of modern pharmacology in the 19th century. The use of animal models to study how chemicals affect living things started to spread. Animal experiments were used, for instance, in Claude Bernard's research on the function of the pancreas in order to comprehend physiological processes. The progress in medicine and pharmacology was sped up by the two World Wars. Animal models were essential in the development of vaccines and treatments for different diseases. Study with animals has aided in our grasp of antibiotics, anesthesia, and different surgical methods.

Evolution of legislation:

The 19th century saw the start of the animal welfare movement with the introduction of laws to stop animal cruelty. The Cruelty to Animals Act of 1876 in the UK was revolutionary as it mandated licenses for animal experiments and set standards for treating animals humanely. This measure was a reaction to public worry over how animals are treated in scientific experiments. As scientific advancements continued, knowledge about the moral considerations of animal experimentation also increased. Yet, there was still a lack of regulatory frameworks, and the legislative action was limited during the 1920s and 1930s. The main emphasis was on preventing cruelty, rather than implementing detailed regulations for animal research. Establishing formal regulations was a priority during the mid-20th century.

The legislation known as the Animal Welfare Act was passed in 1966.The **Animal Welfare Act (AWA)** was put into effect in the United States in 1966, representing a notable progression in laws regarding animal welfare. The AWA implemented thorough guidelines for the care of animals used in research, which included. Registration and Licensing Requirements for Care and there handling procedures, the **AWA** has been amended multiple times to widen its reach and enhance protections for animal welfare. In 1985, an amendment mandated the creation of **Institutional Animal Care and Use (IACUCs)** to supervise and assess animal research procedures.
Along with the AWA, the Public Health Service Policy on Humane Care and Use of Laboratory Animals was put in place to provide direction to organizations that receive government funding. This policy highlighted the significance of ethical factors in animal research and strengthened the role of IACUCs.

1. International and Regional Legal Frameworks

Throughout the years, the oversight of animal utilization in biotechnology and the pharmaceutical industry has gradually developed, shaped by scientific advancements, regulatory alignment, and ethical considerations. At the global level, initiatives like the International Council for Harmonisation (ICH) have encouraged the standardization of safety and efficacy testing frameworks, including common standards for animal research among significant jurisdictions. In Europe, the Council of Europe’s Convention (ETS 123, 1986) established a basis for uniform standards, outlining species protection, minimization of pain, and researcher qualifications—subsequently incorporated into the EU Directive. This directive enforces the “3Rs”—Replacement, Reduction, and Refinement—and prohibits cosmetic testing in the EU since 2009. Collectively, these frameworks establish a cohesive legal foundation for animal

welfare in research throughout Europe.

In the UK, the Animals (Scientific Procedures) Act 1986 (ASPA) implements EU standards through a comprehensive licensing framework—mandating personal, project, and establishment permits prior to any regulated procedure—and compulsory harm-benefit analyses for all applications. Official reports have characterized ASPA as one of the most stringent systems worldwide, necessitating a clear evaluation of animal harm for every license submission.
This reform does not prohibit animal testing completely, but it offers legal recognition for non-animal methods, a significant change supported by NIH, FDA, and industry participants.

Based on existing laws, regulators are now promoting NAMs in actual practice. In April 2025, the FDA revealed a new initiative to gradually discontinue conventional animal testing for specific categories (e.g., monoclonal antibodies), incorporating AI-driven toxicity models and human cell-derived approaches in a plan intended to make animal testing "the exception" in the next three to five years. At the same time, the European Union's REACH regulation incorporates 3Rs principles and bans on cosmetic testing, endorsing approved in vitro alternatives. Together, these changes represent a worldwide shift: Europe, North America, and nations such as India and South Korea are increasingly validating and endorsing non-animal testing in regulatory frameworks.

