Barking Up the Right Tree: Navigating Enforcement Risks in Animal Health

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Valerie Cohen
Partner | +1 212.370.6205 | vcohen@Venable.com

W. Warren Hamel
Partner | +1 410.244.7563 | wwhamel@Venable.com

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Introductions

Valerie Cohen
Partner
+1 212.370.6205
vcohen@Venable.com

Valerie Cohen is an accomplished litigator with nearly two decades of experience representing clients in highly regulated industries—particularly healthcare and financial services—in complex civil litigation, regulatory investigations, and enforcement proceedings. As a leader in Venable's healthcare practice, Valerie advises healthcare insurers, pharmaceutical companies, hospitals and health systems, health technology firms, and financial institutions on False Claims Act (FCA) litigation, internal and government investigations, whistleblower matters, and compliance redesign. Her practice spans issues involving managed care reimbursement, pharmacy benefits, medical devices, telehealth, and prescription drug pricing.

W. Warren Hamel
Partner
+1 410.244.7563
wwhamel@Venable.com

Warren Hamel chairs Venable's Investigations and White Collar Defense Practice. Warren conducts internal investigations and aggressively defends individual, corporate, and nonprofit clients in a wide range of white collar and environmental criminal defense and civil enforcement litigation. Clients also seek his advice on compliance and internal controls, including information governance, managing whistleblower issues, FCPA compliance, and Sarbanes-Oxley–related matters. Before joining Venable in 2002, Warren served as an assistant U.S. attorney for the District of Maryland and was chief of Environmental Crimes and Enforcement for that office.

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Agenda

- Animal Health Criminal Enforcement Trends
- Animal Health Civil Litigation Trends
- Potential False Claims Act Theories in Animal Health
- TriPaw Case Study
- Animal Health Compliance Program

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Criminal Enforcement Trends

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Animal Health Criminal Enforcement Landscape

- Animal Health Prescription (Rx) Drug diversion
  - **Opioids –** FDA warns veterinarians of opioid diversion: "In the event you encounter a situation involving opioid diversion or clients seeking opioids under the guise of treating their pets, you should have a safety plan in place."
    - **"Dr. Shopping":** Taking pet to multiple vets to obtain opioids has prompted some states to include vets in Prescription Drug Monitoring Programs (PDMPs).
    - **Pretextual Injury:** Pet owners intentionally harming their animals to obtain painkillers (as reported here).
  - **Xylazine**—Common animal tranquilizer, FDA approved only for veterinary use, particularly on large animals; has sedative, analgesic (pain reliever), and muscle relaxant effects that make it susceptible to diversion for human use.
- **Misbranding / distribution-chain integrity** – Distribution from non-pharmacy locations to end-users and shipments to non-authorized locations are deemed "misbranded."

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Animal Health Criminal Settlements

- **Corporate criminal settlements** typically include significant forfeitures, fines/penalties, probation, go-forward compliance requirements, and even oversight (Memorandum of Agreement).
- **Individual criminal settlements** often include incarceration.
- **All Veterinary Supply, Inc. (AVS) January 2026 ~$767K DOJ (E.D. Penn.) Settlement**
  - AVS sold xylazine to two wholesalers in Puerto Rico. AVS triggered enforcement attention by exceeding its state permit, which excluded sales to other wholesalers. The government, including the Drug Enforcement Administration (DEA) and Food and Drug Administration (FDA), traced AVS-supplied xylazine to the illicit drug supply in Philadelphia.
  - AVS pleaded guilty to one count of introduction and delivery of misbranded drug, **xylazine**, into interstate commerce and was sentenced to three years of probation, an $18,000 fine, and forfeiture of $748,507.25, which approximated AVS's gross profit from the illicit sales.

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Animal Health Criminal Settlements (cont'd)

- **Midwest Veterinary Supply $11M+ 2023 DOJ Settlement (W.D. Va.)**
  - Midwest Veterinary Supply, a Minnesota-based company that supplies prescription drugs for animals to veterinarians, farms, feedlots, and other businesses, agreed to pay $11+ million in criminal fines and forfeiture and one-year probation to resolve drug misbranding allegations. According to court documents, from 2011-2021, Midwest shipped prescription drugs from their non-pharmacy locations throughout the US to end-users that were not authorized to receive prescription drugs. In addition to forfeiting $10,150,014 (the value of misbranded drugs Midwest shipped to end-users), Midwest paid $1,000,000 to the Virginia Department of Health Professions, and a $500,000 fine.
- **Animal Health International 2020 $52M+ DOJ Settlement (W.D. Va.)**
  - Animal Health International Inc., a Colorado corporation that obtains prescription drugs for animals from manufacturers for further distribution to veterinarians, farms, feedlots, and other facilities, pleaded guilty in February 2020 to introducing and causing the introduction and delivery into interstate commerce of veterinary prescription drugs that were misbranded. It was ordered to forfeit over $46 million, pay $1 million to the Virginia Department of Health Professionals, pay a $5 million fine, and serve one-year probation.
  - Its corporate parent, Patterson Companies, Inc., entered into a non-prosecution agreement in which it committed to enhance its compliance program and fully comply with the law.

