

The USDA's Failure to Enforce the AWA

By Gabriella Miller

Introduction

Humans rely on animals for everything from companionship to testing whether life-saving drugs and innovative technology are safe for human use. Despite this, animals are often treated poorly in return—especially in laboratories. The Animal Welfare Act (AWA) has been instrumental in providing protections to certain categories of animals who are used in laboratory settings, mandating that these animals be given humane treatment and that their suffering is minimised.¹ While the AWA seeks to minimise the harm caused to animals, the United States Department of Agriculture (USDA) does not do enough to enforce the rules that it has set. There has been a recent decline in the USDA's already insufficient enforcement against research facilities that has troubling implications for the future of animals used for experimentation.²

Animal testing, which is controlled by the USDA, is not regulated enough. The definition of "animal" under the AWA does not cover every species that is used for animal testing, leaving many animals to suffer despite the AWA's facial intent to minimise their pain and suffering.³ Animals like birds, rats, and mice are some examples of animals that are not protected by the AWA. Animals that are covered are subjected to extremely minimal protections when it comes to experimentation.⁴ This is problematic because there is a gap where researchers can exploit the use of specific animals. Experiments like those conducted

by Neuralink expose the shortcomings of the USDA, as the USDA did not enforce restrictions upon Neuralink when they rushed and repetitive experiments caused pain and suffering to many animals, killed more animals than necessary, and showed a general lack of attentiveness when planning and carrying out their experiments.⁵

The USDA should increase its enforcement of the AWA to ensure the humane treatment of animals in research settings. Further, it should fill in the gaps where the AWA allows for insufficient enforcement and protections. Part II of this paper examines how the USDA neglects to enforce the AWA as it pertains to animal testing. Part III discusses specific instances of these failings. Part IV outlines the shortcomings of the AWA, both facially and in its enforcement. Part V uses the Neuralink experiments to showcase the problems with AWA enforcement in an ongoing experiment. Part VI discusses how the USDA can improve its enforcement of the AWA.

The USDA Neglects to Enforce the AWA in Animal Testing

The AWA protects animals used in research facilities.⁶ It enforces humane treatment of animals by ensuring that animals are not unnecessarily subjected to multiple major experiments and that animals are provided with a high standard of care.⁷ Section 2143 discusses the promotion of "psychological well-being of primates" and experiments ensuring that "animal pain and distress are minimized."⁸ Research facilities should be regularly in-

1 7 U.S.C.A. § 2131, 2143, 2144 (2023).

2 Cathy Liss, 'Why Won't USDA Enforce the Animal Welfare Act?' (The Hill, 21 September 2019), <<https://thehill.com/opinion/energy-environment/462348-why-wont-usda-enforce-the-animal-welfare-act/>> accessed 14 August 2024.

3 7 U.S.C.A. § 2132(g) (2023).

4 *Ibid.*

5 See Rachael Levy & Marisa Taylor, 'Insight: At Musk's Brain-Chip Startup, Animal-Testing Panel Is Rife with Potential Conflicts' (Reuters, 9 May 2023), <<https://www.reuters.com/technology/musks-brain-chip-startup-animal-testing-panel-is-rife-with-potential-conflicts-2023-05-04/>> accessed 14 August 2024.

6 7 U.S.C.A. §§ 2131, 2143, 2144 (2023).

7 *Ibid.*

8 7 U.S.C.A. § 2143(2)(B)–(3)(A) (2023).

spected so that the Secretary of Agriculture can enforce the AWA, ensuring that research facilities do not cause unnecessary pain or suffering to animals and that animals receive humane treatment.⁹

The USDA enforces the AWA through unannounced inspections.¹⁰ If the inspector is unsatisfied with the conditions of the facility, that facility is given time to fix the problems before a later, follow-up inspection.¹¹ Some violators are permitted to pay a penalty instead of going through “formal administrative proceedings,” and more serious and continued violations can lead to “license suspensions, revocations,” and more.¹² The USDA purports to distinguish high-priority cases based on the severity of animal suffering, the facility’s past compliance, public or animal safety or health concerns, and more.¹³

Overview of AWA Standards for Protecting Laboratory Animals

The Secretary has leeway when it comes to enforcement of the AWA. Section 2143 states that “[t]he Secretary shall promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors.”¹⁴ Further, § 2416 states that the Secretary shall “inspect each research facility at least once each year and . . . shall conduct such follow-up inspections as may be necessary.”¹⁵ This Act was created to provide animals with reasonable protections. It is the USDA’s responsibility to enforce these standards and to ensure that the animals covered by the AWA are provided with humane treatment.

The USDA promulgates regulatory standards set by the AWA. The AWA requires the minimisation of “discomfort, distress, and pain to the animals” during research procedures and that researchers “consider alternatives” to these

procedures.¹⁶ Additionally, the USDA stipulates that, in compliance with the AWA, animals’ living conditions should be appropriate for their species.¹⁷ All research staff should be qualified and properly trained.¹⁸ All research facilities are required to provide adequate veterinary care and to maintain sufficient institutional animal care and use committee (IACUC) records.¹⁹ These provisions are often violated by the USDA failing to enforce these animal welfare provisions.

