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Response to Drug Industry Claims on Price Differences Between Human and Animal Drugs

**Prepared by Minority Staff
Special Investigations Division
Committee on Government Reform
U.S. House of Representatives**

Industry Claim: Price differences are caused by differences in research and development costs for human and animal drugs.

The Facts: Differences in research and development costs do not appear to explain the cost differences between identical human and animal drugs.

As with human drugs, it is expensive to research and develop an animal drug. According to the industry:

All animal health products go through a stringent seven-step process that involves testing to discover a product, testing to approve the product, and testing to monitor the product once it's been approved....Bringing an animal health product to market is a complex process. Only one in 20,000 discovered chemicals ever makes it from the laboratory to the farm. And only one in 200 potential drugs makes it through pre-clinical testing and approval.¹

Relative to the size of the markets, drug manufacturers appear to spend approximately as much on research and development of animal drugs as they do on research and development of human drugs. Pfizer, an industry leader in animal drug sales, had revenues of \$1.3 billion from animal drugs in 1998, and spent approximately \$200 million – over 15% of total sales -- on research and development of animal drugs.² Pfizer also spent approximately the same proportion of revenues -- 17% -- on research and development of human drugs.³

According to an industry expert consulted by the minority staff, Dr. Alan Sager of the Boston University School of Public Health:

The observed price differences cannot be explained by differences in research costs. Research is a fixed or sunk cost. Manufacturers do not set their prices based on recovery of these costs. Instead, they set their prices as high as possible in order to maximize revenue and profit.⁴

In the case of the drugs investigated in the congressional study comparing the prices of human and animal drugs, most of the drugs have been on the market for over ten years. Medrol, the drug with the highest price differential, has been on the market since 1960. For these drugs, the manufacturers have already had more than enough time to recoup their research and development costs.

Industry Claim: The minority staff report is flawed because there are only two drugs that are used in the same dose and formula for animals and humans.

The Facts: There are approximately 400 animal drugs that contain active ingredients that are also used in human drugs. In many cases, these drugs are used in a liquid form for animals and a pill form for humans because it can be difficult to administer pills to animals.

In an effort to provide as direct a comparison as possible, the minority staff examined eight brand name drugs that are administered to animals and humans in the same form. There are eight such drugs among the 200 most popular drugs for humans, two of which, Lodine and Vasotec, are administered in both the same form and the same dosage.

The minority staff report also examined six additional brand name prescription drugs that are manufactured by the same or related companies and administered in both the same form and the same dosage to both human and animals: Medrol, Winstrol, Robaxin, Cleocin, Robinul, and Fulvicin. For these eight drugs sold in the same formula and dosage, the human price was 131% higher than the animal price at the manufacturer level.

Industry Claim: Price differences are caused by differences in drug quality and drug production costs.

The Facts: There do not appear to be major differences in quality between animal and human drugs. The Food and Drug Administration regulations governing drug quality and production, the so-called “good manufacturing practice” (BMP) requirements, are codified in 21 C.F.R. part 211. These requirements, which are designed to ensure drug quality and consistency, apply equally to both human and animal drugs. According to FDA:

The methods, facilities, and controls under which animal drugs are manufactured, processed, packaged, or held for sale must conform to the requirements of the regulations for Current Good Manufacturing Practices in the drug industry generally.⁵

Moreover, because the cost of production is only a small part of the final costs of a drug, any differences in production costs are unlikely to be the cause of the high price differentials. The typical marginal cost of manufacturing additional volumes of a medication has been estimated to be only 5% of the retail cost.⁶

Industry Claim: Price differences are caused by differences in liability costs for human and animal drugs.

The Facts: Differences in liability costs do not appear to explain the price differences observed between human and animal drugs. The congressional report comparing the pricing of animal and human drugs investigated the pricing of eight popular drugs and eight directly comparable drugs. A review of reported cases shows virtually no damage awards involving these drugs. The eight popular drugs have been on the market for a combined total of over 146 years without a reported case awarding a plaintiff damages for the drugs.⁷ Similarly, the directly comparable drugs have been on the market for a combined total of over 153 years with only four reported cases in which a manufacturer has been forced to pay damages.⁸ The total dollar amount of these judgments was less than \$10 million.⁹

Industry Claim: Price differences involving brand-name drugs are not relevant because generic drugs are available that cost less than the brand-name versions.