A strong legal framework supports these scientific changes. Licensing frameworks (e.g., UK's ASPA, US IACUC oversight, India's CPCSEA structures) guarantee that ethical review committees and inspectors oversee research practices

2. Ethical Principles, the 3Rs (and 4th R)

The legal foundation of animal-testing regulations are the ethical guidelines referred to as the 3Rs—Replacement, Reduction, and Refinement—initially articulated by Russell and Burch in 1959, and now integrated into laws worldwide. Replacement mandates that researchers utilize accepted non-animal methods whenever feasible, such as cell cultures, organoids, and micro physiological "organ-on-chip. **Refinement** involves modifying procedures to alleviate or minimize pain, suffering, and distress—implemented through humane anaesthetic use, non-invasive techniques, and enriched housing—again mandated by Directive 2010/63/EU and echoed in U.S. GLP and IACUC standards In India, animal welfare takes a further step via a legally recognized **"4th R"—Rehabilitation**, enforced by the CPCSEA under the Prevention of Cruelty to Animals framework. After experimental use, animals must receive post-procedure care and support aimed at social and pain recovery, and possibly be re-homed . This additional requirement underscores the evolving ethical standards in emerging biotechnology hubs.

Crucially, these ethical imperatives are not mere guidelines but legally mandated obligations. **Directive 2010/63/EU**, particularly Article 4, requires all EU Member States to systematically apply the 3Rs in every authorized scientific procedure and to facilitate ongoing research into alternative methods

ip" systems, and computational in silico models. The European Medicines Agency and the EMA-supported Directive 2010/63/EU require these alternatives in every facet of medicinal testing, aiming ultimately for full replacement. Similarly, Asia, North America, and global organizations are progressively embracing validated New Approach Methodologies (NAMs) in accordance with FDA Modernization 2.0 and ICH guidelines. Reduction necessitates the

minimization of animal use while still obtaining statistically valid outcomes; this concept is applicable in various jurisdictions worldwide, such as the EU's REACH chemical regulations and U.S. IACUC guidelines, which mandate clear justifications for sample sizes. Refinement entails adjusting methods to lessen or reduce pain, suffering, and distress—executed through the humane application of anesthetics, non-invasive methods, and improved housing—once again required by and reflected in U.S. GLP and IACUC guidelines. In India, animal welfare progresses further with a legally acknowledged "4th R"—Rehabilitation, upheld by the CPCSEA under the Prevention of Cruelty to Animals framework. Following experimental procedures, animals require post-treatment care and assistance focused on social and pain recovery, and may eventually need to be re-homed. In parallel, U.S. **IACUC protocols**, under PHS policy, legally demand project-specific alternatives searches, justification of animal numbers, and detailed pain mitigation strategies. NIH and USDA oversight ensure compliance through protocol review and facility inspections. In India, **CPCSEA and ICMR guidelines** require institutional animal ethics committees to ensure all four R's are systematically incorporated into pre-clinical study designs. These integrated legal-ethical frameworks have transformed animal-use protocols—from mere procedural checklists into deeply embedded ethical commitments—ensuring scientific rigor is balanced with moral responsibility.

3. Alternatives to Animal Testing & Regulatory Shift

The model of preclinical research is rapidly transitioning from conventional animal testing to New Approach Methodologies (NAMs)—including human-relevant organoids, organ-on-chip systems, 3D bioprinted tissues, advanced in vitro cell assays, computational toxicology, and AI-driven models—providing more ethical, predictive, and cost-efficient alternatives to animal studies. The pivotal change occurred with the FDA Modernization Act 2.0, enacted in December 2022, which eliminated the obligatory requirement for animal data before human clinical trials and explicitly broadened regulatory acceptance to cover cell-based assays, micro physiological systems, bio printed tissues, and in silico models. This legislative update, the first significant alteration since the 1938 FD&C Act, now permits pharmaceutical developers to incorporate solid non-animal evidence—such as "clinical trials in a dish" utilizing human induced pluripotent stem cells (iPSCs), organoids, or organ-on-chip systems—directly in IND and NDA submissions. These innovative technologies not only mimic human organ structure and function (e.g., liver, brain, tumor microenvironments) with enhanced physiological relevance but also capture genetic variability, various cell types, and dynamic responses that animal models often overlook. **Canada's draft strategy** mandates the use of NAMs in chemical risk assessments, while India's 2023 drug rule revisions now formally permit organoids, organ-on-chip systems, and computational models in safety evaluations. South Korea, through KoCVAM, likewise validates and advocates for NAMs across biomedical sectors. Such harmonization across North America, Europe, and Asia reflects a global consensus: animal testing should no longer be the default when human-relevant alternatives exist.

