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Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

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International Pricing and Distribution of Therapeutic Pharmaceuticals – An ethical minefield

Authors:

Joan Buckley,
Lecturer
Department of Management and Marketing
University College Cork
Cork
Ireland
Email jb@ucc.ie
Tel +353 21 4902928

Séamus O Tuama
Lecturer
Department of Government
University College Cork
Cork
Ireland
Email sotuama@ucc.ie
Tel +353 21 4903238

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ABSTRACT

This paper seeks to identify and consider ethical issues relating to the international pricing of pharmaceuticals, drawing especially on liberal rights theories. It suggests why and how some of these issues might be resolved. It examines and critiques arguments presented by major pharmaceutical manufacturers. It addresses a range of ancillary issues like current pricing policies, R&D, intellectual property rights, rights to profits, the public good and regulation. It proposes a potential model for moving forward on the pricing of pharmaceuticals, with a view to increasing access to essential drugs.

International Pricing and Distribution of Therapeutic Pharmaceuticals – An ethical minefield

The Context: Rights, Ethics and Ideology

The international pharmaceutical manufacturing sector (Big Pharma) is a constant source of polemic and sometimes emotive debate. It is a sector unlike most in that its products have the potential to significantly improve health, and in many cases save lives. For that reason the international community has long grappled with whether or not such significant products should be left solely in the control of the private sector, and whether market forces should be allowed to determine access to products such as the anti-retroviral (ARVs) drugs used to combat HIV/AIDS. Intuitively it would seem clear that if there are remedies/significant medications available to treat pandemics such as AIDS then society is morally obliged to make them available and accessible to AIDS sufferers.

On deeper examination a raft of difficult, and virtually unanswerable questions arise out of this proposition. Which manufacturer's products are to be used? Who rewards the manufacturer and how? Which epidemics are to be addressed? Do we relate remedy to the severity of the illness, must it for example be life threatening, or is it sufficient that it threatens eyesight, sanity, or sexual function? Should all drugs be treated equally? How do we define society? Do we mean citizens of particular states or do we mean everyone on the planet? How are the drugs made available? How might they be priced so that they are available even where national governments have per-capita health budgets of US$2 per capita per annum? How can we ensure that, if the drugs are appropriately priced, they could actually be accessed by those in need? Should such drugs be available at the same price in poor and rich countries – should a millionaire AIDS victim in Europe or the United States be accorded the same price as a starving indigent in Sub-Saharan Africa?

Once we raise these questions there is a temptation to offer simplistic responses like: "obviously the priority must be life-threatening diseases". Even this relatively simple question exposes an underlying layer of complexity. One might legitimately hold that severe depression is potentially as life threatening as AIDS. Once these types of questions are raised we enter into the sort of difficult terrain that bedeviled definitions of relative and absolute poverty from as long ago as the pioneering work of Booth and Rowntree. In this case the arguments are very similar, we could say 'relative or absolute need' vis-à-vis the severity of the illness, or the individual's ability to buy or access the drugs. This leaves us with a dichotomy about simple definitions on one side and the nature of ethics on the other. We would be naïve not to imagine that both discussions are interrelated.

Concerns around the ethical operation of markets continue to resonate in political debates. While this is not new, today it is articulated in the context of an ideological unity never previously experienced since the emergence of industrialization. Neo-liberalism has positioned itself as the unchallenged dogma of enterprise, the starting point for understanding market forces and the driver for a new order in the global market spearheaded by the WTO. While there may be an unprecedented level of confidence in the market, there is a keen awareness, as Walsh (2004) states, that 'economic processes can and should be subject to normative evaluation'(241). He connects this concern back

to some of the leading medieval theorists who expressed concern about 'the Just Price and the prohibition of usury'. This may seem peculiar language to adopt when addressing issues very much related with life in the 21st century. However the topic has an indisputable pertinence to the subject of this paper and specifically in relation to how an ethics of pricing of drugs might be achieved.

Pogge (2002) clearly articulates a blind spot relative to 'moral universalism' when it comes to how the developed world views the abject poverty experienced by a considerable percentage of the world's population who live in less developed countries. For him 'socio-economic rights' such as are enshrined in Article 25 of the Universal Declaration of Human Rights are 'the most frequently violated human rights'(29). In short he says such disparities and injustices would not be tolerated within the nation states of the developed world, yet are tolerated vis-à-vis the less developed world through a sort of moral filter. At the very least this demonstrates a moral ambiguity, but may perhaps express as much a political pragmatism. Economic leaders may have as little taste for moral dilemmas at home as abroad, but may be acting as true rational actors in recognizing that utilitarian maximizing strategies are best achieved through a bifurcated strategy that eases public conscience at home while exploiting unrestrained market forces abroad. It is consistent to believe ethics have no place in the market and still accept political necessities.

Neo-liberalism's political climb to the ascendancy since the 1970s has tended to sideline ethical concerns in the face of the profit motive and the 'greed is good' mantra. This approach is built on an interpretation of the classical economics cannon, centred on Adam Smith (1776), which espouses complete faith in the market to solve all societal problems (if indeed the very existence of society is acknowledged) [i]. Lynch and Walsh (2003) put this as 'accounts of the profit-motive that purge it of all other-regarding elements'(43). Smith is presented as the prophet and famous quotations like that from his *Wealth of Nations* (Book One, Chapter II) are presented to copper fasten the argument:
'It is not from the benevolence of the butcher, the brewer or the baker that we expect our dinner, but from their regard to their own interest. We address ourselves, not to their humanity but to their self-love, and never talk to them of our necessities but of their advantage'.

