■ EFILED IN OFFICECLERK OF SUPERIOR COURT
DECATUR COUNTY, GEORGIA

24CV00181LAWTON C. HEARD, JR. AUG 14, 2024 01:39 PM

IN THE SUPERIOR COURT OF DECATUR COUNTY STATE OF GEORGIA

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JUNE FAIRCLOTH, CHAD DOLLAR, KERI			Cecilia Willis, Clerk Decatur County, Georgia
DOLLAR, JOHN T. REYNOLDS, JR.,			
MYRNA D. (PENNY) REYNOLDS, JOHN T.)		
REYNOLDS, III, DANA MARTIN, KRISTINA)		
MARTIN, DAVID BARBER, DONNA	Civil Action No		
BARBER, LARRY FUNDERBURKE,)		_
CAROLYN FUNDERBURKE, WALTER)		
(TED) LEE, LISA DASILVA, ELISE BOYD,)		
EPIC DESIGN BY JUNE FAIRCLOTH, LLC,)		
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE)		
II LLC,)		
, , , , , , , , , , , , , , , , , , ,)		
Plaintiffs,			
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v.)		
)		
SAFER HUMAN MEDICINE, INC.,)		
DECATUR COUNTY-BAINBRIDGE)		
INDUSTRIAL DEVELOPMENT)		
AUTHORITY, and DEVELOPMENT			
AUTHORITY OF BAINBRIDGE AND			
DECATUR COUNTY,			
DECITOR COUNTY)		
Defendants.			

VERIFIED COMPLAINT

Plaintiffs June Faircloth, Chad Dollar, Keri Dollar, John T. Reynolds, Jr., Myrna D. (Penny) Reynolds, John T. Reynolds, III, Dana Martin, Kristina Martin, David Barber, Donna Barber, Larry Funderburke, Carolyn Funderburke, Walter (Ted) Lee, Lisa DaSilva, Elise Boyd, Epic Design By June Faircloth, LLC, L2 Bainbridge LLC and L2 Bainbridge II LLC (collectively, "Plaintiffs") hereby file this Verified Complaint against Defendants Safer Human Medicine, Inc., Decatur County-Bainbridge Industrial Development Authority, and the Development Authority of Bainbridge and Decatur County (collectively, "Defendants"), respectfully showing the Court as follows:

Parties, Venue and Jurisdiction

1.

Plaintiff June Faircloth is an individual resident of Decatur County, Georgia, and is the owner of and resides at certain real property located at 214 Riverview Drive, Bainbridge, Decatur County, Georgia.

2.

Plaintiffs Chad Dollar and Keri Dollar are individual residents of Decatur County, Georgia, and are the owners of and reside at certain real property located at 1565 Newton Road, Bainbridge, Decatur County, Georgia.

3.

Plaintiffs John T. Reynolds, Jr, and Myrna D. (Penny) Reynolds are individual residents of Decatur County, Georgia and are the owners of and reside at certain real property located at 1555 Newton Road, Bainbridge, Decatur County, Georgia.

4.

Plaintiff John T. Reynolds, III, is an individual resident of Decatur County, Georgia and is the owner of and resides at certain real property located at 344 Flint River Heights Road, Bainbridge, Decatur County, Georgia.

5.

Plaintiffs Dana and Kristina Martin are individual residents of Decatur County, Georgia and are the owner of and reside at certain real property located at 1001 E. College Street, Bainbridge, Decatur County, Georgia.

Plaintiffs David Barber and Donna Barber are individual residents of Decatur County, Georgia and are the owners of and reside at certain real property located at 1817 Pondtown Road, Bainbridge, Decatur County, Georgia.

7.

Plaintiffs Larry Funderburke and Carolyn Funderburke are individual residents of Decatur County, Georgia and are the owners of and reside at certain real property located at 206 Flint River Heights Road, Bainbridge, Decatur County, Georgia.

8.

Plaintiff Walter (Ted) Lee is an individual resident of Decatur County, Georgia and is the owner of and resides at certain real property located at 1339 East River Road, Bainbridge, Decatur County, Georgia.

9.

Plaintiff Lisa DaSilva is an individual resident of Decatur County, Georgia and is the owner of and resides at certain real property located at 3813 Bethel Road, Bainbridge, Decatur County, Georgia.

10.

Plaintiff Elise Boyd is an individual resident of Leon County, Florida and resides at 8893 Winged Foot Dr., Tallahassee, Florida.

11.

Plaintiff Epic Design by June Faircloth, LLC is a Georgia corporation with its principal business office located at 224 S. West Street, Bainbridge, Decatur County, Georgia.

Plaintiff L2 Bainbridge LLC is a Georgia corporation with its principal business office located at 8893 Winged Foot Dr., Tallahassee, Florida.

13.

Plaintiff L2 Bainbridge II LLC is a Georgia corporation with its principal business office located at 8893 Winged Foot Dr., Tallahassee, Florida.

14.

Defendant Safer Human Medicine, Inc. ("SHM") is a Delaware corporation with its principal business office located at 21 Sheldon Road, Cohasset, Massachusetts 02025. SHM can be served through its registered agent CT Corporation System, 289 South Culver Street, Lawrenceville, Georgia 30046.

15.

Defendant Decatur County-Bainbridge Industrial Development Authority (the "Industrial Authority") is a body corporate and politic, and public instrumentality of the State, duly created and validly existing pursuant to the laws of the State, including particularly that certain amendment to the Constitution of the State, 1968 Ga. Laws 1780, as amended by 1981 Ga. Laws 3482 and as continued by 1985 Ga. Laws 3930. Its principal business office is located at 100 Boat Basin Circle, Bainbridge, GA 39818, and it may be served through its chairman, Keith Lyle.

16.

Defendant Development Authority of Bainbridge and Decatur County (the "Development Authority") is a development authority formed under the Georgia Development Law, O.C.G.A. § 36-32-1, *et seq.*, by joint resolution of the Decatur County Board of Commissioners and the Mayor

and Council of the City of Bainbridge. Its principal place of office is located at 100 Boat Basin Circle, Bainbridge, GA 39818, and it may be served through its chair, Keith Lyle.

17.

The Court has subject matter over this case pursuant to Georgia Constitution art. VI, section IV, para. 1.

18.

The Court has personal jurisdiction over the defendants in this action because they are residents of Georgia or have availed themselves to the jurisdiction of this Court.

19.

Venue in this Court is proper pursuant to the Georgia Const. art. VI, sect. II, para. III and VI because two of the defendants reside in Decatur County, Georgia, and because the torts and damages complained of herein have occurred and are occurring in Decatur County.

Facts

The Primate Breeding Facility

20.

In the Fall of 2023, the City of Bainbridge, Georgia (the "City"), the Development Authority, and the Industrial Authority met with SHM behind closed doors to discuss "Project Liberty," a proposed primate breeding facility that, if built, will import and house up to 30,000 primates (the "Proposed Facility"). The Proposed Facility will import endangered long-tailed macaques and perhaps other species of primates from various locations, such as Asia and Mauritius, which then will be shipped from the Proposed Facility to other locations for experimentation.

The location of the Proposed Facility is in the Downrange Industrial Park, which is located within the city limits of Bainbridge, and abuts both residential and agricultural properties.

22.

SHM is a Delaware corporation that was formed on February 24, 2023, that does not have an office, but is run out of a private residential property in Massachusetts. None of its employees, officers, or owners reside in Georgia.

23.

On October 5, 2023, the Development Authority, together with the City's City Manager, Chris Hobby, presented a proposed incentive package for SHM, which included local incentives, many of which were to be provided by the City and Decatur County (the "County") through tax dollars, totaling \$58,602,988.56.

24.

Despite extensive public safety, environmental, and ethical considerations, as well as the significant tax dollars pledged on behalf of the City and the County, the City and the Development Authority purposefully concealed Project Liberty from the public, including residents located immediately adjacent to the Proposed Facility and other local taxpayers.

25.

For example, Plaintiffs Chad and Keri Dollar own a home located next to the Proposed Facility site and have spent considerable money improving their home, where they intend to raise their children. They were never alerted of plans to construct the Proposed Facility next to their home, which will now put their children and their domestic animals in danger. Plaintiff Chad and Keri Dollar have 44 hens, four roosters, one pig, four dogs, and three cats who will be put at risk

and will certainly be stressed by the construction and operation of the Proposed Facility. They have put their plans for constructing a 3.5-acre goat area on hold because they can no longer invest in their property and will have to sell their property at a potential loss if the Proposed Facility is constructed.

26.

If the Proposed Facility is constructed, they will suffer further loss of use and enjoyment, and their children will play within feet of tens of thousands of monkeys, and will be routinely exposed to the risk of infectious agents emanating from the facility and other potential safety issues. They will also be exposed to excessive odors and noise.

27.

The Proposed Facility will also be located next to agricultural properties, putting crops and agricultural businesses in danger from water and soil contamination originating from operations at the Proposed Facility.

28.

Upon information and belief, at least one resident has been advised that produce harvested from lands located adjacent to the Proposed Facility will no longer be purchased by local retailers.

The Bond Validation Process

29.

To further finance Project Liberty, the Industrial Authority also agreed to issue its Taxable Revenue Bonds in the principal amount of \$300 million (the "Bonds").

30.

To construct the Proposed Facility, the Development Authority also promised to sell approximately 200 acres of land within its Downrange Industrial Park (the "Property"), which has

a fair market value of \$2,000,000, to SHM for \$10.00. The Development Authority further agreed to pay SHM's broker an additional \$120,000 brokerage fee. As part of the Bond Transaction, the Property would be titled to the Industrial Authority and leased back to SHM pursuant to a rental agreement (the "Rental Agreement") so that SHM could avoid paying some or all of its *ad valorem* taxes. However, there is no evidence that there was an agreement to convey that Property that was approved at an open meeting or that otherwise complies with the law.

31.

The Industrial Authority also prepared a "Project Agreement," which was to be entered into by the Industrial Authority, SHM, the County, the City, the Decatur County School District (the "School District"), the Decatur County Tax Commissioner ("Tax Commissioner"), and the Decatur County Board of Tax Assessors ("BOTA").

32.

The Industrial Authority also prepared a "PILOT Agreement," to be entered into by the Industrial Authority, SHM, the County, the City, the School District, the Tax Commissioner, and the BOTA. Pursuant to the PILOT Agreement, SHM agreed to make certain payments in lieu of taxes to the Industrial Authority as part of the consideration for the Project Agreement, the Rental Agreement, and other benefits.

33.

On December 5, 2023, the Industrial Authority and the City's City Manager communicated to the City a plan to have a Special Called Joint Meeting at 11:00 a.m. on December 11, 2023 (the "Special Called Meeting") to approve the Project and PILOT Agreements, as well as a bond resolution.

The Special Called Meeting was held, but it did not meet the requirements of the Georgia Open Meetings Act, O.C.G.A. § 50-14-1, *et seq.* and therefore the actions taken by the Industrial Authority, the City, the County, the BOE, and the BOTA are not binding, pursuant to O.C.G.A. § 50-14-1(b)(1).

35.

A lawsuit has been commenced in this Court seeking a declaration that the actions taken by the City, the County, the BOE, the BOTA and the School District are not binding because of the Open Meetings Act violations. *See Dollar, et al. v. City of Bainbridge, et al*, Case No. 24CV00046.

36.

A bond validation case was filed for the purposes of issuing the Bonds under O.C.G.A § 36-82-60 *et seq* (the "Revenue Bond Law"), and the bond validation order issued in that case has been appealed based on, among other things, the Industrial Authority's failure to comply with the validation procedures under the Revenue Bond Law.

37.

Even if affirmed on appeal, the bond validation order is not relevant to the relief sought in this litigation.

38.

Section 1.7 of the PILOT Agreement provides that the Industrial Authority has the right to elect not to proceed with the Project before the Bonds are issued.

On February 2, 2024, the Industrial Authority voted to revoke its participation in Project Liberty, and therefore, to the extent that the PILOT Agreement is binding, pursuant to Section 1.7 of the PILOT Agreement, the Industrial Authority elected not to issue the Bonds.

40.

Also pursuant to Section 12.2 of the Project Agreement, to the extent the Project Agreement is valid, by February 29, 2024, if (i) SHM did not receive confirmation from the State that SHM would receive certain State incentives; (ii) there was no closing on the Purchase and Sale Agreement ("PSA"); (iii) there was not a final judgment issued by the Superior Court of Decatur County confirming and validating the bonds, or the validation had not been appealed; and (iv) the bonds were not issued, then the Project Agreement would be of no further force and effect.

Safer Human Medicine

41.

While SHM is a newly formed corporation, SHM's principals and officers include former executives from other animal research/breeding companies that have been cited previously for numerous violations of the federal Animal Welfare Act ("AWA"), the Clean Water Act, and other federal laws..

42.

Indeed, SHM's principals, who will be charged with operating the Proposed Facility in Bainbridge, have an established pattern of disregarding laws and engaging in unethical practices, and upon information and belief, will continue those practices if they are permitted to operate any animal breeding facility in Bainbridge.

Jim Harkness, the Chief Executive Officer of SHM, was the Chief Operating Officer of Envigo, a private company that procured, bred, and sold animals, including beagles and monkeys, for experimentation. See Meredith Wadman, In a First, State Bill Would Require Nearly Perfect Welfare Record for Research Dog and Cat Suppliers, SCIENCE (Mar. 9, 2022), https://www.science.org/content/article/first-state-bill-would-require-nearly-perfect-welfare-record-research-dog-and-cat, attached hereto as <a href="https://www.science.org/content/article/first-state-bill-would-require-nearly-perfect-welfare-record-research-dog-and-cat, attached hereto as <a href="https://www.science.org/content/article/first-state-bill-would-require-nearly-perfect-welfare-record-research-dog-and-cat, attached hereto

44.

Under Mr. Harkness' leadership, Envigo exhibited a disregard for animal welfare and sanitation. Inspectors from the United States Department of Agriculture found numerous violations of the federal AWA, including "live insects, worms, maggots, beetles, flies, ants, mold, and feces," in the dogs' food and said that 300 puppies had died in the span of seven months of "unknown causes." *See United States of America v. Envigo RMS, LLC*, Case No. 6:22cv-00028 (W.D. Va.) (Temporary Restraining Order), attached hereto as Exhibit B; *see also* Affidavit in Support of an Application Under Rule 41 for a Warrant of Search and Seize filed *in In the Matter of Search of Envigo*, Case No. 6:22mj3 (W.D. Va.), attached hereto as Exhibit C.

45.

The Department of Justice found thousands of dogs in acute distress and seized nearly 4,000 beagles from Envigo. In July 2022, the United States District Court for the Western District of Virginia entered a consent order barring the Virginia Envigo facility from any activity requiring a federal AWA license. See DOJ Press Release, Justice Department Secures the Surrender of Over

4,000 Beagles from Virginia Breeder of Dogs for Research, (July 18, 2022), attached hereto as Exhibit D.

46.

Under Harkness' management, Envigo also failed to undertake any steps to monitor and test for diseases, and regularly failed to "prevent, control, diagnose, and treat diseases and injuries," in the animals under Envigo's care and as required by law. *See* Ex. B (citing 9 C.F.R. § 2.40(b)(2)).

47.

Under Harkness' management, Envigo also violated the Clean Water Act, 33 U.S.C. §§ 1311 and 1319(c)(2)(A), by failing to comply with effluent limitation standards.

48.

Ultimately, in June 2024, Envigo pled guilty to violations of the AWA and the Clean Water Act and was fined \$35 million. *See United States v. Envigo RMS*, *LLC*, No. 6:22-cv-00028-NKM (W.D.Va. June 3, 2024) (Plea Agreement).

49.

David Johst, the current President of SHM, retired in 2019 as Corporate Executive Vice President, General Counsel & Chief Administrative Officer of Charles River Laboratories, a company with a sordid history of violating the AWA and damaging fragile ecosystems. Charles River Laboratories is currently under civil and criminal investigation by the DOJ, the U.S. Fish & Wildlife Service ("USFWS"), and the United States Securities and Exchange Commission for conduct pertinent to the alleged illegal importation of endangered wild-caught long-tailed macaque monkeys.

Kurt Derfler, the Chief Operating Officer of SHM, retired as executive director of primate operations at Charles River Laboratories in May 2023. During his tenure with Charles River Laboratories, USFWS denied entry to more than 1,000 long-tailed macaques, allegedly illegally imported into the United States from Cambodia. Prior to this, Derfler was Vice President of North America Operations at Envigo and Executive Director of Operations at Covance Research Products, a similar company that was subsequently acquired by Envigo and at the heart of the alleged conspiracy to illegally import and market endangered long-tailed macaques.

51.

Zach Wienberg, a Director of SHM, has publicly espoused on X (f/k/a Twitter), views that "we shouldn't spend 1 minute thinking about protecting endangered animals," and states that the "biggest impediment to environmental progress is environmental review."

Health and Safety Concerns - Disease

52.

There are considerable health risks associated with the primates that SHM intends to bring into the Proposed Facility. The Centers for Disease Control and Prevention ("CDC") has warned that primates pose a significant risk to public health, as diseases and environmental pollution are likely to spread to people and animals despite the use of quarantine facilities and other purported safeguards, putting Decatur County and areas beyond at significant risk.

53.

The Proposed Facility would be the largest primate breeding facility, not just in the United States, but in the entire Western Hemisphere, holding up to thirty thousand (30,000) monkeys. By

comparison, the next largest facility in the United States holds about seven thousand (7,000) primates.

54.

Upon information and belief, the monkeys will be imported from Asia and Mauritius, a country in East Africa, from facilities that have been identified as harboring and exporting monkeys infected with highly virulent zoonotic pathogens, including bacteria, viruses and parasites, which can be spread to humans and other animals.

55.

Primates imported and used for breeding and experimentation are known to carry and transmit multiple pathogens and diseases, including Herpes B Virus, Tuberculosis, Ebola-like Viruses, Simian Hemorrhagic Fever Virus, Shigellosis, Salmonellosis, Campylobacter, Malaria, Dengue, and Leprosy.

56.

There will be numerous potential exposure pathways originating from the Proposed Facility. For example, the primates will have indoor-outdoor environments and their waste will be aerosolized during even routine cleaning, which will contaminate the surrounding soil and surface water.

57.

There will also be significant solid and biological wastes and fomites requiring disposal, including biomedical waste and sharps, soiled bedding, food contaminated with fecal matter, and primate carcasses, the handling of which will increase possible exposure to pathogens.

Just one example of a possible outbreak that may arise from the extreme concentration of primates is Melioidosis. *Burkholderia pseudomallei* is a bacterium that causes an infectious disease called Melioidosis, which has a mortality rate approaching 50 percent. The bacterium is shed in primatal bodily fluids and can survive in contaminated soil or water for years.

59.

Burkholderia pseudomallei was detected in a monkey colony operated by the CDC in 2013, and in an outdoor monkey colony in Louisiana in 2015, and in Envigo's current primate quarantine facility in Texas in 2014 and 2015 and in 2021. Most monkeys imported into the U.S. originate in countries where melioidosis is currently endemic. The CDC has acknowledged the inability of quarantine to consistently detect infected monkeys.

60.

Diagnostics testing for Melioidosis infections in monkeys is notoriously challenging. The incubation period for Melioidosis in primates is not definitively known but can be prolonged, laying dormant for many years until becoming active; one report described a macaque that developed Melioidosis 10 years after importation into the U.S, suggesting that quarantining monkeys after importation does not rid a breeding, housing, or research facility of the risk of an eventual spread.

61.

Primates are also capable of carrying zoonotic malarial parasites, which can be transmitted through mosquitoes to the residents of South Georgia.

62.

In December 2023, the CDC revealed that from 2021 to 2023, there was a significant increase in imported shipments of monkeys with Tuberculosis, which is transmissible from animals to humans.

63.

Indeed, four different strains of Tuberculosis entered the United States through monkeys since 2020, and the CDC confirmed that monkeys with these strains have exited CDC-mandated quarantine undetected. The CDC has further confirmed that institutions receiving primates may not have implemented the same level of controls to reduce the risk of Tuberculosis transmission as do quarantine facilities

64.

As a result of failed quarantines in June 2023, imported monkeys at a lab in Michigan tested positive for Tuberculosis—despite having undergone a thirty-one (31) day CDC-mandated quarantine at a facility in Florida—and at least two workers were exposed and referred for treatment.

65.

Multiple Ebola-like virus outbreaks also have occurred in primate laboratories in the U.S.

66.

In 1989, Reston Ebola Virus ("RESTV") was introduced into quarantine facilities in Virginia and Pennsylvania by monkeys imported from the Philippines.

67.

In 1989-1990, RESTV was introduced into primate quarantine facilities in Texas by monkeys imported from the Philippines. In 1996 in Alice, Texas, an outbreak occurred at the Texas Primate Center (now Inotiv).

68.

Ebola is a filovirus, and the CDC reported that between 2019 and 2022 multiple monkeys were imported with clinical signs consistent with filovirus infection.

69.

While the CDC is aware of these risks, there are currently no statutes or regulations in place that force or compel importers of monkeys to screen imported animals for diseases; this process is left entirely up to the importer of monkeys to decide.

70.

SHM principals, who each have proven failures with respect to disease control, animal welfare, and federal environmental regulations, will now create a hotspot in the middle of Bainbridge by bringing in tens of thousands of primates to act as a reservoir for disease transmission in a residential area of Bainbridge.

Health and Safety – Risk of Escape

71.

The risk of monkeys escaping into the suburban and rural environment of Bainbridge, where people and animals (both wild and domesticated) live amplifies the physical danger of those people and animals encountering the foreign, deadly diseases for which the species of monkeys caught up in the international trade of wildlife are known to be common carriers.

Primates have escaped from even the most respected monkey facilities. In 2018, four baboons who had broken out of Texas Biomedical Research Institute were spotted on a roadway by residents before they were recaptured.¹ Primates have also escaped from MD Anderson Cancer Center;² Tulane University;³ Oregon Health & Science University;⁴ Emory University;⁵ and Wake Forest University.⁶

73.

There is also the potential for escape when the primates are transported from one location to another. For example, in Pennsylvania, a truck hauling 100 long-tailed macaques to a quarantine facility collided with another vehicle resulting in the escape of several monkeys, some of which had direct contact with motorists who stopped to survey the scene of the accident. At least one individual required preventive treatment after being exposed to macaque bodily fluids.⁷

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¹ See Japhanie Gray, Baboons on the Loose Returned to Texas Biomedical Research Institute, KSAT News (Apr. 16, 2018), https://www.ksat.com/news/2018/04/16/baboons-on-the-loose-returned-to-texas-biomedical-research-institute/.

²See Escaped Research Chimp Killed, ABC13 (Mar. 13, 2008), https://abc13.com/archive/6018837/

³ See 2 Dozen Monkeys Escape from Tulane Center, CHRON. HIGHER EDUC. (Oct. 30, 1998), https://www.chronicle.com/article/2-dozen-monkeys-escape-from-tulane-center/

⁴ See Kaylee Tornay, *Primate Research Center in Oregan Leads Nation in Violations*, OPB (Jan. 19, 2023), https://www.opb.org/article/2023/01/19/oregon-primate-research-center-violations-ohsu/ and Kay Mitchell, *Oregan Great Primate Escape Nearly Over* – 8 of 9 Captured, OR. LIVE (Apr. 5, 2009), https://www.oregonlive.com/news/2009/04/some_monkeys_flee_ohsu_lab may.html

⁵ See David Ibata, Search Ends in Gwinnett for Missing Research Monkey, AJC (Aug. 22, 2011), https://www.ajc.com/news/local/search-ends-gwinnett-for-missing-research-monkey/BxH5q6i02evDRwXRh55iDL/

⁶ See Wake Forest Baptist Cited After Monkey's Escape, Fox 8 (Aug. 8, 2012), https://myfox8.com/news/wake-forest-baptist-cited-for-violating-federal-law-after-monkeys-escape/

⁷ See Pa. woman exposed to lab monkeys after crash irked by lack of answers from CDC, state (Feb. 09, 2022), https://www.pennlive.com/news/2022/02/lack-of-answers-from-cdc-health-department-irks-pa-woman-exposed-to-lab-monkeys.html

74.

Escaped primates can also be aggressive.⁸ Even macaques that are raised by humans can be aggressive to both people and companion animals, as evidenced by the killing of a pet macaque in May 2024 near Charleston, South Carolina that was attacking dogs.⁹

75.

Primates are also highly intelligent and adapt to their surroundings out of captivity. Florida now has colonies of primates that originated from only a few breeding pairs. These colonies have impacted agriculture and created safety and disease concerns in those locales.

76.

When compounded with their likelihood of escape and the presence of 30,000 macaques at a single facility, the chances of monkeys getting out of the Proposed Facility and into the community creates an untenable risk, which in turn, has created intense fear among Bainbridge residents.

Environmental Impact

77.

Prior smaller breeding operations have resulted in ecological catastrophes. In the 1970s, Charles Rivers Laboratories constructed a much smaller breeding facility in a fragile ecosystem in the Florida Keys. Some of the monkeys escaped and established colonies that decimated protected coastal mangroves, which had been home to a variety of species, resulting in an eroded shoreline.

⁸ Georgia is one of many jurisdictions that prohibit private ownership of primates for public safety reasons. *See* O.C.G.A § 27-5-5.

⁹ See Tim Renaud, Escaped Monkey Was Shot by Homeowner, Officials Say, COLLETON CNTY. NEWS (May 29, 2024), https://www.counton2.com/news/local-news/colleton-county-news/missing-monkey-in-walterboro-was-not-captured-alive-officials-say/.

Also, the waste of more than 2,500 monkeys polluted the waters, leaving a line of brown algae that impacted marine life. After damaging public resources for decades, it took years of lawsuits for Charles River to finally turn the land—now dead—back over to the state of Florida.

79.

Primate urine, feces, saliva, blood, food waste, carcasses, cleaning agents, and other waste associated with operations at the Primate Facility will be routinely generated and will require routine disposal and containment.

80.

Even the act of routine cleaning primate group enclosures will cause pathogencontaminated waste to become aerosolized, which means that before any solid waste disposal and wastewater treatment, pathogens and chemicals will have entered the environment.

81.

SHM has already estimated that the Proposed Facility will generate an estimated 444,000 gallons of wastewater per day before it reaches its full operational capacity.

82.

The present wastewater infrastructure that services the Property is not sufficient to treat the waste that will be generated at the Proposed Facility and an alternate treatment facility has not been and cannot be reasonably constructed.

83.

The Proposed Facility would be located in an area of historical flooding, and will be situated within approximately 500 meters of the Flint River.

Ultimately, the wastewater generated at the Proposed Facility will impact soil and will be released to the Flint River, and it will in turn travel downstream, ultimately impacting other areas.

85.

The Development Authority has already started clearing the Property to prepare for the construction of the Proposed Facility, and, in doing so, has already received a notice of violation for failing to comply with environmental laws, including the Georgia Water Quality Control Act, O.C.G.A. § 12-5-20 *et seq.*

86.

More specifically, on February 5, 2024, the Georgia Department of Natural Resources Environmental Protection Division ("EPD") issued a Notice of Violation, which resulted in a \$10,000 fine against the Development Authority and required corrective action.

87.

Defendants also engaged in unlawful land disturbing practices, potentially destroying gopher tortoise and indigo snake habitats, in violation of the Endangered Species Act and USFWS rules and regulations.

88.

SHM's CEO's former workplace is currently under investigation for violating the federal Clean Water Act, the Texas State Water Control Law and local water pre-treatment requirements for their Alice, Texas facility—which holds tens of thousands fewer primates than would eventually be housed at the Proposed Facility.

All of these violations are part of a larger pattern, as evidenced by Envigo's past violations of the Clean Water Act, and Mr. Weinberg's admitted contempt for environmental protection laws.

Noise, Odors and Wildlife Concerns

90.

The housing of the primates, in both indoor and outdoor enclosures, is expected to result in unbearably loud noises that will impact the comfort and well-being of the residents and workers within close proximity to the Proposed Facility.

91.

The housing of the primates will also result in intense, persistent odors that will impact adjacent landowners.

92.

The Proposed Facility will also attract and increase the presence of wildlife, including racoons, feral swine, and animals deemed pests under law, including rodents, snakes, mosquitoes, flies, and other insects. In addition to the loss of use and enjoyment of residential property owners, the increase in pests will cause damages to crops and the probable transmission of diseases to people, livestock, companion animals, and crops.

93.

Increased truck traffic is also expected to occur near the Proposed Facility, which will further increase health and safety concerns. Some of the vehicles traveling to and from the location will transport biological waste, including, potentially, animal carcasses and primate bodily fluids.

The Proposed Facility has Already Caused Economic Losses

94.

The Proposed Facility, and therefore Bainbridge, has been the subject of national and international news since the Proposed Facility was announced, which has resulted in reputational damage to Bainbridge.

95.

As a result of the announcement, real estate investors have declared that they are going to cease further investment in Bainbridge.

96.

Plaintiffs L2 Bainbridge LLC and L2 Bainbridge II LLC are two such investors that owns a building with retail and rentable residential spaces in Bainbridge. The construction of the Proposed Facility will reduce their investments in the building, and they have ceased further investment in the area until it is certain the Proposed Facility will not be built. The loss on the investment also results in loss of revenue for an owner of the investment companies, Plaintiff Elise Boyd.

97.

Plaintiff Epic Design by June Faircloth, LLC, a design consulting business owned by Plaintiff June Faircloth, has also already been impacted, with business slowing as investment in Bainbridge real estate has declined.

98.

Notwithstanding that Plaintiffs Chad and Keri Dollar have invested a significant amount of money into improving their home, if they can sell it, it will be at a reduced value because of its

close proximity to the Proposed Facility, which has also impacted their use and enjoyment of their home.

99.

Plaintiffs Johnny and Penny Reynolds, retirees who live on a fixed income, reside on a property that directly abuts the Proposed Facility. They are already aware that their property has been made unmarketable due to its location because they have been unable to sell it.

100.

Plaintiffs David and Donna Barber are senior citizens who live only 400 feet from the Proposed Facility, who are concerned about their health, the noise, the odor, the increased traffic, and the safety risks that will be created by the Proposed Facility. They are also aware that the value of their home will continue to decline if the Proposed Facility is constructed.

101.

In addition to the decline in real estate values and in investment in Bainbridge, farmers also will be negatively impacted by the presence of the Proposed Facility because, although crops will likely continue to grow, there is still a risk of contamination caused by the close proximity of the primates and fouled wastewater.

102.

Plaintiffs June Faircloth, Walter (Ted) Lee, and Larry and Carolyn Funderburke live on the Flint River and are familiar with historical flooding that has occurred in the area of the Proposed Facility. They are concerned about the impact to their properties and the Flint River, especially with respect to surface water pollution and continued Clean Water Act violations.

Plaintiffs John T. Reynolds, III, Dana Martin, Kristina Martin, and Lisa DaSilva all reside in the community and have made significant investments in their properties, which will be impacted by the construction and operation of the Proposed Facility.

104.

An enterprise in Florida similar to the Proposed Facility is indicative of the future conditions and economic losses that will exist here. BC US operates a facility in Florida for the quarantine, holding and breeding of imported monkeys for use in research and testing. A recent lawsuit involving BC US identifies violations of environmental laws and improper disposal of animal waste by BC US resulting from just 2,500 monkeys (a fraction of the 30,000 monkeys that the Proposed Facility will hold), and the landowner in that case describes canals, "filled with floating solid animal feces, algae, and scum resulting from overloading of nutrients" that are a threat to the Big Cypress National Preserve, and to the water resources that are essential to a healthy ecosystem and the clean water that Florida's people, animals and plants depend upon." 10

CAUSES OF ACTION

COUNT ONE – DECLARATORY RELIEF UNDER O.C.G.A. § 9-4-2 - NUISANCE

105.

Plaintiffs restate and re-allege the averments of all preceding paragraphs as if fully set forth herein.

25

¹⁰ See Huge Florida Monkey Farm Sues Competitor Over Land Purchase (Jul. 30, 2024), https://www.swflorida.blogspot.com/2024/07/huge-florida-monkey-farm-sues.html?m=1

There is an actual and justiciable controversy presented by facts stated herein regarding the construction of the Proposed Facility, and whether the Proposed Facility can be allowed to operate as proposed within Bainbridge to the detriment of Plaintiffs and other citizens. The potential operation of the Proposed Facility has created uncertainty and insecurity for Plaintiffs with regard to their respective rights. Specifically, the dangers posed by the Proposed Facility will result in an unsafe environment for Plaintiffs, could create life-threatening conditions, and is already destroying the economic fabric of the community.

107.

As a result of this present, actual and justiciable controversy created by the Proposed Facility, the Court should declare and find that Defendants' current and future acts relating to the development of the Property, development of infrastructure to serve the Property, and the development of the Proposed Facility constitute a continuing nuisance and declare that actions constituting the continuing nuisance are prohibited.

COUNT TWO – DECLARATORY RELIEF UNDER O.C.G.A. § 9-4-2 – TERMINATION OF PILOT AND PROJECT AGREEMENTS

108.

Plaintiffs restate and re-allege the averments of all preceding paragraphs as if fully set forth herein.

109.

There is also an actual and justiciable controversy presented by facts stated herein regarding whether the Project Agreement and PILOT Agreement, even if validated, were terminated by the vote of the Industrial Authority on February 2, 2024, and whether any bonds

may now be issued since the validated Project Agreement would have terminated on February 29, 2024.

110.

The Court should further declare that the actions taken by the Industrial Authority on February 2, 2024, effectively terminated the Industrial Authority's participation in the Proposed Facility, and that the Bond Validation Order is therefore of no further purpose or effect.

COUNT THREE – DECLARATORY RELIEF UNDER O.C.G.A. § 9-4-2 – VIOLATIONS OF GRATUITIES CLAUSE AND DEVELOPMENT AUTHORITIES LAW

111.

Plaintiffs restate and re-allege the averments of all preceding paragraphs as if fully set forth herein.

112.

The Georgia Constitution prohibits the General Assembly from granting any donation or gratuity, or vacating any public property, for the sole benefit of a private individual. *See* Ga. Const., art. III, sec. VI, para. VI. For purposes of the constitutional provision, a "gratuity" is something given freely or without recompense, where the giver receives no substantial benefits in exchange.

113.

The Industrial Authority and Development Authority exist under the Development Authority Laws, O.C.G.A. § 36-62-1, et seq.

114.

The Development Authorities Law, O.C.G.A. § 36-62-6(7), permits a development authority:

to dispose of any real property for fair market value or any amount below fair market value as determined by the board of directors of the authority, regardless of prior development of such property as a project, whenever the board of directors of the authority may deem such disposition to be in the best interests of the authority if the board of directors of the authority prior to such disposition shall determine that such real property no longer can be used advantageously as a project for the development of trade, commerce, industry, and employment opportunities and if title to such real property is to be transferred to the state.

115.

Neither the Gratuities Clause nor the Development Authorities Law permit the gift of a \$2,000,000 property to SHM for \$10 as contemplated under the Project Agreement (if valid). Similarly, neither the Gratuities Clause nor the Development Authorities Law permit payment of \$120,000 to a broker for a property gifted by the Development Authority to either the Industrial Authority or SHM.

116.

The Development Authorities Law also does not permit the transfer of real property pursuant to contracts that have been rescinded, invalidated, revoked or terminated.

117.

Accordingly, the Court should declare that the conveyance of real property to SHM for any amount that is below the fair market value or that is conveyed pursuant a rescinded, invalidated, revoked or terminated contract is invalidated.

COUNT FOUR - INJUNCTIVE RELIEF UDER O.C.G.A. § 9-4-3

118.

Plaintiffs restate and re-allege the averments of all preceding paragraphs as if fully set forth herein.

119.

Under Georgia law:

[a] nuisance is anything that causes hurt, inconvenience, or damage to another and the fact that the act done may otherwise be lawful shall not keep it from being a nuisance. The inconvenience complained of shall not be fanciful, or such as would affect only one of fastidious taste, but it shall be such as would affect an ordinary, reasonable man.

O.C.G.A. § 41-1-1. Georgia law also prohibits interference with the rights of property owners, which includes interference through increased wildlife, noise, odors, and unreasonably dangerous conditions. Once the Proposed Facility is constructed, the surrounding properties are also one large storm away from an unrecoverable disaster.

120.

SHM's principals have historically failed to comply with numerous environmental laws, such as the federal Clean Water Act, the AWA and the Endangered Species Act and the rules and regulations promulgated thereunder. And, the Development Authority has recently violated the Georgia Water Quality Control Act and the Endangered Species Act with respect to preparing the land to build the Proposed Facility.

121.

There exists an immediacy of need to require and compel Defendants to cease and desist from further failures and refusals to comply with their duties and responsibilities under common law and statutory law.

122.

Plaintiffs therefore respectfully request that this Court issue an order enjoining Defendants both temporarily and permanently, from continuing their refusal to comply with their common law and statutory obligations and duties, and further enjoining them from undertaking any further activities that harm and will continue to harm Plaintiffs, including the continuing nuisance arising from the construction and operation of the Proposed Facility.

COUNT FIVE – NUISANCE

123.

Plaintiffs restate and re-allege the averments of all preceding paragraphs as if fully set forth herein.

124.

Defendants' announcement of the Proposed Facility and the dangers that it poses on the community have already caused hurt, inconvenience, and damages to Plaintiffs, constituting a public nuisance pursuant to O.C.G.A. § 41-1-1.

125.

Defendants' future operation of the Proposed Facility will cause hurt, inconvenience, and damage to Plaintiffs, constituting a public nuisance pursuant to O.C.G.A. § 41-1-1.

126.

In addition to the public nuisance, Defendants' construction and operation of the Proposed Facility is also a private nuisance to the owners of real property whose land abuts or will be immediately affected by the polluting effects of the Proposed Facility pursuant to O.C.G.A. § 41-1-2 because the construction and operation of the Proposed Facility will cause pollution, potential disease, noise, increased traffic, unpleasant odors, and property devaluation.

127.

If the consequence of a nuisance about to be erected or commenced will be irreparable and such consequence is not merely possible but is to a reasonable degree certain, an injunction may be issued to restrain the nuisance before it is completed pursuant to O.C.G.A. § 41-2-4.

128.

A landowner should not have to wait until a contemplated structure is built before bringing suit for declaratory, injunctive, or other relief. *Hitch v. Vasarhelyi*, 680 S.E.2d 411, 413 (Ga. 2009).

129.

It is reasonably certain that the Proposed Facility will cause irreparable damage to the Plaintiffs.

130.

Therefore, Plaintiffs request that this Court issue an injunction enjoining the construction and operation of the Proposed Facility.

131.

Monetary damages to Plaintiffs will not redress the hurt, inconvenience, and damage Defendants will cause by the construction and operation of the Proposed Facility.