Despite progress, challenges persist. NAMs often require rigorous **validation** to meet regulatory robustness standards, especially in complex biology such as oncology or neurological toxicity.Even with advancements, difficulties remain. NAMs frequently demand thorough validation to fulfill regulatory robustness criteria, particularly in intricate biological areas like oncology or neurological toxicity. Scalability, standardization, technical intricacies, and significant infrastructure investments continue to hinder widespread implementation. Moreover, guaranteeing that AI models effectively forecast infrequent toxicities requires comprehensive

datasets and clear interpretability. However, early NAM applications—like in vitro liver-on-chip models and initial organoid-based cancer platforms—have produced convincing safety signals and, importantly, Sanofi's organ-on-chip-based IND for sutimlimab signifies a landmark where the FDA authorized a clinical trial based entirely on NAM findings. Essentially, industry, regulators, and academia are aligning efforts to establish NAMs not as secondary options, but as primary tools in drug development. The FDA's 2025 roadmap and EMA's support framework indicate that animal testing is quickly becoming a last option, used solely when non-animal methods are scientifically insufficient

CONCLUSION

In summary, the legal framework regulating animal use in biotechnology and pharmaceutical sectors is experiencing a significant change, propelled by scientific progress, changes in societal standards, and evolving regulatory requirements. At both international and regional dimensions, significant instruments—like the Council of Europe's European Convention ETS 123 (1986) and the EU's Directive 2010/63/EU enacted in 2013—have created unified, high-quality frameworks that align policies among member states. These instruments embed essential ethical principles—the 3Rs of Replacement, Reduction, and Refinement—into legally enforceable commitments, ndia's innovative inclusion of Rehabilitation highlights a rising global trend focusing on not only regulated experimentation but also the welfare of animals after procedures. These principles are not mere rhetorical tools—they hold legal significance. For example, Article 4 of Directive 2010/63/EU mandates that EU Member States consistently adopt the 3Rs and enhance method validation, whereas U.S. IACUCs and CPCSEA's IAECs necessitate comprehensive justifications for animal usage, alternatives evaluated, and strategies to minimize pain. In 2025, the FDA also initiated a roadmap and pilot program allowing monoclonal antibody developers to submit INDs solely predicated on NAM-based, human-relevant data—offering expedited approvals and lowered R&D expenses. Simultaneous initiatives by the EMA consist of qualification processes and innovation engagement programs that promote voluntary NAM submissions, standardizing data evaluation among EU member states. Countries such as Canada, India, and South Korea are adjusting their regulatory frameworks—Canada mandates NAM integration in chemical safety evaluations, India's updated drug regulations officially recognize organoid and computational testing, and South Korea implements NAM policy through KoCVAM. However, extensive NAM implementation still encounters issues with validation, standardization, and infrastructure—highlighting the need for regulatory changes to align with scientific rigor and capacity development.

Ultimately, strong oversight, adherence to regulations, and transparent processes guarantee that these legal and ethical goals are fulfilled in reality. Licensing frameworks in the UK, U.S., EU, and India require thorough evaluations prior to any experiment, involving trained staff, facility certifications, and organized inspections to guarantee responsibility. GLP compliance ensures methodological integrity, whereas voluntary but impactful accreditation organizations such as AAALAC strengthen best practices among institutions. Transparency initiatives—spanning from EU reports on animal usage every three years to organizations such as the Basel Declaration promoting public discourse—illustrate an increasing alignment between scientific research and societal responsibility.

establishing a worldwide benchmark for reconciling scientific advancement with animal welfare. Similarly, important national legal frameworks like the UK's ASPA (1986, revised 2013) maintain some of the most rigorous licensing standards globally, mandating comprehensive harm–benefit evaluations and strict supervision. In the U.S., the combined regulatory framework of the Animal Welfare Act and PHS Policy—supported by IACUC review processes and GLP standards—likewise integrates ethical evaluation into protocol authorization and facility oversight. In developing countries like India, laws including the Prevention of Cruelty to Animals Act (1960), along with CPCSEA and ICMR guidelines, have progressed legal requirements by acknowledging a "fourth R" of Rehabilitation, requiring researchers to ensure post-experiment care and social reintegration for animals Collectively,

These cohesive advancements—from enforceable global agreements to domestic regulations, from a principled 3R/4R basis to a NAM-driven regulatory transformation, and from stringent monitoring to societal responsibility—represent a future where animal testing is not automatically assumed necessary, but rather a scientifically validated final option.