



# Do Animal Health Companies Need to Learn How to Speak to Animals?

## The Rise of Failure-to-Warn Claims



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# Introductions



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Kathleen Hardway, a co-chair of Venable's Product Liability and Mass Torts Group, represents pharmaceutical, vaccine, and medical device manufacturers in product liability and mass tort litigation in state and federal courts nationwide. She also represents a chemical manufacturer in personal injury claims involving the manufacture and sale of certain PFAS chemicals.



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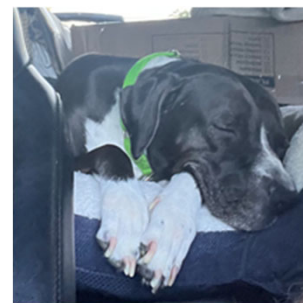
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Jason Rose, co-chair of Venable's Product Liability and Mass Torts Group, is an experienced litigator who focuses on the efficient resolution of pharmaceutical and medical device litigation, business torts, and commercial contract disputes. Jason has represented a number of companies in different capacities, including coordinating counsel, expert witness development, briefing substantive and *Daubert* issues, company defense and witness development, fact and expert depositions, and trial support.

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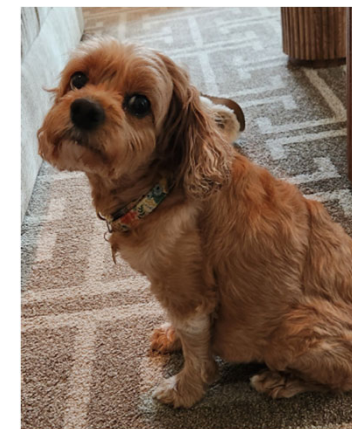
**Coraline**



**Cupcake**



**Beau**



**Lola**

# Introductions



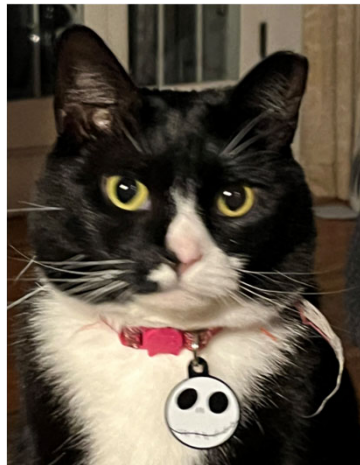
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Sarah Louise Scott focuses on product liability and mass tort litigation. Sarah’s litigation experience extends from arbitration hearings to federal courts, and from pre-litigation strategy to appeals. She has represented pharmaceutical, heavy equipment, and other manufacturers in product liability disputes. Sarah has developed experts in areas ranging from blood-brain barrier pharmacology to mechanical engineering.



**Orange Snow**



**Queen Kong**



## TriPaw Health

*Complete Care, From Nose to Tail*

**Nutrition | Animal Care | Therapeutics**

TriPaw Health is a diversified animal healthcare company delivering science-backed solutions that support the full spectrum of animal wellness.

From nutrition and everyday care to veterinary services and prescription therapeutics, TriPaw serves pets and their people with innovation and integrity.

TriPaw sells directly to consumers through retail platforms and to veterinarians through representatives who visit individual clinics, offer outings such as dinners or games, and other channels, such as marketing at veterinary conferences.

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## From the Headlines

# Class-action lawsuit filed against producer of Seresto flea and tick collars

**Johnathan Hettinger** Midwest Center for Investigative Reporting

March 26, 2021, 12:18 p.m. ET



## Paylean: Drug in Conventionally Raised Meat Linked to Cancer and Heart Disease

Tuesday, March 17, 2009 by: Barbara L. Minton  
[Paylean](#), [health news](#), [Natural News](#)

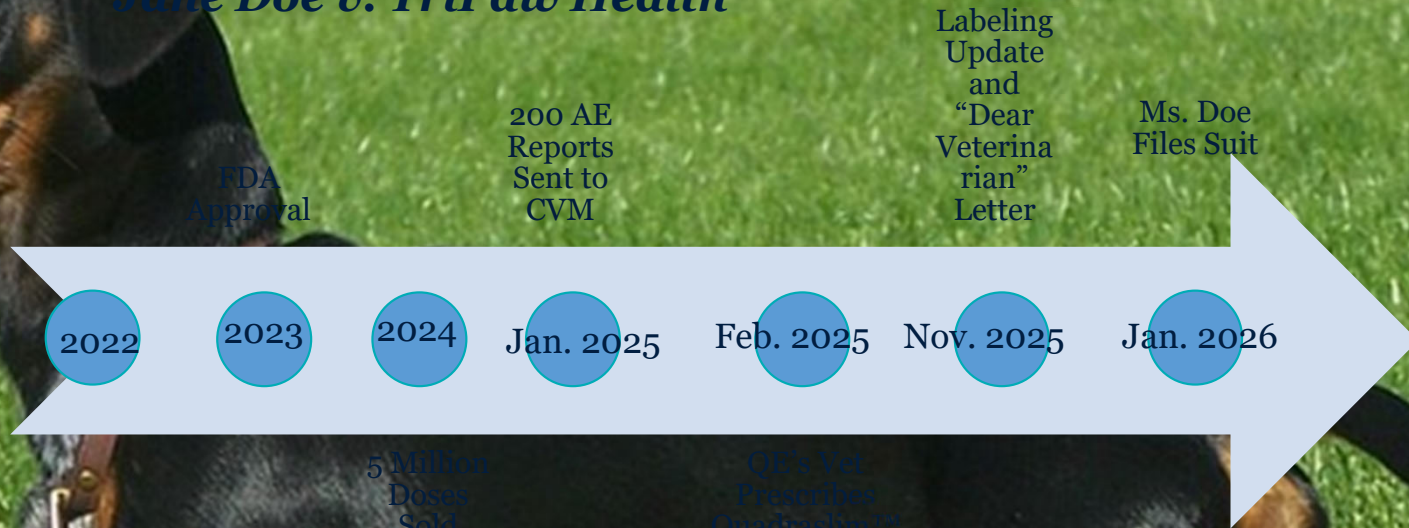
## Zoetis defeats failure-to-warn suit over canine arthritis drug

