United States
Consumer Product Safety Commission
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Ballot Vote Sheet

TO: The Commission
Alberta E. Mills, Secretary

DATE: January 19, 2022

THROUGH: Austin C. Schlick, General Counsel
Mary T. Boyle, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel, Regulatory Affairs
Meridith L. Kelsch, Attorney, Regulatory Affairs

SUBJECT: Petition Requesting Rulemaking on Commercially Bred Dogs (CP 21-2)

BALLOT VOTE DUE: Tuesday, January 25, 2022

CPSC staff is forwarding to the Commission a briefing package regarding a petition for rulemaking submitted by the Humane Society of the United States and the Humane Society Legislative Fund on February 17, 2021. The petition requests that the Commission initiate rulemaking under sections 7 and 9 of the Consumer Product Safety Act to establish warning requirements regarding the risk to consumers of contracting *Campylobacter* infection from contact with commercially bred dogs. On July 21, 2021, the Office of the General Counsel submitted to the Commission a draft *Federal Register* notice, seeking comments on the petition. On July 27, 2021, the Commission voted on the draft *Federal Register* notice, but did not reach a majority vote.[1] Accordingly, the *Federal Register* notice was not published. In the attached briefing package, staff recommends that the Commission deny the petition.

Please indicate your vote on the following options:

I. Grant the petition, and direct staff to initiate rulemaking.

_____ _____
(Signature) (Date)

[1] Record of Commission Action, available at: https://www.cpsc.gov/s3fs-public/RCA-FRN-Petition-Requesting-Rulemaking-on-Commercially-Bred-Dogs-Sold-to-Consumers.pdf. Acting Chairman Adler voted to publish the notice and issued a statement with his vote; Commissioner Baiocco voted not to publish the notice; and Commissioners Kaye and Feldman voted to "[d]etermine that the request does not satisfy the criteria for docketing a petition set forth in 16 C.F.R. §§ 1051.5(a) and 1051.6(a) because the request addresses a topic outside the jurisdiction of the Commission."

Ballot Vote Sheet

II. Defer action on the petition.

_____ _____
(Signature) (Date)

III. Deny the petition, and direct staff to submit a draft denial letter for Commission vote.

_____ _____
(Signature) (Date)

IV. Take other action specified below.

_____

_____

_____

_____

_____ _____
(Signature) (Date)

Attachment: *Staff Briefing Package - Petition to Require that Commercially Bred Dogs Placed into Commerce Be Accompanied by Written Warnings of the Risk of* Campylobacter *Infection from Contact with the Dogs*

United States
Consumer Product Safety Commission

Staff Briefing Package – Petition to Require that Commercially Bred Dogs Placed into Commerce Be Accompanied by Written Warnings of the Risk of *Campylobacter* Infection from Contact with the Dogs

January 19, 2022

This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

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Executive Summary

On February 17, 2021, the Humane Society of the United States and the Humane Society Legislative Fund (collectively, the Petitioner) submitted a petition to the United States Consumer Product Safety Commission (CPSC). The petition requests a rulemaking to require that commercially bred dogs placed into commerce be accompanied by written warnings about the risk that people may be infected with the bacteria *Campylobacter* due to contact with the dogs.

In August 2017, the U.S. Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture, and various state health departments were first alerted to an outbreak of *Campylobacter* infections in people that was linked to contact with commercially bred dogs sold in pet stores. The CDC subsequently completed two outbreak investigations that confirmed a close genetic relationship between *Campylobacter* isolates collected from infected people and from dogs sold in pet stores. In addition, the CDC found that medical care for the involved *Campylobacter* bacteria may be complicated by the finding that the bacteria were resistant to several first-line antibiotic medicines commonly used to treat bacterial infections. After learning of the petition submitted to the CPSC, the CDC contacted CPSC staff to emphasize the related public health implications. According to the Petitioner, multidrug-resistant *Campylobacter* found in commercially bred dogs is thought to be due to the prophylactic use of antibiotics in dogs that are maintained in unsanitary conditions along their distribution chain.

CPSC staff evaluation of the Petitioner's request included an analysis of the nature of the related health effects due to infection of people with multidrug-resistant *Campylobacter*, the effectiveness of the Petitioner's proposed warning label in mitigating deleterious health outcomes, the CPSC and CDC injury data, and the economic implications of the Petitioner's request. Staff did not identify injury data related to the petition in either the Consumer Product Safety Risk Management System or the National Electronic Injury Surveillance System. CPSC staff evaluation of the petition indicates that the health risks and medical outcomes associated with infection of people with multidrug-resistant *Campylobacter* from commercially bred dogs are serious and include the possibility of death. Furthermore, there may be a lack of public information related to the risk of infection.

Staff also found that a warning is unlikely to be effective at preventing infection of consumers with multidrug-resistant *Campylobacter* due to contact with commercially bred dogs. Furthermore, staff indicates that there could be a minimal cost burden to individual entities within the commercially bred dog industry for implementation of the Petitioner's proposed warnings. In addition, there is a lack of statistically valid data from both the CPSC and the CDC regarding the extent of multidrug-resistant *Campylobacter* infection in people from commercially bred dogs and the relationship to the total cost to society of treating those infections as well as the consequent benefit of reducing those costs. However, the benefits of the Petitioner's request would likely exceed the costs if there was a small reduction in the number of cases that require hospitalization, a reduction in the number of cases that cause adverse long-term health outcomes, or if at least one death per year was avoided. Staff data analysis indicates that approximately 2.4 million puppies are obtained from industry sources within the scope of the

Petitioner's request. In addition, CDC data include a total of 32 hospitalizations related to multidrug-resistant *Campylobacter* infections during outbreaks that occurred in 2016 through 2018 and 2019 through 2021. However, rulemaking may require substantial agency resources and realignment of agency priorities to accommodate the need for such resources. Therefore, staff recommends that the Commission deny the petition and direct staff to prepare a letter of denial.

United States
Consumer Product Safety Commission
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TO: The Commission
Alberta E. Mills, Secretary

DATE: December 8, 2021

THROUGH: Austin Schlick, General Counsel

Mary T. Boyle, Executive Director

DeWane Ray, Deputy Executive Director for Safety Operations

FROM: John N. Stabley, Ph.D.
Project Manager, Commercially Bred Dogs Petition
Physiologist, Division of Pharmacology and Physiology Assessment

SUBJECT: Petition to Require that Commercially Bred Dogs Placed into Commerce Be Accompanied by Written Warnings of the Risk of *Campylobacter* Infection from Contact with the Dogs

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I. Introduction

This briefing package evaluates the petition from the Humane Society of the United States and the Humane Society Legislative Fund (collectively, the Petitioner) regarding infection in humans with multidrug-resistant *Campylobacter* due to contact with commercially bred dogs. For the purposes of this briefing package, commercially bred dogs are dogs that are bred for sale in pet stores or via online sellers as described in the petition.

Staff reviewed the petition by (1) evaluating U.S. Centers for Disease Control and Prevention (CDC) incident information about multidrug-resistant *Campylobacter* infection from commercially bred dogs, (2) evaluating the effectiveness of the warning label proposed by the Petitioner to mitigate multidrug-resistant *Campylobacter* infections in humans from commercially bred dogs, (3) evaluating injury data in the U.S. Consumer Product Safety Commission (CPSC) databases, and (4) evaluating the commercially bred dog market and costs associated with the implementation of the warning the Petitioner proposed. The Briefing Memorandum will summarize findings from staff supporting the petition evaluation including the Division of Pharmacology and Physiology Assessment in the Directorate for Health Sciences (HSPP), the Division of Human Factors in the Directorate for Engineering Sciences (ESHF), the Division of Hazard Analysis in the Directorate for Epidemiology (EPHA), and the Directorate for Economic Analysis (EC).

II. Background

The Petitioner requests that the CPSC initiate rulemaking activity under sections 7 and 9 of the Consumer Product Safety Act (CPSA) to "(1) establish requirements that dogs bred commercially for distribution in commerce be accompanied by clear and adequate warnings of the risk to people of contracting *Campylobacter* infection, or campylobacteriosis, from contact with the dogs, and (2) establish requirements with respect to the form of the warnings, including

the form of signage to be posted near the dogs' cages in pet stores or on the websites where dogs are being sold or advertised online."

Campylobacter is a genus of bacteria with more than 20 distinct species. The species *Campylobacter jejuni* is associated with 90 percent of human illness caused by *Campylobacter* bacteria in general (CDC 2019b). Common sources of *Campylobacter* infection include contaminated food and water, travel to low- or middle-income countries, and contact with animals (CDC 2019a). Drug-resistant *Campylobacter* is classified as a serious threat by the CDC (CDC 2019a).

The symptomatology of infection with *Campylobacter*, sometimes termed campylobacteriosis, includes diarrhea, abdominal pain, fever, nausea, and vomiting. Severe infections may cause bloodstream infections or symptoms similar to acute appendicitis or ulcerative colitis. Potential long-term health outcomes associated with *Campylobacter* infection include arthritis, irritable bowel syndrome, and Guillain-Barré syndrome (CDC 2019b). Importantly, *Campylobacter* related to the infected dogs described in the petition are resistant to several antibiotic medicines commonly used to treat bacterial infections and may increase the likelihood of more severe infections described above (CDC 2018).

Investigations by the CDC revealed close genetic relationships among *Campylobacter* isolates collected from infected people and from puppies sold in pet stores (CDC 2018, CDC 2021). In addition to the multidrug resistance of *Campylobacter* associated with the commercially bred dogs, infected dogs may appear healthy and thus essentially mask the risk of any infection potential to humans (CDC 2021). According to the Petitioner, the origin and spread of multidrug-resistant *Campylobacter* in commercially bred dogs is thought to occur due to the prophylactic use of antibiotics to treat commercially bred dogs housed in unsanitary conditions throughout the associated distribution chain. A brief timeline of events related to the multidrug-resistant *Campylobacter* infection of people from commercially bred dogs as well as the history of this petition is displayed in Table 1.

Table 1. Brief timeline of events related to multidrug-resistant *Campylobacter* transmitted to humans from commercially bred dogs and petition history

Date	Description
August 2017	CDC, USDA Animal and Plant Health Inspection Service, and state health departments first alerted to *Campylobacter* outbreak
30 January 2018	CDC Final Outbreak Advisory published (CDC 2018)
17 February 2021	Petition delivered to the CPSC
15 April 2021	CDC Final Outbreak Information update published (CDC 2021)
21 July 2021	Office of General Counsel submits to the Commission a draft *Federal Register* notice inviting comments on petition
3 August 2021	Record of Commission Action[1]

CDC, Centers for Disease Control and Prevention; USDA, United States Department of Agriculture; CPSC, Consumer Product Safety Commission

[1] The Commission voted 1-1-2 regarding whether to publish notice of the petition in the *Federal Register* and seek comments on it. There was one vote in favor of publication; one vote against publication; and two votes to take other action, which stated that the petition addressed a topic outside the jurisdiction of the Commission. Accordingly, the notice was not published. The Record of Commission Action is available at https://www.cpsc.gov/s3fs-public/RCA-FRN-Petition-Requesting-Rulemaking-on-Commercially-Bred-Dogs-Sold-to-Consumers.pdf.

III. Factors Relevant to the Commission's Decision on a Petition

The Commission's petition regulations set forth the major factors for the Commission to consider when deciding whether to grant or deny a petition (16 CFR § 1051.9). These factors include (1) whether the product presents an unreasonable risk of injury, (2) whether a rule is reasonably necessary to eliminate or reduce the risk of injury, and (3) whether consumers would be unreasonably exposed to the risk of injury described by the petition if rulemaking was not pursued. The regulation also states that, when considering these factors, the Commission is to evaluate the relative priority of the risk of injury associated with the product and the agency resources available for rulemaking to address the hazard. Staff considered these factors during evaluation of the petition and during development of the briefing package's recommendation.

IV. Discussion

A. Health Sciences

HSPP staff confirms that unsanitary conditions in which dogs are exposed to the excrement of infected dogs facilitate the spread of multidrug-resistant *Campylobacter* among dogs and that the prevalence of multidrug-resistant *Campylobacter* is greatest among dogs less than or equal to one year old. The prophylactic use of antibiotics without veterinary oversight may also enable the proliferation of multidrug-resistant *Campylobacter* among commercially bred dogs and possibly to humans.

Most cases of *Campylobacter* infection in people do not require treatment with antibiotics unless serious symptoms occur. However, when required, medical treatment of multidrug-resistant *Campylobacter* in people involves the use of expensive intravenous antibiotics typically reserved for the treatment of hospital-acquired diseases. Such medical management often results in prolonged hospital stays.

Since commercially bred dogs infected with multidrug-resistant *Campylobacter* may be asymptomatic, the infection may not be readily apparent, and HSPP staff notes that there is a lack of public information available about the potential infection in commercially bred dogs and the possible risk to people. Furthermore, people in chemotherapy, with compromised immune systems, or with acquired immunodeficiency syndrome (AIDS) are at increased risk for life-threatening *Campylobacter* infection. According to the reports from the CDC (CDC 2019a, CDC 2018, CDC 2021) and information from the medical literature, HSPP concludes that commercially bred puppies or dogs sold online or in pet stores may be infected with multidrug-resistant *Campylobacter* that can lead to sickness, severe illness, or death in people.

B. Human Factors

ESHF staff describes warnings as a means of conveying safety information to a target audience to prompt safety-related behavior. Staff's evaluation of the Petitioner's proposed warning label indicates that the label lacks adequate identification of the hazard, fails to describe adequately the consequence(s) of the hazard, and identifies only a few of the many possible precautions that consumers must take to avoid the hazard. Furthermore, the Petitioner's proposed warning

label is not formatted in a manner consistent with best practices for warnings, and thus, the warning is unlikely to be effective. Given the deficiencies in the Petitioner's proposed warning label, ESHF staff developed a new warning label based on current best practices for developing warnings (see Tab C).

Although it is an improvement over the Petitioner's proposed warning, the revised warning label developed by ESHF staff is unlikely to overcome the factors that influence the effectiveness of warnings as identified by research on warnings. Such factors include the perception of hazard, familiarity of the product, and the cost of compliance with the warning as it relates to time, effort, and convenience. ESHF staff notes that people are not likely to perceive commercially bred dogs as a risk for infection with multidrug-resistant *Campylobacter*. In addition, commercially bred dogs infected with multidrug-resistant *Campylobacter* may appear healthy, and this may further reduce the perception of the hazard associated with these dogs. Furthermore, according to ESHF staff, dogs are familiar animals. ESHF staff describes research that indicates a reduced likelihood to seek out and heed warnings associated with a familiar product, especially if the perception of the hazard associated with the product is low. Moreover, according to ESHF staff, given the common and intimate incorporation of dogs into an owner's family or lifestyle, it may be difficult to reconcile the intentions of the warnings with routine interactions with dogs thus increasing the cost of compliance with the warning in terms of time, effort, and convenience. ESHF staff indicates that if consumers perceive that the cost of compliance with a warning is high, they are less likely to comply with a warning.

In sum, ESHF staff's evaluation of the Petitioner's request for a warning label regarding the risks of infection with multidrug-resistant *Campylobacter* from commercially bred dogs indicates that a warning is unlikely to be effective in preventing consumers from contracting *Campylobacter* infection from contact with the dogs.

C. Epidemiology

According to EPHA staff, after a review of both the Consumer Product Safety Risk Management System (CPSRMS) and the National Electronic Injury Surveillance System (NEISS), no records could be identified associated with commercially bred dogs or *Campylobacter*. Product codes do not exist for pets (beyond pet supplies) within either system, a search for "campylobacter" did not retrieve any records associated with a dog, and searches of "breed" or "bred" did not reveal incidents associated with infections attributed to dogs. However, EPHA staff summarized available incident data related to multidrug-resistant *Campylobacter* from commercially bred dogs published by the CDC (CDC 2018, CDC 2021; see Table 2). In addition to pet store consumers, CDC data indicate instances of infection with multidrug-resistant *Campylobacter* among pet store employees. Furthermore, there may have been an unreported number of instances of infection with multidrug-resistant *Campylobacter* among people who did not visit pet stores themselves, but who encountered people who had visited pet stores (CDC 2018). The CDC indicates that *Campylobacter* does not typically spread among people (CDC 2019c).

Table 2. Multidrug-resistant *Campylobacter* outbreaks linked to commercially bred dogs reported by the CDC

	2016-2018 Outbreak (CDC 2018)	2019-2021 Outbreak (CDC 2021)	Total
All Infections	113	56	169
Infections with Follow-up Interview	103	41	144
Infections After Contact with Dog (% of Infections with Follow-up Interview)	102 (99%)	38 (93%)	140 (97%)
Infections After Contact with Dog from Pet Store (% of Infections with Follow-up Interview)	90 (87%)	21 (51%)	111 (77%)
Hospitalizations (% of Infections with Follow-up Interview)	23 (22%)	9 (22%)	32 (22%)
Deaths	0	0	0

CDC, Centers for Disease Control and Prevention

D. Economics

EC staff evaluation of the petition reveals that the Petitioner's request for implementing a warning would represent a small cost for an individual business selling commercially bred dogs. However, when multiplied across the large number of commercially bred dog breeders and distributors in the market, the total cost to the industry may be several million dollars. If the warning label can prevent one death per year due to infection with multidrug-resistant *Campylobacter* from commercially bred dogs or can prevent several severe cases with hospitalizations or long-term health impacts, then the benefits to society (in terms of reduced medical costs) would likely exceed the costs to the commercially bred dog industry.