132.

Absent injunctive relief, Plaintiffs have no other adequate remedy at law such that injunctive relief limiting Defendants' operation of the Proposed Facility is warranted and will not hurt the public interest.

133.

Plaintiffs therefore request that the Court issue a permanent injunction to halt the construction and operation of the Proposed Facility to abate the current nuisance and prevent a future nuisance.

134.

The Court should also award Plaintiffs other damages to be determined by a jury.

COUNT IV – INVERSE CONDEMNATION

135.

Plaintiffs restate and re-allege the averments of all preceding paragraphs as if fully set forth herein.

136.

Plaintiffs are entitled to maintain a private cause of action for injunctive relief and damages against Defendants for their actions which constitute a continuing nuisance or inverse condemnation under Article I, Section 3, Paragraph 1(a) of the Georgia Constitution.

137.

Defendants have engaged in reckless behavior that has resulted in harm, trouble and expense for Plaintiffs, and are undertaking actions that are putting Plaintiffs' health and property in danger.

138.

Defendants' actions have caused property values to plummet and have caused the properties of Bainbridge residents to become worthless.

139.

Plaintiffs are entitled to an award for inverse condemnation in an amount equal to the lost values of their properties.

COUNT V – ATTORNEY'S FEES AND EXPENSES UNDER O.C.G.A. § 13-6-11

140.

Plaintiffs restate and re-allege the averments of all preceding paragraphs as if fully set forth herein.

For the reasons set forth herein, Defendants have been stubbornly litigious, have not acted in good faith, and have caused unnecessary trouble and expenses to Plaintiffs. As a result, Plaintiffs have been forced to file this action.

142.

As a result of Defendants' foregoing conduct, Plaintiffs are entitled to recover their reasonable attorney's fees and expenses from this action.

WHEREFORE, Plaintiffs respectfully pray that:

- (a) the Court issue a declaratory judgment declaring that (a) the Defendants' current and future acts relating to the development of the Property, development of infrastructure to serve the Property and the development of the Proposed Facility constitute a continuing nuisance and declare that actions constituting the continuing nuisance are prohibited; (b) the Resolution adopted by the Industrial Authority on February 2, 2024, effectively terminated the Industrial Authority's participation in the Proposed Facility, and that the Bond Validation Order is therefore of no further purpose or effect; and (c) there is no lawfully-approved agreement to sell or otherwise convey the Property and any sale of the Property for less than the fair market value is invalid because it violates the Gratuities Clause and the Development Authorities Law;
- (b) the Court issue an Order to temporarily and permanently enjoin Defendants from continuing to disregard their statutory and common law duties and obligations, and issue an order enjoining Defendants both temporarily and permanently from undertaking any further activities that are harming and will continue to harm Plaintiffs. Such activities to be enjoined include the (1) further land disturbance activities at the

Property; (2) further economic investment in the Proposed Facility; (3) the transport

and location of primates to the Proposed Facility, if constructed; and (4) the issuance

of the Bonds;

(c) the Court issue a permanent injunction to halt the construction and operation of the

Proposed Facility to abate the current nuisance and prevent a future nuisance;

(d) the Court should also award Plaintiffs damages for Defendants' unlawful conduct to be

determined by a jury;

(e) the Court award Plaintiffs monetary damages equal to the diminished value of their

properties; and

(f) Defendants be ordered to pay all reasonable costs and legal fees incurred by Plaintiffs,

or that would be billed to Plaintiffs or that are incurred on behalf of Plaintiffs by their

attorneys, in the normal course of representation.

Respectfully submitted this 14th day of August 2024.

ARNALL GOLDEN GREGORY LLP

/s/ Rebecca A. Davis

Rebecca A. Davis

Georgia Bar No. 141711

Jennifer Shelfer

Georgia Bar No. 557213

Natalie Cascario

Georgia Bar No. 634589

Ryan P. Lynn

Georgia Bar No. 450269

Attorneys for Plaintiffs

171 17th Street, N.W., Suite 2100 Atlanta, Georgia 30363-1031 404-873-8500

Rebecca.Davis@agg.com

Jennifer.Shelfer@agg.com

Natalie.Cascario@agg.com

Ryan.Lynn@agg.com

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IN THE SUPERIOR COURT OF DECATUR COUNTY STATE OF GEORGIA

JUNE FAIRCLOTH, CHAD DOLLAR, KERI)
DOLLAR, JOHN T. REYNOLDS, JR.,)
MYRNA D. (PENNY) REYNOLDS, JOHN T.)
REYNOLDS, III, DANA MARTIN, KRISTINA	A)
MARTIN, DAVID BARBER, DONNA) Civil Action No
BARBER, LARRY FUNDERBURKE,)
CAROLYN FUNDERBURKE, WALTER)
(TED) LEE, LISA DASILVA, ELISE BOYD,)
EPIC DESIGN BY JUNE FAIRCLOTH, LLC,	
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE	
II LLC,)
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Plaintiffs,)
a special section of)
V.)
)
SAFER HUMAN MEDICINE, INC.,)
DECATUR COUNTY-BAINBRIDGE)
INDUSTRIAL DEVELOPMENT)
AUTHORITY , and DEVELOPMENT)
AUTHORITY OF BAINBRIDGE AND)
DECATUR COUNTY)
Sales Control of the Sales Sal)
Defendants.	1

VERIFICATION

I. June Faircloth, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge. Jung Faircloth

Sworn to and subscribed before me this at day of July, 2024

NOTARY PUBLIC

Commission expires:

CLA C COAL EXPIRES GEORGIA July 29, 2025

IN THE SUPERIOR COURT OF DECATUR COUNTY STATE OF GEORGIA

JUNE FAIRCLOTH, CHAD DOLLAR, KERI	
DOLLAR, JOHN T. REYNOLDS, JR.,)
MYRNA D. (PENNY) REYNOLDS, JOHN T.)
REYNOLDS, III, DANA MARTIN, KRISTINA)
MARTIN, DAVID BARBER, DONNA) Civil Action No
BARBER, LARRY FUNDERBURKE,)
CAROLYN FUNDERBURKE, WALTER)
(TED) LEE, LISA DASILVA, ELISE BOYD,)
EPIC DESIGN BY JUNE FAIRCLOTH, LLC,	
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE)
II LLC,)
)
Plaintiffs,)
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V.)
)
SAFER HUMAN MEDICINE, INC.,)
DECATUR COUNTY-BAINBRIDGE)
INDUSTRIAL DEVELOPMENT)
AUTHORITY, and DEVELOPMENT)
AUTHORITY OF BAINBRIDGE AND)
DECATUR COUNTY)
)
Defendants.	_)

VERIFICATION

I. June Faircloth, state that I have read the foregoing Complaint for Relief, and am informed and believe that the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge, information, and belief, which is based on either personal knowledge or information obtained by or through agents or representatives of Plaintiff Epic Design by June Faircloth, LLC.

Epic Design by June Faircloth, LLC

u Fairly

Its:

Manager

Sworn to and subscribed before me

this Jamaday of July, 2024

NOTARY PUBLIC Commission expires:

EXPIRES GEORGIA July 29, 2025

JUNE FAIRCLOTH, CHAD DOLLAR, KERI	1
DOLLAR, JOHN T. REYNOLDS, JR.,	Ý.
MYRNA D. (PENNY) REYNOLDS, JOHN T.	Ý.
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REYNOLDS, III, DANA MARTIN, KRISTINA	
MARTIN, DAVID BARBER, DONNA) Civil Action No
BARBER, LARRY FUNDERBURKE,)
CAROLYN FUNDERBURKE, WALTER)
(TED) LEE, LISA DASILVA, ELISE BOYD,)
EPIC DESIGN BY JUNE FAIRCLOTH, LLC,)
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE)
II LLC,)
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Plaintiffs,)
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v.)
SAFER HUMAN MEDICINE, INC.,)
DECATUR COUNTY-BAINBRIDGE)
INDUSTRIAL DEVELOPMENT)
AUTHORITY , and DEVELOPMENT)
AUTHORITY OF BAINBRIDGE AND)
DECATUR COUNTY)
)
Defendants.	_)

VERIFICATION

I, Donna Barber, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

Donna Barber

Sworn to and subscribed before me

this 12 day of 14ty, 2024

NOTARYPUBLIC

Commission expires: 23, lug 208



JUNE FAIRCLOTH, CHAD DOLLAR, KERI)
DOLLAR, JOHN T. REYNOLDS, JR.,)
MYRNA D. (PENNY) REYNOLDS, JOHN T.)
REYNOLDS, III, DANA MARTIN, KRISTINA)
MARTIN, DAVID BARBER, DONNA) Civil Action No
BARBER, LARRY FUNDERBURKE,)
CAROLYN FUNDERBURKE, WALTER)
(TED) LEE, LISA DASILVA, ELISE BOYD,)
EPIC DESIGN BY JUNE FAIRCLOTH, LLC,)
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE)
II LLC,)
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SAFER HUMAN MEDICINE, INC.,)
DECATUR COUNTY-BAINBRIDGE)
INDUSTRIAL DEVELOPMENT)
AUTHORITY, and DEVELOPMENT)
AUTHORITY OF BAINBRIDGE AND)
DECATUR COUNTY)
)
Defendants.	_)

VERIFICATION

I, David Barber, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

David Barber

Sworn to and subscribed before me

this 12 day of 14, 2024

NOTARY PUBLIC

Commission expires: 23 aug 200



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VERIFICATION

I, Fisc boys, state that I have read the foregoing Complaint for Relief, and am informed and believe that the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge, information, and belief, which is based on either personal knowledge or information obtained by or through agents or representatives of Plaintiff L2 Bainbridge II LLC.

L2 Bainbridge II LLC

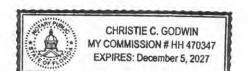
Its: Manager

Sworn to and subscribed before me this day of July 2024

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NOTARY PUBLIC

Commission expires: 18 5 3027



JUNE FAIRCLOTH, CHAD DOLLAR, KERI)
DOLLAR, JOHN T. REYNOLDS, JR.,)
MYRNA D. (PENNY) REYNOLDS, JOHN T.	
REYNOLDS, III, DANA MARTIN, KRISTINA	.)
MARTIN, DAVID BARBER, DONNA) Civil Action No
BARBER, LARRY FUNDERBURKE,)
CAROLYN FUNDERBURKE, WALTER)
(TED) LEE, LISA DASILVA, ELISE BOYD,)
EPIC DESIGN BY JUNE FAIRCLOTH, LLC,)
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE	
II LLC,)
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Plaintiffs,)
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v.)
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SAFER HUMAN MEDICINE, INC.,)
DECATUR COUNTY-BAINBRIDGE)
INDUSTRIAL DEVELOPMENT)
AUTHORITY, and DEVELOPMENT)
AUTHORITY OF BAINBRIDGE AND)
DECATUR COUNTY)
)
Defendants.	_)

VERIFICATION

I, Elise Boyd, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

Flise Boyd

Sworn to and subscribed before me this _____ day of July, 2024

(()

NOTARY PUBLIC
Commission expires: 25 202



JUNE FAIRCLOTH, CHAD DOLLAR, KERI)		
DOLLAR, JOHN T. REYNOLDS, JR.,		
MYRNA D. (PENNY) REYNOLDS, JOHN T.)		
REYNOLDS, III, DANA MARTIN, KRISTINA)		
MARTIN, DAVID BARBER, DONNA)	Civil Action No.	
BARBER, LARRY FUNDERBURKE,)		
CAROLYN FUNDERBURKE, WALTER)		
(TED) LEE, LISA DASILVA, ELISE BOYD,		
EPIC DESIGN BY JUNE FAIRCLOTH, LLC,		
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE)		
II LLC,		
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Plaintiffs,		
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SAFER HUMAN MEDICINE, INC.,		
DECATUR COUNTY-BAINBRIDGE)		
INDUSTRIAL DEVELOPMENT)		
AUTHORITY, and DEVELOPMENT)		
AUTHORITY OF BAINBRIDGE AND)		
DECATUR COUNTY)		
)		
Defendants)		

VERIFICATION

I, Lisa Wheeler, state that I have read the foregoing Complaint for Relief, and am informed and believe that the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge, information, and belief, which is based on either personal knowledge or information obtained by or through agents or representatives of Plaintiff L2 Bainbridge LLC.

By: Manager

ainbridge L/LC

Sworn to and subscribed before me this 9 to day of July, 2024.

NOTARY PUBLIC

Commission expires:

EXPIRES 7 GEORGIA MARCH 27, 2027

JUNE FAIRCLOTH, CHAD DOLLAR, KERI)
DOLLAR, JOHN T. REYNOLDS, JR.,)
MYRNA D. (PENNY) REYNOLDS, JOHN T.)
REYNOLDS, III, DANA MARTIN, KRISTINA)
MARTIN, DAVID BARBER, DONNA) Civil Action No
BARBER, LARRY FUNDERBURKE,)
CAROLYN FUNDERBURKE, WALTER)
(TED) LEE, LISA DASILVA, ELISE BOYD,)
EPIC DESIGN BY JUNE FAIRCLOTH, LLC,)
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE)
II LLC,)
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Plaintiffs)
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SAFER HUMAN MEDICINE, INC.,)))
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SAFER HUMAN MEDICINE, INC., DECATUR COUNTY-BAINBRIDGE INDUSTRIAL DEVELOPMENT AUTHORITY, and DEVELOPMENT AUTHORITY OF BAINBRIDGE AND)))))))))))))))))))

VERIFICATION

I. Larry Funderburke, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

Sworn to and subscribed before me this 127 day of July, 2024

Commission expires: Jan. 25, 2027

COURTNEY CHAVERS Notary Public - State of Georgia Decatur County My Commission Expires Jan 25, 2027

DOLLAR, JOHN T. REYNOLDS, JR., MYRNA D. (PENNY) REYNOLDS, JOHN T. REYNOLDS, III, DANA MARTIN, KRISTINA)		
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MARTIN, DAVID BARBER, DONNA)	Civil Action No.	
BARBER, LARRY FUNDERBURKE,)	
CAROLYN FUNDERBURKE, WALTER)	
(TED) LEE, LISA DASILVA, ELISE BOYD,		
EPIC DESIGN BY JUNE FAIRCLOTH, LLC,)	
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE)	
II LLC,)	
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Plaintiffs,)	
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v.)	
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SAFER HUMAN MEDICINE, INC.,)	
DECATUR COUNTY-BAINBRIDGE)	
INDUSTRIAL DEVELOPMENT)	
AUTHORITY, and DEVELOPMENT)	
AUTHORITY OF BAINBRIDGE AND)	
DECATUR COUNTY)	
)	
Defendants.)	

VERIFICATION

1, Carolyn Funderburke, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

Carolyn Funderburke

Sworn to and subscribed before me

this 12th day of July, 2024

Commission expires: Jan . 25th. 2027

COURTNEY CHAVERS Notary Public - State of Georgia **Decatur County** kiy Commission Expires Jan 25, 2027

Plaintiffs,) SAFER HUMAN MEDICINE, INC., DECATUR COUNTY-BAINBRIDGE INDUSTRIAL DEVELOPMENT AUTHORITY, and DEVELOPMENT AUTHORITY OF BAINBRIDGE AND DECATUR COUNTY) Defendants. VERIFICATION 1, Lisa DaSilva, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best-of my knowledge. Sworm to and subscribed before me this 12 day of July, 2024 NOTARC PUBLIC Commission expires: Quil 21 2026 IN THE SUPERIOR COURT OF DECATURE COUNTY STATE OF GEORGIA IN THE SUPERIOR COURT OF DECATURE COUNTY STATE OF GEORGIA IN THE SUPERIOR COURT OF DECATURE COUNTY STATE OF GEORGIA	
SAFER HUMAN MEDICINE, INC., DECATUR COUNTY-BAINBRIDGE INDUSTRIAL DEVELOPMENT AUTHORITY, and DEVELOPMENT AUTHORITY OF BAINBRIDGE DECATUR COUNTY Defendants. VERIFICATION 1. Lisa DaSilva, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best-of my knowledge. Sworn to and subscribed before me this 12 day of July, 2024 August WILL August NOTARY PUBLIC Commission expires: Quil 21, 2021 IN THE SUPERIOR COURT OF DECATUR COMPTS UBLIC.	
SAFER HUMAN MEDICINE, INC., DECATUR COUNTY-BAINBRIDGE INDUSTRIAL DEVELOPMENT AUTHORITY, and DEVELOPMENT AUTHORITY OF BAINBRIDGE AND DECATUR COUNTY Defendants. VERIFICATION I, Lisa DaSilva, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best-of-my knowledge. Sworm to and subscribed before me this 12 day of July, 2024 Avaisat OTAR NOTARE PUBLIC Commission expires: Quil 21, 2021 IN THE SUPERIOR COURT OF DECATUR COUNTY CO	
SAFER HUMAN MEDICINE, INC., DECATUR COUNTY-BAINBRIDGE INDUSTRIAL DEVELOPMENT AUTHORITY, and DEVELOPMENT AUTHORITY OF BAINBRIDGE AND DECATUR COUNTY Defendants. VERIFICATION I, Lisa DaSilva, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best-of-my knowledge. Sworm to and subscribed before me this 12 day of July, 2024 Avaisat OTAR NOTARE PUBLIC Commission expires: Quil 21, 2021 IN THE SUPERIOR COURT OF DECATUR COUNTY CO	
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INDUSTRIAL DEVELOPMENT AUTHORITY, and DEVELOPMENT AUTHORITY OF BAINBRIDGE AND DECATUR COUNTY Defendants. VERIFICATION I, Lisa DaSilva, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge. Lisa DaSilva Sworn to and subscribed before me this 12 day of July, 2024 Manual NOTAR PUBLIC Commission expires: April 21, 2026 IN THE SUPERIOR COURT OF DECATUR COUNTY COURT OF DECATURE COURT OF	
AUTHORITY, and DEVELOPMENT AUTHORITY OF BAINBRIDGE AND DECATUR COUNTY Defendants. VERIFICATION 1. Lisa DaSilva, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best-of my knowledge. Sworm to and subscribed before me this 12 day of July, 2024 August NOTARY PUBLIC Commission expires: 1 pul 21, 2021 IN THE SUPERIOR COURT OF DECATUR COUNTS COU	
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DOLLAR, JOHN T. REYNOLDS, JR.,	
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REYNOLDS, III, DANA MARTIN, KRISTINA	
MARTIN, DAVID BARBER, DONNA) Civil Action	
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BARBER, LARRY FUNDERBURKE,	
CAROLYN FUNDERBURKE, WALTER)	
(TED) LEE, LISA DASILVA, ELISE BOYD,	
EPIC DESIGN BY JUNE FAIRCLOTH, LLC,	
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE	
II LLC,	
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Plaintiffs,	
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SAFER HUMAN MEDICINE, INC.,	
DECATUR COUNTY-BAINBRIDGE	
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JUNE FAIRCLOTH, CHAD DOLLAR, KERI)	
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MYRNA D. (PENNY) REYNOLDS, JOHN T.)	
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EPIC DESIGN BY JUNE FAIRCLOTH, LLC,	
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE)	
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INDUSTRIAL DEVELOPMENT)	
AUTHORITY, and DEVELOPMENT)	
AUTHORITY OF BAINBRIDGE AND)	
DECATUR COUNTY)	
)	
Defendants.	

VERIFICATION

I, John T. Reynolds, III, state that I have read the foregoing Complaint for Relief, and the

facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

John T. Reynolds, III

Sworn to and subscribed before me this 12 day of July, 2024

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NOTARY PUBLIC

Commission expires: Florwary 2,2025



JUNE FAIRCLOTH, CHAD DOLLAR, KERI)
DOLLAR, JOHN T. REYNOLDS, JR.,)
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BARBER, LARRY FUNDERBURKE,)
CAROLYN FUNDERBURKE, WALTER)
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EPIC DESIGN BY JUNE FAIRCLOTH, LLC,)
L2 BAINBRIDGE LLC, and L2 BAINBRIDGE)
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DECATUR COUNTY-BAINBRIDGE)
INDUSTRIAL DEVELOPMENT)
AUTHORITY, and DEVELOPMENT)
AUTHORITY OF BAINBRIDGE AND)
DECATUR COUNTY)
)
Defendants.)

VERIFICATION

I, Myrna D. (Penny) Reynolds, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

Penny Reynolds

Sworn to and subscribed before me this 12 day of July, 2024

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NOTARY PUBLIC

Commission expires: February 2,2025



JUNE FAIRCLOTH, CHAD DOLLAR, KERI)
DOLLAR, JOHN T. REYNOLDS, JR.,)
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INDUSTRIAL DEVELOPMENT)
AUTHORITY, and DEVELOPMENT)
AUTHORITY OF BAINBRIDGE AND)
DECATUR COUNTY)
)
Defendants.	_)

VERIFICATION

I, John T. Reynolds, Jr. state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

ohn T. Reynolds, Jr.

Sworn to and subscribed before me

this 12 day of July, 2024 August

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NOTARY PUBLIC

Commission expires: Florwary 2,2025



JUNE FAIRCLOTH, CHAD DOLLAR, KERI)	
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INDUSTRIAL DEVELOPMENT	
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AUTHORITY OF BAINBRIDGE AND	
DECATUR COUNTY)	
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Defendants.	
VERIFICAT	ION
I, Walter (Ted) Lee, state that I have read the f	oregoing Complaint for Relief, and the facts
	

set forth in this Complaint for Relief are true and correct to the best of my knowledge.

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this \mathcal{A}	day of Ayop\$2024	
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INDUSTRIAL DEVELOPMENT)		
AUTHORITY, and DEVELOPMENT)		
AUTHORITY OF BAINBRIDGE AND)		
DECATUR COUNTY)		
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Defendants.		

VERIFICATION

I, Chad Dollar, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

Chag Dollar

Sworn to and subscribed before me this /2 day of July, 2024

NOTARY PUBLIC

JUNE FAIRCLOTH, CHAD DOLLAR, KERI)
DOLLAR, JOHN T. REYNOLDS, JR.,)
MYRNA D. (PENNY) REYNOLDS, JOHN T.)
REYNOLDS, III, DANA MARTIN, KRISTINA)
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BARBER, LARRY FUNDERBURKE,)
CAROLYN FUNDERBURKE, WALTER)
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DECATUR COUNTY-BAINBRIDGE)
INDUSTRIAL DEVELOPMENT)
AUTHORITY, and DEVELOPMENT	
AUTHORITY OF BAINBRIDGE AND)
DECATUR COUNTY)
)
Defendants.	

VERIFICATION

I, Keri Dollar, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

Keti Dollar

Sworn to and subscribed before me

this 17th day of July, 2024

NOTARY PUBLIC

JUNE FAIRCLOTH, CHAD DOLLAR, KER	I)
DOLLAR, JOHN T. REYNOLDS, JR.,	j.
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BARBER, LARRY FUNDERBURKE,)
CAROLYN FUNDERBURKE, WALTER)
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DECATUR COUNTY)
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Defendants.)

VERIFICATION

I, Dana Martin, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

Dana Martin

Sworn to and subscribed before me this D day of July, 2024

August

NOTARY PUBLIC

JUNE FAIRCLOTH, CHAD DOLLAR, KERI)	
DOLLAR, JOHN T. REYNOLDS, JR.,	
MYRNA D. (PENNY) REYNOLDS, JOHN T.)	
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INDUSTRIAL DEVELOPMENT)	
AUTHORITY, and DEVELOPMENT)	
AUTHORITY OF BAINBRIDGE AND)	
DECATUR COUNTY)	
Defendants.	

VERIFICATION

I. Kristina Martin, state that I have read the foregoing Complaint for Relief, and the facts set forth in this Complaint for Relief are true and correct to the best of my knowledge.

Kristina Martin

Sworn to and subscribed before me this 12 day of July, 2024

August

NOTARY PUBLIC

Commission expires:

EXHIBIT A

HOME > NEWS > SCIENCEINSIDER > IN A FIRST, STATE BILL WOULD REQUIRE NEARLY PERFECT WELFARE RECORD FOR RESEARCH DOG AND CAT SUPPLIERS

SCIENCEINSIDER PLANTS & ANIMALS

In a first, state bill would require nearly perfect welfare record for research dog and cat suppliers

Unanimously passed Virginia law, now awaiting governor's approval, targets research beagle supplier Envigo

9 MAR 2022 · 3:40 PM ET · BY MEREDITH WADMAN



A dam with eight puppies in a small cage that violated Animal Welfare Act space requirements during a July 2021 inspection at Envigo's Cumberland, Virginia facility. RACHEL PEREZ-BAUM/USDA

SHARE:

















Update, 7 April, 4 p.m.: On 4 April, Virginia Governor Glenn Youngkin signed the bill into law.

A major supplier of dogs and other animals for academic and corporate research, which was cited last year for dozens of Animal Welfare Act (AWA) violations at its Virginia beagle-breeding facility, was targeted by the state's lawmakers this week. On 7 and 8 March, both houses of the Virginia General Assembly unanimously passed a bill that would cripple a large facility run by a

company called Envigo if a single serious animal welfare offense is documented there. The bill was sent yesterday to the desk of Republican Governor Glenn Youngkin, who has 30 days to sign or veto it, although any veto could be overturned with enough votes from legislators.

The legislation does not specify Envigo by name but is clearly designed to apply to the firm, the leading research animal supplier in the state. The bill would make Virginia the first state able to punish research animal breeders for violations of the AWA, a federal law enforced by the U.S. Department of Agriculture (USDA).

If it is signed into law, Virginia facilities that breed cats or dogs for research will be prohibited from selling the animals for 2 years if USDA inspectors document a single serious animal welfare violation, beginning on 1 July 2023. Facilities would face the same penalty if they are cited for three lesser violations, or for refusing access to USDA inspectors twice consecutively. USDA itself can remove a breeding facility's license after egregious, repeated violations, but that slow-moving regulatory process typically takes years. The agency confirmed today that it has opened an investigation of Envigo, the first step in such a process.

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The Virginia law is "brilliant" for providing states an immediate means to police research breeders, which are frequently exempt from state animal cruelty laws, says Russ Mead, an animal law professor at Lewis and Clark Law School. "This new Virginia [bill] is a road map to states who want to shut down the cruelest operators." He adds that "It should be the USDA, not the state of Virginia, shutting down breeders with AWA violations. But the dogs won't care who ends the nightmare."

Americans for Medical Progress, a group that supports responsible animal research, declined to comment directly on the bill. But its executive director, Paula Clifford, emphasized the need for animal research in an emailed statement: "Animal studies in a wide variety of species—including limited research involving dogs—remain critically important for continued advancements in human medicine ... [and] new veterinary treatments and medications."

Virginia lawmakers made it clear they were responding to <u>dozens of animal welfare act violations</u> that USDA documented during unannounced inspections at Envigo's nearly 5000-beagle facility in Cumberland <u>in July</u> and <u>October</u> 2021, as well as to <u>an undercover investigation</u> by People for the Ethical Treatment of Animals (PETA), published last fall. "We're doing this because of what these reports have revealed. We're doing this because of the film and footage," State Senator William Stanley said at a subcommittee hearing last month.

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A puppy's front paws protrude through a large gap between the cage floor and gate, one of dozens of Animal Welfare Act violations found during a July 2021 inspection of Envigo's Virginia facility. RACHEL PEREZ-BAUM/USDA

The 2021 violations documented by USDA included untreated, ill, and injured dogs; gutters overflowing with feces; dozens of dogs euthanized after being wounded by other dogs; and more than 300 puppy deaths that Envigo attributed to unknown causes and did not investigate. One staff veterinarian was responsible for about 5000 dogs. Of 39 citations issued in July and October 2021, 19 were in the serious categories that would shut down sales immediately under the Virginia legislation.

"For dogs, Virginia is now poised to become a leader in Animal Welfare Act enforcement and we urge other states to follow in its steps," said Daphna Nachminovitch, senior vice president of cruelty investigations at PETA. The advocacy group said its investigation included footage of workers with no veterinary credentials injecting euthanasia drugs directly into puppies' hearts without sedation, and soaking dogs to the skin with water from high pressure hoses.

Envigo, which was valued at \$545 million when it was acquired by the larger contract research organization Inotiv last year, said in a statement: "Envigo is following the Virginia legislative process and has provided relevant testimony during the committee discussions. We are proud of the investments and improvements we have made at the Cumberland, Virginia, facility and continue to work with policymakers to ensure the critical need for human and animal medical research is met in a safe and humane way."

The company also said yesterday it "has made significant progress in hiring and inventory reduction to drop our ratio of dogs to staff members from 167 to 115," in part by adopting out more than 400 dogs.

Indiana-based Inotiv brought its top brass to the Virginia state capitol of Richmond to lobby against the bill. But CEO Robert Leasure and Jim Harkness, the company's chief operating officer for research models and services, failed to persuade lawmakers: The bill was passed on votes of 98-0 and 39-0 in the House of Delegates and the Senate respectively.

Envigo has supplied beagles to research universities; government agencies such as the U.S. Food and Drug Administration and the U.S. National Institutes of Health (NIH); medical centers such as the Children's Hospital of Philadelphia; and major drug developers including AstraZeneca and Genentech.

The NIH, which obtained beagles from Envigo under three contracts in the last 18 months, said on Tuesday that <u>the most recent</u> of those contracts, which expires on 12 March, will not be renewed. "No future purchases are planned" from Envigo, agency spokeswoman Emma Wojtowicz said in an email.

Three related bills were also sent to Youngkin's desk on unanimous votes. They amend Virginia's animal cruelty law to extend its protections to dogs and cats raised for research, require research breeders to adopt out cats and dogs they don't need, and require breeders to submit records quarterly on all dogs and cats sold for research.

Correction, 9 March, 4:30 p.m.: This article has been updated to correct the name of the governor of Virginia, and to note that one bill requires quarterly, not annual, submissions.

doi: 10.1126/science.adb1967

RELEVANT TAGS:

PLANTS & ANIMALS

POLICY

SCIENTIFIC COMMUNITY

ABOUT THE AUTHOR



Meredith Wadman 🞽 X

Author

Meredith Wadman has been a staff writer in *Science*'s Washington, D.C., bureau since 2016. Her beat focuses on the intersection of biology and policy and ranges from the health effects of climate change to the investigation of sexual harassment. A University of Oxford—trained physician and Columbia University Journalism School graduate, Wadman turned to medical reporting after a career-bending experience in South Africa, where she worked as a medical student in an overwhelmed hospital during the apartheid era. She spent 2 decades covering medical research and policy from Washington, D.C., for *Nature* and *Fortune*. Her reporting has won awards from Time Warner and the American Society of Tropical Medicine and Hygiene.

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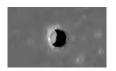
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EXHIBIT B

UNITED STATES DISTRICT COURT WESTERN DISTRICT OF VIRGINIA LYNCHBURG DIVISION

CLERK'S OFFICE U.S. DIST. COURT
AT LYNCHBURG, VA
FILED
5/21/2022

JULIA C. DUDLEY, CLERK
BY: S/ C. Amos
DEPUTY CLERK

UNITED STATES OF AMERICA,

v.

Case No.: 6:22-cv-00028

Plaintiff,

J

ENVIGO RMS, LLC,

TEMPORARY RESTRAINING ORDER (ISSUED EX PARTE)

Judge Norman K. Moon

Defendant.

On May 19, 2022, the United States of America filed a complaint and motion requesting an *ex parte* temporary restraining order directed against Envigo, a company that breeds and sells animals for use in scientific research. Envigo's facility in Cumberland, Virginia, raises thousands of beagles for these purposes at any given time. This Court now concludes that the Government has provided sufficient evidence that Envigo is engaged in serious and ongoing violations of the Animal Welfare Act, and that an immediate temporary restraining order must issue to put a halt to such violations pending further proceedings.

Over 300 beagle puppies have died onsite due to "unknown causes" over seven months. Many were not given anesthesia before they were euthanized by intracardiac injection. Beagles with even minor injuries or easily treated medical conditions were euthanized rather than given veterinary care. Nursing female beagles were denied food, and so they (and their litters) were unable to get adequate nutrition. The food that the beagles did receive was observed to contain live insects, worms, maggots, beetles, flies, ants, mold, and feces.

Beagle puppies remained housed in their enclosures as they were hosed down with cold water, leaving them shivering. Over an eight-week period, 25 beagle puppies died from cold exposure. The enclosures were overcrowded. The facility was understaffed. Inspectors found over 900 beagle and beagle puppy records to be incomplete or inaccurate. The list of serious violations of the Animal Welfare Act and its regulations goes on and on. Indeed, pursuant to federal search warrant executed days ago (May 18, 2022), law enforcement has seized 145 dogs and puppies from the facility that veterinarians determined needed immediate care to alleviate life-threatening illnesses or injuries.

The Government has demonstrated that extraordinary relief in the form of an *ex parte* temporary restraining order is warranted to put an immediate halt to such practices. Defendants will have the opportunity to plead their case on an expedited basis.

Background

Congress enacted the Animal Welfare Act ("AWA"), in part, "to insure that animals intended for use in research facilities ... are provided humane care and treatment." 7 U.S.C. § 2131(1); *People for the Ethical Treatment of Animals v. U.S. Dep't of Ag.*, 861 F.3d 502, 508 (4th Cir. 2017) ("Congress passed the AWA in 1966 to regulate the research, exhibition, and sale of animals, as well as to assure their humane treatment.").

The AWA authorizes the Secretary of Agriculture to "promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of [the AWA]." 7

U.S.C. §§ 2132(b), 2151. The Secretary has promulgated many such regulations under the AWA. See 9 C.F.R. § 1.1–3.142. The AWA and its regulations "set forth minimum requirements for the treatment of animals by dealers, research facilities, and exhibitors, including how animals are to be handled, housed, fed, transported, and provided veterinary care." *United States v. Lowe*, No.

20-cv-0423, 2021 WL 149838 at *11 (E.D. Okla. Jan. 15, 2021) (citing 7 U.S.C. § 2143(a)(1)-(a)(2)(A); 9 C.F.R. § 3.1-.142).

Envigo RMS, LLC operates a facility in Cumberland, Virginia where it deals in beagles intended for use at research facilities. Dkt. 1 ("Compl.") ¶ 3. Up to 5,000 beagles have been housed at this facility since July 2021. *Id.* In 2019, the United States Department of Agriculture ("USDA") issued Envigo a "Class A" license under the AWA to breed and sell dogs (AWA license 32-A-0774). *Id.* ¶¶ 3, 48; Dkt. 2-1 p. 3.

Between July 2021 and March 2022, USDA's Animal and Plant Health Inspection

Service ("APHIS") conducted five inspections of Envigo's Cumberland facility—documenting
over 60 citations for Envigo's failing to comply with the AWA and its regulations, and over half
of those were "critical" or "direct" violations, which are the most serious type of violation. *See*Compl. ¶¶ 4, 50–54; Dkts. 2-2 – 2.6.² On May 18, 2022, USDA agents and other law
enforcement officers executed a federal search warrant at the Cumberland facility, seizing 145
dogs and puppies that were determined to be in "acute distress" and needing immediate
veterinary care to alleviate life-threatening illnesses or injuries. Compl. ¶ 55; Dkt. 2-8 ¶ 8

("Moffett Decl."); Dkt. 2-9 ¶ 6 ("Hollingsworth Decl.").

On May 19, 2022, the Government filed this federal lawsuit against Envigo, alleging six violations of the Animal Welfare Act and its implementing regulations. *See* Compl. Later that

¹ In November 2021, Inotiv, Inc., announced it had acquired Envigo, but the site still operates under Envigo's AWA license. Compl. ¶ 52.

² These include a "routine inspection" and a separate "focused inspection" conducted in July 2021 (Dkts. 2-2, 2-3), a focused inspection conducted in October 2021 (Dkt. 2-4), a routine inspection conducted in November 2021 (Dkt. 2-5), and another focused inspection conducted in March 2022 (Dkt. 2-6).

day the Government also filed an *ex parte* motion and brief requesting that the Court issue a temporary restraining order against Envigo. *See* Dkts. 2, 2-1.

Standard of Review

Rule 65 of the Federal Rules of Civil Procedure provides that "[t]he court may issue a temporary restraining order without written or oral notice to the adverse party or its attorney only if" two conditions are met. Fed. R. Civ. P. 65(b)(1). First, the movant must provide "specific facts in an affidavit or a verified complaint [that] clearly show that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition." Fed. R. Civ. P. 65(b)(1)(A). Second, the movant's attorney must "certify in writing any efforts made to give notice and the reasons why it should not be required." Fed. R. Civ. P. 65(b)(1)(B).

A temporary restraining order "is intended to preserve the status quo only until a preliminary injunction hearing can be held." *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 422 (4th Cir. 1999); *see also Granny Goose Foods, Inc. v. B'hood of Teamsters & Auto Truck Drivers Local No. 70*, 415 U.S. 423, 439 (1974) (explaining that ex parte temporary restraining orders under federal law "should be restricted to serving their underlying purpose of preserving the status quo and preventing irreparable harm just so long as is necessary to hold a hearing, and no longer").

As with a plaintiff seeking a preliminary injunction, a plaintiff seeking a temporary restraining order³ must establish (1) "that he is likely to succeed on the merits," (2) "that he is likely to suffer irreparable harm in the absence of preliminary relief," (3) "that the balance of

³ "The standard for granting either a TRO or preliminary injunction is the same." *Toure v. Hott*, 458 F. Supp. 3d 387, 396 (E.D. Va. 2020) (quoting *Sansour v. Trump*, 245 F. Supp. 3d 719, 728 (E.D. Va. 2017)).

equities tips in his favor," and (4) "that the injunction is in the public interest." *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Moreover, "*Winter* made clear that *each* of these four factors must be satisfied to obtain preliminary injunctive relief." *Henderson ex rel. NLRB v. Bluefield Hosp. Co.*, 902 F.3d 432, 439 (4th Cir. 2018). Such relief constitutes an "extraordinary remedy" that is never awarded as of right. *See Winter*, 555 U.S. at 24.

The AWA includes a provision setting forth statutory "authority to apply for injunctions." 7 U.S.C. § 2159. It states that, "[w]henever the Secretary has reason to believe that any dealer, carrier, exhibitor, or intermediary handler ... is placing the health of any animal in serious danger in violation of this chapter of the regulations or standards promulgated thereunder, the Secretary shall notify the Attorney General." *Id.* § 2159(a). The Attorney General then "may apply to the United States district court in which such dealer, carrier, exhibitor, or intermediate handler resides or conducts business for a temporary restraining order or injunction to prevent any such person from operating in violation of this chapter of the regulations and standards prescribed under this chapter." *Id.* This provision further states that "[t]he court shall, upon a proper showing, issue a temporary restraining order or injunction under subsection (a) without bond." *Id.* § 2159(b).

