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The *Other* Global Drugs Crisis: Assessing the Scope, Impacts and Drivers of the Trade in Dangerous Counterfeit Pharmaceuticals

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ABSTRACT

This paper deals with a topic heretofore largely neglected in studies of health and social policy, namely the challenge presented by the growing global trade in dangerous counterfeit medicines. Empirically, the scope and scale of this trade is assessed, along with its public health risks and impacts. Analytically, a range of social, political and economic processes are identified as contributing to this problem. These include the impact of on-going neo-liberal globalisation and the emergence of patent regimes that favour the developed over the developing nations. Current anti-counterfeiting policy initiatives, at both national and trans-national levels, are also critically examined. It is argued that such measures are unlikely to be effective unless combined with more radical challenges to the chronic lack of access to safe medicinal drugs in the developing world.

Keywords: Counterfeit medicines; globalisation; health and health policy; intellectual property, criminal justice

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Introduction

Intellectual property (IP) crimes, such as counterfeiting and trademark theft, are now estimated to make up 5% of total world trade, amounting to some $450 billion per annum (Vithlani 1998, p.5; Forzley 2003, p.9). Consequently, issues of IP protection have in recent years come increasingly to the forefront of the political and legal agenda relating to world trade and economic competition. One area upon which focus has fallen is the burgeoning global trade in counterfeit pharmaceuticals – according to the World Health Organisation, counterfeits now account for an estimated 10% of the global medicines market (WHO 2003). In sharp contrast, IP crime has been largely neglected by academic criminologists and sociologists of crime (for exceptions, see Vagg and Harris 2000; Hetzer 2002). While the market for drugs has drawn attention from those specialising in the study of organised crime and the development of a global criminal economy, such literature has dealt almost exclusively with prohibited narcotics, to the neglect of medicinal drugs (see, for example, Abadinsky 1985; Albanese et al 2003). This neglect is surprising, in that the social impact of such criminal activities is increasingly well documented. The direct economic impact alone (such as loss of revenues for licensed pharmaceutical manufacturers and patent/trademark holders) is estimated at $U.S.32 billion per annum (WHO 2003). Moreover, studies emerging from public health and pharmacological analysis document thousands of cases of death and serious injury every year, arising from use of dangerous and non-effective counterfeit pharmaceuticals; such social harms fall disproportionately (albeit not exclusively) upon the most disadvantaged populations in developing and newly industrialising countries.

The aims of the present article are two-fold. At the empirical level, it aims to establish the scope, scale, and global distribution of the trade in counterfeit pharmaceuticals, and to assess its social costs in terms of damage to public health. At the analytical level, it aims to identify the drivers which create and sustain the market in counterfeit pharmaceuticals, such as the income inequalities between developed and developing nations, the impact of global 'free trade' and new intellectual property regimes, and the transition toward the (neo) liberalisation of health care delivery. It is argued that official strategies for curtailing the problem of counterfeit pharmaceuticals are unlikely to yield the desired benefits unless they are combined with a more radical challenge to the current political-economic organisation of intellectual property rights and trade relations.

The article is organised into four sections. In the first, I asses the nature, scope and scale of the counterfeit pharmaceuticals trade, drawing upon a range of sources published by academic researchers, industrial and trade bodies, national governments, international law enforcement agencies, and trans-national health promotion organisations. In the second section, I turn to consider the social costs incurred as a result of this trade, focusing in particular upon mortality and morbidity (otherwise avoidable death and/or injury). In the third section, I examine the complex array of social, economic, political, and legal factors that can help to explain the emergence and growth of this trade. In the fourth and final section, I critically assess the crime control strategies advocated by governmental and commercial actors, and suggest that, if taken alone, they are unlikely to prove successful in addressing the medicinal drugs crisis.