In terms of pricing policy for pharmaceuticals the question of ethics is both a practical and philosophical issue. In pure practical terms price policy is about profit seeking and the maximizing of potential returns. It is about addressing the free market to obtain the maximum return. At this practical level exploitation of the market at once brings personal or corporate gain, but also facilitates the notion of the invisible hand to achieve the common good of increasing wealth. For Smith the invisible hand is essentially the unseen outcome of individual rational choices supporting the common good serendipitously rather than arising from any moral motives by the actor to achieve that goal, apart from self-interest. In simple terms it might be considered ethical to act selfishly as that is what is required to make the market fully functional. Any deviation from this course could be construed as damping down the market's potential. This leads to the philosophical questions which concern the meaning of ethics, intentionality and the meaning of the

common good. On the basis of arguments derived from Smith and with the additional impetus of interpreting support from Friedrich von Hayek, the Neo-Liberal can hold that ethics has no place in the market and in fact could ultimately lead to negative rather than positive outcomes. Hayek's seminal work *The Road to Serfdom*, occupies as sacred a role in neo-liberalism as *The Wealth of Nations*. Jones (2002) suggests it was '… treated as holy writ of the Thatcherite counter revolutionaries of the 1970 and 1980s'. If Hayek is the latter day prophet, then his message is clear that all actions aimed at social engineering, planning and central organization are wrong. Pricing policy that contains an ethic of other regarding in Hayek's terms is simply wrong. From this perspective pricing in the pharmaceutical industry that bears no relation to either need or ability to pay is perfectly consistent.

While neo-liberals may be able to justify self-maximizing strategies as part of the essential workings of the market, they fall into the delusion of assuming that the market and society are one and the same. This is demonstrated with reference to Margaret Thatcher's understanding of society as discussed above. This approach operates on the assumption that rights are unidimensional, while in fact they comprise of two poles– entitlements and obligations. It is not just a case of the rational actor exploiting his or her autonomous rights, but as Kant (1991) outlined in *The Metaphysics of Morals* they are also obligated to act responsibly. This is drawn out in his second formulation of the categorical imperative: 'so act that you always treat humanity, whether in your own person or in the person of any other, never merely as a means but always at the same time as an end'(133). Liberalism cannot survive on the basis of a disavowal of other-regarding. While the Neo-Liberals take their cues from Smith and Hayek, equal claims to the core of liberalism can be based on John Stuart Mill and Keynes. Rights cannot be understood only in positive terms. All actions have consequences. Responsibility or obligation is about taking on board potential consequences, seeking the balance is ethically demanded as Kant (1991) clearly outlined:'Every action which by itself or by its maxim enables the freedom of each individual's will to co-exist with the freedom of everyone else in accordance with a universal law is right'(133).

<u>Classifying Pharmaceutical Pricing</u>

Pharmaceutical pricing, and in particular international pharmaceutical pricing, is a prime illustration of the equivocal nature of many decisions in business. We classify them into three groups:

1. Technical: This addresses the process of determining prices for individual drugs in relation to particular markets. It considers what relationship exists between price and the cost of production.
2. Ethical: As discussed above this could be understood as the conflicting demands of on one side a Neo-Liberal paradigm based on utilitarian principles of a free-market stripped of any need for ethical reflection against a responsible paradigm emanating from a welfare Liberal paradigm epitomized by theorist such as Kant or Keynes. The latter still subscribes to a free-market model, but one not exempt from ethical considerations.
3. Governmental:

3. i. Regulation: Regulation is a word greatly despised by neo-liberals, but nonetheless Adam Smith was prepared to acknowledge that government has a role in the delivery of certain forms of public good 'chiefly those for facilitating the commerce of society' (Wealth of Nations: v.1.70). Population health surely fits into this category. When faced with a security crisis, highlighted by the events of 9/11, governments were willing to introduce a spectacular range of regulations. Why, it may be asked, cannot the same energy be addressed at health especially in the light of the AIDS pandemic and growing problems around diseases like tuberculosis and malaria. Should governments and intergovernmental organisations like the World Health Organisation (WHO), and World Trade Organisation (WTO) have a responsible role in regulating the pricing and distribution of certain pharmaceuticals and in relation to certain diseases.

3. ii. Research All of these issues tie into research and development, free inquiry, cross-subsidization and the legitimate expectation to achieve profits. Dealing with these issues in the light of the common good is not in conflict with the essentials of a liberal free-market. Adam Smith's concept of non-profitable public works 'in the highest degree advantageous to a great society' sits perfectly with these concerns (Wealth of Nations: v.1.69).