The Facts: In the case of some of the drugs examined in the minority staff report, generic equivalents are available, as noted in the report.¹⁰ This benefits sophisticated buyers, such as HMOs and other third-party payers, who either buy the lower priced generic version or use the existence of a generic alternative to negotiate lower prices from the brand-name manufacturer. These sophisticated buyers pay for 65% of all prescriptions.¹¹ But many senior citizens without drug coverage are unaware of the generic equivalent and end up paying full price for the brand-name version. In part, this is due to the fact that the drug manufacturers spend \$19,000 per doctor each year to convince doctors to prescribe their brand-name products.¹²

Lodine is one of the drugs examined in the minority report that has a generic version available at a lower cost than the brand-name version. Despite the availability of the generic alternative, it appears that approximately half of the senior citizens without prescription drug coverage purchase the brand name version.¹³

Industry Claim: The AVMA has said that animal drug pricing cannot be compared to human drug pricing.

The Facts: The minority staff consulted with the American Veterinary Medical Association (AVMA) during the development of the animal drug pricing analysis and addressed many of the AVMA's concerns, such as which level of the market provides the most accurate comparison (the manufacturer level rather than the retail level) and how to select directly comparable drugs. In fact, the AVMA specifically recommended that four drugs be used to compare human and animal drug pricing, stating: "the American Veterinary Medical Association . . . has developed a list of four drugs we feel are fair comparisons for your use."¹⁴

The four drugs recommended by the AVMA as “fair comparisons” were included in the price comparisons. The average price difference for the four drugs was 163% -- even higher than the average price differentials emphasized in the report (Table 1).

In a March 8, 2000, letter sent to clarify the record, AVMA’s director of governmental relations wrote to Rep. Waxman: “Since my last letter dated June 30th 1999, I have met with your minority staff regarding the pharmaceutical pricing study, and they have addressed my concerns.”¹⁵

Table 1: Four Drugs Recommended by the AVMA for Animal-to-Human Price Comparisons Have a Large Price Differential.

Drug Name	Manufacturer	Human Use	Manufacturer Price (Monthly Supply)		Price Differential
			Animal Market	Human Market	
Winstrol	Sanofi	Anemia; Renal Disease	\$5.40	\$19.20	256%
Lodine	American Home Products	Arthritis	\$37.80	\$108.90	188%
Robaxin	A.H. Robins	Pain Relief	\$15.00	\$31.20	108%
Lasix	Hoechst Marion Roussel	High Blood Pressure	\$4.80	\$9.60	100%
Average for Four AVMA Recommended Drugs					163%

Endnotes

¹ Animal Health Institute, *Testing...testing....testing: Food Safety and Animal Drugs* (May 1999).

² Pfizer, Inc., *1998 Annual Report* (1999); Los Angeles Times, *Animal Drugs Become Big Pet Project for Industry* (Oct. 12, 1999).

³ Pfizer, Inc., *1998 Annual Report* (1999).

⁴ Dr. Alan Sager, Boston University School of Public Health, *Response to Rep. Henry A. Waxman* (Aug. 1999).

⁵ U.S. Food and Drug Administration, *Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration* (1999) (online at <http://www.fda.gov/opacom/morechoices/smallbusiness/blubook.htm#animalprod.html>).

⁶ Alan Sager and Deborah Socolar, *Affordable Medications for Americans* (July 27, 1999).

⁷ Committee on Government Reform, Minority Staff, *Analysis of Federal and State Cases Available on Westlaw Database* (Nov. 1999).

⁸ *Id.*

⁹ *Id.*

¹⁰ Minority Staff Report, fn 21.

¹¹ National Association of Chain Drug Stores, Chain Pharmacy Industry Profile, *Retail Prescriptions by Source of Payment, 1990-1998* (1999).

¹² Drug companies spend \$7 billion annually on sales representatives who market to doctors and provided doctors and nurses with \$7.2 billion worth of free samples in 1999. *See New Script: Drug Firms, Stymied in the Lab, Become Marketing Machines*, Wall Street Journal (July 6, 2000); *Use of Samples in Drug Industry Raises Concern*, Wall Street Journal (July 19, 2000). This amounts to \$19,000 for each of the 740,000 doctors in the United States. Statistical Abstract of the United States, 1999, Labor Force, Employment and Earnings, *Employed Civilians, by Occupation, Sex, Race, and Hispanic Origin: 1983 and 1998* (1999).

¹³ According to data from the Pennsylvania Pharmaceutical Assistance Contract for the Elderly program (PACE), older Americans without drug coverage buy the brand-name version of Lodine in 48% of all cases, nearly half the time. Etodolac and Lodine Claims in 1999, Pennsylvania Department of Aging, Pennsylvania Pharmaceutical Assistance Contract for the Elderly (Sept. 2000). PACE is one of the country's largest outpatient prescription drug programs for older Americans and has been used by analysts as a proxy for prescription drug usage by all American seniors.

¹⁴ Letter from Dr. Niall B. Finnegan, American Veterinary Medical Association to Rep. Henry A. Waxman (June 30, 1999).

¹⁵ *Id.*