2006

From Scientists to Merchants: The Transformation of the Pharmaceutical Industry and its Impact on Health

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Abstracts

The number of innovative drugs reaching the market has decreased steadily during the last several years to a handful per year. At the same time, the amount of resources allocated by the pharmaceutical industries to promotion and marketing has increased at a faster pace than those allocated to research and development of new products. The paper presents the hypothesis that for the large corporations, the production of me-too drugs is more profitable than to invest in research and development of innovative products. Gaining a market share of me-too drugs requires large investments in promotion and marketing, one result of which is a division of labor among pharmaceutical firms. Because small firms lack the large resources needed for promotion and marketing, they carry out an increasing share of the research and development and sell the patents to the large corporations.

De Científicos a Comerciantes: La Transformación de la Industria Farmacéutica y su Impacto en la Salud

El número de medicamentos que representan verdaderos avances terapéuticos y que se comercializan anualmente ha ido decreciendo durante los últimos años y ahora no son más que un puñado. A la vez, la cantidad de recursos que la industria invierte en promoción y marketing ha aumentado a una velocidad más rápida...
que las inversiones en investigación y desarrollo de productos nuevos. Este trabajo discute la hipótesis de que la producción de medicamentos “yo también (me too en inglés)” es más lucrativa que la inversión en la investigación y desarrollo de productos innovadores. Para poder controlar una parte significativa del mercado con los medicamentos “yo también” la industria necesita invertir considerablemente en promoción y marketing, y como consecuencia ha habido una división de tareas entre los diferentes tipos de industria farmacéutica. Las compañías pequeñas no tienen recursos suficientes para la promoción y marketing, y cada vez tienen un papel más importante en la investigación y desarrollo de productos innovadores, luego estas compañías venden las patentes a las grandes corporaciones.

Des scientifiques aux marchandeurs: la transformation de l’industrie pharmaceutique et l’effet sur la santé

Le nombre des médicaments innovateurs sur le marché diminue depuis plusieurs années jusqu’au point où ils n’y sont qu’une poignée par an. En même temps, les ressources reparties par les industries pharmaceutiques pour la promotion et la commercialisation augmentent plus vite que celles qui sont reparties pour la recherche-développement des médicaments nouveaux. Dans cet article, on formule l’hypothèse que quant aux entreprises les plus larges il est plus profitable de produire les “moi aussi” médicaments (qui sont à la mode) qu’il est profitable d’investir dans la recherche-développement des nouveaux produits efficaces. Pour gagner un marché des “moi aussi” médicaments il faut des investissements dans la promotion et la commercialisation, dont un résultat est la division de travail parmi les entreprises pharmaceutiques. Puisque aux petites entreprises, il manque les ressources assez larges pour la promotion et la commercialisation, au lieu de les faire elles-mêmes, elles font la plupart de la recherche-développement et vendent les brevets d’invention aux entreprises plus larges.

From Scientist to Merchants: The Transformation of the Pharmaceutical Industry and its Impact on Health

For a number of years, the prices of medicines have increased at a higher rate than inflation. The transnational innovative pharmaceutical industries, known as big PhRMA, are large corporations which, regardless of the country where they originated, are members of Pharmaceutical Research and Manufacturers of America. Big PhRMA claims that to maintain the rhythm of discoveries that have produced the miracle pills requires ever-growing investments in research and development (R&D). Many organizations and scholars have a different explanation for the high costs of medicines. According to them, the high costs are explained by PhRMA’s interest in maintaining
huge profits, high salaries and stock options for their executives, and more fundamentally by the high expenditures in marketing and administration; and are not a consequence, as the industry asserts, of the high costs of R&D.

Families USA uncovered that in 2001 the executives of 10 big firms received an average compensation of US$23 million exclusive of unexercised stock options, the average of which was US$48 million. Between 1991 and 2001, the pharmaceutical industry was the most profitable industry in the US or about five-and-one-half times more profitable than the average of the Fortune 500 companies, with an annual rate of return to shareholders, between 1996 and 2001, of 18.4 percent compared with a median return of 9.2 for the Fortune 500 shareholders.

