GADA

GENERIC ANIMAL DRUG ALLIANCE

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Federal Trade Commission
Office of the Secretary, Room H-113 (Annex X)
600 Pennsylvania Avenue NW
Washington, DC 20580
Electronic Submission –
https://ftcpublic.commentworks.com/ftc/petmedsworkshop

Re: Pet Medications Workshop, Project No. P12-1201

The Generic Animal Drug Alliance (GADA) is an independent professional trade organization that represents the interests of generic animal health companies before Federal regulatory agencies and Congress. Our member companies are focused on the development, FDA approval, and marketing of generic animal drugs.

Generic animal drugs provide significant benefits for consumers by providing cost-effective alternatives to name brand pioneer animal drugs. As with human generic drugs, generic animal drugs are subject to the FDA approval process, during which application sponsors must demonstrate that the drugs are safe and effective for their intended use and are manufactured under the same quality standards that apply to all FDA-approved drugs.

GADA appreciates this opportunity to comment for the FTC's Pet Medications Workshop and to provide information on the distribution practices in the pet medications industry. In particular, these comments focus on pet medication distribution practices as they pertain to prescription generic drugs for companion animals (*i.e.*, those generic animal drugs that can only be dispensed under a veterinarian prescription). We hope that the information provided supports the FTC's efforts to empower consumers to obtain the highest quality and most cost-effective pet medications for their pets, and helps ensure consumers are able to fully benefit from the options provided by generic animal drugs.

Below please find GADA's responses to the questions posed by the Commission pertaining to pet medication distribution practices:

How are pet medications distributed to consumers?

The most widespread channel for distributing animal drugs is through veterinary distributors who in turn supply the many, fragmented veterinary practices in each state. Veterinary distributors are comprised of large, national distributors and smaller, regional distributors. Three national veterinary distributors have an estimated 70% of the market for companion animal drugs distributed to veterinarians in the United States, and market analysts expect continued consolidation of market share by the biggest three distributors.[1]

The most typical distribution arrangement is that a manufacturer sells its products to all three national distributors, and the distributors then market and sell the drugs to veterinary practices across the United States. Sometimes one or more smaller, regional distributors also markets and sells the products to veterinarians; however, the share and reach of the regional distributors is limited to a geographic region or a specific list of veterinary customers. Veterinary distributors typically mark up the prices of prescription drugs by a significant margin to cover the cost of maintaining a sizable sales force to call on veterinary clinics. Some animal pharmaceutical companies also have a national field sales force and choose to market, sell, and distribute their products directly to veterinarians.

Veterinarians purchase animal drugs primarily from veterinary distributors and then dispense (re-sell) the drugs to the pet owners. Some treatments take place in the veterinary practices (such as with an injectable medication), while the majority of drugs are dispensed to pet owners for a prescribed treatment regimen (for example, antibiotic tablets to be dosed at home).

Alternate distribution channels also exist through which pet owners can obtain prescription pet medications, such as via the Internet. The market share of these alternatives is very small compared to sales through veterinarians and veterinary distributors. Informal surveys and anecdotal information from veterinarians suggest that online retailers do not offer much if any discount over veterinarians' prices. The sale of a prescription veterinary drug must be pursuant to a valid prescription, and in the case of online purchases by pet owners it can be harder to verify whether a valid veterinarian-pet relationship exists, and whether a valid prescription was obtained.

Additionally, pet owners may obtain pet medications via retail channels such as human pharmacies, by providing the veterinarians' prescription to be filled. While not previously a widespread mechanism for pet medication distribution, these channels may be becoming more available; however, human retail pharmacies have limited access to FDA approved veterinary pharmaceuticals.

[1] William Blair & Company L.L.C., 2011 Veterinary Survey, page 32.

What are the business rationales for various pet medication distribution practices?

A large number of veterinary practices exist in the United States, and these practices are diverse in both their geography and their practice size. Therefore, it is expensive to call on, market to and ship product to the approximately 25,000 companion animal veterinarian clinics across the United States. From the manufacturer's perspective, utilizing distributors provides a means to distribute their products broadly and take advantage of the efficiencies distributors provide. This is especially helpful for smaller companies, like generic animal drug companies, that cannot afford to distribute products themselves or support national sales and marketing field forces.

How has competition to sell medications to pet owners evolved in light of these distribution practices?

Pioneer drug companies (those selling the original name brand version of an animal drug) can afford to have the sales and marketing personnel and resources needed to sell directly to veterinary customers. However, nearly all pioneer drug companies utilize distributors as well and these large companies represent a significant portion of distributors' business. Therefore, these large pioneer drug companies can have substantial influence over distributors.

As more generic drugs enter the market, pioneer drug companies can utilize this influence over distributors to limit the distribution channels available to generic drug competition. The result is to severely limit veterinarians', and in turn, consumers', options and ability to conveniently purchase generic animal drugs. For example, GADA is aware that at least two large pioneer companies entered into agreements with large national distributors stipulating that the distributors can only purchase the pioneer drugs if they agree not to purchase generic versions of those and other similar drugs, or limit the fees and/or margins earned by the distributor if the distributor offers generics.

These restrictive agreements are unique to animal health distribution channels. We are unaware of any similar restrictions in the distribution of human generic drugs, and generally, large human drug distributors make higher margins from selling, and switching their customers to, generic drugs. While it is expected that veterinary drug distributors would benefit from carrying generic animal drugs, as human drug distributors do, these agreements prevent them from doing so.

