

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
LYNCHBURG DIVISION**

UNITED STATES,	)	
	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 6:22-cv-28-NKM
	)	
ENVIGO RMS, LLC,	)	
	)	
Defendant.	)	
	)	
	)	
	)	

DECLARATION OF DR. JOHN E. SAGARTZ, DVM, PHD, DACVP

I, John E. Sagartz, DVM, PhD, DACVP, declare the following to be true and correct to the best of my knowledge:

1. I have been the Chief Strategy Officer at Inotiv Inc. (“Inotiv”) since November 2018. Inotiv is a leading contract research organization specializing in nonclinical and analytical drug discovery and development services.

2. I began my career as a toxicologic pathologist at Searle/Monsanto in 1996. I served as a section head, director, and preclinical development site head at Pharmacia following its merger with Monsanto. I founded Seventh Wave Laboratories in 2003 and served as the company’s president and chief executive officer, and chief strategy officer over the course of 15 years.

3. I received my Bachelor of Science and Doctor of Veterinary Medicine degrees from Kansas State University and, after completing residency training in anatomic pathology, earned my Doctor of Philosophy from The Ohio State University.

4. To the best of my knowledge, the matters set forth in this declaration are true and correct.

5. Inotiv acquired Envigo RMS, LLC (“Envigo”) in November 2021. Envigo provides a broad range of animal research models and related services to the pharmaceutical and biotechnology industries, government, academia and other life science organizations. It is the second largest producer of canines for use in medical research and clinical testing.

6. Envigo’s Cumberland, Virginia facility (the “Cumberland Facility”) is a USDA-regulated animal production facility focused on the generation of beagle dogs. These purpose-bred beagle dogs are essential for biomedical research and the development of lifesaving drugs and medical devices. Specifically, these dogs are instrumental to evaluating the efficacy and safety of novel medicines, including those designed to treat various cancers and autoimmune disorders amongst other conditions.

7. Pursuant to Food and Drug Administration (“FDA”) guidance, certain new molecule medicines and biomedical devices *must* be evaluated in at least two animal species, at least one of which is not a rodent. Additionally, other domestic and international regulatory authorities require laboratory animal testing prior to clinical trials, both for general toxicity and for specific patient populations, including women of childbearing age, juveniles, and those with rare diseases. Failure to conduct these studies has historically demonstrated unacceptable levels of risk in human clinical trials, and a lack of this testing would result in regulatory “hold” before such human clinical trials would be allowed to progress.

8. Historically, the Envigo Cumberland facility has produced up to 25 percent of the beagle dogs used domestically in the development of new medicines.

9. In the months before this lawsuit was filed, Envigo (and later Inotiv) were working closely with the United States Department of Agriculture (“USDA”) to address concerns raised about the facility. Since then, Envigo and Inotiv have devoted millions of dollars in upgrading the facility.

10. These improvements include: (1) enhanced staff training, (2) visual cue cards for reference throughout the site, (3) enhanced pest control while ensuring we would not expose the canines to poisonous toxins, (4) enhanced treatment forms to capture additional information, (5) infrastructure changes to eliminate any flooring/panel gaps, and (6) installing HVAC units to maintain temperature compliance. Envigo also hired additional staff, including a veterinarian and two veterinary technicians, and increased salaries, and offered additional incentives to bolster its workforce.

11. As a result of these changes, the Cumberland facility saw significant improvement in health outcomes, including an approximately 60 percent drop in post-wean mortality. A USDA inspection report from early May 2022 reflected the significant improvements that resulted from Envigo and Inotiv’s compliance efforts, citing only one non-direct non-compliance which involved flooring (which currently cannot be obtained due to supply chain issues).

12. On May 18, 2022, as Inotiv and Envigo were in the midst of implementing even more improvements, federal agents raided the facility.

13. Since this Court’s May 21, 2022 Order, Envigo and Inotiv have continued to devote substantial resources to complying with the Order and to bringing the facility into full compliance with the Animal Welfare Act and its implementing regulations.

14. In light of the serious allegations raised in the Complaint, and despite a tremendous investment of resources to comply with the Order, Inotiv and Envigo are now

considering winding down operations at the facility and transferring all dogs currently housed there to fulfill their intended role in biomedical research or to more suitable homes. This would serve the dual purposes of removing beagles from the Cumberland facility and advancing pharmaceutical research.

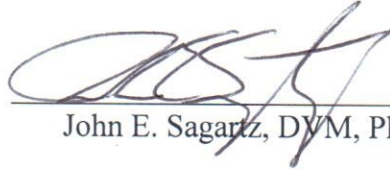
15. The Government action that resulted in the halting of operations at the Cumberland Facility has had and will continue to have a significant impact on new drug development and testing in the United States.

16. There are a number of early stage medicines that will be unable to progress to human clinical trials if Envigo is unable to fulfill existing orders for beagle dogs. Given the relatively few alternative providers of animals for these purposes it is likely that critical research and drug development will be delayed. We believe that pharmaceutical companies will continue developing their products through off-shored contracts, most likely in China, where animal welfare practices are almost certainly less robust and unmonitorable.

17. The Cumberland facility currently houses 3,188 canines, including 3,035 canines over 6 weeks in age, 56 mothers with pre-wean litters, and 97 pregnant or mated females. Envigo has existing contractual commitments to ship out more than 500 dogs within the next 30 days. Inotiv and Envigo believe that the transfer of dogs out of the Cumberland Facility through the fulfillment of existing customer orders would significantly minimize the immediate and long-lasting impact of this litigation on the pharmaceutical industry.

18. Pursuant to 28 U.S.C. § 1746(2), I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on June 13, 2022.

A handwritten signature in blue ink, appearing to read 'J. Sagarz', is written over a horizontal line.

John E. Sagarz, DVM, PhD, DACVP