The Scope and Scale of the Counterfeit Pharmaceuticals Problem

There is considerable plasticity in current economic and legal uses of the term 'counterfeit'. In a restricted usage, it relates to the manufacture or provision of goods and services that entail the unauthorised exploitation of intellectual property (such as copyrighted content and trademarks). In this strict sense, in order for such IP violations to constitute 'counterfeiting', the goods under question must be misleadingly marketed as legitimate products issuing from the authorised manufacturer (typically achieved by reproducing or approximating the genuine product's appearance and packaging, thereby misleading consumers as to its true provenance). However, more capacious definitions include within counterfeiting various forms of misidentification, wherein a product or service is fraudulently 'passed off' with respect to its content and composition, as well as its origin. Thus the WHO defines a counterfeit pharmaceutical as:

> '*one which is deliberately and fraudulently mislabelled with respect to identity or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient ingredients or with fake packaging*' (cited in Clarke 2003, p. 453; see also WHO 1999, p. 4)

Thus counterfeit pharmaceuticals can include, for example, legitimate medicines that have been diluted or 'bulked out' with other substances, or those whose expiry date has been altered, thereby presenting them as still within their window of safe and effective use. Following the WHO's definition, it is clear that there exists today a global market in an astonishing

array of counterfeit pharmaceuticals, including: insulin, birth control pills, antiretrovirals (for treating HIV/AIDS), anti-malarials, anti-meningitis vaccines, antibiotics, growth hormones, immuniglobins, antipsychotics, cough medicines, paracetamol, steroids, blood pressure pills, and viagra (Pécoul et al 1999, p. 363; Newton et al 2002, p.800; Forzley 2003, p.33; Thompson 2003a,p.1090; ABPN, 2003, p.1196).

Assessing the overall scale of this trade is difficult, since, as with criminal activities more generally, there is very likely a large hidden or 'dark' figure (Coleman 1996). As already noted, counterfeits are estimated to make up some 10% of overall world trade in medicines. However, the prevalence of counterfeit pharmaceuticals is highly differentiated across countries and regions, with the highest rates being found in developing and least developed countries, and the lowest in the advanced industrial nations. In Peru, for example, up to 80% of drugs are estimated to be counterfeit (Watt 2004, p.172). Both Pakistan and Nigeria have counterfeit rates for medicines estimated at about 50% (EFPIA 2005, p.1). The circulation of counterfeits is also widespread in the former Soviet Republics, with rates estimated at 12% for Russia and 40% for Ukraine (Clarke, 2003, p.453). The *production* of counterfeit pharmaceuticals is also globally differentiated; India, for example, is thought to account for some 35% of all counterfeit medicines production, with goods being exported to countries such as Bangladesh, Burma and neighbouring former Soviet Republics such as Uzbekistan (Chatterjee 2001, p.1776). However, it would be misleading to present pharmaceuticals counterfeiting as a problem confined to the developing world. Both production and consumption are now globally distributed. Some 14% of drugs imported to the US are thought to be counterfeit (Thompson 2003b, p.1507), with recent documented cases including antiretrovirals, antibiotics, and anti-anaemia drugs (IACC 2003, pp.9-10). In the UK and elsewhere, there is a burgeoning trade in counterfeit viagra and anabolic steroids (Clarke 2003, p. 454), much of it sold via the Internet and distributed by post (WHO 2003,p.1). On the production side, authorities in Italy recently uncovered nearly 250,000 units of counterfeit medicines and two tons of raw materials, which had been imported from China and India, and were being repackaged for subsequent sale in the Americas (EFPIA 2005, p.1). Such seizures indicate that there now exist elaborate and organised chains of production, distribution and marketing which span the developed and developing nations.

Production of counterfeits is situated at a range of organisational scales. At one end, we find large, industrial-scale enterprises that manufacture sophisticated counterfeits complete with high quality packaging. As already noted, such enterprises may well be part of elaborate trans-national

organised crime networks, with production, distribution and sales located across nations and continents (see also Castells 1998). Such counterfeits are often introduced into legitimate pharmaceutical supply chains, and sold (wittingly or otherwise) via licensed pharmaceutical traders to both the public and health care providers such as hospitals (Thompson 2003b; Young 2004a). At the other end of the scale, we find 'shanty factories' and home-based production, typically aimed at local, informal markets. Moreover, the line between licensed and unlicensed manufacturers is sometimes blurred; for example, in India counterfeits are often made by manufacturers who are licensed to produce generic drugs, but who seek to supplement the relative low returns from this trade by simultaneously manufacturing counterfeits of high-value branded medicines (Chatterjee 2001, p.1116).

Health Risks and Costs of the Counterfeit Trade

The heath risks generated by counterfeit pharmaceuticals can be differentiated between [a] those arising from the non-effectiveness of drugs that contain limited or no effective ingredients, and [b] those arising from drugs adulterated with toxic and dangerous substances. Each will be considered below.