Approximately 39 percent of dogs acquired per year, including approximately 2.4 million puppies, are obtained from industry sources within the scope of the Petitioner's request. The remaining 61 percent of dogs acquired each year are obtained from friends or acquaintances, animal protection organizations, or picked up from the street. According to EC staff, Census data indicate that there may be as many as 15,000 businesses with 20,000 distinct facilities within scope of the Petitioner's request including commercial dog breeders, pet stores, and online sellers. Supply chain contributors, such as dog brokers and other intermediaries, may also be impacted by the Petitioner's request.

Analysis by EC staff using Census data for labor costs to employers indicates that the cost of the warning requested by the Petitioner would be minimal on a per supplier basis and represents little to no burden on small businesses. However, with the number of impacted entities possibly exceeding 20,000, the total cost to the economy could be $2 million to $4 million per year. The preceding estimate assumes a cost of $100 to $200 per year per entity for labor and materials, and the estimate depends on whether a single store sign or a printed warning to accompany every dog sold is used.

The economic benefits of the Petition to society would be reduced medical costs from treatment of multidrug-resistant *Campylobacter*. The cost per case or the total cost to society for the medical treatment of multidrug-resistant *Campylobacter* from commercially bred dogs may be estimated using cost data and analyses from cases involving *Campylobacter* infection of foodborne origin, but this may not correspond well with the cost of infections from commercially bred dogs that are the subject of the Petitioner's request. The CDC incident data summarized in Table 2 do not provide enough information to make statistically valid estimates of the number of infections in the future due to multidrug-resistant *Campylobacter* from commercially bred dogs, the associated cost of those infections, or how costs might be reduced by the Petitioner's request. According to U.S. Department of Agriculture (USDA) Economic Research Service analysis of CDC data, EC staff note that 94 percent of foodborne *Campylobacter* infections are resolved without a doctor, 5 percent involve medical care that does not include hospitalization, and approximately 1 percent of cases require hospitalization while 0.1 percent of cases lead to death. The cost to society of these foodborne cases is approximately $2,283 per case – this is the average cost for all cases including the 94 percent of cases that are resolved without a doctor (the cost of each case requiring hospitalization is much higher). Based on EPHA staff's review of CDC data, there were 169 cases linked to commercially bred dogs in the period from 2016 through 2021 (see Tab D).

Due to the limited incident information, staff is unable to estimate the number of multidrug-resistant *Campylobacter* infections from commercially bred dogs that might be prevented by the Petitioner's request or if the cost per case would be different than the cost per case for foodborne cases. However, if the rulemaking activity related to the Petitioner's request prevented one death per year, prevented a small number of hospitalizations per year, or reduced long-term health impacts, then the benefits would likely exceed the costs of the proposed warnings.

E. Relevant Existing Standards

To the best of staff's knowledge there are no relevant voluntary standards related to the Petitioner's request regarding multidrug-resistant *Campylobacter* infection from commercially bred dogs sold online or in pet stores. The International Organization for Standards (ISO) administers two standards concerning the testing procedures for detecting *Campylobacter* in the food chain of animals and humans (ISO 2017a, ISO 2017b). The CDC indicates that improving the hygiene of commercially bred dogs sold in pet stores or online along their distribution chain may reduce the risk of transmitting multidrug-resistant *Campylobacter* to people (CDC 2018).

V. Summary

HSPP staff's evaluation (Tab B) discusses the serious nature of infection of people with multidrug-resistant *Campylobacter* transmitted from commercially bred dogs. If commercially bred dog industry practices to prophylactically treat these animals with antibiotics continue, and if the incidence of infection of people with multidrug-resistant *Campylobacter* increases, it may become increasingly difficult to render effective medical care to people who experience severe infections. The CDC has previously identified drug-resistant *Campylobacter* as a serious threat

to public health (CDC 2019a). For example, there has been a substantial increase in the percentage of *Campylobacter* resistant to the antibiotic ciprofloxacin since about 1997 with a related foodborne origin, from exposure during travel to low- and middle-income countries, or from contact with animals (CDC 2019a).

According to ESHF staff's evaluation (Tab C) of the Petitioner's request, including the proposed warning label and staff's suggested warning label revision, a warning is unlikely to be effective at mitigating the risk of infection with multidrug-resistant *Campylobacter* transmitted from commercially bred dogs as identified in the Petitioner's request.

Staff is not aware of any previous CPSC activity related to the petition request. According to EPHA staff (Tab D), there are no incidents related to the petition request in CPSC databases (*i.e.*, NEISS and CPSRMS). As described above, CDC investigations provide information about two outbreaks in people of multidrug-resistant *Campylobacter* transmitted from commercially bred dogs.

EC staff indicates (Tab E) that there could be minimal cost burden to individual entities within the industry for implementation of the Petitioner's proposed warning. Although the benefit of a reduced number of multidrug-resistant *Campylobacter* infections in people could not be estimated in a statistically valid manner, EC staff indicates that the benefits of the Petitioner's request would likely exceed the costs if the warning resulted in a small reduction in the number of cases that require hospitalization, a reduction in the number of cases that cause adverse long-term health outcomes, or if at least one death per year was avoided.

VI. Staff's Assessment of Commission Options

The Commission may grant the petition, deny the petition, or defer action on the petition. There are several factors relevant to the Commission's decision on a petition (see section III. Factors Relevant to the Commission's Decision on the Petition) that staff considered during assessment of these options. Relevant considerations include whether the product presents an unreasonable risk of injury, whether a rule is necessary to reduce the hazard, whether failure to issue a rule would unreasonably expose consumers to the hazard, the relative priority of the risk of injury, and agency resources.

A. Grant the Petition

Granting the petition may help to mitigate the risk of multidrug-resistant *Campylobacter* transmission from commercially bred dogs to people. However, staff's evaluation suggests that the warning proposed by the petition is unlikely to be effective. The CPSC has no reports of multidrug-resistant *Campylobacter* infection from commercially bred dogs in the CPSRMS or NEISS databases, and the incident information available from the CDC lacks the statistical validity to estimate the possible cost benefits of the Petitioner's request. Furthermore, rulemaking activity indicates a potential need for substantial agency resources or the realignment of agency priorities.

Granting a petition does not require the Commission to issue a rule under the authority cited in the petition. The Petitioner requests that the CPSC initiate rulemaking activity per the statutory authority defined in sections 7 and 9 of the CPSA to mitigate the risk of infection of people with multidrug-resistant *Campylobacter* transmitted from commercially bred dogs via a warning. It may also be possible to conduct rulemaking activities under alternative authority, such as section 27(e) of the CPSA. If the Commission grants the petition, staff will evaluate statutory options in developing a rulemaking.

In addition, granting a petition does not require the Commission to issue a rule in the specific form requested by the Petitioner. Given ESHF staff's findings that the Petitioner's proposed warning is unlikely to be effective, the Commission may consider a performance requirement as an alternative to a warning. For example, an alternative rule could require a negative test for *Campylobacter* infection in commercially bred dogs prior to sale. However, it is possible that such a testing requirement could prompt even more widespread use of antibiotics along the distribution chain for commercially bred dogs thus exacerbating the current problem of multidrug-resistant *Campylobacter* infection in these animals and transmission to people. Furthermore, staff is currently not familiar with the testing procedures for *Campylobacter* infection in dogs including test sensitivity, effectiveness, and other considerations.

B. Deny the Petition

Denying the petition would preserve CPSC resources and priorities. Resources required to review data, evaluate mitigation strategies, and conduct economic analyses necessary to develop a briefing package would require significant staff commitments. Given that a warning is unlikely to be effective, granting the petition may have a limited effect in addressing this hazard. However, denying the petition may preserve the risk of illness if the public is not aware of the risk of infection of people with multidrug-resistant *Campylobacter* from commercially bred dogs. Proliferation of multidrug-resistant *Campylobacter* increases the likelihood of serious illness and possibly death especially among people with compromised immune systems.

C. Defer Action on the Petition

If the Commission concludes that more information is required before it can decide whether to grant or deny the petition, the Commission may defer a decision and direct staff to collect additional information and reconsider the petition after that work is completed. Deferring the petition would enable staff to reallocate resources from other priorities and further evaluate the Petitioner's request and possible alternatives to the proposed warning label.

VII. Staff's Recommendation and Conclusion

In aggregate, while the health and medical risks associated with infection of people with multidrug-resistant *Campylobacter* from commercially bred dogs that may appear healthy are serious and include the risk of death, the Petitioner's proposed warning label is unlikely to be effective at mitigating the risk of infection with multidrug-resistant *Campylobacter* from contact with the dogs. Furthermore, the benefit of a warning label to consumers may be minimal unless

the warning is able to reduce associated hospitalizations, long-term adverse health outcomes, or prevent deaths. In addition, rulemaking may require substantial agency resources and realignment of agency priorities. Therefore, staff recommends that the Commission deny the Petitioner's request for rulemaking to require a warning label regarding the risk of infection of people with multidrug-resistant *Campylobacter* to accompany commercially bred dogs sold in pet stores or online.

VIII. References

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Centers for Disease Control and Prevention. Information for Health Professionals. (2019b). 2019 December 19. https://www.cdc.gov/campylobacter/technical.html.

Centers for Disease Control and Prevention. Questions and Answers – *Campylobacter*. (2019c). 2019 December 23. https://www.cdc.gov/campylobacter/faq.html.

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Hoffman, Sandy et al "Economic Burden of Major Foodborne Illnesses Acquired in the United States." USDA Economic Research Service, EIB 140, 2015. https://www.ers.usda.gov/publications/pub-details/?pubid=43987.

International Organization of Standards. (ISO 2017a). ISO 10272-1:2017 Microbiology of the food chain — Horizontal method for detection and enumeration of Campylobacter spp. — Part 1: Detection method. https://www.iso.org/standard/63225.html, 2017.

International Organization of Standards. (ISO 2017b). ISO 10272-2:2017 Microbiology of the food chain — Horizontal method for detection and enumeration of Campylobacter spp. — Part 2: Colony-count technique. https://www.iso.org/standard/63228.html, 2017.

TAB A: Petition[2]

[2] The complete Petition including exhibits is available at https://cpsc-d8-media-prod.s3.amazonaws.com/s3fs-public/Petition-from-Human-Society-Commercially-Bred-Dogs-for-Sale-to-Consumers_0.pdf.

BEFORE THE U.S. CONSUMER PRODUCT SAFETY COMMISSION

PETITION REQUESTING THE COMMISSION UNDERTAKE A RULEMAKING TO REQUIRE THAT COMMERCIALLY BRED DOGS PLACED INTO COMMERCE BE ACCOMPANIED BY WRITTEN WARNINGS OF THE RISK OF CONTRACTING *CAMPYLOBACTER* INFECTION FROM CONTACT WITH THE DOGS

Submitted by the Humane Society of the United States and the Humane Society Legislative Fund

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I. INTRODUCTION

Pursuant to Sections 7 and 9 of the Consumer Product Safety Act, 15 U.S.C. §§ 2056(a)(2) and 2058 (CPSA or the Act), the U.S. Consumer Product Safety Commission (CPSC or the Commission) regulations, 16 C.F.R. § 1051, *et seq*., and Section 553(e) of the Administrative Procedure Act, 5 U.S.C. § 553(e), the Humane Society of the United States (HSUS) and the Humane Society Legislative Fund (HSLF) submit this petition requesting the Commission initiate rulemaking to (1) establish requirements that dogs bred commercially for distribution in commerce be accompanied by clear and adequate warnings of the risk to people of contracting *Campylobacter* infection, or campylobacteriosis, from contact with the dogs, and (2) establish requirements with respect to the form of the warnings, including the form of signage to be posted near the dogs' cages in pet stores or on the websites where dogs are being sold or advertised online.[1]

Campylobacteriosis is a serious infectious disease caused by a family of bacteria, one species of which--*Campylobacter jejuni*--recently sickened nearly 150 people who contracted it from infected, contagious dogs sold in pet stores in more than 20 states.[2] *Campylobacter* infection is characterized by diarrhea (frequently bloody), abdominal pain, fever, nausea, and sometimes vomiting.[3] Infection can result in long-term consequences, such as arthritis, irritable bowel syndrome (IBS), and Guillain-Barré syndrome (GBS).[4] Most concerning, according to the Centers for Disease Control and Prevention (CDC), "[t]he outbreak strain of *Campylobacter jejuni* is exceedingly resistant" to

[1] 15 U.S.C. § 2056 (the Commission may promulgate consumer product safety standards to require that a consumer product be accompanied by clear and adequate warnings or instructions, or requirements respecting the form of warnings or instructions.)

[2] Centers for Disease Control and Prevention, *Outbreak of Multidrug-resistant Campylobacter Infections Linked to Contact with Pet Store Puppies* (Dec. 17, 2019), https://www.cdc.gov/campylobacter/outbreaks/puppies-12-19/index.html, attached as Ex.1; Centers for Disease Control and Prevention, *Multistate Outbreak of Multidrug-Resistant Campylobacter Infections Linked to Contact with Pet Store Puppies* (Jan. 30, 2018), https://www.cdc.gov/campylobacter/outbreaks/puppies-9-17/index.html, attached as Ex. 2.

[3] Centers for Disease Control and Prevention, *Campylobacter (Campylobacteriosis): Information for Health Professionals*, https://www.cdc.gov/campylobacter/technical.html (last reviewed Dec. 23, 2019), attached as Ex. 3.

[4] *Id*.

antibiotics.[5] Antibiotic resistance is a significant public health issue, and the increased resistance of *Campylobacter* bacteria is considered a serious health threat.[6] As described more fully below, antibiotics are used prophylactically throughout the puppy mill industry as a hedge against the dogs becoming ill from the unsanitary, overcrowded conditions in which they are kept. Antibiotics are also used indiscriminately as a substitute for veterinary care for the dogs.

When alerted to the first *Campylobacter* outbreak in August 2017, the U.S. Centers for Disease Control (CDC), the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS), and state health departments undertook a comprehensive investigation to trace the bacterial strain, with the goal of limiting future illnesses.[7] They traced the strain to dogs being sold in pet stores, specifically Petland pet stores,[8] and learned that throughout the commercial breeding and retail industry, antibiotics are given even to healthy dogs, to slow the spread of disease in the overcrowded, unsanitary environments in which the dogs live.[9] Dr. Robert Tauxe, Director of the Division of Foodborne, Waterborne and Environmental Diseases at CDC's National Center for Emerging and Zoonotic Infectious Diseases, wrote at the conclusion of the first investigation: "The puppy story is not over – it is difficult to control with a whole system that lacks hygiene at many points and seems to use antibiotics instead."[10] This overuse explains why the outbreak strain was exceedingly resistant to antibiotics: "Prophylaxis appears to be nearly universal with a variety of agents against agents of diarrhea and pneumonia….There seems to be no concept of stewardship."[11]

The rule requested in this petition is necessary because the public is unaware of the risk of

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[5] Email dated Nov. 1, 2017 from Dr. Robert V. Tauxe, M.D., M.P.H., Director, Division of Foodborne, Waterborne and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, CDC, to colleagues, attached as Ex. 4.

[6] Centers for Disease Control and Prevention, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES: 2019 at 4 (Dec. 2019), https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar- threats-report-508.pdf.

[7] *Supra* note 2, Ex. 2.

[8] *Id.*

[9] Email dated Jan. 19, 2018, from Dr. Robert V. Tauxe, CDC, to J.A. Wagenaar, attached as Ex. 5.

[10] *Id.*

[11] Email dated Feb. 7, 2018, from Dr. Robert V. Tauxe, CDC, to colleagues in Australia, attached as Ex. 6.

contracting this serious infection (made more serious by its resistance to the antibiotics commonly used to treat it[12]) simply from contact with puppies in pet stores.[13] The transmission of infectious disease from nonhuman animals to humans is of great concern now, due to Covid-19, and the pandemic has starkly illustrated the important role of an informed public in combatting infectious disease. While campylobacteriosis is less dangerous than Covid-19, we believe this public health risk, which is closely connected to consumer behavior, deserves the Commission's attention.