It is clear even from this brief elucidation that there are many interconnections between these issues. If one considers the issue of the relationship of price and cost, it is impacted on by issues of cross-subsidization, degree to which the product fulfils an essential need, and target market. We have a complex web of issues that cannot be considered discretely: how can we responsibly deal with life-saving drugs; how and who funds research and development of pharmaceuticals; how can we exploit market forces to good effect; is governmental intervention desirable; how does cross-subsidization impact on the market; is the American market carrying too heavy a burden; how do we deal with parallel importing of drugs from low- to high-priced markets; who pays for drugs and how much should they pay (this is particularly pertinent for developing countries and economically marginalized populations).

<u>Context: The Market</u>

At Marrakech in 1994 World Trade Organisation (WTO) member nations signed the Trade Related Aspects of Intellectual Property Rights (TRIPs) agreement, which established minimum levels of protection that each government would give to intellectual property of fellow WTO members. The agreement requires that 20-year patent protection be available for all inventions. One of the industries to benefit significantly from TRIPs was the pharmaceutical sector. Pharmaceutical manufacturers could expect patent protection in all member states of the WTO. This patent protection meant that for innovative drugs, manufacturers could set prices without fear of competitive response, the creation as it were of a time limited monopoly.[ii]

Over the following seven years there was intense international lobbying and public debate between Big Pharma and national governments and non-governmental organisations (NGOs). Developing-country governments and NGOs such as Medicins Sans Frontiers (MSF) and Oxfam consistently argued that the international patent protection afforded to the manufacturers of pharmaceuticals under the TRIPs agreement had unsustainable implications for the public health of many poorer countries (MSF 2003). They believed that such countries did not have the economic or technical expertise to manufacture their own affordable medicines and they had therefore to rely on imports of high-priced, patented pharmaceuticals. For example less than 5% of those living with HIV/AIDS have access to the most successful medications, due to cost considerations (AMSA 2002).

At the November 2001 WTO meeting in Doha it was agreed that developing countries should, under certain conditions, be allowed to derogate from the provisions of the TRIPs agreement. “implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines” (17) (WTO 2001). The so-called Doha declaration meant that where the administrations of such countries were able to demonstrate that adherence to TRIPs would seriously impact on the health profile of a large sector of their population they would be allowed to override the obligations of patent protection and access cheap, quality, generic versions of the drugs to combat public health emergencies such as HIV/AIDS, malaria and tuberculosis. A number of governments including the Brazilian government have successfully invoked the provisions of the Doha declaration to allow them manufacture generic versions of drugs used to combat HIV/AIDS.

However many argue that the protection of intellectual property and high prices are not the reasons for lack of access to essential medicines in Sub-Saharan Africa, and other less-developed countries (Attaran 2004**)** They argue that in fact the issue is one of systemic weakness and the absence of a developed health system.

This argument seems in part to be borne out by the experiences of Cipla, an Indian pharmaceutical manufacturer. In 2001 it offered a cocktail of ARVs internationally at less than US$1 a day, but there was little demand for it. Even at that significantly reduced price it was still too expensive for many HIV/AIDS-sufferers, particularly in sub-Saharan Africa. Additionally many governments in the region either cannot afford or lack the political will to buy such products. The WTO point out that many of the countries with severe disease problems have annual per capita drugs budgets of less than US$2. Attaran and Gillespie-White (2001) also point out that many companies actually donate drugs to certain governments, but the absence of distribution and administrative infrastructure means that they frequently do not reach the right people in the right way. It is clear that the issue of access to pharmaceuticals is not simply one of price.

Neither is it an issue between the developed world and developing world alone. Such a dichotomy would suggest that in the developed world all necessary drugs therapies are available to, and affordable by, all consumers. While access to essential medications is

more widespread in the United States for example, it is by no means universal, and is the subject of considerable controversy within the United States itself (Brody 1995, Spinello 1992). Similarly recent debates over the so-called 'post code lottery'[iii] highlight the variations in access to certain therapeutic pharmaceuticals in the UK. Health funding bodies, such as the Health Maintenance Organisations (HMOs) in the United States, and the National Health Service (NHS) in the United Kingdom have, in a number of cases, not included certain drugs on their formularies, basing their decisions on cost-benefit arguments. This has on occasion led to industry lobbying to have drugs added to formularies. Boseley (1999) highlights the case of Biogen who engaged a PR firm to help it rally multiple sclerosis sufferers to lobby for the NHS to pay for and prescribe beta-interferon, a very expensive therapy. High prices therefore impact on availability both directly to individual consumers and also indirectly through funding agencies.

Pharmaceutical industry perspective

Big Pharma has consistently argued that high prices and multilateral patent protection afforded by TRIPs are reasonable rewards for highly expensive and often fruitless research and development of pharmaceuticals, which are ultimately of benefit to society (Medawar and Hardon 2004). Research and development costs in the pharmaceutical sector can be substantial. Cutting Edge (2003**)**, a private sector industry monitor, estimated the cost as US$900 billion. Because of low success rates Big Pharma argues that profits from the few successful products are essential. This confirms Adam Smith's analysis, as discussed earlier, but proposes a market solution in place of his governmental one.

Brody (1995) confirms a correlation between industry profit levels and levels of research and development and subsequent successful innovations. It does not though make reference to the mitigating factors of tradition, and critical mass and the tendency of Big Pharma to site R&D in the headquarter country. These figures may not reflect a direct relationship between profit earned and R&D levels, but rather the pattern of industry ownership and history.

