



Animal Welfare Institute

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Honorable Xavier Becerra
Secretary
Department of Health and Human Services
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Washington, DC 20201
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Honorable Lloyd Austin
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Washington, DC 20301-1000
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By hardcopy and email

Re: Abuse and trafficking by suppliers of
animals for research funded by HHS and DOD

Dear Secretary Becerra, Secretary Austin and Acting Director Tabak:

Events of the past few months necessitate that the Department of Health and Human Services and the Department of Defense re-evaluate their reliance on, and support for, providers of animals for research that have demonstrated an inability or unwillingness to ensure that those animals are treated humanely and are not the product of illegal trafficking operations. Two recent examples provide a compelling basis for HHS and DOD to halt, at least temporarily, procurement of animals from sources that have either proven themselves unqualified or have been implicated in civil and/or criminal investigations and prosecutions involving serious allegations of abuse or trafficking. Not only are the welfare of the animals and respect for the law at stake; these issues also undermine the validity and reliability of research undertaken with mistreated and/or questionably sourced animals.

1. Abuse of beagles at Cumberland, VA, facility

Over the past year, the Animal Welfare Institute (AWI) has written about the horrific conditions of dogs bred for research at a Cumberland, Virginia, facility.¹ That facility was owned by Envigo, a company that was purchased by Inotiv in November 2021. In May 2022, a federal court in Virginia took the extraordinary step of granting the Justice Department a temporary restraining order—an emergency procedure used to halt ongoing conduct threatening irreparable harm—and then a preliminary injunction, to address those abusive conditions. The court concluded that such extraordinary relief was necessary because of the serious and repeated Animal Welfare Act citations documented by U.S. Department of Agriculture investigators over a 10-month period.

The court’s order offers a chilling account of conditions at the facility:

*Over 300 beagle puppies have died onsite due to “unknown causes” over seven months [including 173 so decomposed it was no longer possible to determine cause of death]. 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 The food that the beagles did receive was observed to contain live insects, worms, maggots, beetles, flies, ants, mold, and feces. ... 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 ... goes on and on.*²

The order followed execution of a federal search warrant at the facility, during which law enforcement officers seized a total of 446 dogs and puppies needing immediate care to “alleviate life-threatening illnesses or injuries,” and identified many others requiring medical attention. To argue for the restraining order, DOJ included a necropsy report describing a puppy’s cause of death as “unknown” because the puppy had been “eaten—only has a head left.”³ This horrific situation stands in sharp contrast to Inotiv’s online assertion of a “long and impeccable regulatory history.”⁴

Although Inotiv agreed to shut down the Cumberland facility, its USDA license was not suspended or revoked. We understand from government data that HHS purchased dogs from Envigo, including multiple purchases in 2021—with one completed even after USDA began documenting these appalling conditions.

¹ Search awionline.org, keyword “Envigo.”

² The key court orders and pleadings are available at [Envigo/Inotiv | Animal Welfare Institute \(awionline.org\)](https://awionline.org).

³ [Court Intervenes to Halt Horror at Beagle Breeding Facility | Animal Welfare Institute \(awionline.org\)](https://awionline.org). The necropsy report was completed two days before execution of the search warrant began—approximately six months after Inotiv took ownership of Envigo and the Cumberland facility.

⁴ [Why Inotiv - Inotiv \(inotivco.com\)](https://inotivco.com).

2. Laundering and trafficking of Cambodian primates by key providers of those animals for research

On November 16, the U.S. Attorney’s Office for the Southern District of Florida (SDFL) announced an indictment of two Cambodian forestry officials and representatives of Vanny Bio Research (Cambodia) Corporation (VBRC) and associated Hong Kong–based companies, alleging a conspiracy to smuggle thousands of long-tailed macaques (also known as crab-eating macaques) into the United States by illegally classifying (*i.e.*, laundering) wild-caught monkeys as captive born.⁵ One day later, Inotiv (whose subsidiary Envigo describes itself as the “world’s largest and most trusted source of nonhuman primates”)⁶ told the Securities and Exchange Commission that Cambodian officials and employees of its “principal supplier” of primates had been criminally charged by the SDFL with conspiring to illegally import monkeys.⁷

The indictment also details the activities of two unindicted co-conspirators (UCC)—entities that imported over 2,000 monkeys—to sites in the Southern District of Florida and Alice, Texas. It is unclear where another 1,080 monkeys imported in 2021 ended up.