Additionally, people who contracted campylobacteriosis and had to be hospitalized during the pandemic have had to cope with the added fear, and risk to their health, of contracting Covid-19 because they were in a hospital setting.[14] HSUS was recently contacted by a consumer whose daughter was infected with campylobacteriosis from their new Petland puppy and who had to be hospitalized for a week during the pandemic. Katrina Metzler of Arlington, Virginia contacted HSUS after her 18-year-old daughter contracted *Campylobacter* from a puppy purchased at the Petland in Athens, Ohio, while visiting family there. The young woman was sick for a month, hospitalized for a week, and required two blood transfusions in April 2020, during the first spike of community spread of the novel coronavirus. Ms. Metzler was permitted to visit her daughter daily at the hospital despite a stay-at-home order in Washington, D.C. at that time, though fear of contracting the potentially lethal virus was a concern for the entire family, especially her daughter who was weakened by the campylobacteriosis and severe anemia. The hospital was inundated with positive Covid-19 cases, and staff were stretched thin while the pandemic reached new heights in the area.

While other federal agencies work to limit the spread of disease, it is uniquely within the mission of the CPSC to warn consumers about risks posed by products in the marketplace, so they can make informed choices. CDC continues to investigate the second, ongoing Campylobacter outbreak from

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[12] *Supra* note 2, Ex. 2.

[13] *Id*.

[14] *See*, *e.g.*, Doctors worry the coronavirus is keeping patients away from US hospitals as ER visits drop: 'Heart attacks don't stop', CNBC, Apr. 14, 2020, https://www.cnbc.com/2020/04/14/doctors-worry-the-coronavirus-is-keeping-patients-away-from-us-hospitals-as-er-visits-drop-heart-attacks-dont-stop.html (discussing trend across the country of people avoiding hospitals even when they need care, out of fear they will get Covid-19), attached as Ex.7.

pet store dogs[15] and Campylobacter is still being transmitted to people through pet store puppies.[16] But CDC has also asserted its position that it lacks regulatory authority to regulate pet stores or their practices.[17]

Dogs are undeniably sentient creatures capable of feeling pain, physically and psychologically. When they are commercially bred and sold at retail, however, they meet the CPSA's definition of "consumer products." Accordingly, they are subject to the Commission's jurisdiction, as discussed in section III. Dogs bred in puppy mills and sold at retail are products under the CPSA because they are manufactured as if they were inanimate objects: widgets, rather than living, social animals with emotional lives, the ability to suffer and feel pain, and natural instincts and needs. At commercial breeding facilities puppies and breeding dogs typically live in cramped, unsanitary conditions and receive inadequate veterinary care, which directly cause the diseases they contract so frequently.[18]

In support of this Petition and as recommended by the Commission, Petitioners have included herein relevant factual background on the practices of the commercial dog breeding industry that encourage the spread of disease and drug-resistant bacterial strains, and CDC's traceback of the *Campylobacter* strain to puppies in pet stores, predominantly Petland stores.[19] *See* section IV.

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[15] *Supra* note 2, Ex. 1.

[16] *See, e.g.,* letter dated April 14, 2020, from Dr. Robert V. Tauxe, CDC, to J.P. Goodwin, HSUS, ("Recent investigations led by CDC and state health departments indicate that Campylobacter is still being transmitted to people through pet store puppies"), attached as Ex. 8.

[17] *Id*. While HSUS does not agree with this position and thinks CDC may have more authority than it has stated, we recognize that it has taken this position.

[18] *Supra* note 9, Ex. 5 (commercial breeding industry is "a whole system that lacks hygiene at many points and seems to use antibiotics instead" to fight off infections); Humane Society Veterinary Medical Association, VETERINARY REPORT ON PUPPY MILLS 6 (2013), http://www.hsvma.org/assets/pdfs/hsvma_veterinary_report_puppy_mills.pdf (puppy mill dogs suffer from many diseases, parasites and illnesses in addition to *Campylobacter*, including parvovirus, canine brucellosis, canine distemper virus, Bordetella bronchiseptica (kennel cough), pneumonia and other respiratory infections, as well as Giardia and Coccidia), attached as Ex. 9.

[19] 16 C.F.R. § 1051.5(b) ("The Commission encourages the submission of as much information as possible related to the petition. Thus, to assist the Commission in its evaluation of a petition, to the extent the information is known and available to the petitioner, the petitioner is encouraged to supply the following information or any other information relating to the petition.").

II. INTEREST OF THE PETITIONERS

Petitioner the HSUS, headquartered in Washington, D.C., is the largest animal protection organization in the United States, with millions of members and supporters worldwide. Since its founding in 1954, HSUS has worked to combat animal abuse and exploitation and to promote animal welfare. As one of its core campaigns, HSUS actively strives to improve the lives and end the suffering of the millions of adult dogs and puppies confined in inhumane, substandard commercial breeding factories commonly referred to as puppy mills.[20] Pet stores are a major outlet for puppy mill puppies, largely because they provide a readily available supply of "desirable" breeds, and as consumers in pet stores do not see the deplorable conditions the puppies are born and raised in, pet stores are able to mislead consumers about the puppies' origins and sell the puppies at tremendous mark-ups.[21]

Petitioner HSLF, also based in Washington, D.C., is the separate lobbying affiliate of HSUS that works to pass animal protection laws at the state and federal levels, to educate the public about animal protection issues, and to support humane candidates for office. HSLF works to end the suffering of puppies and adult dogs in puppy mills by working directly with federal regulators and lawmakers to improve the standards of care, hold bad actors accountable, and protect consumers who fall victim to the deceptive practices commonly used in the industry.

Petitioners engage in education and advocacy to expose the cruelty involved in commercial breeding operations and to encourage consumers not to purchase puppies born in such facilities. Over the past two years HSUS conducted eight undercover investigations at Petland stores; Petland is the only national pet store chain still selling puppies. These investigations revealed widespread neglect and abuse of dogs, including the denial of veterinary care, the failure to test even

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[20] Humane Society of the United States, PUPPY MILLS: FACTS AND FIGURES (Jan. 2021), https://www.humanesociety.org/sites/default/files/docs/Puppy%20Mill%20Facts%20and%20Figu res%20January%202020.pdf, attached as Ex. 10.

[21] *See*, *e.g.*, Humane Society of the United States, PETLAND CORPORATE STORE FOUND COVERING UP DISEASE OUTBREAKS – AN UNDERCOVER INVESTIGATION BY THE HUMANE SOCIETY OF THE UNITED STATES 6 (Nov. 2019), https://www.humanesociety.org/sites/default/files/docs/FlorenceKY%20Petland%20Investigation%20Report.pdf, attached as Ex.11.

symptomatic puppies for contagious diseases such as *Campylobacter*,[22] as well as rampant deceptive conduct toward consumers regarding the health of the puppies, and the sale of sick animals.[23]

III. THE COMMISSION HAS JURISDICTION OVER COMMERCIALLY BRED DOGS AS CONSUMER PRODUCTS.

The Commission has the power to regulate the interstate sale of commercially bred dogs because such dogs fit within the Act's definition of "consumer product": "any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise."[24] Commercially bred dogs are "produced" and "distributed" "for sale" to "consumers" for the "enjoyment" in their "household."

A 1974 Commission opinion concluded that pet turtles are consumer products and subject to regulation by the Commission.[25] Pet turtles, the opinion noted, fit within the definition of consumer product: "Such turtles are more frequently raised in ponds on turtle farms rather than caught in the wild or they are imported. Thus, they are customarily produced or distributed for sale, or for personal use or enjoyment."[26] The same is true for puppies bred in commercial breeding facilities.

The opinion further noted that Congress did not include pet animals in the list of specific articles that may not be called consumer products, such as tobacco and pesticides.[27] The Commission

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[22] Humane Society of the United States, UNDERCOVER INVESTIGATION OF PETLAND IN FRISCO, TEXAS, FINDS UNDERWEIGHT AND SICK PUPPIES; SICK RABBIT LEFT TO DIE, https://www.humanesociety.org/sites/default/files/docs/Petland%20Frisco%20Report%20Final%209.10.19.pdf (last visited Feb. 9, 2021), attached as Ex. 12.

[23] *Id*.

[24] 15 U.S.C. § 2052.

[25] Opinion of the Commission dated January 29, 1974 (number 78), attached as Ex. 13.

[26] *Id.*

[27] 15 U.S.C. § 2052. *See Madar v. United States Citizenship & Immigration Servs.*, 918 F.3d 120, 123 (3d Cir. 2019) ("Under the interpretive canon *expressio unius est exclusio alterius*, we presume that "[t]he expression of one thing implies the exclusion of others." The 1952 Act, as amended,

opinion further concluded that the Commission also has jurisdiction over pet turtles, who can transmit salmonellosis,[28] based on section 2(b) of the Act, which states that "one of the Act's purposes is to promote research and investigation into the causes and prevention of product-related illnesses … as well as product-related deaths and injuries."[29] This rationale applies equally here, given that the *Campylobacter*-infected pet store puppies are diseased, and Petitioners are asking the agency to issue regulations to combat the spread of this disease from puppies, as the "product," to the consumer.

A subsequent Commission opinion issued in 1990 re-examined the 1974 opinion, and appeared to conclude that a wolf hybrid dog, as a living animal, was not a product and thus lay outside Commission jurisdiction.[30] The opinion also made clear, however, that animals that were subjected to processing, or manufactured, might be consumer products under the Act.[31] Commercially bred dogs are indeed processed and manufactured through an essentially factory-like process, as more fully described below, and are treated as products in commerce, and thus come within the Commission's jurisdiction based on the reasoning in this opinion.

Relatedly, several courts have found that, especially when people are injured by diseased pets that are sold to consumers, the pets are products for purposes of plaintiffs' products liability claims because it is more fair for a breeder, distributor, or retailer, and not a consumer, to be responsible for the consequences arising from the commercial enterprise. In *Beyer v. Aquarium Supply Co.*, the plaintiff became ill after contact with a diseased hamster. A New York court stated:

> The purpose for imposing this doctrine in the products liability field is to distribute fairly equitably the inevitable consequences of commercial enterprise and to promote the marketing of safe products. Accordingly, there is no reason why a breeder, distributor or vendor who places a diseased animal in the stream of commerce should be less accountable for his actions than one who markets a

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identifies just two exceptions to the physical presence requirement…"[T]he existence of these two articulated exceptions to the physical presence requirements undermines [the] argument that this Court should add a third…." *Tullius v. Albright*, 240 F.3d 1317, 1321 (11th Cir. 2001).").

[28] *Supra* note 25, Ex. 13.

[29] *Id.*

[30] Opinion of the Commission dated April 16, 1990 (number 311), attached as Ex. 14.

[31] *Id.*

> defective manufactured product. The risk presented to human wellbeing by a diseased animal is as great and probably greater than that created by a defective manufactured product and in many instances, for the average consumer, a disease in an animal can be as difficult to detect as a defect in a manufactured product.[32]

A Connecticut court cited the *Beyer* court's reasoning when it ruled that a puppy purchased at a pet store, which was diseased and carrying a parasite when it was sold, was a product.[33] The plaintiff's child suffered serious eye damage and loss of sight in one eye from exposure to the diseased puppy.[34] The court also noted that the state legislature clearly addresses pets as products in the state's "Pet Lemon Law," and that the Uniform Commercial Code recognizes animals as "goods."[35] Dogs also generally are considered property as a legal matter.[36]

In *Sease v. Taylor's Pets*, which involved a pet skunk that turned out to be rabid, the court rejected the defendant pet store's argument that the skunk was not a product and pointed out that the Restatement (Second) of Torts makes expressly clear that a product need not be manufactured or processed to be considered a "product" that allows liability to attach.[37] The court found that the protection offered by the products liability statute to consumers injured by defective products was appropriate for pets, where diseased conditions might not be apparent to consumers.[38]

While these rulings are not binding on the Commission, their reasoning is persuasive here when considering commercially bred dogs as consumer products, and why fairness principles dictate they should be treated as such, given the proven risk they pose to consumers. Commercial breeders are

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[32] *Beyer v. Aquarium Supply Co*., 94 Misc. 2d 336, 337, 404 N.Y.S.2d 778, 779 (N.Y. Sup. Ct. 1977).
[33] *Worrell v. Sachs*, 41 Conn. Supp. 179, 180, 563 A.2d 1387, 1387 (Conn. Super. Ct. 1989).
[34] *Id*.
[35] *Id*.
[36] *See, e.g., Bennett v. Bennett*, 655 So. 2d 109, 110 (Fla. Dist. Ct. App. 1995) ("While a dog may be considered by many to be a member of the family, under Florida law, animals are considered to be personal property"); *Barking Hound Vill., LLC v. Monyak*, 299 Ga. 144, 147, 787 S.E.2d 191, 194 (2016) ("Georgia law clearly provides, that a pet dog has value and is considered the personal property of its owner"); *Covatch v. Cent. Ohio Sheltie Rescue, Inc*., 2016-Ohio-1241, ¶ 18, 61 N.E.3d 859, 863 ("Ohio law considers a dog to be personal property").
[37] *Sease v. Taylor's Pets, Inc*., 74 Or. App. 110, 116, 700 P.2d 1054, 1058 (1985).
[38] *Id*.

making the usual tradeoffs between profit and spending that every manufacturer makes. To decrease overhead and increase profits breeders generally spend very little money on care for the dogs or even providing a safe, hygienic environment.[39] The commercial production and retail sale of dogs is big business. An estimated 10,000 commercial dog breeding facilities operate in the United States.[40] These facilities churn out approximately 2.4 million puppies sold annually.[41] Breeders could choose to keep dogs in larger cages that provide significantly more space per puppy, or provide regular and thorough veterinary care and exercise, all of which would likely reduce the occurrence and spread of infectious diseases. Instead, large-scale commercial breeders overuse antibiotics to try to slow the spread of diseases that flourish in the cramped, unsanitary, and unnatural conditions that they chose to create. Commercial breeders thus externalize their costs, and the public is paying the true cost through exposure to increasingly antibiotic-resistant bacteria. CDC categorizes drug-resistant *Campylobacter* as a "serious threat" to public health that requires "prompt and sustained action."[42] The people sickened by infected puppies pay an additional price personally when their treatment options are narrowed because the bacteria they are infected with is susceptible to so few antibiotics.[43]

Commercially bred dogs also should be considered products under the CPSA because the statute is a "[r]emedial safety" law that "should be broadly construed to effectuate its purpose."[44] Because dogs produced in commercial breeding facilities and marketed in pet stores and online are consumer products, the Commission can and should regulate their sale with respect to consumer safety.

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[39] *See, e.g.*, email dated Aug. 23, 2017, from Susan Lance, CDC, to Dr. Robert V. Tauxe, CDC ("There are a couple shelter medicine programs at vet schools (UC Davis and Florida) that are developing infectious disease guidelines that could be adapted to puppy mill situations but in my experience, the mass producers of puppies expect some 'loss' but they make so much money they're willing to live with it, and since there is generally no emotional attachment to the animal, the money is all that counts. http://www.thepuppymillproject.org/relevant-laws/"), attached as Ex. 15.

[40] *Supra* note 20, Ex. 10.

[41] *Id.*

[42] Centers for Disease Control and Prevention, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2019 at 4 (Dec. 2019), https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.

[43] *Id.*

[44] *U.S. v. One Hazardous Prod. Consisting of a Refuse Bin*, 487 F. Supp. 581, 588 (D.N.J. 1980).

IV. FACTUAL BACKGROUND: THE PRACTICES OF THE COMMERCIAL DOG BREEDING INDUSTRY THAT CONTRIBUTED TO CREATING THE ANTIBIOTIC- RESISTANT STRAIN OF CAMPYLOBACTER TRACED TO PETLAND STORES

A. The Commercial Dog Breeding Industry

As noted above, the puppies produced by the commercial dog breeding industry for sale in pet stores and online are treated like products from start to finish, with little regard to their needs as sentient creatures. The puppies suffer in the unsanitary facilities where they are born (and where they are separated from their mother when only weeks old), during transport (by truck, often for days without meaningful rest or exercise), and at pet stores where they are often denied basic veterinary care.[45]

The regulations implementing the Animal Welfare Act (AWA) – the federal law that provides for licensing and oversight by the United States Department of Agriculture of commercial breeding facilities – establish minimal, essentially survival-level standards for the care of dogs in commercial facilities. For example, under the AWA regulations breeding dogs and puppies may legally be confined in small wire-bottom cages with no solid resting space, which are stacked in rows one above the other, a practice that allows the feces and urine of the dogs in one row to fall onto the dogs in the cages in the row below them.[46] The use of wire flooring in the dogs' cages is highly detrimental to the dogs' physical and emotional health. The dogs' paws often slip through the wire flooring, sometimes trapping the dog, and puppies rarely get to feel a solid surface beneath their paws.[47] The regulations authorize cages that are far too small; essentially, a dog may be kept in a small square wire box with sides a mere six inches longer than her body length, and a height only

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[45] *Supra* note 22, Ex. 12.

