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COUNTERFEIT DRUGS

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Worldwide pharmaceutical sales amounted to $492 billion in 2003, with sales in North America accounting for roughly one-half of the total. The three leading therapy classes were cholesterol and trigylceride reducers, anti-ulcerants, and anti-depressants, each with worldwide sales of approximately $20 billion or more. Lipitor tops all other drugs with global sales of more than $10 billion in 2003 [IMSa, pp. 1-2]. Global sales of all pharmaceuticals in 2007 are projected at more than $650 billion [Business Communications, pp.1-2]. By 2008 global sales of generic drugs are expected to reach $80 billion [IMSb, p. 1]. The sheer volume of global production, along with the high prices of many prescription drugs and the ever-increasing dependence on medicines to prevent, cure, and ameliorate human pain and suffering are powerful incentives to manufacture, distribute, and sell counterfeit drugs.

A counterfeit drug may contain no active ingredients, too much or too little active ingredients, the wrong or contaminated ingredients, or may be manufactured in the wrong dosage [Food and Drug Administration, p.4]. In 1999 the WHO stated that the extent and nature of counterfeit drugs worldwide is not fully known [WHO 1999, p.19]. More recently the Food and Drug Administration claimed that about 10 percent of the drugs in South East Asia are counterfeit. In China counterfeit drugs account for 50 percent of the product on the market. Deaths in 2001 due to the use of fake drugs in China alone have been put at 192,000 [Washington Post, p. 1]. During a meningitis outbreak in Niger in 1995, more than 50,000 persons were inoculated with fake vaccines obtained free from another country and presumed to be safe; 2,500 subsequently died [WHO2003, p. 1]. In underdeveloped countries the amount of counterfeit drugs ranges from an estimated 25 to 40 percent [BBC,p.1; Food and Drug Administration, p. 4; Forzley, p.16]. The problem according to the World Health Organization is related in part to lower trade barriers worldwide [WHO2003, p. 2].

A 2004 report prepared by the General Accountability Office in which 68 drug samples were purchased via the internet stated that there were problems with 21 of the samples related to handling, FDA-approval status, and authenticity. The GAO discovered that 14 of the websites were under investigation for selling counterfeit drugs or providing drugs where no valid doctor-patient relationship exists, including nine in the United States. Six orders placed and paid by GAO never were received [GAO, p. 1].

China and India are the main sources of the active ingredients used in the manufacture of counterfeit drugs worldwide. The trade in counterfeit drugs resembles narcotics trafficking in that the product is sourced in one country, formulated into tablets or capsules in another country, packaged in a third country, and transshipped through other countries on its way to its final destination [Glover, pp. 89, 90].

Detection and Authentication

When is a product a counterfeit drug and when is it authentic? The problem is compounded because counterfeiters are able to circumvent anti-counterfeiting measures within 18-24 months. The equipment available today to counterfeiters makes it difficult even for the authentic manufacturer to detect fake drugs [Food and Drug Administration, p.11, 17].

Economic globalization and deregulation have created greater opportunities for counterfeiters [Cohen, p.4]. According to the United States Customs Service, the overall volume of pharmaceuticals shipped by mail is "enormous" [Durant, p.45]. Roughly two million parcels containing regulated products enter the United States via international mail, most of which are released by the Customs Service to the addressee without review by the Food and Drug Administration [Dingell, p.8].

Even when a parcel is reviewed by the Food and Drug Administration, detection is made more difficult due to the mingling of fake drugs with the authentic product thereby reducing the probability that random sampling will identify any fake drugs in the shipment [Christian, p.93].

Regulatory agencies are just becoming aware of the problem of counterfeit drugs and the risk they pose to public health. The first study to compile information on the extent of this problem was published in 2003. Addressing this problem will require more regulatory oversight in which counterfeit goods are seen as a disease mechanism [see Forzley, pp.ii, 30]. However, less than one-third of developing countries have fully functioning drug regulatory agencies. Ten to 20 percent of sampled drugs fail quality control tests in many developing countries. Poor manufacturing practices often result in toxic, sometimes lethal, products [WHO, "Essential Drugs," p.2]. The Food and Drug Administration states that it costs between $6000 and $15,000 to authenticate a box of ten drugs [Hubbard, p.66].

The task at hand can be separated into four processes: prevent counterfeit drugs from entering the distribution network; improve the detection and authentication of drugs; reduce the risk of harm from using counterfeit drugs; avoid adding unnecessarily to the cost of producing authentic pharmaceuticals [Food and Drug Administration, p.24]. But the simple fact that in late 2003 the task force assigned to assist the Food and Drug Administration had prepared an *interim* report indicates that there is much to be done to deal with the growing problem of counterfeit drugs.