The UCCs are unidentified, but from AWI’s review of available records, the only relevant entities (breeders, dealers, etc.) listed by the USDA as operating in Alice Texas, are Envigo Global Services Inc. and Orient BioResource Center. Inotiv acquired these entities in 2021 and 2022, respectively, along with their three Alice, Texas, primate sites.⁸ AWI has previously detailed the suffering of long-tailed macaques imported from Asia to these sites.⁹

On February 16, 2022, Inotiv disclosed to the SEC a June 2021 grand jury subpoena to Envigo from the SDFL related to primate imports from Cambodia, China, and/or Vietnam.¹⁰ It subsequently reported SDFL primate-related subpoenas to Orient and Envigo (as well as one directed to certain Envigo employees related to the company’s Cumberland dog-breeding site).¹¹ In August 2021, Gary Tucker, then–vice president of Orient, pleaded guilty to the felony of willfully lying to investigators during a prior wildlife trafficking investigation regarding the laundering of monkeys from Cambodia. According to the SDFL, Tucker was well aware of laundering issues in the industry and, since 2009, had conducted frequent personal visits to Asia to procure monkeys and “to determine the condition of both the facilities and the specimens” proposed for export. A government sentencing memorandum explained that Tucker “categorically den[ied] that any audit reports or site visit reports of any description were

⁵ See Cambodian Officials and Six Co-conspirators Indicted for Taking Part in Primate Smuggling Scheme | USAO-SDFL | Department of Justice and related documents.

⁶ https://insights.envigo.com/hubfs/resources/data-sheets/product-sheet_buy-and-board.pdf.

⁷ https://www.sec.gov/Archives/edgar/data/720154/000110465922119766/tm2230829d1_8k.htm.

⁸ <https://www.sec.gov/Archives/edgar/data/720154/000155837022013530/notv-20220630x10q.htm>.

⁹ Beagle Breeder Atrocities Leave USDA-APHIS Unmoved | Animal Welfare Institute (awionline.org).

¹⁰ <https://www.sec.gov/Archives/edgar/data/720154/000155837022001236/notv-20211231x10q.htm>.

¹¹ <https://www.sec.gov/Archives/edgar/data/720154/000155837022013530/notv-20220630x10q.htm>.

prepared and submitted to [Orient], ... [even though he] well knew . . . preparation and submission of site visit reports was a standard procedure at [Orient].”¹²

It seems difficult to escape the conclusion that Inotiv, through its due diligence in acquiring Envigo and Orient, either knew, or should have known, that the companies it was acquiring were embroiled in primate laundering investigations,¹³ not to mention the multitude of Animal Welfare Act citations at the Cumberland beagle facility (about which investors have already filed a securities class action).¹⁴ Inotiv’s duty to ferret out and disclose this information is particularly salient given that Inotiv has expressly emphasized its reliance on the experience and expertise of its predecessor companies in disclosures to the SEC and investors. (*E.g.*, Inotiv’s 10Q filed on 6/30/22 states: “We are the second largest commercial provider of research models and services globally, and *our predecessors have been supplying research models since 1931*” (emphasis added)).¹⁵ And just this month, Inotiv claimed in an investor presentation that its Research Models and Services (RMS) business has “[l]ong-standing, dependable supplier relationships with critical suppliers across an international logistics network.”¹⁶

Concerning the other unidentified UCC, a review of inspection reports for primate dealers located within the Southern District of Florida suggests that Worldwide Primates (WWP) may be the only Florida primate dealer located within that jurisdiction with sufficient size to accomplish what the indictment alleges. WWP founder Block is also a convicted felon who was sentenced to 13 months in federal prison for an attempt to smuggle six infant orangutans in 1990.¹⁷

According to USDA inspection report inventories, Inotiv is the United States’ largest commercial monkey dealer, with WWP ranked third. The companies currently house over 13,600 monkeys collectively, with the vast majority being long-tailed macaques—the focus of the current indictment and of Tucker’s previous felony conviction. AWI’s review of federal records indicates that HHS and DOD have purchased significant numbers of primates from both Envigo and WWP.

