

Big Pharma: Private profit before public health

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Very few people, at least in the western world, will go through life without some form of pharmaceutical treatment. The global market in pharmaceuticals was worth in excess of \$954 billion in 2011 and has been predicted to exceed \$1.1 trillion by 2014¹. With such huge revenues it is inevitable that the pharmaceutical industry will exhibit some of the very worst attributes of modern capitalism. The fact that these attributes occur in an industry that is directly related to peoples' health and well-being presents a stark contrast between the stated goals of the pharmaceutical companies to develop treatments to improve people's health and the reality of the capitalist system, which places profit above all other considerations.

Ireland is a significant hub for the multi-national pharmaceutical sector. Of the top 10 global pharmaceutical companies, eight have bases in Ireland including Pfizer, Eli Lilly, Genzyme, Merck, Elan and Allergan, and a number of the world's top selling prescription medicines are produced in Ireland. In all some 120 global and indigenous pharmaceutical companies operate in Ireland and the chemical and pharmaceutical sector accounts for over 50 percent of exports from Ireland, with 27 percent coming from prescription drugs. The Irish Times lists 94 pharmaceutical companies in its list of the top 1000 businesses in Ireland². The policies of suc-

cessive Irish governments has been to give the multi-national corporations everything they ask for and then some more for good measure, so it is not surprising given the sector's importance to the Irish exports and the mantra of 'export led growth', that pharmaceutical companies in Ireland have been able to more or less dictate terms to the government.

In order to entice companies to set up operations in Ireland the state made every effort to accommodate them. Ringaskiddy in Cork harbour has been a major hub for the pharmaceutical industry since the early 1980s. To facilitate their development, Cork County Council provided the largest capacity supply of fresh water in the country through the creation of the Harbour and City Water Supply Scheme and the ESB (Electricity Supply Board) supplied the necessary power infrastructure³. On top of this licences were granted for the direct release of effluent from the plants into Cork harbour. In fact, it has been suggested that a major factor for many pharmaceutical companies setting up in the area was the 'County Council planning department being particularly undemanding of companies where it came to pollution control'⁴.

All these concessions were piled on top of the key plank in the strategy of Irish governments for attracting foreign direct investment, the sacred cow of a 12.5 per-

¹http://www.imshealth.com/deployedfiles/ims/Global/Content/Corporate/Press%20Room/Top-Line%20Market%20Data%20&%20Trends/2011%20Top-line%20Market%20Data/Regional_Pharma_Market_by_Spending_2011-2016.pdf

²<http://www.top1000.ie/industries/pharma>

³Chris van Egeraat *Spatial Concentration in The Irish Pharmaceutical Industry: The Role of Government Intervention and Agglomeration Economies* <http://www.nuim.ie/nirsa/research/documents/WP%2028%20Chris%20van%20Egeraat.pdf>

⁴Quoted in Chris van Egeraat *Spatial Concentration in The Irish Pharmaceutical Industry: The Role of Government Intervention and Agglomeration Economies* above.

cent corporation tax rate. This strategy of allowing multi-nationals to keep even more of their profits has been key to the establishment of many companies in Ireland, despite the questionable benefits to the state given the relatively low levels of employment and the low tax receipts generated from their profits. Following the acquisition of Irish pharmaceutical company, Elan by US company Perrigo, the Financial Post noted that:

Buying the Dublin-based business allows Perrigo, based in Allegan, Michigan, to re-domicile itself in Ireland, where the corporate income-tax rate is 12.5%⁵

Despite the common narrative often heard from government ministers about our highly skilled and educated workforce it is this ability to pay little or, as in the case of many companies engaged in complex tax avoidance schemes, virtually no tax that encourages companies to base operations in Ireland.

Indeed the level of compliance the Irish state extends to the pharmaceutical industry is such that in 2011, in the midst of the recession, the Taoiseach Enda Kenny wrote a foreword for a document for Pharmaceutical Ireland (the organisation representing the pharmaceutical sector within the employers body IBEC) where he not only boasted of the 12.5 percent corporation tax rate but also that ‘an estimated 14% improvement in unit labour costs relative to the euro area is expected by 2012.’⁶ While workers were suffering from declining pay and conditions the head of govern-

ment was using this as a means to encourage companies to set up in Ireland, with the added incentive of paying low tax rates on any profits generated.

