December 15, 2017

Eli Lilly and Company

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VIA E-MAIL: shareholderproposals@sec.gov

Office of Chief Counsel
Division of Corporation Finance
Securities and Exchange Commission
100 F Street, NE
Washington, D.C. 20549

Re: Shareholder Proposal of People for the Ethical Treatment of Animals

Ladies and Gentlemen:

This letter and the enclosed materials are submitted by Eli Lilly and Company (the "Company") to notify the Securities and Exchange Commission (the "Commission") that the Company intends to omit from its proxy statement and form of proxy for its 2018 Annual Meeting of Stockholders (the "2018 Proxy Materials") a shareholder proposal and supporting statement (the "Proposal") submitted by People for the Ethical Treatment of Animals (the "Proponent"). We also request confirmation that the staff of the Division of Corporation Finance (the "Staff") will not recommend enforcement action to the Commission if the Company omits the Proposal from the 2018 Proxy Materials for the reasons discussed below.

In accordance with Section C of Staff Legal Bulletin No. 14D (Nov. 7, 2008), we are emailing this letter to the Staff at shareholderproposals@sec.gov. In accordance with Rule 14a-8(j) of the Securities Exchange Act of 1934, as amended, we are simultaneously sending a copy of this letter and its attachments to the Proponent as notice of the Company's intent to omit the proposal from the 2018 Proxy Materials. Likewise, we take this opportunity to inform the Proponent that if the Proponent elects to submit any correspondence to the Commission or the Staff with respect to the Proposal, a copy of that correspondence should be provided concurrently to the undersigned on behalf of the Company.

THE PROPOSAL

The Proposal (attached hereto as Exhibit A) provides in pertinent part:

RESOLVED, in light of disturbing mistreatment of animals at external research organizations with which our Company has conducted business, the Board should strengthen our Company's policy and practices regarding contract animal laboratories and issue a report to shareholders.

BASIS FOR EXCLUSION

The Company hereby respectfully requests that the Staff concur in its view that the Company may exclude the Proposal from the 2018 Proxy Materials pursuant to Rule 14a-8(i)(10), which provides that a shareholder proposal may be omitted from a company's proxy materials if "the company has already substantially implemented the proposal." As described in greater detail below, the information requested by the Proponent to be included in a report to shareholders has already been publicly disclosed by the Company in the Company's "Animal Care and Use" policy (the "Animal Care Policy"), which can be found on the Company's website. A printed copy of the Animal Care Policy is attached hereto as Exhibit B.

ANALYSIS

The Proposal May Be Excluded Under Rule 14a-8(i)(10) Because the Company Has Substantially Implemented the Proposal.

A. Rule 14a-8(i)(10) Background.

Rule 14a-8(i)(10) allows a company to exclude a shareholder proposal from its proxy statement if the company has substantially implemented the proposal. The purpose of Rule 14a-8(i)(10) is "to avoid the possibility of shareholders having to consider matters which have already been favorably acted upon by management." SEC Release No. 34-12598 (Jul. 7, 1976). Importantly, Rule 14a-8(i)(10) does not require a company to implement every detail of a proposal in order for the proposal to be excluded. The Staff has maintained this interpretation of Rule 14a-8(i)(10) since 1983, when the Commission reversed its prior position of permitting exclusion of a proposal only where a company's implementation efforts had "fully" effectuated the proposal. SEC Release No. 34-20091 (Aug. 16, 1983).

Based on this revised approach, the Staff has consistently taken the position that a proposal has been "substantially implemented" and may be excluded as moot when a company can demonstrate that it has already taken actions to address the essential elements of the proposal. *See, e.g., Exelon Corp.* (Feb. 26, 2010) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting a report disclosing policies and procedures for political contributions based on Exelon's publicly-disclosed political spending report); *NetApp, Inc.* (Jun. 10, 2015) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting elimination of supermajority voting provisions based on the fact that the company had previously eliminated all supermajority voting requirements from the company's by-laws). Applying this standard, the Staff has stated that "a determination that the company has substantially implemented the proposal depends upon whether [the company's] particular policies, practices and procedures compare favorably with the guidelines of the proposal." *Texaco, Inc.* (Mar. 28, 1991) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting that the Company subscribe to the Valdez Principles

where the company had already adopted policies, practices and procedures with respect to the environment that compared favorably to the Valdez Principles).

