

## The Global Pharmaceutical Industry : A profile 2010

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### **The Global Pharmaceutical Industry: A Profile 2010.**

The **pharmaceutical industry** develops, produces, and markets drugs licensed for use as medications.<sup>[1]</sup> Pharmaceutical companies can deal in generic and/or brand medications. They are subject to a variety of laws and regulations regarding the patenting, testing and marketing of drugs.

#### **History**

The earliest drugstores date back to the Middle Ages. The first known drugstore was opened by Arabian pharmacists in Baghdad in 754,<sup>[2]</sup> and many more soon began operating throughout the medieval Islamic world and eventually medieval Europe. By the 19th century, many of the drug stores in Europe and North America had eventually developed into larger pharmaceutical companies.

Most of today's major pharmaceutical companies were founded in the late 19th and early 20th centuries. Key discoveries of the 1920s and 1930s, such as insulin and penicillin, became mass-manufactured and distributed. Switzerland, Germany and Italy had particularly strong industries, with the UK, US, Belgium and the Netherlands following suit.

Legislation was enacted to test and approve drugs and to require appropriate labelling. Prescription and non-prescription drugs became legally distinguished from one another as the pharmaceutical industry matured. The industry got underway in earnest from the 1950s, due to the development of systematic scientific approaches, understanding of human biology (including DNA) and sophisticated manufacturing techniques.

Numerous new drugs were developed during the 1950s and mass-produced and marketed through the 1960s. These included the first oral contraceptive, "The Pill", Cortisone, blood-pressure drugs and other heart medications. MAO Inhibitors, chlorpromazine (Thorazine), Haldol (Haloperidol) and the tranquilizers ushered in the age of psychiatric medication. Valium (diazepam), discovered in 1960, was marketed from 1963 and rapidly became the most prescribed drug in history, prior to controversy over dependency and habituation.

Attempts were made to increase regulation and to limit financial links between companies and prescribing physicians, including by the relatively new U.S. Food and Drug Administration (FDA). Such calls increased in the 1960s after the thalidomide tragedy came to light, in which the use of a new tranquilizer in pregnant women caused severe birth defects. In 1964, the World Medical Association issued its Declaration of Helsinki, which set standards for clinical research and demanded that subjects give their informed consent before enrolling in an experiment. Pharmaceutical companies became required to prove efficacy in clinical trials before marketing drugs. Also, the concept of good manufacturing practices (GMP) came into existence as a result of the thalidomide tragedy.

Cancer drugs were a feature of the 1970s. From 1978, India took over as the primary center of pharmaceutical production without patent protection. The industry remained relatively small scale until the 1970s when it began to expand at a greater rate. Legislation allowing for strong patents, to cover both the process of manufacture and the specific products, came in to force in most countries. By the mid-1980s, small biotechnology firms were struggling for survival, which led to the formation of mutually beneficial partnerships with large pharmaceutical companies and a host of corporate buyouts of the smaller firms. Pharmaceutical manufacturing became concentrated, with a few large companies holding a dominant position throughout the world and with a few companies producing medicines within each country.

The pharmaceutical industry entered the 1980s pressured by economics and a host of new regulations, both safety and environmental, but also transformed by new DNA chemistries and new technologies for analysis and computation. Drugs for heart disease and for AIDS were a feature of the 1980s, involving challenges to regulatory bodies and a faster approval process.

Managed care and Health maintenance organizations (HMOs) spread during the 1980s as part of an effort to contain rising medical costs, and the development of preventative and maintenance medications became more important.

A new business atmosphere became institutionalized in the 1990s, characterized by mergers and takeovers, and by a dramatic increase in the use of contract research organizations for clinical development and even for basic R&D. The pharmaceutical industry confronted a new business climate and new regulations, born in part from dealing with world market forces and protests by activists in developing countries. Animal Rights activism was also a problem.

Marketing changed dramatically in the 1990s, partly because of a new consumerism. The Internet made possible the direct purchase of medicines by drug consumers and of raw materials by drug producers, transforming the nature of business. In the US, Direct-to-consumer advertising proliferated on radio and TV because of new FDA regulations in 1997 that liberalized requirements for the presentation of risks. The new antidepressants, the SSRIs, notably Fluoxetine (Prozac), rapidly became bestsellers and marketed for additional disorders.

