

Public Hearing on Final Rule Implementing PDMA
Food and Drug Administration
Rockville, Maryland
October 27, 2000

Comments from:

Charles F. Franz, DVM

President, American Veterinary Distributors Association
Suite 1200, 106 West 11th, Kansas City, MO 64105

Director of Professional Services, NLS Animal Health
11407 Cronhill Drive, Owings Mills, MD 21117

Thank you for allowing me to testify on a regulation that without modification will cripple the supply of prescription drugs in our nation. I will address issues that affect the animal health aspects of this regulation. I speak today on this issue from three perspectives - (1) as a veterinarian, concerned about the availability and cost of medications to treat companion animals; (2) as an employee of NLS Animal Health, a veterinary distributor based in Maryland servicing veterinarians in 75% of the country; and, (3) as President of the American Veterinary Distributors Association, a trade association of animal health companies representing the vast majority of our industry.

With extensive industry consolidation in the past decade and the decrease in the number of distributors to which pharmaceutical manufacturers will sell their products, available sources from which veterinarians may purchase drugs have diminished. The need for secondary wholesalers of pharmaceuticals continues to increase. Veterinarians must have human labeled drugs readily available since, in many cases, there is no FDA

1015 '00 OCT 27 P3:37

92N-0297

TS2

approved veterinary-labeled drug to treat numerous companion animal illnesses. Veterinary distributors fill this need by providing human label drugs to veterinarians. These drugs are primarily purchased from various human pharmaceutical distributors, some are authorized distributors and some are not. To require the distributor to pass pedigree information on to the veterinarian would prohibit veterinary distributors from supplying most of these products. The veterinarians, their clients, and the animal patients would all suffer. In a society that expects, demands, and deserves cutting edge care for its 110 million dogs and cats, it is essential that these products remain readily available. If veterinary distributors were no longer able to carry these products, larger authorized distributors and drug manufacturers would not be able nor would they want to carry the cost of servicing the 22,000 U.S. veterinary hospitals. Secondary wholesalers are essential in the efficient distribution of these pharmaceuticals. To eliminate or curtail these secondary wholesalers would not only reduce price competition but also reduce the ability of the drug distribution system to effectively move products to the areas of need. The pedigree information would be impossible to provide since the distributor's source of many of these products would not be required to provide the pedigree. More importantly, this burdensome paperwork is unnecessary to assure the safety of the drugs within the supply chain. Existing regulations already require that complete records of receipt, distribution, and other disposition be retained by wholesale distributors and available for inspection by FDA, state authorities, and law enforcement.

Questions have surfaced asking whether deleting the pedigree requirement would cause an increased risk of distribution of counterfeit, expired, adulterated, misbranded, or

otherwise unsuitable drugs. The language proposed in HR-4301 provides additional safeguards in the form of written certification from an unauthorized distributor that the drugs were first purchased by an authorized distributor. This certification would be provided by unauthorized distributors to customers and would be subject to strict criminal penalty if falsified. This bill maintains the integrity and standards created by the PDMA without the burdensome, impractical pedigree requirement. There is no increase in risk to the consumer by allowing this more practical solution to replace the pedigree.

With the suggestion that authorized distributors be required to provide pedigree information, substantial additional costs would ultimately be passed on to the consumer. As the current election process winds to a close next week, we are all aware of extensive dialog this year concerning the cost and availability of drugs to consumers and patients. Do we want to place unnecessary burdens on distributors that can only increase those costs and provide no real benefit to the public? The veterinary distribution industry already operates under extremely low margins. There is no room for any absorption of increased costs; those costs likely would be passed entirely on to the consumer.

In the veterinary side of this business, it is essential that distributors be recognized as authorized strictly based on the presence of sales between the manufacturer and distributor. Very few relationships between these two parties are consummated by a written agreement. To require written agreements as evidence of an authorized distributor relationship would further drive distributors out of business. This would certainly result in higher prices and decreased availability of drugs to the consumer. The

PDMA is plain in defining an authorized distributor as one that has "an ongoing business relationship." There is no need for FDA to change this language.

The issues surrounding the assurance of a good supply of safe and effective drugs in the marketplace, whether for humans or animals, is of utmost concern to all. Our industry must work with the regulatory authorities to insure that this is the case. However, the final rule on PDMA, as published in the Federal Register on December 3, 1999, places unnecessary burdens on the pharmaceutical industry. There is no possible good to come from severely limiting competition in this industry. We must continue to improve the supply of safe, effective drugs available to the consumer. These drugs must be available from multiple sources if we are to have the price competition that is so important to our economic system. I believe adoption of language similar to that proposed in HR-4301 would provide sufficient safeguards to assure safety in pharmaceuticals, while insuring the availability of the drugs that consumers need to maintain health and viability for themselves and their pets. Your consideration in revising the final rule on the PDMA is strongly urged and sincerely appreciated.