The Staff has provided no-action relief under Rule 14a-8(i)(10) when a company has satisfied the "essential objective" of a proposal, even if the company did not take the exact action requested by the proponent, did not implement the proposal in every detail, or exercised discretion in determining how to implement the proposal. *See, e.g., FedEx Corporation* (Jun. 15, 2011) (proposal requesting amendments to FedEx's corporate governance guidelines to adopt and disclose a written and detailed succession planning policy, substantially implemented by the "Succession Planning and Management Development" section of FedEx's publicly disclosed Corporate Governance Guidelines); *Citigroup Inc.* (Jan. 19, 2010) (proposal requesting the board of directors adopt a by-law amendment requiring the company to have an independent director serve as lead director substantially implemented by the fact that the company had an independent director serving as board chairman and a by-law in place requiring a lead director if the board chairman was not an independent director); *ConAgra Foods, Inc.* (Jul. 3, 2006) (proposal requesting publication of a sustainability report substantially implemented by the fact that the company had posted online a report on the topic of sustainability); *Talbots, Inc.* (Apr. 5, 2002) (proposal requesting that the company implement a corporate code of conduct based on the International Labor Organization ("ILO") human rights standard substantially implemented where the company had already implemented a code of conduct addressing similar topics but not based on ILO standards); *Nordstrom, Inc.* (Feb. 8, 1995) (proposal requesting a code of conduct for its overseas suppliers substantially implemented by existing company guidelines).

Applying these principles, the Staff has consistently concurred with the exclusion of shareholder proposals that request a report to shareholders containing information the company has already publicly disclosed. *See, e.g., Wal-Mart Stores, Inc.* (Feb. 21, 2017) (exclusion of a proposal requesting that the company establish "time-bound, quantitative goals" for reducing food waste in the United States and issue a report on its plans to achieve these goals where the company noted that it had already established a goal to achieve zero waste to landfills in key markets, including the United States, by a certain date, and that the company detailed its plans to achieve this goal in a report available on its website); *The Boeing Company* (Feb. 3, 2016) (concurring that a proposal requesting a semiannual report disclosing specific information about the company's charitable contributions was substantially implemented where such information was already available on the company's website and in various sets of guidelines that had already been adopted); *Duke Energy Corporation* (Feb. 21, 2012) (permitting exclusion of a shareholder proposal which requested that a committee of independent directors of the company review the actions the company was or could be taking to build shareholder value and reduce greenhouse gas and other emissions and to report to shareholders on how the company planned to achieve these goals where the company noted that it provided extensive information regarding its efforts to reduce emissions in its public filings with the Commission, as well as in a sustainability report which was available on the company's

website); *The Coca-Cola Company* (Jan. 25, 2012) (concurring that a proposal requesting a report on the company's responses to public policy challenges associated with the use of Bisphenol-A, or BPA, was substantially implemented where the company provided disclosure on this subject across its website).

The Staff has taken this position with respect to shareholder proposals that, like the instant proposal, sought the publication of a report concerning the humane treatment of animals. *See generally Pfizer Inc.* (Jan. 11, 2013) (proposal requesting a report on measures to reduce the use of animal testing and plans to promote alternatives to animal use was excludable where existing company laboratory animal care guidelines and policy were available on the company's website).

Pfizer is noteworthy because it involved a proposal that requested "a report to shareholders detailing all measures implemented to reduce the use of animals, especially in painful procedures, and plans to promote alternatives to animal use." Pfizer argued that it already produced a report that contained such information, rendering the proposal moot under Rule 14a-8(i)(10), noting that:

- the company made a set of company guidelines and policies on laboratory animal care publicly available on its website;
- these guidelines and policies detailed the measures the company had implemented to reduce the use of animals and to promote alternatives, and also described the company's commitment to certain principles of animal research;
- the company had a governance board that sponsored an awards program to recognize individuals and teams committed to certain principles of animal research;
- the company and its contract laboratories were subject to the Animal Welfare Act of 1966 (the "AWA"), which, among other things, required the annual filing of information with the United States Department of Agriculture (the "USDA") regarding the usage of animals;
- the company voluntarily attained and maintained accreditation from the Association for the Assessment and Accreditation of Laboratory Animal Care (the "AAALAC"), demonstrating that the company did more than meet the minimum standards required by the AWA;
- the company trained all employees involved in the use of animals to ensure that they were competent, aware of the ethical issues involved in the treatment of animals and that demonstrated respect toward and humane treatment of animals; and
- the company regularly monitored and updated its guidelines and policies to ensure compliance with applicable laws and alignment with company and shareholder values.