Drug development progressed from a hit-and-miss approach to rational drug discovery in both laboratory design and natural-product surveys. Demand for nutritional supplements and so-called alternative medicines created new opportunities and increased competition in the industry. Controversies emerged around adverse effects, notably regarding Vioxx in the US, and marketing tactics. Pharmaceutical companies became increasingly accused of disease mongering or over-medicalizing personal or social problems.<sup>[3]</sup>

## **Research and development:**

### *Backbone of pharmaceutical industry- Drug discovery and Drug development*

**Drug discovery** is the process by which potential drugs are discovered or designed. In the past most drugs have been discovered either by isolating the active ingredient from traditional remedies or by serendipitous discovery. Modern biotechnology often focuses on understanding the metabolic pathways related to a disease state or pathogen, and manipulating these pathways using molecular biology or Biochemistry. A great deal of early-stage drug discovery has traditionally been carried out by universities and research institutions.

**Drug development** refers to activities undertaken after a compound is identified as a potential drug in order to establish its suitability as a medication. Objectives of drug development are to determine appropriate Formulation and Dosing, as well as to establish safety. Research in these areas generally includes a combination of in vitro studies, in vivo studies, and clinical trials. The amount of capital required for late stage development has made it a historical strength of the larger pharmaceutical companies.

Often, large multinational corporations exhibit vertical integration, participating in a broad range of drug discovery and development, manufacturing and quality control, marketing, sales, and distribution. Smaller organizations, on the other hand, often focus on a specific aspect such as discovering drug candidates or developing formulations. Often, collaborative agreements between research organizations and large pharmaceutical companies are formed to explore the potential of new drug substances.

### **The cost of innovation**

Drug discovery and development is very expensive; of all compounds investigated for use in humans only a small fraction are eventually approved in most nations by government appointed medical institutions or boards, who have to approve new drugs before they can be marketed in those countries. Each year, only about 25 truly novel drugs (New chemical entities) are approved for marketing. This approval comes only after heavy investment in pre-clinical development and clinical trials, as well as a commitment to ongoing safety monitoring. Drugs which fail part-way through this process often incur large costs, while generating no revenue in return. If the cost of these failed drugs is taken into account, the cost of developing a successful new drug (New chemical entity or NCE), has been estimated at about 1 billion USD<sup>[4]</sup>(not including marketing expenses). A study by the consulting firm Bain & Company reported that the cost for discovering, developing and launching (which factored in marketing and other business expenses) a new drug (along with the prospective drugs that fail) rose over a five year period to nearly \$1.7 billion in 2003.<sup>[5]</sup>

In 2010, it takes about 10 years of active research and nearly \$ 3 billion spending for a new drug to come to market.

These estimates also take into account the opportunity cost of investing capital many years before revenues are realized (see Time-value of money). Because of the very long time needed for discovery, development, and approval of pharmaceuticals, these costs can accumulate to nearly half the total expense. Some approved drugs, such as those based on re-formulation of an existing active ingredient (also referred to as Line-extensions) are much less expensive to develop.

Calculations and claims in this area are controversial because of the implications for regulation and subsidization of the industry through federally funded research grants.

### **Drug development and testing**

There have been increasing accusations and findings that clinical trials conducted or funded by pharmaceutical companies are much more likely to report positive results for the preferred medication.<sup>[6]</sup> In response to specific cases in which unfavorable data from pharmaceutical company-sponsored research was not published, the Pharmaceutical Research and Manufacturers of America have published new guidelines urging companies to report all findings and limit the financial involvement in drug companies of researchers.<sup>[7]</sup> US congress signed into law a bill which requires phase II and phase III clinical trials to be registered by the sponsor on the clinicaltrials.gov website run by the NIH.<sup>[8]</sup>

Drug researchers not directly employed by pharmaceutical companies often look to companies for grants, and companies often look to researchers for studies that will make their products look favorable. Sponsored researchers are rewarded by drug companies, for example with support for their conference/symposium costs. Lecture scripts and even journal articles presented by academic researchers may actually be 'ghost-written' by pharmaceutical companies.<sup>[9]</sup> Some researchers who have tried to reveal ethical issues with clinical trials or who tried to publish papers that show harmful effects of new drugs or cheaper alternatives have been threatened by drug companies with lawsuits.<sup>[10][11]</sup>

### **Product approval in the US, Canada**

In the United States, new pharmaceutical products must be approved by the Food and Drug Administration (FDA), while in Canada, its Health Canada a regulatory body that governs drugs as being both safe and effective.