Lack of USDA Enforcement

The AWA gives the Secretary authority to inspect research facilities and to address any deficiencies in the facilities’ care of their animals and necessity of their experiments.²⁰ However, the USDA does not effectively enforce the AWA. Recently, the USDA has made “courtesy” and “compliance” visits to facilities rather than completing full inspections, and “[i]nspectors are reportedly discouraged from citing non-compliances, and licensees and registrants are given ample opportunity to challenge any noncompliant items that are documented during inspections and make them disappear.”²¹ In 2016, the USDA issued almost 5000 citations out of 8869 reports, and in 2018, that number dropped to 1800 citations out of a similar number of reports.²² This shows that the USDA is neglecting to enforce the AWA, impacting the welfare of the animals who are supposed to benefit from the AWA’s provisions. “More often than not, rather than handing out fines, the USDA doesn’t issue any,” even when there is “extreme cruelty or neglect.”²³

9 7 U.S.C.A. § 2146 (2023).

10 ‘Animal Welfare Act Enforcement’ (U.S. Department of Agriculture, 13 August 2024), <https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/ct_awa_enforcements> accessed 14 August 2024.

11 Ibid.

12 Ibid.

13 Ibid.

14 7 U.S.C.A. § 2143(a)(1).

15 7 U.S.C.A. § 2146(a) (2023).

16 U.S. Department of Agriculture, Animal Welfare Act and Animal Welfare Regulations (2023) (citing 9 C.F.R. § 2.31 (2023)).

17 Ibid [68].

18 Ibid [71] (citing 9 C.F.R. § 2.32 (2023)).

19 Ibid [72, 74] (citing 9 C.F.R. § 2.33, 2.35 (2023)).

20 Ibid.

21 ‘Administration Persists with Deconstruction of Animal Welfare Act’ (Animal Welfare Institute, 2019) <<https://awionline.org/awi-quarterly/summer-2019/administration-persists-deconstruction-animal-welfare-act>> accessed 14 August 2024.

22 Liss (n 2).

23 Rachel Fobar, ‘Toothless and ‘Paltry’: Critics Slam USDA’s Fines for Animal Welfare Protection’ (National Geographic, 12 December 2022) <<https://www.nationalgeographic.com/animals/article/toothless-and-paltry-critics-slam-usda-fines-for-animal-welfare-violations>> accessed 14 August 2024.

The USDA's established pattern of administering low fines gives laboratories—which are often wealthy due to grants and other funding²⁴—little incentive to follow AWA guidelines. Even when the USDA does attempt to enforce the AWA, it does not do enough to deter facilities from continued violations. The USDA can fine laboratories that fail to meet AWA standards.²⁵ However, these fines are often so low that they are not viewed as punitive but merely as “a cost of doing business.”²⁶ For example, Colorado State University's poor care of the bats they used in research resulted in a \$5,800 fine—less than 2% of the \$306,504 fine that they could have been required to pay based on their numerous AWA violations.²⁷ This is such a common practice that researchers acknowledge that “[t]he USDA ‘coddles research’” and that fines leveled against large research facilities are the same as those brought against smaller animal operations, thus rendering “penalties for larger facilities ‘negligible.’”²⁸ This is particularly egregious because the AWA specifically provides that the size of the business can be considered when determining the penalty amount.²⁹

There are many examples of the AWA failing to impose sufficient fines, which, in general, are ineffective in dissuading further violations.³⁰ Biomedical Research Institute had three AWA violations due to the deaths of two macaques.³¹ Despite the blatant neglect of these animals, who were found dead with almost no body fat and high levels of dehydration, the facility was only fined \$6,200 out of a maximum of \$293,733. A Labcorp laboratory was fined \$3,375 out of a maximum of \$38,313 for failing to properly handle their animals and equipment.³² In 2014, the Office of Inspector General (OIG) condemned the AWA's penalty

discounting, stating that “IES issued penalties that were reduced by an average of 86 percent from Animal Welfare Act's (AWA) authorized maximum penalty per violation” and that “some [IACUCs] . . . are not always adequately monitoring experimental procedures on animals.”³³ These issues result in “reduced assurance that protocols are properly completed, approved, and adhered to and that animals are always receiving basic humane care and treatment.”³⁴

Discussion of Instances of USDA Failing to Enforce the AWA

The purpose of USDA inspectors visiting animal research facilities is to protect these animals by enforcing the standards of care outlined in the AWA, which includes looking at records and facilities to ensure that no AWA violations are present.³⁵ Due to recent changes to USDA standards of inspection, the agency now requires only “partial ‘focused’ inspections for labs accredited by a private organisation of veterans and scientists called AAALAC [the Association for the Assessment and Accreditation of Laboratory Care] International.”³⁶ Focused inspections have relaxed animal welfare standards, which means that in-depth inspections are not taking place and the USDA is giving its responsibilities to a third party.

Issues with USDA enforcement are not a recent development. *Animal Legal Defense Fund v. Glickman*, which was argued in 1999 and decided in 2000, brought up concerns with regulations regarding the psychological well-being requirement for primates in laboratories.³⁷ The Secretary set these standards for primates, which plaintiffs found insufficient because their vagueness left much interpre-

24 Ibid (discussing Colorado State University's \$6.7 million research grant).

25 7 U.S.C.A. § 2149(b), (d) (2023).

