CHOICES
a publication of AAEA Agricultural & Applied Economics Association
The Magazine of Food, Farm and Resource Issues

1st Quarter 2011 | 26(1)

HEALTHY COMPETITION IN THE ANIMAL HEALTH INDUSTRY

Brian L. Buhr, Derald Holtkamp, and Steve Sornsen
JEL Classifications: Q13, Q18, L11, L22, L2, L66
Keywords: Pharmaceutical Industry, Five Forces, Animal Health, Veterinary, Competition, Economics

Modern medicines, veterinary oversight, biosecurity measures, improved housing systems and nutritional advancements have greatly improved the health and productivity of livestock. The animal health industry has been a crucial partner in achieving these gains. Its continued advancement and growth can help livestock producers humanely and economically achieve production levels needed to affordably meet future food demands.

The animal health industry is driven by basic and applied science. Chemistry, biochemistry, biology and genomic sciences are applied and translated into improved products to promote animal health. The animal health industry is inherently influenced by many of the same issues as the animal protein sector including: animal welfare, supply chain structure, identity preservation, food safety, globalization and changing consumer demands.

However, two distinctively compelling influences include the economics of patents and regulation for new product development, and the linkage to human health. The linkage to human health includes improving the quality and safety of food, addressing issues of zoonotic diseases that threaten both animal and human health, and assuring safe and efficacious animal health products that do not adversely affect human health. We will use Porter's Five Factor framework to describe the forces that shape the industry and consider strategic issues confronting today's animal health providers which are a vital economic partner in the animal protein sector.

The Animal Health Industry's Relevant Market

For this discussion, animal health product scope includes biological agents (vaccines), antibiotics, anthelmintics (de-wormers), antifungals, and parasiticides. The geographic markets in the animal health sector are defined by national boundaries dictated by regulatory requirements and trade restrictions, but many of the companies are global. Table 1 shows the top seven animal health manufacturers based on the market capitalization of the parent company. These firms emerged in the late nineteenth or early twentieth century as human medicine firms based on chemical ingredients. All have now evolved to include antibiotics and vaccines.

Pharmaceutical firms are quite large, with the top four firms having between $30 and $50 billon in total revenues. Even though the pharmaceutical industry is often characterized as "big pharma", it is actually quite fractionalized. The 2007 U.S. Census of Manufacturing reports that there are over 1,500 pharmaceutical and medicine manufacturing firms in the United States. (NAICS code #32541). Leaving out King Pharmaceuticals, which only has U.S. operations and is now part of Pfizer, the U.S. share of total revenue of the multi-nationals is about 41%. The U.S. Census of Manufacturing reports total U.S. pharmaceutical manufacturers revenue as $188.53 billion. Based on this total U.S. revenue and the top four firms' U.S. revenues, the Herfindahl-Hirschman Index of market concentration is calculated as 215.81. Industries with an HHI below 1,000 are considered "competitive" industries by the U.S. Department of Justice.

The same report shows that there are over 100 firms in the United States that have over $100,000 in sales of veterinary medicines, biolgicals/vaccines, and medicinal botanicals. This includes those products used for

pets and production animals and some of these firms are in both markets. The animal health division revenue share of the firms' total revenue ranges from about 2% to 6% percent for the major manufacturers. This is not a precise estimate because in some cases the animal health segment is commingled with other products such as over-the-counter consumer products. The 2007 U.S. Census of Manufacturing reports that total U.S. revenues from veterinary pharmaceuticals are over $5.41 billion. Animal health revenue in Table 1 is greater than this because it includes global sales. No information was found on the firms' respective U.S. share of sales and so an HHI calculation on the animal health share of the pharmaceutical industry is not possible.