[46] Humane Society of the United States, FACTS ABOUT CAGE STACKING (2010), https://www.humanesociety.org/sites/default/files/docs/cage-stacking-factsheet.pdf, attached as Ex. 16. Some states have passed laws prohibiting wire-bottomed cages and cage stacking, given the inherent cruelty, but the overcrowding and mass production of dogs still leads to inhumane conditions for the dogs. *See* Mo. Code Regs. Tit. 2 § 30-9.030 (wire strand flooring prohibited); 3 Pa. Stat. Ann. § 459-207 (i)(3)(i) (cage stacking and metal strand flooring prohibited). Moreover, due to the infrequency of inspections it is likely that many breeders and distributors continue to use wire-bottomed cages and stack them. *See* Missouri Department of Agriculture Report of Inspection on 1/31/18 for Pleasant Valley Puppies (ten puppies kept on elevated wire strand flooring, although such flooring had been prohibited as of January 1, 2016), attached as Ex. 17.

[47] *Supra* note 46, Ex. 16.

six inches higher than her body height.[48] Further, the regulations do not require that dogs in commercial breeding facilities be let outside of their cages for exercise for any specific period of time or at regular intervals.[49] These inhumane conditions are legal under the AWA regulations and common practice throughout the industry.

Although the standards are minimal, violations of the federal or similar state regulations occur frequently. Dogs in commercial breeding facilities are often denied even essential veterinary care.[50] Basic grooming needs are neglected to the point where the fur can become matted and cause painful skin irritations and sometimes make it difficult for the dogs to defecate.[51] Often dogs are kept outside in inclement weather without adequate shelter, in or near mud and standing water, which subjects them to disease hazards and risks of physical injury.[52] Food and water bowls are

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[48] 9 C.F.R. § 3.6(c)(1)(i), (iii). This space is barely sufficient for most dogs to be able to comfortably turn around and lie down in a clean spot, or move around if they so desire.

[49] *See* Humane Society of the United States, PUPPY MILLS AND THE ANIMAL WELFARE ACT (2018), https://www.humanesociety.org/sites/default/files/docs/puppy-mills-awa-booklet-lores.pdf, attached as Ex. 18.

[50] *See e.g.*, USDA Inspection Report dated June 3, 2019 for Stevie Hoover in Dundee, New York (inspector found dead puppy that had gone unnoticed by the licensee), attached as Ex. 19; Nebraska Department of Agriculture Inspection Report dated May 23, 2018 for Rocking T Kennel (noting two female dogs with open wounds and fresh blood on them), attached as Ex. 20; Missouri Department of Agriculture Inspection Report dated Dec. 27, 2018 for Debra Ritter (poodle with missing fur, squinting her right eye, who had "yellow mucoid ocular discharge"), attached as Ex. 21; USDA Inspection Report dated June 4, 2019 for John David Shirk in Penn Yan, New York ("The licensee was tube feeding the puppy for an extended period of time but stopped several days ago. The puppy appears to be declining and its condition should be communicated to the attending veterinarian in a timely manner."), attached as Ex. 22.

[51] *See* USDA Inspection Report dated October 15, 2018 for Stevie Hoover in Dundee, New York (dog heavily matted over 90% of his body, with "heavy matted fur in the anal region … trapping fecal matter making it difficult for the dog to continue to defecate"), attached as Ex. 23.

[52] *See* Commonwealth of Pennsylvania Kennel Inspection report dated December 3, 2018 for Stone Lion Kennel at 3 ("[D]ogs housed in areas of the kennel grounds that had puddles of standing water and was, otherwise, a mud pit. The dogs viewed were covered in mud, muck and [exposed to] potential disease hazard"), attached as Ex. 24.

infrequently cleaned[53] and dogs often are forced to sit in their own waste.[54]

Dogs in commercial breeding facilities are also subject to cruel breeding practices. To maximize profits, female breeding dogs in puppy mills are routinely kept in small cages[55] for their entire lives and bred at every opportunity, without sufficient (or any) recovery time between litters.[56] Once a breeding dog is no longer "productive," she may be auctioned off to another breeder or killed, often through inhumane methods.[57] Thus, breeding dogs in puppy mills are essentially treated as machines to make puppies.

Irresponsible breeding practices, such as failing to screen parent dogs for ailments or hereditary conditions common to their breed, also contribute to commercially bred puppies having debilitating and life threatening conditions, including epilepsy, heart disease, kidney disease, musculoskeletal disorders, endocrine disorders, blood disorders, deafness, eye problems, and respiratory disorders.[58] And, due to the unsanitary and overcrowded conditions, many transmissible diseases and infections in addition to *Campylobacter* are prevalent in puppy mill puppies, including giardia, parvovirus,

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[53] *See* USDA Inspection Report dated April 6, 2019 for Cory Mincey, Puppy Love Kennel (water was "opaque and mud-like"; another receptacle had a small amount of water with worms in it; dogs using this water were thin and had loose stools) attached as Ex. 25; USDA Inspection Report dated July 12, 2018 for Riverside, Iowa kennel (name withheld by USDA, believed to be Loren Yoder) ("there was a thick build-up of dark black to dark brown dirt, grime, hair, etc. on the rim of many of the water buckets. Plastic puppy water receptacles had a layer of grime in the bowl and a layer of orange-ish brown film visible on the inside of the tank."), attached as Ex. 26.

[54] *See* Missouri Department of Agriculture Inspection Report for inspection on Feb. 7, 2019 for Patchwork Kennel ("The pens still exhibited an excessive accumulation of feces, urine, and hair on the floor, and some dogs could not avoid contact with their own waste."), attached as Ex. 27.

[55] *Supra* note 49, Ex.18.

[56] *E.g.*, *Colorado Animal Rescue Saves Discarded Dogs, Finds Homes for Them*, Fox 31 Denver (Nov. 21, 2012), https://kdvr.com/news/colorado-animal-rescue-saves-discarded-dogs-from-horrible-lives-or-worse/ (organization rescued over 7,000 dogs from puppy mills in five years, with many adult dogs discarded because they "may not be able to produce puppies any longer, they may be old or sick, or the breeder might be going out of business," and puppies discarded because "they are too old to sell to pet stores"), attached as Ex. 28; *see also* Alex Mayyasi, *How We Treat Pets in America*, Priceonomics Blog (Feb. 28, 2013), https://priceonomics.com/post/44230885813/how-we-treat-pets-in-america ("Oftentimes, after the breeder dog has reached the age of 4 years, it is no longer needed and killed."), attached as Ex. 29.

[57] *Supra* note 56, Ex. 28.

[58] *Supra* note 18, Ex. 9.

distemper, upper respiratory infections, kennel cough, pneumonia, heartworm, mange, intestinal parasites, and chronic diarrhea.[59] Dogs and puppies in these environments often also suffer from treatable or altogether preventable conditions such as dental problems.[60]

After middlemen distributors (also known as brokers) purchase puppies from a breeder, the dogs generally endure cramped, unsanitary conditions while they are being trucked, often for days, to other distributors or to pet stores.[61] And because distributors pack many dogs from multiple breeders into the delivery trucks, it is easy for disease to spread among the dogs.[62] During transport puppies often go for days without waste being removed from their cages and without sufficient water or food.[63]

Given the conditions and neglect these dogs endure from birth, it is not surprising that many puppies are sick by the time they arrive at pet stores. HSUS routinely receives complaints from consumers who were assured the dog in the pet store had a clean bill of health, only to be faced with high veterinary bills and the heartache that comes from caring for a sick or dying dog. A veterinarian who worked with the Petland in Kennesaw, Georgia for almost ten years wrote in an affidavit: "There was no way for me to save all the animals from death and prolonged illness because they

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[59] *Supra* note 18, Ex. 9.

[60] *Supra* note 18, Ex. 9.

[61] *See, e.g.*, "Dozens of puppies heading to local Petland found in filthy conditions", https://www.winknews.com/2018/02/23/dozens-puppies-heading-local-petland-found-filthy-conditions/, attached as Exhibit 30. In February 2018 a truck full of dogs driven by Puppy Travelers, a Missouri-based transport company, was intercepted at the back of a Petland store in Lee County, Florida, and the dogs seized by animal control officers. According to news reports, puppies were kept in crowded cages full of feces and urine without any water. The company admitted to investigators that feces are not cleaned out of the cages until after return to Missouri.

[62] *See also*, Tauxe email, *supra* note 5, Ex. 4 ("It seems there are entire companies dedicated to collecting and transporting the dogs from the dog breeders, to the stores. They use specialized transport trucks, with racks of plastic cages, and gather the puppies in waypoints to spend the night in communal spaces….It does seem to be standard practice to treat/pretreat the puppies with a number of antibiotics to prevent the spread of various pathogens. It seems to be likely that each puppy has received more than one antibiotic by the time they reach the store.")

[63] *Supra* note 61, Ex. 30.

were already incredibly sick when they arrived at the store."[64]

Once in pet stores, dogs are often deprived of adequate veterinary care, and some die in the store. During an HSUS undercover investigation at the Petland in Kennesaw, Georgia, a store employee told the investigator that she sometimes came into work and found that a puppy had passed away, and that this had happened about three times in the four months she had been working there.[65] After hearing about other puppies who had died in the store, the investigator became suspicious about a black plastic bag she had seen in the freezer, and looked in it one day to find a dead puppy inside.[66]

Rather than provide dogs with adequate veterinary care, pet stores often instruct employees with no veterinary training to "treat" and medicate the dogs. HSUS undercover investigators observed puppies routinely being given antibiotics without first receiving a specific diagnosis or being seen by a veterinarian, and sometimes to temporarily mask symptoms of illness, such as a cough or diarrhea, so the puppies can be placed on the sales floor and sold as healthy.[67] For instance, HSUS's undercover investigation of a Petland store in Frisco, Texas showed that kennel staff with no veterinary training were routinely force-feeding sick puppies and administering medications at the direction of management, instead of having the dogs seen by a licensed veterinarian.[68] At the Novi, Michigan Petland, HSUS undercover investigators also observed sick animals being given medications at the discretion of store employees, without any veterinary care or clinical diagnoses.[69] A store employee was captured on camera discussing how the puppies are routinely given

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[64] Humane Society of the United States, PETLAND, INC.: SICK PUPPIES, HEARTBROKEN FAMILIES 3–4 (Dec. 2018), https://blog.humanesociety.org/wp-content/uploads/2018/12/HSUS-Petland-Report-2018-FINAL-IN-NEW-TEMPLATE.pdf, attached as Ex. 31.

[65] *Id.* at 1-2.

[66] *Id.* at 2.

[67] *See* Humane Society of the United States, EXPANDED UNDERCOVER INVESTIGATION REVEALS MORE SICK AND DEAD PUPPIES AT PETLAND STORES 4 (May 2019), https://www.humanesociety.org/sites/default/files/docs/PetlandReport_FINAL-May2019.pdf, attached as Ex. 32.

[68] *Supra* note 22, Ex. 12.

[69] *Supra* note 67, Ex. 32.

antibiotics as a preventative measure.[70]

During another HSUS investigation at a Petland store in Florence, Kentucky, an undercover buyer asked the store manager about the obvious diarrhea a puppy was having in the store.[71] The manager stated to the puppy buyer: "this puppy has had diarrhea [but] that's not Campylobacter," and added that the buyer would have ".002% chance of getting campylobacter from a puppy from here."[72] The manager also claimed the puppy had had a fecal test with normal results, but did not provide any documentation of the test, and after purchase an independent veterinarian diagnosed the puppy with *Campylobacter*.[73] The store manager later told the undercover investigator that the store does not test most of the sick puppies for *Campylobacter* because most of them would test positive.[74]

In sum, the commercial dog breeding industry engages in practices that facilitate the spread of antibiotic-resistant infections to consumers. While pet stores, breeders and transporters could and must reform their practices to avoid creating this situation in the first place. The CPSC is uniquely positioned and authorized to protect consumers in the meantime, however. The CPSC can and should require that warnings be provided to consumers so that they may be adequately informed of the risks associated with interacting with or purchasing a commercially bred puppy. Given the continued prevalence of this bacteria in pet store puppies and the potential harm to puppy purchasers (despite multiple investigations by governmental agencies and non-governmental organizations like HSUS), we urge the CPSC to do so. Indeed, requiring pet sellers to inform the public about these risks will likely have the effect not only of warning consumers of the risks, but also of encouraging sellers, breeders and transporters to clean up their act to reduce those risks.

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[70] Mary Beth Sweetland, *Petland Antibiotics*, Vimeo (Mar. 25, 2020, 2:35 PM), https://vimeo.com/400695494 (video and audio recording taken at Petland in Novi, Michigan on March 26, 2019).

[71] *Supra* note 21, Ex. 11.

[72] *Id.* at 1-2.

[73] *Id.* at 2.

[74] *Id.*

B. Campylobacter Outbreaks and CDC's Traceback to Petland Puppies

Campylobacter infection, or campylobacteriosis, is caused by the presence of *Campylobacter* bacteria.[75] People with *Campylobacter* infection usually have diarrhea (often severe), fever, and stomach cramps.[76] Nausea and vomiting may accompany the diarrhea.[77] Some people experience complications, such as temporary paralysis and arthritis.[78] In people with compromised immune systems, such as those with a blood disorder or who are receiving chemotherapy, *Campylobacter* may spread to the bloodstream and cause a life-threatening infection.[79] *Campylobacter* infection can result in long-term consequences, such as arthritis, IBS, and GBS, an autoimmune disorder causing nerve damage, muscle weakness, and sometimes permanent paralysis.[80] Estimates indicate that as many as 40% of GBS cases in the United States might be triggered by *Campylobacter* infection.[81]

CDC became aware of the first *Campylobacter* outbreak in August 2017, when the Florida Department of Health notified CDC of six *Campylobacter jejuni* infections linked to Petland.[82] CDC examined whole-genome sequencing data and identified six isolates from Petland puppies in Florida that were highly related to an isolate from a Petland customer in Ohio.[83] This information prompted a multistate investigation by local and state health and agriculture departments and CDC

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[75] Centers for Disease Control and Prevention, *Campylobacter (Campylobacteriosis) Questions and Answers* (Dec. 23, 2019) https://www.cdc.gov/campylobacter/faq.html, attached as Ex. 33.
[76] *Id.*
[77] *Id.*
[78] *Id.*
[79] *Id.*
[80] *Id.*
[81] *Supra* 3, Ex. 3.
[82] Martha P. Montgomery, MD, et al., *Multidrug-Resistant Campylobacter jejuni Outbreak Linked to Puppy Exposure – United States, 2016-2018*, 67 Morbidity and Mortality Weekly Report 1032, 1032 https://www.cdc.gov/mmwr/volumes/67/wr/mm6737a3.htm (dated September 21, 2018, last reviewed September 23, 2019), attached as Ex. 34. This article does not name Petland, but only refers to a "national pet store chain based in Ohio." Subsequent CDC reports and correspondence cited throughout the Petition state that the chain is Petland, which is based in Ohio.
[83] *Id.*

to identify the outbreak source and prevent additional illness.[84] Health officials from six states visited pet stores and collected puppy fecal samples, antibiotic records, and traceback information.[85]

CDC discovered that the pet store strain of bacteria was "exceedingly resistant" to antibiotics, which puzzled CDC officials, until they learned about the large commercial dog breeding industry and how it operates. As Dr. Tauxe of CDC explained:

> The outbreak strain of Campylobacter jejuni is exceedingly resistant-both by genetic resistance prediction and by traditional MIC testing. Resistant to azithro-, erythro-, and telithromycin, ciprofloxacin, tetracycline, clindamycin and nalidixic acid. Some also R tongentamicin and florfenicol. We think this leaves only carbapenems as possible treatment (not approved for that purpose). How did they get this resistant, we wonder? This particular chain of stores is particularly focused on dogs, and gets them from many breeders through a complex distribution network. It seems there are entire companies dedicated to collecting and transporting the dogs from the dog breeders, to the stores. They use specialized transport trucks….The scale of this business was surprising to us….It does seem to be standard practice to treat/pretreat the puppies with a number of antibiotics to prevent the spread of various pathogens. It seems to be likely that each puppy has received more than one antibiotic by the time they reach the store.[86]

CDC investigators thus learned that the entire commercial breeding distribution chain uses antibiotics prophylactically, to slow the spread of disease and illnesses among the dozens or hundreds of dogs living in these inhumane commercial breeding facilities: "Multiple dog breeds, multiple dog transport companies and multiple original breeders. Entire distribution chain seems to use antibiotics of a variety of types prophylactically, little stewardship recognized."[87] "We are collecting data on antibiotic exposure. Prophylaxis appears to be nearly universal with a variety of agents against agents of diarrhea and pneumonia. This is during transport and distribution, and at stores. We don't know what happens at the breeders. There seems to be no concept of stewardship."[88]

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[84] *Id.*
[85] *Id.*
[86] *Supra* note 5, Ex. 4.
[87] Email dated Dec. 13, 2017 from Dr. Robert V. Tauxe, CDC, to CDC colleagues, attached as Ex. 35.
[88] *Supra* note 11, Ex. 6.