And yet in spite of the benefits extended to the pharmaceutical industry Irish drug prices remain scandalously high. There appears to be a strong preference among doctors to prescribe more expensive on patent drugs over available cheaper generics and pharmacists are obliged to dispense the specific brand of medication prescribed even if a cheaper generic is available. However even the price of generic versions of off patent drugs in Ireland are well above average and this is exacerbated by the use of branded generics. The reasons why healthcare professionals tend to supply patented rather than generic (and branded generic over non branded generic) will be addressed later in this article. The pharmaceutical industry in Ireland offers many excuses for this and has published many surveys on pricing in Ireland which seem to contradict the experiences of anyone who has ever purchased prescription medication in other countries such as France or Spain. On June 19 2013 for example the Irish Pharmaceutical Healthcare Association (IPHA) published details of a survey conducted by IMS Healthcare which despite acknowledging the high price of generic medicines in Ireland claimed that the price of

the 200 most frequently prescribed on patent medicines which amount to over 99% of the on patent segment of the market were examined, Irish prices were in line with those

⁵‘Perrigo to buy Irish drug company Elan for \$8.6-billion to get low tax base’ *Financial Post* <http://business.financialpost.com/2013/07/29/perrigo-to-buy-irish-drug-company-elan-for-8-6-billion-to-get-low-tax-base/>

⁶ *IRELAND The location of choice for scientific investment* Pharmaceutical Ireland, <http://www.idaireland.com/news-media/publications/library-publications/external-publications/Pharmaceutical.pdf>

in Austria, Belgium, Denmark, Finland, France, Germany, Netherlands, Spain and the UK.⁷

This assessment of drug pricing in Ireland was almost immediately contradicted by an ESRI report published on June 27 2013 which found that

New (i.e. single source in-patent) and generic pharmaceutical prices in Ireland are high relative to comparable EU Member States.⁸

How can we account for the discrepancy in these studies? IMS Healthcare, who we will meet again later, describe themselves as ‘a leading provider of information, services and technology to the pharmaceutical industry’ whilst the IPHA mainly represents the interests of the manufacturers of in patent drugs and so it is not surprising that their reports reflect their position and attempt to downplay the high price of prescription drugs in Ireland.

While industry spin may account for the differing survey results it still doesn’t explain why Irish consumers are paying so much for medication. The ESRI report offers a plausible answer locating the prices in

the series of negotiated voluntary agreements between the State and pharmaceutical representative bodies or trade associations.⁹

In other words the reason we pay higher prices for medication is the same reason the pharmaceutical industry has based itself in Ireland to such an extent, the relationship it has with the Irish state which has demonstrated time and again it’s willingness to do anything to keep big pharma happy.

The myriad of abuses perpetrated by the large pharmaceutical companies can, and indeed have, filled countless pages in many books and are far too numerous to deal with in any great depth in the space available here. In this article we will limit our scope to outlining some of the major issues relating to the global pharmaceutical industry at this moment in time.

Big Pharma

The global pharmaceutical industry is dominated by a small handful of large companies with the top ten, including such giants as Novartis, Pfizer, Merck, Glaxo-SmithKline, Johnson & Johnson and Abbott, accounting for around 40 percent of the global market and 52 percent of the protected or patented section of the market. Despite the value of the industry globally, and the continuing profitability of the sector, many changes are currently becoming evident in both the structure and focus of the pharmaceutical companies. In a 2013 white paper on the top ten pharmaceutical companies IMS Healthcare identified 4 key events shaping the global pharmaceutical market¹⁰. Examining some of these ‘market events’ and looking into how they have come about can serve as an in-

⁷‘New study shows prices of IPHA medicines in Ireland at European average’ <http://www.ipha.ie/news/latest-news.aspx?article=8bf296e2-5752-4f60-8ff0-204f3f6acd47>