Table 1

Top Pharmaceutical Manufacturers of Animal Health Products (by market capitalization)

Parent Company[1]	Animal Health Division(s)	Global Market Capitalization (billion dollars)	Total Revenue (billion dollars)	U.S. Revenue (billion dollars)	U.S. Share of Total Revenue (percent)	Animal Health Revenue (billion dollars)	Animal Health Share of Parent Total Revenue (percent)	Research and Development Expenditures (billion dollars)
Pfizer Inc.	Pfizer Animal Health, Wyeth, Fort Dodge Animal Health	$132.30	$50.00	$21.75	44%	$2.76	5.5%	$7.80
Novartis AG	Novartis	$119.00	$44.27	$14.25	32%	$1.10	--	--
Merck & Company	Intervet-Shering Plough, Merial	$109.40	$27.40	$9.53	35%	$0.49	1.8%	$5.80
Sanofi-Aventis	Merial, Intervet - Shering Plough	$78.80	$41.02	$13.19	32%	$2.55	6.2%	$6.44
Eli Lilly & Company	Elanco	$38.30	$21.84	$12.29	56%	$0.54	2.5%	$4.33
Boehringer Ingelheim	Boehringer Ingelheim	--	$12.72	$5.76	45%	$0.85	6.7%	$3.08
King Pharmaceuticals	Alpharma	--	$1.77	$1.61	91%	$0.36	20.3%	$0.10
Total U.S. (2007)[2]				**$188.53**				
Estimated HHI				**215.81**				

[1]Source: Respective firms' annual reports

[2]Source: U.S. Bureau of Census. (2007). Economic Census. NAICS Code 32541. Available at: http://www.census.gov/econ/census07/.

Threat of New Entrants

The pharmaceutical industry is comprised of basically two production stages: new product development and manufacturing and distribution. The threat of entrance from new product development occurs primarily through small scale innovative start-ups launched from university or other research enterprises. The primary threat of entrance for manufacturing comes from generic drug manufacturers who do not focus on research and development.

Since the 1970s, new entrants in pharmaceuticals have generally come through advancements in biotechnology. The use of recombinant DNA technologies enables companies such as Genentech to manufacture large quantities of product in efficient processes. However, there are large economies of scale and intensive knowledge requirements that create high barriers to entry. Small scale start-ups require a large amount of capital and face many risks, including regulatory risks, in taking a product from concept to market.

The primary form of entrance on the manufacturing side of the pharmaceutical industry is through generic drugs. The Waxman–Hatch Act of 1984 defined the process for approval of generic versions of pioneer drugs. Generic drugs that have the same active, inert and additive ingredients as the pioneer drug are required to test for purity and potency. However, they may not be required to conduct tests to show human or animal safety and efficacy if they are bioequivalent to the pioneer drug according to Food and Drug Administration rules for Abbreviated New Drug Applications (ANDA). This greatly reduces the costs of testing and regulatory approval and eases entrance. However, the pioneer drug manufacturers' patent protection period creates an opportunity to develop a brand, a reputation for effectiveness, and manufacturing and scale efficiencies so that launching a generic drug is not riskless.

Animal drug competition is less susceptible to generic influences than human drugs because there are not the intervening insurance and employer programs that require the selection of generic alternatives when available. Hence, brand recognition can be more effective at creating market buffers. As reported by the Generic Animal Drug Alliance (GADA), "of the top 20 human drugs that lost patent protection between 2005 and 2007, 100% went generic; and of the top 20 veterinary companion animal drugs during the same time frame, only 20% went generic."

The multinational presence of pharmaceutical firms means that most firms already have operations in the United States. However, new entrance may occur on a product by product basis depending on regulatory structures. For example, a superior product in one country may displace an inferior product in a second country if the superior product is approved in the inferior product country. In this sense regulatory structures can create international barriers to entry.

Internal Rivalry

According to the Pharmaceutical Research and Manufacturers of America (PhRMA) the average cost to develop a new human drug in 2005 was $1.3 billion dollars, partly due to the 10 to 15 year development pipeline, but also because of the high rate of failure. For example PhRMA, also reports that there were 2,950 new medicines in development in 2010 and only 34 were approved in 2009. Figures are not available for animal health products, but the processes are similar, creating similar high costs to develop and release new drugs.