After this discovery, CDC reached out to Petland and recommended measures to reduce risk, such as testing dogs and ceasing the injudicious use of antibiotics.[89] CDC also met with Petland officials about their findings and reducing risk.[90] During these meetings with CDC, Petland agreed to stop selling symptomatic dogs and all dogs with diarrhea.[91] The fact that Petland agreed to *stop selling sick dogs* as a concession shows how reluctant Petland is to change its ways, and underscores the need for the proposed rule. However, even in the face of these outbreaks that were traced back to their puppies, and personal injury lawsuits brought by people who contracted Campylobacter from Petland puppies, Petland has not even met its commitment to not sell dogs with diarrhea. In other words, the one "concession" Petland made to not sell sick dogs – which should already be a given and which reveals that Petland routinely, and knowingly, *does* sell sick dogs – has not even been met. As just one example, during a 2019 HSUS investigation at Petland in Florence, Kentucky, an undercover buyer purchased a dog with obvious diarrhea.[92] After the purchase an independent veterinarian tested the dog and confirmed the dog had *Campylobacter*.[93] The investigator working at the store also contracted *Campylobacter*, as did another investigator working at Petland's Frisco, Texas store.[94]

By the time CDC concluded its investigation into the first outbreak, it had identified 118 people in 18 states who had been infected, nearly all of whom had been in contact with pet store puppies.[95] This included 29 employees of pet stores where puppies were sold.[96] At least 26 of those infected were hospitalized.[97] CDC's *Morbidity and Mortality Weekly Report (MMWR)* reported that

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[89] Memorandum dated Oct. 18, 2017, from Ian Williams, CDC, to Elizabeth Kunzelman, Director of Public Affairs, Petland, Inc., attached as Ex. 36.

[90] *See* CDC notes entitled "Campylobacter Outbreak associated with puppies from Petland – 10/11/17" at 2, attached as Ex. 37.

[91] *Id*.

[92] *Supra* note 21, Ex. 11.

[93] *Supra* note 21, Ex. 11 at 2.

[94] *Supra* note 21, Ex. 11 at 4.

[95] *Supra* note 82, Ex. 34.

[96] *Id.*

[97] *Id.* Several people were hospitalized, some more than once, and some people who were infected suffered for months. One man with an existing chronic disease became ill within a week of

"[o]utbreak strains were resistant to all antibiotics commonly used to treat *Campylobacter* infections."[98] Reviews of pet store records revealed that, among 149 investigated puppies, 142 (95%) received one or more courses of antibiotics.[99]

CDC's investigation of the 2019 outbreak is still ongoing, as the agency believes pet store dogs are still infecting people with *Campylobacter*.[100] As of December 17, 2019, CDC had identified 30 people infected in 13 states.[101] Of these, four people were hospitalized.[102] Twelve of these cases were linked to Petland, and include five Petland employees.[103] "Laboratory evidence indicates that bacteria from ill people in this outbreak are closely related genetically to bacteria from ill people in the 2016–2018 outbreak of multidrug-resistant *Campylobacter* infections linked to pet store puppies."[104] The 2019 outbreak strain of *Campylobacter* bacteria also appears resistant to all common antibiotics.[105]

While the CPSC is not an agency dedicated to fighting infectious disease, it *is* an agency dedicated to protecting consumers and informing them of risks associated with consumer products. There is clear scientific evidence that pet store puppies are transmitting *Campylobacter* to people. The Commission can and should take note of this evidence and exercise its authority to require warnings to protect unsuspecting consumers.

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purchasing a puppy at a pet store. He experienced diarrhea and excruciating lower back pain and was hospitalized with failing kidneys. Only one type of antibiotic was able to treat his resistant *Campylobacter* infection. Due to complications from this infection and his chronic disease, he needed surgery to remove a dead section of stomach. U.S. Department of Health and Human Services: Centers for Disease Control and Prevention, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2019, at 80 (Dec. 2019), https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.

[98] *Supra* note 82, Ex.34.

[99] *Supra* note 82, Ex. 34 at 1032.

[100] *Supra* note 2, Ex. 1.

[101] *Id.*

[102] *Id.*

[103] *Id.*

[104] *Id.*

[105] *Id.*

V. THE COMMISSION HAS THE AUTHORITY TO TAKE THE REQUESTED ACTION TO PROTECT CONSUMER SAFETY.

Under the CPSA the Commission can issue a safety standard such as the one proposed, if it finds (i) that the rule is reasonably necessary to eliminate or reduce an unreasonable risk of injury; (ii) that the promulgation of the rule is in the public interest; (iii) that the expected benefits from the rule bear a reasonable relationship to its costs; and (iv) that the rule imposes the least burdensome requirement to reduce the risk of injury.[106]

A determination of unreasonable risk involves balancing the likelihood and severity of injury with any harm that a regulation could impose on manufacturers and consumers.[107] Thus, under the unreasonable risk balancing test, even a very remote possibility that a product would inflict a severe injury could pose an "unreasonable risk of injury" and if the proposed safety standard is likely to reduce the risk, without unduly increasing the product's price, or decreasing the product's availability or its usefulness, the standard has been met.[108]

The proposed safety standard is reasonably necessary because the potential injury, becoming ill from the *Campylobacter* infection, is severe. In addition, the fact that a novel strain of bacteria, one that is exceedingly resistant to antibiotics, has been identified, means that extra precautions are appropriate to protect public health. Although there is little historical data about the relevant risk, which the Commission often considers when considering whether to require warnings for a product, this is only because this is an emerging new risk.[109] Meanwhile, CDC's view on this crisis, as recently stated in a letter to the HSUS, is that Campylobacter is still being transmitted to people through pet store puppies, and the risk to employees and customers exposed to puppies sold in pet stores is continuing.[110]

Despite significant evidence that irresponsible use of antibiotics is causing a multidrug-resistant

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[106] 15 U.S.C. § 2058(f)(3). *See also* 16 C.F.R. § 1051.9 (specifying the major factors the Commission considers in granting or denying rulemaking petitions).
[107] *See Southland Mower Co. v. Consumer Prod. Safety Comm'n*, 619 F. 2d 499, 508-09 (5th Cir. 1980).
[108] *Id.*
[109] 16 C.F.R. § 1051.5(b)(3).
[110] *Supra* note 16, Ex. 8.

strain of *Campylobacter* to sicken people and dogs, the commercial breeding and retail industry currently has no incentive to curb its use of antibiotics and appears totally disinclined to do so.[111] Therefore it is not surprising that CDC considers the risk of transmission from pet store puppies to be ongoing.[112] Given the ongoing risk to consumers from commercially bred puppies, it is imperative that the CPSC use its authority to warn the public about the possibility of becoming infected with a multidrug-resistant strain of *Campylobacter* from puppies at these stores as well as from puppies being sold directly to the public online. Exercising the agency's authority also might encourage the industry to reform its practices that provide such fertile breeding grounds for the infectious diseases.

The proposed rule to require consumer warnings is an inexpensive method for alerting consumers to the risk of this potentially severe infectious disease. The cost to the industry of providing warnings is extremely low if not *de minimis*. Commercial dog breeders could readily include a written warning in the file containing other paperwork to be conveyed with the purchase of the dog, such as health records, certificates of veterinary inspection, registration papers, or receipts. Breeders are already including paperwork with the puppies they sell, and that paperwork is transferred with a puppy at each point of transfer – e.g., from breeder to broker, to transport company, to store. And when breeders sell directly to the consumer, they include this paperwork with the sales. This would simply be one more piece of paperwork kept in that file.

As for pet stores selling puppies, they would be required to post signs warning of the risk of contracting *Campylobacter* from handling the dogs. Thus, there would be warnings in the puppies' paperwork file. Similarly, breeders selling directly to consumers via a website and other online sellers could readily place a warning on their website. This distribution and posting of warnings to reduce the risk of harm could not possibly be costly to the industry, especially when compared to other industry changes that have been mandated to reduce risk. For example, in *D.D. Bean & Sons Co. v. Consumer Product Safety Commission*, 574 F.2d 643, 649-50 (1st Cir. 1978), the court found that given the relatively small cost of less than one million dollars to the matchbook industry, a rule requiring a design change to include a closed cover was "reasonably necessary" to reduce the hazard

[111] *Supra* note 21, Ex. 11.

from accidental matchbook ignitions.

The proposed rule is also the least burdensome way to reduce the risk of *Campylobacter* transmission. Petitioners are not requesting that the Commission issue rules to change how the industry produces commercially bred dogs, or even to require that commercially bred dogs be tested for *Campylobacter* before sale.[113]

Currently there is no voluntary safety standard to reduce the risk of transmission for the Commission to consider. Under the Act, the Commission would be obliged to consider as part of the rulemaking process.[114] Indeed, the actors in the commercial breeding and pet retail industry—breeders, distributors, transporters and pet stores—are acting only in their own self-interest, with virtually no oversight regarding the risk of *Campylobacter* infection and the injudicious use of antibiotics. A [few months] into the investigation of the first outbreak, Dr. Tauxe wrote to a colleague, "Seems like we have stumbled on another Wild West."[115] Finally, the cost for implementing the rule requiring warnings is *de minimis*, and even more costly measures should be deemed acceptable given the evidence that pet stores are *deliberately hiding the risk* of *Campylobacter* infection from consumers.[116]

Another factor weighing in favor of the rulemaking is the likelihood that the risk of contracting *Campylobacter* from pet store dogs will only increase in the future, since there is no incentive for the commercial breeding and pet retail industry to scrap its highly profitable blueprint, where unhygienic and inhumane conditions and insufficient veterinary care can be covered up partly by

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[113] Boone County, Kentucky enacted an ordinance in November 2020 to require that pet store puppies be tested for parasites including *Campylobacter* prior to sale, and to require that pet stores post signs alerting consumers if there has been an outbreak at the store or if puppies test positive. The ordinance has not yet been codified, but attached as Ex. 38 is a draft believed to reflect the substance of the version enacted.

[114] 15 U.S.C. 2058(f)(3)(D).

[115] Email dated August 23, 2017 from Dr. Robert V. Tauxe, CDC, to Susan Lance, CDC, attached as Ex. 15.

[116] *Supra* note 21, Ex. 11. Although Petland leadership had been informed of known human *Campylobacter* cases linked to the Florence, Kentucky store, symptomatic puppies were not tested or treated, and undercover buyer was expressly told puppy did not have *Campylobacter*. After purchase the puppy tested positive for *Campylobacter* (as well as giardia, another serious zoonotic disease.

irresponsible use of antibiotics.[117] As Dr. Tauxe wrote to a colleague in January 2018, "The puppy story is not over - it is difficult to control with a whole system that lacks hygiene at many points and seems to use antibiotics instead."[118] Finally, the Commission also has the benefit of CDC's thorough investigations and considered judgment, and thus the rulemaking should not require a significant expenditure of Commission resources available for rulemaking actions for all consumer products.

VI. SUBSTANCE OF THE PROPOSED RULE

The warnings should be printed to be conspicuous, with text in a large font, using the signal word "Warning" or a like term, in red if practicable, and the warning sheet should accompany the other documents (such as immunization records or certificates of veterinary inspection) that are transferred with the dog at the time of sale. Breeders who sell dogs to consumers online and who must be licensed under the AWA should be included in the regulation.[119] Online breeders who ship dogs to consumers should include the warning sheet in the file of documents, such as veterinary records, that accompany the dogs in transit. If an online seller delivers a dog to a consumer in person, the warning sheet can be included with the other documents. The Commission also should require that pet stores conspicuously post the warning language near the cages where dogs are displayed, to put consumers on notice of the risk before they handle the dogs.[120] Online sellers – and online marketplaces that host advertisements from various breeders – should be required to include a notice like the one described below prominently on their websites.

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[117] 16 C.F.R. § 1009.8(c)(3). ("Certain products, although not presently associated with large numbers of frequent or severe injuries, deserve priority attention if there is reason to believe that the products will in the future be associated with many such injuries.").

[118] *Supra* note 9, Ex. 5.

[119] Under AWA regulations, breeders with five or more breeding females must be licensed, including those who sell dogs exclusively or partly online. 9 C.F.R. § 2.1(a)(3).

[120] *Supra* note 82, Ex. 34. As CDC investigators found, *Campylobacter* can be transmitted at any point during distribution because puppies from different breeders are commingled at distributors' facilities, during transport, and in pet stores.

A proper warning shall contain, at a minimum, the following or equivalent text:

WARNING!

Pet store puppies have been linked to a multi-drug resistant strain of *Campylobacter jejuni*, **which can be passed from dogs to people, and which has caused serious illness in people**. Immediately take your new puppy to a qualified veterinarian for a fecal test, as this store does not routinely test dogs for this bacteria. Wash hands after contact with dogs. See reverse for symptoms of *Campylobacter* infection.

[Reverse side or second page]

SYMPTOMS OF CAMPYLOBACTER INFECTION

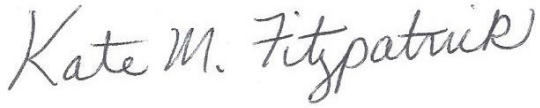
Symptoms include diarrhea, fever, and abdominal cramps, sometimes accompanied by nausea and vomiting. These symptoms usually start within 2 to 5 days after exposure and last about a week. In people with weakened immune systems, such as people receiving chemotherapy or people with AIDS, *Campylobacter* occasionally spreads to the bloodstream and can become life-threatening. Seek medical assistance immediately if you suspect infection.

VII. REQUESTS TO INITIATE RULEMAKING AND FOR A HEARING

CPSC should take the proposed action because the Commission's mandate is to protect consumers from the risks presented by products offered in the marketplace, and because it is the agency that has the authority and expertise to issue rules to protect consumers and their families from contracting Campylobacter from puppies sold in pet stores. Petitioners request that the Commission initiate a rulemaking requiring that a written warning accompany a commercially bred dog offered for sale into commerce and warning signage be posted in pet stores near the cages of the dogs offered for sale, or, in the case of internet sellers, on the websites where dogs are advertised or sold.

Petitioners further request a hearing before the Commission to consider the issues raised in this petition.

Respectfully submitted this 17th day of February 2021.



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TAB B: Health Sciences Evaluation

United States
Consumer Product Safety Commission
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Memorandum

TO: John Stabley, Ph.D., Project Manager for Commercially Bred Dogs Petition, Physiologist, Division of Pharmacology and Physiology Assessment

DATE: November 15, 2021

THROUGH: Stefanie Marques, Ph.D., Director, Division of Pharmacology and Physiology Assessment

FROM: Andrei Komarov, M.D., Ph.D., DABT, Physiologist, Division of Pharmacology and Physiology Assessment

SUBJECT: Health Sciences Evaluations of the Commercially Bred Dogs Petition

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I. Introduction

The Humane Society of the United States and the Humane Society Legislative Fund (petitioners) submitted a petition requesting the U.S. Consumer Product Safety Commission (CPSC) to adopt mandatory warnings of the risk to people of contracting *Campylobacter* infection from contact with commercially bred dogs sold online or in retail stores.

The Centers for Disease Control and Prevention (CDC) has advised CPSC that extensively drug-resistant (XDR) *Campylobacter jejuni* strains have emerged as a cause of illness among pet store customers, employees, and visitors (Dr. Francois Watkins, 2021). CDC also found earlier that infections caused by these strains cannot be treated with commonly recommended oral antibiotics, because bacteria carry "multiple antimicrobial resistance genes and mutations" (CDC, 2018). Another recent CDC report stated that antibiotic-resistant *Campylobacter* outbreaks present a "serious threat" to public health in the United States (CDC, 2019).

II. Discussion

A. Disease

Approximately 90 percent of human *Campylobacter* illness is due to a gram-negative bacterium, *Campylobacter jejuni*. Other species of this bacteria can also infect people (CDC, 2019a). Infected people usually have diarrhea, nausea, vomiting, fever, and stomach cramps. These symptoms start 2 to 5 days after exposure to the bacteria and last about 1 week (CDC, 2019b). Young children, senior adults, and people with weakened immune systems could be more susceptible to serious illness (CDC, 2021). Infected people rarely become chronic carriers of the disease. The CDC indicates that *Campylobacter* does not typically spread between people (CDC 2019d).

Most people with *Campylobacter* infection do not require antibiotics and are advised to follow a recommended treatment course of drinking plenty of fluids. People with serious illnesses might need antibiotics azithromycin and ciprofloxacin (CDC, 2019c). However, about 30 percent of all infections are resistant to these common antibiotics. These cases can be harder to treat, last longer, and lead to severe illness (CDC, 2019d).

Campylobacter can spread from animals to people through contaminated food and water. People may also become infected through contact with animals and their environments. International travel to developing countries can increase the risk of infection with antibiotic-resistant *Campylobacter* (CDC, 2019*)*. CDC estimates that *Campylobacter* infection from contaminated food and water, contact with infected animals or their environments, and international travel affects 1.5 million U.S. residents and causes 70 deaths every year (from all the infection sources listed above). Most cases are not part of recognized outbreaks (CDC, 2019). There are an estimated 450,000 antibiotic-resistant infections in the United States each year (CDC, 2019; JAMA Network, 2021).