Likelihood of Success on the Merits

1. Failure to Provide Adequate Veterinary Care

The Government contends that Envigo has consistently failed, despite repeated warnings and opportunities for correction, to meet its obligations under AWA's implementing regulations to provide adequate veterinary care. *See* Dkt. 2-1 pp. 10–11. Based on the overwhelming evidence produced by the Government, the Court agrees.

The AWA has authorized the Secretary of Agriculture to "promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors," which include the "minimum requirements" for "adequate veterinary care," among other things. 7 U.S.C. § 2143(a)(1)-(2)(A); *see also* 9 C.F.R. § 3.13 ("Veterinary care for dogs"); 9 C.F.R. § 2.40 ("Attending veterinarian and adequate veterinary care").

Programs of "adequate veterinary care" require "[d]aily observations of all animals to assess their health and well-being." 9 C.F.R. § 2.40(b)(3). While that "daily observation" need not always be conducted by a licensed veterinarian, "a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian." *Id.* ⁴ The regulations also require that medical observation be followed-up with "an appropriate program of veterinary care for dogs that is developed, documented in writing, and signed by the attending veterinarian." 9 C.F.R. § 3.13(a). The program must include a yearly physical examination by a veterinarian, vaccinations, treatment for parasites, and other preventative care; including "treatment to ensure healthy and unmatted hair coats, properly trimmed nails, and clean and healthy eyes, ears, skin, and teeth." Id. The program of medical care must be appropriate to "prevent, control, diagnose, and treat diseases and injuries." 9 C.F.R. § 2.40(b)(2). The Government has put forward evidence clearly showing that Envigo regularly failed, and continues to fail, to abide by those requirements; resulting in lasting and deteriorating serious health conditions that could have been rectified if observed and treated in a timely manner.

⁴ Indeed, the regulations require "the availability of emergency, weekend, and holiday care." 9 C.F.R. § 2.40(b)(3).

For instance, in July 2021, inspectors identified 15 beagles with medical problems that were not previously observed or treated by Envigo, including beagles that had eye and ear conditions, skin infections, wounds and lesions, and severe dental disease. Compl. ¶ 65; Dkt. 2-2 pp. 1–5. One beagle was found with "patchy hair loss" covering over 70% of her body and yellow scabs. Dkt. 2-2 p. 2.

During the November 2021 inspection, inspectors identified 30 beagles with severe dental disease that had not been treated despite having been observed by Envigo staff. Compl. ¶ 57; Dkt. 2-5 p. 2. One nursing female was clearly emaciated. Dkt. 2-5 p. 2. Records showed that she had been underweight for three months, yet she had not received any medical attention. Id. Seven beagles had foot conditions, one beagle had an ear infection, and another had large patches of hair loss along its entire back. Dkt. 2-5 pp. 2-3. The inspectors found another 34 beagles with medical conditions that had not been previously observed or treated by Envigo, including: seven beagles with severe dental disease; three beagles with weakness or lethargy; eight beagles and beagle puppies with traumatic wounds "to the legs, chest, abdomen, neck, ears and tails," many of which appeared to have dried blood matting fur; eight beagles with lameness or foot medical conditions; six with eye conditions; two with ear conditions; three with skin conditions; and two with masses, including a beagle puppy with a "large, soft, fluid filled, swelling on the top of his head." Dkt. 2-5 p. 3-4. Medical records also indicated several instances of beagles that had died from some ailment which would ordinarily be preceded by significant clinical signs—yet records did not indicate that any such observations were made. Compl. ¶¶ 69–70; e.g., Dkt. 2-5 p. 4 (necropsy for beagle stated she was diagnosed with a ruptured uterus, with no records of prior symptoms). To be clear, these are but a few examples of the many failures in veterinary care documented in the APHIS inspections before the Court. *See also* Dkts. 2-2-2-6.

Envigo's level of veterinary care for its beagles has not improved since those earlier inspections. Veterinary exams ensuing from the May 18, 2022, search warrant determined that 145 beagles were in "acute distress," meaning that the beagles required "immediate veterinary treatment or other care to promptly alleviate a life-threatening illness/injury or any suffering." Moffitt Decl. ¶ 8. The Court understands this number is likely to grow as the Government's veterinarians continue to examine dogs throughout the weekend. Dkt. 2-1 p. 6. Even those beagles not currently in "acute distress" are suffering from significant and serious health conditions, including wounds that required wound care and antibiotics or anti-inflammatory medications, or swollen or enflamed paws, or had dental disease, or other health issues.

Many beagles and beagle puppies did not make it that far. Mortality records indicate that over 300 beagle puppies died between January and July of last year as a result of "unknown causes." Dkt. 2-3 p. 1. Over 150 beagle puppies under 5 weeks of age, and 16 adult beagles, were found dead and medical records indicated their corpses had already begun to decompose and so no other cause of death could be identified. *Id.* 2.9 Despite these harrowing statistics, Envigo's

⁵ See, e.g., Dkt. 2-11 (veterinary records) ECF pp. 2, 3, 4, 6 (diagnosed with puncture wounds, scarring, "missing quarter sized part of ear"), 66. Other beagles suffered from reducible umbilical hernias requiring surgical correction. *Id.* 8, 37, 59, 60.

⁶ See, e.g., Dkt. 2-11 ECF pp. 9, 10, 12, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, et seq.

⁷ See, e.g., Dkt. 2-11 ECF pp. 5, 8, 18, 22, 24, 25, 27, 74, 75, 76.

⁸ See, e.g., Dkt. 2-11 ECF pp. 73 (abscess on head), 79 ("fecal impaction on all four feet, painful dental disease"), 47 ("very thin," recommending "monitor, improve nutrition"), 55 ("very distended abdomen," and recommending de-wormer), 56, 58, 61 (same).

⁹ For instance, more recent medical records detail one particularly grisly, current similar instance. Dkt. 2-7 (necropsy report, reading: "unknown – pup eat[e]n – only has a head left").

attending veterinarian apparently does not require Envigo staff to notify her when a puppy is found dead. Compl. ¶ 72; Dkt. 2-3 p.1. The Government maintains, and the Court agrees, that such a policy is inconsistent with Envigo's obligation to utilize methods appropriate to the prevention of disease and injury. *See* Compl. ¶ 72. Those medical records which are present (even if incomplete) and other evidence submitted further demonstrate that Envigo was failing to attend to beagles' wellbeing or provide them adequate veterinary care with respect to any injuries, illnesses, or serious health conditions which caused the deaths of these particular beagles and beagle puppies and further suggest Envigo's failure to make efforts to learn from these (hundreds) of premature deaths to ensure other litters' health and safety.

The Government has alleged that Envigo instead used non-veterinarian employees both to provide medical care and to euthanize beagles. Compl. ¶¶ 60–61. Perhaps the most heinous discovery of the November 2021 inspection was that Envigo had allowed staff to euthanize dogs without anesthesia, in violation of the facility's own program of care. *Id.* ¶ 62; Dkt. 2-5 p. 1 ("Inspectors reviewed 171 medical records documenting euthanasia of 196 dogs and puppies and found that many young puppies are not receiving anesthesia prior to being euthanized via intracardiac injection as required by the SOP."). The October 2021 inspection similarly showed that medical care, including medication for serious ailments, was provided by non-veterinary staff, even though this was a violation of Envigo's program of medical care. Compl. ¶ 63; Dkt. 2-4 p. 1. Records also showed that many beagles did not receive their annual physical at all. Dkt. 2-5 pp. 20.

Based on the foregoing evidence, the Court concludes that the Government is likely to succeed on the merits by showing that Envigo has failed to provide beagles at its Cumberland facility with adequate veterinary care, in violation of 9 C.F.R. §§ 3.13, 2.40, among others.

2. <u>Failure to Provide Uncontaminated, Wholesome, Palatable Food of Sufficient Quantity and Nutritive Value and to Make Potable Water Continuously Available</u>

The Government's evidence also displays a disturbing failure by Envigo to meet its obligation to provide each beagle with clean, palatable food of adequate quantity and nutritive value. *See* Dkt. 2-1 pp. 11–12.

A. Food and Water Quality

Minimum standards of nourishment are established by 9 C.F.R. § 3.9, which provides, in relevant part, that dogs must be fed, "at least once each day," "uncontaminated, wholesome, palatable" food that is of "sufficient quantity and nutritive value." *Id.* § 3.9(a). It also provides that food receptacles must be "located so as to minimize contamination by excreta and pests." *Id.* § 3.9(b). Water must be potable and water receptacles must be kept clean and sanitized according to prescribed standards. *Id.* § 3.10(a) & (c).

The July 2021 inspectors discovered that nursing females were being denied food for 42-hour periods—apparently in an effort to reduce milk production. Dkt. 2-2 p. 6. In lieu of the daily feeding required by § 3.9(a), food receptacles were placed in front of the mothers' enclosures, so that they could see and smell the food but not eat it. *Id.* 7. *See also id.* ("Three dams were observed to be reaching their front paws through the doors of the cages to reach the food in the top of their feeders, these dogs were seen trying to scoop or dig out food from the feeders but could only retrieve the occasional piece of kibble."). The reduced milk production resulting from this practice almost certainly meant that nursing puppies were not having their nutritional needs met either. *See* Compl. ¶¶ 80–81.

When food was provided, it clearly fell short of the "uncontaminated, wholesome, [and] palatable" requirement. The July 2021 investigation found that the beagles' food contained live

insects. Dkt. 2-3 pp. 11–12. *See also id.* 11 (recording inspectors' observation of ants "going in and out of self feeders").

Envigo fared no better in the November 2021 inspection. Taking random samples of food contained in receptacles in two rooms, inspectors found in each instance that food was "wet, caked, and/or moldy." Dkt. 2-5 p. 15. Two receptacles also contained "large numbers of maggots." *Id.* Envigo was again directed to correct the issue. *Id.* Inspectors also noted that food receptacles were mounted in such a way that back-splashed water containing feces was mixed into the beagles' food when staff pressure washed the enclosures. *Id.* 16.

In March 2022, inspectors again found that "self-feeders at the facility are not being cleaned adequately and do not prevent molding, deterioration, and caking of feed." Dkt. 2-6 p. 6.

B. Food and Water Access

Respecting access to food and water, the regulations provide that water must be continually available, 9 C.F.R. § 3.10(a), and that a dog's food must be "readily accessible," *id.* § 3.9(b).

The July 2021 inspection nevertheless revealed that Envigo failed to make food receptacles available to all of the dogs in its facility. Dkt. 2-5 pp. 15–16. Between four to eleven animals were forced to share a single receptacle, which could be accessed by only one dog at a time. *Id.* 16. Despite being instructed to correct the issue, *id.*, Government officials observed the same problem when executing the search warrant on May 18. Dkt. 2-10 ¶ 21 ("Taylor Decl."). One investigator observed that each receptacle contained the same food, regardless of whether the enclosure housed adult dogs, nursing mothers, or young puppies. *Id.* ¶ 20. *See also* Moffitt Decl. ¶ 9 (noting that puppies and younger dogs have "food needs that are different from the

food needs of adult dogs"). The inspector also observed that many beagles, including puppies, could not access water spigots. Taylor Decl. ¶ 18.

Based on the foregoing evidence, the Court concludes that the Government is likely to succeed on the merits by showing that Envigo has failed to provide beagles at its Cumberland facility the minimum standards for nourishment, in violation of 9 C.F.R. § 3.9, and continually available water and readily accessible food, in violation of § 3.9 and § 3.10(a).

3. Failure to Maintain Minimum Handling & Housing Standards to Keep Dogs Safe

The Government contends that Envigo is failing to meet the minimum standards for handling and housing the beagles in violation of the AWA, resulting in their suffering and death. Dkt. 2-1 p. 12. AWA regulations require that all animals be handled "as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort." 9 C.F.R. § 2.131(b)(1). "Physical abuse" and "deprivation of food or water" cannot be used to "train, work, or otherwise handle animals." *Id.* § 2.131(b)(2)(i)-(ii). Any "short-term withholding of food or water" is only allowed "as long as each of the animals affected receives its full dietary and nutrition requirements each day." *Id.* § 2.131(b)(2)(ii). Moreover, dogs that are "housed in the same primary enclosure must be compatible," and "[a]ny dog ... exhibiting a vicious or overly aggressive disposition must be housed separately[.]" 9 C.F.R. § 3.7.

The Government alleges and has offered evidence in support of the following facts. Due to overcrowding and incompatibility between dogs housed together, and due to inadequate protection from Envigo, beagles at the Cumberland facility have repeatedly injured one another and suffered injury, disease, and death due to exposure to the environment. Dkt. 2-1 p. 12.

Records show that 48 beagles at the facility were found with fight wounds between January and

July 2021, and that three dogs died from fight wounds. Dkt. 2-3 p. 8. APHIS inspectors instructed Envigo to ensure that there was a mechanism in place to protect the dogs from one another, but when inspectors returned to the facility in October 2021, they found more dogs with serious fight injuries. Dkt. 2-4 p. 9. Envigo staff had failed to notice the fight wounds. *Id.* Also in October 2021, a female beagle was found dead with evidence that her littermates had chewed on her; the mortality log attributed her death to evisceration. *Id.* p. 10. When APHIS investigators asked to talk to the employee who found the dead dog, they were told that the employee was unavailable. *Id.*

During a November 2021 inspection, APHIS inspectors noted continued aggression between the dogs, and the inspection had to be repeatedly stopped temporarily for fighting beagles to be separated. Dkt. 2-5 p. 14. Inspectors observed more of the same in March 2022. *See* Dkt. 2-6.

In addition to compatibility issues, APHIS inspectors found that Envigo had failed to provide the minimum amount of space needed to house 742 beagles and weaned puppies. *See* Dkt. 2-5 pp. 13–14. Inspectors observed beagles fighting over limited food. *Id.* pp. 15–16.

The records also show that Envigo has failed to keep beagle puppies safe by allowing them to become wet when Envigo staff hosed down their enclosures with water. *Id.* p. 7. In November 2021, inspectors found 21 puppies damp and shivering in building G3. *Id.* Three days later, inspectors found additional damp and cold puppies in building G3. *Id.* Envigo records show that in the eight weeks before the November 2021 inspection, 25 puppies had been found dead in building G3 with a cause of death attributable to cold exposure. *Id.*

The Government offers additional evidence arising from the execution of the search warrant in May 2022. Federal investigators observed "widespread fighting" between beagles

sharing food sources in the same cages. Taylor Decl. ¶¶ 15–16. Investigators also observed beagles fighting between adjacent cages; they observed "beagles stand[ing] on their hind legs to physically attack beagles located in adjacent enclosures through openings in the partition between the enclosures." *Id.* ¶ 16. Investigators noted inadequate partitions between the enclosures to prevent such fighting. *Id.*

Based on the foregoing evidence, the Court concludes that the Government is likely to succeed on the merits by showing that Envigo has failed to keep beagles at its Cumberland facility safe and is in violation of 9 C.F.R. § 2.131(b) and § 3.7.

4. Failure to Provide Safe and Sanitary Conditions

The Government's evidence also shows that Envigo has failed to fulfill its obligation to provide safe and sanitary living conditions for the beagles it houses.

A. Cleaning, Sanitation, and Pest Control

Minimum sanitation requirements are set forth in 9 C.F.R. § 3.11. Beginning with an animal's primary enclosure, the regulations provide that feces and food waste must be removed from the interior of enclosures daily, and from beneath enclosures as often as necessary to prevent soiling the dogs inside and to reduce risk of disease, attracting pests and insects, and creating odor. *Id.* § 3.11(a).

Used enclosures, as well as food and water receptacles, must be sanitized at least once every 2 weeks using prescribed methods. *Id.* § 3.11(b)(2). Surrounding buildings and grounds must be in good repair and free of trash and junk to protect dogs from injury. *Id.* § 3.11(c). And facilities must establish and maintain an effective program of pest control. *Id.* § 3.11(d).

In July 2021, inspectors observed a buildup of "brown organic material" inside enclosures housing nursing beagles and their puppies. Dkt. 2-3 p. 10. The facilities manager

admitted to inspectors that enclosures are disinfected only between liters or every six weeks. *Id.*Inspectors also noted that "[a]round the entire facility are large populations [of] live insects including house flies, drain flies, water bugs, cockroaches, and spiders with cobwebs." *Id.* 9.

Despite being directed to correct these issues, *id.* 9, 12, the October 2021 inspection revealed "accumulations of waste and an overpowering fecal odor" emanating from beneath a large percentage of enclosures, Dkt. 2-4 p. 11. The November 2021 inspection likewise found that Envigo had failed to clean waste under the beagles' enclosures with sufficient frequency to prevent accumulation of filth. Dkt. 2-5 p. 16. In some instances, moldy food and excreta was allowed to pile several inches high. *Id.* Predictably, the inspectors also observed infestations of insects, including large numbers of flies and maggots, in and around enclosures and in food receptacles. *Id.* 17. When investigators returned to execute the May 18, 2022, warrant, they observed bugs "present in many of the enclosures in this building." Taylor Decl. ¶ 8. They also observed mold and buildup of old food around the feeder. *Id.* ¶ 19.

B. Primary Enclosure Design Requirements

Envigo also had an obligation to construct its primary enclosures in such a way as to safely contain the beagles and protect them from other animals. 9 C.F.R. § 3.6(a)(2). Specific requirements include floors that protect dogs' feet and legs—e.g., floors that "do not allow the dogs' ... feet to pass through any openings in the floor." *Id.* § 3.6(a)(2)(x). Each primary enclosure must also provide a "minimum amount of floor space" in accordance with a statutory formula. *Id.* § 3.6(c)(1)(i). Additional floor space must be provided for a mother with nursing puppies. *Id.* § 3.6(c)(1)(ii).

As previously mentioned, Envigo's enclosures contain gaps that allow beagles to attack one another from adjacent enclosures. The July 2021 inspection showed that 71 beagles were

harmed in this way. Dkt. 2-3 at p. 7. Despite instruction to address this problem, *id.* 8, mortality records ¹⁰ reviewed during the next inspection revealed that nine beagles were injured in the same manner between August 2021 and October 2021, Dkt. 2-4 p. 8. When inspectors returned in November 2021, they again noted "numerous examples of body parts being pulled into adjacent enclosures by neighboring dogs causing injuries to the dogs involved." Dkt. 2-5 p. 12. Envigo was once again directed to address the issue. *Id.* But in March 2022, inspectors found major gabs in the fencing, including at least one that would have permitted beagles to pass easily between enclosures. Dkt. 2-6 p. 3.

The enclosures were also unsafe for occupants, and especially for puppies. July 2021 inspectors observed over 200 puppies housed in enclosures with gaps in the flooring that were large enough for the puppies' feet to fall through up to their shoulders. Dkt. 2-2 pp. 9–10. Inspectors observed one adult beagle with her front left paw caught in the flooring. *Id.* 10. Employees could not say how long the dog had been trapped. *Id.* Despite being directed to correct the issue, *id.*, inspectors observed the same problem during the October 2021 inspection. During the November 2021 inspection, inspectors determined that approximately 75% of enclosures had gaps as much as two inches wide between the flooring and fencing of enclosures, along with other issues. ¹¹ Dkt. 2-5 pp. 7–8. Inspectors observed six beagles actively stuck in the flooring. *Id.* 12. Upon their return in March 2022, inspectors found 130 enclosures with gaps large enough for a beagles' foot or leg to pass through. Dkt. 2-6 p. 3. They also observed two

 $^{^{10}}$ Envigo appears to have had a practice of euthanizing beagles that sustained even a minor injury. Compl. ¶¶ 75–77; Dkt. 2-3 p. 6; Hollingsworth Decl. ¶ 5.

¹¹ See Dkt. 2-5 p. 9 ("noting that in some enclosures, "the floors bounce up and down, shift, tilt, or sink under the weight of the dogs as they move about the enclosure.").

beagles stuck in the flooring, and medical records indicated that at least 12 additional dogs had been injured in the same way since the last inspection. *Id.* 4.

Investigators executing the May 18, 2022, search warrant found one "beagle with its jaw stuck within" the welded bars used for the enclosure walls. Taylor Decl. ¶ 10. They observed "widespread problems with the flooring in the enclosures," including several which moved up and down with the animals. Id. ¶ 11. Investigators also "repeatedly observed" beagles who were trapped in the flooring of their enclosures. Id. ¶ 12.

Envigo fairs no better with respect to floor space. In July 2021, inspectors observed 62 nursing mother beagles with a total of 393 puppies that were not provided the minimum required floor space. Dkt. 2-2 p. 11. And in November 2021, inspectors concluded that 742 beagles and weaned puppies lacked the minimum required space. Dkt. 2-5 pp. 13–14.

Based on the foregoing evidence, the Court concludes that the Government is likely to succeed on the merits by showing that Envigo has failed to provide beagles at its Cumberland facility safe and sanitary living conditions and safely designed enclosures, in violation of 9 C.F.R. § 3.11 and § 3.6.

Irreparable Harm

To secure a preliminary injunction or temporary restraining order, the movant must further establish that "he is likely to suffer irreparable harm in the absence of preliminary relief." *Winter*, 555 U.S. at 20.¹² Irreparable harm is that which is "actual and imminent," not "remote or

¹² The Court notes that some courts have held that because the AWA provides for a TRO or injunction upon satisfaction of the statutory standard, the traditional, four-part showing for an injunction including irreparable harm need not be satisfied. *See United States v. Gingerich*, No. 4:21-cv-283, 2021 WL 6144690, at *2 (S.D. Iowa Sept. 28, 2021). The Court has determined that the Government has satisfied the AWA's statutory requirements for injunctive relief, *see* 7 U.S.C. § 2159, as well as the four-part test, so the Court need not consider whether a temporary

speculative." *Direx Israel, Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 812 (4th Cir. 1991) (internal quotation marks omitted). "Generally, irreparable harm is suffered when monetary damages are difficult to ascertain or are inadequate." *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551 (4th Cir. 1994) (internal quotation marks omitted); *Variable Annuity Life Ins. Co. v. Coreth*, 535 F. Supp. 3d 488, 517 (E.D. Va. 2021) (quoting *Update, Inc. v. Samilow*, 311 F. Supp. 3d 784, 796 (E.D. Va. 2018)) (same). However, the "possibility that adequate compensatory or other corrective relief will be available at a later date ... weighs heavily against a claim of irreparable harm." *Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017). Rule 65(b) further states that a temporary restraining order without notice may only issue if the movant sets forth "specific facts in an affidavit or a verified complaint" that "clearly show that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition." Fed. R. Civ. P. 65(b)(1)(A).

The Court concludes that the Government has put forward a clear showing of irreparable harm if the temporary restraining order did not issue, and clearly shown with specific facts in affidavits (and other supporting evidence) that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition. *See Winter*, 555 U.S. at 20; *see also* Fed. R. Civ. P. 65(b)(1)(A). The AWA authorizes an application for injunctive relief when the Secretary "has reason to believe that any dealer, carrier, exhibitor, or intermediate handler ... is placing the health of any animal in serious danger in violation of this chapter" and its implementing regulations, 7 U.S.C. § 2159(a), and further states that "[t]he court

restraining order or injunction might in some other case issue absent irreparable harm. *See Lowe*, 2021 WL 149838, at *13–14.

shall, upon a proper showing, issue a temporary restraining order or injunction under subsection (a) without bond," *id.* § 2159(b).

As described above, the Court finds the Government has clearly demonstrated that irreparable harm will result absent injunctive relief. Specifically, Envigo has been operating and continues to operate in a manner that flagrantly disregards numerous health protocols, placing the health of animals in serious danger and risk of death. *See* 7 U.S.C. § 2159. USDA inspection records documented dozens of instances in which dogs were euthanized rather than provided medical care when they had an injury, no matter how substantial or minor. *E.g.*, Dkt. 2-3 p. 6; Hollingsworth Decl. ¶ 5.

Indeed, while USDA agents and other law enforcement officers have seized 145 of beagles at the Cumberland facility that were at the most acute and immediate risk to their health, Moffitt Deel. ¶ 8, many more beagles still face inadequate food and water, veterinary care, and the other torturous conditions described, Hollingsworth Deel. ¶ 6. The grave health risks to the beagles remaining in Envigo's care remain—they are immediate and substantial. In fact, as recently as May 18, 2022, USDA's teams conducting field-exams at the Cumberland facility found "two deceased puppies found in enclosures with their respective nursing mothers and littermates." Moffitt Deel. ¶ 7. An investigator found one beagle with its "jaw stuck within the welded bars" of its enclosure, *id.* ¶ 10; and had to assist six different beagles whose feet had gotten stuck in the flooring, *id.* ¶ 12. In multiple enclosures, puppies were unable to access the spigots to get water on their own, and when the investigator "held down the spigot to release water," the puppies "immediately rushed to the spigot to get water, and drank heavily and quickly." *Id.* ¶ 18. Simply put, the Court will not be able to unwind or in any way remedy the

physical harm done to these dogs at the end of this case if the Court does not grant the requested immediate relief.

The Court finds irreparable harm clearly shown and the AWA's statutory provisions authorizing injunctive relief satisfied. *See, e.g., Lowe*, 2021 WL 149838, at *14 (explaining that "the health and safety of the animals remaining in Defendants['] care continues to be at risk of irreparable harm absent injunctive relief').

Balance of Equities and Public Interest

The last two *Winter* factors are whether the balance of the equities tips in the plaintiff's favor, and the public interest is furthered by issuing the temporary restraining order. *See Winter*, 555 U.S. at 20. The Court concludes that each factor supports issuing the temporary restraining order against Envigo.

Turning first to the balance of the equities (or hardships), the Court does not discount that hiring sufficient staff, providing suitable enclosures and adequate veterinary care would impose costs on Envigo. It very well could be difficult to find and afford sufficient staff. However, any expense required to fulfill those obligations was voluntary taken by Envigo when it applied for and received a license by the USDA to raise animals intended for research facilities, namely that it would comply with the AWA and applicable regulations. For its part, the Government has a strong interest in ensuring compliance with federal law and regulations to safeguard humane treatment of animals, as well as to ensure the efficacy of USDA's inspection and licensing regime. In addition, as the Government argues, "it is always in the public interest for citizens to follow the law and not financially profit from their law-breaking endeavors." Dkt. 2-1 p. 16.

Especially considering the tailored nature of the relief sought by the Government, the Court concludes that any incremental added expense or other hardship faced by Envigo as necessary to

comply with governing regulations is significantly outweighed by the equities that weigh in the Government's favor.

The Court concludes that the public interest would be supported by issuing the temporary restraining order. *See Winter*, 555 U.S. at 20. The public interest "may be declared in the form of a statute," and "[a] federal statute prohibiting the threatened acts that are the subject matter of the litigation has been considered a strong factor in favor of granting a preliminary injunction." Charles Alan Wright & Arthur R. Miller, 11A Fed. Prac. & Proc. Civ. § 2948.4 (3d ed.). Here, issuing the temporary restraining order would give effect to Congress's purpose in enacting the AWA, to ensure that "animals intended for use in research facilities ... are provided humane care and treatment." 7 U.S.C. § 2131(1); *PETA*, 861 F.3d at 508 ("Congress passed the AWA in 1966 to regulate the research, exhibition, and sale of animals, as well as to assure their humane treatment."). Moreover, the Court agrees that injunctive relief is further supported against a regulated entity when a regulatory agency has issued it repeated warnings of its non-compliance, which have been ignored or insufficiently remedied. *See* Dkt. 2-1 p. 16.

Lastly, in addition to the Government's clear demonstration that all of the *Winter* factors weigh in support of the Court issuing a temporary restraining order, and further that the statutory requirements of the AWA have been satisfied for imposition of injunctive relief, the Court also finds that the Government has also satisfied Rule 65(b)(1)'s requirements for issuing a temporary restraining order without notice. As described above, the Government has provided "specific facts" in affidavits and other evidence that "clearly show that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party could be heard in opposition." *See id.*; *see supra*, Irreparable Harm. The Court further credits and finds persuasive the reasons cited by the Government attorney for why prior notice to Envigo should not be required before

the Court issues the temporary restraining order, noting particularly Envigo's repeated non-compliance with inspectors' violation reports and with the AWA, as well as the substantial, documented risk of irreparable harm in the absence of prompt injunctive relief. *See* Fed. R. Civ. P. 65(b)(1)(B); Hollingsworth Decl. ¶¶ 6–8. Moreover, the record is replete with instances of Envigo's failure to comply with AWA's documentation and recordkeeping requirements, and harm or injury to beagles that is severe and ongoing, not properly documented. Hollingsworth Decl. ¶ 7 (and supporting documents). The Court finds that prior notice and the resulting delay before the Court imposes the tailored, interim measures requested by the Government, would risk jeopardizing the ability to effectively enforce the AWA and protect the health of the beagles still in Envigo's care.

Conclusion

For the reasons discussed above, the Court has concluded that the Government has made a clear showing that the requested ex parte temporary restraining order should issue. Therefore, the Government's motion for a temporary restraining order will be and hereby is **GRANTED**.

See Dkt. 2. Defendant Envigo and its agents, servants, employees, and anyone who works in active concert with Envigo shall be **ORDERED** to comply with the following:

- I. Within <u>twenty-four (24) hours</u> of this Order, Envigo is **ORDERED** to
 - 1. Comply with the requirement in 9 C.F.R. § 3.7 that only compatible dogs are housed together in an enclosure.
- II. Within <u>forty-eight (48) hours</u> of this Order, Envigo is **ORDERED** to
 - 2. Provide to counsel for the United States the name and contact information for the attending veterinarian at the Cumberland Facility and a program of veterinary care that complies with 9 C.F.R. § 3.13.
 - 3. Ensure that every puppy who is no longer housed in the same enclosure with their nursing mother is provided access to potable water from a water receptacle that the puppy can easily drink from without any assistance.

4. Ensure that every beagle is provided uncontaminated, wholesome, palatable food of sufficient quantity and nutritive value to maintain the normal condition and weight of the animal. The diet must be appropriate for the individual animal's age and condition. Envigo must feed each beagle at least once a day. Envigo must seek consent of counsel for the United States or, if counsel does not consent, a court order to feed any animal less than once a day. See 9 C.F.R. § 3.9.

III. Within seven (7) days of this Order, Envigo is **ORDERED** to

5. Provide to counsel for the United States an inventory of every dog and puppy at the Cumberland Facility. The inventory must list each beagle individually with its sex, age, unique identification number, and enclosure location and number.

IV. Within fourteen (14) days of this Order, Envigo is **ORDERED** to

- 6. Add to each enclosure enough food receptacles so that every weaned puppy and dog in the enclosure can access food at the same time. *See* 9 C.F.R. § 3.9(b).
- 7. Comply with the requirement for flooring provided in 9 C.F.R. $\S 3.6(a)(2)(x)$.
- 8. Install solid partitions between all adjacent enclosures. See 9 C.F.R. § 3.1(a).

V. Envigo is further **ORDERED** to

- 9. Provide veterinary treatment by a licensed veterinarian, within **ten (10) days** of receiving field examination forms from the United States, in accordance with the recommendations set forth on the forms.
- 10. Provide to counsel for the United States medical records for any veterinary care provided to any dog or puppy at the Cumberland Facility within **seventy-two (72) hours** of the animal receiving care or treatment. All medical records must comply with 9 C.F.R. § 3.13(b), and must include:
 - a. the unique identification number, identifying marks, sex, and age of the dog;
 - b. if a problem is identified (such as a disease, injury, or illness), the date and a description of the problem, examination findings, test results, plan for treatment and care, and treatment procedures performed, when appropriate;
 - c. the names of all vaccines and treatments administered and the dates of administration;

- d. the dates and findings/results of all screening, routine, or other required or recommended test or examination.
- 11. Provide notice to counsel for the United States within **seventy-two (72) hours** of any dog or puppy found having injuries attributable to or consistent with a fight, as well as wounds of an unknown cause, including lacerations to ears and tail injuries.
- 12. Have a licensed veterinarian document the death of any dog or puppy and timely perform a necropsy.
- 13. Provide notice and a copy of the necropsy report to counsel for the United States within **seventy-two (72) hours** of receiving the necropsy report from the veterinarian.
- 14. Immediately cease disposing of any beagle at the Cumberland Facility by transferring from the Cumberland Facility or euthanizing any beagle at the Cumberland Facility without the consent of counsel for the United States or, if they do not consent, a court order. Any euthanasia must be performed by a licensed veterinarian or a licensed veterinary technician who is acting under the direct supervision of a licensed veterinarian.
- 15. Immediately cease breeding, selling, or otherwise dealing in beagles at the Cumberland Facility, until in full compliance with this order.
- 16. Provide notice to counsel for the United States within **seventy-two (72) hours** of the birth of any puppies, including the number of puppies born, the unique identification number of the dam, and the sex and unique identification numbers assigned to the puppies.
- 17. Permit unencumbered access to the Cumberland Facility by the United States, its agents and any contractor assisting the United States to check for compliance with this Order.

This Order shall be in effect for **fourteen (14) days** from the date of its issuance. Fed. R. Civ. P. 65(b)(2). No bond shall be required. Fed. R. Civ. P. 65(c); 7 U.S.C. § 2159(b).

It is further **ORDERED** that counsel for the United States shall serve a copy of this Order on Envigo forthwith.

The Clerk of the Court is directed to schedule a hearing on this temporary restraining order, as well as any motion thereon or other request for preliminary injunctive relief, on or about **ten (10) days** from the issuance of this Order. *See* Fed. R. Civ. P. 65(b)(3).

It is so **ORDERED**.

The Clerk of Court is directed to send a copy of this order to all counsel of record.

Entered this 21st day of May, 2022, at 11:50 a.m.

NORMAN K. MOON
SENIOR UNITED STATES DISTRICT JUDGE

EXHIBIT C

UNITED STATES DISTRICT COURT WESTERN DISTRICT OF VIRGINIA LYNCHBURG DIVISION

IN THE MATTER OF THE SEARCH
OF ENVIGO
482 FRENCH'S STORE RD
CUMBERLAND, VA 23040

Case No.	6:22mj3	
Case No.	0.ZZIIIJO	

AFFIDAVIT IN SUPPORT OF AN APPLICATION UNDER RULE 41 FOR A WARRANT TO SEARCH AND SEIZE

Stanley Wojtkonski, a Special Agent with the United States Department of Agriculture Office of Inspector General ("USDA-OIG"), being duly sworn, states:

PURPOSE OF AFFIDAVIT

- 1. This affidavit is made in support of an application for a warrant authorizing the search of Envigo, 482 French's Store Rd, Cumberland, VA (the "SUBJECT PREMISES"), and more specifically described in Attachment A, as well as the seizure of the items described in Attachment B.
- 2. Based on my training and experience and the facts as set forth in this affidavit, there is probable cause to believe that Envigo, its management, and employees, knowingly violated provisions of the federal Animal Welfare Act (AWA), in violation of 7 U.S.C. § 2149(d) ¹, corruptly obstructed, influenced, or impeded, an official proceeding, that is, an official government inspection carried out under authority of the federal Animal Welfare

Any dealer, exhibitor, or operator of an auction sale subject to section 2142 of this title, who knowingly violates any provision of this chapter shall, on conviction thereof, be subject to imprisonment for not more than 1 year, or a fine ... or both.

¹ 7 U.S.C. §2149(d) provides, in relevant part, that:

Act (AWA), and attempted to do so, in violation of 18 U.S.C. § 1512(c), made false statements and representations in a matter within the jurisdiction of the executive branch of the Government of the United States, in violation of 18 U.S.C. § 1001, and knowingly and willfully conspired to defraud the United States by impeding, impairing, obstructing, and defeating the lawful governmental functions of the United States Department of Agriculture in the ascertainment of violations of the Animal Welfare Act, in violation of 18 U.S.C. § 371. Further, there is probable cause to believe that evidence, instrumentalities, and fruits of violations of these offenses will be found at the SUBJECT PREMISES.

AFFIANT'S BACKGROUND

- 3. I am a Special Agent with the USDA-OIG. As such, I am an "investigative or law enforcement officer" within the meaning of 18 U.S.C. § 2510(7) in that I am an officer of the United States who is empowered by law to conduct investigations and to make arrests for federal felony and misdemeanor offenses.
- 4. I have been a Special Agent with the USDA-OIG since April 2010. Prior to my employment with the USDA-OIG, I was a federal criminal investigator for 1.5 years as a Special Agent with the Criminal Investigations division of the Internal Revenue Service.
- 5. I completed the Federal Law Enforcement Training Center Criminal Investigator Training Program in June of 2008 and have also received extensive advanced training in fraud, asset forfeiture, financial crimes, and public corruption through the IRS-CI Special Agent Investigation Training at the Federal Law Enforcement Training Center.
- 6. As a USDA-OIG Special Agent, I am authorized to investigate violations of the laws of the United States and am a law enforcement officer with authority to execute warrants

issued under the authority of the United States. My duties include investigating alleged violations of laws enforced by USDA. I am currently assigned to the USDA-OIG's Beltsville, Maryland office, which handles investigations in Maryland, District of Columbia, and Virginia. Since being involved with law enforcement, I have participated in numerous investigations involving criminal activities, including, but not limited to, employee misconduct and public corruption. My prior experience conducting investigations has included the use of confidential informants, undercover officers, and electronic surveillance. I have participated in many aspects of criminal investigations, including conducting surveillance, issuing subpoenas, and pursuing court-ordered pen registers and trap and trace intercepts. I have also debriefed or participated in the debriefings of numerous defendants, informants, and witnesses.

7. I am familiar with the facts set forth herein based on my personal observations or information provided to me by other individuals participating in this investigation. I am also familiar with the facts set forth based on my review of documents, reports, and photographs. I have not set forth each and every fact known concerning this investigation. Where statements of others are set forth in this affidavit, they are set forth in substance and in part. In addition, the events described in this affidavit occurred on or about the dates provided herein.

STATUTORY AND REGULATORY BACKGROUND

8. Congress, having found it "essential to regulate . . . the transportation, purchase, sale, housing, care, handling, and treatment of animals by carriers or by persons or organizations engaged in using them for research or experimental purposes or for exhibition purposes or holding them for sale as pets or for any such purpose or use[,]" enacted the Animal Welfare Act (AWA), codified at 7 U.S.C. § 2131 *et seq.*, to "insure that animals intended for use in research facilities or

for exhibition purposes or for use as pets are provided humane care and treatment." 7 U.S.C. § 2131.