How do these practices affect prices to consumers?

These distribution restrictions can limit availability of generic drugs and significantly affect prices to consumers. Generic animal drugs offer safe, effective, high quality, cost-effective alternatives to pioneer animal drugs. The more the availability of generic alternatives is limited by these practices, the more

veterinarians and ultimately consumers are prevented from purchasing these less expensive alternatives and are forced to purchase the higher priced drugs.

The extensive availability and use of human generic drugs over brand name alternatives results in enormous cost savings. In 2011 alone, human generic drugs saved consumers and the nation's health care system $192 billion.[2] GADA believes that for generic animal drugs to generate proportionally similar benefits and costs savings to consumers, the restrictive, anti-competitive distribution practices by these pioneer companies must end.

How do these practices affect product supply and quality?

The restrictions in distribution described not only make generic drugs less available, but force generic companies to seek alternate distribution channels. Some current alternative channels may not have the same assurances as distributors in maintaining the appropriate storage and quality of the product, or may not have the safeguards in place to ensure drugs are dispensed per veterinary prescription. Therefore, the reliable supply and quality of the products may be diminished.

How do these practices affect consumer choice?

Ultimately, practices that restrict mainstream distribution channels for generic drugs limit pet owners' ability to access quality products at the most reasonable prices under the advice and consultation of a veterinarian. This puts pet owners in the position of having to make tough financial decisions when it comes to the health and treatment of their pets.

For example, a study conducted for one of our members showed that when a generic NSAID was introduced into veterinary practices, the number of pets treated with an NSAID rose in one year by 14.1%,[3] indicating that having a cost-effective generic option available affected the number of pets able to receive the treatment recommended by their veterinarian. By implication, without the generic option available, some pets that otherwise would have been prescribed the treatment, might not have received it.

How do these practices affect entry into the pet medications market?

Knowing that pioneer drug companies can control a major share of the market via distribution deters developing generic drugs. Developing a generic drug and taking it through the FDA approval process requires significant investment that can cost millions of dollars and take many years. Generic companies are typically much smaller than pioneer companies and have fewer resources and therefore, every

[2] Generic Pharmaceutical Association Report, "Saving $1 Trillion Over 10 Years: Generic Drug Savings in the U.S. (Fourth Annual Edition, 2012)."
[3] VetMetrics private study, June 2010.

product has a significant impact on the bottom line. Furthermore, business owners and investors are reluctant to fund development of generic drugs if they are unable to get their products to the majority of the market.

When generic drug manufacturers are blocked from ensuring that their products reach significant numbers of customers and that their development costs are recouped, they are likely to determine the costs of development outweigh the potential return on investment. The company may choose not to pursue the generic drug, and perpetuate the limitations on the number of generic drug options available to veterinarians and pet owners. If a company has already invested the resources to seek FDA approval of a generic drug and then learns of a distribution blocking arrangement, the company is unable to effectively sell their product and can suffer significant losses that can jeopardize the success of the company.

How do these practices affect innovation in the pet medications market?

In the human pharmaceutical market, branded companies expect generic competition when their patents expire, which incentivizes them to develop new and improved formulations of drugs. In the veterinary pharmaceutical sector, the absence of generic competition allows pioneer companies to continue to raise prices on and market drugs whose patents have expired, decreasing their incentive to innovate.

What efficiencies or inefficiencies are associated with these practices?

The traditional model under which pet owners obtain pet medications has some inherent efficiencies. Distributors offer a wide array of products from numerous manufacturers and in essence, serve as a one-stop-shop for veterinarians. In turn, when pet owners have their pets treated by veterinarians, they can often get the medical advice and services and the medications they need all at the veterinary practice as part of the same transaction. As discussed above, blocking generic drugs from this model means generic drug manufacturers cannot take advantage of these efficiencies and cost-effective generic drug options become less available to pet owners.

What, if any, product safety or counterfeiting issues exist with respect to these practices? Have there been instances in which false or misleading information about product safety risks was disseminated to consumers?

Generic drug manufacturers seek to ensure their products are distributed only through secure supply chains. However, if a veterinarian cannot purchase desired drugs through their usual distributors, they may be forced to obtain them from an alternative source, such as an Internet retailer, that may have obtained the drugs via diversion. Once product is diverted from the manufacturer's authorized distribution channel, product quality and integrity can not be ensured.

Are there other factors that should be considered when analyzing the competition and consumer protection issues related to the distribution of pet medications?

Our member companies find that there is a fundamental lack of awareness about generic animal drugs and the fact that they are safe and effective FDA-approved drugs, manufactured under the same quality standards as pioneer FDA-approved drugs. This stems from the large pioneer companies' domination of distribution channels and is further proliferated when more generic drugs are blocked from these channels. Furthermore, generic drug companies do not have the resources to maintain large sales forces to have the direct communication with veterinarians about their products.

Therefore, as the FTC examines pet medication distribution practices and seeks to ensure the most effective distribution channels are in place to protect consumer choice and price competition, as well as consumers' ability to verify product safety and efficacy, we encourage the FTC to ensure clear distribution channels are available for generic drugs. Generic drugs are FDA approved as equivalent to pioneer products in safety, efficacy, and quality. The lack of full awareness and availability of generic drugs can deprive consumers of this cost-effective option and in turn, can deprive consumers' pets of much-needed treatments.

Sincerely,

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