3. Science’s reporting on the indictment

On November 23, *Science* reported that one of the two companies that received monkeys implicated in the indictment was Inotiv.¹⁸ The company reportedly told *Science* “while we do not yet know if these allegations will be proven true, Inotiv strongly condemns any and all unauthorized trading/importation of endangered species,” and a spokesperson for a pro-research

¹² CM/ECF – Live Database – flsd-CM/ECF – Live Database – flsd (uscourts.gov); <https://www.justice.gov/usao-sdfl/pr/man-convicted-lying-federal-agents-during-international-wildlife-trafficking> and related documents.

¹³ While an indictment is not proof of guilt, and a grand jury subpoena is neither an allegation nor proof of guilt, they flag issues that, at minimum, warrant further investigation.

¹⁴ See, e.g., [Inotiv Class Action Lawsuit NOTV | Deadline August 22, 2022 - Securities Class Action Directory](https://www.sec.gov/Archives/edgar/data/720154/000155837022013530/notv-20220630x10q.htm).

¹⁵ <https://www.sec.gov/Archives/edgar/data/720154/000155837022013530/notv-20220630x10q.htm>.

¹⁶ <https://ir.inotivco.com/events-and-presentations/default.aspx>.

¹⁷ <https://awionline.org/awi-quarterly/2010-winter/twentieth-anniversary-bangkok-six-smuggling-case; A Primate Dealer's Pitiful Con - Animal Welfare Institute>

¹⁸ <https://www.science.org/content/article/indictment-monkey-importers-could-disrupt-u-s-drug-and-vaccine-research>.

lobby said that there is not much companies like Inotiv can do to determine animal provenance, other than take import documents at face value. Yet, the indictment's two-page "Manner and Means of the Conspiracy" section alleges that the Texas and Florida UCCs worked with the named defendants to export the wild-caught monkeys.¹⁹ The indictment alleges that these UCCs were not merely passive recipients of the laundered monkeys, but instead active participants.

It is important to note that the shipments of laundered monkeys to Alice, Texas, cited in the indictment occurred in 2019 and 2020, before Inotiv acquired Envigo Global Services Inc. and Orient BioResource Center. However, it is difficult to understand how Inotiv's due diligence in acquiring those businesses could fail to uncover these issues. Prior to Inotiv's November 2021 purchase of Envigo, the latter company (and its predecessor company in Alice, Covance) had received grand jury subpoenas in 2019 and June 2021 seeking information about the importation of nonhuman primates.²⁰ Moreover, at least three members of what Inotiv still calls its "Accomplished Senior Leadership" are themselves holdovers from Envigo, including its current executive vice president (longtime Envigo CEO Adrian Hardy) and current group president of Inotiv's RMS/animal supply division.²¹ Similarly, prior to Inotiv's acquisition of Orient (through Envigo) in January 2022, Inotiv should have learned—particularly since the information was public—that Orient vice president Gary Tucker pleaded guilty to lying when he claimed there was no documentation of the due diligence Orient conducted in investigating foreign sources of nonhuman primates—documentation that the government alleged was "standard procedure" at Orient.²²

That Inotiv touts the experience of its predecessors and suppliers in disclosures to the SEC and to its investors makes it untenable to then suggest that it should not be responsible for knowing how those predecessors and suppliers operated.

In response to the announcement of the monkey smuggling indictment, Inotiv told *Science* of its plans to conduct audits to ensure its screening processes "are (and were) solid." Envigo has previously claimed to be "very selective in our breeding farm partners," that its "extensive audit program" ensures good animal welfare, and that its export facilities are "high-quality and reliable." As noted above, however, its prior audits apparently either failed to uncover the laundering scheme or were disregarded by those who received them.

¹⁹ The indictment alleges, among other things, that the named defendants and unindicted co-conspirators established facilities in Cambodia purporting to breed long-tailed macaques for export; engaged with customers and entered contracts to sell and export purportedly captive-bred monkeys; established a logistics system to inspect monkeys prior to sale; secured false CITES export permits; illegally purchased wild-caught monkeys from black market dealers; provided transport permits that allowed monkeys unsuitable for export to be euthanized and then have their identification tags transferred to wild-caught monkeys; and delivered and caused the delivery of wild-caught monkeys to various international airports in the United States.