The petitioners attributed drug-resistant *Campylobacter* in puppies to antibiotic overuse by breeders and pet-store owners. They also cited unsanitary conditions at puppy breeders, stores, and during dog transportation. Staff confirmed that dogs become infected with *Campylobacter* after exposure to the feces of sick animals (Iannino et al., 2019; LaLonde-Paul et al., 2019; Leahy et al., 2017). A significantly higher prevalence of *Campylobacter* is reported in 1-year-old or younger dogs, compared to older dogs (Thepault et al., 2020). The lack of proper veterinary supervision over antibiotic use in dogs could spread drug-resistant *Campylobacter* (MMWR, 2018; CDC, 2018; CDC, 2021a). Thus, CDC data and other sources confirm claims made in the petition.

Campylobacter jejuni is the predominant bacteria in dogs (Thepault et al., 2020; Campagnolo et al., 2016). The CDC has reported 113 human cases in the first outbreak (2016-2018) and 56 human cases in the second outbreak (2019-2021) that are related to pet-store puppies in 17 states. These cases have led to 32 hospitalizations and 0 deaths (CDC, 2018; CDC, 2021a). *Campylobacter* strains from infected people and puppies in the 2016-2018 outbreak were resistant to antibiotics that would be normally given for such an infection, which would require the use of other more toxic drugs. Isolates (bacteria samples isolated from infected people or dogs for laboratory testing) were resistant to azithromycin, ciprofloxacin, clindamycin, erythromycin, nalidixic acid, telithromycin, and tetracycline. In addition, 10 isolates were resistant to gentamicin, and 2 isolates were resistant to florfenicol. The CDC also identified multiple genetic changes in bacteria leading to broad antibiotic resistance in most samples from people and puppies in this outbreak (CDC, 2018). *Campylobacter* strains in the second outbreak (2019-2021) were also resistant to multiple antibiotics (CDC, 2021a).

The CDC traced extensively drug-resistant *Campylobacter jejuni* strains, or XDR strains, to the commercial dog breeding and distribution chain (JAMA Network, 2021). XDR *Campylobacter* isolates were resistant to fluoroquinolones, macrolides, and three or more additional antibiotic classes (JAMA Network, 2021). Furthermore, CDC surveillance data indicate that XDR strains, which account for 1.3% of all *Campylobacter jejuni* samples, have been circulating in the United States for at least 10 years (JAMA Network, 2021). Medical treatment of XDR *Campylobacter jejuni* infection requires costly intravenous antibiotics carbapenems (reserved for hospital-acquired disease). Failure of traditional antibiotics can also lead to complications. Patients had prolonged hospital admission and multiple courses of antibiotics to which their strain was resistant (Goyal et al., 2021). Thus, limiting the spread of XDR *Campylobacter* from dogs to humans can also prevent further growth of antibiotic resistance in *Campylobacte*r.

Dogs play an important role as a reservoir of antibiotic-resistant *Campylobacter* bacteria for humans (Iannino et al., 2019). In many cases, dogs are asymptomatic carriers of *Campylobacter jejuni,* meaning that infected dogs may appear healthy to consumers. Although

dogs may be asymptomatic, they could test positive for the bacteria. Staff noted that many online dog health sites, except for the CDC site (CDC, 2021), do not even mention campylobacteriosis as a significant disease in dogs. Thus, there is also a lack of information about this infection for a new dog owner.

Based on the data, staff concludes that puppies or dogs sold online or in pet stores can carry antibiotic-resistant *Campylobacter* that can make people sick, even though infected dogs may appear healthy. There is also a lack of public information about this infection in dogs and its effects on humans.

B. Complications

Complications from *Campylobacter* infections are infrequent, but they could be severe and include irritable bowel syndrome (IBS) and reactive arthritis (RA). In people with weakened immune systems, such as those with a blood disorder, with AIDS, or receiving chemotherapy, *Campylobacter* can spread to the bloodstream and become a life-threatening infection (CDC, 2019d).

Campylobacter infection can also lead to Guillain-Barré syndrome (GBS). The CDC estimates that only 0.2 to 1.7 in every 1,000 *Campylobacter* illnesses lead to GBS, but *Campylobacter* infections are responsible for 5 percent to 41 percent of GBS illnesses (CDC, 2019a). GBS is a rare, autoimmune disorder in which a person's immune system damages the nerves, causing muscle weakness and sometimes paralysis. GBS symptoms last for a few weeks to several years. Most people recover fully, but some could have permanent nerve damage. Some people have died of GBS. Infection with *Campylobacter jejuni* is one of the most common risk factors for GBS (CDC, 2019d).

Staff concludes that complications from *Campylobacter* infection could be severe. This disease presents a significant threat of severe illness or death to consumers.

III. Staff Conclusions and Recommendations

Staff concludes that puppies or dogs sold online or in pet stores can carry drug-resistant *Campylobacter,* which can cause severe illness or death. To mitigate this risk, the dogs should be seen by a veterinarian soon after their purchase. Even a healthy-looking dog can be a source of infection in humans. Testing for *Campylobacter* is most important for commercially bred dogs that are 1-year-old or younger. Staff also noted a lack of public information about this infection in dogs and its effects on humans.

IV. References

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TAB C: Human Factors Evaluation

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: John Stabley, Ph.D., Physiologist,
Project Manager for Commercially Bred Dogs Petition

DATE: November 22, 2021

THROUGH: Mark Kumagai, Associate Executive Director for Engineering Sciences

Rana Balci-Sinha, Ph.D., Director,
Division of Human Factors

FROM: Sharon R. White,
Division of Human Factors

SUBJECT: Petition for Commercially Bred Dogs to Be Accompanied by a Warning of the Risk of Contracting *Campylobacter* Infection from Contact with the Dogs

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I. Introduction

The Humane Society of the United States (HSUS) and the Humane Society Legislative Fund (HSLF) (the Petitioner) petitioned the Consumer Product Safety Commission (CPSC) to initiate rulemaking to require that dogs bred commercially for distribution in commerce (1) be accompanied by a warning of the risk to people of contracting *Campylobacter* infections, or campylobacteriosis, from contact with the dogs, and (2) to establish requirements with respect to the form of the warning, including the form of signage to be posted near the dogs' cages in pet stores or on the websites where dogs are being sold or advertised.

This memorandum evaluates the Petitioner's proposed warning label and assesses its effectiveness.

II. Injury Data

The Directorate for Epidemiology (Tab D) indicates that no records could be identified associated with commercially bred dogs or *Campylobacter* in CPSC's Consumer Product Safety Risk Management System (CPSRMS) and the National Electronic Injury Surveillance System (NEISS). The CDC, however, has conducted extensive investigations of illnesses linked to drug-resistant *Campylobacter* in commercially bred dogs. Therefore, staff from the Division of Human Factors (ESHF) considered injury data from the Petition (Tab A)[3],[4],[5] and the Directorate for Epidemiology (Tab D).

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[3] Multistate Outbreak of Multidrug-Resistant *Campylobacter* Infections Linked to Contact with Pet Store Puppies | Multistate Outbreak of Human *Campylobacter* Infections Linked to Pet Store Puppies | September 2017 | Salmonella |CDC.
[4] Outbreak of Multidrug-resistant *Campylobacter* Infections Linked to Contact with Pet Store Puppies | CDC
[5] https://www.humanesociety.org/sites/default/files/docs/FlorenceKY%20Petland%20Investigation%20Report.pdf.

III. Discussion

A. Considerations for Warnings

Warnings are a method for communicating safety information to a target audience for the purpose of inducing safety-related behavior. Warnings should inform users of the hazard, the consequences of ignoring the warning, and what to do to avoid the hazard. Before evaluating and developing warnings, it is important to know first, the characteristics of the product user, the product, and product use, and environmental factors and the interaction between these factors that contribute to an incident. This can assist ESHF staff in determining what a warning should communicate to induce safety-related behavior and the effectiveness of warnings.

Based on the injury data provided in Tab A, the users range in age from 2 months to 86 years. The product is a commercially bred dog sold to pet stores and online. The product use is contact with the dogs. Additionally, nearly all who became ill had contact with pet store puppies, including consumers and store employees, before and during the purchase of dogs. According to the Petitioner, "at commercial breeding facilities puppies and breeding dogs typically live in cramped, unsanitary conditions and receive inadequate veterinary care, which directly cause the diseases they contract so frequently." Therefore, the environmental factors include sick puppies sold at retail.

B. Petitioner's Proposed Warning Label

The Petitioner proposed a warning label intended to alert consumers to the risk of contact with commercially bred dogs. The Petitioner proposed that the warning label shall contain, at a minimum, the following or equivalent text:

WARNING!

Pet store puppies have been linked to a multi-drug resistant strain of *Campylobacter jejuni*, which can be passed from dogs to people, and which has caused serious illness in people. Immediately take your new puppy to a qualified veterinarian for a fecal test, as this store does not routinely test dogs for this bacteria. Wash hands after contact with dogs. See reverse for symptoms of *Campylobacter* infection.

[Reverse side or second page]

SYMPTOMS OF CAMPYLOBACTER INFECTION
Symptoms include diarrhea, fever, and abdominal cramps, sometimes accompanied by nausea and vomiting. These symptoms usually start within 2 to 5 days after exposure and last about a week. In people with weakened immune systems, such as people receiving chemotherapy or people with AIDS, *Campylobacter* occasionally spreads to the bloodstream and can become life-threatening. Seek medical assistance immediately if you suspect infection.

C. Analysis of Petitioner's Warning Label

Content

Statement of Hazard. The hazard is the source of the injury. In this case, it is sick pet store puppies. The Petitioner's proposed statement of hazard, "Pet store puppies have been linked to a multi-drug resistant strain of *Campylobacter jejuni*, which can be passed from dogs to people …" could be stated more directly. Additionally, the Petitioner requests that consumers be warned about the risk of contracting *Campylobacter* from dogs sold online. Therefore, the hazard statement should mention online sellers too. An explicit statement of the hazard is necessary to make it easy for consumers to understand. While the hazard statement is science- and health-based, it is not suitably written for the general public. Research suggests that a reading level of grade 6 to grade 8 is considered suitable for the public, but an even lower level may be desirable for critical information (Singer et al., 2003). Therefore, the proposed hazard statement may be more effective if revised and rewritten to state: "Puppies sold in pet stores and online have gotten sick from *Campylobacter jejuni* which can be passed from dogs to people."

Statement of Consequence. The statement of consequences informs users of what happens when users ignore the warning. In this case, the statement of consequence is "… and which has caused serious illness in people." The statement of consequence, however, is not written in a way that suggests that the warning applies to the consumer who may purchase a puppy. Research indicates that personalization increases the relevance of the warning to the user (Wogalter, M.; Racicot, B.; Kalsher, M.; and Simpson, S., 1993). Personalizing the warning makes it difficult for users to conclude that the warning is not directed to them and that it is not important to comply with the warning (Wogalter, M.S.; Kalsher, M.J.; and Raciot, B.M. (in press)). Therefore, ESHF staff suggests that the statement of consequence may be more effective if rewritten as: "You can become seriously ill or die if you contract *Campylobacter jejuni* because this disease is resistant to multiple drugs." Staff suggests that mention of the symptoms after that statement could follow. Therefore, following the statement "You can become seriously ill…," the warning should read: "Symptoms include diarrhea, fever, and abdominal cramps, sometimes accompanied by nausea and vomiting. These symptoms usually start within 2 to 5 days after exposure and last about a week. In people with weakened immune systems, such as people receiving chemotherapy or people with AIDS, *Campylobacter* occasionally spreads to the bloodstream and can become life-threatening. Seek medical assistance immediately if you suspect infection."

Precautionary Statements. The precautionary statement tells consumers what to do to avoid the hazard. In this case, the current precautionary statements are written as: "Immediately take your new puppy to a qualified veterinarian for a fecal test, as this store does not routinely test dogs for this bacteria [sic]. Wash hands after contact with dogs."

Interaction patterns with dogs that may facilitate transmission of the bacteria may inform additional measures to take to avoid contracting the disease. They are adapted from the CDC's advice to pet owners and pet store workers.[6] They include, but are not limited to:

- Letting dogs lick around a person's mouth and face;
- Letting dogs lick open wounds or areas with broken skin; and
- Eating and drinking in areas where animals are kept and exercised.

Staff also found that other interaction patterns include employees spraying fecal matter off cage trays while talking and laughing, consumers who keep their dogs in the kitchen, and consumers who feed dogs from the table while consumers are eating. Additionally face-to-face cuddling may be another source of transmission of the disease.[7] Thus, a statement telling consumers not to engage in these practices could be included in a warning.

Format

ANSI format. The signal word "WARNING" is the appropriate signal word for this warning label. However, the signal word is not presented in the ANSI Z535.4 format with the signal word preceded by the hazard alert symbol (exclamation point in an equilateral triangle) (*i.e.*, ! WARNING) and should be (ANSI Z535.4 – 2011). Additionally, the signal word should be in black letters surrounded by an orange background. Also, the warning is not surrounded by a black border. Placing a border around the warning is a way to make the warning stand out from, or contrast with, its background, by enhancing the figure-ground relationship (Wogalter and Vigilante, Jr., 2006).

Bullet/list Format. The proposed warning is written in paragraph format. Research suggests that warnings written in paragraph format are more likely to be skimmed and perceived less effective than warnings presented in a list format (Desaulniers, 1987) or meaningful chunks.

White Space. White space in a warning label is the blank area around and between wording and other elements. The current warning lacks sufficient white space because of its paragraph format. Use of white space is necessary to divide the information into more manageable chunks and to improve the organization of the warning.

Highlighting Text. Based on information the Petitioner provided, the public is unaware of the risk of contracting this infection simply from contact with pet store puppies. Therefore, ESHF staff recommends that key text be highlighted in bold to draw the user's attention and to increase the likelihood that users would read the warning.

[6] CDC, Outbreak of Multidrug-resistant *Campylobacter* Infections Linked to Contact with Pet Store Puppies, at: https://www.cdc.gov/campylobacter/outbreaks/puppies-12-19/index.html.
[7] These were seen in statements from pet store managers to HSUS investigators and through personal observations of staff.

D. An Example Warning

Based on ESHF staff's revisions to the Petitioner's proposed warning, staff provides an example warning that could be written and appear as follows[8]:

⚠ WARNING

Puppies sold in pet stores and online have gotten sick from Campylobacter jejuni which can be passed from dogs to people.

You can become seriously ill or die because this disease is resistant to multiple drugs. Symptoms include diarrhea, fever, and abdominal cramps, sometimes accompanied by nausea and vomiting. These symptoms usually start within 2 to 5 days after exposure and last about a week.

In people with weakened immune systems, such as people receiving chemotherapy or people with AIDS, Campylobacter occasionally spreads to the bloodstream and can become life-threatening.

Seek medical assistance immediately if you suspect infection.

- IMMEDIATELY take your new puppy to a veterinarian for a fecal test. This store does not test dogs for this bacteria.
- DO NOT purchase a sick puppy even though it may look healthy.
- ALWAYS wash hands after contact with dogs.
- DO NOT let dogs lick around your mouth and face.
- DO NOT not let dogs lick open wounds or areas with broken skin.
- DO NOT not eat and drink in areas where animals are kept and exercised.
- DO NOT not dry hands on clothing. Use a clean paper towel or air-dry them.

E. Effectiveness of the Warning

ESHF staff revised the Petitioner's warning, in content and format, to make the warning presentation more consistent with established warning practices. However, improvements to the warning do not necessarily mean that the warning would be effective. The research on warnings maintains that there are three factors that may influence the effectiveness of warnings. These factors are the perception of hazard associated with the product; product familiarity; and cost of compliance with the warning. The cost of compliance may include time, effort, convenience, or even money, to carry out the behavior instructed by the warning (and does not refer to the costs of a firm to provide the warning).

[8] Other precautionary measures could be added to the list of bullets.

Perception of Hazard

Research on warnings maintain that the greater the perceived level of hazard and consequences, the more likely consumers will comply with the warning. Consumers who do not perceive a product to be hazardous are less likely to notice or read a warning (Wogalter and Laughery, 2006), even a well-designed warning. Puppies and/or dogs are not likely to be perceived as hazardous. Although these animals have teeth, and therefore, can bite, consumers are not likely to be aware that they can also carry a germ that can be passed on to them and make them seriously ill. The Petitioner is aware of this, because the Petitioner suggests that ". . . consumers are unaware of the hidden risk of contracting campylobacteriosis from contact with dogs sold in retail stores and online." Also, many of the pet store puppies that are sick look otherwise clean and healthy. This may increase the likelihood that consumers are not likely to perceive these animals as posing a health risk.