DeGeorge (2003) states that Big Pharma defends its pricing and associated intellectual property (IP) protection strategies with what he terms the 'Standard Argument'. This is based on notions of fairness and the need to encourage new products for the common good. Fairness is constructed as the right of pharmaceutical firms to benefit unhindered from their work, for a reasonable period (which provides the rationale for IP protection). Associated with this, Big Pharma argues that in order to encourage continued investment in research and development leading to new products, which can potentially benefit all (the common good), there has to be an adequate perceived financial reward to make investment in R&D attractive. Industry members also argue that the constant risk of obsolescence must be considered in setting prices for pharmaceuticals, which further supports their argument for the necessity of high prices to harvest their investments while they can.

In sum the industry argues that the prices they charge for their products are a reasonable reward for their investment in expensive research and development which ultimately

benefits society at large, and that theirs is a high risk industry for which there must be appropriate rewards to induce participation.

Critique of industry perspective

Many would argue that the estimated costs of research and development are overstated for a number of reasons. Firstly up to 50% of Big Pharma's current research and development budget is spent on developing modifications/enhancements of drugs in already crowded markets (Goozner 2004). This viewpoint is supported by Light and Lexchin (2003) who show that only 18% of Big Pharma's research spend is actually on basic research, while the preponderance of spend goes on derivate innovations on existing drugs and testing. They also point out that half of the sum attributed to R&D costs for new drugs is in fact an accounting for opportunity costs rather than actual spend. They estimate that the real cost of the development of a new drugs as: i. US$108 million in 93% of cases (innovations deriving primarily from extensions of existing drugs); and ii. US$400 million in just 7% of cases (innovations not derived from existing drugs).

A great deal of the key R&D in the pharmaceutical sector is funded by governments and other grant-aiding agencies. For example two of the key drugs used in the fight against HIV/AIDS were developed by Yale University and the University of Minnesota and are licensed exclusively to Bristol-Myers Squibb and Glaxo Smith Kline respectively.

Conversely it is clear from the OECD report *Funding of Public Research and Development* that industry plays an increasing role in funding research: "… an aggregate trend can be identified… an increase in R&D financed and performed by business (respectively shifting from 50% and 66% in 1981 to 63% and 69% in 2001) and a decline in the public sector's share in financing (down from 45% in 1981 to around 30% in 2001)." (47) (Maass 2003)

This trend is a public good in that it reduces pressures on the public purse, but it also raises questions about the relationship between *'free inquiry'* and the *'free market'* (Fuller 2000). At an ethical level it also raises questions about public control of the research agenda, Zimmerman (1995) identified a general trend of shifting a central governance function from the political realm to industry or in his terms 'some of the most significant and powerful institutions of our time'(86). In these terms the justification for extended exclusive licenses (time limited monopolies) for certain drugs that have very high public good utility is not at all proven. Instead of giving monopolies to corporations, for potentially the full life cycle of a therapy, it might make more sense to offer publicly funded incentives to engage in joint-research for projects of major public concern like HIV/AIDS, malaria or tuberculosis. All relevant actors including Big Pharma and the universities could be encouraged to cooperate. Priorities might be set at national level by governmental agencies and at international level by say the WHO. Licenses to produce drugs in this category could be offered on a shareware basis to firms capable of producing the drug to the standards required, thus allowing the free-market to operate in the sorts of terms contemplated by Adam Smith. Doubtless the research effort would produce serendipitous discoveries that have always been a feature in science (Roberts 1989) to the benefit of Big Pharma in areas of less critical public good. Likewise independently

researched discoveries directly relevant for this high level public good could be purchased into the system, rather than being developed under exclusive licenses.

Much of the cost attributed as R&D cost can be identified as marketing cost, which ultimately contributes to company profits, and is only incurred in the case of successful products. Cutting Edge estimate (2003) the costs include the commercialization budget and *'early-stage marketing'*. In a separate study Cutting Edge (2003a) estimate that pharmaceutical brand teams spend 46% of their total marketing budgets for individual products during the launch phase. Big Pharma's claim that marketing costs are an essential element of their budgets and that it is reasonable to attribute them to the overall cost of the drug make sense only in areas of low public good where vital public health issues are not involved. We need to carefully distinguish between the legitimate aspiration of Big Pharma to generate profits and the public good. These are not mutually exclusive, but must include a level of responsibility taking both by Big Pharma itself and governmental and intergovernmental agencies.