In permitting exclusion of the shareholder proposal from the company's proxy materials, the Staff noted that the company's "public disclosures compare favorably with the guidelines of the proposal and that Pfizer has, therefore, substantially implemented the proposal."

Likewise, in *Merck & Co., Inc.* (Mar. 14, 2012), the Staff allowed the exclusion of a similar shareholder proposal, again submitted by the Proponent, requesting that the company publish an annual report regarding the proper treatment of animals, on the basis that the company's disclosures "compare[d] favorably with the guidelines of the proposal" and that the company had, therefore, substantially implemented the proposal. In its request for relief, the company noted a number of measures implemented by the company similar to those outlined in *Pfizer*, including extensive disclosures regarding its treatment of animals on its website, adherence to similar animal research principles and compliance with the AWA, and voluntary accreditation from the AAALAC.

B. The Company Has Substantially Implemented the Proposal

Similar to *Pfizer* and *Merck*, the Company has substantially implemented the Proposal. The essential objective of the Proposal is to "strengthen our Company's policy and practices regarding contract animal laboratories and issue a report to shareholders." The Company is continually strengthening its policies and practices regarding contract animal laboratories and these efforts are outlined in the Company's Animal Care Policy (publicly available at https://www.lilly.com/animal-care-and-use).

The Animal Care Policy is Publicly Available on the Company's Website and Details the Measures the Company has Implemented Related to the Use of Animals

The publicly available Animal Care Policy details measures that the Company has already implemented surrounding the Company's use of animals, especially in painful procedures, and by describing the policies that it has developed and will continue to strengthen around the Company's use of animals. The Animal Care Policy sets forth the Company's recognition of its moral and ethical responsibility for the welfare of animals used in research. Accordingly, the Company, similar to the companies in *Pfizer* and *Merck*, has adopted certain principles, the "3Rs," with respect to animal care and use. The Animal Care Policy provides that the 3Rs must be applied before beginning any study involving animal testing, and are as follows:

- Replacement of animals with alternative non-animal methods including the application of in vitro (test tube) systems or in silico (computer based) systems as well as the use of a species lower in the phylogenetic scale, such as using the nematode instead of sheep.
- Reduction in the number of animals used by the application of good experimental design and the proper statistical methods.

- Refinement of experimental technique to eliminate or minimize pain or distress and to enhancements in animal husbandry to improve overall well-being in their colony environment (e.g. environmental enrichment).

At the core of these three principles is the continuous strengthening of the Company's policies and practices with respect to use of contract animal laboratories. Each of these principles espouses an aspirational goal that the Company is continually working toward.

In implementing the 3Rs, the Company has publicly committed to various initiatives on a voluntary basis to ensure proper animal care and improve living conditions of animals used in testing. Furthermore, as part of Lilly's commitment to the 3Rs, the Company instituted a "3Rs Global Steering Community," which is charged with ensuring implementation of the 3Rs and providing "3Rs Awareness Training" to all Company employees who are involved with animal research. The Company, through the 3R Global Steering Committee, highly encourages the sharing of 3R information across all research sites.

The Company's disclosures make clear that any animal research conducted by the Company or by contract research organizations ("CROs") should be performed only after consideration of the 3Rs. Once the 3Rs have been implemented, the principles outlined in the Animal Care Policy require the humane treatment of animals used in research. Specifically, the Animal Care Policy disclosed that the Company will adhere to the following principles:

- Living conditions for research animals must be appropriate for their species and contribute to their health and well-being.
- Personnel who care for animals or who conduct animal studies must be appropriately qualified for the proper care and use of animals in research.
- Studies involving animals must be designed and conducted in accordance with applicable country and local regulatory guidance and the following widely recognized principles of animal care and use:
    - with due consideration of the study relevance to human or animal health and the advancement of scientific knowledge,
    - selecting only animals appropriate for that study,
    - using the minimum number of animals required to obtain valid results,
    - using alternative methods instead of live animals where appropriate, and
    - avoiding or minimizing discomfort and distress to the animals.