26 Gil H. Harden, U.S. Department of Agriculture, Animal and Plant Health Inspection Service Oversight of Research Facilities (Audit Report 33601-0001-41 3, 2014) <<https://usdaoig.oversight.gov/sites/default/files/reports/2022-09/33601-0001-41.pdf>>.

27 Fobar (n 23).

28 Ibid.

29 7 U.S.C.A. § 2149(b) (2023).

30 Delcianna J. Winders, ‘Administrative Law Enforcement, Warnings, and Transparency’ (2018) 79 Ohio St. L. J. 451, 454.

31 Fobar (n 23).

32 Ibid.

33 Office of Inspector Gen., USDA, Animal and Plant Health Inspection Service Oversight of Research Facilities 2 (Audit Report No. 33601-0001-41, 2014).

34 Ibid.

35 7 U.S.C.A. § 2140, 2146(a) (2023).

36 David Grimm, ‘USDA Now Only Partially Inspects Some Lab Animal Facilities, Internal Documents Reveal’ (ScienceInsider, 5 May 2021) <<https://www.science.org/content/article/usda-now-only-partially-inspects-some-lab-animal-facilities-internal-documents-reveal>> accessed 14 August 2024.

37 [2000] D.C. Cir., [2000] 204 F.3d 229. The court ultimately ruled that the regulations were valid despite not explicitly accounting for primates' psychological well-being.

tation to the research facilities.³⁸ Initially, the USDA proposed that nonhuman primates be placed in social housing because social deprivation would have detrimental psychological effects on primates, who are social animals.³⁹ However, the USDA's regulation ultimately did not require social housing for primates, a confusing change after their recognition that the lack of such housing would be psychologically damaging. This issue still persists because the USDA's guidelines did not adhere to the needs of different species of primates and were too vague to be beneficial for the primates it sought to protect.

Another example of the USDA's failures is the Moulton Chinchilla Ranch (MCR), where chinchillas who were being bred for research were not properly cared for and suffered terrible neglect.⁴⁰ Despite the poor treatment of these animals, in 2021, MCR was "the only USDA-licensed supplier of chinchillas for research."⁴¹ The USDA did issue a complaint against MCR, which detailed "85 animals that failed to receive veterinary care" and "an excrement-ridden, understaffed barn housing lethargic animals with weeping, open wounds; putrid abscesses; and...infected eyes swollen or crusted closed."⁴² Despite these prevalent and continuing issues, the USDA delayed sanctions against MCR, blaming the pandemic for their lack of action on behalf of

38 Ibid [232].

39 Delcianna J. Winders, 'Treating Humans Worse than Animals? Exposing a False Solitary Confinement Narrative' in Lori Gruen & Justin Marceu (eds), *Animal Law in Context: The Limits of Carceral Strategies* (Cambridge University Press 2022) (quoting Proposed Rule, 54 Fed. Reg. 10987, 10913 (Mar. 15, 1989)).

40 Nancy Blaney, 'How the USDA Fails to Enforce the Animal Welfare Act' (Independent Media Institute, 25 August 2022) <<https://independentmediainstitute.org/2022/08/25/how-the-usda-fails-to-enforce-the-animal-welfare-act/>> accessed 14 August 2024.

41 Ibid (citing Dina Fine Maron, 'The U.S.'s Only Research Chinchilla Supplier Has Been Shut Down. Here's Why That Matters' (National Geographic, 8 October 2021) <<https://www.nationalgeographic.com/animals/article/usda-has-shut-down-the-nations-only-chinchilla-research-supplier-heres-why-that-matters>> accessed 14 August 2024); Meredith Wadman, 'Sick Chinchillas Languish at Farms That Supply U.S. Researchers' (ScienceInsider, 26 May 2020), <<https://www.science.org/content/article/sick-chinchillas-languish-farms-supply-us-researchers>> accessed 14 August 2024.

42 Meredith Wadman, 'Sick Chinchillas Languish at Farms That Supply U.S. Researchers' (ScienceInsider, 26 May 2020) <<https://www.science.org/content/article/sick-chinchillas-languish-farms-supply-us-researchers>> accessed 14 August 2024.

these animals.⁴³ In 2021, MCR's director, Daniel Moulton, finally had his license revoked, but was fined only \$18,000 and was allowed to keep 700 chinchillas.⁴⁴

The USDA has shown a decline in enforcement of the AWA, as reported by the Animal Welfare Institute.⁴⁵ From 2015 to 2020, there has been a decrease in AWA inspections resulting in citations: a drop from 70% to less than 20%.⁴⁶ This shows the discrepancy between AWA enforcement in 2015 and 2020, a change that likely goes back to the "focused" inspections that do not require as in-depth inspections as before.⁴⁷ If the USDA does not enforce the humane standards set by the AWA, animals will be left to suffer unnecessarily.

The USDA has failed to protect animals used in biomedical research.