The high costs of promotion and marketing

It is difficult to provide accurate figures of the amounts that big PhRMA spends on promotion and marketing (P&M) because official industry figures combine the expenditures on promotion, marketing and administration in a single category, and in addition, as we will see, some firms report under R&D expenditures that many consider should be included under P&M. Although the industry presents a very different picture, there is an agreement among independent researchers that the amount of funds spent on R&D of innovative drugs are less than the amounts spent on administration, marketing, and promotion by a factor of two or more.

The following summary presents P&M activities carried out by big PhRMA:

1. Recruitment and training of drug representatives. In the US there are 100,000 representatives to inform physicians with an average salary of US$62,400 and additional US$19,300 for cash bonuses.

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1 Families USA 2002, pp. 6–7.
2 Families USA 2002, p. 1; p. 3; p. 13.
3 Public Citizen 2001a, 12.
4 Pharmaceutical Research and Manufacturers of America 2004.
5 Families USA 2002, p. 3.
2. Advertisements in the professional literature and directed to the consumer (DTC) (only the US and New Zealand allow DTC advertising of prescription drugs). It is estimated that in 2002, only in the US, the pharmaceutical firms spent in promotion US$21 billion.8

3. The continuing education courses that all physicians are required to take are almost entirely financed by pharmaceutical industries. About US$1.9 billion are yearly spent by the industry in organizing conferences and courses.9 There is a growing number of physicians that consider that such funding creates a conflict of interest because each company uses these courses to promote its drugs.10 In 2000 the industry sponsored 314,000 events for physicians.11 In addition to the courses, the industry sponsors the participation of physicians at professional meetings, (in some instances with a companion). In developing countries most physicians attend international overseas meetings courtesy of the industry. It is understood, that there is a quid pro quo and physicians who do not prescribe the firms’ products risk not being invited again. Wazana carried out a survey to assess the impact of travel support, scholarships and gifts by the industry on prescribing practices and found that they did influence them.12 There is no information about the costs of these activities but given the large number of events and scholarships granted it can be presumed to be sizeable.

4. Paying well-recognized physicians to head Phase IV clinical trials. These studies take place once a drug has been approved and is already commercialized. Their purpose is to discover if the drug has any unknown side effects, or if it can be used for other indications or for a special population group. In some cases, these studies are required by the Food and Drug Administration. These studies have also the non-written objective of promoting the use of the drug.13 The pharmaceutical industry selects a well-recognized specialist or renowned professor who will receive a

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8 Norris et al. p. 1.
12 Wazana 2000.
DOI: 10.1163/187219106777304287
substantial payment for carrying-out the study; the expectation is that he/she would be able to find that the drug has more benefits or fewer risks than other existing products. The sponsor expects that the professional status of the director of the study will influence his/her colleagues to prescribe the drug. There is no information on the number and costs of Phase IV studies because most are not registered and the results are not always disclosed. It has been estimated that the cost per patient enrolled in a cardiovascular clinical trial in industrial societies ranges from US$5,000 to 10,000 depending on the complexity of the study, and the investigator receives a fee between US$2000 and 3000 for each patient recruited for the study. Phase IV studies are also carried out in developing countries, but there is secrecy about payments to the carefully selected directors of the studies, and information surfaces only when irregularities are brought to the attention of the media or in audits. There is no information about the costs of Phase IV studies, but they are bound to be high. We can assume that the industry considers these expenditures to be part of its R&D costs, all of which are tax deductible.

5. The industry sponsors research and pays scholars to write in leading academic journals. It has been discovered that, compared to independent research, sponsored research frequently finds more therapeutic advantages and fewer side effects of drugs manufactured by the sponsoring manufacturer; it is also known that the industry pays scholars to sign articles written by ghost writers – also paid by the industry – that present findings about the benefits of the drugs, regardless if this is the case or not. Subsequently, they buy thousands of reprints of these articles to be distributed to physicians at meetings (without these purchases and drug advertisements many medical journals would cease to exist). A survey conducted by Martinson et al. found that 15.5 percent of US scientists funded by the National Institute of Health had changed the design, methodology or results of a study in response to pressure from a funding agency. It is probable that research grants and costs related to publications are categorized as R&D, even if its primary objective is promotion.