Two Dilemmas

There is a huge and still-growing demand around the world for prescription drugs to fight a wide variety of conditions and diseases. This demand in turn drives pharmaceutical

research and development. However, only one new compound in 250 that survives pre-clinical testing is approved by the Food and Drug Administration [NIH, p. 1]. The first dilemma is that as an antiviral drug is used more widely the virus tends to mutate rendering the drug less and less effective and adding to the pressure on pharmaceutical manufacturers to develop an effective replacement. In order to retrieve the cost of developing a new prescription drug that in 2003 averaged $897 million [Tufts, p. 1] and to realize the economic gain necessary to maintain the company as a viable enterprise, it is necessary to protect new drugs with patents and to allow those drugs to be priced so that their costs are recovered and the required gain realized within the period of the patent protection. The second dilemma is that for many persons who need those drugs, their prices make them unaffordable and therefore out of reach.

Thus while we struggle to figure out how to continue the research and development effort in a way that makes the newly developed drugs effective and affordable, counterfeiters are seizing this opportunity to exploit the needy by offering cheaper alternatives that are ineffective, dangerous, or both.

References

BBC. "Global Rise in Use of Fake Drugs," November 11, 2003 <http://www.bbc.co.uk/mpapps/pagetools/print/news.bb.co.uk/2/hi/health/3261385.stm> (July 2004).

Business Communications Company. "The $400 Billion Worldwide Drug Industry Continues to Evolve," <http://www.bccresearch.com/editors/RC-181N.html> (October 2003).

Christian, James. Testimony before the Subcommittee on Oversight and Investigations, House of Representatives, United States Congress, June 7, 2001.

Cohen, Mark Allen. "Statement," roundtable discussion before the Congressional-Executive Commission on China, United State Congress, February 3, 2003.

Dingell, John. Remarks before the Subcommittee on Oversight and Investigations, House of Representatives, United States Congress, June 7, 2001.

Durant, Elizabeth. "Statement" before the Special Committee on Aging, United States Senate, July 9, 2002.

Food and Drug Administration. "FDA Counterfeit Drug Task Force Interim Report," Rockville, Maryland: October 2003.

Forzley, Michele. "Counterfeit Goods and the Public's Health and Safety," International Intellectual Property Institute, Washington: July 2003.

GAO. "Internet Pharmacies: Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices," June 17 2004 (highlights), complete report at www.gao.gov/cgi-bin/getrpt?GAO-04-888T (July 2004).

Glover, John D. "Prepared Statement" and testimony before the Subcommittee on Oversight and Investigations, House of Representatives, United States Congress, June 7, 2001.

Hubbard, William K. "Prepared Statement" before the Subcommittee on Oversight and Investigations, House of Representatives, United States Congress, June 7, 2001.

IMSa. "IMS Reports 9 Percent Constant Dollar Growth in '03 Global Pharma Sales," <http://www.imshealth.com/ims/portal/front/articleC/0, 2777, 6599_3665_45365325,00. html >(July 2004).

IMSb. "Generics Market Expected to Soar to $80 Billion by 2008," <http://www.imshealth.com/ims/portal/front/articleC/0, 2777, 6599_52651243,00…> (July 2004).

National Institutes of Health. "A Plan to Ensure Taxpayers' Interests are Protected," July 2001 <http://www.nih.gov/news/070101wyden.htm> (October 2003).

Pharmaceutical Security Institute. "About PSI," 2002 <http://www.psi-incomabout.htm> (November 2003).

Tufts Center for the Study of Drug Development. "Tufts Raises Estimate of Cost of Drug Development," May 2003 <http://www.lists.essential.org/pipermail/iphealth/ 2003May/004723.htm> (October 2003).

Washington Post. "China's Killer Headaches: Fake Pharmaceuticals," August 30, 2002 <http://www.washingtonpost.com/ac2/wp-dyn/A13785-2002Aug29> (July 2004).

World Health Organization 1999. "Counterfeit Drugs: Guidelines for the Development of Measures to Combat Counterfeit Drugs," Geneva: 1999.

World Health Organization. "Essential Drugs and Medicines Policy," <http://www.who.int/medicines/rationale.shtml> (October 2003).

World Health Organization 2003. "Substandard and Counterfeit Medicines," November 2003 <http://www.who.int/mediacentre/factsheets/fs275/en/print.html> (July 2004).

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