In 2020, the New England Anti-Vivisection Society (NEAVS) filed a lawsuit, *New England Anti-Vivisection Soc'y v. Goldentyer*, against the USDA because the USDA and the Animal Plant and Health Inspection Service (APHIS) did not increase the psychological wellbeing standards created by the AWA for primates used in biomedical research.⁴⁸ NEAVS alleged that they suffered "an added burden of obtaining information about the treatment of non-human primates in research facilities due to the lack of informative reports."⁴⁹ Goldentyer, the Acting Deputy Administrator for Animal Care at APHIS and Sonny Perdue, the Secretary of the USDA, "refused] to upgrade the standards for the psychological well-being of primates . . . under the Administrative Procedure Act" and did not provide NEAVS with information "regarding the conditions under which primates are being maintained in laboratories."⁵⁰ The court ruled in NEAVS's favor, indicating that new and heightened standards

43 Ibid.

44 Blaney (n 40).

45 'USDA Urgently Needs Upward Trajectory in Enforcement of Animal Protection Laws' (Animal Welfare Institute, 2021) <<https://awionline.org/awi-quarterly/spring-2021/usda-urgently-needs-upward-trajectory-enforcement-animal-protection-laws>> accessed 14 August 2024.

46 Ibid.

47 Grimm (n 36).

48 [2021] D. Md. GJH-20-2004, [2021] WL 4459217.

49 Ibid.

50 Ibid.



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apply to the care of primates in laboratories.⁵¹ The USDA would be required to document the non-compliance and make that information public.⁵² However, the USDA still must go through a rulemaking process to promulgate these standards, so further work is necessary to enforce these well-being standards for primates.

Primates are not the only animals subject to mistreatment in bioresearch facilities. Many different types of animals are subjected to pain for the sake of research and are often housed in facilities that do not provide them with sufficient space.⁵³ After being used in multiple experiments, animals that do not die as a result of these experiments are often killed so their organs can be used for further studies.⁵⁴

51 *Ibid.*

52 *Ibid.*

53 Larry Carbone, 'Pain in Laboratory Animals: The Ethical and Regulatory Imperatives' (2011) 6(9) PLoS One; John Copps, 'Issues Related to the Use of Animals in Biocontainment Research Facilities' (2005) 46(1) ILAR J. 34.

54 Committee on the Use of Laboratory Animals in Biomedical and Behavioral Research, Commission on Life Sciences, National Research Council, & Institute of Medicine, 'Use of Laboratory Animals in Biomedical and Behavioral Research' (1988) 19(7) National Academies Press.

A recent inspection at Dartmouth College found that three voles were left in a dirty cage without food and water.⁵⁵ The employee responsible was terminated, but the only other method of recourse was retraining of the other employees.⁵⁶ Another example occurred at the University of California-Riverside, where poor communication led to the deaths of eleven voles.⁵⁷ The report states that "corrective action" was taken to prevent recurrence of the issue, but does not describe what exact measures were taken.⁵⁸ These recent examples prove that the USDA continues to neglect its responsibilities to research animals. Although the USDA did enforce punishments for these violations, the lack of clarity in their public reports and the lack of substantial consequences for these violations indicate that deterrence for future infractions is unlikely and that the USDA is not doing enough to pre-

55 U.S. Department of Agriculture Animal and Plant Inspection Service, Inspection Report: Trustees of Dartmouth College (INS-0000804861, 2022).

56 *Ibid.*

57 U.S. Department of Agriculture Animal and Plant Inspection Service, Inspection Report: University of California-Riverside (INS-0000885588, 2023).

58 *Ibid.*

vent similar issues from occurring again.

The USDA does not impose sufficient punishments upon those who mistreat animals used for research. The lack of care that researchers show towards these animals emphasizes how important it is for the USDA to uphold the AWA's standards to protect these animals.

Animal Testing Is Not Regulated Enough

This part discusses the lack of regulation of animal testing. Because the AWA's definition of "animal" is insufficient, many animals are left without protection as the USDA is not required to regulate their treatment within laboratories. According to the AWA, animals are defined as "any live or dead dog, cat, monkey (nonhuman primate animal), guinea pig, hamster, rabbit, or such other warm-blooded animal...being used, or is intended for use, for research, teaching, testing, experimentation, or exhibition purposes, or as a pet."⁵⁹ This definition goes on to explicitly exclude birds, rats, mice, and farm animals and impliedly exclude cold-blooded animals like fish, frogs, octopuses, and turtles.⁶⁰

Animal testing is not regulated enough, even when AWA standards are perfectly met. Some AWA standards are overseen by a laboratory veterinarian who may exhibit a biased or easily swayed view of what is an appropriate standard of care for animals; for example, when they have financial stakes in the company.⁶¹ For housing dogs, providing primates with psychological well-being, and providing both of these species with physical enrichment, research facilities often find loopholes to meet these standards at the barest minimum possible, such as providing no variation between environmental factors meant to effect physical enrichment.⁶²

A prevalent shortcoming of the AWA is that the Secretary can only enforce regulations

⁵⁹ 7 U.S.C.A. § 2132(g) (2023).