The Company has supplemented these principles with further policies geared specifically toward in vivo research, and veterinary guidelines covering a variety of procedures and animal handling. Specifically, the Company has 26 policies and 23

veterinary guidelines for internal use, with CROs expected to have the same or similar policies as needed.

The Company and its CROs Comply with Applicable Laws, Regulations and Codes of Conduct Regarding the Use of Animals

Similar to the animal care and use policies described in *Pfizer* and *Merck,* the Animal Care Policy also reinforces the Company's requirement that its research and development staff, its CROs and the organizations which supply animals to the Company comply with all applicable country and local laws, regulations, standards and code of conduct regarding the care and use of animals. Importantly, the Animal Care Policy provides that the Company require[s] contractors to adhere to the principles outlined in the Animal Care Policy "even if these principles are more stringent than applicable local laws." The primary example of the regulatory framework that the Company is subject to with respect to the use of animals is the AWA, which specifies minimum welfare standards for animals used by research facilities and other entities. Under the AWA, the Company and its CROs must file annual reports with the USDA regarding the use of animals in testing and outlining, *inter alia,* the specific housing, handling, sanitation and veterinary care procedures. Additionally, the Animal Care Policy notes that the Company is subject to unannounced external review and site inspections by the USDA and by local and national authorities in Europe.

The Company has Maintained AAALAC Accreditation and Provides for the Use of Oversight Committees

As with the companies in *Pfizer* and *Merck,* for over 35 years the Company has voluntary maintained accreditation from AAALAC, which provides independent review and confirmation of appropriate animal care and use. The Company actively encourages its CROs to also obtain and maintain such accreditation. Also, through oversight committees at every research site, the Company conducts semiannual reviews and other self-inspections of its research programs and facilities, and regularly audits its CROs and reassesses the appropriateness of their treatment of animals. As provided in the Animal Care Policy, such oversight committees "approve and oversee animal research activities and care programs and ensure that people using animals are appropriately qualified." Notably, the Animal Care Policy states that its veterinarians and scientists who serve on these oversight committees "evaluate every procedure in an effort to eliminate or minimize pain or distress."

The Company Regularly Updates the Animal Care Policy and Monitors Compliance with Applicable Laws and Regulations

Finally, in a continual effort to strengthen its policies regarding the use of animals, similar to the companies in *Pfizer* and *Merck,* the Company regularly monitors and evaluates its Animal Care Policy and the Company's compliance with applicable laws and regulations, such as the AWA, to ensure that all animal research conducted by either its

employees or by third party CROs on the Company's behalf is in line with Company and shareholder values.

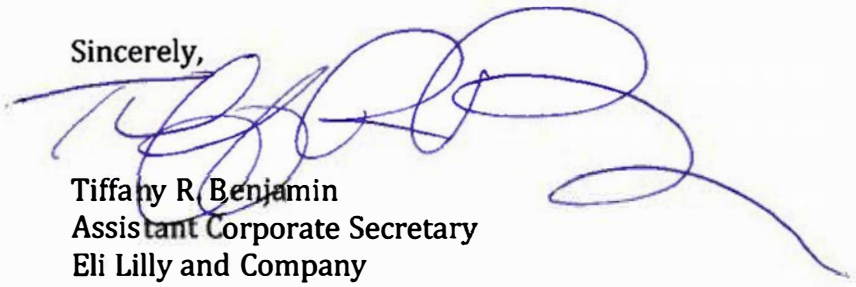
As evidenced by the above, the Company has taken, and will continue to take, great measures to ensure that it and its CROs (i) reduce the use of animals in testing and promote alternatives to the use of animals in research, (ii) minimize the potential for pain and distress to those animals used in research, and (iii) demonstrate a strong commitment to the welfare of animals utilized in Company research and testing. In addition, the Company has already published a report on these efforts as well as other aspects of the Company's policies and procedures regarding the humane treatment of animals. Accordingly, similar to *Pfizer* and *Merck*, the Company believes that it has satisfied the essential objective of the Proposal and that its public disclosures outlined in the Animal Care Policy compare favorably to the guidelines of the Proposal. As a result, the Company has substantially implemented the Proposal and believes the Proposal is excludable under Rule 14a-8(i)(10).