14 Bassand et al. 2003, p. 1172.
17 Martinson et al. 2005, p. 737.
7. Grants to patients’ associations are used to make dubious claims about the need to use certain drugs while minimizing their side effects. For example, the National Sleep Foundation receives funding from firms that market sleeping pills; for the years 1999 and 2000 Citizens for Better Medicare, a group that without public knowledge had been created by the pharmaceutical industry, spent US$65 million on “issue ads”.18 In the European Union the funding by and links between the industry and the European Patients’ Forum, an advocacy group for the defense of patients, have been uncovered.19 This group is a coalition that represents several organizations of patients and has become the official mediator of patients before the European Union. The scandals resulting from the relations of organizations that purport to represent patients and the industry has reached such levels that the new code of practice of the Association of the British Pharmaceutical Industry requires from all industries working in the United Kingdom full disclosure of the relations with and funding of all advocacy groups.20 Figures of grants are not available but, compared with other promotional and marketing costs are probably not high.

8. Distribution of millions of free samples to physicians, which in 2001 were valued at US$11 billion, but it is not clear if this figure is based on their retail or factory price; if the figure is based on retail prices, the firms may obtain some additional tax benefits because they are deducting more than the real costs.

Other expenditures: Protecting and defending big PhRMA’s interests

Like other corporations, big PhRMA firms spend large amounts of funds in protecting and defending their interests. The following is a listing of these activities:

1. Maintaining a large number of lobbyists to influence legislation and persuade staff of the regulatory agencies in decisions that favor the industry over the protection of citizens. In the US, in 2004 the drug industry had

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18 Public Citizen 2001b, p. 11.
1,291 lobbyists (52 percent were former federal officials) at a cost of US$123 million, higher than any other industry, and in the seven years from 1998 to 2004 they lobbied more than 1,600 bills.\textsuperscript{21}

2. Contributing donations to political parties and political candidates. In the US in seven years, from 1998 to 2004, the industry contributed to federal campaigns in the amount of US$87 million and the political contributions to state governments amounted to US$46 million.\textsuperscript{22}

3. Maintaining a top class team of lawyers to find loopholes to extend the market exclusivity, and to fight legal and class action suits. When needed the industry hires the best law firms. The total costs paid to the lawyers and legal firms are not known, but it can be assumed that they are substantial.

4. Payment of multimillion-dollar settlements and fines. For example, in January of 2006, Bristol-Myers Squibb reserved US$185 million in anticipation of a possible settlement of a class-action lawsuit filed by users of the once-promising heath drug Vanlev;\textsuperscript{23} in 2005 GlaxoSmithKline was fined US$150 million for the fraudulent price increase of two drugs; the same year Serono, a Swiss biotech firm was fined US$704 million for the illegal promotion of a drug in the US; also in 2005 the government of Brazil fined twenty firms among them Abbott, Ely Lilly, Schering Plough, Roche, Bristol-Myers Squibb, Aventis Pharma, Bayer, Glaxo Wellcome, AstraZeneca, Boehringer Ingelheim, Aventis, Behring, Sanofi-Synthelabo, Wyeth-Whitehall for colluding to impede the commercialization of generics in the country.\textsuperscript{24} Tap Pharmaceuticals paid US$875 million for a fraud against the US government.\textsuperscript{25} In its first case against Vioxx, the court condemned Merck to pay US$253 million and some analysts have speculated that the thousands of cases pending could cost Merck billions. Rarely, a month goes by without at least one multimillion court case or a fine against a pharmaceutical firm.

\textsuperscript{23} Anonymous 2006, 19.
\textsuperscript{24} Anonymous 2005a, p. 87.