This process generally involves submission of an Investigational new drug filing with sufficient pre-clinical data to support proceeding with human trials. Following IND approval, three phases of progressively larger human clinical trials may be conducted. Phase I generally studies toxicity using healthy volunteers. Phase

It can include Pharmacokinetics and Dosing in patients, and Phase III is a very large study of efficacy in the intended patient population.

A fourth phase of post-approval surveillance is also often required due to the fact that even the largest clinical trials cannot effectively predict the prevalence of rare side-effects. Post-marketing surveillance ensures that after marketing the safety of a drug is monitored closely. In certain instances, its indication may need to be limited to particular patient groups, and in others the substance is withdrawn from the market completely. Classic example being Valdecoxib (Vioxx) a popular Cox 2 inhibitor. Recent controversial drug is Rosiglitazone (Avandia); although investigations are in progress.

Questions continue to be raised regarding the standard of both the initial approval process, and subsequent changes to product labeling (it may take many months for a change identified in post-approval surveillance to be reflected in product labeling) and this is an area where congress is active.<sup>[12]</sup>

The FDA provides information about approved drugs at the Orange Book site.<sup>[13]</sup>

**Updates on quality requirements for pharmaceuticals and life science products are posted regularly at <http://www.QA-Expert.com>**

### **Orphan drugs**

There are special rules for certain rare diseases ("orphan diseases") involving fewer than 200,000 patients in the United States, or larger populations in certain circumstances. <sup>[14]</sup> Because medical research and development of drugs to treat such diseases is financially disadvantageous, companies that do so are rewarded with tax reductions, fee waivers, and market exclusivity on that drug for a limited time (seven years), regardless of whether the drug is protected by patents.

The trend is many of well-known multinationals namely GSK, Pfizer, Roche are NOW aiming research on drugs for "rare diseases". Does this mean that patients would be beneficial? Will they be able to purchase their medication at the high costs? Only time will tell.

### **Legal issues**

Where pharmaceuticals have been shown to cause side-effects, civil action has occurred, especially in countries where tort payouts are likely to be large. Due to high-profile cases leading to large compensations, most pharmaceutical companies endorse tort reform. Recent controversies have involved Vioxx and SSRI antidepressants.

### **Product approval elsewhere**

In many non-US western countries a 'fourth hurdle' of cost effectiveness analysis has developed before new technologies can be provided. This focuses on the efficiency (in terms of the cost per QALY) of the technologies in question rather than their efficacy. In England NICE approval requires technologies be made available by the NHS, whilst similar arrangements exist with the Scottish Medical Consortium in Scotland and the Pharmaceutical Benefits Advisory Committee in Australia. A product must pass the threshold for cost-effectiveness if it is to be approved. Treatments must represent 'value for money' and a net benefit to society. There is much speculation<sup>[15]</sup> that a NICE style framework may be implemented in the USA to ensure Medicare and Medicaid spending is focused to maximise benefit to patients and not excessive profits for the pharmaceutical industry. In the UK, the British National Formulary is the core guide for pharmacists and clinicians.