New discoveries, except perhaps in some very rarefied field, are the culmination of all previous research. It is disingenuous to present costs as being company-specific, especially since a great degree of such research is done in publicly funded institutions and other non-industry contexts. There is little truly basic research. If for example a cure is discovered for a common cancer, that discovery will have drawn on previous research and discoveries, and analysis of the effects and impacts of existing therapies. The controversy over Glaxo Smith Kline's (GSK) patenting of AZT (a key anti-retroviral) reflects this scenario. Two scientists, who claim discovery of the compound and its effectiveness in treating HIV/AIDS, are publicly supporting the AIDS Healthcare Foundation (AHF) in its legal suit against GSK. The AHF, with the support of these two scientists, claims that GSK patented a drug it did not invent, which consequently limited access to the drug.[iv]

<u>Pricing Policy: Utilitarian and Ethical factors</u>

The cost base used (at least in part) to determine pharmaceutical prices is difficult to pin down and is open to interpretation and finessing. While acknowledging the difficulties associated with determining cost and the complexities therein, it would be simplistic to think that costs are the only factor determining pricing in the pharmaceutical sector. One must also consider the market opportunities that are available. If Friedman's (1970) somewhat polemic statement: 'The social responsibility of business is to increase its profits: s13' is the guide, then pricing strategy should be determined based on market value and on what the consumer is prepared to pay. In fact Friedman spoke specifically of the pharmaceutical industry and suggested that it would be inappropriate for managers to set their prices according to social objectives and that in so doing they would be shirking their primary duty to shareholders, as: "Managers lack the wisdom and ability to resolve complex social problems, such as the equitable distribution of pharmaceutical products:" (s13) (Friedman 1970).

Part of Friedman's assessment of managers, is tenable, even if New Public Management takes a different view. However, it hardly absolves the responsibilities of the boards of Big Pharma. Ultimately it is not about wisdom but responsibility. Accepting that one does

not have wisdom (presumably meaning specific expertise) is not a justification for not taking responsibility. Kant's *'categorical imperative'* charges all individuals to act responsibly 'regardless of their individual desires' or in this case expert competence (Ó Tuama 2004). A non-swimmer is not expected to dive into the sea to rescue someone in distress, but even the most lax of moral codes would acknowledge that the non-swimmer still has responsibility to help save the individual through alternative strategies, for instance calling for help or throwing a life-line.

Notwithstanding Friedman, the actions of Big Pharma indicate that they do not operate solely from a pure profit motivation aimed at a short-term healthy balance sheet. AMSA (2002) figures indicate that 77% of the global pharmaceutical market is accounted for by the North American, European and Japanese markets. All of Africa counts for only 1% of the pharmaceutical market. If one considers only profit motivation and shareholder value then Big Pharma would focus only on advanced economies where many consumers are capable of paying substantial prices for pharmaceuticals. It is clear that pharmaceutical firms do not restrict themselves to these markets, and in some cases give away product in some poorer markets. However some commentators would say rigorous international patent protection, and the continued use of market skimming price strategies amounts to a decision to focus only on the wealthier markets. One must therefore ask the question, why do Big Pharma continue to vigorously protect their patents in markets where the likely financial return is always going to be low.

Big Pharma argue that the key concern is the risk of parallel importing from the lower priced environments into their more lucrative markets. Essentially patent protection is about price protection. This has become an issue of real concern to the pharmaceutical sector in recent years. Dyer (2002) quotes cases where essential drugs being channeled to the African market at significantly reduced prices have been re-diverted to the more lucrative European market by parallel importers.

Big Pharma ostensibly seeks to enforce national patents and related rights, but this may mask a deeper strategy. As Feddersen (2003) notes while a patent provides the opportunity to obtain recompense for creative effort, it does not guarantee a profit, a view supported by the European Court of Justice. It would seem that in many cases Big Pharma is looking for the courts to support its policy of differential pricing rather than to police actual patent infringement. Practice would seem to support the contention that Big Pharma sets prices according to what the market can bear, and once prices are set, it actively seeks to protect them. A clear public good issue is that some consumers even in wealthier markets will find higher prices unaffordable.

The technical issue of how drug price is determined, successive researchers agree, is strongly based on an assessment of what the market can bear, rather than any cost-based pricing system. Spinello (1992) gives the example of the controversy of the then Burroughs Wellcome's pricing of AZT. He indicates that industry observers believed the price was not based on costs but with reference to expensive cancer therapies, which might be considered of similar therapeutic significance. This appears to be borne out by the differing pricing approaches used internationally. In the US prices are high reflecting

both the wealth of the market, and also the high degree of co-payment by insurers, and or state bodies. In some markets such as France, Ireland and the United Kingdom where there is strong state participation in health care provision, Big Pharma tailor their prices to levels acceptable to the key payers, the national health systems. Even in countries with national health systems these prices can be quite high and especially so for life-saving therapies, and those for rare and uncommon conditions. So price is flexible, and depends a great deal on market conditions, likely demand, and who is paying (Brazell 2003).

If one goes on to consider the ethical issues around pricing it becomes more complex. Marketing ethics literature shows that there is a great deal of descriptive ethical theory relating to marketing (Hunt & Vitell 1986, Ferrell & Gresham 1985, Graddy & Robertson 1999) and a lot less normative theory. This, it is widely agreed, is due to the difficulties in defining absolutist understandings of what constitutes ethical marketing practice. There is even less normative material around issues of pricing, though many refer specifically to the difficulty of determining and evaluating pricing policy for life-saving drugs.

Using Smith's (1995) test of consumer sovereignty it is clear that there are ethical dilemmas. He suggests three dimensions should be considered: consumer capability; information; and choice. While Smith refers specifically to age, education and income as vulnerability factors, in relation to consumer capability it would seem obvious that ill health would also be a vulnerability factor. So the potential consumers of drugs may not be sovereign in relation to capability. In regard to information sovereignty is suspect due to the degree to which drug purchase decisions are mediated by third parties such as prescribers and health agencies. With regard to choice, in many cases there is limited choice or no choice. Applying other frameworks for assessing the potential for ethical dilemmas such as Laczniak & Murphy (1993), also confirm that there are numerous potential conflicts in this area.