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Costs of innovation vs. R&D

There is consensus that the cost of bringing highly innovative drugs to the market is increasing, but there is disagreement among experts about the cost of developing them. DiMasi et al., using confidential data of 68 selected drugs provided by ten firms arrived at the average figure of US$802 million (in US$ of 2000). These findings have been contested by several other researchers that raised questions about the methodology and offered evidence that the price of a new innovative drug could be as low as one-fourth to half of the DiMasi’s estimate. Critics of DiMasi indicate that the Tuft Center for the Study of Drug Development, where he is based, receives large unrestricted grants from the pharmaceutical industry, which has a vested interest in demonstrating that the development of new drugs is very expensive in order to justify high sale prices.

Indian pharmaceutical industries claim that in India innovative molecular entities (NMEs) can be brought to the market for a fraction of the US$802 million, or about US$50 million. Although not always reflected in their reports, some PhRMA industries are outsourcing parts of the development process to China and India.

The industry’s lack of transparency makes it difficult to know with certainty the real allocations to innovative R&D and to other activities designed to increase sales and profits. If today’s industry’s estimate of producing a new drug is US$1 billion and we multiply this amount by the average number of innovative drugs per year (eight or nine), the total amount is considerably less that the figure estimated by Family USA for P&M and administration expenditures. According to this Foundation in 2001 the Merck, Pfizer, Bristol-Myers Squibb, Abbot, Wyeth, Pharmacia (purchased by Pfizer in 2003), Eli Lilly, Schering-Plough and Allergan spent US$45 billion for marketing, advertisement and administration.

The shift from science to trade

By the time that a Lancet’s editorial noted in 2002 that big PhRMA was falling behind in bringing to the market “truly new drug discoveries,” it was well
known that the interest in research by big PhRMA was declining. Several months earlier the National Institute for Health Care Management had published a report documenting that of the 1035 drugs approved by the FDA between 1989 and 2000, only 153 were highly innovative drugs (priority-rated new molecular entities, see note 1 for the definition) or about 13 per year for the 12-year period. The decline in innovation continued. During 1999–2002 the average yearly number of highly innovative drugs was reduced to eight. Perhaps it was this deterioration that led Lancet to recommend that the industry invest “preferentially in the creative minds in their laboratories”. The Lancet editor had failed to understand that big PhRMA’s interests have shifted from innovative research to gaining a market share.

PhRMA expenditures in R&D more than doubled from 1993 to 2003. According to the industry, in 2000 the private for-profit sector invested US$35.4 billion in R&D, the number of approvals of new molecular entities declined (See Figure 1). If PhRMA’s increasing expenditures in R&D cannot be attributed to the high costs of producing a few new highly innovative drugs, the question that needs to be answered is where do the rest of the R&D expenditures go. Our hypothesis is that capitalism has forced the pharmaceutical industry to spend a sizeable amount of R&D funds to produce drugs that do not add new therapeutic value to the market. The purpose of these drugs is to compete with innovative blockbuster drugs, those that generate more than US$1 billion of yearly sales. It is this competition to gain a market share that forces industry to make very large investments in P&M. Industries that fail in the competition are bought out by the others. Those that support capitalism affirm that competition fosters innovation, but this does not seem to be the case in the pharmaceutical sector, the contrary might be true.

The returns from developing true innovative molecular entities for an illness or condition for which there is a high demand in Western nations are very high, and the financial success of the PhRMA industries depends on bringing

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30 Kaplan and Laing 2004, p. 15.
34 Food and Drug Administration 2004, p. 2.
into the market a few blockbusters. For example, the combined sales of Norvasc (Pfizer), Zoloft (Merck), and Neurontin (Bristol-Myers Squibb) amounted in 2004 to over US$10 billion, and in 2002 Lipitor by itself represented US$7.4 billion or 21 percent of all Pfizer’s sales.

Figure 1  Research and Development expenses and new molecular entities approved 1970–2002

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<th>Number of NMEs</th>
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Note: Line relates to the right y axis and denotes worldwide R&D spending by PhRMA member companies according to their official figures. Inflation-adjusted to constant 2002 US$. The source for new molecular entities approved is the US Food and Drug Administration Center for Drug Evaluation and Research. New molecular entities may not be innovative, i.e. they may not add any therapeutic value to the drugs already in the market. Some of the new molecular entities are withdrawn from the market when post-commercialization surveillance uncovers serious side effects; the number of withdrawals has increased in recent years. Some new molecular entities are for ‘created diseases’ and therefore of little therapeutic value.