- 9. The AWA establishes minimum standards of care and treatment to be provided for certain animals bred and sold for use as pets, used in biomedical research, transported commercially, or exhibited to the public. *See generally* 7 U.S.C. § 2131 *et seq*.
- 10. The AWA is administered by the Secretary of Agriculture or his representative. 7 U.S.C. § 2132(b). The AWA authorizes the Secretary to "promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of [the AWA]." 7 U.S.C. § 2151. The Secretary has delegated his authority to the APHIS Administrator.
- 11. The AWA defines a "dealer" as "any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a carrier, buys, or sells, or negotiates the purchase or sale of, (1) any dog or other animal whether alive or dead for research, teaching, exhibition, or use as a pet." 7 U.S.C. § 2132(f); *see also* 9 C.F.R. § 1.1 (definition of dealer).
- 12. A "person" includes any "individual, partnership, firm, joint stock company, corporation, association, trust, estate, or other legal entity." 7 U.S.C. § 2132(a).
- 13. Anyone who falls within the statutory definition of a dealer must obtain and maintain a valid license from the Secretary. 7 U.S.C. § 2134; *see also* 9 C.F.R. § 2.1(a)(1) (licensing requirements).
- 14. The Secretary shall issue a license to a dealer upon application, provided that no such license shall be issued until the dealer shall have demonstrated that his facilities comply with the standards promulgated by the Secretary pursuant to 7 U.S.C. § 2133.
- 15. By signing the application form, the applicant acknowledges that it has reviewed the AWA and its regulations and standards and "agrees to comply with them." 9 C.F.R. § 2.2.

- 16. Regulated activities may only be conducted at sites that have been inspected and approved by the United States Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service's (APHIS) Animal Care program ("Animal Care"). 9 C.F.R. § 2.1(b)(1).
- 17. The AWA makes it unlawful for any dealer to knowingly violate the AWA. 7 U.S.C. § 2149(d).
- 18. A Class "A" dealer must identify all live dogs "held on the premises, purchased, or otherwise acquired, sold or otherwise disposed of, or removed from the premises for delivery. . . to another dealer, or for sale, through an auction sale or to any person for use as a pet, . . . by an official tag . . . affixed to the animal's neck by means of a collar made of material generally considered acceptable to pet owners as a means of identifying their pet dogs" or "by a distinctive and legible tattoo marking acceptable to and approved by the Administrator." 9 C.F.R. § 2.50(a)(1).
- 19. The Secretary has promulgated regulations and standards to govern the humane handling, care, treatment, and transportation by dealers, which includes the minimum requirements for handling, housing, feeding, watering, sanitation, ventilation, shelter from extreme weather and temperatures, adequate veterinary care, and separation by species. 7 U.S.C. § 2143(a)(1)-(a)(2)(A). Dealers must comply in all respects with the regulations and standards for the humane handling, care, treatment, and transportation of dogs. 9 C.F.R. §§ 3.1-3.20.
- 20. When construing or enforcing the provisions of this chapter, the act, omission, or failure of any person acting for or employed by a dealer is deemed the act, omission, or failure of the dealer. 7 U.S.C. § 2139.
- 21. With regard to food, it must be uncontaminated, wholesome, palatable, and of sufficient quantity and nutritive value to maintain the normal condition and weight of the animal.

- 9 C.F.R. § 3.9(a). Further, supplies of food must be stored so as to minimize contamination by excreta and pests, and protected from rain and snow. 9 C.F.R. § 3.9(b). Measures must be taken to ensure that the food is not molding. *Id*.
- With regard to cleaning and sanitation, primary enclosures must be cleaned and both primary enclosures and food and water receptacles must be sanitized. 9 C.F.R. § 3.11. The primary enclosures must be cleaned daily to remove excreta and food waste, and to reduce disease hazards, insects, pests and odors. 9 C.F.R. § 3.11(a). Primary enclosures and food and water receptacles must be sanitized. 9 C.F.R. § 3.11(b). The surrounding buildings and grounds must be in good repair and free of trash and junk to protect the dogs from injury. 9 C.F.R. § 3.11(c). An effective program for pest control must be established and maintained to promote the health and well-being of the animals. 9 C.F.R. § 3.11(d).
- With regard to facilities, indoor and outdoor housing facilities must be structurally sound and maintained in good repair to protect animals from injury and to contain the animals. 9 C.F.R. § 3.1(a). The surface of housing facilities must be constructed in a way that allows them "to be readily cleaned and sanitized, or removed or replaced when worn or soiled." 9 C.F.R. § 3.1(c)(1). The housing facilities must have floors cleaned to ensure that all animals can avoid contact with excreta, 9 C.F.R. § 3.1(c)(3). The housing facilities must have food and bedding supplies stored in a manner that protects them from "spoilage, contamination, and vermin infestation." 9 C.F.R. § 3.1(e).
- 24. The primary enclosures of the dogs must be constructed and maintained so that they protect the dogs from injury. 9 C.F.R. § 3.6(a)(2)(ii). The primary enclosures must also have floors that protect the dogs' feet and legs from injury, and that, if of mesh or slatted construction, do not allow the dogs' feet to pass through any openings in the floor. 9 C.F.R. § 3.6(a)(2)(x).

- 25. Each dog housed in a primary enclosure, including weaned puppies, must be provided a "minimum amount of floor space." 9 C.F.R. § 3.6(c)(1)(i). Each "bitch with nursing puppies" must be provided with "an additional amount of floor space" that is "in accordance with generally accepted husbandry practices as determined by the attending veterinarian." 9 C.F.R. § 3.6(c)(1)(ii).
- 26. Dog enclosures must be constructed and maintained so that they keep other animals from entering the enclosure. 9 C.F.R. § 3.6(a)(iv).
- 27. All dogs that are housed in the same primary enclosure must be compatible. 9 C.F.R. § 3.7.
- 28. All interior surfaces within indoor housing facilities that are "in contact with the animals" must be "impervious to moisture," and the ceilings of indoor housing facilities must be "impervious to moisture or be replaceable." 9 C.F.R. § 3.2(d).
- 29. The sheltered part of sheltered housing facilities must be "sufficiently heated and cooled when necessary" to protect the dogs from temperature or humidity. 9 C.F.R. § 3.3(a). At "all times," dogs must be provided with adequate shelter from the elements to "protect their health and well-being." 9 C.F.R. § 3.3(d).
- 30. With regard to veterinary care, each dealer must employ an "attending veterinarian," who "shall provide adequate veterinary care to [the dealer's] animals in compliance with [the AWA]." 9 C.F.R. § 2.40(a); *see also* 9 C.F.R. § 1.1 (definition of "[a]ttending veterinarian"). The dealer must "assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use." *Id.* § 2.40(a)(2).

- 31. The dealer "must follow an appropriate program of veterinary care for dogs that is developed, documented in writing, and signed by the attending veterinarian." 9 C.F.R. § 3.13(a). The written program of veterinary care must be made available for inspection by APHIS inspectors. *Id.* The written program of veterinary care must include, among other things, a "complete physical examination from head to tail of each dog by the attending veterinarian not less than once every 12 months," "[v]accinations for contagious and/or deadly diseases of dogs (including rabies, parvovirus and distemper) and sampling and treatment of parasites and other pests (including fleas, worms, coccidia, giardia, and heartworm) in accordance with a schedule approved by the attending veterinarian," and "[p]reventative care and treatment to ensure healthy and unmatted hair coats, properly trimmed nails, and clean and healthy eyes, ears, skin, and teeth." 9 C.F.R. § 3.13(a); *see also id.* § 2.40(b).
- 32. The dealer must "establish and maintain" a program of "adequate veterinary care" that addresses the "use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care." *Id.* § 2.40(b)(2). The program of veterinary care must also include "[d]aily observation of all animals to assess their health and well-being," and although the daily observation "may be accomplished by someone other than the attending veterinarian" there must be a "mechanism of direct and frequent communication" so that "timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian." *Id.* § 2.40(b)(3).
- 33. With regard to the number of employees, a facility must include a sufficient number of employees who are practicing husbandry under the supervision of an individual who has the knowledge, background, and experience in proper husbandry and care of dogs to supervise others. 9 C.F.R. § 3.12.

- 34. With regard to handling, all licensees must ensure that animals are handled "in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort." 9 C.F.R. § 2.131(b)(1).
- 35. The AWA requires the Secretary to make investigations and inspections as necessary to determine whether any dealer has violated any provision of the AWA, or any regulation or standard issued thereunder. 7 U.S.C. § 2146(a). The inspector shall have access to the places of business and the facilities, animals, and records. *Id.*; 9 C.F.R. § 2.126.
- 36. Dealers must make, keep, and retain records for at least one year pertaining to the purchase, sale, transportation, identification, and previous ownership of each dog, which fully and correctly discloses information concerning the animal purchased or otherwise acquired, owned, held, leased, or otherwise in his or her possession or under his or her control, or which is transported, sold, euthanized, or otherwise disposed of (including records of any offspring). 7 U.S.C. § 2140; 9 C.F.R. §§ 2.75(a)(1)-(3), (b)(1).
- 37. Dealers must also keep and maintain copies of medical records for dogs –including for at least 1 year after any given dog is euthanized—and make those records available for APHIS inspection. 9 C.F.R. § 3.13(b), (c)(2). These records must include the "identity of the animal, including identifying marks, tattoos, or tags on the animal and the animal's breed, sex, and age." 9 C.F.R. § 3.13(b)(1). The medical records must also include "the date and a description" of any "disease, injury, or illness," as well as "examination findings, test results, plan for treatment and care, and treatment procedures performed." 9 C.F.R. § 3.13(b)(2).
- 38. The AWA defines "euthanasia" as "the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without

evidence of pain or distress" or a "method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death." 9 CFR §1.1.

- 39. A licensee "shall notify Animal Care no fewer than 90 days and obtain a new license before any change in the name, address, substantial control or ownership of his business or operation, locations, activities, and number or type of animals." 9 C.F.R. § 2.1(b)(1).
- 40. Title 18, United States Code, Section 1001 makes the following conduct a crime:
 - whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—
 - (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;
 - (2) makes any materially false, fictitious, or fraudulent statement or representation; or
 - (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.
- 41. Title 18, United States Code, Section 1512 prohibits "corruptly" obstructing, influencing, or impeding any official proceeding.
- 42. Title 18, United States Code, Section 371 makes it unlawful for "two or more persons to conspire . . . to defraud the United States."

FACTUAL BACKGROUND

43. Envigo is a company that breeds and sells animals to other companies, government entities, and organizations for use in scientific research. From www.envigo.com/about:

Envigo, an Inotiv company, provides the broadest range of research models and related services to the pharmaceutical and biotechnology industries, government, academia and other life science organizations. As the largest organization that is solely dedicated to providing research models and related products and services, we are committed to helping researchers realize the full potential of their critical

R&D projects as we fulfill our mission to work together to build a healthier and safer world.

- 44. According to the Envigo website, it operates facilities in the several locations including Cumberland, Virginia.
- 45. The Envigo location for which application is made to issue a search warrant is located at 482 French's Store Rd, Cumberland, VA 23040. This site is primarily in the business of breeding beagle-type dogs for sale to medical research facilities. This location is a large multi-building facility that houses upwards of 5,000 dogs at any given time. Any references in this affidavit to Envigo in relation to violations of the law refer to the Envigo facility at Cumberland, Virginia.
- 46. This site has a secondary business model of housing and conducting animal research. The research animal population consists mainly of beagle-type dogs and domestic cats. The research animal population is a fraction of the overall number of animals on location, comprising less than approximately 2% of the total population during the period of investigation.
- 47. Since this facility operates as a dog breeder and research facility, it is a business that is regulated by the AWA through USDA APHIS Animal Care.
- 48. Envigo operates multiple such locations in the United States and abroad. Because of the multiple locations operated in the United States, APHIS licenses all the Envigo sites under one "customer" (account) number. Envigo sites also share the same "certificate" (license) number associated to the type of regulated business they conduct (i.e. breeding or research).
- 49. Envigo is listed in the APHIS publicly accessible data base (https://aphisefile.force.com/PublicSearchTool/s/inspection-reports) as having customer number 506554.

- 50. Envigo's animal breeding operations are listed under certificate number 32-A-0774. The "A" in the certificate number denotes that this license is for breeding animals on site with the intent to sell them. APHIS refers to these type of businesses as "A Dealers".
- 51. Envigo's research locations are listed under certificate number 23-R-0187. The "R" in the registration number denotes that this number is issued for research purposes. APHIS refers to these businesses as "Registrants" or "R Registrants".
- 52. The "A" license for 482 French's Store Rd, Cumberland, VA lists this address as "Envigo Site 005".
- 53. The "R" registration for 482 French's Store Rd, Cumberland, VA lists this address as "Envigo Site 002."
- 54. For the purposes of this affidavit, APHIS AC license numbers 23-R-10187 Site 002 and 32-A-0774 Site 005 are both the same physical location, 482 French's Store Rd, Cumberland, VA.
- 55. For the purposes of this affidavit, the entire location at 482 French's Store Rd will be referred to as "Site 005/002" or "Envigo."
- 56. Envigo applied to USDA for a Class A license around June 2019. USDA issued Class A license 32-A-0774 to Envigo. By signing the application form, Envigo acknowledged that it had reviewed the AWA, and its implementing regulations and standards and agreed to comply with them. *See* 9 C.F.R. § 2.2.

² On June 5, 2019, Envigo Chief Operating Officer Jim Harkness submitted an application for licenses to Animal Care. However, this application did not include the site in Cumberland, VA that would ultimately become Envigo sites 005/002. On July 19 of 2019, AC issued a license to Envigo. The license did not include site 005. Technically, Envigo was doing business without a license at Site 005. On September 23, 2019, Sarah Fleener sent an email, from an "Envigo.com" email address to Katie Whisenton of Animal Care asking that site 005 in Cumberland be added to their current license. According to inspection records available, this New License Inspection at 005/002 never occurred. This was most likely due to Envigo site 005/002 not being listed on the submitted application.

- 57. On June 3, 2019, Envigo acquired LabCorp's Covance Research Products' business, which included the Cumberland Facility.
- 58. The first inspection by APHIS of the Cumberland Facility following Envigo's acquisition of the site took place in July 2021. During the routine inspection, APHIS documented violations of 18 different AWA provisions, of which 10 of the violations were deemed to be "direct" or "critical." A "critical" noncompliance is one that has a "serious or severe adverse effect on the health and well-being of the animal[s]." Animal Welfare Inspection Guide, USDA, 2-10 (revised Nov. 2021). A "direct" noncompliance is a critical noncompliance that is having a serious or severe adverse effect on the health and well-being of the animal during at the time of the inspection. *Id.* at 2-11.
- 59. APHIS conducted a "focused" inspection of the Cumberland Facility in October 2021. During this focused inspection, APHIS documented violations of 13 different AWA provisions. Seven of the violations were direct or critical violations that APHIS had already identified during the July 2021 inspection.
- 60. On November 5, 2021, Inotiv, Inc. announced that it had acquired Envigo. Nevertheless, the Cumberland Facility remained an approved site under Envigo's AWA license 32-A-0774.
- 61. APHIS conducted another routine inspection of the Cumberland Facility in November 2021. APHIS inspectors observed numerous noncompliances, including serious violations of the AWA. During the inspection, APHIS documented violations of 26 different AWA provisions, of which 14 were deemed to be "direct" or "critical." Of the 14 "direct" or "critical" violations, ten were repeat violations.

- 62. In March 2022, APHIS conducted a focused inspection of the Cumberland Facility. During the inspection, APHIS officials documented violations of five different AWA provisions, of which two were direct violations. Envigo had been on notice that it needed to correct those serious issues for eight months at that point, with the violations being identified on all three previous inspection reports.
- 63. On or about May 3, 2022, APHIS conducted another focused inspection of the Cumberland Facility. Inspectors noted continued AWA violations by Envigo.

VIOLATIONS OF THE AWA

Envigo Has Violated the AWA By Failing to Provide the Beagles at the Cumberland Facility Adequate Veterinary Care

- 64. Envigo's attending veterinarian failed to provide and oversee the provision of adequate veterinary care to the beagles at the Cumberland Facility in violation of the AWA, and its regulations and standards 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. § 2.40(a).
- 65. Envigo delayed the provision of veterinary care for beagles, including those with severe and painful medical conditions. During the November 2021 inspection, APHIS inspectors identified 30 beagles ranging from two to seven years old with severe dental disease who had not been treated despite Envigo staff observing the condition in some of the beagles as early as August 2021. The beagles' symptoms ranged from loose teeth that moved with light pressure, exposed roots of teeth, pus along the gum lines, bleeding gums, hair and foreign material embedded in the gum lines, severe recession of the gums, missing teeth and significant accumulations of dark colored calculus along the teeth. *See* Ex. 4 (November 2021 Routine Inspection Report) at 2.
- 66. Of the 30 beagles with severe dental disease, 12 had additional issues for which they had not received adequate veterinary care. One nursing female was in poor body condition, with extremely prominent bones in the shoulders, ribs, hips and back. Records show she had been

under weight for three months but had not been provided any treatment for either condition. Seven beagles had foot conditions, including masses between their toes that were inflamed and often oozing discharge. One beagle had an ear infection and another had large areas of hair loss along the entire length of the back and reddened skin. *See* Ex. 4 (November 2021 Routine Inspection Report) at 2-3.

- 67. As of November 2021, Envigo's veterinary staff had not completed the required annual hands-on physical examination for a number of beagles over the age of one year. The failure to have a veterinarian examine a dog at least annually can result in delays in the diagnosis and treatment of underlying medical conditions. *See* Ex. 4 (November 2021 Routine Inspection Report) at 19.
- 68. Envigo staff are failing to follow approved procedures for euthanizing beagles, which has caused pain and discomfort to the beagles. The facility's program of veterinary care and guidance on euthanizing dogs requires that all dogs be unconscious when performing intracardiac euthanasia achieved by using medication and a sedative. However, when inspectors reviewed 171 medical records documenting the euthanasia of 196 beagles and beagle puppies during the November 2021 inspection, they found that many young beagle puppies were not receiving anesthesia prior to being euthanized via intracardiac injection. Intracardiac injections have been found to be painful, stressful, and uncomfortable. *See* Ex. 4 (November 2021 Routine Inspection Report) at 2.
- 69. Medical records reviewed by APHIS inspectors during the October 2021 inspection indicated that animal care technicians had identified three beagles as being too thin. The records further indicated that the beagles were given medication but there was no record that a veterinarian had been consulted regarding the diagnosis of poor body condition or the prescription of

medication to these beagles. Further, the program of veterinary care did not allow animal care staff to start medication for beagles determined to be thin. APHIS inspectors brought the matter to the attention of the attending veterinarian who then examined the beagles and directed that the medication be stopped. *See* Ex. 3 (October 2021 Focused Inspection Report) at 1.

- 70. Daily observations of each dog are required to ensure the health and welfare of every animal at the Cumberland Facility. *See* 9 C.F.R. § 2.40(b)(3). Envigo staff have failed to observe medical problems in the dogs that require veterinary attention.
- 71. During the July 2021 inspection, APHIS inspectors identified 15 beagles who had medical problems that had not been identified or treated prior to the inspection. The medical problems included eye conditions, ear conditions, skin infections, wounds and lesions, and severe dental disease. One female beagle suffering from severe dental disease had swollen gums that had pulled back from some of the teeth exposing the roots of the teeth. Another beagle had patchy hair loss encompassing approximately 80% of her entire coat and several small yellow scabs spread throughout the hair loss. Despite the skin condition affecting the majority of the beagle's body and the daily observation requirement, Envigo's attending veterinarian stated that no one had observed the condition prior to the inspection. Ex. 1 (July Routine Inspection Report) at 1-4.
- 72. APHIS reminded Envigo that animals "with medical conditions including eye, skin, ear, and dental problems, may suffer from pain, discomfort, infection, and stress." Envigo was directed to immediately comply with the daily observation requirement "by observing animals on a daily basis to identify physical, medical or behavioral problems, and communicate all findings to the attending veterinarian promptly." Ex. 1 (July Routine Inspection Report) at 5.
- 73. Nevertheless, when APHIS inspectors returned in October 2021, they observed a male beagle puppy with an abnormal eye, a female beagle with swollen tissue between the toes of

her right rear paw, and another female beagle with multiple skin lesions and swelling on all four feet. Envigo staff had not previously identified these medical issues and, thus, the beagles were not receiving any treatments for the conditions. *See* Ex. 3 (October 2021 Focused Inspection Report) at 2-4.

- 74. When APHIS inspectors returned in November 2021, they identified 34 beagles with medical conditions that had not been observed by Envigo staff and, thus, had not been treated. This was in addition to the 30 beagles whose medical conditions had been identified but Envigo veterinary staff had failed to treat. Envigo staff had failed to observe the following conditions: seven beagles with severe dental disease; one beagle and two beagle puppies with serious conditions resulting in weakness; eight beagles and beagle puppies with traumatic wounds; eight beagles with lameness or foot injuries; and two with masses, including a puppy with a large, soft fluid filled mass on top of his head. The inspectors observed beagles with untreated eye, ear, and skin conditions as well. *See* Ex. 4 (November 2021 Routine Inspection Report) at 3-4.
- 75. Medical records also indicated that a female beagle had recently been found dead. The necropsy showed that she had died as a result of a ruptured uterus. However, the beagle's medical records did not contain any observations that would be expected with this diagnosis, such as abdominal pain, vaginal discharge, difficulty whelping, or other similar signs. *See* Ex. 4 (November 2021 Routine Inspection Report) at 4.
- 76. Additionally, the mortality and medical records for certain puppies who supposedly died from conditions that present with clinical signs prior to death contained no such observations. The lack of documentation prior to the puppies' deaths indicates that Envigo staff either failed to comply with the daily observation requirement or failed comply with the requirement to document their observations.

- 77. Envigo also has failed to use appropriate methods to prevent, control, diagnose, and treat diseases and injuries in beagles at the Cumberland Facility. *See* 9 C.F.R. § 2.40(b)(2).
- 78. Hundreds of beagle puppies have been found dead at the Cumberland Facility. Mortality records show that between January 1, 2021, and July 22, 2021, the deaths of over 300 beagle puppies were attributed to "unknown causes." The attending veterinarian does not require Envigo staff to notify her when beagle puppies are found dead. Rather, animal care technicians, who upon information and belief have no formal veterinary training, are permitted to make the decision whether a necropsy should be performed. Envigo's failure to consistently apply methods to accurately diagnose the cause of the deaths of hundreds of beagle puppies has limited the Cumberland Facility's ability to implement changes that would prevent future deaths. *See* Ex. 2 (July Focused Inspection Report) at 1.
- 79. Medical records reviewed during the July 2021 inspection indicate that, for an additional 173 beagle puppies, Envigo staff could not identify a cause of death because the bodies had already begun decomposing. *See* Ex. 2 (July Focused Inspection Report Part) at 2.
- 80. Envigo has failed to provide adequate veterinary care to the puppies at the Cumberland Facility, including daily observations and implementation of appropriate methods to diagnose disease post-mortem, which has resulted in the deaths of hundreds of young puppies.
- 81. Envigo may have opted to euthanize beagles rather than provide adequate veterinary care for easily treatable conditions or injuries.
- 82. APHIS inspectors reviewed records during the July 2021 inspection, which showed that, between January 1, 2021, and July 22, 2021, 71 beagles were injured when a body part, such as an ear or tail, was pulled through the wall of the kennel by a beagle in an adjacent kennel.

According to the records, however substantial or minor the injury, Envigo euthanized all the beagles rather than provide them veterinary care. *See* Ex. 2 (July Focused Inspection Report) at 6.

83. During the October 2021 inspection, APHIS inspectors once again reviewed mortality records, which showed that nine beagles had been injured after a body part was pulled through the wall by a dog in an adjacent kennel. Regardless of whether the injury was minor or substantial, Envigo euthanized all the beagles rather than provide them veterinary care. *See* Ex. 3 (October 2021 Focused Inspection Report) at 7.

Envigo Violated the AWA by Failing to Provide Each Beagle With Uncontaminated, Wholesome, Palatable Food of Sufficient Quantity and Nutritive Value.

- 84. Envigo has failed to provide each beagle at the Cumberland Facility with food of sufficient quantity and nutritive value to meet the beagle's nutritional needs in violation of the AWA and its implementing regulations and standards. *See* 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. § 3.9(a).
- 85. During the July 2021 inspection, APHIS inspectors discovered that nursing females were being denied food for 42 hours to reduce milk production. The inspectors noted that during the 42-hour period, food receptacles were left on the door of the enclosure but were turned around so that the beagles could see and smell the food but could not eat it. The inspectors observed several nursing females reaching their front paws through the doors of the cages to try to reach the food but were only able to retrieve the occasional piece. One nursing female was observed to be vigorously licking the back of the food receptacle. *See* Ex. 1 (July Routine Inspection Report) at 6.
- 86. The beagle puppies' only source of food is to nurse on their mothers. Envigo does not provide the beagle puppies any supplemental food. Thus, if the nursing female is not producing sufficient milk to meet the puppies' nutritional needs, the puppies' nutritional needs are not being

met. As a result, those beagle puppies may experience hunger, dehydration, stress, low blood sugar, and increased susceptibility to infections.

- 87. During the July 2021 inspection, APHIS inspectors observed 13 litters of six-week-old beagle puppies who were kept with their mothers during the period in which the mothers were denied food. Puppies were observed vocalizing and nursing on their mothers, while the mothers stood and tried to gain access to the food outside their cages. *See* Ex. 1 (July Routine Inspection Report) at 11.
- 88. Envigo also has failed to make food receptacles available to all dogs. Most of the feeders at the Cumberland Facility accommodate only one adult beagle's head at a time. Enclosures with four to eleven dogs contain only one food receptacle. As a result, many beagles exhibited food guarding behaviors during the November inspection. Envigo was directed to correct the problem and make the food "ready accessible to all dogs" by February 11, 2022. *See* Ex. 4 (November 2021 Routine Inspection Report) at 14-15.
- 89. The food that Envigo does provide the beagles at the Cumberland Facility is contaminated and is not considered wholesome or palatable. During the July 2021 inspection, food in the receptacles in the beagles' enclosures and in the feed silo in certain buildings contained live insects, including small black worm-type insects, small black beetle-type insects, and flies. APHIS inspectors observed flies in the food receptacles and crawling on the food. *See* Ex. 2 (July Focused Inspection Report) at 11.
- 90. During the July 2021 inspection, APHIS inspectors also observed large numbers of ants on the floor and adjacent to food receptacles mounted on the front of enclosures. Live ants were observed going in and out of the receptacles containing the beagles' food. *See* Ex. 2 (July Focused Inspection Report) at 10.

- 91. APHIS reminded Envigo that food contaminated with insects can decrease the nutritive value of the food and can result in reduced food consumption. Envigo was directed to correct the issue by August 15, 2021.
- 92. However, during the November 2021 inspection, APHIS inspectors checked a random sample of food receptacles in two rooms housing a total of 85 nursing females and 488 puppies. Every food receptacle contained food that was wet, caked, and/or moldy. Two receptacles also contained "large numbers of live maggots." APHIS inspectors directed Envigo staff to clean the food receptacles and replace the food as soon as possible. But when APHIS inspectors returned three days later, the receptacles again contained moldy and/or caked feed.
- 93. When APHIS inspectors returned to the Cumberland facility in March 2022, they again found that Envigo was not adequately cleaning food receptacles. The food receptacles in one building contained moldy, wet food. Excessive grime was also found in some feeders. *See* Ex. 5 (March 2022 Focused Inspection Report) at 5.
- 94. Envigo also failed to ensure that food receptacles are located so as to minimize contamination by excreta and pests. *See* 9 C.F.R. § 3.9(b). APHIS inspectors observed "grossly contaminated" food during the November 2021 inspection. The food receptacles in all buildings are mounted with the opening where the beagles access food located only 1 to 2 inches from the enclosure floor. When Envigo staff pressure wash the enclosures, back-splashed water mixed with feces is being sprayed into the food receptacles and contaminating the food. There are also excessive amounts of grime in the receptacles because Envigo staff are not cleaning them frequently enough. Envigo was directed to correct the problem by February 11, 2022, by relocating the receptacles to minimize contamination and ensuring that they are kept clean and sanitized. *See* Ex. 4 (November 2021 Routine Inspection Report) at 15.

Envigo Violated the AWA by Failing to Keep the Beagles Safe

- 95. Envigo is failing to meet the minimum standards for handling and housing the beagles in violation of the AWA, and its regulations and standards resulting in the unnecessary suffering and, at times, death of beagles at the Cumberland Facility. 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. §§ 2.131(b); 3.7.
- 96. Beagles at the Cumberland Facility are killing each other because Envigo has failed to ensure that all beagles housed in an enclosure are compatible, that all dogs have access to food of sufficient quantity and nutritive value, and because the enclosures are overcrowded.
- 97. Records from January 2021 to July 2021 showed that 48 beagles had fight wounds. Two female beagles were found dead from fight wounds, while another female beagle was found dead after being killed by a cage mate. APHIS directed Envigo to ensure that there was a mechanism of observation in place to ensure compatibility and prevent fighting. *See* Ex. 2 (July Focused Inspection Report) at 7.
- 98. When APHIS inspectors returned to the Cumberland facility in October 2021, they found that there continued to be issues with beagles fighting each other. For example, two female beagles housed together had multiple puncture and other wounds. Envigo staff had failed to notice that the dogs were fighting or that either dog had wounds. Records showed that two additional female beagles were being treated for fight wounds. One of the beagles had wounds on her rear end and shoulder, while the other beagle had wounds on her chest and left ear. *See* Ex. 3 (October 2021 Focused Inspection Report) at 8.
- 99. APHIS inspectors noted on the October 2021 inspection report that Envigo had taken no steps in the three months to address the issue of beagles attacking each other at the Cumberland Facility. *See* Ex. 3 (October 2021 Focused Inspection Report) at 8-9.

- 100. Records also showed that another female beagle was found dead on October 14, 2021, and her littermates had chewed on her. The mortality log attributed the beagle's death to evisceration. Records showed that she was being co-housed with nine other beagles of the same age—10 weeks. Envigo staff could not provide any additional details about the beagle's death and there was no record of post-mortem examination findings. When APHIS asked to speak with the employee who found the beagle, the inspectors were told that the employee was unreachable due to leave. *See* Ex. 3 (October 2021 Focused Inspection Report) at 9.
- 101. APHIS noted on the inspection report that "[d]ogs attacking/chewing on another dog, whether alive or deceased, is an uncommon behavior for dogs with adequate nutrition and likely indicates a compatibility issue." *See* Ex. 3 (October 2021 Focused Inspection Report) at 9.
- 102. During the November 2021 inspection, APHIS inspectors observed that Envigo's facility continued to have "severe compatibility problems amongst the adult dogs and puppies." Inspectors observed "numerous serious dog fights during the inspection, found dogs with injuries from recent fights, and observed dogs aggressively guarding food from cage mates." At times, the inspection had to be temporarily stopped to separate fighting beagles. Envigo records also documented injuries due to fighting among the beagles. *See* Ex. 4 (November 2021 Routine Inspection Report) at 13.
- 103. In addition to the widespread compatibility issues, APHIS inspectors also found during the November 2021 inspection that Envigo was failing to provide 742 beagle and weaned puppies the minimum space required by the AWA. Some of the buildings house ten to eleven beagles in enclosures that are approximately 20 square feet too small for that number of dogs. APHIS noted that overcrowded enclosures can lead to increased and long-term aggression and

reduced compatibility, a widespread issue at the Cumberland Facility. *See* Ex. 4 (November 2021 Routine Inspection Report) at 13.

- 104. APHIS inspectors also observed aggressive behavior in the form of food guarding, which the inspectors attributed to Envigo failing to make a sufficient number of food receptacles available to the beagles. Enclosures with four to eleven dogs contain only one food receptacle and most of those receptacles can be accessed by only one beagle at a time. *See* Ex. 4 (November 2021 Routine Inspection Report) at 15.
- 105. In March 2022, APHIS inspectors identified an additional 97 beagles who had suffered injuries, sometimes severe, consistent with a fight. Envigo medical records identified 59 dogs as having injuries attributable to a fight. An additional 38 beagles were treated for wounds of an unknown cause, including lacerations to ears and tail injuries. *See* Ex. 5 (July 2022 Focused Inspection Report) at 4.
- 106. Envigo failed to keep beagle puppies safe by allowing the puppies to become wet when staff hose down the enclosures with cold water. Under the AWA, Envigo is required to handle animals as carefully and expeditiously as possible to prevent excessive cooling. Allowing puppies to become wet and chilled during cleaning or failing to provide them sufficient heating may result in illness or death.
- 107. On November 16, 2021, 21 beagle puppies were found damp, shivering and cold in building G3. The enclosures that housed these puppies had recently been cleaned. The enclosures had no solid resting surface or bedding, and no heat lamps were installed. APHIS inspectors rechecked building G3 three days later and found additional beagle puppies shivering and no heat lamps installed. *See* Ex. 4 (November 2021 Routine Inspection Report) at 6.

108. According to Envigo's records, an additional 25 puppies had been found dead with cause of death attributed to cold exposure in building G3 in the previous eight weeks. *See* Ex. 4 (November 2021 Routine Inspection Report) at 6.

Envigo Violated the AWA by Exposing Beagles to Unsafe and Unsanitary Conditions

- 109. Envigo exposed the beagles at the Cumberland Facility to unsafe and unsanitary conditions in violation of the AWA, and its implementing regulations and standards. *See* 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. §§ 3.1; 3.6; 3.11.
- 110. Envigo has been on notice for over nine months that the beagles' enclosures fail to protect them from injury. *See* 9 C.F.R. §§ 3.1(a); 3.6(a)(2).
- 111. The majority of enclosures are constructed using either metal wire or mesh to separate beagles in adjacent enclosures. However, the gaps in the enclosure walls allow beagles to attack beagles in adjacent enclosures.
- 112. Based on the records APHIS reviewed during the July 2021 inspection, 71 beagles were injured after each was attacked by a beagle in an adjacent enclosure who pulled a body part through the gaps in the enclosure walls. Envigo then euthanized all the injured beagles even if they sustained only minor injuries. *See* Ex. 2 (July Focused Inspection Report) at 7-8. APHIS directed Envigo to ensure that primary enclosures protect the beagles from injury, including injury by beagles in adjacent enclosures.
- 113. During the next inspection, APHIS inspectors reviewed mortality records from August 2, 2021, to October 3, 2021, and discovered that nine beagles were injured from having a body part, such as a limb or tail, pulled through the enclosure wall. Envigo then euthanized all of the injured beagles even if they sustained only minor injuries. *See* Ex. 3 (October 2021 Focused Inspection Report) at 7.

- that Envigo's enclosures failed to protect the beagles at the facility from injury. Inspectors noted "numerous examples of body parts being pulled into adjacent enclosures by neighboring dogs causing injuries to the dogs involved." During the inspection, APHIS inspectors observed one beagle grab the ear of a beagle in a neighboring enclosure who then "vocalized loudly indicating pain while the other dog continuously pulled his ear." Two additional beagles were identified in the mortality logs from November with similar severe ear injuries, which resulted in those beagles being euthanized. The inspection report noted that openings in the dividers between the enclosures were large enough that feet, tails, and ears could be pulled through by beagles in adjacent enclosures. APHIS inspectors determined that the enclosures were particularly dangerous in light of the "widespread compatibility problems" identified at the facility. *See* Ex. 4 (November 2021 Routine Inspection Report) at 11.
- 115. Because the enclosures failed to keep the beagles safe from unnecessary pain, suffering, and death, Envigo was once again directed to ensure that all enclosures were constructed and maintained in a manner that prevents injury to the animals.
- 116. Envigo also violated the AWA by housing many beagles, including puppies, in enclosures containing dangerous flooring that contains gaps wide enough for a limb, paw, or digit to pass through, and which has resulted in beagles becoming trapped or injured.
- 117. During the July 2021 inspection, APHIS inspectors observed that over 200 beagle puppies were housed in enclosures that contained flooring with openings large enough for the beagle puppies' feet to pass through up to their shoulders in violation of 9 C.F.R. § 3.6(a)(2)(x). *See* Ex. 1 (July Routine Inspection Report) at8-9.

- 118. APHIS inspectors also observed an adult female beagle whose front left paw was caught in the flooring. The beagle was unable to free her foot and was panting rapidly and making small movements as the other beagles in her enclosure jumped around her excitedly. It took two Envigo employees approximately three minutes to free the beagle. After the beagle was freed, her foot was examined, and two toes were red and swollen. Envigo employees did not know how long the dog had been trapped in the flooring, but medical records indicated that the animal was mildly dehydrated. *See* Ex. 1 (July Routine Inspection Report) at 9.
- 119. Envigo was warned that when an animal becomes entrapped, they can become distressed, dehydrated and injured. Envigo was directed to take measures to ensure that the flooring at the Cumberland Facility did not allow the beagles' feet or legs to pass through. *See* Ex. 1 (July Routine Inspection Report) at 9.
- 120. Nevertheless, during the October 2021 inspection, APHIS inspectors observed multiple beagle puppies with legs and feet passing through the openings in the floors of their enclosures. APHIS inspectors also observed two enclosures that did not have the cardboard cage liners that Envigo had previously stated it would install as a temporary measure until it could permanently address the noncompliant flooring. *See* Ex. 3 (October 2021 Focused Inspection Report) at 7.
- 121. During the November inspection, APHIS inspectors determined that approximately 75% of enclosures had gaps between the flooring and fencing of up to two inches wide. Inspectors observed beagles fall or step into the gaps in the flooring. Envigo records documented at least 10 additional beagles and beagle puppies that were significantly injured by improperly constructed and maintained enclosures. *See* Ex. 4 (November 2021 Routine Inspection Report) at 8. Other enclosures had flooring that was not secured to the framework beneath it or lacked support from

underneath. In those enclosures, the floors bounced up and down, shifted, tilted or sank under the weight of the beagles as they moved within the enclosure. APHIS directed Envigo to correct the problem by February 11, 2022, to ensure that no dogs become injured as a result of the Envigo's noncompliant facilities. *See* Ex. 4 (November 2021 Routine Inspection Report) at 7-8.

- 122. APHIS inspectors also observed six beagles actively stuck in the flooring, requiring Envigo staff to manually remove them. Based on Envigo's records, at least nine additional beagles were found trapped in the flooring, several of which were injured and required treatment for lameness and wounds. Young beagle puppies are also being housed in enclosures with the same flooring. Rather than installing flooring that would keep the beagle puppies safe, Envigo put down butcher paper to cover the gaps. However, APHIS inspectors observed the beagle puppies urinating on and tearing the paper. The puppies were exposed to the "dangerous flooring within minutes of paper being put into the enclosure." *See* Ex. 4 (November 2021 Routine Inspection Report) at 11-12.
- 123. The beagles' continued exposure to dangerous flooring is particularly concerning in light of Envigo's failure to employ sufficient staff. Envigo's severe staffing shortage increases the risk that a beagle or beagle puppy will be trapped in the noncompliant flooring, possibly with injuries, for an extended amount of time.
- 124. In March 2022, APHIS inspectors again found that Envigo had failed to implement effective corrections to eliminate the risk of entrapment and injury from the dangerous flooring installed in enclosures for beagles over 12 weeks of age. Inspectors observed two beagles stuck in the flooring, one of which had to be removed by facility representatives. Medical records indicated that at least 12 additional dogs were injured after becoming trapped in the flooring. The injuries

ranged from mild soreness to pressure wounds that required over two weeks of treatment. *See* Ex. 5 (March 2022 Focused Inspection Report) at 3.