Walton (1969) and Kehoe (1985) acknowledge the difficulties in assessing the morality of pricing policy. The underlying difficulty seems to be one of determining how price should be set. This is essentially an ideological issue between the concepts of classical and neo-classical liberals against those of welfare liberals and social democrats. It is also a matter of confusion about the role of the state vis-à-vis the economy. In the first case the debate is between the primacy of formal equality over factual equality, the second is about the role of government. These issues have been at the heart of the neo-liberal project from the 1970s that has sought to dismantle what it deems as the excesses of the welfare state model.

The divide between formal and factual equality is essentially about the meaning of rights. From a classical liberal perspective the business of rights is primarily about establishing the means by which the individual can enjoy a set of rights that hold that all individuals are equal. This approach assumes that rights are comprised only of political and legal entitlements and that responsibility (or obligation) and solidarity are alien to the liberal concept of rights. The matter of obligation or responsibility in Kantian terms is a *sine qua non* at the very core of rights. For Kant the basis for understanding that human rights exist is that all humans are innately equal and are due that recognition not on the basis of

political argumentation but on the basis of an *a priori* natural right. In those terms human rights are an integrated whole not a menu of discreet parts. At their most basic rights mean certain entitlements, certain obligations and mutual recognition. In attempting to alienate obligation and mutual recognition from rights classical and neo-classical liberals are attempting to remove the problematic aspect[v] of rights that demand reciprocity and obligation. If we do that then rights in a liberal sense no longer have meaning, as they are neither justifiable nor enforceable.

In terms of mutual recognition John Stuart Mill, followed by figures like Keynes and Marshall pushed the parameters of liberalism to encapsulate social or factual rights: "…that for such actions as are prejudicial to the interests of others, the individual is accountable, and may be subjected either to social or to legal punishment (104) (Mill 1991)". According to Rees (1985), Mill holds that the state and society should not encroach too closely on the affairs of the individual and that the individual is charged with a responsibility to his/her fellow citizens individually and collectively. This project was carried forward by T.H. Marshall (1973) who presented a model of rights which was premised on three pillars, the first two broadly those of the classical liberals but his third passed firmly into the realm of social rights:"… the right to a modicum of economic welfare and security to the right to share to the full in the social heritage and to live the life of a civilized being" (72).

Classical and neo-classical liberals have fundamental objections to these rights. Adam Smith's concept of the invisible hand holds against such constructs. Herein lies the kernel of the problem. Essentially for market convenience there is an attempt to slice rights into their component parts and cast adrift concepts like responsibility and reciprocity. As discussed above that type of argumentation undermines the very nature of rights. It is a circular convenience for the justification of action that flies in the face of the very liberal rights that are the bedrock of liberalism and the free-market, being justifiable, immutable and inalienable.

<u>Ethical Concerns in Practice</u>

De George (2003) argues that the rights endowed by patent protection, and the implied right to profit from invention, are outweighed by more fundamental human rights. Shue (1981) holds firmly with the welfare strand of liberalism referring to 'needs which must be satisfied in order not to seriously endanger a person's health and sanity'. According to Shue the essence of a basic right is its necessity as a pre-requisite for the enjoyment of other rights, he argues that:'… no individuals or institutions, including corporations, may ignore the universal duty to avoid depriving persons of their basic rights'.
His rationale is similar to that used by stakeholder theorists who argue that 'underlying the stakeholder management approach is the ethical imperative that mandates business... to respect and fulfill these stakeholders' rights' (Weiss 2002). Similarly Donaldson (1989) presents the notion of a social contract between business organisations and society, which carries associated obligations for both business and society: '… society has the right to expect that productive organisations will, all other things being equal, enhance the general interests of consumers and employees'.

If one accepts De George and Shue's arguments then it is clear that Big Pharma's rights to IP and reasonable reward are far outweighed by human rights in the case of essential drugs. However it doesn't follow that Big Pharma must give such products away. Nickel (1987) expands on the obligations imposed by human rights, taking a Lockean view that they have to be '*affordable*' and balanced against other obligations and constraints. Locke believed in 'a communion, friendship, and mutual assistance' or in today's terms obligation or duty to fellow citizens (Wilhelm 1999). Like Locke, Donaldson (1989) endorses this perspective using the term *'fairness-affordability'* to describe the balance required. He places a reasonable limit on obligation citing certain therapeutic and diagnostic techniques like CAT scans and kidney dialysis as examples. His idea of reasonable limits could not be stretched to apply to a pandemic like HIV/AIDS that threaten the lives of millions of people in an unpredictable fashion, and which must be considered extraordinary. On the other hand it is clear that the solution to such extraordinary problems is beyond the responsibilities and obligations that we can expect of industry. To quote Weiss (2002): 'Corporations ought to do what they reasonably can do', but to solve a problem of such scale requires a broader response.