Even if consumers read the warning, if a puppy looks otherwise healthy, and stores do not disclose the puppy's condition, consumers are unlikely to comply with the warning. Furthermore, a hazard statement, such as: "Pet store puppies have been linked . . ." may not be convincing, which may influence consumers to take the label less seriously, and not comply with the warning. Although a statement, such as: "Puppies sold in pet stores . . . have gotten sick" may be more convincing; if a puppy looks otherwise healthy, and stores do not disclose the puppy's condition, labeling is not likely to prevent the spread of the infection to an unsuspecting purchaser.

Product Familiarity

Puppies and dogs are very familiar animals. Consumers own these animals, visit family and friends who own them, see others walking them in the neighborhood, or see these animals riding in cars with their owners. The research demonstrates quite clearly that users who are more familiar or experienced with a product, or a similar product, are less likely to look for and notice warnings (Wogalter, Desaulniers, Brelsford, Jr., 1986; Sanders and McCormick, 1993; Vrendenburgh and Zackowitz, 2006; and Wogalter, Laughery, Sr., and Mayhorn, 2012) especially when the perception of hazard is low.

Cost of Compliance

The cost associated with complying with a warning can be a strong motivator. If consumers perceive that the cost of compliance with a warning is high,[9] they are less likely to comply with a warning.

According to the Petitioner, puppies in pet stores are often sick because many of them come from inhumane and unsanitary facilities. Additionally, the Petitioner asserts that puppies in pet stores are not provided adequate veterinarian care. Accordingly, the CDC is concerned that the

[9] In this usage, commonly accepted in the scholarly research on warnings, the cost of compliance does not refer to the cost to a firm to provide the warnings but rather the cost to the consumer of complying with the warning. The cost of compliance may include time, effort, convenience or even money to carry out the behavior instructed by the warning.

risk to consumers exposed to puppies in pet stores continues. As stated, consumers may not be aware of the puppy's health condition, especially if the puppy appears otherwise healthy and clean, and if retail personnel do not disclose the puppy's health status. Therefore, given the CDC's concerns and consumers' lack of awareness of a puppy's health condition, consumers may have difficulty complying with the second precautionary measure to avoid purchasing a sick puppy. The Directorate for Health Sciences memorandum (Tab B) indicates that infected dogs may be asymptomatic; therefore, consumers may not be aware that the puppy they purchased is sick.

Consumers may not know how to comply with the precaution to take a new puppy to a veterinarian immediately for a fecal test. First, they must consider what the word, *immediately*, means. Does it mean that consumers must take the puppy to the veterinarian on the same day of purchase? Does it mean consumers should take the puppy to the veterinarian within 2 or 3 days of purchase? Even if consumers took a puppy to the veterinarian on the same day of purchase, this provides no guarantee that a consumer will not become infected with *Campylobacter* if the puppy is already sick with *Campylobacter* at the time of purchase. Second, it may not be convenient for a variety of reasons, including appointment availability, for a consumer to take a puppy to the veterinarian on the same day of purchase, or even a few days after purchase.

Moreover, some people may not be in a location where they can wash their hands after playing with a puppy, they may not customarily wash their hands after every interaction with their dog or may not wash their hands at all after interacting with their dog. Additionally, it is not uncommon for consumers to allow dogs to lick them around their face and mouth, to be cuddled face-to-face, to be hand fed from the table, and engage in similar behaviors. As discussed, these interactions may increase the likelihood of humans contracting *Campylobacter* from a dog. Therefore, the cost of complying with the warning, by avoiding such interactions, is likely to be high for consumers who engage in these behaviors.

Other Considerations

The Petitioner requests that a warning accompany commercially bred dogs sold at retail or online. The warning would be posted at the retail store, or via website, and located in a conspicuous place where it is visible to the consumer. The Petitioner also recommends that the warning be required to accompany other documents that are provided with the dog, upon sale. Once consumers leave the store, or purchase their puppy via a website, the posted warning would no longer be visible. Even if a warning accompanied the puppy home, via an informative brochure, or some other form of a warning, the warning may get misplaced or discarded. A warning, even a well-designed one, located out of view, is less likely to be effective. Even if consumers do not misplace or discard the warning, according to the labeling research, warning information may not be what the consumer is thinking about at the time the information is needed (Wogalter and Laughery, 2006).

Additionally, consumers who interact with commercially bred dogs may not necessarily be the ones who purchase the dogs. Thus, any warnings accompanying these animals would not be visible to users who are non-purchasers.

Considering that consumers' perception of the hazard associated with contact with commercially bred dogs is low, the familiarity of puppies/dogs is high, and the cost of complying with a warning is high, a warning accompanying a commercially bred dog or puppy is unlikely to be effective. Other factors considered when determining the effectiveness of a warning also suggest that a warning is unlikely to be effective.

IV. Conclusion

To respond to the petition, ESHF staff evaluated the Petitioner's proposed warning and assessed its effectiveness. ESHF staff determined that although the Petitioner's proposed warning contains a hazard statement, statement of consequences, and precautionary measures, the warning could be improved. Therefore, ESHF staff provided a revised warning that staff believes communicates more clearly the safety message. However, this does not necessarily mean that staff's revised warning would induce safety-related behavior, and hence, constitute an effective warning.

Labeling research maintains that certain factors may influence a warning's effectiveness. These factors are perception of hazard, product familiarity, and cost of compliance, in terms of time, effort, and convenience. ESHF staff considered other factors to determine the effectiveness of a warning.

Based on ESHF staff's assessment of the effectiveness of a label warning people of the risk of contracting campylobacteriosis, or *Campylobacter* infections from contact with dogs, staff believes that labeling is unlikely to be effective in preventing consumers from contracting these illnesses.

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TAB D: Summary of Commercially Bred Dog Transmitted *Campylobacter* Outbreaks

United States
Consumer Product Safety Commission
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Memorandum

TO: John N. Stabley, Ph.D.
Project Manager, Commercially Bred Dogs Petition
Physiologist, Division of Pharmacology and Physiology Assessment

DATE: November 12, 2021

THROUGH: Stephen Hanway
Associate Executive Director
Directorate for Epidemiology

Risana Chowdhury
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM: Blake Smith
Mathematical Statistician, Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT: Summary of Commercially Bred Dog transmitted *Campylobacter* Outbreaks

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I. Introduction

To assess the petition filed by the Humane Society of the United States and the Humane Society Legislative Fund regarding rulemaking to address the hazard associated with *Campylobacter* infections linked to commercially bred dogs, staff from the Directorate for Epidemiology reviewed readily available information regarding this product and hazard. This memorandum presents data on multidrug-resistant *Campylobacter* infections linked to contact with commercially bred dogs.

II. Incident Data

A. Consumer Product Safety Commission (CPSC) Data Sources

After a review of both the CPSC's Consumer Product Safety Risk Management System (CPSRMS) and the National Electronic Injury Surveillance System (NEISS), no records could be identified associated with commercially bred dogs or *Campylobacter*. Product codes do not exist for pets (beyond pet supplies) within either system; nor did a search for "campylobacter" retrieve any records associated with a dog, or searches of "breed" or "bred" did not reveal incidents associated with infections attributed to dogs.

B. Center for Disease Control and Prevention (CDC) Data

Staff identified and reviewed two CDC outbreak investigation reports on multidrug-resistant

Campylobacter infections in humans that were linked to contact with pet store puppies.[10] This section provides descriptive statistics, combining findings from the two CDC outbreak reports; these summaries provide an overview of the national outbreak impact of *Campylobacter* infections linked to commercially bred dogs.

Two outbreaks were observed spanning approximately 4 years combined, the first from early 2016 to early 2018, and the second from early 2019 to early 2021. Both outbreaks affected a total of 17 states. For the 2016 through 2018 outbreak, "ill people ranged in age from less than 1 year to 86, with a median age of 27" and for the 2019 through 2021 outbreak, "ill people ranged in age from 2 months to 84 years, with a median age of 40," according to the CDC reports. The similarity in length of the outbreak investigations, comparable age range, and number of states affected allows us to combine the two investigations for an aggregate summary.

Combined, the reports identified a total of 169 cases in humans of laboratory-confirmed infections or symptoms consistent with *Campylobacter* infection. Of these 169 cases, 144 provided further information by interview. Of the interviewed subset, 140 reported having contact with a puppy the week before illness started, 111 reported having contact with a puppy from a pet store the week before illness started (73 customers, 38 employees)[11], and 32 required hospitalizations. There were no deaths reported in either outbreak related to *Campylobacter* infection. A further breakdown of each outbreak is below:

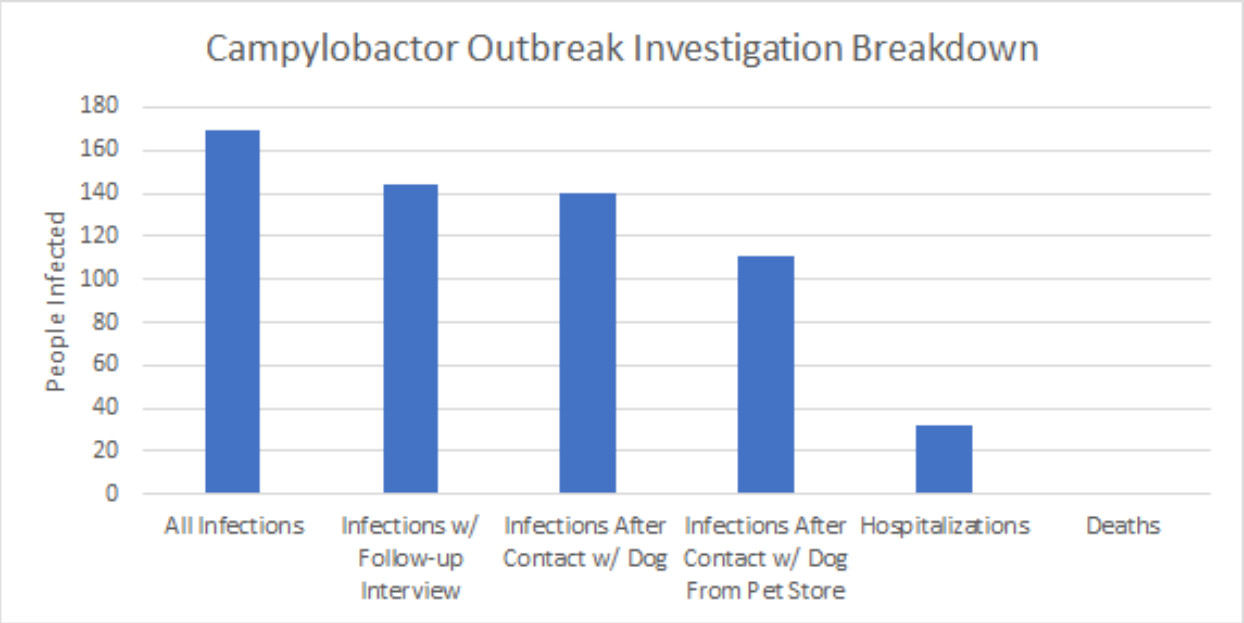
***Campylobacter* Outbreak Breakdown:**

	2016-2018 Outbreak	2019-2021 Outbreak	Total
All Infections	113	56	169
Infections w/ follow-up interview	103	41	144
Infections After Contact w/ Dog (% of all Infections w/ interview)	102 (99%)	38 (93%)	140 (97%)
Infections After Contact with Dog from Pet Store (% of Infections with Follow-up Interview)	90 (87%)	21 (51%)	111 (77%)
Hospitalizations (% of all Infections w/ interview)	23 (22%)	9 (22%)	32 (22%)
Deaths (% of all Infections w/ interview)	0	0	0

[10] "Multistate Outbreak of Multidrug-Resistant *Campylobacter* Infections Linked to Contact with Pet Store Puppies." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 30 Jan. 2018, https://www.cdc.gov/campylobacter/outbreaks/puppies-9-17/index.html.

"Outbreak of Multidrug-Resistant *Campylobacter* Infections Linked to Contact with Pet Store Puppies." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 15 Apr. 2021, https://www.cdc.gov/campylobacter/outbreaks/puppies-12-19/index.html.

[11] The first CDC outbreak investigation (early 2016- early 2018) also included in this value ill people who had contracted *Campylobacter* from contact with a person who became sick after contact with a puppy from a pet store.


Campylobactor Outbreak Investigation Breakdown
People Infected
180
160
140
120
100
80
60
40
20
0
All Infections
Infections w/ Follow-up Interview
Infections After Contact w/ Dog
Infections After Contact w/ Dog From Pet Store
Hospitalizations
Deaths

TAB E: Market and Economic Considerations for the Petition

United States
Consumer Product Safety Commission
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Memorandum

TO: John N. Stabley, Ph.D.
Project Manager, Commercially Bred Dogs Petition
Physiologist, Division of Pharmacology and Physiology Assessment

DATE: November 19, 2021

THROUGH: Alex Moscoso
Associate Executive Director
Directorate for Economic Analysis

FROM: Susan Proper and Mark Bailey
Economists
Directorate for Economic Analysis

SUBJECT: Market and Economic Considerations for Petition Requesting that the Commission undertake a Rulemaking to Require that Commercially Bred Dogs Placed into Commerce Be Accompanied by Written Warnings of the Risk of Contracting *Campylobacter* Infection from Contact with Dogs

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I. Introduction

On February 17, 2021, the Humane Society of the United States and the Humane Society Legislative Fund submitted a petition requesting that the CPSC initiate a rulemaking under sections 7 and 9 of the Consumer Product Safety Act (CPSA) to "(1) establish requirements that dogs bred commercially for distribution in commerce be accompanied by clear and adequate warnings of the risk to people of contracting *Campylobacter* infection, or campylobacteriosis, from contact with the dogs, and (2) establish requirements with respect to the form of the warnings, including the form of signage to be posted near the dogs' cages in pet stores or on the websites where dogs are being sold or advertised online." The petition states that this regulatory action "requiring pet sellers to inform the public about these risks will likely have the effect not only of warning consumers of the risks, but also of encouraging sellers, breeders and transporters to clean up their act to reduce those risks."

This memorandum provides information on the market for commercially bred dogs and the economic considerations related to the petition. The analysis is based on information that is readily available, including information provided by the Petitioner, peer-reviewed literature, readily available market research, and public websites of government agencies and private-sector organizations.

Based on this preliminary analysis, it appears that the action requested by the Petitioner would present a small cost to suppliers of commercially bred dogs. However, given the large number of commercially bred dog breeders and sellers, even a small cost for individual businesses could represent several million dollars in annual costs to the industry.

Regarding the benefits from this potential action, staff has determined that it is unlikely that a warning to consumers of the hazard would change their behavior and reduce the risk of

consumers contracting *Campylobacter* from bred dogs, as discussed in the Human Factors memorandum (see Tab C). There is no evidence that such a warning would, in fact, "encourage sellers, breeders, and transporters to clean up their act and reduce those risks," as the Petitioner claims, because the requested action offers no economic incentives to any individual seller to reduce that risk or post hoc rewards for reducing risk.

II. Market – Numbers of Dogs and Commercially Bred Dog Suppliers

There are about 6.4 million puppies sold, adopted, or given away in the United States every year. Around 2.4 million of those, or 39 percent, come from a source within the scope of the proposed action. More than 15,000 businesses, including pet stores, breeders, dog brokers, and online dog sellers, would be within the scope of this proposed action.

A. Number of Dogs Sold in the United States, and How Acquired

The American Veterinary Medicine Association (AVMA)[12] estimates that in 2018 there were more than 76.8 million pet dogs owned in the United States. A 2020 survey of 1,040 dog owners[13] found that 21 percent bought a dog from a breeder, 7 percent bought from a pet shop, 8 percent from a private online ad, and 3 percent from an offline ad. In total, 39 percent of the total dog "market" could thus be within the scope of the proposed action. The remaining 61 percent of dogs were either adopted from a shelter, acquired from a friend or acquaintance, acquired through an animal protection organization, or adopted off the street. The American Society for the Prevention of Cruelty to Animals[14] estimates that 2 million dogs are adopted from shelters each year, and that animal shelters make up 23 percent of total dog acquisitions, which would make the total dog "market" each year, including both adult dogs and puppies, about 8.7 million.

Assuming that adult dogs and puppies are adopted/sold at approximately the same rates through the same channels, 39 percent of 6.4 million puppies would be approximately 2.5 million puppies. The Petitioner has stated that more than 2,300 pet stores have signed their pledge to stop selling puppies, and instead sell only pet supplies and/or shelter dogs,[15] so some of the dogs in the 7 percent of dogs acquired from pet shops would not necessarily be commercially bred puppies. However, as the Petitioner notes, some shelter dogs are abandoned or confiscated commercially bred puppies. Thus, the number of commercially bred puppies acquired annually could be slightly higher or lower than this approximate estimate.