### **Industry revenues**

For the first time ever, in 2006, global spending on prescription drugs topped \$643 billion, even as growth slowed somewhat in Europe and North America. The United States accounts for almost half of the global pharmaceutical market, with \$289 billion in annual sales followed by the EU and Japan. Emerging markets such as China, India, Brazil, Russia, South Korea and Mexico outpaced that market, growing a huge 81 percent.<sup>[16]</sup>

US profit growth was maintained even whilst other top industries saw slowed or no growth.<sup>[17]</sup> Despite this, "...the pharmaceutical industry is — and has been for years — the most profitable of all businesses in the

U.S. In the annual Fortune 500 survey, the pharmaceutical industry topped the list of the most profitable industries, with a return of 17% on revenue.<sup>[18]</sup>

Pfizer's cholesterol pill Lipitor remained a best-selling drug world-wide until June 2010 (prior to its patent expiry in Canada). Its annual sales were \$12.9 billion, more than twice as much as its closest competitors: Plavix, the blood thinner from Bristol-Myers Squibb and Sanofi-Aventis; Nexium, the heartburn pill from AstraZeneca; and Advair, the asthma inhaler from GlaxoSmithKline.<sup>[16]</sup>

IMS Health publishes an analysis of trends expected in the pharmaceutical industry in 2007, including increasing profits in most sectors despite loss of some patents, and new 'blockbuster' drugs on the horizon.<sup>[19]</sup>

*Teradata Magazine* predicted that by 2007, \$40 billion in U.S. sales could be lost at the top 10 pharmaceutical companies as a result of slowdown in R&D innovation and the expiry of patents on major products, with 19 blockbuster drugs losing patent.<sup>[20]</sup>

### Market leaders in terms of revenue

The following is a list of the 20 largest pharmaceutical and biotech companies ranked by healthcare revenue. Some companies (e.g., Bayer, Johnson and Johnson and Procter & Gamble) have additional revenue (from non-pharmaceutical sales) and hence is not included here.

The phrase **Big Pharma** is often used to refer to companies with revenue in excess of \$3 billion, and/or R&D expenditure in excess of \$500 million.

Revenue Rank 2008	Company	Country	Total Revenues (USD millions)	Healthcare R&D 2006 (USD millions)	Net income/ (loss) 2006 (USD millions)	Employees 2006
1	Novartis	Switzerland	53,324	7,125	11,053	138,000
2	Pfizer	USA	48,371	7,599	19,337	122,200
3	Bayer	Germany	44,200	1,791	6,450	106,200
4	GlaxoSmithKline	United Kingdom	42,813	6,373	10,135	106,000
5	Johnson and Johnson	USA	37,020	5,349	7,202	102,695
6	Sanofi-Aventis	France	35,645	5,565	5,033	100,735
7	Hoffmann-La Roche	Switzerland	33,547	5,258	7,318	100,289
8	AstraZeneca	UK/Sweden	26,475	3,902	6,063	50,000+
9	Merck & Co.	USA	22,636	4,783	4,434	74,372
10	Abbott Laboratories	USA	22,476	2,255	1,717	66,800
11	Wyeth	USA	20,351	3,109	4,197	66,663
12	Bristol-Myers Squibb	USA	17,914	3,067	1,585	60,000
13	Eli Lilly and Company	USA	15,691	3,129	2,663	50,060
14	Amgen	USA	14,268	3,366	2,950	48,000
15	Boehringer Ingelheim	Germany	13,284	1,977	2,163	43,000

16	Schering-Plough	USA	10,594	2,188	1,057	41,500
17	Baxter International	USA	10,378	614	1,397	38,428
18	Takeda Pharmaceutical Co.	Japan	10,284	1,620	2,870	15,000
19	Genentech	USA	9,284	1,773	2,113	33,500
20	Procter & Gamble	USA	8,964	n/a	10,340	29,258

Source: *Top 50 Pharmaceutical Companies Charts & Lists*, Med Ad News, September 2008<sup>[21]</sup>

### Market leaders in terms of sales

The top 15 pharmaceutical companies by 2008 sales are:<sup>[5],[22]</sup>

Rank	Company	Sales (\$M)	Based/Headquartered in
1	Pfizer	43,363	US
2	GlaxoSmithKline	36,506	UK
3	Novartis	36,506	Switzerland
4	Sanofi-Aventis	35,642	France
5	AstraZeneca	32,516	UK/Sweden
6	Hoffmann–La Roche	30,336	Switzerland
7	Johnson & Johnson	29,425	US
8	Merck & Co.	26,191	US
9	Abbott	19,466	US
10	Eli Lilly and Company	19,140	US
11	Amgen	15,794	US
12	Wyeth	15,682	US
13	Teva	15,274	Israel
14	Bayer	15,660	Germany
15	Takeda	13,819	Japan