A significant proportion of counterfeit medicines have been found to contain reduced levels of clinically effective ingredients (through dilution or inappropriate preparation) or to be placebos containing no effective ingredients whatsoever. The damage to patient health resulting from the use of such drugs is difficult to calculate, as non-effectiveness is likely to be attributed by physicians to the underlying disease or illness, rather than suspecting that the medicines themselves are defective (Young 2004a, p.1978). However, morbidity and mortality arising from use of counterfeits does become apparent in cases of mass ineffectiveness, as with the failure of vaccines to protect patients during an epidemic. Thus, for example, authorities in Niger initiated a vaccination program in 1995 to counter a meningitis epidemic. Some 60,000 people were inoculated with a counterfeit vaccine that contained no active ingredients, resulting in an estimated 2500 otherwise avoidable deaths (Pécoul et al 1999, p.363; WHO 2003, p.2). Other documented instances of such 'placebos' include: eye drops made of tap water; ampicillin made of turmeric; contraceptive pills made of wheat flour; and antibiotics and snake antivenom containing no active ingredients (Newton et al 2002, p.800). The distribution and use of such counterfeits clearly indicates that they are responsible for a large, though often undetected, numbers of deaths and injuries.

A clearer picture of the morbidity and mortality consequences of counterfeits emerges in relation to those products that have been adulterated or manufactured from actively dangerous substances. However, even here a considerable portion of incidents may go unrecorded for a number of reasons, such as poor reporting systems; local cultural practices may also lead to non-recognition of counterfeit-related injuries, as for example in Nigeria where deaths and worsening illness are often attributed to witchcraft (Clarke 2003, p.454). Nevertheless, there is ample evidence of the serious harms that such dangerous counterfeits can cause:

- Consumption of cough syrup made using diethylene glycol (a toxic antifreeze) resulted in 89 deaths in Haiti (in 1995) and 39 deaths in India (in 1998) (WHO 2002, p.2)
- 1000 people were hospitalised in 2001 in Volgograd, Russia, after using counterfeit insulin (Forzley 2003,p.33)
- In Nigeria, counterfeits have been implicated in causing kidney failure, liver damage, and heart failure (Kapp 2002, p.1080)
- In Nigeria, 109 children died in 1990 after being given counterfeit paracetamol (Erhun et al 2001, p.23)
- In 1999-2000, 17 people died in the US after taking a counterfeit antibiotic (IACC 2003,p.10)
- In 2001, Chinese authorities reported at total of 192,000 deaths attributed to unspecified counterfeit drugs (Forzley 2003, p.3)

If we factor in addition those likely cases of death and serious injury that pass unattributed, unreported and/or unrecorded, it becomes clear that counterfeit pharmaceuticals present a clear and substantial threat to public health. Indeed, Dora Akunyili, chief executive of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) claims that the problem has reached such a scale in her country that counterfeit medicines now pose a threat more severe than those from malaria, HIV/AIDS and armed robbery combined (Clarke 2003, p.453).

Driving the Trade: Socio-Economic, Political and Legal Contributors to the Growth of Pharmaceutical Counterfeiting

This section will move from the empirical to the analytical level, in an attempt to identify the array of factors that are currently contributing to the proliferation of pharmaceuticals counterfeiting.

At the political and economic levels we must note the impact of globalisation and trans-nationalisation, particularly with respect to trade relations. At the

regional level, we have witnessed the consolidation of free trade agreements and economic integration, institutionalised by the likes of the EU, NAFTA, ASEAN, and MERCOSUR. At the global level, first the General Agreement on Trade and Tariffs (GATT) and then the establishment of the World Trade Organisation (WTO) have opened domestic markets to global flows of goods and services. This has resulted in an expansion of trans-nationally distributed chains of production, distribution and consumption (Held et al 1999). As 'legitimate' world trade is increasingly ordered around networks of flows in goods and services (Castells 1996) so a parallel illegal global economy develops in its shadow (Castells 1998; Newman 1999; Wang and Zhu 2003p.98-101). Problems also arise around the policing of borders and the operation of customs controls. Given the increasing dependence on international trade, there emerge pressures to alleviate border restrictions in order to encourage the free flow of goods and to minimise the transaction costs incurred by business (Vithlani 1998, p.26; Robinson, 1999, p.81-2). This sits in tension with the need to institute more rigorous regimes of border inspection to curtail movement of illicit goods, especially in the context of a significant increase of such movements (see Nelken 1997 and Ruggeiro 2000). Given the absence of additional resources needed to keep pace with the increase in cross-border flows, customs agencies are unable to inspect more than a small proportion of shipments (In 1997, U.S. customs inspected only 3% of shipments entering the country – Vithlani 1998, p.26). Hence one side effect of increasingly porous borders has been to create greater opportunities for trans-national shipments of illicit goods to reach potentially lucrative markets. This problem has been exacerbated by the development of global networks of information and communication technology (ICT) such as the Internet. This has enabled the flourishing of direct business-to-customer (B2C) relations, providing a powerful and flexible tool for marketing counterfeit pharmaceuticals and other products. There have also been documented cases in which counterfeiters have utilised the Internet in order to procure materials (such as authentic-looking vials and packaging) essential to the production process (Thompson 2003b, p.1507).