⁸*Ireland: Pharmaceutical Prices, Prescribing Practices and Usage of Generics in a Comparative Context*, ESRI 2013 <http://www.esri.ie/UserFiles/publications/RS32.pdf>

⁹ibid

¹⁰*The changing face of the top 10 pharmaceutical companies*, IMS Health 2013 http://www.imshealth.com/deployedfiles/ims/Global/Asia%20Pacific/Content/Insights/Top10%20Pharma%20Companies%20WP%20final_for%20clients.pdf

structive starting point in analysing how the relentless pursuit of profit has shaped the modern pharmaceutical industry, as we know it.

The first of these events is described as:

Rising healthcare costs leading to inevitable payer pressure in the pharmaceutical market, which coupled with the ongoing financial crisis has tipped the emphasis from slowing pharma spend growth to actually cutting pharma spend in many mature markets.

While most of us are familiar with the catastrophic cuts implemented in health spending by governments and the reduced spending on health care by ordinary people suffering the affects of the austerity policies implemented in response to the global crisis currently engulfing capitalism, there is in reality far more behind this point than simply a reduction in pharmaceutical spending due to recession in much of the western world. In order to understand how the pharmaceutical industry, which as we have seen is still a highly profitable industry, views this trend of ‘cutting pharma spend’ we need to understand how the pharmaceutical industry has grown over the years. While there may be a germ of truth to the narrative of the pharmaceutical industry that they have developed an ever larger range of ever more effective drugs which have greatly improved peoples general health, the modern pharmaceutical industry owes its revenue generating position much more to aggressive marketing and business decisions geared towards increased profit.

The aggressive marketing strategies of global pharmaceutical companies have long been a source of criticism. Prohibited from direct advertising of drugs to patients in many jurisdictions (the USA being a major exception) companies aggressively market to doctors and other health care professionals, such as pharmacists, in order to encourage them to prescribe or recommend their treatments. These marketing strategies go beyond simply dispensing literature or branded paraphernalia or even sales reps visiting doctors. Company expense accounts are often used to wine and dine medical professionals or pay for their attendance at various ‘conferences’ as in one case in Ireland where Novartis, now the biggest pharmaceutical company globally, paid for a group psychiatrists to stay in the exclusive K Club in Kildare and to attend a series of lectures on hyperactivity, which recommended Ritalin, a drug manufactured by Novartis, as the preferred drug to treat the condition¹¹.

While these practices represent attempts by companies to increase their market share many companies are also keen to create new markets. In many cases these new markets are developed in ways many people find unsettling. There have been many incidences of companies promoting the so-called ‘off-label’ prescription of various drugs. Prescribing drugs off-label refers to the practice of prescribing drugs approved for the treatment of a particular condition (or a particular condition in a particular group) for other conditions (or other groups) for which it has not received approval. In 2012, Glaxo-Smith-Kline and Abbott pleaded guilty in the US to promoting the off-label use of a number

¹¹P. O’Grady *Why is the Irish health service in crisis?* Dublin Bookmarks 2005

¹²USDOJ: ‘GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data’ <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>

¹³USDOJ: ‘Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote’ <http://www.justice.gov/opa/pr/2012/May/12-civ-585.html>

of their drug products and were fined \$3 billion and \$1.5 billion respectively.¹²¹³

In addition to these attempts to broaden the potential consumer base for their products pharmaceutical companies may also attempt to devise new markets by creating a perceived need for new medications. In an article in the *Wall Street Journal*, Erik Simanis, a researcher at the Center for Sustainable Global Enterprise at Cornell University's Johnson School of Management, writing on problems faced by companies looking for a consumer base in developing countries puts forward the argument that:

Companies must create markets - new lifestyles - among poor consumers. They must make the idea of paying money for the products seem natural, and they must induce consumers to fit those goods into their long-held routines.¹⁴

He goes on to describe a failed venture by Proctor & Gamble to sell a water purification treatment and notes that in acknowledging the failure of the venture:

The company agrees that the real hurdle to cross when introducing a new product, in any market, is helping the consumer understand the benefit of doing something in a different way.¹⁵

While Proctor and Gamble may have failed in this particular venture, overall the pharmaceutical industry has been

highly successful in creating their own markets in particular in the developed world. The market creation strategies used by these companies generally follow a pattern of increased medicalisation of human behaviour. This process is often backed by supposed independent scientific research identifying a problem to which pharmaceutical companies can then market a treatment. This phenomenon is prevalent in the treatment of psychiatric disorders and is often referred to as 'a pill for every ill', but it extends well beyond psychiatric diagnoses. A particularly striking example of this approach occurred in 1999 with the publication in the *Journal of the American Medical Association* of an article entitled 'Sexual Dysfunction in the United States, Prevalence and Predictors'¹⁶. In this article it was claimed that 43 percent of American women experienced female sexual dysfunction. This highly questionable diagnosis was immediately the subject of intense scrutiny and the following edition of the *Journal of the American Medical Association* carried a correction noting that some of the authors had financial ties to Pfizer, the manufacturer of the male impotency treatment Viagra, who were at the time working on developing a drug known as UK-414-495, which was designed to treat female sexual dysfunction.

Another frequently cited example of this type of market creation is the prevalence of treatments for high cholesterol. Despite criticism of the evidence for a link between high cholesterol levels and heart disease pharmaceutical companies successfully promoted the idea that high cholesterol was linked to heart disease, culminat-

¹⁴E. Simanis 'At the Base of the Pyramid' *Wall Street Journal* June 15 2012 available at <http://online.wsj.com/article/SB10001424052970203946904574301802684947732.html#articleTabs%3Darticle>

¹⁵Ibid.

¹⁶Laumann EO, Paik A, Rosen RC. 'Sexual Dysfunction in the United States: Prevalence and Predictors'. *JAMA*. 1999;281(6):537-544. doi:10.1001/jama.281.6.537. <http://jama.jamanetwork.com/article.aspx?articleid=188762>

ing in the rewriting of the US National Institute of Health guidelines on what constitutes high cholesterol in 2004. The guidelines were written by a group of 9 experts 8 of which had links to large pharmaceutical companies. The result of this rewrite was that the market for drugs aimed at those with high cholesterol rose from 13 million in 1990 to 40 million in 2004.¹⁷ Indeed the Pfizer manufactured drug Lipitor, which is used to treat high cholesterol, is still the most successful drug in history and was until very recently the world's top selling prescription drug.

These cases serve to highlight the influence exerted by drug companies in both academia and government. Through funding of research large corporations can influence what research is carried out and researchers may be unable to publish results critical of the products manufactured by these corporations for fear of losing their funding source and damaging their chances of gaining future funding from other corporations. On a governmental level, the pharmaceutical companies as giant corporations with massive financial resources have the ability to effectively lobby for particular health policies.

This influence, which the pharmaceutical companies can bring to bear, is perhaps best illustrated in the process of running clinical trials for new pharmaceutical products. Before they can market drugs for use on the general public pharmaceutical companies must show in clinical trials that they are effective in treating the conditions they are designed to treat and also quantify any adverse effects from the drug. Despite the supposedly rigorous testing pro-

cedures required to bring a drug to market these clinical trials are often open to varying levels of abuse both in the design of the trials themselves and in the presentation and analysis of the trial data after the fact. The ways in which pharmaceutical companies manipulate these trials is a major subject of a recent book by Ben Goldacre, *Bad Pharma*¹⁸. In this book he describes many of the 'wily tricks, close calls, and elegant mischief at the margins of acceptability' that characterise these trials. Some of the common abuses he lists include the use of unrepresentative patient groups, comparing new drugs with older treatments either known not to be effective or known to be effective in different dosages or treatment regimes and stopping trials early. He also provides accounts of the various analytical tricks used to conceal negative outcomes such as publishing results for a subgroup of the trial, which may suggest a more positive outcome than the overall results or publishing results as relative rather than absolute risk reductions to make a treatment seem more effective¹⁹. Goldacre points to the systematic publishing bias where negative results remain unpublished and to the fact that while ultimately regulators may see all, or at least the majority, of the trial data no one else outside of the company will, unless they decide to publish their results. There is also the problem of so-called seed trials where the real purpose is not to gather useful information on the drug being tested but to encourage doctors to prescribe it.