- 125. During the March 2022 inspection, the inspectors also identified at least 130 enclosures with gaps large enough for a foot or leg to pass through. In some areas, inspectors also identified gaps in the fencing where the chain link had become detached. In one spot, the gap extended the length of the enclosure sidewall. The fencing was so loose that a beagle could have pushed its way under the gap to enter the adjacent enclosure. *See* Ex. 5 (March 2022 Focused Inspection Report) at 2.
- 126. In May 2022, APHIS inspectors again found that dogs being trapped in the flooring continued to be an issue. In one building alone, the inspectors located two dogs who were trapped during the inspection, one of which required a couple minutes of manipulation before her foot was freed by facility representatives. *See* Ex. 6 (May 2022 Focused Inspection Report) at 1.
- 127. Envigo has been on notice for over nine months that the primary enclosures fail to provide the beagles at the Cumberland Facility sufficient space to keep the beagles safe and healthy. See 9 C.F.R. § 3.6(c).
- 128. Mother beagles and puppies without adequate floor space in an enclosure may suffer from distress, discomfort, crowding, poor sanitation, increased trauma and mortality.
- 129. During the July 2021 inspection, APHIS inspectors observed that 62 nursing female beagles with a total of 393 beagle puppies were in enclosures that did not provide the minimum amount of floor space for the number of beagles in the enclosure. *See* Ex. 1 (July Routine Inspection Report) at 10.
- 130. In November 2021, APHIS inspectors determined that Envigo was failing to provide a total of 742 beagles and weaned puppies with the minimum space required by the AWA.

Envigo housed as many as nine puppies in an enclosure measuring 16 square feet. The AWA requires that enclosures containing that many puppies be at least 21.8 square feet. APHIS inspectors found additional overcrowded enclosures in another building containing 15 enclosures with four to five-month-old beagles. APHIS inspectors determined that those enclosures measured a total of 39.7 square feet. However, some of the enclosures housed as many as 10 beagles each, which would require 60.4 square feet per enclosure. Sixty enclosures in another room measured around 39.7 feet. However, Envigo co-housed as many as eleven dogs in each enclosure, which would require a minimum of 58.9 square feet of space. *See* Ex. 4 (November 2021 Routine Inspection Report) at 12-13.

- 131. In addition to causing discomfort, distress, poor sanitation, and increased incidence of illness, housing dogs in overcrowded enclosures can also lead to long-lasting negative behaviors, such as increased aggression and future incompatibility with other dogs, behaviors that are widespread at the Cumberland Facility.
- 132. Envigo has been on notice for over nine months that the Cumberland facility is unsanitary. *See* 9 C.F.R. § 3.11(a). The buildup of feces, urine, food waste and water waste are a breeding ground for pests and insects, expose dogs to unnecessary disease hazards, and cause noxious odors.
- 133. During the July 2021 inspection, APHIS inspectors observed that the waste gutters below the main sheltered housing in Buildings G1, G2, and G3 contained large quantities of feces, urine, standing water, dead and alive insects, and uneaten food under the raised indoor and outdoor kennel floors. Near the outside gutters, there was an "overpowering ammonia and fecal odor that emanates from below the kennels inside the buildings." *See* Ex. 2 (July Focused Inspection Report)

at 8. Envigo staff claimed that the gutters were usually cleaned every other day, but that the pump that cleans the gutters had been broken for six days. *Id.* at 8.

- During the July 2021 inspection, APHIS inspectors also observed a "buildup of brown organic material" in the enclosures where nursing mothers and their puppies are housed. Envigo's facility operations manager admitted that the enclosures are disinfected only between litters or every six weeks. Envigo was reminded that "[i]nadequate cleaning and disinfection may lead to animal sickness, outbreaks of disease, or proliferation of pests." *See* Ex. 2 (July Focused Inspection Report) at 10.
- 135. Inspectors also noted that, "[a]round the entire facility are large populations [of] live insects including house flies, drain flies, water bugs, cockroaches, and spiders with cobwebs." See Ex. 2 (July Focused Inspection Report) at 9. Inspectors further noted that "[t]here is an extensive, widespread pest problem throughout all animal-housing buildings at the facility." See Ex. 2 (July Focused Inspection Report) at 11. In particular, "a very large number of live flies" were observed in all of the whelping rooms in building 97 where dogs were present. The flies were observed on the walls, ceilings, flying in the air and in the drains in the rooms housing dogs. See Ex. 2 (July Focused Inspection Report) at 11.
- 136. Envigo was directed to correct these sanitation issues by July 30, 2021. *See* Ex. 2 (July Focused Inspection Report) at 8.
- 137. Envigo continued to have sanitation issues in subsequent visits. In October 2021, they observed that the Cumberland Facility continued to have sanitation problems. In at least 50% of the rooms being used within Buildings G1 and G2, there were still "accumulations of waste and an overpowering fecal odor" emanating from below the enclosures. APHIS inspectors also noted that significant accumulations of animal waste on top of two pulley systems used to scrape solid

waste underneath the enclosures were contributing to the excessive odor in the facility. *See* Ex. 3 (October 2021 Focused Inspection Report) at 10.

138. In November 2021, APHIS inspectors found once again that Envigo was failing to clean waste under the primary enclosures frequently enough to prevent the accumulation of feces and food waste to reduce disease hazards, odors, and the proliferation of pests. Many rooms had white, moldy accumulations of spilled feed and excreta in the pits that were several inches high and created areas of standing liquid. A majority of rooms in two buildings had significant accumulations of dropped feed and excreta on the ledges just underneath the suspended flooring. APHIS inspectors observed that the waste had been there long enough that in many rooms it was either white, brown, or black with mold and flies were congregating on the waste. Envigo was once again directed to correct the problem. *See* Ex. 4 (November 2021 Routine Inspection Report) at 15-16.

139. Consistent with the sanitation issues, APHIS inspectors also observed insect infestations in multiple buildings at the Cumberland Facility. Small gnat-sized black flies and large flies were observed throughout the facility, including on food receptacles and around the enclosures. Large numbers of small white fly larvae or maggots were present in spilled feed under enclosures and many areas of wet flooring appeared to be almost completely covered in maggots. Large numbers of small, white thread-like worms were also seen in several rooms throughout a building where there was pooled water. Envigo was once again directed to correct the pest problem. *See* Ex. 4 (November 2021 Routine Inspection Report) at 17-18.

Envigo Violated the AWA By Failing to Employ a Sufficient Number of Qualified Employees to Care for the Thousands of Beagles at the Cumberland Facility

- 140. Envigo failed to meet the minimum standards for handling, feeding, sanitation, and adequate veterinary care by employing an insufficient number of qualified employees to care for the thousands of beagles at the Cumberland Facility. 7 U.S.C. § 2143(a)(1), (2); 9 C.F.R. § 3.12.
- 141. Adequate staffing is essential for carrying out the level of husbandry and care required by the AWA to maintain the health and welfare of the dogs and maintain safe and sanitary facilities. *See* 9 C.F.R. § 3.12.
- 142. Envigo does not employ a sufficient number of adequately trained staff to provide humane care and treatment to the thousands of beagles at the Cumberland Facility.
- 143. In the inspection report for July 2021, Envigo was cited for failure to adequately staff the Cumberland Facility. APHIS noted that Envigo employed only one attending veterinarian to oversee veterinary care for over 5,000 beagles. In addition, Envigo employed a total of only 6 trained staff members to complete the required daily observations of the 5,000 dogs, with 3-4 employees conducting daily observations each day. These employees had additional duties, including providing treatments to dogs and carrying out husbandry practices. *See* Ex. 1 (July Routine Inspection Report) at 12.
- 144. The lack of adequate staffing of the Cumberland Facility has contributed to Envigo's failure to meet other AWA requirements, including daily observations of all dogs to assess their health and well-being. During the July 2021 inspection, APHIS inspectors noted that Envigo failed to identify 15 beagles with medical issues prior to the inspection. Several of those beagles were found in need of critical care, including a beagle puppy found by inspectors under the enclosure in the tray used for urine and feces collection. *See* Ex. 1 (July Routine Inspection Report) at 12.

sufficient number of personnel to carry out the level of care and husbandry practices required by the AWA. However, Envigo failed to correct the issue. As of the October 2021 inspection, APHIS inspectors found that there continued to be "severe staffing shortages" with only 17 staff members directly responsible for all husbandry, daily observations, and medical treatments for almost 5,000 beagles. APHIS inspectors identified four beagles with medical conditions that required treatment that should have been discovered by staff during daily observations. Additionally, "numerous dogs that have been identified with severe periodontal disease by veterinarians and still require prescribed dental cleanings." APHIS inspectors also noted that "basic husbandry such as cleaning out kennels daily to remove feces, cleaning contact surfaces to prevent buildup of debris, and general housekeeping including dead pest removal is not being performed in accordance with the AWA regulations." *See* Ex. 3 (October 2021 Focused Inspection Report) at 11.

146. In November 2021, Envigo was once again cited for failure to have a sufficient number of employees to meet the requirements of the AWA. At the time, Envigo employed only 21 full-time and three part-time employees who are responsible for all husbandry and daily observations for 4,652 beagles and beagle puppies. APHIS concluded that the failure to employee a sufficient number of employees was contributing to Envigo's failure to undertake required daily observations of the beagles, medical treatments, cleaning and sanitization, and facility maintenance. Envigo was once again directed to correct the problem. *See* Ex. 4 (November 2021 Routine Inspection Report) at 18.

Envigo Violated the AWA By Failing to Make and Retain Accurate and Complete Records

- 147. Envigo has failed to keep accurate records regarding the identification and disposition of dogs. In addition, medical records are frequently inaccurate and incomplete. *See* 7 U.S.C. § 2140; 9 C.F.R. § 2.75; 9 C.F.R. § 3.13(b).
- 148. Accurate and complete recordkeeping of all acquisitions, including births, and dispositions is important for animal identification, traceability of animals, and investigation of disease outbreaks or animal theft.
- 149. Envigo has been cited by APHIS for poor recordkeeping since July 2021. During the July 2021 inspection, a review of disposition records showed that three beagles were marked "missing" and an additional 21 beagle puppies were recorded as "miss." The attending veterinarian claimed that the records noting the beagle puppies as "miss" were likely due to administrative error and would be corrected when the beagles were identified. *See* Ex. 2 (July 2021 Focused Inspection Report) at 3-4. APHIS directed Envigo to correct the issue by August 30, 2021. *See id.* at 4.
- 150. When APHIS inspectors returned in October 2021, once again Envigo still did not have complete acquisition or disposition records for the beagles at the Cumberland Facility. APHIS inspectors noted that Envigo's inventory for the Cumberland Facility continued to list beagles who were no longer present.
- 151. One beagle puppy was listed in the original litter count but was no longer present as of October 14, 2021. Envigo had no record of the beagle puppy dying or being euthanized. When asked about the missing puppy, Envigo staff stated that they did not know if the beagle puppy existed in the first place or was missing.
- 152. Envigo staff mentioned that a newborn beagle puppy had been found in a drain under an enclosure on October 13, 2021 and died later that day. Envigo failed to record the birth (or acquisition) of the beagle puppy. Envigo also failed to record the death of the puppy on the

mortality log and, thus, no disposition record exists for the puppy. *See* Ex. 3 (October 2021 Focused Inspection Report) at 5-6. Thus, Envigo had no record of the existence of a beagle puppy that died as a result of Envigo's failure to ensure that the enclosures are safe for the dogs at the Cumberland Facility.

- 153. In November, APHIS inspectors determined that acquisition, disposition and inventory records were incomplete and inaccurate for at least 937 beagles and beagle puppies. Envigo identified an additional 99 beagles and beagle puppies with inaccurate disposition records.
- 154. Envigo has also failed to create and maintain accurate and complete medical records in violation of 9 C.F.R. § 3.13(b). The lack of accurate and complete medical records may hide adverse trends in animal health, medical errors, and the failure to provide adequate medical care to the beagles at the Cumberland Facility. Specifically, the lack of accurate and complete medical records prevents Envigo staff from learning from any mistakes they are making in caring for the beagles at the Cumberland facility and prevents USDA from determining Envigo's compliance with certain AWA regulations and standards.
- 155. During the July 2021 inspection, APHIS inspectors found that medical records for numerous beagles were incomplete. For example, medical records showed that four beagles suffered from a fracture, though the record failed to specify the location and type of fracture. An addition two beagles were euthanized for fractures, including one beagle that was euthanized for a broken tail. When asked the cause of the fractures, the attending veterinarian stated that she had investigated a nutritional cause but was unable to determine with certainty the cause. Another beagle suffered a laceration when his leg got caught in the enclosure, but the record did not indicate the location of the laceration or describe the injury with detail. The APHIS inspection report noted that "[f]ractures and lacerations may result from improper handling, unsafe primary enclosures,

incompatibility of animals, improper nutrition, or many other causes. *See* Ex. 2 (July Inspection Report) at 11-12.

- 156. The mortality log failed to identify the cause of death for two beagles. Although the attending veterinarian stated that Envigo staff is supposed to notify her whenever an adult beagle is found dead so that she can perform a necropsy examination, there is no record of the results of any necropsy for these two beagles. The mortality log listed the cause of death of another beagle as "pull," but the beagle's individual record contained no information about the beagle's death. *See* Ex. 2 (July Inspection Report) at 13.
- 157. Envigo was directed to correct the recordkeeping issues by August 30, 2021, by maintaining records for all beagles that include a date and description of any problems identified, examination findings, test results, plans for treatment and care, and treatments performed.
- 158. When APHIS inspectors returned in October 2021, they found additional mortality records for dead beagle puppies. For some, the records noted that necropsies had been performed but no exam findings or test results were recorded. In addition, the medical records contained no description of symptoms leading up to the beagle puppies' deaths. The APHIS inspectors concluded that, for at least some of the diagnoses listed on the mortality records, they could not be made without either a history of symptoms or further diagnostic testing. *See* Ex. 3 (October 2021 Focused Inspection Report) at 12.
- 159. Medical records for another beagle puppy indicated that the beagle was "lame on all four legs" and had a "broken left femur" but failed to contain additional physical examination findings, diagnostics, or test results. The staff member who found the beagle said that they had not observed obvious limping on any specific leg. However, a manager stated that when the attending veterinarian examined the beagle, she felt a pop in the beagle puppy's left femur, suspected a

fracture, and recommended euthanasia. The medical records, however, did not include any of the veterinarian's examination findings but rather only a presumptive diagnosis. *See* Ex. 3 (October 2021 Focused Inspection Report) at 13.

160. Envigo was once again reminded that, as a result of the incomplete records, Envigo could not determine the exact cause of death and, therefore, ensure the health of the rest of the beagle puppies. Further, if the diagnoses are accurate, the Envigo staff appear to have missed the clinical signs, including weakness, lethargy, coughing, heavy breathing, lack of appetite, diarrhea, and vomiting, which would have been apparent if they were undertaking the required daily observations. *See* Ex. 3 (October 2021 Focused Inspection Report) at 13-14.

161. APHIS inspectors again found incomplete and inaccurate medical records in November 2021. Envigo's medical records omitted critical information such as descriptions of the medical problem, treatments administered, and procedures performed to diagnose the condition or provide care. Envigo claimed that it did not understand that records describing physical examinations, medical procedures, treatments, deaths, and the administration of controlled substances constituted medical records that must comply with 9 C.F.R. § 3.13(b)(1). Envigo was directed to ensure that by February 11, 2022, every medical record included the identity of the animal, including identifying marks, tattoos, or tags, the animal's breed, sex, and age.

179. Because of the unusual nature of these violations, and that a dog's physical condition constitutes evidence of a crime, the requested warrant authorizes the United States to seize live animals. However, to limit the number of animals seized, the United States will only

seize animals which a veterinarian has opined are in acute distress. Because the United States is not adequately equipped to care for such animals seized the United States has sought and obtained a commitment by the Humane Society of the United States to assist in the assessment of the dogs on the premises and in the temporary placement of dogs seized so that the dogs may be appropriately cared for.

180. In addition to tangible objects and live animals, this application seeks permission to search for records that might be found on the SUBJECT PREMISES, in whatever form they are found. One form in which the records might be found is data stored on a computer's hard drive or other storage media. Thus, the warrant applied for would authorize the seizure of electronic storage media or, potentially, the copying of electronically stored information, all under Rule 41(e)(2)(B).

ELECTRONIC MEDIA

- 181. This application seeks permission to search for records that might be found on the SUBJECT PREMISES, in whatever form they are found. One form in which the records might be found is data stored on a computer's hard drive or other storage media. Thus, the warrant applied for would authorize the seizure of electronic storage media or, potentially, the copying of electronically stored information, all under Rule 41(e)(2)(B).
- 182. I submit that if a computer or storage medium is found on the SUBJECT PREMISES, there is probable cause to believe those records will be stored on that computer or storage medium, for at least the following reasons:
 - Based on my knowledge, training, and experience, I know that computer files or remnants of such files can be recovered months or even years after they have been downloaded onto a storage medium, deleted, or viewed via the Internet. Electronic files

downloaded to a storage medium can be stored for years at little or no cost. Even when files have been deleted, they can be recovered months or years later using forensic tools. This is so because when a person "deletes" a file on a computer, the data contained in the file does not actually disappear; rather, that data remains on the storage medium until it is overwritten by new data.

- Therefore, deleted files, or remnants of deleted files, may reside in free space or slack space—that is, in space on the storage medium that is not currently being used by an active file—for long periods of time before they are overwritten. In addition, a computer's operating system may also keep a record of deleted data in a "swap" or "recovery" file.
- Wholly apart from user-generated files, computer storage media—in particular, computers' internal hard drives—contain electronic evidence of how a computer has been used, what it has been used for, and who has used it. To give a few examples, this forensic evidence can take the form of operating system configurations, artifacts from operating system or application operation, file system data structures, and virtual memory "swap" or paging files. Computer users typically do not erase or delete this evidence, because special software is typically required for that task. However, it is technically possible to delete this information.
- Similarly, files that have been viewed via the Internet are sometimes automatically downloaded into a temporary Internet directory or "cache."
- 183. This application seeks permission to locate not only computer files that might serve as direct evidence of the crimes described on the warrant, but also for forensic electronic evidence that establishes how computers were used, the purpose of their use, who used them, and when.

There is probable cause to believe that this forensic electronic evidence will be on any storage medium in the SUBJECT PREMISES because:

- Data on the storage medium can provide evidence of a file that was once on the storage medium but has since been deleted or edited, or of a deleted portion of a file (such as a paragraph that has been deleted from a word processing file). Virtual memory paging systems can leave traces of information on the storage medium that show what tasks and processes were recently active. Web browsers, e-mail programs, and chat programs store configuration information on the storage medium that can reveal information such as online nicknames and passwords. Operating systems can record additional information, such as the attachment of peripherals, the attachment of USB flash storage devices or other external storage media, and the times the computer was in use. Computer file systems can record information about the dates files were created and the sequence in which they were created, although this information can later be falsified.
- As explained herein, information stored within a computer and other electronic storage media may provide crucial evidence of the "who, what, why, when, where, and how" of the criminal conduct under investigation, thus enabling the United States to establish and prove each element or alternatively, to exclude the innocent from further suspicion. In my training and experience, information stored within a computer or storage media (e.g., registry information, communications, images and movies, transactional information, records of session times and durations, internet history, and anti-virus, spyware, and malware detection programs) can indicate who has used or controlled the computer or storage media. This "user attribution" evidence is analogous to the search for "indicia of occupancy" while executing a search warrant at a residence. The

existence or absence of anti-virus, spyware, and malware detection programs may indicate whether the computer was remotely accessed, thus inculpating or exculpating the computer owner. Further, computer and storage media activity can indicate how and when the computer or storage media was accessed or used. For example, as described herein, computers typically contain information that log: computer user account session times and durations, computer activity associated with user accounts, electronic storage media that connected with the computer, and the IP addresses through which the computer accessed networks and the internet. Such information allows investigators to understand the chronological context of computer or electronic storage media access, use, and events relating to the crime under investigation. Additionally, some information stored within a computer or electronic storage media may provide crucial evidence relating to the physical location of other evidence and the suspect. For example, images stored on a computer may both show a particular location and have geolocation information incorporated into its file data. Such file data typically also contains information indicating when the file or image was created. The existence of such image files, along with external device connection logs, may also indicate the presence of additional electronic storage media (e.g., a digital camera or cellular phone with an incorporated camera). The geographic and timeline information described herein may either inculpate or exculpate the computer user. Last, information stored within a computer may provide relevant insight into the computer user's state of mind as it relates to the offense under investigation. For example, information within the computer may indicate the owner's motive and intent to commit a crime (e.g., internet searches indicating criminal planning), or consciousness of guilt (e.g., running a

- "wiping" program to destroy evidence on the computer or password protecting/encrypting such evidence in an effort to conceal it from law enforcement).
- A person with appropriate familiarity with how a computer works can, after examining
 this forensic evidence in its proper context, draw conclusions about how computers were
 used, the purpose of their use, who used them, and when.
- The process of identifying the exact files, blocks, registry entries, logs, or other forms of forensic evidence on a storage medium that are necessary to draw an accurate conclusion is a dynamic process. While it is possible to specify in advance the records to be sought, computer evidence is not always data that can be merely reviewed by a review team and passed along to investigators. Whether data stored on a computer is evidence may depend on other information stored on the computer and the application of knowledge about how a computer behaves. Therefore, contextual information necessary to understand other evidence also falls within the scope of the warrant.
- Further, in finding evidence of how a computer was used, the purpose of its use, who used it, and when, sometimes it is necessary to establish that a particular thing is not present on a storage medium. For example, the presence or absence of counter-forensic programs or anti-virus programs (and associated data) may be relevant to establishing the user's intent.
- 184. In most cases, a thorough search of a premises for information that might be stored on storage media often requires the seizure of the physical storage media and later off-site review consistent with the warrant. In lieu of removing storage media from the premises, it is sometimes possible to make an image copy of storage media. Generally speaking, imaging is the taking of a complete electronic picture of the computer's data, including all hidden sectors and deleted files.

Either seizure or imaging is often necessary to ensure the accuracy and completeness of data recorded on the storage media, and to prevent the loss of the data either from accidental or intentional destruction. This is true because of the following:

- 185. Not all evidence takes the form of documents and files that can be easily viewed on site. Analyzing evidence of how a computer has been used, what it has been used for, and who has used it requires considerable time, and taking that much time on premises could be unreasonable. As explained above, because the warrant calls for forensic electronic evidence, it is exceedingly likely that it will be necessary to thoroughly examine storage media to obtain evidence. Storage media can store a large volume of information. Reviewing that information for things described in the warrant can take weeks or months, depending on the volume of data stored, and would be impractical and invasive to attempt on-site.
- 186. Computers can be configured in several different ways, featuring a variety of different operating systems, application software, and configurations. Therefore, searching them sometimes requires tools or knowledge that might not be present on the search site. The vast array of computer hardware and software available makes it difficult to know before a search what tools or knowledge will be required to analyze the system and its data on the Premises. However, taking the storage media off-site and reviewing it in a controlled environment will allow its examination with the proper tools and knowledge.
- 187. Records sought under this warrant could be stored in a variety of storage media formats that may require off-site reviewing with specialized forensic tools.
- 188. Based on the foregoing, and consistent with Rule 41(e)(2)(B), the warrant I am applying for would permit seizing, imaging, or otherwise copying storage media that reasonably appear to contain some or all of the evidence described in the warrant and would authorize a later

review of the media or information consistent with the warrant. The later review may require techniques, including but not limited to computer-assisted scans of the entire medium, that might expose many parts of a hard drive to human inspection in order to determine whether it is evidence described by the warrant.

189. Because several employees work at the SUBJECT PREMISES, some of the employees may have storage media, including in the form of a cellular phone or other personal electronic device, that may predominantly be used, and perhaps owned, by such employees. It is likely such persons have used their devices to send texts, emails, or perhaps taken photos concerning Envigo. Also, this storage media will likely contain location data concerning the employee which will be evidence concerning Envigo's failure to maintain proper levels of staffing. Accordingly, because the things described in this warrant could be found on any of those computers or storage media, the warrant applied for would permit the seizure and review of those items as well.

BIOMETRIC UNLOCKING

- 190. I am further seeking permission, pursuant to this warrant to permit law enforcement to, using a device's biometric features, compel any employees or agents of Envigo to unlock any cellular devices located on the premises. I seek this authority based on the following:
- 191. From training and experience, I know that users of cellular devices also carry their cellular devices on their persons or keep them in close proximity so they can access them.
- 192. I know from my training and experience, as well as from information found in publicly available materials published by device manufacturers, that many electronic devices, particularly newer mobile devices and laptops, offer their users the ability to unlock the device through biometric features in lieu of a numeric or alphanumeric passcode or password. These

biometric features include fingerprint scanners, facial recognition features, and iris recognition features. Some devices offer a combination of these biometric features, and the user of such devices can select which features they would like to utilize.

- 193. If a device is equipped with a fingerprint scanner, a user may enable the ability to unlock the device through his or her fingerprints. For example, Apple offers a feature called "Touch ID," which allows a user to register up to five fingerprints that can unlock a device. Once a fingerprint is registered, a user can unlock the device by pressing the relevant finger to the device's Touch ID sensor, which is found in the round button (often referred to as the "home" (button) located at the bottom center of the font of the device. The fingerprint sensors found on devices produced by other manufacturers have different names but operate similarly to Touch ID.
- 194. If a device is equipped with a facial-recognition feature, a user may enable the ability to unlock the device through his or her face. For example, this feature is available on certain Android devices and is called "Trusted Face." During the Trusted Face registration process, the user holds the device in front of his or her face. The device's front-facing camera then analyzes and records data based on the user's facial characteristics. The device can then be unlocked if the front-facing camera detects a face with characteristics that match those of the registered face. Facial recognition features found on devices produced by other manufacturers (such as Apple's "Face ID") have different names but operate similarly to Trusted Face.
- 195. If a device equipped with an iris-recognition feature, a user may enable the ability to unlock the device with his or her irises. For example, on certain Microsoft devices, this feature is called "Windows Hello." During the Windows Hello registration, a user registers his or her irises by holding the device in front of his or her face. The device then directs an infrared light toward

the user's face and activates and infrared-sensitive camera to record data based on patterns within the user's irises. Iris-recognition features found on devices produced by other manufacturers have different names but operate similarly to Windows Hello.

- 196. In my training and experience, users of electronic devices often enable the aforementioned biometric features because they are considered to be a more convenient way to unlock a device than by entering a number or alphanumeric passcode or password. Moreover, in some instances, biometric features are considered to be a more secure way to protect a device's contents. This is particularly true when the users of a device are engaged in criminal activities and thus have a heightened concern about securing the contents of a device.
- 197. The passcode or password that would unlock the cellular devices subject to search under this warrant currently is not known to law enforcement. Thus, law enforcement personnel may not otherwise be able to access the data contained within such devices, making the use of biometric features necessary to the execution of the search authorized by this warrant.
- 198. I also know from my training and experience, as well as from information found in publicly available materials including those published by device manufacturers, that biometric features will not unlock a device in some circumstances even if such features are enabled. This can occur when a device has been restarted, inactive, or has not been unlocked for a certain period. For example, Apple devices cannot be unlocked using Touch ID when: (1) more than 48 hours has elapsed since the device was last unlocked; or, (2) when the device has not been unlocked using a fingerprint for 8 hours and the passcode or password has not been entered in the last 6 days. Similarly, certain Android devices cannot be unlocked with Trusted Face if the device has remained inactive for four hours. Biometric features from other brands carry similar restrictions. Thus, in the event law enforcement discover that the device is locked and equipped with biometric

features, the opportunity to unlock the device through a biometric feature may exist for only a short time.

199. Based on the foregoing, if law enforcement personnel encounter a cellular device and the phone may be unlocked using one of the aforementioned biometric features, this warrant permits law enforcement personnel to obtain the display of any physical biometric characteristics (such as fingerprint/thumbprint or facial characteristics) necessary to unlock the device, including to (1) press or swipe the fingers (including thumbs) of the aforementioned person to the fingerprint scanner of the device; (2) hold the device in front of a face to activate the facial recognition feature; and/or (3) hold the device in front of a face to activate the iris recognition feature, for the purpose of attempting to unlock the device in order to search the contents as authorized by this warrant.

200. The proposed warrant does not authorize law enforcement to require that a person provide the password, or identify specific biometric characteristics (including the unique finger(s) or other physical features) that may be used to unlock or access the device and any other electronic device seized. Nor does the proposed warrant authorize law enforcement to use the fact that the warrant allows law enforcement to obtain the display of any biometric characteristics to compel the aforementioned person to state or otherwise provide that information. However, the voluntary disclosure of such information by the aforementioned person would be permitted under the proposed warrant.

SEALING ORDER REQUESTED

201. It is respectfully requested that this Court issue an order sealing, until further order of the Court, all papers submitted in support of this application, including the application and search warrant. I believe that sealing this document is necessary because the affidavit contains information that if revealed could negatively impact the criminal investigation and the Confidential Human Source referenced in the affidavit.

CONCLUSION

- 202. Based on the above statements, I believe there is probable cause to find that violations of 7 U.S.C. §2149(d), 18 U.S.C. § 1001 and 18 U.S.C. § 1512, occurred, and that evidence of such violations (described in Attachment B) will be found at the SUBJECT LOCATION (described in Attachment A).
- 203. Based upon the foregoing, I respectfully request that this Court issue a search warrant for the SUBJECT PREMISES, more particularly described in Attachment A, authorizing the seizure of the items described in Attachment B. Permission is sought to allow the USDA-OIG to obtain the assistance of Federal, State, and local law enforcement in executing the search of the SUBJECT PREMISES, described in Attachment A. Permission is also sought to allow these parties to seize items identified in Attachment B.
- 204. Permission is also sought to allow the assistance of non-governmental organizations (NGOs) with expertise in animal welfare to assist law enforcement officers executing this search and evaluating and caring for the animals found on the SUBJECT PREMISES.

Respectfully submitted,

Stanley Wojtkonski, Special Agent U.S. Department of Agriculture Office of the Inspector General

Sworn and attested to by telephone on May 13, 2022.

Robert S. Ballon

HON. ROBERT S. BALLOU United States Magistrate Judge



DCARE 2016090000739001 Insp. id

Inspection Report

ENVIGO RMS LLC

8520 Allison Pointe Blvd., Suite 400 INDIANAPOLIS, IN 46250

Customer ID: 506554

Certificate: 32-A-0774

Site: 005

ENVIGO RMS LLC

Type: ROUTINE INSPECTION

Date: 20-JUL-2021

2.40(b)(3)

Direct

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

15 animals had medical problems that had not been identified or treated by the facility prior to the inspection.

July 20th, 2021:

***An adult female beagle (CLDCCL) had an abnormal right eye. There was a moderate amount of thick greenish yellow discharge around the edge of the eye. The membrane at the inner corner of the eye was protruding ("cherry eye"). The surface of the eye was slightly grey and there was an irregular, roughened area approximately ¼ inch diameter within this grey area near the inner corner of the eye. This eye condition was not previously identified by the facility and the dog was not receiving any treatments for the eye. The attending veterinarian examined the dog and stated that the eye condition was likely not present for more than two days, and treatment was started for the eye condition.

***An adult female beagle (CGDCEX) had severe dental disease. The back 4 upper teeth on the left side were completely covered with hard, brown tartar and the gums were red. There was hair embedded in the tartar. The right upper canine tooth was 50% covered with tartar, and the gums adjacent to the tooth were inflamed. The 2 back upper teeth on the right side were 90% covered with hard, brown tartar, and there was hair embedded in the tartar. The gums were red. The attending veterinarian examined the dog and stated that the dog had severe dental disease. The animal last had a dental cleaning in May 2019.

Prepared By: DIANA CARE

USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Facility Representative

Date:

18-OCT-2021

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EXHIBIT



DCARE **2016090000739001** Insp. id

Inspection Report

***An adult female beagle (CGGCAE) was itching her right ear continuously. When the ear flap was lifted, the ear canal was thickened, reddened, and there was a brown waxy debris in the ear. The left ear canal was also thickened, reddened, and contained waxy brown debris and a small amount of clear discharge. There were small red scabs on the outside of both the right and left ears. The facility had not previously identified this dog's ear condition and the dog was not currently being treated for its ear condition, but the facility started treatment during the inspection.

***One adult female beagle (CKKCPZ) had a skin issue. The dog had patchy hair loss and a thinning coat along with some scabs affecting approximately 70% of the right side of the dog's rib cage and side. The skin appeared mildly irritated and red. According to the attending veterinarian, the dog's skin condition had not been observed previously and the dog was not being treated for this condition, and treatment was started the same day.

***One adult beagle (CNACDX) was identified with large quantities of fur stuck on the bottoms of the front paws and between the toes of these paws. On examination, an approximately 1-inch diameter area of hair loss with yellow crusts and red skin was identified at the tail base. The hair surrounding this area was crusty. According to the attending veterinarian, the dog's skin condition had not been observed previously and the dog was not being treated for this condition, but treatment was started the same day.

***One adult female beagle (CFECGS) in the broodstock area (G1, room #10) had severe dental disease. The 2 upper left back teeth were completely covered with hard brown tartar, and there were pieces of hair in the tartar. The gums above these teeth were red and bled slightly when touched. The dog was prioritized for a dental cleaning.

***One adult female beagle (CICCYS) in the broodstock area (G1, room #10) had severe dental disease. There was gingivitis, gum recession, and some hair in the tartar. The attending vet examined the dog's teeth and agreed that severe dental disease was present.

July 21, 2021

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***One adult female beagle (CLGCST) located in G2, room 2, kennel #44, had a wound on the outer surface of her left ear. The wound was approximately 1 inch long and ½ inch wide, and was covered by a dark brown scab. The scab had pulled away from the ear on the front edge and there was a small amount of red and pink milky fluid in the area. There was a small amount of patchy hair loss at the base of the ear. Facility personnel had not previously identified this lesion, and began treatment immediately.

***One male puppy (CMCCIZ) located in G2, room 3, kennel #73, was reluctant to bear weight on the right front foot. The underside of each of the middle two toes on the front right foot had a small circular red area approximately 1/3 inch in diameter. There were yellow crusts or scabs on the underside of all four toes on this foot. Facility personnel had not previously identified this lesion, and began treatment immediately.

***One adult male beagle (CKDCBZ) located in G2, Room 8, Kennel 48, was reluctant to stand and bear weight on his left rear leg. He would stand for a short period of time and then lay down, despite his cage mates jumping around excitedly. This toe was swollen, and skin in the area between this toe and the next was red. The toe nail was curved tightly against the underlying pad. The attending veterinarian further trimmed the nail on this toe and there was a depression left in the toe pad where the nail had been. Facility personnel had not previously identified this issue, and created a treatment plan immediately and was given pain medication the same day.

***One adult female beagle (CGASCD), located in G1, Room 3, Kennel #24, had severe dental disease and a skin issue.

On both sides of the mouth, the upper back teeth were completely covered in a hard brown tartar, the adjacent gums were red, swollen, and had pulled back from the teeth. On the right side, there was a greyish substance along the gum line. On the left side of the dog's neck, where the neck meets the lower jaw, there was an yellowish brown scab approximately 1 inch wide and 1.5 inches long. The skin around the edges of the scab was hairless and red, and there was a small amount of clear fluid at the center of the scab. Facility personnel had not previously identified this issue, and

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created a treatment plan immediately.

***One adult female beagle (CFHCAS), located in G1, room 4, kennel 23, had severe dental disease. On the left side of the mouth, the upper back teeth were completely covered in hard brown tartar, and there was hair stuck in the tartar. The adjacent gums were red and swollen and pulling away from the teeth. On the right side of the mouth, the upper middle teeth were completely covered in hard brown tartar, and the gums were swollen and had pulled back from some of the teeth exposing the roots of the teeth. There was greyish material along the gum line. Facility personnel had not previously identified this issue. The dog was prioritized for a dental cleaning.

*** In Building G2, Room 1, an adult female beagle (CLACHJ) has a large, firm, pink and swollen area of skin between the 3rd and 4th toes of her right front paw. The cyst was approximately 1" in length and approximately 70-80% the length of the toes. She was reluctant to bear her full weight on the right front limb. According to the attending veterinarian, the condition was not previously identified by the facility and no treatments had been initiated prior to the time of observation. The dog received treatment immediately.

***In Building G2, Room 5, an adult male beagle (CMBCIA) has discharge in the left eye. The eye has milky, yellow discharge around the edges and there are crusts on the surrounding eyelid. The eye and surrounding tissues were mildly inflamed and red. The condition was not previously identified by the facility and treatment began immediately.

***In Building G1, Room 3, an adult female beagle (CHICPT) has a large amount of patchy hair loss encompassing approximately 80% of her entire coat. The hair loss is primarily over the trunk, sides, and top side of her tail. There are several small yellow scabs spread throughout the hair loss and the skin is red over the tail where the hair is missing. She was not found scratching or chewing during inspection. According to the attending veterinarian, this issue had not been observed and the dog had not been started on any medical treatment prior to the inspection. The attending veterinarian examined the dog and created a treatment plan.

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Animals with medical conditions including eye, skin, ear, and dental problems, may suffer from pain, discomfort, infection, and stress. Daily observation of animals to identify medical problems is essential for animal health and welfare.

Correct by July 23, 2021 by observing animals on a daily basis to identify physical, medical or behavioral problems, and communicate all findings to the attending veterinarian promptly.

2.131(b)(1)

Direct

Handling of animals.

***In Building 97, Room 15, at 1:36 PM on 07/20/21, a 3-week-old male puppy was found in the pan below cage # 97-1115. The puppy was huddled, depressed and not actively vocalizing or searching for his dam. He had dried excreta in his fur. When handled he remained listless and quiet. Upon removing the puppy from the pan and replacing him into the cage above, with his dam (CHBCMX), he immediately began crawling towards the rest of the litter. According to the facility operations manager, the room had been cleaned around 9 AM that morning and this puppy belonged in the cage above the tray where he was found. The facility operations manager indicated that this puppy must have fallen into the tray during the morning cleaning. There are no gaps or areas where the puppy could fall out of the cage when the cage door is closed. The puppy was immediately examined and treated by the attending veterinarian.