A second crucial factor in the growth of pharmaceuticals counterfeiting has been the consolidation of global regimes of IP protection, especially in the wake of the TRIPS (trade related aspects of intellectual property) agreement under the auspices of the WTO in 1994. TRIPS makes mandatory the requirement that all WTO member nations make provision for establishing and enforcing rigorous intellectual property laws that protect the rights of patent, copyright- and trademark-holders. Which such moves should ostensibly curtail counterfeiting activities, they in fact may have quite the opposite effect. Pharmaceutical patent holders (located primarily in the US

and Europe) have utilised TRIPS provisions to challenge drugs manufactures in countries such as India and Brazil, where the state-licensed production of cheaper versions of high-price branded and patented drugs has been established practice since the 1950s. The US authorities in particular have been extremely aggressive in protecting American right-holders in other territories. The office of the United States Trade Representative (USTR) is charged with monitoring IP violations worldwide. If a country is deemed to be giving insufficient protection to US rights-holders (by, for example, failing to protect patents which have international recognition under TRIPS), they will be placed on a 'watch list', which in turn may lead the US to initiate economic sanctions through bilateral trade relations (what is known as the 'Special 301' process). Between 1984 and 2002, the U.S. initiated the 'Special 301' process against no less than 44 countries, mostly in the developing world (Drahos 2001, p.50-51). In 1988, the US initiated trade sanctions against Brazil for refusing to grant patent protection for pharmaceutical products – something Brazilian authorities saw as essential for providing low-cost variants of essential drugs, especially at a time when the country was experiencing a large growth in HIV/AIDS cases and patented antiretrovirals were prohibitively expensive (Drahos with Braithwaite 2002, p.104-5). The pressure of sanctions had its desired effect, and by 1996 the USTR could note with satisfaction that Brazil had taken 'the admirable step of enacting a modern patent law' (Ibid., p.105) i.e. one that would protect the interests of US pharmaceutical companies. As of May 2004, 34 countries were on the 'watch list', including 12 that were deemed to be giving inadequate protection for US pharmaceutical patent-holders (Canada, Chile, Croatia, the Dominican Republic, Hungary, Italy, Jamaica, Malaysia, Peru, Poland, Venezuela, and Vietnam) (USTR 2004). The effect of these developments has been two-fold: first, they have incrementally limited developing nations' ability to access essential and safe medicines at other than the unaffordable high prices set by Western pharmaceuticals manufacturers[1] (see Pécoul et al 1999, p.366); second, the consolidation of high drug prices afforded by patent protection has incentivised unregulated counterfeiting, as such medicines come to offer high profit potentials.

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[1] efenders of TRIPS counter that the agreement contains 'flexibilities' to allow developing countries access to essential drugs, for example through enabling 'compulsory licensing' (wherein a country may, on the grounds of 'national emergency or extreme urgency', license the domestic production of a pharmaceutical even if it is protected by patent). However, it must be noted that, firstly, compulsory licensing requires that the patent holder be given 'adequate remuneration', thereby inflicting cost burdens on the licensing nation; secondly, such licensing is of little help for those many countries that simply lack the necessary production capacity, resource base, technological infrastructure and skilled professionals, to manage domestic production of the drugs in question. For further discussion of 'flexibilities', see WHO 2002