CONCLUSION

Based on the foregoing facts and analysis, we respectfully request that the Staff concur that the Company may exclude the Proposal from the 2018 Proxy Materials. Should the Staff disagree with the conclusions set forth in this letter, or should you require any additional information in support of our position, we would welcome the opportunity to discuss these matters with you as you prepare your response.

We would be happy to provide you with any additional information and answer any questions that you may have regarding this subject. Correspondence regarding this letter should be sent to Keir Gumbs at kgumbs@cov.com. If we can be of any further assistance in this matter, please do not hesitate to call me at (317) 433-2588 or Keir at (202) 662-5500.

Sincerely,



Tiffany R. Benjamin
Assistant Corporate Secretary
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285
U.S.A.

Enclosures

cc: People for the Ethical Treatment of Animals

Exhibit A
Proposal

AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

PETA

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

Washington, D.C.
1536 16th St. N.W.
Washington, DC 20036
202-483-PETA

Los Angeles
2154 W. Sunset Blvd.
Los Angeles, CA 90026
323-644-PETA

Norfolk
501 Front St.
Norfolk, VA 23510
757-622-PETA

Oakland
554 Grand Ave.
Oakland, CA 94610
510-763-PETA

Info@peta.org
PETA.org

November 14, 2017

Bronwen L. Mantlo
Corporate Secretary
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Via UPS Next Day Air Saver

Dear Ms. Mantlo:

Attached to this letter is a shareholder proposal submitted for inclusion in the proxy statement for the 2018 annual meeting. Also enclosed is a letter from People for the Ethical Treatment of Animals' (PETA) brokerage firm, RBC Wealth Management, confirming ownership of 56 shares of Eli Lilly and Company common stock, which were acquired at least one year ago. PETA has held at least $2,000 worth of common stock continuously for more than one year and intends to hold at least this amount through and including the date of the 2018 shareholders meeting.

Please communicate with PETA's authorized representative Jared S. Goodman if you need any further information. Mr. Goodman can be reached at Jared S. Goodman, PETA Foundation, 2154 W. Sunset Blvd., Los Angeles, CA 90026, by telephone at (323) 210-2266, or by e-mail at JaredG@PetaF.org. If Eli Lilly and Company will attempt to exclude any portion of this proposal under Rule 14a-8, please advise Mr. Goodman within 14 days of your receipt of this proposal.

Sincerely,

Sara Britt, Corporate Liaison
PETA Corporate Affairs

Enclosures: 2018 Shareholder Resolution
RBC Wealth Management letter

Affiliates
- PETA India
- PETA Australia
- PETA Germany
- PETA Asia-Pacific
- PETA Netherlands
- PETA Foundation (U.K.)

Establish Accountability for Animal Welfare

RESOLVED, in light of disturbing mistreatment of animals at external research organizations with which our Company has conducted business, the Board should strengthen our Company's policy and practices regarding contract animal laboratories and issue a report to shareholders.

Supporting Statement

In spite of its "commitment to the ethical treatment of animals." which extends to external laboratories, our Company has repeatedly conducted business with contract laboratories where substandard animal care practices have been documented by government agencies.

Our Company's animal care policy states that "animals used in research shall be treated humanely, with pain or distress eliminated or minimized." Additionally, our Company requires all contract research organizations "to adhere to [its animal welfare] policies and principles." Yet our Company has paid for services conducted at and purchased animals from at least three contract laboratories—Liberty Research, Inc. (Liberty), Professional Laboratory and Research Services (PLRS), and Covance—with serious violations of federal animal welfare laws.