⁶⁰ *Ibid.*

⁶¹ Pamela D. Frash, 'Gaps in US Welfare Law for Laboratory Animals: Perspectives from an Animal Law Attorney' (2016) 57 *ILAR J.* 285, 289; Rachael Levy & Marisa Taylor, 'Insight: At Musk's Brain-Chip Startup, Animal-Testing Panel Is Rife with Potential Conflicts' (Reuters, 9 May 2023), <<https://www.reuters.com/technology/musks-brain-chip-startup-animal-testing-panel-is-rife-with-potential-conflicts-2023-05-04/>> accessed 14 August 2024.

⁶² *Ibid.*

when they do not interfere with experiments, subject to limited exceptions.⁶³ The AWA provides that the Secretary cannot "promulgate rules, regulations, or orders with regard to the performance of actual research or experimentation by a research facility as determined by such research facility" or "interrupt the conduct of actual research or experimentation."⁶⁴ Although the AWA permits the Secretary to oversee research facilities, the Secretary cannot interfere in a meaningful way. Further, the vagueness of the AWA does not allow for a standardized level of care sufficient for the well-being of animals in researchers' care. Much change is necessary for the AWA to adequately protect animals in research facilities to minimize their unnecessary pain, suffering, and general unhappiness.

The USDA Only Partially Inspects Some Laboratories

As discussed in Parts III and IV, the USDA now only partially inspects animal facilities.⁶⁵ This change was only revealed after a public records request from Harvard, and the documents suggested that mainly labs that were accredited by AAALAC, a private company, were being given less stringent inspections.⁶⁶ This means that laboratory facilities are not being held to equal standards, and that some are allowed to bypass certain requirements based on accreditation that does not come directly from the USDA. It also continues a pattern of disingenuous behaviour from the USDA, furthering their tendency to hide information related to animal welfare.⁶⁷

In a recent lawsuit, *Rise for Animals. v. Vilsack*, *Rise for Animals* argued that the USDA relied on AAALAC to "evade its statutory obligation to conduct full annual inspections of research

⁶³ 7 U.S.C.A. § 2143(a)(6)(A)(i)-(iii) (2023).

⁶⁴ 7 U.S.C.A. § 2143(a)(6)(A)(ii)-(iii) (2023).

⁶⁵ Catherine Offord, 'USDA Only Carries Out Partial Inspections of Some Animal Labs' (*TheScientist*, 5 May 2021) <<https://www.the-scientist.com/news-opinion/usda-only-carries-out-partial-inspections-of-some-animal-labs-68738>> accessed 14 August 2024.

⁶⁶ *Ibid.*

⁶⁷ *Ibid.* (citing Jef Akst, 'Animal Welfare Records Return to USDA Website' (*TheScientist*, 20 February 2020), <<https://www.the-scientist.com/news-opinion/animal-welfare-records-return-to-usda-website-67139>> accessed 14 August 2024).

facilities as required under the [AWA].⁶⁸ This violates the AWA because the USDA should not delegate its responsibilities to a group that is not affiliated with the government.⁶⁹ The USDA's partial inspections damage the organization's authority over the AWA and call into question its ability to enforce this act. By giving AAALAC inspection power, the USDA does not acquire that inspection information for itself and does not make that information available to the public, thus limiting the ability of organizations like Rise for Animals to monitor the USDA's actions in the interest of the animals they oversee.⁷⁰ The USDA should perform full inspections on its own rather than giving that responsibility to others because they need to enforce strict standards backed by governmental authority.

How the Neuralink Experiment Exposes the USDA's Shortcomings

Elon Musk's Neuralink is a medical device company that is creating a brain implant to cure people who are suffering from neurological ailments.⁷¹ Musk has hastened development of this device, which has unfortunate consequences for the animals upon whom he has tested this device.⁷² These rushed experiments led to "botched experiments," such as the careless use of incorrect equipment, which killed many animals and meant that more were used to replace them.⁷³ Further, Neuralink is involved in conflicts of interest involving IACUCs.⁷⁴ Some IACUCs are closely involved with Neuralink and have financial stakes in the company—and the USDA claims not to have found any conflicts of interest.⁷⁵ This exposes the fact that the USDA does not enforce AWA standards, even when animals are blatantly being used in rushed, careless experiments.

68 Compl. for Declaratory Relief and Vacatur 1 [2022] D. Md. [2022] No. 8:22-cv-00810-TJS.

69 Ibid [2].

70 Ibid [6].

71 Rachael Levy, 'Exclusive: Musk's Neuralink Faces Federal Probe, Employee Backlash Over Animal Tests' (Reuters, 6 December 2022) <<https://www.reuters.com/technology/musks-neuralink-faces-federal-probe-employee-backlash-over-animal-tests-2022-12-05/>> accessed 14 August 2024.

72 Ibid.

73 Ibid.

74 Levy & Taylor (n 5).

75 Ibid.

This part discusses Elon Musk's Neuralink experiment and how it exemplifies the USDA's failures to enforce the AWA. The particular factors that will be discussed include conflict-of-interest issues, carelessness in experiments, and FDA concerns.