Issue of relationship between price and therapeutic value

Kehoe (ibid) argues, "ethically any price set by a firm should be either equal to or proportional to the benefit received". Herein lies the difficulty with pharmaceutical pricing, that of assessing benefit received, and how to relate it to price. Not all drugs are of equal therapeutic value, and therefore it may be appropriate to consider the issue of pricing policy differently for different categories of drugs. A useful categorization is:
i. *Essential and Breakthrough Drugs* – such as the ARVs developed to combat HIV/AIDS;
ii. *Me-Too Drugs* - which include the drugs developed by competitors of patented products, which typically have many of the same properties but fall outside the patent; and iii. *Cosmetic Drugs* – these are non-essential drugs, for instance Botox in cosmetic applications. Each of these categories could be argued to carry a common good emanating from a *laissez faire* or invisible hand analysis to a more demanding ethical analysis. It is reasonable from our discussion so far to conclude that governments and policy-makers should focus their concern on *Essential and Breakthrough Drugs*, this applies to both *laissez faire* and ethically motivated positions. The market should mediate pricing for non-essential therapies, while a more proactive public policy approach is needed for essential drugs

Defining what is essential has its pitfalls. Spinello (1992) suggests this can be resolved by posing a set of appropriate questions: i. The nature of the malady; ii. Whether it is life-threatening, or fundamentally threatening to the quality of life; iii. The availability of other options, is it a drug of last resort; iv. What other drugs are available and at what prices? v. At planned prices will people be deprived? vi. What support can be expected from funding sources in co-payment? vii. Who is the likely end-user? and viii. What is their capacity to pay?

The WHO actually defines a list of essential medicines, which includes 319 medicines (Attaran 2004**)** but in so doing considers cost-effectiveness in defining its core list. MSF

(2001) argue that a number of drugs that could be considered medically essential are not included because of patent requirements, or cost considerations. With both Spinello (1992) and the WHO's definition of essential there are two key difficulties. Firstly, there is implicit in both a price floor of affordability. In Spinello's case he refers to the need to identify a pricing level at which people might be deprived, and in the WHO case they consider cost-effectiveness. Secondly there is also an issue of relativity. The perception of how essential a drug is relates to overall societal norms of health and well-being, which tend to vary with national wealth.

A further very real risk with such discrimination is that firms would focus their efforts and their research and development on the categories of drugs that would be less restricted, and reduce emphasis on the essential/breakthrough category because of the high degree of intervention. It could be argued that this is already occurring and that some firms are re-focusing their R&D strategies away from the essential drug category since the Doha decision. This is premised on a perceived risk of intervention in pricing strategy should a firm develop a breakthrough drug of sufficient significance, e.g. a cure for a major cancer.

It is intuitively easy to accept the arguments of NGOs, disease victims and national governments that restricting the access to essential drugs through high pricing policy is undesirable. What is not so easy is to identify a way forward. We propose a number of potential strategies that should be considered to deal with a very real common good issue, while both balancing the rights of industry and ensuring the continued pursuit of free inquiry and discovery in pharmaceuticals.

Potential Policy and Pricing Strategies

We have seen in the discussion above that the current *ad hoc* arrangements do not work, even where there is goodwill on all sides to reach a solution. Issues like parallel trade, medical training and infrastructure, poverty, distribution, aid, corruption, and ideology all interact with the prospects of reaching a common approach. We don't propose a single solution as much as possible strategies for dealing with a major global crisis.

A. Low Intervention—Strong Free-Market Model

In debates on pharmaceutical pricing in the United States Big Pharma argues that free enterprise and unrestrained competition will encourage fair prices. However it is a misrepresentation to suggest that even in the United States a free market exists for pharmaceuticals. As long as newly developed drugs are under patent they are protected from competition and the manufacturer can charge higher prices than they would be able to in a competitive marketplace, even accepting the presence of me-too drugs in the market. Bell (2001) points out that the pharmaceutical market is inherently an imperfect market, i.e. one where competition 'is flawed by the ability of one or more parties to influence prices'. He cites as a specific illustration the case of Big Pharma in Africa where the industry has such power over the price of drugs. So in essence there is no free market.

B. Mediated Intervention-Mediated Market Model

The current system operated by the British government, the Pharmaceutical Price Regulation Scheme (PPRS)[vi] 1999 offers a good model. The PPRS builds on the Voluntary Price Regulation Scheme established in 1953. It restricts pharmaceutical industry profit levels and seeks to do this by referencing the capital markets. Pharmaceutical firms are allowed to achieve profits in the range of 17-21%, with a margin of tolerance of 8.4%. Originally developed as a voluntary model, in recent years it has been underpinned by statutes giving the NHS the right to reduce prices where participating companies are reluctant to reduce prices. In calculating costs before profits they are allowed to include costs of production, a sales promotion allowance and a research and development allowance. Firms whose prices lead to profits beyond this must reduce their prices or pay a rebate to the government. The adoption of a similar model on an agreed international basis could deal with the issue of industry profit levels, and reduce some of the inflationary pressure, but it does not solve the pricing issue. However given that profits are directly related to prices achieved, if there is monitoring and management of overall profit levels it is reasonable to expect an impact on pricing levels.