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If the firm that launches a blockbuster drug can, through patents and other means, hold market exclusivity and control the price for a number of years, one would think that the company would not need too many breakthroughs and that most efforts would be focused on extending the market exclusivity period. But when there is a breakthrough, a new blockbuster, other big PhRMA firms try to benefit from the discovery by developing similar drugs that will use the same action mechanism and produce very similar effects. These medicines are called “me-too drugs.” In some cases, the me-too drug may offer some advantages over the original product (i.e. could be easier to use, safer or more convenient to administer) but this is not always the case. There is little difference among the statins that are available in the market: Mevacor, Lipitor, Zocor, Pravachol, Lescol and the more recent one Crestor; but the manufacturers of these drugs have to fight to increase their market share.

To capture the market the companies incur in large P&M expenditures to convince prescribers, patients and the community at large that their product is better than that of the competitor. There are cases where pharmaceutical companies reach the market with a similar product almost simultaneously, and during the final development stages the companies race to reach the market first and capture the clientele (i.e. Vioxx and Celebrex). Regardless of the process, once me-too drugs are in the market, all owners have the same common interest in extending the life of the patents.

The competition to gain a market share of blockbusters has changed the behavior of big PhRMA and explains the need for the activities described earlier that require large outlets in P&M. In 1999, Merck placed Vioxx in the market and the following year spent US$161 million advertising the drug to gain a market share from Pfizer’s Celebrex that had been launched earlier.37 By February of 2004, before Vioxx was withdrawn from the market, it controlled 37 percent of the market of the Cox-2 inhibitors (Vioxx, Arcoxia, Celebrex and Bextra), and Celebrex 41 percent. The industry had estimated – before the side effects of Cox-2 inhibitors were made public – that in 2009 the total sales of these medicines would be US$8.5 billion.38

The priority given to M&R over biological sciences has an important effect in the organizational culture and behavior of big PhRMA firms. If what is

38 Bowe 2004b, p. 16.

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considered relevant is P&M, then selecting the leadership, the status and rewards within the organization are bound to be granted to those employees that excel in the marketing and promotional side of the corporation rather than to the scientists.

The promotion and marketing of new-disease and life-style drugs

Drug sales are not exclusively based on the needs of patients to get healthy. The parameters used to diagnose risk factors for diseases have been recently modified with the help of the industry. We have seen modifications in blood pressure thresholds that have resulted in a significant number of patients being classified as borderline or hypertensive, in the glucose levels to diagnose pre-diabetic conditions, and in the optimal levels of LDL cholesterol. According to Moynihan and Cassels eight of the nine members of the panel that in 2004 revised the cholesterol parameters and lowered them were on drug company payrolls, a lowering that trebled the anti-cholesterol drugs adults in need of statins to 40 million, and nine of the 11 experts on the panel that lowered the parameter for hypertension had financial links to the industry.39 In addition, behavioral problems have been transformed into new diseases. Such are the cases of attention deficit, social anxiety disorder, premenstrual dysforic disorder, and gastroesophageal reflux disease.40 Psychiatrists also on the pay-rolls of the pharmaceutical industry have offered a medical explanation for the new disease known as attention deficit.

Blockbusters are also developed to achieve certain desirable conditions or to provide a chemical solution to a health problem that some patients could resolve with less risks through behavior modification, these are called life-style drugs. The definition of what constitutes a life-style drug is controversial41 but there is agreement that certain drugs to control obesity, to treat male baldness, to enhance the erectile function in healthy young men, or to control smoking can be classified as life-style drugs. The number of new-disease and life-style drugs is growing. After parameters or thresholds are officially

40 Moynihan et al., 2002; Angell 2004, pp. 86–87.
41 Lexchin, 2001, p. 1449.
modified or new diseases are created, the P&M machine of big PhRMA starts working to promote sales of medicines for these conditions.42