Conflict-of-Interest Issues

The conflict-of-interest issues within the Neuralink experiment impact research integrity. Originally, Neuralink partnered with the University of California, Davis (UC Davis) to "help conduct and oversee its animal tests."⁷⁶ Partnerships with universities avoid conflict-of-interest issues, as universities "prohibit people with direct financial interests from serving on IACUCs or voting on animal experiments."⁷⁷ Neuralink ended their partnership with UC Davis because the university's processes were "too slow and bureaucratic."⁷⁸ Neuralink effectively broke ties with the institution that prevented them from engaging in conflicts of interest.

At Neuralink, employees have direct financial stakes in experiment outcomes.⁷⁹ When employees have stakes in the experiments that they facilitate, it gives them an incentive to ensure that these experiments are successful no matter what. According to Neuralink staffers, "some senior-level employees stand to make millions of dollars if the company secures critical regulatory approvals."⁸⁰ Securing this approval is impossible unless animal trials are successful and lead to a viable commercial product.⁸¹ Employees with financial stake in Neuralink are incentivized to carry out hasty experiments in order to push out a viable product faster.

The USDA rarely enforces conflict-of-interest issues. In the last decade, they have only enforced eight citations out of 11,000 inspections.⁸² Those that oversee experiments must be independent, as this is "critical to protecting the integrity of animal research that could im-

76 Levy & Taylor (n 5).

77 Ibid.

78 Ibid.

79 Ibid.

80 Ibid.

81 Ibid.

82 Ibid.

pact humans in future clinical trials.”⁸³ Financial conflicts in research can severely impact the integrity of experiments, as it prompts researchers to promote financial gain over proper experiments. Many research departments at universities have strict policies regarding conflicts of interest. The American Psychological Association specifically states that violations of their conflict-of-interest policies could result in complete suspension of research activities.⁸⁴ The University of Iowa points out that “an individual’s professional actions or decisions . . . could be influenced by considerations of personal gain,” which could compromise professional judgment within the realm of research.⁸⁵ Musk has also used this financial incentive as a method to speed up animal testing by threatening to “trigger a ‘market failure’ at Neuralink unless they made more progress, a comment perceived by some employees as a threat to shut down operations.”⁸⁶

Carelessness Issues

Neuralink has killed over 1500 animals since its experiments began in 2018.⁸⁷ In contrast, Synchron, a rival of Neuralink’s that “is developing a different implant with less ambitious goals for medical advances,” comparatively killed 80 sheep throughout its research.⁸⁸ Carelessness in animal experimentation is not exclusive to Neuralink: “thousands of animals are spent on scientific experiments, [but] the majority of these studies are not published.”⁸⁹ These studies view animals as tools for scientific advancement, ignoring the fact that they “feel pain and enjoy life as humans [do].”⁹⁰ The careless use of animal lives in research

83 Ibid.

84 ‘Financial Conflict of Interest Policy’ (American Psychological Association, 2021) <<https://www.apa.org/about/financial-conflict-of-interest>> accessed 14 August 2024.

85 ‘Conflict of Interest in Research’ (University of Iowa, 2023) <<https://coi.research.uiowa.edu/about>> accessed 14 August 2024.

86 Rachel Levy, ‘Musk’s Neuralink Faces Federal Inquiry After Killing 1,500 Animals in Testing’ (The Guardian, 5 December 2022) <<https://www.theguardian.com/technology/2022/dec/05/neuralink-animal-testing-elon-musk-investigation>> accessed 5 December 2024.

87 Levy (n 71).

88 Rachel Levy, ‘Musk’s Neuralink Faces Federal Inquiry After Killing 1,500 Animals in Testing’ (The Guardian, 5 December 2022) <<https://www.theguardian.com/technology/2022/dec/05/neuralink-animal-testing-elon-musk-investigation>> accessed 5 December 2024.

89 Elif Akkaya & Harun Resit Gungor, ‘The Dark Side of the Animal Experiments’ (2022) 33 *Jt. Dis. Relat. Surg.* 479.

90 Ibid.

displays a concerning lack of empathy and understanding of the true depth and value of these animals’ lives.

Repeat Experiments Increase Animal Deaths

Musk pushing for faster experiments led to increased animal deaths.⁹¹ Former Neuralink employees have reportedly stated that they “had advocated for a more traditional testing approach, in which researchers would test one element at a time in an animal study and draw relevant conclusions before moving on to more animal tests.”⁹² Specifically, four experiments involving eighty-six pigs and two monkeys were botched due to human error resulting from rushed conditions.⁹³ These failed experiments had to be repeated, which meant sacrificing more animals to obtain the necessary results.⁹⁴ Staff members stated that “Neuralink launches tests in quick succession before fixing issues in earlier tests or drawing complete conclusions,” so mistakes are unnecessarily repeated and more animals are killed as a result.⁹⁵ Musk even encouraged employees to “imagine they had a bomb strapped to their heads in an effort to get them to move faster.”⁹⁶

Potential Animal-Welfare Violations

At Neuralink, animal welfare issues are a concern as well. Six monkeys died due to health issues that resulted when the wrong surgical glue was used on them.⁹⁷ This glue, known as BioGlue, “had never been approved for use in the experiment,”⁹⁸ which was a direct violation of the AWA. However, instead of citing the violation, USDA effectively concealed it.⁹⁹

91 Levy (n 71).

92 Ibid.

93 Ibid.

94 Ibid.

95 Ibid.

96 Rachel Levy, ‘Musk’s Neuralink Faces Federal Inquiry After Killing 1,500 Animals in Testing’ (The Guardian, 5 December 2022) <<https://www.theguardian.com/technology/2022/dec/05/neuralink-animal-testing-elon-musk-investigation>> accessed 5 December 2024.