### Patents and generics

Depending on a number of considerations, a company may apply for and be granted a patent for the drug, or the process of producing the drug, granting exclusivity rights typically for about 20 years.<sup>[23]</sup> The 20 year term has been made a standard as per the Patent Cooperation Treaty (PCT) and TRIPS 1993. Companies can file a single patent application and designate countries where they desire patent protection to their invention. However, patent protection is not global and therefore companies have to file national phase application in each country of their choice. Details are available at <http://www.PharmaceuticalPatentsAndIntellectualProperty.com>

However, only after rigorous study and testing, which takes 10 to 15 years on average, will governmental authorities grant permission for the company to market and sell the drug.<sup>[24]</sup> Patent protection gives monopoly of invention to its owner and enables the owner of the patent to recover the costs of research and development through high profit margins for the branded drug. When the patent protection for the drug expires, a generic drug is usually developed and sold by a competing company. The development and approval of generics is less expensive, allowing them to be sold at a lower price. Often the owner of the

branded drug will introduce a generic version before the patent expires in order to get a head start in the generic market or may enter into a business agreement with a generic manufacturer (Authorized generics) giving the generic manufacturer the permission for the generic version of the drug.<sup>[25]</sup>

### **Medicare Part D**

In 2003 the United States enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), a program to provide prescription drug benefits to the elderly and disabled. This program is a component of Medicare (United States) and is known as Medicare Part D. This program, set to begin in January 2006, will significantly alter the revenue models for pharmaceutical companies. Revenues from the program are expected to be \$724 billion between 2006 and 2015.<sup>[26]</sup>

Pharmaceuticals developed by biotechnological processes often must be injected in a physician's office rather than be delivered in the form of a capsule taken orally. Medicare payments for these drugs are usually made through Medicare Part B (physician office) rather than Part D (prescription drug plan).

### **Mergers, acquisitions, and co-marketing of drugs**

A merger, acquisition, or co-marketing deal between pharmaceutical companies may occur as a result of complementary capabilities between them. A small biotechnology company might have a new drug but no sales or marketing capability. Conversely, a large pharmaceutical company might have unused capacity in a large sales force due to a gap in the company pipeline of new products. It may be in both companies' interest to enter into a deal to capitalize on the synergy between the companies.

### **Prescriptions**

In the U.S., prescriptions have increased over the past decade to 3.4 billion annually, a 61 percent increase. Retail sales of prescription drugs jumped 250 percent from \$72 billion to \$250 billion, while the average price of prescriptions has more than doubled from \$30 to \$68. [Retail prescription drug sales 1995 to 2006 PDF from http://www.census.gov](http://www.census.gov)

### **Publications**

The drug company Merck & Co. publishes the Merck Manual of Diagnosis and Therapy, the world's best-selling medical textbook, and the Merck Index, a collection of information about chemical compounds.

### **Marketing**

Pharmaceutical companies commonly spend a large amount on advertising, marketing and lobbying. In the US, drug companies spend \$19 billion a year on promotions.<sup>[7]</sup> Advertising is common in healthcare journals as well as through more mainstream media routes. In some countries, notably the US, they are allowed to advertise direct to the general public. Pharmaceutical companies generally employ sales people (often called 'drug reps' or, an older term, 'detail men') to market directly and personally to physicians and other healthcare providers. In some countries, notably the US, pharmaceutical companies also employ lobbyists to influence politicians. Marketing of prescription drugs in the US is regulated by the federal Prescription Drug Marketing Act of 1987.

In developing countries, a doctor's promotional items could comprise of organizing medical conferences, sponsoring vacation trips for the doctor and his family or even financing the doctor's daughter's wedding! Law makers in such countries have finally become cognizant of such unscrupulous practices and are attempting to take stricter measures against drug companies that allegedly offer extravagant promotional items.