The above-noted developments have served to exacerbate an already difficult situation in which the world's poorest countries struggle to access affordable medicines. Let us consider one example, that of Malawi. The per capital GNP of this 'least developed country' is only $210, average per capita income is only $146, and over 60% of the population live below the poverty line (Lewis-Lettington and Banda 2004, p.9; FINCA International 2005). At the same time, the country has twice in recent years suffered epidemics of type-1 dysentery, which is highly contagious and is lethal in up to 15% of cases. However, the only effective antibiotics available today (fluoroquinolones) sell at $20 per treatment (Pécoul et al 1999, p.363), well beyond the affordable range of either its citizens or the rudimentary and chronically under resourced health care system. The WHO calculates that most patented drugs sell at 20-100 times their marginal cost (cited in Lewis-Lettington and Banda 2004, p.9). This search for 'hyper-profits' has also skewed the research and development (R&D) strategies of major pharmaceutical manufacturers in critical ways. Given that a typical R&D program for a new drug costs some $160 million dollars (Pécoul et al 1999, p.364), it is unattractive for manufacturers to invest in developing medicines to treat diseases that are found mainly in the developing world. Given the low purchasing power of such populations/nations, drugs developed for these markets are deemed unlikely to yield the desired returns. Thus, for example, of the 1233 'new chemical entities' commercialized between 1975 and 1997, only 1% were for the treatment of tropical diseases (Ibid.,). Again, this lack of commitment to addressing the health problems of the developing world leaves the poorest populations dependent on such pharmaceutical provisions as are [a] available and [b] affordable, even if they may well be ineffective or even prove deadly.

A fourth 'driver' of the growth in counterfeit pharmaceuticals has been the move, especially in the industrialised nations, toward the (neo) liberalisation of health care provision (Wolffers, 1995; Player and Pollock, 2001; Hall and de la Motte, 2004). This has been particularly apparent in the US, where healthcare has been traditionally market-mediated rather than a matter of centralised public provision. This commodification of healthcare has created a competitive market in which a plethora of pharmaceutical wholesalers vie to provide consumers with drugs at the lowest cost. As Henri Mansa, of the American Society of Health-System Pharmacists, puts it: 'We have allowed the capitalist spirit to go beyond rational public health policy. We treat these medications so much as a bag of M&Ms' (in Young 2003, p.1712). There are now an estimated 6000-7000 wholesale pharmaceutical distributors in the US, creating many points at which counterfeits may enter the legitimate supply chain, and find their way onto the shelves of pharmacies and the medicine stocks of hospitals and physicians (Young 2004a, p.1978;

Thompson 2003b, p.1506). In 2004, a man in New York filed a lawsuit against one of the US's major pharmaceutical distributors, after he took counterfeit Epogen (a liver drug) which had entered their supply chain. At the same time, the proliferation of wholesalers-distributors makes attempts at regulatory inspection of supplies difficult, and creates resource problems for the responsible agencies, such as the Food and Drug Administration (FDA). This situation can be contrasted with the UK, where socialised rather than market-based healthcare prevails: no counterfeit product has been found in the legitimate supply chain for some 20 years (Clarke 2003, p.454). However, as pressures toward the privatisation of healthcare increase, and the public health sector is subjected to marketisation, we may expect an expansion of opportunity structures for counterfeits to enter legitimate supply chains.

Strategies and Limitations: Measures to Curb the Counterfeit Pharmaceuticals Trade

Recent years have seen concerted efforts to address the problem of pharmaceuticals counterfeiting at a number of levels. Major manufacturers, both individually and consortially, have begun to pressure national governments to take action against counterfeiters, in defence of their intellectual property rights. There now exist numerous umbrella organisations for the pharmaceuticals sector, such as EFPIA (The European Federation of Pharmaceutical Industries and Associations), the Pharmaceutical Research and Manufacturers of America (PhRMA), the International Federation of Pharmaceutical Manufacturers' Association (IFPMA), the Pharmaceutical Security Institute (PSI), as well as numerous anti-counterfeiting alliances in which pharmaceutical manufacturers are represented (such as the Anti-Counterfeiting Group (ACG), the Counterfeiting Intelligence Bureau (CIB), the International Intellectual Property Alliance (IIPA), the International Anti-Counterfeiting Coalition (IACC), the Alliance Against Counterfeiting and Piracy (AACP), and the Coalition for Intellectual Property Rights (CIPR), to name but some). Such bodies undertake a range of activities, ranging from research and evidence gathering, through lobbying and campaigning, to private policing and investigation. At the public level, both national regulatory authorities (such as the FDA) and trans-national health promotion organisations (such as the WHO), have devised programs and strategies for combating counterfeiting. The range of such strategies will be outlined and assessed below.