Criminal Enforcement – Potential Consequences

- Financial forfeitures
- Penalties – potentially to state and/or regulatory bodies
- Probation
- Go-forward compliance enhancements – suspicious order monitoring (SOM) system, mandatory employee training, self-audits of compliance with federal, state, and local controlled substance statutes and regulations
- Ongoing oversight / monitoring
  - E.g., Memorandum of Agreement (MOA) allowing DEA to audit a company's suspicious order monitoring (SOM) system, mandatory employee training, and overall compliance with federal, state and local controlled substance statutes and regulations
- Downstream state licensure proceedings
- Corporate parent non-prosecution agreement risk
- Adverse business impacts / reputational harm

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Civil Litigation Trends

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Animal Health Civil Litigation Landscape

- Humanization of Pet Care
  - Raw diets, dietary supplements, SSRIs (e.g., Prozac), CBDs, vet-formulated meal toppers, wearables (collars), AI diagnostic software, vaccine hesitancy
  - *N.Y. Times,* Sept. 13, 2025, The Wellness Industry Carves Out a New Niche: Pets
- Telemedicine – laws vary state to state
- State licensure boards – enforcement by state boards of pharmacy and vet medicine
- Class actions – antitrust, products liability, failure to warn
  - Join Venable products liability team for deeper dive
    - May 20, 2026: Do Animal Health Companies Need to Learn How to Speak to Animals? The Rise of Failure-to-Warn Claims, Jason Rose and Kathleen Hardway

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Animal Health Civil Litigation – Exemplars

- **Diagnostic software**
  - In January 2026, two L.A.-based veterinary clinics filed a complaint alleging that pet healthcare diagnostics company Idexx Distribution Inc. fraudulently concealed a software algorithm defect that allegedly led to at least 40 dogs dying and hundreds of animals getting sick or missing treatment due to false diagnostic testing. *ATSC Melrose Inc. v. Idexx Distribution Inc. et al.*, No. 26STCV00414 (Cal. Sup. Ct, L.A. Cty., filed Jan. 7, 2026).
- **Consumer Class Action Settlements**
  - **Antitrust.** In 2025 and 2026, several defendants resolved antitrust consumer class allegations that Elanco Animal Health, a global animal health pharmaceutical company, paid pet supply retailers incentives or rebates conditioned on not stocking generic versions of its Advantix topical flea and tick prevention product, thereby unlawfully restraining competition. *See, e.g., Susan Kraus-Silfen v. Elanco Animal Health Inc.*, No. 1:25-cv-00168 (S.D. Ind.); *Tracy Spradlin v. Elanco Animal Health Inc.*, No. 1:24-cv-01299 (S.D. Ind.).
  - **Products Liability/Failure to Warn**. In 2025, final approval was granted to a ~$15 million settlement to resolve allegations—without admission of wrongdoing—that Seresto flea and tick collars caused pet injuries and deaths and that defendants failed to provide adequate warnings regarding potential risks. *See In re: Seresto Flea and Tick Collar Marketing, Sales Practices and Products Liability Litig.*, MDL No. 3009, Lead Case No. 1:21-cv-04447 (N.D. Ill.).

Potential Novel False Claims Act Theories

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Animal Health – False Claims Act Exposure?

- **False Claims Act (FCA)**, 31 U.S.C. § 3729, *et seq*. – Imposes liability on any person who knowingly submits, or causes the submission of, false claims for government payment, makes false statements material to the government's payment decision (including falsely certifying compliance with statutory, regulatory, or contractual requirements), or improperly avoids obligations owed to the government.
  - **Consequences:** Treble damages, per-claim civil penalties, exclusion from federal healthcare programs, potential parallel criminal liability.
  - **Qui tam relator (a.k.a. whistleblower) actions:** FCA allows private individuals to stand in the government's shoes and bring FCA actions to redress harm to the government.
- Most states also have their own state False Claims Act.
- FCA has not historically been a major enforcement tool in animal drug, veterinary care, or device cases because animal health services and products do not typically involve reimbursement by federal or state funding, as with Medicare or Medicaid.
  - *However,* legal architecture for expanding the FCA into animal health appears in place—e.g., federal grant funding and DEA compliance certifications.