### **To healthcare professionals**

Physicians, physician assistants and nurse practitioners are perhaps the most important players in pharmaceutical sales because they write the prescriptions that determine which drugs will be used by the patient. Influencing the physician is often seen as the key to prescription pharmaceutical sales.<sup>[27]</sup> A medium-sized pharmaceutical company might have a sales force of 1000 representatives. The largest companies have tens of thousands of representatives. Currently, there are approximately 100,000 pharmaceutical sales reps in the United States pursuing some 120,000 pharmaceutical prescribers.<sup>[28]</sup> The number doubled in the four years from 1999 to 2003. Drug companies spend \$5 billion annually sending

representatives to physician offices. Pharmaceutical companies use the service of specialized healthcare marketing research companies to perform Marketing research among Physicians and other Healthcare professionals.

### **To insurance and public health bodies**

Private insurance or public health bodies (e.g. the NHS in the UK) decide which drugs to pay for, and restrict the drugs that can be prescribed through the use of formularies. Public and private insurers restrict the brands, types and number of drugs that they will cover. Not only can the insurer affect drug sales by including or excluding a particular drug from a formulary, they can affect sales by tiering or placing bureaucratic hurdles to prescribing certain drugs as well. In January 2006, the U.S. instituted a new public prescription drug plan through its Medicare program known as Medicare Part D. This program engages private insurers to negotiate with pharmaceutical companies for the placement of drugs on tiered formularies.

### **To retail pharmacies and stores**

Commercial stores and pharmacies are a major target of non-prescription sales and marketing for pharmaceutical companies.

### **Direct to consumer advertising**

Since the 1980s new methods of marketing for prescription drugs to consumers have become important. Direct-to-consumer media advertising was legalized in the FDA Guidance for Industry on Consumer-Directed Broadcast Advertisements.

### **Controversy about drug marketing and lobbying**

There has been increasing controversy surrounding pharmaceutical marketing and influence. There have been accusations and findings of influence on doctors and other health professionals through drug reps, including the constant provision of marketing 'gifts' and biased information to health professionals;<sup>[29][30]</sup>

Highly prevalent advertising in journals and conferences; funding independent healthcare organizations and health promotion campaigns; lobbying physicians and politicians (more than any other industry in the US<sup>[31]</sup>); sponsorship of medical schools or nurse training; sponsorship of continuing educational events, with influence on the curriculum;<sup>[32]</sup> and hiring physicians as paid consultants on medical advisory boards. To help ensure the status quo on U.S. drug regulation and pricing, the pharmaceutical industry has thousands of lobbyists in Washington, DC that lobby Congress and protect their interests. The pharmaceutical industry spent \$855 million, more than any other industry, on lobbying activities from 1998 to 2006, according to the non-partisan Center for Public Integrity.<sup>[33]</sup>

Pfizer spend \$ 5.6 M on government lobbying in fourth quarter 2009-10. The US Drug industry group PhRMA spent \$7M in 1st quarter lobbying on generic drug and other issues.

<http://finance.yahoo.com/news/Drug-industry-group-spent-7M-apf-1052072225.html?x=0&.v=1>

Some advocacy groups, such as No Free Lunch, have criticized the effect of drug marketing to physicians because they say it biases physicians to prescribe the marketed drugs even when others might be cheaper or better for the patient.<sup>[34]</sup>

There have been related accusations of disease mongering<sup>[3]</sup> (over-medicalising) to expand the market for medications. An inaugural conference on that subject took place in Australia in 2006.<sup>[35]</sup> In 2009, the Government-funded National Prescribing Service launched the "Finding Evidence - Recognising Hype" program, aimed at educating GPs on methods for independent drug analysis.

A 2005 review by a special committee of the UK government came to all the above conclusions in a European Union context<sup>[36]</sup> whilst also highlighting the contributions and needs of the industry.