In terms of research and development a model (discussed above) of publicly funded incentives to engage in joint-research for projects of major public concern could be included. Big Pharma could participate with other private and public institutions like universities and hospital. Priorities could be set through a consultative process at national and/or international level. The process of licensing would focus on public good imperatives and the capacity of licensees to deliver and distribute quality pharmaceuticals. The model should also allow for the purchase of independently researched discoveries of major public good utility.

Conclusion

Building on the analysis that has been developed in this paper, we would propose adopting some form of *B. Mediated Intervention-Mediated Market Model.* International drug pricing is so central an issue as to require an extra-industry solution. The international community cannot disassociate itself from contributory responsibility for ongoing difficulties in access to therapeutic pharmaceuticals. Governments, and extra-governmental organisations such as the UN should seek to partner with industry to arrive at useful resolutions. This must include an acceptance of the need for some element of price control and regulation. This would not be without pain for all parties, but would deliver clear public goods, among which being market competition.

The industry would have to submit to greater monitoring and intervention, though perhaps with a concomitant increase in public goodwill and a reduction in negative publicity. There are precedents for this type of voluntary industry submission to regulation. For example on a national level: the Institute of Nuclear Power Operators (INPO) established in the United States in 1979 in the wake of the Three Mile Island disaster; and the Public Company Accounting Oversight Board set up under the Sarbanes Oxley Act 2002 following the Enron and Worldcom debacles, and on an international level: the Chemical Manufacturers Association's (CMA) Responsible Care programme developed in the 1980's in response to the Bhopal Disaster which involves manufacturers

in 37 countries on five continents. While some would critique these as being merely "multi-million dollar public relations exercises" (447) (Rees, 2003), there is evidence to suggest that the CMA and the INPO have achieved progress in both industry behaviour and realization of responsibility.

National governments would have to agree to joint positions on pricing, and the current subvention of some markets by others would be likely decline. The United States government in particular is likely to have significant difficulty in reaching agreement on this given the long history of government industry interdependence. However the advent of trading blocs such as NAFTA and the newly expanded EU should in part facilitate this. In fact in October 2002 the European Commission proposed the development of a price regulation scheme for the entire European Union, though the mechanics and operation of such a scheme are still very much in development.

How Big Pharma determines prices for new products will continue to be an issue. Moving towards the type of model we propose might in fact help the industry to stabilize prices and reduce risk. Big Pharma would be less exposed to acute market vagaries like that which hit Elan over the Tysabri crisis in February/March 2005[vii], by avoiding having all its eggs in one basket. For high volume public good pharmaceuticals they would share both the costs and benefits. In the areas of low market returns like very poor economies or very specialized therapies risk would be softened by a governmental cushion as envisaged by thinkers from Adam Smith to J.M. Keynes.

Already there is scope within the industry itself to deal with pricing policy in a more ethical way without risking major costs. Big Pharma firms generally have a range of products, they operate internal cross-subsidization of products, and negotiate with major buyers across their entire product range, rather than on specific products. All of these strategies reduce exposure.

Pharmaceutical pricing is a complex issue. However we can achieve greater clarity on rights and obligations when addressing essential drugs. What is clear is that this issue is more than commercial, it is essentially about the common good. Facing up to that reality is an important starting point. Adam Smith, as discussed above, saw the limitations of the free-market and the necessity of governmental intervention in certain cases. Essential pharmaceuticals to deal with a global level crisis like HIV/AIDS must fall into that category. Once we accept this premise, then it is a question of how we address the problem. From this base line we can begin to frame the problem not as one only of the market, corporations, share dividend, pricing, patents and licenses, but also of the public good. In terms of the public good we must then engage in the balance of rights and responsibilities, such that the greatest common good can be achieved with the least level of interference with private rights.

The discussion here while focused on the pharmaceuticals has implications across a wide range of industries. Challenges of considerable public concern at a macro-level such as the environment, climate and world development and at a more micro-level including retail banking's impact on social fabric through over-generous lending, or fast food

companies' potential to impact on public health, contain many of the same dilemmas raised here. They all centre around issues concerning the public good and the interests of corporations. The Mediated Intervention – Mediated Market Model might well provide a possible route for addressing some of these challenges.

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[i] In an interview in 1987 Margaret Thatcher stated '… and who is society? There is no such thing! There are individual men and women and there are families' and later in the interview: 'There is no such thing as society'. See Douglas Keay (1987) 'Aids, education and the year 2000!' *Woman's Own* pp8-10. Also available at the Thatcher Foundation http://www.margaretthatcher.com.

[ii] Given Big Pharma's case that pharmaceuticals are constantly at risk of obsolescence the time scale of the patent-guaranteed monopoly may extend beyond the product life cycle of the therapy.

[iii] The term 'post-code lottery' has been used by the UK media to describe the variations that occur in access to health treatments and therapies, based on geographic location.

[iv] www.aidshealth.org/newsroom/press/press_archive/PR120502.htm

[v] By problematic we mean those aspects of rights that challenge a notion of the free-market that has not ethical or moral basis.

[vi] www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/PharmaceuticalPriceRegulationScheme/ThePPRSScheme/fs/en

[vii] "Patient Dies: Biogen, Elan Halt MS Drug" www.reuters.com/financeNewsArticle.jhtml?type=businessNews&storyID=7761714