²⁰ E.g., <https://www.sec.gov/Archives/edgar/data/720154/000155837022013530/notv-20220630x10q.htm>.

²¹ <https://ir.inotivco.com/events-and-presentations/default.aspx>.

²² See, e.g., Man Convicted of Lying to Federal Agents During International Wildlife Trafficking Investigation | USAO-SDFL | Department of Justice and related documents.

Envigo also repeatedly stated that it was addressing the grave issues identified by USDA inspectors at its Cumberland dog-breeding facility, and that the highest level of animal welfare was a core value of the company. Yet in May 2022, *National Geographic* quoted Envigo as stating that a recent inspection “essentially repeats earlier findings, all of which are being addressed.” This was just days before government officials obtained a temporary restraining order and seized 446 dogs in “acute distress” at Cumberland, which eventually resulted in Envigo shuttering the facility.

Action needed from HHS and DOD

As the world’s largest primate supplier, Inotiv is an integral part of that industry and deeply entangled with entities and high-level individuals previously convicted or currently charged or under investigation. That, combined with its track record at the Cumberland site, dictates the need for an immediate halt to purchases from or funding to Inotiv (and its various businesses, including Envigo and Orient), at least while HHS and DOD investigate the allegations relating to the Cumberland dog site as well as the primate laundering allegations that have recently come to light. WWP, potentially implicated in the Cambodian indictment and investigation, should similarly be scrutinized before receiving any further federal purchases or funds. Indeed, funding entities in the EU largely refuse to support research involving wild-caught primates because of the significant animal welfare issues inherent in the primate trade, while a ban on use of wild-caught primates in research is set to begin this month.²³

Apart from the animal welfare and potential criminal issues implicated in the Cambodian indictments and Cumberland investigations and litigation—which by themselves would warrant a halt on future federal purchases or other funding—researchers have documented the potential for study confounds caused by pathogens that can adversely impact colony health and “severely impact study outcome” from animals of questionable provenance. Other researchers have raised the specter of increased chance of viruses jumping from monkeys to people as the trade in wild-caught long-tailed macaques has increased. In fact, the International Union for Conservation of Nature this year changed the classification of long-tailed macaques from “vulnerable” to “endangered” and warned about the real possibility of extinction. It also stated that research demand is threatening the species and “the research industry needs to become accountable for the effects of their actions” on wild populations.²⁴

As the funder of one of the preeminent research organizations in the world, HHS has a unique opportunity and obligation to take the lead in halting government support to, and dependence on, organizations implicated in such operations.

²³ E.g., <https://www.nc3rs.org.uk/sites/default/files/documents/Guidelines/NC3Rs%20guidelines%20-%20Non-human%20primate%20accommodation%20care%20and%20use.pdf>;

<https://www.gov.uk/government/publications/advice-on-non-human-primates-bred-for-use-in-scientific-procedures/commission-of-advice-non-human-primates-bred-for-use-in-scientific-procedures-accessible>.

²⁴ E.g., <https://www.tandfonline.com/doi/full/10.3109/15476910903213521>;

<https://www.motherjones.com/politics/2022/06/animals-testing-monkey-primate-shortage-covid-monkeypox-future-pandemic-vaccines/>; <https://www.iucnredlist.org/species/12551/199563077#assessment-information>.

If animals are to be used in research in the United States, there is an obligation to ensure they are well cared for, not abused, and responsibly sourced. This latest disclosure of primate smuggling makes it obvious that effective controls are lacking. Institutions that fund or conduct research should be held responsible for ensuring that they are purchasing from legitimate sources that prioritize the care of the animals. And at the very least, those caught engaging in abuse and trafficking in illegally obtained animals should have their licenses to operate permanently revoked, and should be ineligible to receive federal contracts or other funding.

At a minimum, HHS and DOD should halt all dealings with Inotiv, Envigo, Orient, VBRC, WWP, and all other entities that rely on their animals, at least while HHS and DOD determine whether these companies can consistently provide animals that are well cared for and lawfully sourced.

I would be happy to discuss this issue in further depth at your convenience.

Sincerely,

A handwritten signature in black ink that reads "Cathy Liss". The script is fluid and cursive, with the first letters of each word being capitalized and prominent.

Cathy Liss
President