A 2017 exposé of Liberty conducted by People for the Ethical Treatment of Animals (PETA) documented, including on video, living and dying conditions for dogs and cats marked by pain and misery. Workers failed to provide adequate anesthesia to dogs whose skulls were opened during invasive surgery and failed to administer humane euthanasia. Liberty used animals in multiple tests despite the long-term effects of experimental compounds and possible interactions with other medications. Cats were forced to live in severely crowded, barren, windowless pens where recently, some suffocated under litter pans; and dogs suffered severe injuries after being confined with incompatible cagemates.

Our company also contracts with Covance, which was cited and fined by the U.S. Department of Agriculture (USDA) in 2016 when negligence resulted in thirteen monkeys dying of hyperthermia.[1] According to recent federal inspections, beagles and monkeys at Covance were denied adequate veterinary care for numerous ailments: monkeys sustained limb fractures and beagles were not adequately treated for inflamed and painful skin. A rabbit was euthanized after she was found with a bell stuck in her mouth. Another rabbit was euthanized after she sustained a spinal injury.

Apparent carelessness in choosing outside laboratories is a long-standing issue for our Company. A 2010 PETA video exposé of PLRS documented repeated violations of federal laws. Workers yelled profanities at cowering, frightened dogs and cats. Employees kicked, threw, dropped, and dragged dogs, and violently threw cats into cages. Animals at PLRS were forced to live in their own feces and urine and suffered constantly from burns and sores—but received no veterinary care for their wounds. Following the release of the video, and inspection by the USDA, this laboratory was forced to close.

[1] http://www.mediapeta.com/peta/PDF/Covance_Research_Products.Stip.July2016.pdf

Shareholders cannot monitor what goes on inside animal testing laboratories, but our Company can and must review federal records and conduct frequent and extensive visits to contract laboratories. The Board must ensure that animal welfare measures are an integral part of our Company's corporate stewardship.

We urge shareholders to vote in favor of this socially and ethically important proposal.

Exhibit B
Animal Care Policy

Animal Care and Use

Since our founding in 1876, Lilly has worked tirelessly to discover medicines that make life better. We've been pioneers behind major breakthroughs against some of the world's most devastating diseases, and therefore understand that developing new medicines demands determination and long-term investment—often requiring years of laboratory research, followed by years of clinical trials.

Prior to the clinical trial phase, a critical part of the laboratory research process is what is known as "in vivo" studies conducted in animals. In these studies, potential new medicines are tested in animals to evaluate how the medicine functions in a living organism. In biomedical research, animals have contributed to lifesaving treatments in the areas of cancer, diabetes, vaccines, high blood pressure, and neurological

disorders, just to name a few. In food and fiber or agricultural research, animals have helped provide solutions in areas such as veterinary medicine, parasite control, analgesia, and ensuring safe and affordable food supplies globally.

Research advances in human and animal medicines have made life better for countless numbers of people as well as those of companion and agricultural animals worldwide. However, at Eli Lilly and Company and Elanco Animal Health, we also recognize that we have a moral and ethical responsibility for the welfare of animals used in research, which is why we have strong policies and principles in place to ensure that all animal research conducted either by our employees or by third parties on our behalf is in line with our values.

Our Commitment to Responsible Animal Research

At Lilly, we know we have both an ethical and a scientific responsibility toward animals used in research. That's why we have adopted "3 Rs" when it comes to our principles of animal care and use. The 3Rs are applied prior to the start of any study involving animal testing:

- Replacement is defined as the replacement of animals with alternative non-animal methods including the application of in vitro (test tube) systems or in silico (computer based) systems as well as the use of a species lower in the phylogenetic scale, such as using the nematode instead of sheep.
- Reduction is defined as the reduction in the number of animals used by the application of good experimental design and the proper statistical methods.
- Refinement is defined as the modification of experimental technique to eliminate or minimize pain or distress and to enhancements in animal husbandry to improve overall well-being in their colony environment (e.g. environmental enrichment).

Our 3Rs Global Steering Committee is charged with ensuring implementation of the 3Rs around the world and is providing 3Rs Awareness Training to all Lilly employees who are associated with animal research. A 3Rs Award is given on a yearly basis to those individuals or teams who best demonstrate incorporation of one or more of the 3Rs principles into ongoing research. Sharing of 3Rs information across all sites is highly encouraged.