97 Levy (n 71).

98 ‘Elon Musk Company Neuralink Given Free Pass for Animal Welfare Act Violations, USDA Reveals in Letter to Congress’ (Physicians Committee for Responsible Medicine, 19 July 2023) <<https://www.pcrm.org/news/news-releases/elon-musk-company-neuralink-given-free-pass-animal-welfare-act-violations-usda>> accessed 5 December 2024.

99 Ibid.

The monkeys subjected to the erroneous use of BioGlue experienced an intense level of suffering.¹⁰⁰ For example, a rhesus macaque called "Animal 21" reportedly "lost coordination and balance, experienced paralysis in both legs, and was suffering from depression."¹⁰¹ An autopsy revealed that BioGlue covered "a large area of [her] left cerebrum," "blood had built up on the surface of her brain," and there were ulcers in her oesophagus and blood in her stomach.¹⁰²

Twenty-five out of sixty pigs died when the wrong-sized devices were implanted into their heads.¹⁰³ Pigs were also subjected to anaesthesia for long periods of time, "risking their health and recovery."¹⁰⁴ Further, staff "accidentally implanted Neuralink's device on the wrong vertebra of two different pigs during two separate surgeries," a mistake that "could have easily been avoided by carefully counting the vertebrae before inserting the device."¹⁰⁵ Due to one of the pig's "low chance of full recovery...and current poor physical wellbeing," Neuralink's veterinarian decided to euthanise her "to end her suffering."¹⁰⁶ These are careless issues that could have been prevented, had the AWA enforced stricter guidelines as to how to handle this type of experimentation. These examples also highlight the unnecessary suffering that animals endure when they are subjected to companies like Neuralink.

Neuralink claims to utilize animal testing "only when it has exhausted other research options."¹⁰⁷ However, the company's records "contained numerous references over several years to exploratory surgeries, and three people with knowledge of the company's research strongly rejected the assertion that Neuralink avoids exploratory tests on animals."¹⁰⁸ While Musk claims to only use confirmatory testing and not exploratory testing, "documents and

company messages suggest otherwise." The head of Neuralink's animal care department also ordered employees to remove the word "exploration" from their study titles retroactively "and stop using it in the future."¹⁰⁹ Clearly, Neuralink is aware of their unlawful maltreatment of animals, but rather than rectify these issues, the company seeks to conceal them. At Neuralink, the welfare of the animals used for experimentation is not being considered and their lives are not being given appropriate value; rather, their welfare is completely pushed to the side in order to promote care-less research.

FDA Concerns

The Food and Drug Administration (FDA) which provides guidelines regarding how animal experiments should be facilitated and indicates that researchers should consider alternative methods,¹¹⁰ is in charge of approving Neuralink's applications for medical device trials.¹¹¹ Their application for human trials was initially rejected (though subsequently approved), with the FDA citing concerns about the safety of the devices, the likelihood that the implant's wires could move to other parts of the user's brain, and whether the device could be removed post-implantation without damaging brain tissue.¹¹² There is little information about the dealings between the FDA and Neuralink, as neither discussed it and the FDA refused to comment.¹¹³

While the FDA's desire for improvements in Neuralink's medical devices might seem heartening in terms of animal welfare, it actually speaks more to the failings of Neuralink. The FDA "has approved about two-thirds of all human-trial applications for devices on the first attempt over the past three years."¹¹⁴ Additionally, the FDA "upholds high standards in vetting all brain implants even as it aims to speed reviews."¹¹⁵ The FDA's initial denial of

100 Ibid.

101 Ibid.

102 Ibid.

103 Levy (n. 71).

104 Ibid.

105 Rachel Levy, 'Musk's Neuralink Faces Federal Inquiry After Killing 1,500 Animals in Testing' (The Guardian, 5 December 2022) < <https://www.theguardian.com/technology/2022/dec/05/neuralink-animal-testing-elon-musk-investigation> > accessed 5 December 2024.

106 Ibid.

107 Ibid.

108 Ibid.

109 Ibid.

110 U.S. Food and Drug Administration, Guidance Document: General Considerations for Animal Studies Intended to Evaluate Medical Devices: Guidance for Industry and Food and Drug Administration Staff (FDA-2015-D-3419, 2023).

111 Levy & Taylor (n 5).

112 Ibid.

113 Ibid.

114 Ibid.

115 Ibid.

Neuralink's human trials is more indicative of Neuralink's rushed and unsafe research methods rather than the agency's interest in upholding standards of welfare for its testing subjects.

The FDA urges researchers to consult with a laboratory veterinarian to determine what animals are suitable for research and to help researchers understand how to handle these animals.¹¹⁶ Research personnel should be experienced and have the proper credentials to carry out these studies.¹¹⁷ The FDA's guidelines also discuss the use of anaesthetics and analgesics, since these tools can cause pain and distress.¹¹⁸ While this is framed to prioritize the efficacy of the experiment, it at least shows that minimal effort is being taken to minimize animals' pain and suffering.