The consolidation of the industry and division of labor
In the past years the pharmaceutical industry has seen a strong consolidation. In 1987 the top ten drug manufacturers had 27.5 percent of the world’s pharmaceutical market and by 2000 the percentage increased to 45.7.43 It could not be otherwise, because the need to spend ever-increasing amounts in M&P requires very large amounts of capital that only very large corporations can accumulate. But consolidations have moved big PhRMA further away from basic research. Analyzing several mergers, Pignarre concludes that the consolidation of the pharmaceutical industry has had a negative impact on innovation.44

The expenditures on P&M by big PhRMA are of such a magnitude that small firms cannot compete, and, therefore, few small firms venture into marketing; this has become the feud of the ever-bigger corporations. The small industries and big PhRMA have understood that a division of labor is financially more attractive for both of them. Small corporations engage in R&D of new molecular entities and big PhRMA buys the patents and takes responsibility for marketing those drugs that are expected to generate sales of over US$250 million per year for at least 14 years;45 if a small firm has several promising drugs in the pipeline, big PhRMA may decide to buy it out. In 2004, Pfizer purchased small Medarex Inc.46 and Roche signed 40 contracts to own the research findings and the commercialization permits of drugs in the process of being developed.47 In 2005 Roche purchased tiny BlycArt Biotechnology.48

The relations between big PhRMA and the small industries are not always easy. Tamiflu (oseltamivir), the drug for the treatment of the common flu,
illustrates the division of labor between large and small pharmaceutical industries and some of the tensions that these arrangements generate. Tamiflu was discovered and developed by Gilead, a small firm, and in 1999 Roche, the giant Swiss pharmaceutical, obtained the exclusivity for its production and marketing. The contract between the two corporations stipulated that Gilead would receive, on top of other pecuniary compensations, a percentage of the revenues generated by Tamiflu sales. Before the avian pandemic, the sales of Tamiflu were modest and limited to the flu season. Gilead started litigation claiming that Roche was not promoting adequately the drug, that is, Roche was not doing its part in the division of labor. The conflict was agreeably settled when purchase requests for Tamiflu suddenly skyrocked with the threat of the avian flu. Instead of litigation the two companies agreed to cooperate to fill the orders from more that 50 countries that decided to stockpile. It was estimated that sales of Tamiflu could reach US1bn in 2005 and 2006.\textsuperscript{49} Tamiflu, by an unpredictable event, became a blockbuster.

The case of the small Tanox is also illustrative. In 2000 Tanox began clinical trials of a NME known as TNX-901, a product to control allergic reactions to peanuts.\textsuperscript{50} Two big PhRMA firms, Genetech and Novartis, were cooperating with Tanox in the production of TNX-901 and the same year forced Tanox to discontinue the trials and develop Xolair, a product that Genetech had in the pipeline to treat the same allergy. Tanox refused and brought Genetech and Novartis to court. As of 2005 Xolair has not proven to be effective to treat the allergy. It is very possible that if the clinical trials had continued, TNX-201 would be today the only available treatment for the allergies caused by peanuts.\textsuperscript{51}

\textsuperscript{49} Cañás and Ugalde 2005, p. 59.
\textsuperscript{50} New molecular entity (NME) is a drug whose active ingredient has never before been approved by the Federal Drug Administration for the US market. Priority drug is a product qualifying for the FDA’s fast ‘priority review’ because it appears to offer clinical improvements over available products and therapies in efficacy, safety, compliance, or use in a new sub-population. National Institute for Health Care Management 2002, p. 4.
\textsuperscript{51} Hamilton 2005, p. 44.
The health impact

As discussed, big PhRMA needs to have market exclusivity to delay the entry of generics into the market and keep the monopoly prices. Once a drug loses market exclusivity, the prices fall rapidly to as little as 20 percent of the original drug. Through legislation, loopholes and illegal avenues, PhRMA firms have been successful in extending the life of the patents.