Because of the high risk and high cost of research and development, firms often seek to compete by jumpstarting their research pipelines through the acquisition of start-ups which may emerge from government or university laboratories. Mergers with larger firms are also a way to capture innovative product lines or enter new markets. In the last three years there have been several major mergers in the animal health segment. For example, as reported in Sanofi Aventis' 2009 Annual Report, from 2007-2010 Merck and Sanofi- Aventis entered a sequence of mergers with Schering-Plough and Merial. This ultimately resulted in a joint venture between Sanofi-Aventis and Merck based on the combining of Merial and Schering-Plough. Merial specialized in pet medicines, while Schering was more focused on livestock health so that the merger represented an attempt to create complementary product lines and gain efficiencies in management and distribution. This is somewhat unique in that mergers in animal health are often initiated to meet human health business objectives.

Technical and sales support is increasingly provided by animal health companies directly to agricultural producers to differentiate and sell products and to help producers better use animal health products. The direct support is replacing mass marketing strategies. As the animal health companies become more

integrated into the decision making process within larger companies involved in animal production, there is increasing competition for a seat at the decision-making table. In some cases, animal health companies are employing veterinarians and others who are dedicated to a single production company. Therefore, there is a trend toward marketing of broad portfolios of differentiated products facilitated by:

- innovation by developing combination vaccines with multiple antigens,
- pricing discounts for multi-product purchases,
- technical service and marketing, and
- outcome-based research directed toward measuring the value of an intervention.

Buyer and Supplier Bargaining Power

The primary buyers of animal health products and services are live animal producers. Over the past 20 years, all species of livestock production have undergone considerable consolidation. Frequently, livestock firms have their own animal health professionals, including in-house veterinary and nutrition services. Due to size, a single account can impact the profitability of a drug firm since health treatment protocols and products frequently become standardized system wide. This creates a 'winner-takes-all' environment for suppliers so that losing a large account has significant implications for profitability.

Animal health companies are also looking beyond producers to interact with packers, retailers, food companies, restaurant chains and even consumers. This is being driven by issues such as food safety, animal welfare and antimicrobial resistance. Due to their expertise, pharmaceutical companies are helping packers and retailers to develop programs, social responsibility statements and communications on these important topics.

Another example of buyer power is increasing demand for social or public good attributes of production. A key shift is that the retail segment is a driver in addressing these externalities, acting as an agent of consumer interests. Both Wal-Mart and McDonald's have social responsibility statements for their suppliers as well as their own operations. McDonald's has specific standards, prohibiting the use of antibiotics used for human medicine and they report that 60% of global suppliers comply with their antibiotics policy. McDonald's also gives preference to suppliers with specific animal welfare practices and these may enhance demand for some products, such as immuno-castration products being produced by pharmaceutical firms. Standards for use of antibiotics may also lead to reduced use of antibiotics, especially growth promotants, marketed by pharmaceutical firms.

The animal health industry is a primary manufacturer and as such has few and diversified suppliers. However, some chemicals and other ingredients used by pharmaceutical firms have very high quality assurance standards to protect against contaminants. This can lead to a form of market power if there are relatively few suppliers of a product who can provide those quality assurances.

Threat of Substitutes

As described earlier, generic manufacturers create substitutes for pioneer drugs. With patent restrictions, these represent a copy-cat strategy more than a strategy that strikes at the foundations of the pioneer drug segment of the industry.

A more fundamental substitution threat is in the form of biopharmaceuticals. In broad terms, biopharmaceuticals are pharmaceuticals manufactured using biotechnology. Biotechnology can be applied to vaccines, antibodies and therapeutic protein products. This has the potential for new competition to emerge and firms in the plant sciences may have a significant stake in this development. For example, Dow Agrosciences has developed a plant-made vaccine technology called "ConcertTM". Plant based vaccines have the potential to reduce the risk of animal virus contamination, are highly stable and cannot produce virulent pathogens that can spread to other animals. In addition, they may be administered as an inherent part of feed, assuring treatment of all animals and reducing the need for additional treatments and management.

