

Statement of

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before the

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Committee on Oversight and Reform
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Chairman Krishnamoorthi, Ranking Member Cloud, and Members of the Subcommittee, I am Jeffrey Simmons, the president and chief executive officer of Elanco Animal Health. Thank you for the opportunity to be here today to discuss Seresto.

Elanco appreciates the Subcommittee's interest in this issue, and as a company dedicated to protecting and enhancing the health of animals, we certainly share the goal of ensuring that the products which families count on for their pets are safe and effective. I hope that my testimony helps clear up misconceptions about Seresto, a proven solution that is not only effective at protecting dogs and cats from disease-carrying fleas and ticks, but also has a strong safety profile, as demonstrated by the fact that it has been approved by more than 80 regulatory bodies around the world.

While my testimony will cover these topics in greater detail, allow me to emphasize a few key points at the outset:

- Seresto was approved by the Environmental Protection Agency ("EPA") based on the positive results from more than 80 safety, toxicity, and efficacy studies.
- A report of an adverse incident does not mean that the adverse incident was caused by a product, and our pharmacovigilance team has not identified any deaths caused by Seresto's active ingredients.
- With more than 33 million collars sold, incident reports (most of which involve minor or moderate incidents) represent an extremely small proportion of the Seresto collars in use.
- While all products carry some risk of side effects, the risk posed by Seresto is not unreasonable, which is why the American Veterinary Medical Association has opposed canceling Seresto's EPA registration.
- The benefits of Seresto are significant. It provides eight months of continuous, affordable coverage for working families against fleas and ticks, which can carry serious and potentially fatal diseases, like Lyme disease, Rocky Mountain spotted fever, and the plague.

I. Background

I joined Elanco in 1989 as a dairy sales representative, straight out of college. At the time, Elanco was a small division of Eli Lilly and Company. Over the next two decades, I worked in a number of positions at the company, ultimately becoming president of Elanco in 2008. In 2018, when Elanco separated from Eli Lilly, I took on the role of chief executive officer. Making animal lives better has been my mission for my 33 years in this industry, all of which I have spent at Elanco.

For nearly 70 years, Elanco has been a trusted partner to farmers, veterinarians, and pet owners, supplying the products they need to keep the animals they work with and share their homes with healthy and well. Since the development of our first product for livestock in 1953, we have been at the forefront of innovation in animal health. Our nearly 10,000 team members strive every day to improve the health and well-being of animals, which play an important role in their lives.

At Elanco, we understand the unique and loving bond pet owners share with their pets, and I can speak personally to that. I care deeply about my dogs, who add so much to our family. When pets are healthy, so are people. This understanding drives our diligent, science-backed approach to safety. We are committed to transparency and take reports of adverse events involving our products seriously. At the same time, our decisions are guided by the best scientific evidence available. That evidence provides robust support for the strong safety profile of Seresto.

Seresto was first approved by the EPA in 2012 following numerous toxicity studies, pharmacokinetic studies, safety studies, laboratory efficacy studies, and field efficacy studies. The collar is designed to be worn by a dog or cat for eight continuous months and contains a polymer matrix of two active ingredients, imidacloprid and flumethrin. Those active ingredients are released slowly and continuously in low concentrations and spread from the collar over the rest of the body.

Because Seresto guards against fleas and ticks for eight continuous months in an easy-to-use, over-the-counter collar, it uniquely helps busy families make sure that their dog or cat is protected. Unlike some products, a dog or cat does not have to absorb or ingest the ingredients in Seresto to protect against fleas and ticks. The Seresto collar is a topical product that works through contact of pests with an animal's hair coat and skin. Seresto repels and can kill fleas and ticks before they bite so they do not have the chance to infect pets and their families.

Fleas and ticks are not just annoying and uncomfortable for pets and people. They can carry parasites like tapeworms and transmit potentially serious diseases that can infect pets and humans, including Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, and plague.

Unfortunately, the incidence of flea- and tick-borne diseases is on the rise. According to findings released by the Centers for Disease Control ("CDC") in 2018, the number of reported tick-borne diseases in people in the United States had more than doubled over 13 years. New diseases carried by fleas and ticks are emerging in the United States, and existing ones are expanding their range across regions of the country. Climate change is likely to accelerate this trend. Seresto is highly effective at protecting against the fleas and ticks that can carry these diseases. Indeed, the CDC had requested that the EPA approve Seresto to help combat Rocky Mountain spotted fever.

II. Safety and Toxicity Studies

The EPA relied on a number of safety and toxicity studies as part of its lengthy and comprehensive approval process for Seresto. Those studies, and ones conducted since then, continue to support a strong safety profile for Seresto and its active ingredients. While any product has potential side effects, the more than 15 companion animal safety studies and more than 60 toxicity studies of Seresto and its active ingredients to date indicate that the product does not pose unreasonable risks.

To confirm the safety of Seresto, more than 525 dogs and more than 525 cats were studied actually wearing the collar. Some animals in these studies wore up to five Seresto collars at a time. There were no treatment-related adverse effects seen in any of these pre-registration studies, except for some mechanically induced local reactions (e.g., hair thinning under the collar), which typically occurred in animals wearing more than one Seresto collar at a time. Safety studies conducted since the time of registration have corroborated the strong safety profile of Seresto.