Our Policy and Principles for the Ethical Treatment of Animals

We recognize we have ethical and scientific obligations to ensure the appropriate and humane treatment of animals used in research, and we have systems in place to fulfill this obligation. Lilly and Elanco have developed a global policy on Animal Care and Use that defines our standards and principles by which we conduct in vivo research. This policy mandates the humane care and use of all animals used in research. Any animal research conducted at Lilly should be performed only after consideration of the 3Rs as described above. Once the 3Rs have been implemented, Lilly's Animal Care and Use Principles state that animals used in research shall be treated humanely, with pain or distress eliminated or minimized.

Specifically, our Principles state:

- Living conditions for research animals must be appropriate for their species and contribute to their health and well-being.

- Personnel who care for animals or who conduct animal studies must be appropriately qualified for the proper care and use of animals in research.
- Studies involving animals must be designed and conducted in accordance with applicable country and local regulatory guidance and the following widely recognized principles of animal care and use:
  - with due consideration of the study relevance to human or animal health and the advancement of scientific knowledge,
  - selecting only animals appropriate for that study,
  - using the minimum number of animals required to obtain valid results,
  - using alternative methods instead of live animals where appropriate, and
  - avoiding or minimizing discomfort and distress to the animals.

Implementing these principles has resulted in increased awareness of the importance of quality animal care and use globally. The global policy and principles have been supplemented by further specific policies specific to in vivo research and veterinary guidelines covering animal handling and a variety of animal procedures.

Lilly Animal Care and Use Ethical Committees

We maintain animal sites only in the United States and Europe. All sites have oversight committees that approve and oversee animal research activities and care programs and ensure that people using animals are appropriately qualified. Committee members undergo intense and continuing training and all committees have volunteer members who are not affiliated with our company to represent the public. Veterinarians and scientists evaluate every procedure in an effort to eliminate or minimize pain or distress. Committees normally meet monthly to review animal use protocols and to conduct program or facility reviews as appropriate. These Committees also regularly recognize scientists who have demonstrated creative or improved novel methods for working with animals or who have demonstrated exceptional dedication in their work with animals.

Our Compliance with Global Animal Research Regulations and Standards

Consistent with our commitment to the responsible and ethical treatment of animals, we maintain the highest standards of animal care and we strive to demonstrate best practices in animal research globally. Lilly requires its R&D staff to comply with all applicable country and local laws, regulations, codes of conduct and standards regarding the care and use of animals. We require the same of all individuals and organizations that supply animals to be used in Lilly research, and with which Lilly contracts for animal research services. Moreover, we require application of the Lilly Animal Care and Use Principles by Lilly researchers and contractors, even if these principles are more stringent than applicable local laws.

Our policy and standards regarding the use of animals are based upon the Animal Welfare Act, the Guide for the Care and Use of Laboratory Animals, and the Guide for the Care and Use of Agricultural Animals in Research and Teaching in the United States. In the United Kingdom, we adhere to the European Directive 63/2010 guidance document.

Inspections and Accreditation

Lilly has been accredited for over 35 years by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC), which provides independent review and confirmation of appropriate animal care and use.

All animal facilities are subject to external review and inspection. In the United States, our facilities are subject to unannounced site inspections by the United States Department of Agriculture (USDA). In Lilly Europe, local and national authorities under authority of the Home Office regularly inspect animal facilities.

In addition to regulatory inspections, we self-inspect our animal research programs and facilities regularly, including semiannual program reviews and facility reviews. In situations where we have recently acquired another company, we work closely with that group to ensure that animal welfare standards align with our policy and principles. We also maintain a global oversight program of all animal research and supply companies with which we do business—including visits by trained specialists to conduct welfare evaluations—and encourage these companies to obtain and maintain accreditation from the AAALAC.

Fulfilling Our Commitment to the Ethical Treatment of Animals

Training

All Lilly employees handling or working with animals in research must be appropriately trained and qualified in the care, use and welfare of animals to ensure that they are competent, that they are aware of humane and ethical issues, and that they demonstrate respect for all research animals. In the US, training consists of modules including regulations, general husbandry and handling of various species, as well as individual training on a wide variety of procedures including anesthesia and surgery. New trainees are mentored and monitored for competency. In the United Kingdom, all employees must complete the national training modules and demonstrate competency as well. Continuing education is provided.