All over the world, high drug prices are the main access barrier. It is estimated that between 1.3 and 2.1 billion people do not have access to essential medicines. Most of those without access are the poor. The poor that have access to drugs spend the most of the health expenditures in the purchase of drugs and have to pay for them out-of-pocket. High prices also impact negatively in the adequate use of pharmaceuticals; for example, poor people cannot afford the entire treatment. In the case of antibiotics, incomplete treatments facilitate the development of microbial resistance to commonly used antibiotics and generate the need to develop newer and more expensive drugs.

A strategy to compete with generics is the promotion of brand loyalty to keep consumers buying their products in the middle of aggressive inroads from competitors. As a result, often in complicity with physicians and pharmacists, patients, including the poor, pay unnecessarily higher prices or purchase less medicine than the amount prescribed and cannot complete the entire course of treatment.

Due to aggressive marketing, life-style drugs can be easily abused; one well-known case is that of the drugs for erectile dysfunction such as Viagra (sildenafil) of Pfizer, Cialis (tadalafil) of Lilly, or Levitra (vardenafil) developed jointly by Bayer and GlaxoSmithKline. These companies have sold millions of pills without prescription in many countries. In some Latin American countries ads, which at times violated the norms established by regulatory agencies, were responsible for generating unnecessary demand for drugs in this therapeutic group. In Argentina, it was estimated that the large majority of users of these drugs were men between 30 and 45 years of age who did not suffer erectile dysfunctions, and in Mexico in 2002 Viagra sales amounted...
to US$550 million. Authorities and the industry have alerted that there are cases of coronary problems and blindness associated with their use.

Big PhRMA cannot afford to develop drugs that do not guarantee high returns because it needs resources for the P&M expenditures. It is for this reason that there are no drugs to cure diseases that affect millions of poor people worldwide (forgotten diseases) or a few persons (rare diseases, of which there are an estimated number of 5000\(^57\)).\(^58\) WHO estimates that only 10 percent of R&D funds are allocated to finding cure to diseases that affect 90 percent of the world’s population;\(^59\) and Sheila Shettle, Communications Officer of Médecins Sans Frontières affirmed that of 1,556 new products marketed globally between 1975 and 2004, only 20 or 1.3 percent were for tropical diseases and tuberculosis.\(^60\)

In a consumer’s society, success requires the creation of unnecessary demands. This basic rule of capitalism applies to the pharmaceutical industry. All drugs are powerful chemicals and their unnecessary use can cause serious iatrogenic effects. Over prescription and self-prescription caused by P&M has costly health and economic costs. In 1993, Wolfe and collaborators published a list containing the number and types of adverse drug reactions that occurred in the US such as thousands of injuries from traffic accidents, of hip fractures from falls, of life-threatening heart toxicity, of mental impairment, of drug-induced parkinsonism and tardive dyskenesia; they estimated that in 1990 only among those 65 years of age and above there were 650,000 hospitalizations caused by adverse drug reactions.\(^61\) Obviously, many of them were produced by errors. If this study would be replicated today, the result would be worse because the average number of medicines consumed per person in the US has increased, in part due to aggressive P&M. The situation is even worse in developing nations where regulations of prescription and dispensation of drugs are very poorly enforced and the educational levels of the majority are low.

\(^{57}\) Medicus Mundi 2003, p. 30.

\(^{58}\) Trouiller et al. 2002.

\(^{59}\) World Health Organization 2004, p. 11.

\(^{60}\) Reuters 2006, http://in.news.yahoo.com/060125/137/6273z.html

\(^{61}\) Wolfe et al. 1993, pp. 16–54.
Conclusions

The model followed by big PhRMA is very questionable. In spite of the many attempts to control the behavior of the industry, the efforts have not changed the model. In fact, the model for the production of pharmaceuticals should be exactly the opposite, a minimum of expenses in P&M and a full dedication to find solutions to the diseases that continue to afflict mankind. If the efforts of the industry were dedicated exclusively to the discovery of new innovative drugs, it is very possible that the industry would profit from the sales of drugs for rare and neglected diseases, and governments could afford to subsidize all drugs needed by their citizens. Perhaps in a capitalist market is not possible to change the current pharmaceutical model. If this is the case, there will be little choice but to find new solutions in which the public sector will have to play a significant role.

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