Young pupplies who fall into trays below their cage may become distressed, cold, hungry, dehydrated, or contaminated with feces and urine.

Correct by July 23rd, 2021 by ensuring all pupples are handled expeditiously and carefully in a manner that does not cause excessive cooling, behavioral stress, or unnecessary discomfort. This noncompliance was discussed with facility management and the facility took steps to address this issue immediately.

***13 nursing adult female beagles, housed in individual cages with their litters of 6-week old puppies (78 total), were fasted for 42 hours. The facility representatives stated that this reduces milk production and is part of their current standard operating procedure for weaning which they believe reduces the risk of mastitis. This was conducted in

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accordance with the facility's "Weaning of puppies" procedure (EGS-SOP-PRD-6616). Metal automatic food dispensers (self-feeders) which were normally mounted on the doors of each cage were turned around and left on the doors of the cage, so that the dogs could see and smell the food but could not eat it. Many of these self-feeders did not have lids, so the dog food was visible through the uncovered top of the feeders. Food access was removed on Monday (07/19/21) after noon, and food access was returned to the dogs on Wednesday (07/21/21) beginning around 6AM when the females were separated from their litters and moved to a different housing area. The inspectors initially observed the dogs at approximately 12PM on Tuesday, 7/20/21. Three dams were observed to be reaching their front paws through the doors of the cages to reach the food in the top of their feeders, these dogs were seen trying to scoop or dig out food from the feeders but could only retrieve the occasional piece of kibble. One dam was observed to be vigorously licking the back of the self-feeder, another was observed intently smelling the side of the feeder.

Deprivation of food causes stress, hunger, and anxiety. Placing the food where it can be seen, smelled, and in some cases touched by dogs while the dogs are fasting is causing unnecessary distress and anxiety.

Correct by July 23rd, 2021 by ensuring that dogs are handled in a manner that does not cause unnecessary discomfort and/or behavioral stress. This noncompliance was discussed with facility management at the time of initial observation on Tuesday 7/20/2021.

3.3(a) Direct

Sheltered housing facilities.

Puppies and adult dogs were housed in sheltered housing facilities in which the temperature inside the sheltered area exceeded 85 degrees Fahrenheit for at least 5 hours.

The temperature was measured in multiple locations in the following rooms:

Building G2, Room 3 (contains 543 puppies and 21 adults including some that are currently receiving medical treatment for minor conditions):

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86.4F, 86.1F, and 86.0F at 11:40AM

89.4F, 89.1F, and 89.2F at 1:30PM

90.5F, 90.3F, 90.2F at 2:36PM

90.8F, 90.7F, 90.8F at 3:42PM

91.3F, 91.2F, 91.0F at 4:55PM

Building G2, Room 2 (contains 112 adult dogs, 219 puppies)

86.4F, 86.2F, and 86.2F at 11:42AM

88.7F, 89.0F, 89.1F at 1:33PM

90.2F, 90.1F, 90.2F at 2:33PM

90.7F, 90.8F, 90.7F at 3:39PM

92.3F, 92.2F, 91.8F at 4:53PM

Building G2, Room 1 (contains 319 dogs)

86F at 11:45AM

88.7F, 88.8F, and 88.9F at 1:36PM

90.0F, 89.1F, 90.1F at 2:31PM

92.0F, 91.8F, 91.9F at 3:37PM

92.3, 92.1, 92.0 at 4:49PM

The outdoor ambient temperature taken mainly in shaded areas were 89F at 11:48AM, 91F at 2PM, 92.3F at 2:30PM, and 92,7F at 4:15PM.

Other buildings, which are constructed in the same way and in which the temperature is managed in the same way, were of similar ambient temperatures in their sheltered areas throughout the day. G2 building, room 8 was 89.0F at 1:18PM.

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G1 building, room 1 was 89.9F at 3:03PM, G1 building, room 4 was 90.1F inside at 4:11PM, G1 building, room 5 (which contained a very small number of dogs) was 88.4F at 4:20PM.

Each room had a large fan at one end and two exhaust fans at the other end. There is no air conditioning or other mechanism in place for cooling this building. The facility stated that they typically monitor temperatures once daily at approximately 7 AM. The adult dogs within the buildings were easily excited by the presence of USDA personnel, and were usually jumping, barking, and panting excitedly when inspectors were present. When USDA personnel returned to the rooms throughout the afternoon as temperatures increased, both dogs and puppies were observed to be sleeping. When sleeping, the dogs were avoiding contact and were splayed out not touching each other. Puppies were frequently observed sleeping on the cinderblock at the bottom of the door between the inside and outside of the kennel. Dogs that were awake and not barking or overly excited were often observed to be panting.

Dogs who are hot may experience discomfort, lethargy, or stress. Pupples and dogs with medical problems are especially vulnerable to the effects of hot weather.

Correct by July 26th, 2021 by providing additional / alternate cooling mechanisms that ensure ambient temperatures that do not exceed 85F for more than 4 consecutive hours when dogs are present, and that adequately provides for animal comfort and wellbeing.

3.6(a)(2)(x)

Primary enclosures.

Direct

In the G3 building, Rooms 1 and 2, the floors in the cages have a grid pattern with openings large enough for young puppies feet to pass through. There are approximately 200 puppies housed with their respective dams in indoor housing comprised of raised plastic-coated metal grate-type flooring. The grid pattern openings in the flooring allow the puppies feet to fall through the flooring up to their shoulders. Three puppies were observed with their limbs through the floor, and these puppies were able to remove their limbs and move around the cage.

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In the sheltered area of kennels in G2, Room 3, there were two kennels with a total of 13 puppies. In one kennel, two puppies were sleeping at the front of the sheltered area of the kennel. The puppies were leaning against the front gate and their front paws were passing down through a gap between the raised grate floor and the bottom of the gate. In the second kennel, three puppies were up at the front gate and walking back and forth. At least four times their back limb and front limbs fell down between the raised grate floor and the gate. Puppies whose limbs passed through this gap between the floor and the bottom of the gate would sink down to their shoulders or hips and could touch the edge of the cement stab below.

In Building G1, Room 3, an adult female beagle (CJICFN) was standing on the outside of the kennel. The dog's left front paw was caught in the raised plastic-coated grate flooring. Her two middle toes were caught in a thin rectangular opening in the grate floor and she was unable to free her foot. She was standing on her other three feet while panting rapidly and making small movements, as the other 3 dogs in the kennel jumped around her excitedly. It took two facility personnel approximately 3 minutes to free the dog's toes from the opening in the floor. Once the toes were free, the dog was examined more closely and the two toes were red and swollen. The facility provided immediate veterinary care. Facility personnel did not know how long the dog's toes had been stuck in the floor. Medical records indicated that the animal was mildly dehydrated.

Raised mesh or slatted flooring that contains openings that are wide enough for a limb, paw, or digit to pass through can lead to an animal becoming trapped or injured. When an animal becomes entrapped as described above, they can become distressed, dehydrated, or may suffer additional injuries.

Correct by 07/30/21 by ensuring that mesh or slat flooring does not allow the animals' feet or legs to pass through and that all flooring is constructed in a manner that protects their feet and legs from injury.

3.6(c)(1)(ii)

Direct

Primary enclosures.

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Inspection Report

62 nursing female dogs (and a total of 393 puppies) in the whelping building (building 97) were housed in cages that did not provide the minimum amount of floor space for the dam and her litter as required by the Animal Welfare Act.

Room 7 has dams housed with their litters in cages that measure 33 inches by 36 inches providing a total floor space of 1,188 square inches. The following dams were identified and measured from nose to base of tail:

CJKCNN measured 28" and has 7 puppies

CIHCLC measured 26" and has 7 pupples

CIJCCF measured 25" and has 5 pupples

CJGCAU measured 28" and has 4 puppies

CKICGJ measured 25" and has 6 puppies

CLDCDA measured 26" and has 6 pupples

CGDCEX measured 25" and has 6 puppies

Additional dams with litters who did have enough floor space were identified in Room 7, Room 10, Room 11, and Room 13. The facility staff stated that the dogs are a consistent size (average female is 25-28 inches). Each of these 62 female dogs had 5 to 9 puppies.

CJKCNN with her seven pupples, requires a minimum floor space of 1560.6 sq.in. The enclosure requires an additional 372 sq.in. of space for compliance with the AWA. CIJCCF, with her five pupples, requires a minimum floor space of 1201.25 sq.in. The enclosure requires an additional 13 sq.in. of space for compliance with the AWA.

Dams and pupples without the minimum amount of floor space may suffer from distress, discomfort, crowding, poor sanitation, increased trauma and mortality.

Correct by July 30th, 2021 by ensuring that all dams and litters are provided with at least the amount of floor space required under the Animal Welfare Act. This issue was identified to the facility during inspection on 7/20/21.

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3.9(a)

Direct

Feeding

***13 litters of 6-week-old beagle pupples were kept with their mothers (dams) while the dams were fasted (did not have food) for 42 hours. Facility representatives stated the purpose of the fast was to decrease milk production and reduce the risk of mastitis for the mother dogs. This was conducted in accordance with the facility's "Weaning of pupples" procedure (EGS-SOP-PRD-6616). The pupples only source of food was to nurse on the mother dogs, who were experiencing decreased milk production. Pupples were observed vocalizing and nursing on their mothers, while the mothers stood and tried to gain access to the food outside their cage.

Puppies who have no food source aside from a dam that is on a program to reduce (and eventually halt) milk production may not get enough nutrition, causing the puppies to experience hunger, dehydration, stress, increased susceptibility to infections, and low blood sugar.

Correct by July 23rd, 2021 by ensuring that puppies and dogs are fed in a manner that provides a sufficient amount of wholesome food and nutrition for their age and condition.

***Food in the self-feeders and feed silo in G1 building, and food in self feeders and storage areas in the G2 building were contaminated with a variety of live insects. Live small black worm-type insects were observed in the feed silo and in four self-feeders. Approximately 5 feeders contained live small black beetle-type inspects. Flies were present inside many of the self feeders, and were observed landing on the feed in those feeders. Facility operations management stated that feed is added to the feeders every other day, or when food levels were low, and that the self feeders were sanitized every 2 weeks. Facility operations management stated that currently the hopper is cleaned at least twice a year.

Feed infested with insects is not considered wholesome and palatable and may lead to reduced feed consumption or poor nutrition. Correct by July 23, 2021 by ensuring that all feed offered to dogs is uncontaminated, wholesome, palatable, and of sufficient quantity and nutritive value. The following day the facility provided alternative, uncontaminated feed to the

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Animal and Plant Health Inspection Service

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dogs in G1.

This noncompliance was discussed with facility management at the time of inspection.

3,12 Direct

Employees

Daily observation failed to identify 15 dogs with medical issues prior to the inspection. A treatment plan was created for each of these dogs following identification by APHIS inspectors, however, there are currently not sufficient employees to recognize these issues effectively. Daily observations regarding veterinary care are made by 6 trained staff members who conduct daily observation in addition to other duties including treatments and husbandry; 3-4 of these employees conduct daily observations each day.

Several animals were found in need of critical care. This included the puppy found by inspectors under the enclosure in the tray used for urine and feces collection and the adult dog with the toes entrapped in the slat flooring. Although both animals received care immediately, they were not identified by animal care staff responsible for providing husbandry care. Two cage cards, and one puppy, were missing from nursery cages. Sheltered housing facilities were not being managed in accordance with the written temperature SOP. The facility currently employs 39 personnel for over 5000 dogs, and there are 5 vacancies which remain unfilled.

Only one attending veterinarian is employed to oversee care for all of the dogs and cats well as assisting in research projects.

Adequate staffing is essential for carrying out the level of husbandry and care required to maintain animal health, welfare, and facility maintenance and sanitation.

Correct by August 31, 2021 by maintaining enough personnel to carry out the level of husbandry practices and care required by the Animal Welfare Act and to assure animal health and wellbeing.

Prepared By: DIANA CARE USDA, APHIS, Animal Care 18-OCT-2021

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Inspection Report

A complete routine inspection was conducted starting on 7/20/2021. This inspection report is limited to the Direct non-compliances identified during that inspection. An additional inspection report will be delivered with the other issues identified during this inspection.

This inspection was conducted with the Manager of Operations and Attending Veterinarian. The exit briefing was conducted on July 22nd, 2021 with the Manager of Operations, the Attending Veterinarian, the Senior Vice President for Vet Services, the Director of Quality Assurance, the Regional Quality Assurance Manager, the Regional Facilities Manager, the Vice President of North American Operations, and the Chief Operating Officer.

Additional Inspectors:

Rachel Perez-Baum, VETERINARY MEDICAL OFFICER

Prepared By: DIANA CARE

USDA, APHIS, Animal Care

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United States Department of Agriculture Animal and Plant Health Inspection Service

Customer: 506554

Inspection Date: 20-Jul-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506554	32-A-0774	005	ENVIGO RMS LLC	20-JUL-2021

Count	Scientific Name	Common Name
003021	Canis lupus familiaris	DOG ADULT
002014	Canis lupus familiaris	DOG PUPPY
005035	Total	



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ENVIGO RMS LLC

8520 Allison Pointe Blvd., Suite 400 INDIANAPOLIS, IN 46250

Customer ID: 506554

Certificate: 32-A-0774

Site: 005

ENVIGO RMS LLC

Type: FOCUSED INSPECTION

Date: 20-JUL-2021

2.40(b)(2)

Critical

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

Mortality records show that during the time period from 01/01/2021 to 07/22/2021 over 300 puppy deaths were attributed to unknown causes, however, the facility has not taken additional steps to determine the causes of death in order prevent similar deaths of other puppies in the future. Current guidance from the attending veterinarian is that she should be notified when adult dogs are found dead, however, when puppies are found dead she may or may not be notified. Instead, the animal care staff (who have significant additional responsibilities) are permitted to make the decision of whether the body is disposed of without examination or if they perform a gross necropsy examination. When a gross necropsy has been conducted, the medical records recording those results are incomplete. The lack of consistently applied methods to accurately diagnose the cause of deaths for these animals and complete record-keeping when tests are performed limits the ability to determine causes of deaths and implement changes that would prevent the deaths of additional animals.

***165 puppies under 5 weeks of age were found dead and the cause of death is identified as "unknown" in the medical records, Individual medical records are not recorded for puppies less than 5 weeks old, instead litter records are maintained. The medical records that were evaluated did not have any recorded information indicating abnormalities observed prior to death and did not include any information regarding a potential cause of death, investigation of death, or

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body condition when found.

****5 puppies (CMBCGY, a 7 week-old female; CLLCFK, a 7.4 week-old female; CMDCHW, a 7.4 week-old male; CMBCHN, a 6.9 week-old male; CLLCMY, a 6.3 week-old male) were found dead in building G2 and the cause of death identified in the medical records is "unknown". These deaths occurred in February, April, and June of 2021. The individual medical records for these animals were evaluated and there were no notations of any abnormalities observed prior to being found dead. There were no post-mortem examination results recorded and no record of any attempt made to determine the cause of death for these animals.

***16 dogs over 5 weeks of age and 157 puppies under 5 weeks of age were found dead and postmortem change ("PMCH") was recorded as the cause of death. According to the attending veterinarian, this code is generally used to indicate that postmortem decomposition (autolysis) was present and no other causes of death could be identified. Individual medical records were only maintained for those puppies over 5 weeks old while "litter records" were maintained for those under 5 weeks old. The subset of records checked did not include any recorded information indicating abnormalities observed prior to death, how long bodies were stored before post mortem examination, or body condition when found.

Adequate veterinary care is essential for preventing, identifying, controlling, and treating animal health issues all stages of life. Due to their immature body systems and small size, young pupples are especially vulnerable to stress, infection, and illness. Failure to provide adequate veterinary care including both adequate observations to recognize subtle signs of illness in live animals (as required by section 2.40(b)(3)) and appropriate methods to diagnose disease post mortem when unexpected deaths occur may result in a failure to implement measures to prevent or control disease for the remaining animals.

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Correct by August 7th, 2021 by providing adequate veterinary care to include the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of after hours and emergency care.

2.50(a)(1)

Time and method of identification.

Weaned puppies and adult dogs are individually identified by a tattoo placed on the inside of the ear when dogs are approximately 5 weeks old. The use of tattoos for official identification must be approved in writing by the APHIS Administrator. Approvals for the use of tattoos typically specify the location of application as well as a standard prefix which will be applied to all animals from the particular licensee or registrant. The tattoos currently in use by the licensee do not appear to conform to the standard tattooing conventions approved by the administrator. Additionally, Animal Care has no record of a tattoo request on file from this licensee and no records of any approval for the use of tattoos as official identification.

Accurate identification of all live dogs is important for animal identification, traceability of animals, and investigation of disease outbreaks or animal theft.

Correct by August 30th, 2021 by obtaining approval from the Administrator for the use of tattoos as dog identification, or by using an alternative method of identification that does not require written approval by the Administrator.

2.75(a)(1)

Records: Dealers and exhibitors.

The facility is currently missing disposition records for several of their dogs and puppies.

Disposition records show that there are three adult dogs whose disposition is recorded as 'missing':

- 1) CLICEE, 9 months old, missing on 7/2/21
- 2) CLGCKD, 1 year old, missing on 7/2/21
- 3) CLJCDN, 4.7 months old, missing on 2/25/21

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Disposition records show that 21 puppies were recorded "miss" during the time frame 01/01/2021 to 07/22/2021.

The attending veterinarian stated that these dispositions, recorded as "miss", are likely due to data collection, data entry or administrative error, and will be corrected when dogs are identified.

Accurate and complete recordkeeping of all acquisitions (including births) and dispositions is important for animal identification, traceability of animals, and investigation of disease outbreaks or animal theft.

Correct by August 30th, 2021 by maintaining records that fully and accurately record the disposition of animals in accordance with 2.75(a)(1).

2.75(a)(2)

Records: Dealers and exhibitors.

The facility is not using official APHIS Forms 7005 and 7006 to record acquisitions and dispositions of dogs and cats. Instead, the facility is maintaining electronic records for acquisition and disposition information. There is currently no approved variance is on file from the APHIS Administrator regarding electronic record keeping.

Recordkeeping is important for animal identification, traceability of animal movement, search for missing animals, and investigation of disease outbreaks or animal theft.

Correct by August 30th, 2021 by using official APHIS Forms 7005 and 7006 for recording acquisition and disposition records, or by requesting a variance from the APHIS Administrator to use electronic records.

3.1(c)(1)

Housing facilities, general.

The facility has widespread problems with maintenance of primary enclosures, dog toys, and dog-contact surfaces:

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*** There are plastic hanging doors in most of the sheltered housing runs in Buildings G1, G2, and G3. Approximately 90% of the plastic hanging doors have badly chewed edges with dirt and grime embedded in the edges. Some of the flaps have been chewed so much that they are completely missing and the metal flashing around the doors is also damaged or missing.

*** Dog toys such as rubber 'Kongs' and plastic dumbbells are provided for many of the dogs. Approximately 75% of the toys are severely worn resulting in irregular, pitted, flaking, and worn plastic surfaces. One Kong was found in an enclosure located in Building G3, Room 1 that was missing a large chunk of rubber; small pieces of rubber were present in the waste trough under the plastic coated metal grate flooring.

*** In Building 96, Room 6, approximately 50% of the solid-floored whelping kennels had areas of chipped and peeling paint and exposed concrete on the back wall of the kennel. The kennels have a nesting area in the rear by the wall with bedding where the pupples stay. The areas of flaking paint are low on the wall and adjacent to the area used by the animals.

*** Throughout Buildings G1, G2, and G3 there are several areas of chipped concrete around the edge of the hole that provides access between the inside and outside areas of each kennel. Some of the chipped concrete creates gaps about ½ inch to 1 inch in size between the concrete and the metal flashing of the door frame. Areas with chunks of concrete missing have an underlying irregular, unsealed, and uneven surface.

*** Metal kennel walls, gates, metal flashing surrounding the dog door flaps, heat lamps, and metal grates covering the waste troughs have excessive accumulations of rust and deterioration. Buildings G1-3 have approximately 5-10% of their kennel walls, gates, or metal flashing surrounding the dog door flaps affected by rust. The rust on the metal kennels leaves a residue on hands and flakes off when touched. The remaining metal has pitting on the surface. In Building G3, Room 2, the metal heating unit suspended above the dog kennels has accumulations of rust on the underside of the

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metal tubing and on supporting brackets. In Building G2 each room has an outdoor waste trough running underneath the raised, plastic-coated metal grate flooring. At one end there is a metal grate covering an access point to the trough.

Closest to the kennels there is an accumulation of flaking rust on the grate covering approximately 5-10% of the surface area.

**** Plastic whelping trays are present in some of the enclosures containing dams and nursing puppies. Approximately 10% of the whelping trays have edges and/or comers that are badly chewed and worn. In some cases, pieces of the plastic are missing altogether. A white plastic board (approximately 2 inches tall) is used as a divider in some solid-floored kennels containing dams and nursing puppies in building 96/97. Approximately 10% of the dividers have deep bite marks, chewed edges, and many of these chewed areas contain organic debris and hair. In Building 97, many of the metal cages containing dams and nursing puppies contain a white plastic board (approximately 2 inches tall) across the base of the door inside the front of the cage. Approximately 10% of these plastic boards were chewed and worn.

Surfaces that are worn, chewed, or in poor repair may harbor organic matter or bacteria that can cause illness, injury, or poor health in dogs. Surfaces and structures in poor repair may trap, cut, or otherwise injure animals.

Correct by August 31, 2021 by maintaining enclosures, toys, and other surfaces in good repair.

3.6(a)(2)(ii)

Critical

Primary enclosures.

Records show that during the time frame January 1, 2021 to July 22, 2021, 71 dogs were injured when a body part (such as an ear or tail) was pulled through the wall of the kennel by a dog in an adjacent kennel and bitten. The exact injury varied in each case, however substantial or minor, the dogs were subsequently euthanized. Although some enclosures had solid walls separating animals from the adjacent enclosure, the majority of kennels in the facility are constructed

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using either metal wire or mesh to separate animals in adjacent enclosures. Dogs with body parts pulled through cage walls have experienced physical harm and unnecessary pain.

Correct by August 7th, 2021 by housing dogs in primary enclosures that protect the dogs from injury, including protecting animals from injury by dogs in adjacent enclosures.

3.7 Critical

Compatible grouping.

Records show that 2 female dogs were found dead from fight wounds, the first on 3/14/21 (CEJCGL) and second on 3/18/21 (CFHCUB). Additionally, on 5/26/21 an intact 6-year-old female dog (CFGCMJ) was found dead killed by a cage mate.

Records show there were 48 dogs (over 5 weeks of age) who had fight wounds during this same time period (01/01/21-07/22/21).

When asked about compatibility, the facility representative stated that following a fight, animals are relocated to a new enclosure.

Dogs injured or killed by cage mates may experience pain, distress, suffering, and death.

Correct by August 7th, 2021 by ensuring that all dogs housed in the same primary enclosure are compatible. Ensure that there is a mechanism of observation in place to ensure compatibility and prevent fighting.

3.11(a)

Cleaning, sanitization, housekeeping, and pest control.

The waste gutters below the main sheltered housing of Buildings G1, G2, and G3 contained a large accumulation of feces, urine, standing water, insects (both dead and alive) and uneaten food under the raised indoor and outdoor kennel floors. Near the outside gutters there is an overpowering ammonia and fecal odor that emanates from below the kennels.

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Inside the buildings, below the raised kennel floors there is an accumulation of feces, urine, insects (dead and alive), and food. Large numbers of cobwebs are present at the access points to the drain trough, which in some cases impede visualization of the length of the trough. There is organic matter and debris surrounding the inside access points to the drains and against the wall of the rooms. Around the entire facility are large populations live insects including house flies, drain flies, water bugs, cockroaches, and spiders with cobwebs. According to the facility operations manager, a pump in the system that cleans the gutters had broken on Thursday of the previous week and the facility had been unable to clean out the gutters since that time. The accumulation of organic material under the kennels has been present for 6 days without waste removal, and was continuing to grow. The facility operations manager stated that the gutters are typically cleaned every other day when the system is operational.

Build up of feces, urine, food waste and water waste provide breeding grounds for pests and insects, expose the dogs to unnecessary disease hazards, and cause noxious odors.

Correct by July 30th by maintaining a cleaning system that ensures excreta and other waste is removed from under primary enclosures often enough to prevent excessive accumulation of feces and food waste, and to reduce disease hazards, insects, pests, and odors. Additionally ensure that drainage and waste disposal is maintained in accordance with 3.1(f).

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3.11(b)

Cleaning, sanitization, housekeeping, and pest control.

In the Buildings 96 and 97, adult female dogs nursing litters of puppies were housed in solid-floored dog runs. There was a build up of brown organic material on the walls of the dog runs, mainly located near the front of the runs. The facility operations manager stated that the floors in the runs were cleaned daily but the walls were spot cleaned with a degreaser (GP-100) and hot water daily or on an as-needed basis. The facility operations manager stated that these kennels are power washed and sanitized between litters, but are not sanitized during the 6 weeks that the dams and puppies are housed there.

Animal enclosures in the whelping building are cleaned in accordance with two procedures. The first procedure, "Whelping building pressure washing" (EGS-SOP-PRD-6512) outlines pressure washing and application of a cold sterilant in the whelping areas, but does not specify when or at what frequency this procedure is completed. The facility operations manager stated that the animal enclosures in the whelping area are only sanitized between litters (approximately every 6 weeks). The facility operations manager stated that while cages and runs are in use, they are spot cleaned daily or as needed using a degreaser (GP-100) which does not have disinfection properties.

The second cleaning procedure, "General Husbandry of the Whelping Area" (EGS-SOP-PRD-6521) states that cages are scrubbed daily with a disinfectant. However, the facility operations manager stated that employees currently use GP-100 as a degreaser to clean cages, but this product is not a disinfectant. The water temperature used for cleaning is not specified or monitored/recorded. The facility operations manager stated that cages and runs in the whelping area are disinfected in between litters (approximately every 6 weeks).

Buildings G1, G2, and G3 are cleaned in accordance with the procedure for "Sanitation methods and frequency of indoor/outdoor facilities using the Landa stationary pressure washer" (EGS-SOP-PRD-6526). That SOP states that indoor/outdoor runs are cleaned with 180 degree Fahrenheit water at least every two weeks, but there is no detergent or

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soap utilized in this cleaning process. The facility operations manager stated that the degreaser (GP-100) used elsewhere in the facility was not used in the broodstock building (G1, which house approximately 1100 adult dogs) due to concerns about its potential impact on fertility.

Cleaning and disinfection is essential for removing waste and killing germs that can cause disease. Inadequate cleaning and disinfection may lead to animal sickness, outbreaks of disease, or proliferation of pests.

Correct by August 7th, 2021 by cleaning and disinfecting facilities in accordance with the Animal Welfare Act.

3.11(d)

Cleaning, sanitization, housekeeping, and pest control.

There is an extensive, widespread pest problem throughout all animal-housing buildings at the facility.

There are live spiders and house flies in the building G3, most abundantly in rooms 1 and 2. Live spiders and spider webs were present throughout this building on ceilings, in corners, in windows, and at the tops of dog runs containing dogs.

Spider and spiderwebs were also present in drains, on equipment, and on overhead heating lamp structures.

Building G3 also has large numbers of ants present on the floor and adjacent to self-feeders mounted on the front of kennels. Live ants were observed going in and out of self feeders containing dog food for dogs.

House flies were present throughout all animal housing buildings at the facility (G1, G2, G3, and 96/97). Live flies were present in moderate numbers on the walls, ceilings, floors, and flying in the air. Upon lifting the lid on many self-feeders containing dog food, flies often emerged or were seen crawling on food within the feeders. Flies were extremely numerous in Building G2, on the walls behind the enclosures.

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In Building G1 live black hairy worm-type insects and live black beetles were present in the metal self-feeders (which contained dog food) which were mounted to sides of kennels containing dogs. These self feeders were the only source of food for the dogs. These live black worm-type inspects, along with live black beetles, were observed in amongst the dog food contained in a large silo/hopper outside building G1. In Building G2, numerous live black worm-type insects were also present in metal self-feeders, and a large bulk feed container in a food storage room.

There were a very large number of live flies ('sewer flies') in all of the whelping rooms containing live dogs in building 97 (rooms 7, 10, 11, 13). The flies were observed on the walls, ceilings, flying in the air, and in the drains in the rooms housing dogs. In Building G1, numerous 'sewer flies' were also present on the walls behind kennels.

Insects which contaminate feed can decreased nutritive value of the feed and/or result in reduced feed consumption.

Insect infestation in other areas may irritate animals and/or can spread disease.

Correct by August 15, 2021 by maintaining an effective program to control pests including insects and spiders.

3.13(b)(2)

Veterinary care for dogs.

Medical records are not complete for numerous dogs. For example:

*CLACJP, an 11-month old male, had a laceration by a leg caught in the run on 01/03/21. The location and description of the injury are not recorded.

*CMBCDM, a 4-month-old male, had a fracture on 06/10/21. The location and type of fracture is not recorded.

*CMACLK, a 4-month-old male, had a fracture on 06/04/21. The location and type of fracture is not recorded.

*CLGCTT, a 9-month old female, had a fracture on 04/23/21. The location and type of the fracture is not recorded.

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*CFEDDY, a 7-year-old female, had a fracture on 06/14/21. The location and type of the fracture is not recorded.

*In addition to these 4 animals with fractures, two other animals were identified in the mortality logs as having been euthanized due to fractures (CLGCHJ a 7-month old female beagle with a broken right rear leg identified on 2/3/2021 and CLDCAH a 1-year old male beagle identified on 4/23/2021 with a broken tail). When the attending veterinarian was asked about how 6 dogs experienced fractures during this period, she stated that she had investigated a nutritional cause, but that she hadn't been able to determine any cause with certainty. Fractures and lacerations may result from improper handling, unsafe primary enclosures, incompatibility of animals, improper nutrition, or many other causes.

Failure to maintain complete and accurate medical records for dogs prevents the attending veterinarian from determining the cause of these injuries and implementing preventive measures. Additionally, this lack of accurate complete record keeping prevents APHIS Officials from determining the facility's compliance with other regulations and standards within the Animal Welfare Act.

*CJKCGC, a 2-year-old female, is listed on the mortality log with a cause of death as "other" on 04/20/21. The animal's individual record contains no information about the animal's death; the record only contains general husbandry information.

*CLBCJF, a 1-year-old female, is listed on the mortality log with a cause of death as "other" on 04/02/21. The animal's individual record contains no information about the animal's death; the record only contains general husbandry information.

During inspection the Attending Veterinarian stated that staff is supposed to notify her when adult dogs are found dead so she can perform a necropsy examination. There is no record of the results for such necropsy examination included in the medical record for either of these two animals.

*CKHCDL, a 1-year-old female, is listed on the mortality log with a cause of death as "pull" (pull injury) on 06/24/21. The

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animal's individual record contains no information about the animal's death; the record only contains general husbandry information.

Complete and Accurate medical records are important for the ensuring provision and continuity of veterinary care, communication with the animal care team, prevention of medical errors, and analysis of animal health. Lack of complete and accurate medical records may result in failure to identify adverse trends in animal health, medical errors, and lack of medical care.

Correct by 08/30/21 by maintaining records for all dogs that include a date and description of problems identified, examination findings, test results, plans for treatment and care, and treatments performed.

This inspection was conducted with the Operations Manager and the Attending Veterinarian.

The exit interview were conducted with the Operations Manager, Attending Veterinarian, Site Director, Regional Quality Assurance Manager, Director of Quality Assurance, Senior Vice President for Veterinary Services, Chief Operations Officer, and Regional Facilities Manager.

This is a continuation of the report for the routine inspection conducted 07/20/21-7/22/2021 and contains the remaining non-compliances found during the inspection from 7/20/2021 to 7/30/2021. The exit briefing for the items included on this report was conducted on 7/30/2021.

Additional Inspectors:

Rachel Perez-Baum, VETERINARY MEDICAL OFFICER

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18-OCT-2021

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United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 506554

Inspection Date: 20-Jul-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506554	32 - A-0774	005	ENVIGO RMS LLC	20-JUL-2021

Count	Scientific Name	Common Name
003021	Canis lupus familiaris	DOG ADULT
002014	Canis lupus familiaris	DOG PUPPY
005035	Total	



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ENVIGO RMS LLC 8520 Allison Pointe Blvd., Suite 400

INDIANAPOLIS, IN 46250

Customer ID: 506554 Certificate: 32-A-0774

Site: 005

ENVIGO RMS LLC

Type: FOCUSED INSPECTION

Date: 25-OCT-2021

2.40(a)(2)

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

Direct

The facility failed to provide adequate authority to the attending veterinarian by treating three animals with medication not approved by the attending veterinarian (AV). The medical treatment records for 26 Oct 2021 showed that caretaker staff had identified three dogs as being too thin (CGDDBN, CJFCLZ, CLHCHF). These records also indicated that a medication (later identified by the attending veterinarian as Cefpodoxime) had been given to these dogs that day. Medical records did not show that a veterinarian had been consulted regarding the diagnosis of thin body condition or prescription of medications to these dogs. There was no guidance in the program of veterinary care allowing caretaker staff to start this medication on dogs they perceived as too thin. The AV verified that she did not prescribe this medication for these dogs nor would she prescribe this for a dog with only a thin body condition. When APHIS officials brought this to the attention of the AV, she completed an examination on these dogs and directed the antibiotics be stopped. Employees who diagnose and prescribe treatment for animals without consulting the AV are undermining the authority of the AV to ensure the provision of adequate veterinary care for the animals. Correct by ensuring that the AV has adequate authority to ensure the provision of veterinary care and to oversee all other aspects of animal care and use. Additionally, ensure that timely and accurate information concerning health of the dogs is communicated to the attending veterinarian in

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accordance with section 2.40(b)(3) so that appropriate methods are used to diagnose and treat all diseases and injuries as required by section 2.40(b)(2). Correct by November 5, 2021

2.40(b)(2)

Direct

Repeat

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

Adult, female beagle (CIACNG) was squinting her right eye and had extensive tear staining and clear discharge around and under her right eye. There were small eyelashes pointing down from the upper lid toward the surface of her eye. This dog received a physical exam on 4 Oct 2021. The physical exam findings documented at that time were consistent with the eye problems seen during the inspection. The veterinarian documented on the physical exam form that the action for this dog was "cull". The facility was unable to provide any documentation showing that this dog had received any kind of treatment since the diagnosis was made during the physical exam on 4 Oct and, as of the time of the inspection, had not been "culled" or otherwise disposed of through either adoption, sale, or euthanasia. This dog's symptoms are consistent with untreated conditions resulting in eye pain. While the condition was diagnosed by the veterinarian, the disease was not treated. The licensee must use appropriate methods to prevent, control, diagnose, and treat diseases and injuries.

2.40(b)(3)

Direct

Repeat

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

Three dogs had medical conditions that had not been identified or treated by the facility prior to the inspection.

October 25, 2021;

*** A male beagle puppy (CMHCKL) has an abnormal left eye. There was yellow-green discharge present at the comer of the eye with dried discharge surrounding the eye. The membrane at the inner corner of the eye was extended slightly and there was increased tearing present. This eye condition was not previously identified by the facility and the dog was not receiving any treatments for the eye. The facility examined the dog and immediately began treatment for an eye infection.

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*** An adult female beagle (CKJCAZ) has a medium firm, pink, and swollen area of tissue between the 4th and 5th toes of her right rear paw. The swelling was approximately 1/3" in diameter and the inflamed tissue was easy to visualize from a distance. The condition was not previously identified by the facility and the dog was not receiving any treatments for the foot. The facility examined the dog and immediately began treatment for an interdigital cyst.

October 26, 2021:

*** An adult female beagle (CGHCAC) has multiple skin lesions on all four feet. The hair between all four feet was discolored red, commonly seen with licking/chewing due to the presence of saliva. On the left front paw there was a small firm and swollen area of tissue between digits 3+4, and a large firm, swollen, and pink area of tissue between digits 2+3. The larger swelling also has a scab present closest to the toe. On the right front paw there is thickening present in the crevice of skin between the 4th + 5th toes with pink skin and a small scab. There is a medium firm, pink, and swollen area of tissue between digits 3+4 with yellow crusts attached and an obzing sore on the top surface. There is also thickening and inflammation of the skin on the 5th digit between digits 4+5 with two more scabs present. On the left rear paw there is swelling of the skin on digit 4 between digits 4+5 with an open wound on the top surface and partial scabbing. In between digits 3+4 there is a lot of inflamed, pink, and thickened skin with numerous crusts/scabs on the front edge of the toe and an exposed raw area of skin. Between digits 2+3 there is a medium firm, swollen, and pink area of tissue with a scab on the top surface. On the right rear paw there is a small firm, swollen, and dark pink area of tissue with white flaking crusts between digits 2+3. The condition was not previously identified by the facility and the dog was not receiving any treatments for her feet. The facility examined the dog and began treatment.

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Animals with medical conditions including eye and skin problems may suffer from pain, discomfort, infection, and stress. Daily observations of animals to identify medical problems is essential for animal health and welfare. The licensee must observe all animals at least daily to identify physical, medical, or behavioral problems. Additionally, ensure that all findings are communicated in a timely manner to the attending veterinarian so that they can examine animals and ensure that appropriate treatment is provided as required by section 2.40(b)(2) and further, that the findings are documented in accordance with section 3.13.

2.75(a)(1)

Repeat

Records: Dealers and exhibitors.

The facility still does not have complete acquisition or disposition records for their animals. Facility records, known as Inventory Change Notices, are used to record newborn puppy numbers, procedures performed, and changes in puppy numbers due to euthanasia or death. The facility continues to have animals which are no longer present for unknown reasons that they have stated to be clerical errors.

***Records indicate that a female puppy born on 9-27-2021, from the dam CIICMP, was not present during a litter count conducted on 10-14-2021. The original litter count was 4 males and 5 females. On 10-14 there were only 4 males and 4 females. There was no record of this puppy dying or being euthanized which would account for its absence. When the facility was asked as to the status of the missing female puppy, they were unable to determine if the original puppy count was wrong (i.e., there were only 4 males and 4 females at birth) or if a female puppy has truly been lost. If the puppy has been lost, the facility does not know how or when.

***On 4 November the facility's Manager of Operations disclosed that she recalled a neonate puppy was found in the drain under an enclosure on 13 October 2021. The puppy was removed from the drain and subsequently died later that

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day. This puppy had not been given an acquisition number and was not included in the acquisition records provided earlier to inspectors. There was no record of this puppy included in the "mortality logs" or other disposition records provided by the facility to inspectors. When asked, the Operations Manager stated that that she was not sure why it had not been included, but perhaps the employees were "not sure how to code it".