As with the use of other genetically modified crops for food production, there are concerns about the environmental and ecological risks of releasing pharmacological plants into the field. Containment in these situations is uncertain with potential for genetic drift to occur or for unknown allergens to be released into the food chain. As such the regulatory structure includes the USDA's Animal Plant Health Inspection Service, the Food and Drug Administration and the U.S. Environmental Protection Agency. As with other genetically

modified organisms, the regulatory structure differs by country so that there are challenges to international regulatory approval as firms seek to expand their markets in these areas.

This raises additional market considerations for competition. Prior to recombinant genetic technologies pharmaceutical firms focused on chemistry and microbiology for their research and development, while biotechnology firms based their work on the field of genomics. However, as their development interests intersected there have been mergers and investments that have essentially vertically integrated genetic technology with the chemistry, biochemistry and manufacturing processes of biopharmaceuticals.

Improved overall health management, diagnostic testing, and bio-security systems are substituting for pharmaceutical treatments. For example, a significant technical change in the swine industry was the use of all-in-all-out multi-site production systems that reduced disease pressure in animals, reducing the need for treatments. Increasingly, intensive diagnostic testing is being used to determine the optimal timing for vaccine or antibiotics and to monitor their effectiveness. Another trend is the use of individual animal identification for targeted individual animal treatments rather than herd or population treatments. With early detection of disease, sick animals can be treated more quickly, reducing the number of treatments and perhaps reducing the infection of more animals in the herd, also reducing treatments. Improved information technologies are being developed to help producers record and manage their use of antibiotics in livestock. This substitution of information for treatment also meets some societal concerns about over-use of drugs and pharmaceuticals in production systems.

A significant effort is being undertaken to find substitutes for antibiotics. These have included cytokines which are proteins that modulate animals' immune systems as well as vaccines that reduce the potential for infections requiring antibiotic treatments.

Another new genetic-based innovation is the identification and testing of genetic markers in livestock for disease resistance. For example, the discovery of a gene marker for E.coli F18 resistance resulted in PIC, a swine genetics company, offering a commercial line of pigs marketed as being resistant to a specific disease. E.coli F18 is an enteric disease which strikes pigs after weaning that can kill them or slow their growth. Progress in this area has been slow and initial attempts to commercialize the technology have not always been successful but the potential is great. Another potential market value for genetic-based innovation may be the ability to design treatments for specific livestock genetic profiles.

Other Drivers of Change

From a policy perspective, there are several key issues affecting the use of animal health inputs in animal agriculture. These include policies related to patent protection and intellectual property, regulations for testing and drug approval and regulations on the use of antibiotics due to concerns about antibiotic resistance. Less directly, the demand for feed ingredients and pharmaceuticals is driven by trends in organic foods and other production systems that rely on alternative methods for managing welfare, growth and health in animals.

The issue of antibiotic resistance is particularly important for animal and human health issues. Restrictions on antibiotic use not only have implications on the profitability of manufacturers, but also on the animal production chain. Antibiotics are used prophylatically to improve the health status of animals which improves their overall productivity. In 2006 the European Union eliminated the use of antibiotics for growth promotion. There are similar concerns in the United States as evidenced by recent legislative action such as the Preservation of Antibiotics for Medical Treatment Act of 2009" (H.R. 1549, 111th Congress 2009-2010) which denies an application for a new animal drug that is a critical antimicrobial for humans unless the applicant demonstrates that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance. The challenge is that the issue of antibiotic resistance represents a complex biological process with potential for unintended consequences. For example, bans on nontherapeutic antibiotics in Denmark have led to increased therapeutic use (DANMAP, 2008).

The increasing concerns for animal welfare, antimicrobial resistance, and demands for low cost, reliable and safe food will likely drive development of new technologies by the animal health sector to meet these demands. The same forces will also create near term demand for alternatives to pharmaceuticals such as vaccines, nutraceuticals, alternative production practices, disease resistant animals and probiotics. Animal welfare issues will also create demand for innovative technologies that allow for elimination of production practices that are viewed unfavorably, such as surgical castration, yet still enable the efficient and safe production of food. An example of a product improving animal welfare is an immuno-castration product

marketed in international markets by Pfizer.