CPSC staff's estimate of 6.4 million puppies born annually, of which less than half are acquired through channels that could be covered by the requested action, is thus roughly consistent with the information provided by the Petitioner for commercially bred puppy sales of 2.4 million. The Petition states that "The commercial production and retail sale of dogs is big business. An estimated 10,000 commercial dog breeding facilities operate in the United States. These facilities churn out approximately 2.4 million puppies sold annually." That Petitioner's estimate appears to be from 2013. Elsewhere in an attachment, the Petitioner provides a 2021 estimate of 2.6 million puppies sold annually.

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[12] https://www.avma.org/resources-tools/reports-statistics/us-pet-ownership-statistics.
[13] Statista.com global consumer survey tool.
[14] https://www.aspca.org/helping-people-pets/shelter-intake-and-surrender/pet-statistics.
[15] https://www.humanesociety.org/sites/default/files/docs/pet-stores-puppy-mills-factsheet.pdf.

B. Number of Entities in Scope of the Proposed Action

The Petitioner did not specify how a "commercial breeder" should be defined. The United States Department of Agriculture's (USDA) Animal Welfare Act (AWA) licensing requirements have exemptions for very small operations, and for sales of certain types of dogs that are not considered pets. The number of USDA licensed breeders is less than half of the Petitioner's estimate. USDA's AWA regulations exempt breeders who sell pet dogs in face-to-face transactions from licensing regulations. They also exempt breeders who sell dogs for breeding stock, hunting, or security purposes. We assume that the Petitioner wishes for the requirements to apply to their estimate of 10,000 commercial dog breeders, including those not licensed by USDA, since they have provided information about USDA's licensing in the petition package and discuss the large number of unlicensed breeders.

The Petitioner's requested action would also apply to pet stores. Pet stores that sell dogs in face-to-face transactions also are exempt from USDA's licensing regulations. There are more than 5,000 firms and about 10,000 establishments in the "Pet and Pet Supply Store" North American Industry Classification System (NAICS) category,[16] using 2018 U.S. Census data[17]; although not all of those sell commercially bred dogs. Some only sell pet supplies, while others sell older dogs or shelter dogs. There are fewer firms than establishments in the Census data because some pet store businesses are chains with more than one store.

Based on the Petitioner's data and staff's analysis of U.S. Census Data, there could be as many as 15,000 businesses with 20,000 separate facilities covered by this action, including commercial breeders, pet stores, and online sellers of bred dogs. The supply chain for commercially bred dogs includes dog brokers and other intermediaries, who could also be impacted by the proposed action. However, we assume that brokers would merely be passing on the warning documents from breeders, and thus brokers would incur no costs.

III. Costs and Benefits to Suppliers, Including Small Businesses

A. Potential Impact on Small Businesses

The Regulatory Flexibility Act (5 U.S.C. §§ 601-612) applies to Commission rulemakings and requires an assessment of whether a rule will have a significant economic impact on a substantial number of small entities. This assessment is not required at this stage. Staff notes, however, that almost all of the commercial dog breeding entities that would be impacted by this action are small businesses as specified in the applicable Small Business Administration (SBA)

[16] NAICS is the system used by federal statistical agencies to classify business establishments for the purpose of collecting, analyzing, and publishing statistical data. For more information, see: https://www.census.gov/naics/.
[17] U.S. Census, Statistics of U.S. Businesses, 2018, "The Number of Firms and Establishments, Employment, and Annual Payroll by State, Industry, and Enterprise Employment Size: 2018."

size standards, including retail pet stores, commercial breeders, and various businesses that sell dogs online.

The cost to any individual supplier to comply with the Petitioner's recommended requirements could be minimal. However, given that potentially 15,000 businesses with 20,000 stores could be within the scope of this action, even a small cost of $100 to obtain and maintain a sign, or update a website, would represent a total cost of about $2 million per year for the industry. If the Commission also required printed written warnings to accompany each dog, as the Petitioner requested, the cost per facility would likely double to $200, and the annual cost would be about $4 million.

U.S. Census data show that the average cost to an employer for a retail sales worker is $19.71 per hour, including wages and benefits.[18] Assuming that printing or obtaining and posting the sign takes one hour, the average cost to the employer would be $19.71 per establishment. If the employer uses a graphic designer or other professional to design the sign, the cost to the employer would be $57.30 for one hour according to U.S Census cost data on private sector information sector workers. Thus, the total cost to the employer would be about $77 for labor, and some unknown but relatively small amount for materials, depending on whether the sign is paper, plastic, or metal. The cost would be similar for adding text and graphics to a website. We have provided an approximate estimate of $100 per establishment for both labor and materials for one sign per establishment. Additional paperwork, such as written warning paperwork provided with each dog sold, would require additional labor and materials costs. If the Commission proceeds with rulemaking, staff can provide a more precise estimate based on the specific requirements in the rule, including how warnings must be provided, as well as size, colors, and materials that the Human Factors staff specifies are necessary and appropriate for the warning sign.

B. Potential Cost for Large Businesses

The burden on large businesses per establishment would be similar to that on small businesses. Staff identified more than a dozen pet store chains with multiple stores that would likely exceed the SBA small business size standard for pet stores of $22 million in annual sales, although many of the large chains do not sell commercially bred dogs. Due to economies of scale, the proportional burden of this proposed action per dollar of revenue from dog sales would be less for businesses with greater annual sales than for smaller businesses. However, large businesses might be more likely to sell commercially bred dogs rather than adult dogs or rescue dogs, and thus those businesses would be more likely impacted by this action.

[18] https://www.bls.gov/web/ecec/ecsuptc.txt, see table 6 for retail workers, and table 8 for workers in information industries.

C. Benefits to Suppliers

Based on a preliminary assessment, CPSC staff did not find quantifiable benefits to suppliers. The petition discusses[19] that there could be some benefits to suppliers from the requested action, such as increased trust by the public, reduced number of local ordinances banning sales of puppies in pet stores, less competition for responsible breeders from breeders who provide marginal care, fewer lawsuits from sick customers, and fewer store closures and quarantines. However, staff cannot determine that any of these benefits would accrue from warning signs or written warning material provided with each dog sold.

IV. Costs and Benefits to Consumers

There would likely be no cost to consumers for the requested action, unless suppliers pass the cost of their compliance to provide the written warning paperwork to consumers by raising the prices for commercially bred dogs. The warning suggests that consumers take their new dog to a veterinarian for an examination, which could result in a cost of approximately $50[20] for the stool test only, plus the cost of the general exam, if they choose to take that action. As discussed in the Human Factors memorandum (Tab C), the cost would also involve the time and inconvenience of scheduling the appointment and taking the dog to the veterinarian. However, the action requested by the Petitioner would not *require* consumers to take their dog to a veterinarian.

Given the currently available information found by CPSC staff, the benefits of the proposed action could not be quantified. We can estimate the costs to society of *Campylobacter* for medically treated cases, the medical costs per case of *Campylobacter*, and the value of a statistical life (VSL). However, we cannot determine how many cases of *Campylobacter* the proposed action would prevent, if any. The readily available cost data and analyses from cases of foodborne illness from various species of *Campylobacter* may not reflect the cost of cases from the antibiotic-resistant species found in commercially bred dogs. Given the cost of hospitalization and the VSL, if even one death per year, or a few hospitalizations were prevented by the requested action, the benefits likely would exceed the relatively small costs.

Since a dog infected with *Campylobacter* can appear healthy, the Petitioner is correct that, absent the requested warning, the risk to consumers is not obvious. Therefore, there is at least some informative benefit to the warning.

A. Cost to Society of *Campylobacter*, Benefits of Avoiding *Campylobacter*

The Petitioner states that consumers would benefit from the warnings about *Campylobacter* infection risks and implies that cases of multidrug-resistant *Campylobacter* infection from commercially bred dogs would decrease as a result. Given the currently available information found by CPSC staff, and particularly the Human Factors analysis that a warning is unlikely to be effective, we could not determine whether the requested action would create the benefits to

[19] in Exhibit 18 – Puppy Mills and the Animal Welfare Act.
[20] https://dogdiscoveries.com/health/dog-stool-sample-test-cost.

consumers that the Petitioner claims. As described in the Epidemiology memorandum analyzing CDC data (Tab D), the recent outbreaks of infections from commercially bred dogs resulted in 169 known cases with 32 hospitalizations.

The HSPP memo discusses that the *Campylobacter* strain in commercially bred dogs could have particularly negative health impacts, and thus there could be a large benefit to society of avoiding those medical costs. As discussed in the market analysis section, less than half of pet dogs are acquired through a pet store, online commercial breeder, or other entity that would be covered by this action.

A recent study by USDA's Economic Research Service (ERS) on the economic burden of foodborne illnesses[21] finds that there are approximately 48 million cases of foodborne illnesses in the United States each year, based on Centers for Disease Control and Prevention (CDC) data. This study is particularly relevant because it was a comprehensive statistical analysis of CDC data of hundreds of thousands of cases, and it includes estimated medical costs to society and the cost per case. The ERS study, using CDC data, analyzed in detail the roughly 80 percent of total *Campylobacter* cases that are foodborne. For the 9.4 million cases of foodborne illness each year where a specific pathogen can be identified as the cause, the economic burden exceeds $15.5 billion (in 2013 dollars) annually. That estimate includes direct, indirect, and intangible costs. *Campylobacter* accounts for about $1.9 billion of that cost and about 845,000 cases of foodborne illness. That relatively large cost to society reflects a mean number of deaths per year from *Campylobacter* of 76 in the years of CDC data analyzed by USDA ERS. The estimated cost per case is $2,283, reflecting that there are many cases, but that about 94 percent of cases are resolved without a doctor. In 5 percent of cases, medical care is sought, but the case does not require hospitalization. Only about 1 percent of cases require hospitalization and about 0.1 percent result in death. Using CDC data[22], ERS estimates that foodborne cases of *Campylobacter*, all species, causes 8,463 hospitalizations a year. Any estimate of the cost to society from *Campylobacter* from a particular source would be sensitive to what percentage of the cases require hospitalization or cause long-term health impacts. Thus, if the strain of *Campylobacter* linked to commercially bred dogs had a higher rate of hospitalizations or deaths, the cost per case would be higher than in the ERS estimates, and the total cost to society would be proportionally higher.

Of the $1.9 billion in costs to society from *Campylobacter* as a foodborne illness, the ERS study estimates that 15 percent of that cost (about $285 million) is from direct medical costs, 12 percent (about $237 million) is from lost productivity, and the remaining 73 percent ($1.4 billion) is from deaths. The ERS study uses a VSL of $8.7 million in 2013 dollars, consistent with EPA cost/benefit analyses at the time. The CPSC also uses EPA's estimate for VSL, but the agency adjusts for inflation so that the current value in CPSC's Injury Cost Model (ICM) is $9.2 million, in 2018 dollars. If the Commission initiates rulemaking, staff can provide a more precise

[21] Hoffman, Sandy et al., "Economic Burden of Major Foodborne Illnesses Acquired in the United States." USDA Economic Research Service, EIB 140, 2015.
[22] Scallan, Elaine et al "Foodborne Illness Acquired in the United States—Major Pathogens." *Emerging Infectious Disease*, 2011, 17(1): 7-15.

estimate of cost to society, and benefits of reducing that cost, using current values for medical costs and CPSC's VSL.

In some cases, *Campylobacter* can cause long-term disabilities. Using CDC data, the ERS study estimates that "Less than 0.25 percent of people who are infected with *Campylobacter*, about 2,000 people a year, develop a rare neurological disease called Guillain-Barré syndrome (GBS). … The CDC reports that as many as 40 percent of GBS cases in the United States may be triggered by *Campylobacter* infections."

The CDC data for the recent commercially bred dog cases, as described in the Epidemiology memorandum (Tab D), involved 169 cases and 32 hospitalizations, which would be a much higher rate of hospitalization – 19 percent of all cases, 22 percent of cases for which the CDC conducted interviews – than in the foodborne cases analyzed by USDA ERS, which had a 1 percent rate of hospitalization. However, these are small numbers from two outbreaks and cannot be used to make statistically valid estimates of how many cases per year can be attributed to *Campylobacter* from commercially bred dogs, what the total cost to society of those cases is, or how much, if any, that cost would be reduced by the action requested by the Petitioner.

B. Cost of *Campylobacter* Per Case, Benefits of Avoiding those Costs

We cannot estimate how many cases of *Campylobacter*, if any, would be prevented by this proposed action. This section provides a range of estimates of cost per case, based on information from foodborne cases of *Campylobacter*, which may underestimate the cost per case from *Campylobacter* spread by commercially bred dogs. The benefit of the proposed action would be the cost per case times number of cases prevented.

The ERS study of foodborne *Campylobacter* estimated the cost per *Campylobacter* case is $2,283. ERS derived the $2,283 by dividing the total cost to society of *Campylobacter* foodborne illness of $1.9 billion by 845,000 cases. For cases that require hospitalization, the estimated cost is close to $15,000 per case, while the cost of a case where someone seeks medical care but isn't hospitalized is under $1,000. As noted, about 2,000 people a year develop Guillain-Barré syndrome as a result of a *Campylobacter* infection. These serious but usually non-fatal cases with long-term medical and productivity costs, as well as some deaths, account for more than half of ERS estimated cost of foodborne *Campylobacter*, at more than $1 billion in medical costs per year. The ERS estimate of the long-term cost per case for GBS exceeds $500,000, including factoring in the VSL of the deaths from GBS.

The cost per case of *Campylobacter* from studies of foodborne illness might underestimate the cost per case of the antibiotic-resistant species of *Campylobacter* that CDC linked to commercially bred dogs, if that species had a higher rate of hospitalizations, GBS, and deaths than the species linked to foodborne illness. The CDC data for the recent commercially bred dog cases, as described in the Epidemiology memorandum (Tab D), involved 169 cases and 32 hospitalizations, which would be a much higher rate of hospitalization – 19 percent – than in the foodborne cases analyzed by USDA ERS, which had a 1 percent rate of hospitalization.

These data from the recent commercially bred dog cases represent too few cases to make any estimates about either the number of cases that the proposed action might prevent in the future, or the cost per case. As with foodborne *Campylobacter*, there may have been a number of mild cases where medical treatment was not sought that were not captured in the CDC report. The species of *Campylobacter* in the outbreaks described by the CDC was antibiotic resistant, so the cost per case could be greater than the USDA ERS study using CDC data that considered all species of *Campylobacter*.

In summary, the cost per case from available data is based on *Campylobacter* cases primarily from food, where hospitalizations due to infection are relatively rare, impacting about 1 percent of cases. The rate of hospitalizations from the recent commercially bred dog outbreaks appear to be much higher, about 19 percent, but there are too few cases to make any quantified estimates of cost per case in the long run specifically from commercially bred dogs.

C. Other Benefit Considerations

This requested action partially addresses what is known in economics as a "negative externality," meaning a cost for society caused by a producer's action that is not borne by the producer or by the immediate customer. The most common example is air pollution from various sources, where the market price of the product or service causing the pollution doesn't reflect the larger negative impact on society. In this case, the conditions in which commercially bred dogs are raised and sold, as described in detail by the Petitioner, costs society millions of dollars a year in medical costs for human illnesses and veterinary bills for pet owners. As described by the Petitioner, animal rescue organizations and shelters spend millions of dollars each year on veterinary care for abandoned and confiscated commercially bred dogs. One benefit of this action would be reducing those negative externalities by an unquantifiable amount.

There is some unknown probability that the antibiotic-resistant species of *Campylobacter* found in commercially bred dogs will provide a vector or reservoir to spread that particular strain to other animals, particularly animals used for food, as well as to people. There are already known issues with antibiotic resistant strains in food animals, due primarily to similar use of antibiotics and crowded conditions for food animals that the Petitioner describes for pet animals.[23] As the CDC notes on their webpage the "FDA withdrew one fluoroquinolone approval for poultry in 2001 and the other in 2005 because of evidence that the use of fluoroquinolones in poultry led to an increase in fluoroquinolone-resistant *Campylobacter* infections in people." If that is the case, there would be large additional benefits to people, and possibly economic benefits to the meat animal industry, of reducing the spread of the *Campylobacter* species that caused the outbreaks in commercially bred dogs.

[23] https://www.cdc.gov/campylobacter/campy-antibiotic-resistance.html.

V. Conclusions

The benefit to consumers of the action requested by the Petitioner would be better information about the *Campylobacter* risk from commercially bred dogs. Since a dog infected with *Campylobacter* can appear healthy, the Petitioner is correct that, absent the requested warning, the risk to consumers is not obvious. Therefore, there is at least some informative benefit to the warning. However, as indicated in the Human Factors assessment in Tab C, consumers are unlikely to comply with a warning accompanying commercially bred dogs. The cost burden on any individual pet store or dog breeder of the warning proposed by the Petitioner likely would be limited. The benefits of reduced cases of *Campylobacter* from the warning could not be estimated at this time, but given the costs of hospitalization and VSL, if even a few cases that require hospitalization or cause serious long-term impacts were avoided with the requested action, or even one death per year was prevented, the benefits likely would exceed the costs.