When IMS Health talks about a trend towards 'cutting pharma spend in many mature markets' what they and the phar-

¹⁷Quoted in K. Allen *The Corporate Takeover of Ireland* Irish Academic Press Dublin 2007

¹⁸B. Goldacre *Bad Pharma: How drug companies mislead doctors and harm patients. Fourth Estate, 2012 (UK)*

¹⁹For example if a particular condition will effect 4 people in a sample of 1000 but only 2 will be effected if a particular drug is taken then the **relative** risk reduction is 50 percent while the **absolute** risk reduction in the sample group is only 0.2 percent.

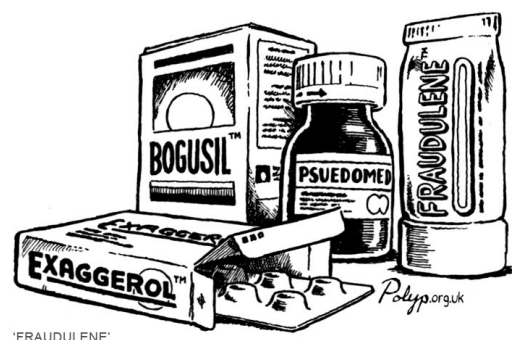
maceutical companies they work for are really concerned with is not that they may be forced to take a hit in their profits due to reduced consumption, indeed it is a near certainty in life that medical treatments and prescription drugs will always be in demand, but that they may not be able to continue to develop new markets for their products in the manner in which they have in the past. This reduced willingness to spend ever increasing amounts on drugs for an ever increasing array of diagnoses, coupled with some of the other ‘market events’ we will discuss shortly, has worried the industry, because they may not be able to continue to increase their profits at the same rate and so will not be able to provide their investors and shareholders with an ever increasing return.

The next ‘market event’ raised by IMS Health deals with the so-called ‘patent cliff’, which will affect many current blockbuster²⁰ drugs:

Significant number of small molecule genericisation events in the primary care market, leading to the demise of many blockbusters: 12 out of the world’s leading 20 blockbuster products are small molecules which either have or will lose their protection by 2016....²¹

These ‘small molecule²² genericisation events’ refer to the expiration of patents on many of the top selling prescription drugs after which other manufacturers will be able to produce generic versions of the product. The pharmaceutical industry

has vigorously defended patent rights over their products including some well publicised cases, such as a group of 39 companies taking the South African government to court in an attempt to block them importing and producing cheap versions of patented drugs to treat AIDS²³ and Novartis taking the Indian government to court over their refusal to grant a patent on one of their cancer drugs²⁴.



‘FRAUDULENE’

Such is the drive for profit for the pharmaceutical companies that when one of their key drugs is approaching its patent expiration they will often produce a new version of the drug with a slightly modified formula and use all of the marketing strategies discussed earlier to ensure it is prescribed over the older parent drug, which can be produced generically. The proliferation of this type of drug, often called ‘me too’ drugs, is a constant source of criticism of the pharmaceutical industry and the patent system they operate under. While supporters of the patent system claim it supports innovation as the process of bringing a new drug to market is so high and the successful drug must also pay for

²⁰Blockbuster drugs are those drugs that make large profits for the producing company. Within the industry a drug is regarded as a blockbuster if it makes more than \$1 billion.

²¹*The changing face of the top 10 pharmaceutical companies*, IMS Health 2013

²²In pharmaceutical terms a small molecule drug is a drug made from a molecule with low molecular weight as opposed to other treatments such as vaccines or proteins which are usually much larger and derived from biological processes as opposed to being chemically synthesised.