Accurate and complete recordkeeping of all acquisitions and dispositions is important for animal identification, traceability or animals, animal loss, and investigation of disease outbreaks or animal theft. Correct by maintaining records that fully and accurately document all dogs and cats acquired by the facility (through birth, purchase, or other method) and all animals that are disposed of (by sale, death, euthanasia, or other method) including all information required in this section.

2.131(b)(1)

Critical

Repeat

Handling of animals.

Animals have not been handled as carefully and expeditiously as possible leading to subsequent death.

*** According to the manager of operations, a newborn puppy was found in the drains below the kennels on 10-13-2021. The Manager of Operations explained that the facility had recently laid down a new type of flooring on top of the existing kennel grate to enhance puppy safety. The manager believes that the puppy fell into the drain because one dam (CKJCCT) had shifted a piece of the flooring, exposing a gap, and whelped on top of the old flooring. The puppy was found between 1-2 pm and immediately brought to the clinic for a bath and was returned to the above dam who had recently whelped near where the puppy was found. The puppy was also provided supplemental heat but died later that day. The Manager of Operations stated that in response to this incident, employees replaced the flooring and added paper to the back of the kennels to prevent another occurrence.

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*** Mortality records show that a 7-week-old puppy (CLICBE) was found deceased on 21 Oct 2020 with its head stuck in the swinging kennel door of a bedded whelping run. Facility representatives state that an investigation of the incident was completed at the time, but they do not have access to the files from previous management. It was determined that the entrapment and subsequent death was a result of employee error. The employee has since been terminated. Failure to handle animals as carefully and expeditiously as possible can lead to injury or death. Employees must take special care when working with small puppies as they are more easily overlooked and seriously injured. The licensee must ensure all animals are handled expeditiously and carefully in a manner that does not cause physical harm, trauma, or unnecessary discomfort.

Failure to handle animals as carefully and expeditiously as possible can lead to injury or death. Employees must take special care when working with small puppies as they are more easily overlooked and seriously injured. The licensee must ensure all animals are handled expeditiously and carefully in a manner that does not cause physical harm, trauma, or unnecessary discomfort.

3.1(c)(3)

Housing facilities, general.

The facility has surfaces in contact with the dogs that are not being spot-cleaned frequently enough to prevent the buildup of grime and dirt and to reduce disease hazards. In multiple enclosures, the outer cement walls housing the dog doors have brown dirt/grime built up. According to the facility, the outdoor enclosures are hosed down once per day with either a pressure washer or a routine hose. Every two weeks the enclosures are sanitized using a product called "Intervention."

Due to the accumulations of dirt and debris on the walls, it is evident that the facility is not spot-cleaning or sanitizing effectively to prevent accumulations or to reduce disease hazards.

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Buildup of feces, dirt, and grime on a surface accessible to the dogs exposes them to unnecessary disease hazards and does not satisfy generally accepted husbandry standards and practices. Correct by November 8, 2021 by ensuring all surfaces in contact with the dogs are spot-cleaned daily and sanitized in accordance with this Subpart.

3.6(a)(2)(ii)

Direct

Repeat

Primary enclosures.

Mortality records show that from 2 Aug 2021 to 3 Oct 2021, nine dogs (CLCCVA, CLBCES, CLFCAB, CLCCUU, CLLCGK, CLLCGS, CLACJT, CLCCIN, and CLECRN) were injured from having a body part (such as a limb or tail) pulled through the wall of the kennel by a dog in an adjacent kennel and bitten. The exact injuries varied in each case, however regardless of whether it was a minor or substantial injury, these nine dogs were subsequently euthanized. Dogs sustaining injuries from being pulled through the enclosure wall have experienced physical harm and unnecessary pain. The facility must ensure that all primary enclosures protect the dogs from injury.

3.6(a)(2)(x)

Repeat

Primary enclosures.

The flooring in G2 which houses puppies from about 6 weeks and older still uses flooring that allows young puppies' feet and legs to pass though the openings. The facility agreed, via conditions of a correction date extension approval, that they would cover the flooring in kennels housing young puppies with cardboard cage liners as a temporary measure and additionally that they would provide increased night monitoring of all animals until all noncompliant floors could be replaced. However, there were two enclosures seen during the inspection that did not have these in place or even the heavy butcher-type paper which was covering the floor in other enclosures. Inspectors witnessed multiple puppies with legs and feet passing through the openings in the floors of these enclosures. Raised mesh or slatted flooring that contains openings that are wide enough for a limb, paw, or digit to pass through can lead to an animal becoming trapped or injured. When an animal becomes entrapped, they can become distressed, dehydrated, or may suffer additional injuries.

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The facility must ensure that floors of primary enclosures are constructed and maintained in such a manner that does not allow dogs' feet and legs to pass through any openings.

3.7

Direct

Repeat

Compatible grouping.

The facility is still having compatibility issues between dogs housed in groups.

October 26, 2021:

***Two adult female beagles (CIBCTG and CJACNF) being housed together had scabs covering multiple small puncture wounds/scrapes, CIBCTG had hair loss present on her back midline and wounds located on her right nose, right ear, left ear, and left cheek, After replacing CIBCTG in the kennel, she began biting and chasing her kennel mate (CJACNF). CJACNF had scabs/wounds on her right knee and inner left thigh. The biting and wounds had not been previously identified by the facility. When questioned, the facility stated that CIBCTG is currently in heat and may be picking fights with her kennel mates. When inspectors identified this issue, the facility representatives removed CIBCTG and placed her in a separate kennel. No steps have been implemented at the facility to prevent potential compatibility issues.

***Two adult female beagles were currently being treated for fight wounds that occurred on 10/25/2021. An adult female beagle (CJACRI) had fight wounds on her chest and left ear. The other adult female beagle (CGFCFA) had fight wounds on her rear end and right front shoulder. These dogs were removed from two different kennels subsequent to fights which resulted in these injuries. According to the facility representative, following a fight, the injured animal is removed and treated medically. Once they are healed, the animal is relocated to a new enclosure in the attempt to find more compatible kennel mates. If one dog is found to be involved in multiple fights and thought to be the aggressor, they may elect to euthanize due to temperament. There is currently no systematic pro-active attempt to identify incompatible animals

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through behavioral observation; rather, dogs are moved only after injuries are sustained.

***Facility records also show on 10/14/2021, a female dog CMHCAC was found dead. The mortality log and mortality record sheet from October 14th attributed the dog's death to evisceration (EVIS). CMHCAC was being cohoused with 9 other dogs approximately the same age (10 weeks old). According to the facility, the dog was found dead and the "littermates had chewed on it." The facility was unable to provide additional information when asked. There is no description of the lesions identified other than the facility code "EVIS" and no record of post-mortem examination findings. When inspectors asked to talk to the employee that found this puppy dead, they were informed she was unreachable due to leave. Dogs attacking/chewing on another dog, whether alive or deceased, is an uncommon behavior for dogs with adequate nutrition and likely indicates a compatibility issue.

Even though this facility continues to have compatibility problems in their group housed animals, there has been no action taken by the facility to proactively identify and potentially house separately those dogs that are incompatible or have an aggressive disposition. Failure to maintain compatible groups of dogs can lead to injuries, pain, and even death in the dogs. Correct this by ensuring all dogs are maintained in compatible groups.

3.11(a) Repeat

Cleaning, sanitization, housekeeping, and pest control.

The facility continues to have general sanitation problems with cleaning of enclosures, waste gutters, and odor control.

***At least two enclosures had old, dried, and moldy feces still present in the outdoor section. According to the facility, the factating females inside do not currently have outdoor access. Additionally, an enclosure in Building G1 housing an adult male beagle contained at least nine to ten piles of feces in the outdoor portion, preventing him from accessing a majority of the outside run without stepping in his own waste and creating a disease hazard. Due to the presence of mold on some

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feces and the excessive number of feces in with the male, it is apparent that some of the enclosures are not being cleaned, at a minimum, daily.

*** In at least 50% of the rooms being used within Buildings G1 and G2 there are still accumulations of waste and an overpowering fecal odor that emanates from below the kennels. Significant accumulations of animal waste and fur on top of 2 pulley systems used to scrape solid waste underneath enclosures are contributing to the excessive odor in the facility. One waste gutter found in Building G2, outside Room 7 had a pile of feces stacked on top of the pulley system approximately 5-6" high. According to the facility, this happens when the gutters are drained and flushed prior to the facility power-washing the enclosures. Another waste gutter found in Building G1, inside Room 8 had a very large collection of fur and fecal matter piled on top of a pipe and the surrounding floor just in front of the pulley mechanism. The waste in the gutters below the main sheltered housing buildings of G1, G2, and G3 have been flushed out since the last inspection and, although the gutters contain much less waste, several waste gutters throughout the facility still had accumulations of feces and urine sitting under the kennels. According to the facility, the waste gutters are limited to being flushed once every other day due to water supply and storage on site.

***Throughout the facility there are areas where a strong sewage odor emanates from the waste gutters surrounding the rooms. The odor is not present at all rooms in a building, but every building has at least one or more rooms with a strong odor. The facility is aware of this issue and has been looking into possible causes and potential solutions.

Buildup of feces, urine, food waste and wastewater provide a breeding grounds for pests and insects and exposes the dogs to unnecessary disease hazards and noxious odors. The licensee must ensure that excreta and food waste is

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removed from and under primary enclosures as often as necessary and with a functioning system that reduces disease hazard, insects, pests, and odors.

3.11(d)

Repeat

Cleaning, sanitization, housekeeping, and pest control.

There are still large numbers of dead flies and spiders noted throughout the facility especially in the corners of buildings, near drains, and in the storage areas. Additionally, some areas near drains have populations of small live black flies. The facility has changed pest control companies and there is an improvement in the number of pests found during this inspection. However, failure to remove dead pests makes it impossible to properly monitor the effectiveness of the pest control program. Correct by ensuring an effective pest control program is established and maintained.

3,12

Direct

Repeat

Employees

The facility continues to have insufficient numbers of employees to successfully care for the animals. There continue to be severe staffing shortages and currently there are approximately 32 employees at the facility, with only 17 staff members directly responsible for all husbandry, daily observations, and medical treatments for almost 5000 dogs. Four dogs were identified by APHIS inspectors with medical conditions that required treatment and should have been found by staff during their daily observations. There are also numerous dogs that have been identified with severe periodontal disease by veterinarians and still require prescribed dental cleanings. Additionally, basic husbandry such as cleaning out kennels daily to remove feces, cleaning contact surfaces to prevent buildup of debris, and general housekeeping including dead pest removal is not being performed in accordance with the AWA regulations. The employees who are responsible for assessing animals for medical problems are also responsible for assisting with husbandry and cleaning. While the facility brought in temporary, visiting veterinary staff following the last inspection to assist in preventive medicine duties such as dentals and physical exams, the facility still has not completed all the needed procedures identified on those exams.

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There is still only one full-time veterinarian to oversee the daily medical care of all the animals as well as assisting with research projects. The facility must ensure that there are sufficient employees to carry out the level of husbandry practices and care required in this subpart.

3.13(b)(2)

Repeat

Veterinary care for dogs.

Veterinary medical records are incomplete for at least 7 dogs. This includes:

*** Mortality records from August 14th and 15th, 2021 shows a list of three puppies coded as deceased from FALV (fatty liver) - CMGCAE, CMGCCZ, and CMGCAU, and two puppies as deceased from ENTE (enteritis) - CMFCYE and CMGCFA. All puppies were approximately 5-6 weeks old. When the complete medical record was requested for these animals, it only listed the facility's code for fatty liver and/or enteritis, respectively. Records indicate necropsies were performed on all these puppies however, there are no exam findings, description of lesions observed, or test results recorded. Additionally, there are no description of symptoms leading up to these animals' deaths. These are diagnoses that can't be made without either a history of symptoms or further diagnostic testing such as histopathology. There are no descriptions in the medical records of problems, daily observation of symptoms leading up to the death, examination findings, or test results listed for these puppies.

*** The mortality records for October 21, 2021 lists a puppy (CMICFA) coded deceased from FALV (fatty liver) and PNEU (pneumonia). The medical record for this puppy lists a mortality code of HPNE (hemorrhagic pneumonia) and FALV (fatty liver). Although, the record indicates a necropsy was performed on the puppy, descriptions of necropsy findings, specific observation, and descriptions of symptoms leading up to the animal's death are not present.

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*** The inventory change sheet and medical record for a puppy (210801001C) shows that it was euthanized due to DMGB (damage by bitch), a broken jaw on August 17, 2021. However, the medical record does not have physical exam findings, such as the location or severity of the fracture of the jaw, type of fracture, diagnostics performed, or test results.

*** Medical records and a treatment form for a 6-week-old puppy (CMFCPH) on August 5, 2021 indicate that the dog was "lame on all four legs" had a "broken left femur" but failed to contain additional physical examination findings, diagnostics, or test results. The facility representative who found the dog told inspectors that they observed a head tilt and the puppy's balance seemed off, but there was no obvious limping on any specific leg. The manager of operations stated that when the Attending Veterinarian examined the dog, she felt a "pop" in the puppy's left femur and suspected a fracture. The AV recommended euthanasia and the dog was subsequently euthanized. The medical records did not include any of the attending veterinarian's examination findings but rather a presumptive diagnosis.

***On 4 November 2021, the facility's Manager of Operations disclosed that a neonate puppy (less than 1 day old) was found in the drain under an enclosure on 13 October 2021. She stated that the puppy was retrieved and was provided a warming pad and was cleaned before being returned to an enclosure. The puppy died later that day. There is no medical record for this animal documenting an examination, treatment, or death of this puppy.

The presumptive diagnoses listed on the medical records are an incomplete record of all findings/lesions on physical exam, necropsy, diagnostic testing, or results. Due to incomplete records, the facility cannot determine the exact cause of death and therefore ensure the health of the entire colony. Additionally, these animals are coded with problems that present with clinical signs prior to death such as weakness, lethargy, coughing, heavy breathing, inappetence, diarrhea,

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and vomiting. The facility appears to have missed these clinical signs during daily observations as there are no records indicating problems found prior to death or treatments initiated.

Incomplete medical records do not allow the attending veterinarian to adequately assess the needs of individual animals as well as the medical needs of the colony as a whole. The licensee must ensure that if a problem is identified in a dog (such as disease, injury, or illness), the date and description of the problem, examination findings, test results, plan for treatment and care, and treatment procedures performed are recorded in the medical records. Additionally, daily observations must be made in accordance with 2.40(b)(3) to prevent unnecessary suffering and death in animals.

This inspection was conducted with the Site Director, Manager of Operations, Attending Veterinarian, and Supporting Veterinarian. The exit briefing was conducted with the Site Director, Manager of Operations, Attending Veterinarian, Supporting Veterinarian, Senior Vice President for Vet Services, the Director of Quality Assurance, the Regional Quality Assurance Manager, the Vice President of North American Operations, and the Chief Operating Officer.

Additional Inspectors:

RANDALL COLEMAN, ANIMAL CARE INSPECTOR

MARGARET SHAVER, VETERINARY MEDICAL OFFICER

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United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 506554

Inspection Date: 25-Oct-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506554	32-A-0774	005	ENVIGO RMS LLC	25-OCT-2021

Count	Scientific Name	Common Name
003283	Canis lupus familiaris	DOG ADULT
001646	Canis lupus familiaris	DOG PUPPY
004929	Total	



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Envigo RMS LLC 8520 Allison Pointe Blvd., Suite 400 Indianapolis, IN 46250

Customer ID: 506554

Certificate: 32-A-0774

Site: 005

ENVIGO RMS LLC

Type: ROUTINE INSPECTION

Date: 16-NOV-2021

2.40(a)(2)

needed.

Direct

Repeat

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

The facility is not ensuring that the attending veterinarian has appropriate authority over medical care and euthanasia of dogs performed by staff members. Staff members that are trained and authorized to conduct euthanasia are not following approved procedures, resulting in the euthanasia of animals using methods that cause pain and discomfort. ***The facility uses an injectable drug (pentobarbital combination) as the primary method of euthanasia. The facility has a written program of veterinary care (PVC) and an SOP (#6014) "Euthanasia of Colony and Research Animals," both

approved by the AV which the AV confirmed that staff performing euthanasia are trained on. These documents state that staff may only use methods deemed acceptable for dogs by the current AVMA Panel on Euthanasia and that all dogs must be unconscious when performing intracardiac euthanasia achieved by using a dissociative medication + sedative as anesthesia and includes instructions for assessing consciousness and providing additional anesthetic medication if

Inspectors reviewed 171 medical records documenting euthanasia of 196 dogs and puppies and found that many young puppies are not receiving anesthesia prior to being euthanatized via intracardiac injection as required by the SOP. ***In addition, employees have failed to follow the AV's direction regarding treatment of other animals at the facility. Veterinarians instructed staff to euthanize two adult dogs in early October. As of the inspection neither dog had been

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euthanized and there is no indication the veterinarian reversed their decision.

Weak or moribund dogs are not necessarily unconscious and can still experience pain and discomfort. Intracardiac injections have been found to be painful, stressful, and uncomfortable. To meet the regulatory requirements of euthanasia, death must be induced without evidence of pain or distress. Failure to provide veterinary care as directed by the attending veterinarian undermines their authority and frequently causes unnecessary pain and distress.

Correct by ensuring that the AV has adequate authority to ensure the provision of veterinary care and to oversee all other aspects of animal care and use.

2.40(b)(2)

Direct

Repeat

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

A total of 30 dogs present on inspection had severe dental disease and had not received adequate care to address this issue, Additionally, 12 of these dogs had concurrent issues which similarly had not received adequate veterinary care. These additional issues included severe medical conditions of the ears, eyes, feet, skin, haircoat, and poor body condition.

***Dental disease: Thirty adult beagles ranging from 2 to 7 years old were found with signs of severe dental disease including: loose teeth which moved with light pressure, exposed roots of teeth, pus along the gumlines, bleeding gums, hair and foreign material embedded in the gumlines, severe recession of the gums, severely reddened and inflamed gums, missing teeth, and significant accumulations of dark colored hard material (calculus) along the teeth. Treatment for these dogs (dental cleanings / extractions) had not been provided despite observation as early as Aug-2021.

***Poor body condition (1 dog): One nursing female dog had extremely prominent bones in the shoulders, ribs, hips, and back and had been underweight since Aug 2021. No treatment was provided for either condition.

***Foot Medical Conditions (7 dogs): The majority of these dogs had masses occurring between their toes that were reddened / inflamed and often oozing discharge consistent with interdigital cysts. One dog had toenails which were

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overgrown to the point that the nails had a severe curve and caused abnormal toe position when the dog was placed on a solid surface.

*** Ear Medical Conditions (2 dogs): . One dog's ear canals and surrounding skin was bright pink and inflamed and had significant accumulations of dark brown waxy material in the ear canals, consistent with an ear infection. The other had wounds on the external ear and significant thickening of the ear pinna.

*** Eye Medical Conditions (1 dog): This dog had a small mass on the lower right eyelid.

*** Skin Medical Conditions (1 dog): This dog had large areas of hair loss along the entire length of its back from neck to hips and across the shoulders and rib cage. Skin is reddened in some areas.

Failure to provide adequate veterinary care to the animals listed above can result in worsening of the conditions and unnecessary discomfort and suffering. Each of the dogs and conditions listed above were identified to the facility while inspectors were on-site (11/16 to 11/19) and provided again during the exit briefing. Correct by assuring all dogs with medical conditions are evaluated by a veterinarian for an accurate diagnosis and to develop an effective treatment plan and then following through with the treatment plan. Each dealer shall use appropriate methods to prevent, treat, diagnose, and control diseases and injuries.

2.40(b)(3) Direct Repeat

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

A total of 34 dogs (in addition to those listed above) had medical conditions that were not identified or treated by the facility prior to the inspection.

***Dental disease (7 dogs): Severe dental disease (similar to those described above).

***Generalized weakness (3 dogs): One adult beagle and two puppies were identified by inspectors with serious medical conditions resulting in weakness. Weakness, lethargy, and the other signs presented by dogs are indicators of serious underlying health conditions.

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***Wounds (8 dogs): Eight dogs and puppies had traumatic wounds that were not identified by the facility prior to inspection. These wounds ranged in severity and included wounds to the legs, chest, abdomen, neck, ears, and tails of these dogs. Many of these wounds had dark brown dried material consistent with blood on the surrounding fur.

***Lameness / Foot Medical Conditions (8 dogs): Injuries included bright, red masses, digits that popped/cracked when manipulated, swollen toes, refusal to bear weight.

***Masses (2 dogs): One puppy had a large soft, fluid filled, swelling on the top of its head. The other, an adult female beagle, had a ½ inch blue colored mass present on her abdomen near her teat.

*** Reproductive Medical Conditions (2 dogs): One dog was present in the kennel with his penis exposed and dry during examination. Another dog was identified in facility records as found dead on 11/1/21. On necropsy she was diagnosed with a ruptured uterus. There was no record of abdominal pain, vaginal discharge, difficulty whelping, or similar sign that preceded the facility finding this dog dead.

*** Eye Medical Conditions (6 dogs): Eye medical conditions observed included cloudy eyes with discharge, pea-sized masses at the corner of the eye, and corneal discoloration with a pigmented mass.

*** Ear Medical Conditions (2 dogs): Two dogs had severe medical conditions of the ears. One had significant redness and inflammation in both ears. The dog was observed shaking its head and scratching its left ear. An additional dog had discharge present at the opening of the ear canal and the skin of the ear canal was reddened with brown debris present and sticking to the skin. A large laceration was also present on this ear.

*** Skin Medical Conditions (3 dogs): Three dogs had significant skin medical conditions characterized by hair loss, peeling skin, crusts, flakes, and dull fur.

Failure to identify animals presenting with abnormal medical conditions can delay necessary veterinary intervention which could prolong any potential suffering and may even result in the animal's death. Daily observations of animals to identify

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medical problems is essential for animal health and welfare. Correct by observing all animals at least daily to identify physical, medical, or behavioral problems. Additionally, ensure that all findings are communicated in a timely manner to the attending veterinarian so that they can examine animals and ensure that appropriate treatment is provided.

2.75(a)(1)

Repeat

Records: Dealers and exhibitors.

The facility's acquisition, disposition, and animal on hand records are incomplete and inaccurate for at least 937 dogs and puppies.

- At least 5 dogs (1 adult CFLCTK and 4 puppies) had no acquisition information, no disposition information, and were missing entirely from the record of animals on hand.
- Disposition Information was present, but inaccurate for one adult dog (CLLCUV). This dog was documented as having been sold on 4/7/2021. This animal was present during the inspection and was undergoing medical treatment. Facility representatives confirmed the identification for this dog.
- Records were missing required information (color and gender) for 832 puppies. This includes: 126 puppies which listed sex and description as "unknown" and 706 puppies that have gender recorded but listed color and distinctive markings as "TBD".
- The facility self-identified approximately an additional 99 dogs and pupples with inaccurate disposition records that were recorded as no longer active but had no disposition records. Accurate and complete recordkeeping of all acquisitions and dispositions is important for animal identification, traceability, and investigation of disease outbreaks or animal theft. The facility must ensure that all required acquisition and disposition information is maintained at all times.

2.131(b)(1)

Direct

Repeat

Handling of animals.

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On 11/16/21, 21 puppies were found to be handled in a manner that they were damp, shivering, and cold in building G3. According to facility records, 25 additional puppies had been found dead with cause of death attributed to cold exposure in building G3 over the last 8 weeks.

***Bldg G3 Room 1 enclosures #54, 55, & 56 housed nursing female beagles and their 4- to 5-week-old puppies. Building G3 Room 2 enclosures #43, 54, & 72 housed 5- to 7-week-old puppies without dams. The enclosures had all recently been cleaned with cold water and kennels were not dried prior to replacing puppies. These enclosures were on the side of the room opposite the radiant heater. None of these enclosures had any solid resting surface or bedding. No heat lamps were present in room 1. Enclosures in room 2 had heat lamps which were present, but not plugged in at the time of inspection. On 11/19/21 Bldg G3, Room 1 was re-checked and there were still no heat lamps installed. Again, several puppies were observed shivering.

All handling of animals, including cleaning activities and housing, must be done as carefully and expeditiously as possible and in a manner that does not cause excessive cooling. Allowing puppies to become wet and chilled during / following cleaning or not providing sufficient heating/bedding causes discomfort and may result in illness or death. Correct by ensuring that all animals are handled as carefully and expeditiously as possible and in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

3.1(a) Direct

Housing facilities, general.

Numerous construction and maintenance issues were identified during the inspection.

***Flooring Gaps: Approximately 75% of enclosures have flooring which is not cut to the same size and shape as the enclosure walls resulting in large gaps between the floor and the fencing. Gaps measured up to 2 inches wide and inspectors saw dogs fall or step into the gaps alongside the flooring. Facility medical records document at least 10 additional dogs and pupples that were significantly injured by improperly constructed and maintained enclosures during

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the period from 9/2/21 to 11/2/21.

***Chain-link Fencing Gaps: Gaps were present in fencing where chain link had become detached from the fence frame.

Gaps range from only a few inches wide to the entire section of chain link forming the barrier between enclosures no

longer being attached to the metal frame. Housing facilities that have not been kept in good repair with numerous areas of

unsecured fencing, may injure dogs by entrapping limbs or may fail to adequately contain the dogs.

***Access Doors: Approximately 30% of the enclosures have access doors with structural damage to the metal frames

and swinging mechanisms (such as broken hinges, doors that won't stay shut, doors where the plastic flap is stuck and

can't move, and damaged door frames which bend outward and leave up to 6-inch gap between the frame and the wall).

Inspectors observed dogs attempting to squeeze through the gap with the guillotine doors locked while others attempted

to squeeze through space between the metal flashing of the door frame and wall.

***Sharp Points: Approximately 50% of enclosures have sharp points and edges. There are multiple areas with sharp

points from broken chain link sticking directly into the enclosure where the dogs would walk, drink water, and jump up

around the feeders.

***Enclosure Walls: Approximately 20% of the enclosures in G1 and G2 do not have enclosure side panels properly

secured to the back wall or to adjacent fencing. Inspectors observed the unsecured panels rock back and forth as the

dogs jumped up and put their forelegs on them.

***Broken Waterers and Self-Feeders: Numerous automatic waterers are leaking water onto the flooring of the cement

walkway and beneath the enclosures. The leaking water is pooling beneath the metal self-feeders where it is mixing with

spilled food creating a wet, moldy environment that is a breeding ground for insects. There are several broken metal self-

feeders that are spilling food onto the cement floor.

***Unsecured Flooring: Several enclosures have flooring that is not secured to the framework beneath it or lacks support

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from underneath. In these enclosures, the floors bounce up and down, shift, tilt, or sink under the weight of the dogs as they move about the enclosure. Flooring that is not properly secured to the framework can cause injury to the dogs and should unsupported flooring collapse, the animal could be seriously injured or escape the enclosure.

Housing facilities for dogs must be constructed and designed so they are structurally sound, kept in good repair and protect the animals from injury. Correct by repairing or replacing damaged or broken facilities and ensure that all aspects of the enclosures are maintained in good repair and are safe for the dogs at all times. To be corrected by: 11 Feb 2022.

3.1(c)(1) Repeat

Housing facilities, general.

The facility continues to have widespread lack of maintenance of the primary enclosures, dog toys, and surfaces in contact with dogs. These issues include chewed plastic dog door flaps, chewed guillotine-style doors, lixit lines chewed to the point the outer pipe is completely missing, chewed plastic boards used to fill gaps along the flooring, excessive rust, and areas of flaking paint and chipped, broken, pitted, unsealed, cracked, and crumbling concrete. Severely rusted metal or damaged concrete can comprise the structural integrity of the object, leading to increased risk of injury in the dogs. Excessive chew damage and issues with concrete can prevent proper cleaning and sanitization. The surfaces of housing facilities and objects within the facility must be constructed in a manner and made of materials that allows them to be readily cleaned and sanitized or removed and replaced when worn or soiled. The dealer must repair or replace damaged surfaces so that they are free from excessive rust and sharp points and able to be cleaned and sanitized effectively.

3.1(c)(3) Repeat

Housing facilities, general.

The facility continues to have surfaces in contact with dogs that are not being cleaned adequately enough to prevent the build-up of dirt and grime. Numerous enclosures have an excessive accumulation of organic material covering on multiple surfaces.

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According to the facility the enclosures receive a "rough hosing" once per day with either a pressure washer or a standard hose. The amount of organic material accumulated on enclosure surfaces indicates the current cleaning frequencies and methods are not adequate. Buildups of organic material increase the risk of disease towards the dogs. Correct by ensuring that all hard surfaces which dogs come in contact with are adequately cleaned in a manner which prevents the accumulation of excreta and reduces disease hazards.

3.1(e)

Housing facilities, general.

Food and bedding supplies are not being stored properly to protect them from spoilage, contamination and vermin infestation. In 96 room 6 there is an open bag of shavings sitting on the floor and 97 room 8 there is an open bag of shavings stored in a trash can with no lid.

Open bags of shavings and food can become contaminated by pests such as insects and rodents which could have a negative impact on the health and well-being of the dogs. All open supplies of food and bedding must be kept in leakproof containers with tightly fitted lids. The licensee must move the open bags of food and shavings into leakproof containers with tightly fitted lids. The licensee must ensure that all food and bedding is properly stored at all times. To be corrected by: 11 Feb 2022.

3.2(d)

Indoor housing facilities.

The indoor housing areas which house whelping dogs are not completely impervious to moisture. In building G3 rooms 1 and 2 the concrete walls and center aisleway are not sealed or painted, and the kennel had been recently washed when the inspection was started. The back wall of the enclosures and center aisleways appeared wet in patches indicating that any prior sealing of the concrete has likely worn and the concrete is no longer impervious to moisture. Some walls have large cracks running down the length of them for several feet which create another avenue for moisture to penetrate the

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concrete.

Surfaces that are not impervious to moisture cannot be properly cleaned and sanitized which could increase the risk of disease hazards towards the dogs. Absorption of water could also undermine a surface's structural integrity causing it to fail and potentially injure an animal. Surfaces of indoor housing facilities, including floors and walls, must be impervious to moisture. The licensee must ensure that the affected surfaces are sealed or painted in a manner that makes them impervious to moisture and that they are maintained appropriately to support the health and well-being of the animals. To be corrected by: 1 April 2022.

3.3(d)

Sheltered housing facilities.

Multiple dogs do not have adequate protection from the elements within their shelter due to missing access door flaps. Enclosure in G1 & G2 are constructed with openings in the back wall to allow the dogs to move between the indoor and outdoor portions of the enclosure. Several enclosures are missing the flap which covers this egress opening. This allows extreme weather, such as frigid temperatures, to enter the sheltered portion. While a guillotine type door is present, this door is only closed during cleaning and is left open ovemight and most of the day providing no break from wind.

Numerous other enclosures have flaps severely damaged by chewing; in those enclosures, 50-75% of the flap is missing leaving it similarly ineffective at providing shelter. During the week of the inspection, ovemight temperatures fell to the low 20s and 30s Fahrenheit. Enclosures with missing flaps housed at least 9 dogs while those with severely damaged flaps housed many more. Dogs in adjacent enclosures were likely exposed to drafts as well.

Failure to fully protect the sheltered portion of the enclosure may not allow the dogs to completely escape extreme

Failure to fully protect the sheltered portion of the enclosure may not allow the dogs to completely escape extreme weather conditions which can result in discomfort or illness. The licensee must repair or replace these flaps in order to provide adequate shelter from the elements including protection from freezing temperatures. To be corrected by: 11 Feb 2022.

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3.6(a)(2)(II) Direct Repeat

Primary enclosures.

The enclosures at this facility continue to fail to protect the dogs from injury. There are numerous examples of body parts being pulled into adjacent enclosures by neighboring dogs causing injuries to the dogs involved. On 11/19/21, APHIS inspectors observed a neighboring dog from an adjacent enclosure reach through the dividing bars and grab the right ear of dog???-CCE. Dog???-CCE. vocalized loudly indicating pain while the other dog continuously pulled his ear. Two additional dogs (CLDCXC and CLCCMT) were identified in facility mortality logs from Nov-2021 with similar severe ear injuries described as "severe damage to R ear" and "missing part of R & L ears." The openings in the dividers between enclosures are large enough that feet, tails, and ears of dogs can be pulled through to an adjacent enclosure. While this type of enclosure would often be suitable for group-housed dogs, the widespread compatibility problems also identified at this facility make this enclosure style inadequate to protect dogs from injury by those in adjacent enclosures.

Enclosures which are constructed in a manner that do not protect animals can lead to injuries caused either by the enclosure itself or animals in adjacent enclosure. This leads to unnecessary pain, suffering, and even death for animals that are injured. Correct by ensuring that all enclosures are constructed and maintained in a manner that prevents injury.

3.6(a)(2)(x) Direct Repeat

Primary enclosures.

The facility continues to house nearly all the dogs on raised slatted floor identified on previous inspections as especially dangerous to the dogs. On this inspection, 6 dogs were found actively stuck in the flooring, requiring facility representatives to manually remove them. Based on records, at least nine other dogs were entrapped in the floor between 8/1/21 and 11/3/21. Several of these dogs were injured and required treatment for lameness and wounds. The 6 dogs found with feet/toes trapped between slats of the flooring were present in both buildings G1 and G2.

-Weaned puppies as young as 6-7 weeks of age also continue to be housed on the same slatted flooring. Inspectors

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witnessed the toes and feet of several puppies pass through the openings of the floor. Butcher paper laid over the existing flooring is not a sufficient correction. Puppies were observed urinating on and playing with the paper by tearing it, resulting in exposure of the dangerous flooring within minutes of paper being put into the enclosure.

The facility has not implemented any effective corrections to eliminate the risk of entrapment to older dogs or to stop the ability of a puppy's feet and legs to pass through the floor openings. After each of the dogs found stuck was released from the floor, the animal was returned to an enclosure with the same flooring.

The risk of serious injury is particularly elevated if dogs are entrapped white no staff is present to help release them from the floor. Openings in the floor that are large enough to allow the feet and legs to pass through can lead to entrapment of a dog which can be painful, distressful, and may result in serious injury to the animal. The licensee must ensure that all floors are constructed in a manner that protects the dogs' feet and legs from injury and that slatted floors do not allow feet and legs to pass through any openings.

3.6(c)(1)(i) Direct

Primary enclosures.

A total of 742 young dogs and weaned pupples were not provided with the minimum space required by the Animal Welfare Act. Representative animals and enclosures were measured in several rooms in buildings G2 and G3. In each case, the Manager of Operations and/or Director of Operations confirmed that the enclosures and animals measured were consistently sized and representative of the those in the room.

- Building G3 Room 2 contained 7 enclosures housing a total of 53 recently weaned puppies. Enclosures measured 47 inches x 49 inches (16 square feet) and average-sized co-housed puppies required 2.4 sq ft each. Enclosures housed as many as 9 puppies (requiring 21.8 sq. feet).
- Building G2 Room 1 contained 4 enclosures with 6 six-month-old beagles each (24 dogs total). Enclosures in this room measured a total of 38.9 sq. feet per enclosure (including both the indoor and outdoor portions). Six average-sized co-

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housed dogs collectively required 39.8 sq feet per enclosure.

- Building G2 Room 6 contained fifteen enclosures (housing a total of 126 four- to five-month-old dogs). Enclosures in this room measured a total 39.7 sq. feet and co-housed dogs required a minimum of 6 sq. feet each. Enclosures housed as many as 10 dogs each (requiring 60.4 sq. feet per enclosure).
- Building G2 Room 7 contained 60 enclosures (housing a total of 539 young dogs). Enclosures measured a total of 39.5 to 39.7 sq. feet and average-sized co-housed dogs required a minimum of 5.35 sq. feet each. Enclosures housed 11 dogs each (requiring 58.9 sq. feet per enclosure).

Failing to provide adequate space can cause discomfort, crowding, distress, poor sanitation, increased incidence of illness, and aggression. Prolonged overcrowding can also lead to engrained and long-lasting negative behaviors (such as increased aggression and future incompatibly, as is seen at this facility) as dogs age. Correct by ensuring that all animals at this facility are provided with at least the minimum space required by the Animal Welfare Act. This issue was identified to facility representatives each day as the rooms were inspected (16, 18, and 19 of November). To be corrected by: 11 Feb 2022.

3.7 Direct Repeat

Compatible grouping.

The facility continues to have severe compatibility problems amongst the adult dogs and puppies. Inspectors witnessed numerous serious dog fights during the inspection, found dogs with injuries from recent fights, and observed dogs aggressively guarding food from cage mates. On multiple occasions the inspection had to be temporarily stopped in order to remove incompatible dogs Facility records documented dogs that have been injured due to fighting outside of the inspection process..

Housing incompatible dogs together or allowing incompatible dogs to have access to each other can result in serious injury or even the death of an animal. Even though this facility continues to have compatibility problems in their group

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housed animals, there has been no action taken by the facility to proactively identify and separate dogs that are incompatible. Currently the facility only responds after a fight occurs and then only by moving one of the dogs if the fight was deemed severe enough to warrant moving the animal. Correct by ensuring that all animals housed together are compatible.

3.9(a)

Direct

Repeat

Feeding

Food being fed to nursing female dogs and their puppies was not wholesome or palatable. On 11/16/21 inspectors checked a random sample of food receptacles in two rooms housing a total of 85 adult dogs and 488 puppies. Every feeder checked contained food that was wet, caked, and/or moldy. The food in two feeders was also contaminated with large numbers of live maggots. Inspectors requested the feeders be cleaned and food be replaced as soon as possible and representatives stated that they would. On 11/19/21, the inspectors returned to this area and conducted another sampling of food receptacles for nursing dogs and pupples. The feeders checked still had either moldy and/or caked feed inside them.

Food that is caked, moldy, and/or infested with insects is not considered wholesome and palatable and may lead to reduced feed consumption, poor nutrition and body condition. Food must be uncontaminated, wholesome, palatable, and of sufficient quantity and nutritive value. The licensee must remove any contaminated or caked food from the feeders and ensure that all food items remain uncontaminated and wholesome at all times.

3.9(b)

Direct

Feeding

The self-feeders at this facility are not accessible to all animals, are located in a manner that fails to minimize contamination and they are not being cleaned and sanitized adequately.