There is also huge concern about the influence of the pharmaceutical industry on the scientific process. Meta-analyses have shown that studies sponsored by pharmaceutical companies are several times more likely to report positive results, and if a drug company employee is involved (as is often the case, often

multiple employees as co-authors and helped by contracted marketing companies) the effect is even larger.<sup>[37][38][39]</sup> Influence has also extended to the training of doctors and nurses in medical schools, which is being fought.<sup>[40]</sup>

It has been argued that the design of the Diagnostic and Statistical Manual of Mental Disorders and the expansion of the criteria represents an increasing medicalization of human nature, or "disease mongering", driven by drug company influence on psychiatry.<sup>[41]</sup> The potential for direct conflict of interest has been raised, partly because roughly half the authors who selected and defined the DSM-IV psychiatric disorders had or previously had financial relationships with the pharmaceutical industry.<sup>[42]</sup> The president of the organization that designs and publishes the DSM, the American Psychiatric Association, recently acknowledged that in general American psychiatry has "allowed the biopsychosocial model to become the bio-bio-bio model" and routinely accepted "kickbacks and bribes" from pharmaceutical companies.<sup>[43]</sup>

### **Developing world**

The role of pharmaceutical companies in the developing world is a matter of some debate, ranging from those highlighting the aid provided to the developing world, to those critical of the use of the poorest in human clinical trials, often without adequate protections, particularly in states lacking a strong rule of law. Other criticisms include an alleged reluctance of the industry to invest in treatments of diseases in less economically advanced countries, such as malaria; Criticism for the price of patented AIDS medication, which could limit therapeutic options for patients in the Third World, where the most people have AIDS. In September 2008 the Open Source Drug Discovery Network was launched in India to combat infectious diseases common to developing countries.

### **Patents**

Under World Trade Organization rules, a developing country has options for obtaining needed medications under compulsory licensing or importation of cheaper versions of the drugs, even before patent expiration (WTO Press Release). Pharmaceutical companies often offer much needed medication at no or reduced cost to the developing countries. In March 2001, South Africa was sued by 41 pharmaceutical companies for their Medicines Act, which allowed the import and generic production of cheap AIDS drugs. The case was later dropped after protest around the world.

### **Nigerian clinical trial**

In 1996, a pediatric clinical trial conducted on behalf of Pfizer tested the antibiotic Trovan allegedly without first obtaining the informed consent of participants or their parents.<sup>[44][45][46][47]</sup>

On 29<sup>th</sup> June 2010, The US Supreme Court on Tuesday dismissed an appeal by Pfizer, which sought to end lawsuits by Nigerian families who accuse the pharmaceutical giant of testing a new antibiotic on their children without proper consent. By not hearing or commenting on the appeal, the justices let stand a US appellate court ruling that reinstated the suits, which accused Pfizer of carrying out an illegal trial of the experimental drug Trovan on 200 sick children during a meningitis outbreak in 1996 in Nigeria's Kano state. Plaintiffs say 11 children died, and another 189 suffered deformities and other conditions such as blindness, brain damage and paralysis as a result of the drug trial.

### **Charitable programmes**

Charitable programs and drug discovery & development efforts are routinely undertaken by pharmaceutical companies. Some examples include:

- "Merck's Gift," wherein billions of River Blindness drugs were donated in Africa <sup>[48]</sup>
- Pfizer's gift of free/discounted fluconazole and other drugs for AIDS in South Africa <sup>[49]</sup>
- GSK's commitment to give free albendazole tablets to the WHO for, and until, the elimination of lymphatic filariasis worldwide.
- In 2006, Novartis committed USD 755 million in corporate citizenship initiatives around the world, particularly focusing on improved access to medicines in the developing world through its Access to Medicine projects, including donations of medicines to patients affected by leprosy, tuberculosis, and malaria; Glivec patient assistance programmes; and relief to support major humanitarian organisations with emergency medical needs.<sup>[50]</sup>

However, some NGOs such as Médecins Sans Frontières do not routinely accept corporate donations of medicines. More precisely, they do not become reliant on such supplies of medicines because the supply is dependent upon the fluid, profit-driven charities of said pharmaceutical companies, and thus may dry up during a critical or otherwise important time. [citation: "An Imperfect Offering" by ex-MSF president James Orbinski]

### Popular Blogs

- [Http://www.drugsinthemaking.com](http://www.drugsinthemaking.com)
- [Http://www.Pharm-Education.com](http://www.Pharm-Education.com)
- [Http://QA-Expert.com](http://QA-Expert.com)
- [Http://PharmaceuticalPatentsAndIntellectualProperty.com](http://PharmaceuticalPatentsAndIntellectualProperty.com)

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**Shruti Accelerates ROI ...**

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