Increasing frequency of emerging diseases such as porcine circovirus type 2 (PCV2) and new strains of existing diseases such as porcine reproductive and respiratory syndrome (PRRS) will increase demand for technologies that will shorten the time required to produce vaccines and other animal health products to deal with them. Many of the human diseases that have been emerging or reemerging are zoonotic, caused by pathogens that originate from animals. Examples include pH1N1 influenza and methicillin-resistant Staphylococcus aureus (MRSA). Longer-term, infectious diseases in livestock may also be affected by regional climate change. Pharmaceutical companies will play a critical role in addressing both animal and human forms of these diseases.

Finally, the animal pharmaceutical industry is affected by the change in demand for meat products. It is expected that global meat consumption will continue to grow as incomes rise in developing markets. However, increasing human populations, increased competition for feed-stocks from biofuels and concerns about the environmental impacts of increased meat consumption will limit meat consumption and demand for animal drugs. Interestingly, pharmaceuticals are endogenous to this process as they increase efficiency of meat production, reducing resource pressures.

Concluding Comments

Animal health and nutrition inputs are critical to the health and wellbeing of animals. This sector is rapidly evolving based on new technology developments in the biological sciences. In all likelihood the sector will continue to evolve as it has over the past one-hundred years, into life-sciences firms relying on genetic innovations to both develop new products and better understand the interaction of animal genetics with animal health outcomes.

Increasingly animal health decisions will not occur independently from production systems, but rather in concert with these production systems as both suppliers and production systems seek to optimize outcomes on animal health. Further demands will be made on the food system by consumers to deliver products in a way that reduces social, environmental and other externalities. This will likely require even greater collaboration and communication among vertical chain participants so that goals of providing high quality protein driven by an increasing array of global demands can be met.

For More Information

DANMAP (2008). DANMAP 2008 – Use of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Bacteria from Food Animals, Foods and Humans in Denmark. Jensen, V.F. and A.M. Hammerum, eds. National Food Institute, Technical University of Denmark. Available online: http://www.danmap.org.

Elbehri, A. (2005). Biopharming and the Food System: Examining the Potential Benefits and Risks. AgBioForum 8, 18-25.

Generic Animal Drug Association (GADA). (2010). Statistics. Available online: http://www.gadaonline.org/statistics.php.

Giddings, G., Allison,G., Brooks, D. and Carter, A., (2000). Transgenic Plants as Factories for Biopharmaceuticals. Nature Biotechnology 18, 1151-1155.

Moschini, G. (2006). Pharmaceutical and Industrial Traits in Genetically Modified Crops: Coexistence with Conventional Agriculture. American Journal of Agricultural Economics 88, 1184-1192.

Peterson, R.D. and Arntzen, C.J.. (2004). On Risk and Plant-Based Biopharmaceuticals. Trends in Biotechnology 22, 64-66.

PhARMA. (2010). Profile: Pharmaceutical Industry 2010. Available online: http://www.phrma.org/sites/default/files/159/profile_2010_final.pdf

Rai, A.K. (2001). “Fostering Cumulative Innovation in the Biopharmaceutical Industry.” Berk. Tech. L.J. 16,

813-852.

Schwietzer, S.O. (2007). Pharmaceutical Economics and Policy. Oxford University Press.

U.S. Bureau of Census. (2007). Economic Census. NAICS Code 32541. Available at: http://www.census.gov/econ/census07/.

Brian Buhr (bbuhr@umn.edu) is Professor and Head of Applied Economics, University of Minnesota, St. Paul, Minn. Derald Holtkamp, (hotlkamp@iastate.edu) DVM, M.S. is Assistant Professor in Veterinary Diagnostic and Production Animal Medicine, Iowa State University, Ames, Iowa. Steve Sornsen, DVM, M.S. (steve.sornsen@pfizer.com) is Senior Director of Veterinary Services for Pfizer Animal Health, Ames, Iowa.