Animal Care

Caretakers ensure animals are socially housed unless otherwise justified. Environmental enrichment for all species is required and monitored by animal care staff.

Contract Research Organizations

Like most pharmaceutical and agricultural animal organizations, the company outsources some research including various in vivo studies to contract research organizations (CROs). All CROs are required to adhere to our policies and principles. A thorough assessment and monitoring program ensures adherence to our policies and principles. Audits of CROs are conducted, and CROs are reassessed on a regular basis. These audits include all animal suppliers, feed vendors, and collaborations as well as those supplying research services. Moreover, we require contractors to adhere to the Lilly Animal Care and Use Principles, even if these principles are more stringent than applicable local laws. Lilly also encourages animal research and animal supply companies globally to obtain and maintain accreditation from the AAALAC. Through active engagement, we are helping to raise the standards of animal care and use.

Engagement

The company participates and collaborates with a variety of national and international organizations whose mission is to promote quality research animal care and/or the development and use of the 3Rs including alternatives or replacement. Nationally, we participate in the Innovation and Quality (IQ) Consortium of PhRMA which has a strong 3Rs working group. We also participate in or collaborate with AALAS, ACLAM, ASLAP, PRIM&R, CAAT and AAALAC. Internationally we have associations and supporting roles with EFPIA, FELASA, and NC3Rs among others. These interactions help keep our company current on alternatives and methods to implement the 3Rs.

Animal Numbers

Lilly is committed to minimize the number of animals used in research studies. The majority of animals used in research are rodents; these are usually the most appropriate species because there are many strains of genetically engineered rodents that have been developed as specific models of disease. Our use of less sentient species such as the zebra fish embryo is also increasing. Other species are used when the disease target is more appropriately expressed in that particular species or, in the case of Elanco Animal Health, when developing therapies for food and companion animal species. Non rodent models are also required by regulatory agencies for safety assessment. As a percentage of research and development (R & D) expenses, the number of animals used has decreased significantly in the past 25 to 30 years. As new technology and methods merge that allow the use of less sentient species, we reduce our reliance upon the use of live animals and expect those numbers to continue to decline.

Nonhuman Primates

Lilly acknowledges the specific concern by the public over the use of nonhuman primates in research. Our current policies dictate that careful consideration is given before any nonhuman primate species is used in research. Special consideration is given to nonhuman primate housing and their social/behavioral requirements. No species of primate that is classified as endangered may be used and the source of animals should be colony-bred and not wild-caught. Nonhuman primates must be obtained from reputable suppliers in compliance with all local, federal, and international regulations.

Animals in Marketing

Our commitment to respect for animals also applies to animals used in advertising by Lilly and Elanco. All animals used must be healthy and handled by qualified people or owners. Animals must be in a natural or appropriate setting.

Abbreviations and References

- AAALAC: Association for the Assessment and Accreditation of Laboratory Animal Care
- AALAS: American Association of Laboratory Animal Science
- ACLAM: American College of Laboratory Animal Medicine. www.aclam.org Ag Guide: 2010. Federation of Animal Science Societies (FASS), 2010. Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, third ed. FASS, Savoy. Champaign, IL
- ASLAP: American Society of Laboratory Animal Practitioners.
- AWA: 1990. Animal Welfare Act. PL (Public Law) 89-544
- CAAT: Center for Alternatives in Animal Testing
- EFPIA: European Federation of Pharmaceutical Industries and Associates
- FELASA: Federation of European Laboratory Animal Science Associations
- ILAR Guide: 2011. National Research Council, 2011. Guide for the Care and Use of Laboratory Animals, eighth ed. National Academy Press, Washington, D.C.
- NC3Rs: National Center for 3Rs.
- PRIM&R: Public Responsibility in Medicine and Research.
- The 3Rs: 1959. Russell, W.M.S. & Burch, R.L. (1959). The Principles of Humane Experimental Technique. xiv + 238pp. London, UK: Methuen

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