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False Claims Act – Exemplar

- **Duke University $112.5M DOJ & qui tam settlement (March 2019)**
  - Duke University agreed to pay the government $112.5 million to resolve allegations that between 2006 and 2018, Duke knowingly submitted and caused to be submitted claims to the National Institutes of Health (NIH) and Environmental Protection Agency (EPA) that contained falsified or fabricated data or statements in thirty (30) grants, causing the NIH and EPA to pay grant funds they otherwise would not have.
  - The government alleged that the results of certain research related to mice conducted by a Duke research technician in its Airway Physiology Laboratory, as well as statements based on those research results, were falsified and/or fabricated.
  - The settlement also resolved a qui tam suit that was first filed under seal in May 2013 and unsealed in August 2016 after DOJ declined to intervene. *U.S. ex rel. Thomas v. Duke University, et al.*, No. 1:17-cv-276 (M.D.N.C.).

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Potential False Claims Act Theories

- **Presentment**: ". . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . ."
- **False Record or Statement:** ". . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . ."
- **Conceals Obligation to Repay (a.k.a. Reverse False Claims Act)**: ". . . knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government . . . ."
- **False Certification**
  - **Express:** Certifying compliance with FDA and DEA requirements in federal research grant application
  - **Implied:** Failing to disclose non-compliance with material legal/contractual requirements in research grant application

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Risk Mitigation – Practice Tips

- If applying for government-funded grants to support research involving animal health, beware that misrepresentations, falsified research, or certifying compliance when on notice of non-compliance can trigger FCA liability.
  - **Pro Tip:** Consider making qualified certification.
  - **Pro Tip:** Consider obtaining compliance attestations
- If entity receives reports of concerns over misuse of federal funds, evaluate those concerns (don't ignore or issue conclusory "no"), launch investigation if appropriate, document, and follow up.
  - **Pro Tip:** Even if original application did not raise FCA risk, failing to follow up on reported concerns may create reverse FCA exposure.

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TriPaw Case Study

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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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TriPaw – Regulatory Risk Accompanying Growth

- As TriPaw expands its clinical operations, animal wellness products, and prescription offerings, it may face new regulatory risks.
- What, if any, risks are presented in the following scenarios . . .

- **PLEASE VOTE!!**

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TriPaw Scenario 1: Children's OTC Medication

- A veterinarian at TriPaw's veterinary clinic recommends children's over-the-counter (OTC) medication for a pet dog's fever. Does this raise potential concerns under:
  - (a) Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*.
  - (b) Animal Medicinal Drug Use Clarification Act of 1994, which amends the FDCA, implemented at 21 U.S.C. § 360b(a)(4), (5) and 21 CFR Part 530
  - (c) Both
  - (d) Neither

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TriPaw Scenario 2: Telemedicine

- TriPaw has expanded its clinical offerings to telehealth veterinary care. A vet licensed only in New York is treating via telehealth a pet located in Florida. Does this raise potential concerns under:
  - (a) State licensure laws
  - (b) Veterinarian-client-patient relationship (VCPR)
  - (c) DEA registration
  - (d) All

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TriPaw Scenario 3: Federal Rural Grant

- TriPaw has received a $1 million federal grant to open veterinary clinics for retired military working dogs (MWDs)—a.k.a. K-9s—in remote rural locations. A TriPaw employee at one of the clinics has emailed #TriPaw Compliance, reporting concerns about some of the grant funds being used for the annual vet office holiday party. Does this raise potential concerns under the False Claims Act?
  - (a) Yes
  - (b) No
  - (c) Maybe

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Animal Health Compliance Program

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Compliance Pro Tips

- Develop Corporate Culture of Compliance
- Maintain and Regularly Evaluate Compliance System
  - Employee and vendor training
  - Suspicious order monitoring (SOM) system
  - Self-audits of compliance with federal, state, and local controlled substance statutes and regulations
- Treat Animal Health Like Regulated Pharma — Because It Is
  - FDCA governs approval, labeling, and distribution
  - DEA enforces Controlled Substances Act
  - DOJ can bring criminal misbranding and diversion cases
- State regulatory licensure reviews
  - State boards also actively regulate VCPR and telemedicine

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Compliance Checklist

- ❑ Build compliance infrastructure proportionate to regulatory exposure
- ❑ Protect the distribution chain
- ❑ Document extra-label use
- ❑ Manage telemedicine expansion
- ❑ Scrutinize rebate and exclusivity programs
- ❑ Substantiate marketing claims
- ❑ Evaluate grant certifications against FCA risk
- ❑ Adopt disciplined Gifts and Entertainment policies
- ❑ Validate diagnostic software
- ❑ Maintain a cross-functional compliance culture

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Questions?

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Thank you (woof woof)

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Upcoming Webinars in the Series

- **April 16, 2026:** Deals and Dollars: Transactions and Financing in Animal Health
  - *Speakers: Jim Nelson (Corporate – San Francisco) and Bill Haddad (Corporate – NY)*

- **May 20, 2026:** Do Animal Health Companies Need to Learn How to Speak to Animals? The Rise of Failure-to-Warn Claims
  - *Speakers: Kathleen Hardway (Product Liability & Mass Torts – Baltimore) and Jason Rose (Product Liability & Mass Torts – Baltimore)*

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