Dogs or cats wearing Seresto absorb very little of the active ingredients, in amounts far below the levels toxicity studies predict would cause them adverse effects. The same is true for people who come into contact with the collar, as the amounts of the active ingredients in Seresto released over time are also much less than the amounts expected to cause any issues.

III. Incident Reports

Incident reports do not equal causation. Elanco is committed to cooperating with the EPA and to being transparent with respect to science-based data concerning our products, and the company takes its incident reporting obligations very seriously. We recognize the impression that can be left when viewing the total number of incident reports potentially associated with Seresto without any context or analysis, and we know that families need to be comfortable with the safety of the products they use on their beloved pets. That is why it is so important to correct misconceptions yielded by raw numbers of incident reports, which are submitted to the EPA without regard to actual causation. While the raw numbers of incident reports may seem high without context, rigorous and science-backed analyses of the incident report data support a favorable safety profile for Seresto.

We encourage veterinarians and pet owners to report adverse events and make it easy to do so. Adverse incidents can be reported in several ways. Consumers or veterinarians may report incidents to Elanco through its 1-800 phone line, which is staffed by veterinarians and certified veterinary technicians employed by Elanco and by an adverse event call center contracted by Elanco. That phone line is monitored 24 hours a day, seven days a week, and 365 days a year. Incidents may also be reported to organizations such as the National Pesticide Information Center, or directly to the EPA. Elanco provides the incident reports it receives to the EPA as required by law.

Per guidance by the EPA, an adverse event must be reported to the agency regardless of whether the incident suggests that the product actually caused the event or even whether the product is theoretically capable of causing it. While incident reports contain information regarding a potential adverse event or health issue, they do not provide an analysis of what caused the event.

I know all too well that dogs and cats have all types of health issues throughout their lives. For the owners who use the Seresto collar continuously as directed, these health issues likely occur while the collar is being worn. It is understandable for concerned pet owners and treating veterinarians to wonder whether a pet's illness has something to do with the Seresto collar – which unlike many other flea and tick preventatives and treatments and medicines is constantly visible on a pet – even when they are entirely unrelated. The vast majority of these reports involve minor or moderate issues or events, like irritation beneath the collar. And with more than 33 million Seresto collars sold from 2012 through 2021, these reports can add up, even when they represent an extremely small proportion of the Seresto collars in use.

Elanco is made up of veterinarians, pet owners, and people committed to animal health, and we understand how difficult losing a pet can be. We recognize the number of incident reports filed involving pet deaths, and we are saddened to hear about each one, no matter the cause. We treat reports of pet deaths with great seriousness, and we evaluate such reports extensively. Analysis done by Elanco's pharmacovigilance scientists on the available incident report data have found no deaths that were probably caused by the active ingredients in Seresto. For this and other reasons, I must respectfully point out that the Subcommittee's title for this hearing, suggesting that 2,500 pet deaths are "linked" to Seresto, insofar as it implies some kind of causation, is simply not accurate.

For context, more than 7 million Seresto collars were sold in the United States during 2020. Assuming each collar was worn for the full 8 months, statistics suggest that approximately 365,000 of those 7 million pets would be expected to die of various causes during that 8-month period, whether they were wearing a Seresto collar or not. By contrast, in 2020, Elanco received fewer than 200 reports involving the death of an animal wearing a Seresto collar. Our pharmacovigilance team has reviewed each of those reports and has not identified any death that was caused by the active ingredients in the collars.

Our pharmacovigilance team has identified some pet deaths regrettably related to the collar becoming trapped on a structure or object, a potential issue for any pet collar, even those with a quick-release safety mechanism like Seresto. While these events do not involve Seresto's active ingredients, we take them very seriously and strongly encourage educational efforts to ensure safe collar usage. Additionally, we are aware of issues involving harms from counterfeit Seresto collars, and we are actively working to keep potentially dangerous counterfeit products off the market.

The reports for events involving people follow a similar pattern as those involving pets. The incident reporting rate is very low when evaluated on a per-collar basis. The vast majority of reported incidents were minor or moderate, and there is a lack of even plausible causation for most of the limited number of major incidents, none of which were deaths.

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No product is without risk. For instance, a broad class of widely used oral flea and tick preventatives is associated with seizures and muscle tremors. What matters is whether those risks are reasonable, particularly in light of the benefits. Numerous studies and the incident report data for Seresto demonstrate that the product does not pose an unreasonable risk and has a strong safety profile.

Elanco has a team made up of veterinarians and experts who closely evaluate causation with respect to each major event, including by following up when possible with the person who reported the event. Those careful analyses demonstrate that the overwhelming majority of

reported major events are not even possibly caused by Seresto's active ingredients. They also demonstrate that the adverse events numbers for Seresto are in line with other flea and tick preventative products, when adjusted for sales and the eight-month lifespan of Seresto.

The risk-benefit profile is even more stark when accounting for the significant benefits of Seresto. As the incidence of serious and potentially fatal flea- and tick-borne diseases increases across the country, Seresto offers pet owners a much-needed option for protecting their pets. Given the robust scientific evidence for Seresto's strong safety profile, we are proud to stand behind the product.

Thank you very much for your time, and I look forward to taking your questions.