The FDA also outlines specifications similar to those found in the AWA, stating that animals should have adequate housing and that social animals should be grouped together.¹¹⁹ The FDA states that animals should have access to "food and water receptacles, species-appropriate resting surfaces, and species-specific enrichment devices."¹²⁰ Further, the "FDA notes that adequate play and exercise are increasingly recognized as important to animal well-being."¹²¹

These guidelines are merely "considerations" and, because they are part of a guidance document, they are not legally enforceable. They are helpful for protecting laboratory animals and provide an outline of what level of care should be expected from a laboratory setting, but unfortunately, they cannot protect animals as thoroughly as if they were compulsory. These guidelines should be made compulsory in order to benefit animals used for experimentation, as they encourage consultations with veterinarians to ensure the proper handling of animals and emphasize animals' access to certain necessities. By enforcing these guidelines in an official capacity, animal welfare could improve.

116 Ibid [5].
117 Ibid.
118 Ibid [9].
119 Ibid [14].
120 Ibid.
121 Ibid.

How the USDA Can Better Enforce the AWA

There are many opportunities for the USDA to improve its enforcement of the AWA. The USDA does not fully inspect laboratories that are accredited by the AAALAC, although this organization is not federally regulated.¹²² The USDA is a governmental agency that has the authority to inspect animal research facilities, and should be the party that conducts full inspections of each lab. The USDA's "focused inspections" include looking at only a few aspects of the labs, rather than an extensive inspection.¹²³ This is likely an AWA violation because there is no guarantee that the facilities that the USDA is not fully inspecting are following the AWA guidelines for minimum welfare standards.¹²⁴

The USDA removed many of its animal inspection records from its online database in 2017 due to "privacy concerns."¹²⁵ Fewer violations as compared to previous years were noted once this data was available, raising concerns about the quality of these inspections and speculations as to why the records were hidden.¹²⁶ Although these records are now available for anyone to search online, thanks to 7 U.S.C.A. § 2146a, the information provided there gives only a vague overview of the violations.¹²⁷ These reports should provide greater detail as to what violations were found, how facilities were inspected, and what repercussions were issued. In doing so, those involved in animal welfare litigation or those reporting on animal welfare violations would have more information to support their advocacy. Further, companies who mistreat animals should face the consequences of having such information public.

As mentioned above, the USDA imposes low

122 AAALAC, 'Accreditation Program' (AAALAC International) <<https://www.aaalac.org/accreditation-program/policies/#:~:text=No%2C%20AAALAC%20is%20not%20a,does%20not%20make%20regulations>> accessed 14 August 2024.

123 Offord (n 6g).

124 Ibid.

125 H. Claire Brown, 'After Three Years, USDA Releases Previously Hidden Animal Cruelty Records' (The Counter, 19 February 2020) <<https://thecounter.org/usda-aphis-hidden-animal-cruelty-inspection-records/>> accessed 14 August 2024.

126 Ibid.

127 7 U.S.C.A. § 2146(a) (2023).

finer for egregious AWA violations that result in animal deaths after long-term suffering.¹²⁸ Because these fines are not high enough for research facilities to consider them punitive, the USDA should enforce much higher fines against facilities that violate the AWA. By doing so, research facilities will see clearer consequences for their violations and will be motivated to follow AWA guidelines more strictly to avoid high fines in the future.

Finally, animal welfare should be enforced more strictly. More animals should be included in the AWA's definition of "animal," and every species should be given adequate space, exercise, and social opportunities. The Secretary should raise its minimum standards for animal care.¹²⁹ While it is important that dogs and primates have species-specific provisions,¹³⁰ all animals should be afforded the same level of care. The Secretary should be able to prevent research that causes excessive cruelty or physical and psychological detriment to animals.¹³¹ The USDA has not enforced many animal welfare citations recently because inspectors are discouraged from doing so.¹³² Congress should amend the AWA to make stricter minimum guidelines for animal welfare, such as ensuring that animals have adequate food, water, and space; and the USDA should more strictly enforce these guidelines.

Conclusion

The use of animals in laboratory testing results in the pain and suffering of many animals throughout their lives. The inhumane treatment of these animals can be rectified if the AWA created stricter guidelines that the USDA actually enforced. Enforcement is a critical aspect of animal welfare that the USDA has neglected. Stricter enforcement of AWA guidelines by the USDA through actual enforcement of AWA regulations, larger fines

128 Fobar (n 23).

129 7 U.S.C.A. § 2143(a)(2)(A) (2023).

130 7 U.S.C.A. § 2143(a)(2)(B).

131 7 U.S.C.A. § 2143(a)(4)(6)(A).

132 Rachel Fobar, 'USDA Accused of Ignoring Animal Welfare Violations in Favor of Business Interests' (National Geographic, 13 October 2021), < <https://www.nationalgeographic.com/animals/article/usda-accused-of-ignoring-animal-welfare-for-business-interests> > accessed 14 August 2024.

and less leeway for violations, and stricter inspections that occur at regular intervals will result in improved animal welfare in laboratories.