

Our view on drug safety: FDA vet tracks dog deaths, gets smeared in the process

Tale of ProHeart 6 raises questions about who calls the shots at agency.

[ProHeart 6](#) — a controversial heartworm drug for dogs — came back on the market last week, almost [four years after it was pulled](#) when hundreds of dogs died and thousands more suffered adverse reactions. Ordinarily, this might be of interest mainly to pet owners and veterinarians. But this is much more than a dog story.

(Photo - Hampshire: Questioned heartworm shot / Leslie E. Kossoff, AP)

During the process that took ProHeart 6 off the market, the drug's maker [investigated and denounced a Food and Drug Administration scientist](#) who gathered the damning data. And instead of protecting its scientist, the FDA booted her off the case and tried to have her criminally prosecuted.

It's a disturbing tale for anyone who relies on pharmaceutical companies and the FDA to ensure that medicines for animals and humans are safe, one that raises questions about the conduct of a major corporation and its federal regulator.

The story begins in 2001, when ProHeart 6 came on the U.S. market. It was regarded as a breakthrough. Veterinarians could inject it once every six months, replacing the once-a-month pill people gave — or often forgot to give — their dogs to ward off potentially deadly heartworms. Though many dogs did fine on ProHeart 6, others had dangerous complications. Eventually, the FDA says, 500 to 600 dogs died and there were "adverse" reactions, including seizures and uncontrolled bleeding, in 5,500 to 6,000.

In 2004, the FDA pushed ProHeart 6 manufacturer Fort Dodge Animal Health, a subsidiary of pharmaceutical giant Wyeth, to [remove the drug from the market](#). Wyeth argued that the drug was safe but agreed to remove it. Then it fought back.

The company [targeted Victoria Hampshire](#), a veterinarian and FDA safety officer who collected and analyzed the adverse drug reports on ProHeart 6. Wyeth hired investigators who dug up information on Hampshire's home, her tax records and a veterinary website where a handful of her friends and veterinary clients could buy drugs and pet supplies. (It's not uncommon for FDA's vets to practice medicine part-time in their off hours.) Wyeth executives then alleged that Hampshire had a conflict of interest.

Without telling Hampshire what was going on, the FDA took her off the ProHeart 6 case and began an internal investigation that culminated when FDA investigators asked the U.S. attorney in Maryland to criminally prosecute her. It took one day for the U.S. attorney to sort through the flimsy referral and refuse to press charges. The FDA [eventually exonerated Hampshire](#), and she now works at the agency in a different job.

ProHeart 6, meanwhile, is back on the market. The manufacturer and the FDA say the drug is safe, free of the solvent residue thought to have caused the earlier problems. But the drug is being administered under a strict "[risk minimization](#)" plan that applies to only a small number of FDA-approved drugs for animals and humans.

We know much of this story not because Wyeth or the FDA disclosed it voluntarily, but because a persistent [investigation by Sen. Chuck Grassley](#), R-Iowa, dragged it out of them. The probe revealed that Wyeth officials had easy, undocumented access to the FDA to lobby for ProHeart 6 and attack Hampshire. FDA managers seemed more interested in placating Wyeth than in dealing fairly with one of its scientists.

The most troubling aspect of this is the effect it will inevitably have on other FDA safety officers. After seeing what can happen when someone gathers evidence that a drug is unsafe, what safety officers wouldn't think twice about risking their careers by antagonizing powerful companies?

That's a terribly dangerous way to run a drug safety process that can ultimately mean life or death to animals and humans alike.

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