In most feeders the opening is circular and accommodates only one adult dog's head at a time. Some enclosures have a

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wider rectangular opening that usually still accommodates only one dog to access feed at a time. The following concerns were noted by inspectors:

- The facility's self-feeders are not accessible to all adults and puppies at the facility due to an inadequate number of feeders and food guarding behaviors which were exhibited by many animals. There is one feeder available for each enclosure of dogs (often 4-11 animals). In building G3 (housing nursing female dogs), access to the food for nursing mother dogs was frequently blocked by 1 or more young pupples sleeping inside this feeder.
- The facility's self-feeders are located in a manner that fails to minimize contamination and grossly contaminated feed was observed in all feeders that were checked in building G3. The feeders in all buildings are mounted with the opening dogs use to access food only 1-2 inches from the floor of the enclosure. This placement allows back splashed water mixed with feces to be sprayed into the feeder during pressure washing of the enclosure. Additionally, the feeders are so low that young puppies are able to fully crawl inside the feeder openings and were frequently found sleeping directly on the food.
- The facility's self-feeders are not currently being cleaned frequently enough. Numerous feeders throughout the facility had an excessive layer of grime covering the interior metal walls

Correct by ensuring food receptacles are readily accessible to all dogs, are located so as to minimize contamination by excreta and pests and are kept clean and sanitized in accordance with 3.11(b). To be corrected by: 11 Feb 2022.

3.11(a)

Cleaning, sanitization, housekeeping, and pest control.

The facility continues to have a general sanitation problem with cleaning waste from under primary enclosures as often as necessary to prevent the accumulation of feces and food waste to reduce disease hazards, odors, and insect pests. Many rooms had white, moldy accumulations of spilled feed and excreta in the pits that were several inches high and created areas of standing liquid. The majority of rooms in buildings G1 & G2 have significant accumulations of dropped

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feed and excreta on the ledges just underneath the suspended flooring. The food waste and organic material build-up has been present long enough that in many rooms it is either white, brown, or black with mold and numerous small pit/sewer flies were observed congregating on the wastes. In several rooms, standing water in the aisleway was cloudy and mixed with large amounts of food debris and contained numerous white thread-like 'worms'.

Buildup of feces, urine, food waste, and wastewater provide breeding grounds for pests and insects. Additionally, they expose dogs to unnecessary disease hazards and noxious odors. Correct by ensuring that excreta and food waste is removed from under primary enclosures and feeders as often as necessary to prevent accumulation and reduce pests and odors.

3.11(b)(2)

Repeat

Cleaning, sanitization, housekeeping, and pest control.

The facility is not sanitizing the enclosures or water receptacles at the minimum frequency of every 2 weeks and frequently enough to prevent the accumulation of dirt, debris and other disease hazards.

- Facility records from October and November showed many rooms are sanitized as infrequently as every 3-4 weeks while some have no documentation of being sanitized at all during October and November.
- Many of the automatic waterers (lixit pipes) and metal nipples are covered in an orange-colored film and there is rust-colored debris stuck on the inside surfaces of the metal nipple. Many also have a black mold-like substance forming on top of the spout. The portions of the metal enclosure directly adjacent to the nipple are frequently covered with rust and/or flaking white particles, hair, dirt and other grime.

Routine sanitization of enclosures and water receptacles for dogs is important to prevent the accumulation of disease hazards towards dogs. Correct by sanitizing primary enclosures and water receptacles for dogs at least once every 2 weeks or as often as necessary to prevent the accumulation of dirt, debris, food waste, excreta, and other disease hazards.

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3.11(c)

Cleaning, sanitization, housekeeping, and pest control.

Buildings on the facility's property are not being kept clean and free of accumulations of trash, junk, waste products, and discarded matter.

- -- Ventilation fans in buildings G1 and G2 are covered in a thick layer of dust, grime and debris with numerous dead bugs and spider webs forming inside the fan housings.
- -The drainage pit covers (which are outside of any primary enclosure) in buildings G1, G2, and G3 are covered with an excessive layer of accumulated hair, dirt, debris, and other waste products.
- -- The facility has a separate building used for storage of feed, supplies, and equipment and cleaning of shipping crates. This building is excessively cluttered and contains excessive trash, junk, dusty unused caging material and equipment. There is also a large store of rusty metal feeders that the facility representative stated they weren't sure which were broken versus which were able to be used. Excessive accumulations of waste such as hair, dirt, and other debris can provide breeding grounds for pests and contribute to odors. Large amounts of clutter provide breeding areas for rodents and other pests. Additionally, the amount of disorganized broken equipment makes it difficult to locate functional equipment when needed.

Correct by ensuring premises, including buildings and surrounding grounds, are kept clean and in good repair and reduce or eliminate breeding and living areas for rodents and other pests and vermin. Also ensure that premises are kept free of accumulations of trash, junk, waste products, and discarded matter. To be corrected by: 1 April 2022.

3.11(d)

Direct

Repeat

Cleaning, sanitization, housekeeping, and pest control.

The facility's plan to control pests is not effective and insect infestations were found in multiple buildings.

Large numbers of small gnat-sized black flies were seen throughout the facility on the wall dividers, feeders, and on

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organic material in the pits beneath the enclosures. Larger flies (house-fly type) were seen throughout the facility in several rooms on walls, feeders, aisleways, and in enclosures of the animals. Large numbers of small white fly larvae or maggots are present in spilled feed under enclosures and many areas of wet flooring appear to be almost completely covered in maggots. Large numbers of small, white, thread-like "worms" were seen in several rooms throughout the facility where there is pooled water.

Failure to control insects may result in discomfort to the dogs as well as cause contamination of the food and environment which could have a negative impact on the dogs' health and well-being. The licensee must establish an effective plan to control the many species of insects infesting the buildings. Additionally, ensure that the plan remains effective at controlling insect, avian, and mammalian pests all times in order to ensure the health and well-being of the dogs.

Repeat

3.12 Direct

Employees

The facility continues to have an insufficient number of employees to provide care and husbandry practices required by the Animal Welfare Act. The facility currently employs only 21 full-time and 3 part-time employees who are responsible for all husbandry and daily observations for 4,652 dogs and puppies. The current staff level is not adequate to perform the tasks required such as daily observations, medical treatments, cleaning and sanitization, and facility maintenance as documented on this and previous reports.

The continued lack of an adequate number of employees needed to carryout basic husbandry practices and care for the animals is having a severe adverse impact to the well-being of these animals by delaying necessary medical treatments and basic husbandry. Correct by ensuring that the dealer employs an adequate number of appropriately trained and supervised employees as needed to carry out the required provisions of the Animal Welfare Act.

3.13(a) Veterinary care for dogs.

Prepared By: DANA MILLER Date:

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The facility's written Program of Veterinary Care (PVC) for dogs is missing required elements. The PVC does not specify the frequency of regularly scheduled visits and is not signed as required by 3.13(a)(1).

A written PVC is important to ensure clear communication of expectations. The written PVC must address the frequency with which the AV will conduct regularly scheduled visits to all premises in order to assess the animals and other aspects of veterinary care, even when the AV is full time. In addition, the PVC allows the full time AV to specify how long they may be away from a facility without needing routine coverage from a relief veterinarian. Failing to address the frequency and/or timing of regularly scheduled visits may lead to excessive intervals between visits or gaps in the assessment of care being provided to animals. In addition, a signature is required on the PVC to document the involvement of the AV in the development of the written plan. Correct by ensuring that a frequency of visits to the areas where animals are housed (in order to assess the adequacy of animal care and use) is specified and further by ensuring that the written PVC is signed by the attending veterinarian. To be corrected by: 10 Feb 2022.

3.13(a)(2) Direct

Veterinary care for dogs.

A complete hands-on physical examination has not been completed within the last 12 months for approximately 10% of the dogs over a year old for which records were evaluated. This dealer only acquires dogs through on-site breeding, so all dogs have been on-site since birth.

. Failure to have dogs examined by a veterinarian at least annually can result in delays in the proper diagnosis and treatment of underlying medical conditions. Correct by ensuring that a complete physical examination from head to tail of each dog is completed by the attending veterinarian not less than once every 12 months. To be corrected by: 11 Feb 2022.

3.13(b)(1)
Veterinary care for dogs.

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Title:	SUPERVISORY ANIMAL CARE SPECIALIST	USDA, APHIS, Animal Care	22-MAR-2022
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The facility does not have all the required components of the identity of each animal on their different medical record documents. The facility currently maintains medical records filed by the type of record and date of procedure rather than by individual animal. Specific types of medical records are missing required information such as breed, age, sex and individual identification on some or all of the medical records. Affected forms include clinical treatment forms, inventory change notices, mortality records, post wean mastitis treatment forms, annual USDA beagle treatment and physical exam forms, and controlled substance administration records.

According to the Manager of Operations, the facility did not realize that each of these documents constitutes a medical record for the dog listed and therefore are subject to 3.13(b)(1). Without these required components, a specific medical record cannot be consistently and accurately linked to an individual animal. Additionally, information such as age, breed, and gender can play a significant role in the proper diagnosis and treatment of medical conditions.

Accurate medical records are crucial for ensuring appropriate veterinary care is being provided to every animal. Correct by ensuring every medical record for dog's includes the identity of the animal, including identifying marks, tattoos, or tags on the animal and the animal's breed, sex, and age. To be corrected by: 11 Feb 2022.

3.13(b)(2) Repeat

Veterinary care for dogs.

The facility does not have complete or accurate medical records for their dogs. The medical records created when problems have been identified (such as disease, injury, or illness) are missing critical components such as complete descriptions of the problem, treatments administered, and procedures performed in order to provide care or diagnose the condition. Additionally, the medical records for several animals contain gross inaccuracies such as one dog (CFLCTK) which stated that it had been euthanized when it had not been.

Approximately 59% of all euthanasia records evaluated (Aug-Nov 2021) were missing the route of administration for euthanasia drugs.

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Incomplete or inaccurate medical records do not allow the attending veterinarian to adequately assess the adherence of employees to specific protocols, ensure humane handling, or assess the needs of individual animals or the colony as a whole. Correct by ensuring that when a problem is identified in a dog (such as disease, injury, or illness), the date and description of the problem, examination findings, test results, plan for treatment and care, and treatment procedures performed are recorded in the medical records.

This inspection was conducted on site November 16-19 with the Manager of Operations, Director of Operations, Attending Veterinarian, and numerous other employees. Records and paperwork were examined remotely for the remainder of the inspection.

The exit briefing was conducted on 12/17/21 with the Manager of Operations, Attending Veterinarian, Direct of Operations, Senior Vice President for Veterinary Services, and the Vice President for North American Operations.

Additional Inspectors:

KELLY MAXWELL, ANIMAL CARE INSPECTOR

Rachel Perez-Baum, Veterinary Medical Officer

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USDA, APHIS, Animal Care

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United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 506554

Inspection Date: 16-Nov-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506554	32-A-0774	005	ENVIGO RMS LLC	16-NOV-2021

Count	Scientific Name	Common Name
002719	Canis lupus familiaris	DOG ADULT
001933	Canis lupus familiaris	DOG PUPPY
004652	Total	



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Envigo RMS LLC

8520 Allison Pointe Blvd., Suite 400 Indianapolis, IN 46250

Customer ID: 506554

Certificate: 32-A-0774

Site: 005

ENVIGO RMS LLC

Type: FOCUSED INSPECTION

Date: 08-MAR-2022

2.40(b)(3)

Repeat

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

A 7-month old male beagle has wounds to the right ear that were not identified or treated by the facility. CMHCFF, a young male beagle, has several scabbed wounds with yellow discharge on the underside of the right ear extending from the base of the ear.

Failure to identify animals presenting with abnormal medical conditions can delay necessary veterinary intervention which could prolong any potential suffering.

Correct by observing all animals at least daily to identify physical, medical, or behavioral problems. Additionally, ensure that all findings are communicated in a timely manner to the attending veterinarian so that they can examine animals and ensure that appropriate treatment is provided.

3.1(a)

Repeat

Housing facilities, general.

The facility continues to have construction and maintenance issues regarding enclosure design, stability and protecting the animals from injury.

*** The enclosures are comprised of stainless steel or chain-link walls with a "tender-foot"-like flooring that is suspended above a waste gutter using long metal rods to provide support. Due to construction variability, the flooring frequently

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Title: VETERINARY MEDICAL

OFFICER

18-MAR-2022

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Date:

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leaves gaps up to two inches along the front and/or sides of the enclosure. These gaps are large enough for a foot or leg to pass through the openings. Throughout the inspection, at least 130 enclosures had these gaps present and dogs were seen with toes in the gaps.

- *** Several enclosures in Buildings G1 and G2 also have flooring that is not properly supported from underneath. These floors consistently bounce, vibrate, or tilt as the dogs move across the floors.
- *** Gaps were also noticed in the fencing where the chain link had become detached from the frame in Building G1 Room
- 4. One gap in the fencing was only a few inches (enough to trap a foot or leg) and located in the corner by the waterer. Another gap was the length of the enclosure sidewall. Two adjacent pens share a common chain-link side wall that is unattached at the base of the enclosure. The metal at the bottom of the wall had rusted to the point of breaking off, leaving a sharp point at floor level. The entire section of chain link forming the barrier between enclosures is no longer attached to the metal frame. This allowed the chain-link to swing easily when dogs were jumping on or pushing against the chain-link. The fencing was so loose that a dog would be able to simply push their way under it to enter the adjacent enclosure.
- *** Multiple enclosures in Buildings G1 and G2 have sharp points at the levels of the dogs. These sharp points are primarily caused by metal that has rusted to the point of disintegration and left behind sharp edges.
- *** A review of medical records for dogs treated for injuries between 11/18/21 and 3/8/22 revealed one dog injured by the enclosure. A female beagle, CMJCIN, was found on 1/11/22 with her left rear leg caught in the door. There was minor swelling associated with the injury and she was treated by the facility and recovered uneventfully. Additionally, another 8 dogs were treated for tail injuries which varied from minor wounds to tail fractures and bone exposure. (CMECVW, CMDCGP, CLHCEW, CMHCAZ, CMHCDK, CMHCJB, CMECTW). The facility stated they are still reviewing these cases for an underlying cause but are looking into possible injury by the new egress doors.

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Housing facilities that have not been kept in good repair, such as unsecured fencing or flooring, gaps around the floor, or sharp points may injure dogs by entrapping limbs or may fail to adequately contain the dogs.

Housing facilities for dogs must be constructed and designed so they are structurally sound, kept in good repair and protect the animals from injury. Correct by repairing or replacing damaged or broken facilities and ensure that all aspects of the enclosures are maintained in good repair and are safe for the dogs at all times.

3.6(a)(2)(x)

Direct

Repeat

Primary enclosures.

The facility houses nearly all dogs over 12 weeks of age on a slatted floor. This flooring is a heavy gauge rubber or plastic-coated metal flooring with rectangular openings that are approximately ½ inch by 2.5 inches. This flooring has been identified on previous inspections to be dangerous because dogs have been found by inspectors with feet / toes stuck in the flooring. Additional instances were identified by the facility that occurred prior to inspection.

- *** On this inspection a total of 2 dogs were found actively stuck in the flooring to the point that the facility representatives had to remove one of them from the flooring.
- In Building G2, Room 8, after a skirmish broke out in an enclosure housing four male beagles, one of the beagles got his back left foot trapped in the flooring for approximately 11 seconds before he was able to pull free.
- In Building G2, Room 5, a male beagle, CMDCCF was found by inspectors with both rear feet trapped in the flooring. The dog was unable to extract itself and required assistance from the facility representative to free the foot from the floor. *** A review of the medical records indicates that at least 12 additional dogs have been entrapped in the floor during the period of 11/18/21 to 3/8/22. Their injuries ranged from mild soreness to pressure wounds that required treatment for over

Openings in the floor that are large enough to allow the feet and legs to pass through can lead to entrapment of a dog which can be painful, distressful, and may result in serious injury to the animal.

two weeks.

Prepared By: RACHEL PEREZ-BAUM

USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL

OFFICER

18-MAR-2022

Received by Title: Facility Representative

Date:

18-MAR-2022



RPEREZ-BAUM 2016090000773217 Insp_id

Inspection Report

Primary enclosures for dogs must have floors that are constructed in a manner that protects the dogs' feet and legs from injury. When floors are of mesh or slatted construction, they must not allow the dogs' feet to pass through any openings in the floor. The licensee must alter the flooring in a manner that eliminates the risk of entrapment and injury and ensures no feet or legs can pass through the floor openings. The licensee must ensure that all flooring is safe for the dogs at all times in order to support their health and well-being.

3.7

Direct

Repeat

Compatible grouping.

The facility continues to have compatibility problems amongst the adult dogs leading to 97 dogs receiving body and/or extremity injuries, some severe. During inspection by APHIS officials, an animal caretaker in Building G2 entered the treatment room with a beagle with a severe ear wound. The left ear was covered with fresh blood and had multiple skin tears requiring skin staples for repair.

Medical records for dogs injured between 11/18/21 and 3/8/22 identified 59 dogs with injuries attributed to a fight.

Documented injuries include lacerations, bite wounds, bruised and damaged extremities, ear damage, and tail damage.

Eight dogs were euthanized as a result. In addition to the 59 dogs, another 38 dogs were treated for wounds of an unknown cause. These wounds primarily comprised of tail injuries and lacerations to ears.

Housing incompatible dogs together or allowing incompatible dogs to have access to each other can result in serious injuries, impacting the welfare of the animals.

The facility must ensure that all animals are always housed in compatible conditions in order to ensure their safety and well-being.

3.9(b)

Repeat

Feeding

Prepared By: RACHEL PEREZ-BAUM Date:
USDA, APHIS, Animal Care 18-MAR-2022

Title: VETERINARY MEDICAL

OFFICER



RPEREZ-BAUM 2016090000773217 Insp_id

Inspection Report

The self-feeders at the facility are not being cleaned adequately and do not prevent molding, deterioration, and caking of feed.

*** Wet food with varying amounts of mold continues to be a problem in Building G3.

- In Building G3 Room 2, which houses nursing female dogs, 6 out of 7 feeders checked had some moldy food located at the bottom front joint of the feeder tray. Two enclosures had moldy kibble while eithers had small amounts mixed with some wet, caked feed.

- In Building G3 Room 1, which houses nursing female dogs, 2 out of 10 feeders checked had some damp food but no mold present.

*** The facility's self-feeders are not currently being cleaned frequently or adequately enough to prevent an accumulation of dirt and debris. Several feeders throughout the facility and all buildings had excessive grime covering the interior metal walls. This grime appeared to be a combination of hair, saliva, food particles, and skin oils. Some of the grime is so thick inspectors had difficulty being able to scrape it off with their fingers. This excessive grime was particularly worse in Building G1, Room 1.

Dirty food receptacles and molding or caking of feed can cause decreased food consumption among animals and put them at unnecessary risk of potential diseases.

Correct by ensuring food receptacles are kept clean and sanitized in accordance with 3.11(b) and measures are taken to ensure there is no molding, deterioration, and caking of feed.

This inspection was conducted with the Manager of Operations, the Attending Veterinarian, the North America Operations Vice President, and the Regional Quality Manager. The exit interview was conducted with the Site Director, Manager of Operations, Attending Veterinarian, North America Operations Vice President, Regional Quality Manager, Senior Vice

Prepared By: RACHEL PEREZ-BAUM USDA, APHIS, Animal Care 18-MAR-2022

Title: VETERINARY MEDICAL OFFICER



United States Department of Agriculture Animal and Plant Health Inspection Service

RPEREZ-BAUM 2016090000773217 Insp_id

Inspection Report

President of Veterinary Services, Chief Operating Officer, Global Director of Quality Assurance, and the Chief Executive Officer.

Additional Inspectors:

MARGARET SHAVER, VETERINARY MEDICAL OFFICER CARLA THOMAS, VETERINARY MEDICAL OFFICER LORI LINN, ANIMAL CARE INSPECTOR

Prepared By: RACHEL PEREZ-BAUM

USDA, APHIS, Animal Care

18-MAR-2022

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Facility Representative

Date:

Date:

18-MAR-2022

Case 6:22-mj-00003-RSB Document 10 Filed 07/20/22 Page 130 of 156 Pageid#: 449



United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 506554

Inspection Date: 08-Mar-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506554	32-A-0774	005	ENVIGO RMS LLC	08-MAR-2022

Count 000079

Scientific Name Canis lupus familiaris Common Name DOG ADULT

000079

Total



United States Department of Agriculture Animal and Plant Health Inspection Service

RPEREZ-BAUM 2016090000789723 Insp_id

Inspection Report

Envigo RMS LLC

8520 Allison Pointe Blvd., Suite 400

Indianapolis, IN 46250

Customer ID: 506554

Certificate: 32-A-0774

Site: 005

ENVIGO RM\$ LLC

Type: FOCUSED INSPECTION

Date: 03-MAY-2022

3.6(a)(2)(x)

Repeat

Primary enclosures.

The facility houses nearly all dogs over 12 weeks of age on a slatted floor. This flooring is a heavy gauge rubber or plastic-coated metal flooring with rectangular openings that are approximately 1/2 inch by 2.5 inches. This flooring has been identified on previous inspections to be dangerous because dogs have been found by inspectors with feet / toes stuck in the flooring.

- *** On this inspection a total of 2 dogs were found actively stuck in the flooring to the point that the facility representatives had to remove one of them from the flooring.
- In Building G1, Room 6, an adult beagle, CHLCSB, was found with his right rear foot trapped in an opening in the slatted floor. He was quickly and easily removed by staff after being found.
- In Building G1, Room 10, an adult beagle, CHICDM, was found with her right rear foot trapped in an opening in the slatted floor. She required a couple minutes of manipulation before her foot was freed by facility representatives. The dog remained calm during manipulation to free the foot. After being freed from the floor and relocated to different flooring, she was observed and displayed no signs of lameness or pain.

Openings in the floor that are large enough to allow the feet and legs to pass through can lead to entrapment of a dog which can be painful, distressful, and may result in serious injury to the animal.

Prepared By: RACHEL PEREZ-BAUM

USDA, APHIS, Animal Care

Date: 06-MAY-2022

Title: VETERINARY MEDICAL

OFFICER

Received by Title: Facility Representative

Date:

06-MAY-2022

EXHIBIT

Case 6:22-mj-00003-RSB Document 10 Filed 07/20/22 Page 132 of 156 Pageid#: 451



United States Department of Agriculture Animal and Plant Health Inspection Service

RPEREZ-BAUM 2016090000789723 Insp_id

Inspection Report

Primary enclosures for dogs must have floors that are constructed in a manner that protects the dogs' feet and legs from injury. When floors are of mesh or slatted construction, they must not allow the dogs' feet to pass through any openings in the floor. The licensee must alter the flooring in a manner that eliminates the risk of entrapment and injury and ensures no feet or legs can pass through the floor openings. The licensee must ensure that all flooring is safe for the dogs at all times in order to support their health and well-being.

This inspection was conducted with the Manager of Operations and the Vice President of North American Operations.

The exit interview was conducted with the Manager of Operations, Attending Veterinarian, Vice President of North American Operation, Regional Quality Manager, Institutional Official/Chief Operating Officer, Global Director of Quality Assurance.

Additional Inspectors:

Jeffrey Shepherd, SUPERVISORY ANIMAL CARE SPECIALIST

Prepared By: RACHEL PEREZ-BAUM

Date:

Title: VETERINARY MEDICAL

06-MAY-2022

OFFICER

Received by Title: Facility Representative

Date:

06-MAY-2022

USDA, APHIS, Animal Care



United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 506554

Inspection Date: 03-May-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506554	32-A-0774	005	ENVIGO RMS LLC	03-MAY-2022

Count	Scientific Name	Common Name
002891	Canis lupus familiaris	DOG ADULT
000222	Canis lupus familiaris	DOG PUPPY
003113	Total	

	en e
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뭐 그런 그릇하는데 이번 소문을 하게 되면 그 사는 그리고 경험하는데게 되었다. 그 작품 등이다	
출입하는 이 뭐 그는 일을 되면 하면 하는 것이 하는 그들을 살았습니다. 이 하는 것은 사람이 나를 살았다.	
통하는 사람들은 보다 되었다. 하는 말을 보고 있는 데 보다는 보고 있는 네트를 보고 있는데 없는데 보고 있다.	
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활용되는 아이들에 나는 사람들이 가게 하는 사람들은 사람이 없어요. 그 나	
할지는 이번 회장 문장들이 보는 경기를 가지 않는 것 같아 나는 것이 없었다. 본 경기 아	

ATTACHMENT A

Property to Be Searched

482 French's Store Rd, Cumberland, VA 23040

482 French's Store Rd, Cumberland, VA 23040 is large-scale commercial animal breeding facility. It consists of multiple large kennels buildings, office buildings, storage facilities, and medical facilities. Attached is a satellite image from Google maps dated "2022".

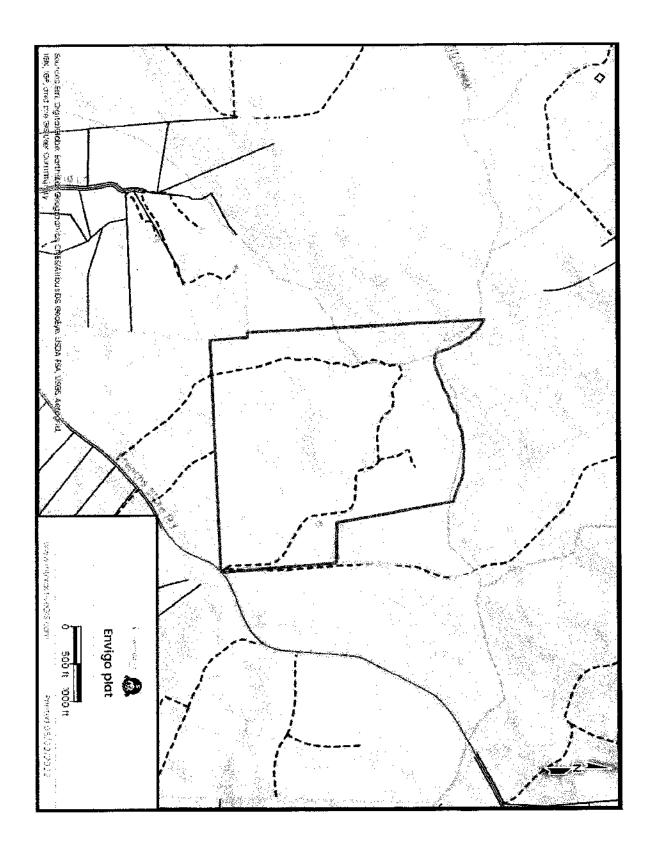
The property map of this area on file with Cumberland County, Virginia lists this parcel as "52-A-24" in the name of "ENVIGO GLOBAL SERVICES INC." Attached is a plat map from https://cumberland.interactivegis.com/map/.

The curtilage of the property is surrounded by a high chain link fence topped with barbed wire. The main gate is also comprised of chain link topped with barbed wire. The gate appears to be electrically powered and rolls across the gate opening when secured. There is a numerical PIN pad and call box mounted on a short pole outside the gate.

The main entrance has no signage indicating the property's business use or owner. There is a sign to the right of the gate marked "VECTOR SECURITY, 482." A photograph of the main gate is attached.

Octobe Majos

Page 2 of 4



Page 3 of 4



Page 4 of 4

ATTACHMENT B

For purposes of this warrant:

The term "including" means "including, but not limited to."

The term "record" includes all forms of creation or storage, including any form of computer or electronic storage (such as hard disks or other media that can store data); any handmade form (such as writing); any mechanical form (such as printing or typing); and any photographic form (such as microfilm, microfiche, prints, slides, negatives, videotapes, motion pictures, or photocopies).

The term "computer" includes all types of electronic, magnetic, optical, electrochemical, or other high speed data processing devices performing logical, arithmetic, or storage functions, including desktop computers, notebook computers, mobile phones, tablets, server computers, and network hardware.

The term "storage medium" includes any physical object upon which computer data can be recorded. Examples include hard disks, RAM, floppy disks, flash memory, CD-ROMs, and other magnetic or optical media.

ITEMS TO BE SEIZED

- 1. Acquisition Records, including:
 - a. APHIS Forms 7005 (Record of Animals on Hand)
 - b. APHIS Forms 7006 (Record of Acquisition, Disposition, or Transport of Animals)
- 2. Disposition Records, including:
 - a. APHIS Forms 7005 (Record of Animals on Hand)
 - b. APHIS Forms 7006 (Record of Acquisition, Disposition, or Transport of Animals)
 - c. Records of euthanasia
- 3. Attending Veterinarian & Adequate Veterinarian Care Records, including:
 - a. Name and contact information for Attending Veterinarian
 - b. Written formal arrangements with Attending Veterinarian
 - c. Written Program(s) of Veterinary Care
 - d. APHIS Forms 7002 and 7002a
 - e. Documentation of any training conducted by Attending Veterinarian of employees at Envigo-Cumberland
 - f. Records reflecting daily observations of all animals
 - g. Records reflecting the training/guidance to personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia
 - h. Health Certificates
 - i. Vaccination records
 - i. Records reflecting sampling and treatment for parasites

- k. Records reflecting preventive care and treatment
- 1. Any medical records
- m. Established protocol for euthanasia
- 4. Veterinary Care Records, including:
 - a. All veterinary care records
 - b. All dental care records
- 5. File Folder and Contents for Every Animal
- 6. Business Records, including:
 - a. Employee records, including training and hours worked
 - b. Payroll records for any contract employees
 - c. Transportation records, including invoices, billing receipts, or documentation of payment for transportation of any animals
 - d. Records reflecting sales
 - e. Invoices showing purchases of food, medical supplies, anesthetics, and controlled drugs on hand
 - f. Inventories of purchases of food, medical supplies, anesthetics, and controlled drugs on hand
 - g. Documentation of preventive medical treatments
 - h. Emergency plan on how to deal with animal attacks or escapes
 - i. Exercise plan as approved by veterinarian
 - j. Animal observation and treatment logs
 - k. Enrichment logs for NHPs
 - 1. Records of feeding of young animals, such as bottle feeding
 - m. Vaccination and preventative health records (individual animal or group/litter)
 - n. Necropsy records
 - o. Surgery records
 - p. Euthanasia records
 - q. Cage wash validation sheets
 - r. Room maintenance logs
 - s. Records reflecting pest control efforts, including contracts with third-parties
 - t. Records documenting waste sanitation and waste sanitation correction efforts
 - u. Standard operating procedures
 - v. Record of visits or other communications with Attending Veterinarian (including date, time, animal ID, treatment and/or observation/follow up instructions)
 - w. Invoices and payments to the Attending Veterinarian.
 - x. Health certificate for transport
 - y. Any records of financial accounts or transactions related to payment for or proceeds from or related to Envigo animals or institutions with which Envigo has done business including account statements, deposits, withdrawals, checks, debits, and wire transfers
 - z. Records that depict, discuss, or diagnose any Envigo animals

- 7. Records containing material discussing the United States Department of Agriculture (USDA) or any current or former employee
- 8. Records of communications between Envigo personnel and USDA personnel
- 9. Records or payments sent to or received from a current or former USDA employee

10. Animals

- a. Any animal in acute distress as determined by a veterinarian
- b. Deceased animals

11. Internet and Computer Activity

- a. Records of Internet activity, including firewall logs, caches, browser history, and cookies, "bookmarked" or "favorite" web pages, search terms that the user entered into any Internet search engine, and records of user-typed web addresses which relate to, depict, discuss or promote animals or institutions that are covered under the federal Animal Welfare Act, or regulated in any way by the United States Department of Agriculture (USDA);
- b. Records of Internet activity, including firewall logs, caches, browser history, and cookies, "bookmarked" or "favorite" web pages, search terms that the user entered into any Internet search engine, and records of user-typed web addresses which relate to, depict, discuss or promote the United States Department of Agriculture (USDA), its agencies, its programs, employees thereof, or the federal Animal Welfare Act (AWA);
- c. Records of Internet activity, including firewall logs, caches, browser history, and cookies, "bookmarked" or "favorite" web pages, search terms that the user entered into any Internet search engine, and records of user-typed web addresses which relate to former or current employees of the United States Department of Agriculture (USDA);

12. Forensic records including:

- a. evidence of who used, owned, or controlled the cell phone at the time the things described in this warrant were created, edited, or deleted, such as logs, registry entries, configuration files, saved usernames and passwords, documents, browsing history, user profiles, email, email contacts, "chat," instant messaging logs, photographs, and correspondence;
- b. evidence of software that would allow others to control the cell phone, such as viruses, Trojan horses, and other forms of malicious software, as well as evidence of the presence or absence of security software designed to detect malicious software;
- c. evidence of the lack of such malicious software;
- d. evidence of the attachment to the cell phone of other storage devices or similar containers for electronic evidence;
- e. evidence of counter-forensic programs (and associated data) that are designed to eliminate data from the cell phone;
- f. evidence of the times the cell phone was used;
- g. passwords, encryption keys, and other access devices that may be necessary to access the cell phone;
- h. evidence of user attribution showing who used or owned the cell phone at the time the things described in this warrant were created, edited, or deleted, such as logs, phonebooks, saved usernames and passwords, documents, and browsing history; As used above, the terms "records" and "information" include all of the foregoing items of evidence in whatever form and by whatever means they may have been created or stored,

- including any form of computer or electronic storage (such as flash memory or other media that can store data) and any photographic form.
- 13. Any evidence of, contraband, fruits of crime, or other items illegally possessed, property designed for use, intended for use, or used in committing a violation of 7 U.S.C. § 2149(d), 18 U.S.C. § 371, 18 U.S.C. § 1001, or 18 U.S.C. § 1512(c).

AUTHORIZATIONS

- 14. This warrant authorizes the use of trained veterinarians, as well as the employees and volunteers of non-governmental organizations (NGOs) with expertise in animal welfare to assist law enforcement officers executing this search. These individuals and law enforcement are authorized to handle animals at the SUBJECT PREMISES to:
 - a. Examine the animals;
 - b. Document the examinations;
 - c. Photograph/video the animals;
 - d. Provide care for the animals, including removal from the facility if necessary to ensure such care, and
 - e. Provide such other assistance as directed by the USDA-OIG.
- 15. This warrant authorizes veterinarians to provide medications as necessary for injuries, sickness, or life-saving care.
- 16. This warrant authorizes the seizure of animals located at the SUBJECT PREMISES, should those animals be in "acute distress" as determined by a veterinarian on scene, as evidence of violations of 7 U.S.C. 2149 (knowingly violating any provision of the Animal Welfare Act).
- 17. This warrant authorizes the seizure of all storage devices on the SUBJECT PREMISES including, but not limited to, computers, personal devices, and mobile phones, for the purposes of searching for and seizing items listed in the "ITEMS TO BE SEIZED."
- 18. This warrant authorizes a review of electronic storage media and electronically stored information seized or copied pursuant to this warrant in order to locate evidence, fruits, and instrumentalities described in this warrant. The review of this electronic data may be conducted by any government personnel assisting in the investigation, who may include, in addition to law enforcement officers and agents, attorneys for the government, attorney support staff, and technical experts. Pursuant to this warrant, the USDA OIG may deliver a complete copy of the seized or copied electronic data to the custody and control of attorneys for the government and their support staff for their independent review.
- 19. During the execution of the search of the Subject Premises described in Attachment A, law enforcement personnel are authorized to (1) press or swipe the fingers (including thumbs) of any individual, who is found at the subject premises and reasonably believed by law enforcement to be a user of a device found at the premises, to the fingerprint scanner of the device; (2) hold a device found at the premises in front of the face those same individuals and

activate the facial recognition feature, for the purpose of attempting to unlock the device in order to search the contents as authorized by this warrant.

EXHIBIT D



PRESS RELEASE

Justice Department Secures the Surrender of Over 4,000 Beagles from Virginia Breeder of Dogs for Research

Monday, July 18, 2022

For Immediate Release

U.S. Attorney's Office, Western District of Virginia

WASHINGTON – In a consent decree entered on July 15 by the U.S. District Court for the Western District of Virginia, Envigo RMS, a company that breeds and sells animals for research, has agreed to a permanent prohibition on engaging in any activity at its facility in Cumberland, Virginia, that requires an Animal Welfare Act (AWA) license. Envigo RMS has also agreed to relinquish all remaining beagles at the Cumberland facility to the Humane Society of the United States (HSUS).

In May, the United States filed suit against Envigo RMS, alleging that the company was failing to provide humane care and treatment to the thousands of beagles at the company's Cumberland facility. Specifically, the complaint alleged that Envigo RMS was failing to meet the AWA's minimum standards for handling, housing, feeding, watering, sanitation and adequate veterinary care, among other requirements. Based on past violations identified during inspections by the Department of Agriculture and evidence of extensive, ongoing AWA violations obtained during a multiday criminal search warrant executed at the Cumberland facility beginning on May 18, the Justice Department moved for a temporary restraining order that the federal court granted on May 21 to ensure the health and welfare of the beagles at the Cumberland facility.

The Justice Department worked with the HSUS to develop a plan to transfer the 4,000 remaining beagles from the Cumberland facility and make those beagles available for adoption. The transfer plan, which was jointly submitted by the Justice Department and Envigo RMS, was approved by the District Court on July 5. Under the transfer plan, the HSUS will coordinate the enormous effort to remove all of the beagles from the Cumberland facility over the course of 60 days.

"This settlement brings to an end the needless suffering caused by Envigo's blatant violations of animal welfare laws at this facility," said Assistant Attorney General Todd Kim of the Justice Department's Environment and Natural Resources Division (ENRD). "We will continue to vigorously enforce animal welfare laws to ensure that animals are provided the humane care that they are legally owed and deserve."

"Due to the efforts of Environment and Natural Resources Division and the U.S. Attorney's Office, more than 4,000 animals have been rescued from dire circumstances, and we will continue to hold accountable those who are responsible," said U.S. Attorney Christopher R. Kavanaugh for the Western District of Virginia. "I am grateful to all those who assisted with this case, especially those who are ensuring that these animals receive the care they deserve."

This settlement is the result of prosecution by Senior Trial Attorney Mary Hollingsworth and Trial Attorney Shampa Panda of ENRD's Wildlife and Marine Resources Section, and First Assistant U.S. Attorney Anthony Giorno for the Western District of Virginia.

Updated February 26, 2024

Topic

ANIMAL WELFARE

Components

Environment and Natural Resources Division USAO - Virginia, Western

Related Content

PRESS RELEASE

Animal Breeder Pleads Guilty to Animal Welfare and Pollution Crimes and Will Pay More than \$35M, Including Record Fine in an Animal Welfare Case

June 3, 2024

PRESS RELEASE

Virginia Veterinary Technician Sentenced for Dogfighting and Promoting Animal Fighting Ventures

July 31, 2023

PRESS RELEASE

Cockfighting Pit That Operated For More Than 30 Years Destroyed; Men Who Owned the Property Sentenced

June 9, 2017

Western District of Virginia

Main Office:

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Roanoke, Virginia 24008-1709

Contact USAO-WDVA

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Charlottesville: (434) 293-4283