2026 PRODDBRF 1516 • By Eilis Murphy

*Animal Medication Co. Sued Over Dog Arthritis Treatment Risks*

# The Journey to a Quadraslim™ Lawsuit

*Jane Doe v. TriPaw Health*



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## Jane Doe v. TriPaw Health--The Plaintiffs



Queen Elizabeth, AKA "Lizzie"



Jane Doe

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## Jane Doe v. TriPaw Health—The Claims

- Violation of the New Jersey Consumer Fraud Act
- Violation of the New Jersey Products Liability Act – Failure to Warn
- Breach of Implied Warranty
- Negligence
- Unjust Enrichment

**BROKE MY TRUST.  
BROKE MY WAISTLINE.**

**TriPaw**  
(firocoxibite)  
oral chewable tablets

**FAILED  
OUR DOGS.  
FAILED US.**



**PLAINTIFF**

**GOOD BOY.  
SEEKING JUSTICE.**

**CLAIMS:**  
FAILURE TO WARN

EXHIBIT A  
WEIGHT GAIN.  
EMOTIONAL DISTRESS.  
VETERINARY BILLS

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**DAMAGES**

## Plaintiff's Burden

Product Use

Injury

Mechanism of Action

Proximate Cause

Damages



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## Defenses

Learned Intermediary Doctrine

Preemption

No General Causation

No Specific Causation

No Damages

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# Learned Intermediary Doctrine

Defenses against Failure-to-Warn Claims

## Application to Date

- **Haste v. American Home Products Corp.**, 577 F. 2d 1122 (10th Cir. 1978)  
Failure-to-warn claims against a bovine vaccine manufacturer
- **Osburn v. Anchor Laboratories, Inc.**, 825 F.2d 908 (5th Cir. 1987)  
Failure-to-warn the administrator of a bovine prescription drug

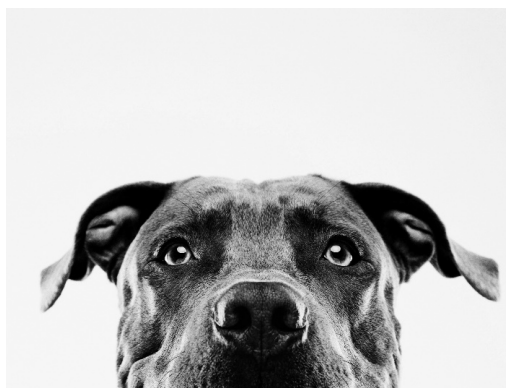


# Learned Intermediary Doctrine

Defenses against Failure-to-Warn Claims

## Recent Developments

- **Hartney v. Zoetis, Inc.**, 2025 WL 2924661 (D. N.J. 2025)  
Includes failure-to-warn claims against manufacturer of a prescription canine drug
- **Stevens v. Zoetis, Inc.**, 2026 WL 837353 (D. Nev. 2026)  
Failure-to-warn claims against manufacturer of a prescription canine drug



# Preemption

Defenses against Failure-to-Warn Claims

## Preemption? Depends

- Is it prescription?
  - Regulated under FDCA by the FDA/CVM
  - Regulations governing changes to prescription animal drugs map onto those for prescription human drugs
    - Compare: 21 C.F.R. § 314.70 and 21 C.F.R. § 514.80



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# Preemption

Defenses against Failure-to-Warn Claims

## Preemption? Depends

### Labeling Changes:

- Major Change
  - Prior Approval Supplement
- Moderate Change
  - Changes-Being-Affected Supplement
- Minor Change
  - Annual Report

*Can the company unilaterally change the label?*

# Preemption

Defenses against Failure-to-Warn Claims

## Preemption? Depends

- Suit against TriPaw—elements to consider:
  - Already in the label?
  - New information?
  - Has CVM already rejected revision?
  - Location on label?



## Causation—Plaintiffs’ Burden of Proof

### Causation Two Ways:

- General
  - can it cause an event?
- Specific
  - did it cause this event in this dog?

*A causal mechanism and causal connection must be demonstrated for each canine plaintiff*



## The Shifting Scope of Damages

- Historically:
  - Animals=property
  - Damages—replacement value



## The Shifting Scope of Damages

- Now:
  - Animals=property(?)
  - Damages—replacement value????
    - + sentimental value?
    - + loss of companionship?
    - ???





# TriPaw Wins Dismissal of Quadraslim™ Suit

ANY QUESTIONS?



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