²³<http://news.bbc.co.uk/2/hi/africa/1285097.stm>

²⁴<http://www.doctorswithoutborders.org/publications/article.cfm?id=5769>

all the other drugs which failed to make it, opponents can point to the huge profits generated by patented drugs while under patent as well as the lack of development of truly new treatments in favour of a series of ‘me too’ drugs, which generally have little or no increased therapeutic efficiency in treating conditions.

The final two ‘market events’ directly follow from the first two and represent the industries attempt to maintain its profits. They are:

The rise of specialty care which combined with the previous trend, means the companies thriving in this new environment are more dependent on specialty care than primary care.²⁵

and

A flattening off in the true number of blockbusters with fewer launches achieving blockbuster status.²⁶

The focus on speciality care over primary care basically represents a shift away from treating conditions, which affect large numbers, to a focus on more rare conditions with smaller markets. This shift is not occurring because there is any shortage of conditions affecting large swathes of people across the globe, but because the drug companies don’t see a profit in treating many of these conditions, particularly those which affect people in developing countries or what Médecins Sans Frontières call ‘neglected diseases’ such as tropical diseases and tuberculosis. This profit driven shift in focus is not something new to the industry simply a continuation of the goal of maximising the returns on an

investment. The drop in the numbers of blockbuster drugs coming to market, only four drugs launched since 2009 have broken \$1 billion in sales, is simply another reflection of this quest as few major conditions are viewed as having the potential to provide the necessary return on the investment required for research and development to bring the treatments to market. Indeed IMS Health takes the view that the only remaining fast growing area of primary care, outside of vaccines, is Diabetes treatment.

In the introduction to *Bad Pharma* Ben Goldacre summarises the way he believes the pharmaceutical industry affects the healthcare we all rely on while alluding to the root cause of these practises, the pursuit of profit.

Drugs are tested by the people who manufacture them, in poorly designed trials, on hopelessly small numbers of weird, unrepresentative patients, and analysed using techniques which are flawed by design, in such a way that they exaggerate the benefits of treatments. Unsurprisingly, these trials tend to produce results that favour the manufacturer. When trials throw up results that companies don’t like, they are perfectly entitled to hide them from doctors and patients, so we only ever see a distorted picture of any drug’s true effects. Regulators see most of the trial data, but only from early on in a drug’s life, and even then they don’t give this data to doctors or patients, or even

²⁵ *The changing face of the top 10 pharmaceutical companies*

²⁶ *ibid.*

to other parts of government. This distorted evidence is then communicated and applied in a distorted fashion. In their forty years of practice after leaving medical school, doctors hear about what works through ad hoc oral traditions, from sales reps, colleagues or journals. But those colleagues can be in the pay of drug companies - often undisclosed - and the journals are too. So are the patient groups. And finally, academic papers, which everyone thinks of as objective, are often covertly planned and written by people who work directly for the companies, without disclosure. Sometimes whole academic journals are even owned outright by one drugs company. Aside from all this, for several of the most important and enduring problems in medicine, we have no idea what the best treatment is, because it's not in anyone's financial interest to conduct any trials at all. These are ongoing problems, and although people have claimed to fix many of them, for the most part they have failed; so all these prob-

lems persist, but worse than ever, because now people can pretend that everything is fine after all.²⁷

Goldacre describes the system by which new drugs are brought to market extremely well and correctly identifies a profit motive for the attendant abuses and the lack of profit as the reason why pharmaceutical companies are not focused on developing new solutions for many existing health problems. However, a full analysis of the problems must go further than this. In order to understand the workings of the pharmaceutical industry we need a much deeper understanding of the internal forces in capitalism which force companies to look at the relatively short term goal of realising a profit and generating a return for investors. This short-term outlook, which sees more spent on aggressive marketing strategies than on research into new and innovative treatments, drastically limits our ability to provide the global population with the necessary treatments to enable them to live full lives. Ultimately these issues must be addressed as part of a wider systematic change that moves away from a capitalist 'for profit' system to a system dictated by peoples' needs. A change that can provide a pharmaceutical industry that doesn't place private profit before public health.

²⁷B. Goldacre *Bad Pharma: How drug companies mislead doctors and harm patients*. Fourth Estate, 2012 (UK)