One level at which counter-measures have been pursued is that of strengthening legal provisions, especially in those developing countries which have the highest rates of circulation and/or production of counterfeit

pharmaceuticals. According to Lembit Rago, the head of drug quality at the WHO, only 20% of 191 WHO member countries have 'well developed' drug regulations, 50% have 'developing' regulations are 'varying levels', and the remaining 30% have 'negligible or no drug regulation' (Kapp: 2002: 1080). In tandem with strengthening legislative provision, there has been increasing attention to issues of enforcement. Even in countries with adequate anti-counterfeiting regulations in place, enforcement may be sporadic, infrequent, or virtually non-existent. Thus for example, Nigeria enacted the *Counterfeit and Fake Drugs Act* in 1990, followed by a number of other provisions for tackling counterfeiting (Erhun et al 2001, pp.24-25); in tandem, a number of task forces on counterfeit drugs have been established, with a dedicated remit of enforcing these laws. However, coordination, monitoring and control by these task forces has been found to be extremely inadequate, creating a situation in which dangerous counterfeits continue to circulate in large quantities (Ibid, p.29). Similar situations have been noted in other developing countries, such as Bangladesh (Roy 1994) and the Dominican Republic (USTR 2004). This situation has led to renewed international efforts to encourage legislation and enforcement, with numerous resolutions and frameworks being agreed under the auspices of the World Health Assembly, the WHO, the Pan-American Health Organisation (PAHO), and the International Conference of Drug Regulatory Authorities (ICDRA). As well as strengthening legal provisions, there have been efforts to encourage better coordination, collaboration and information-exchange between those national-level agencies which have an enforcement role – for example, drug regulators, police, customs, and professional organisations (EFPIA 2005, p.3; PAHO 2005, p.3). The aim of such strategies would appear to be that of building endogenous networks of governance (cf. Rhodes 1997) with an increased capacity for realising law enforcement and public protection goals.

However, such proposals are likely to be undermined by a number of contextual factors that inhibit their realisation, especially in developing countries. Firstly, law enforcement, like other forms of social control and regulation, is dependent upon the resources available. Even the most developed industrialised countries are currently struggling to address demand for intellectual property rights enforcement; the problem is exacerbated by the culture of law-enforcement agencies themselves, for IP crime is generally seen as a low priority and runs counter to the local focus of traditional policing activities (Hyde 1999, p.9). In countries facing urgent economic problems and severely limited resources, with states that may be attempting to impose order under conditions of considerable social and political instability (so-called 'weak states'), the enforcement of IP laws will likely come very low on the list of priorities, if it appears at all. Moreover,

police in such situations may view calls from foreign companies to protect their property rights with some cynicism; Delhi's deputy drugs controller exemplifies this attitude, stating that 'Fake drugs are not Delhi's problem...There may be one or two cases, but a lot of the times it is just old brand rivalry. The big fish cannot bear to find smaller chaps coming out with similar medicines so they say "spurious, duplicate, & c.' (cited in Chaterjee 2002, p.1776). A second type of problem arises with notions of capacity building and cooperation, in that the proposals overlook the role played by *corruption* in undermining law-enforcement efforts. The presence of corruption, understood as 'an illegal act that involves the abuse of a public trust or office for some private benefit' (Abadinsky 1985, p.249), has been documented as a recurrent counterpart to organised criminal enterprises around the world (Albanese et al 2003, p.443; Lyman and Potter 2004, p.88). There have been documented cases of public officials (politicians, police, and customs officials) being implicated in counterfeit drug distribution in countries such as India and Nigeria (Erhun et al 2001, p.29; Chaterjee 2002, p.1776). The pervasive presence of such corruption is likely to severely hinder attempts to institutionalise the kinds of inter-agency systems of cooperation deemed necessary to combat counterfeiting activities.

A further area in which anti-counterfeiting strategies are under development is that of technologies for product identification. There now exists a burgeoning sector of the private security industry that specialises in hi-tech brand protection solutions, which are intended to enable ready discrimination between legitimate and counterfeit goods. These include the marking of legitimate products with:

- Bi-dimensional bar coding, which enables products to carry 10 to 30 times the amount of information on a traditional bar code;
- Holograms, similar to those already used on credit cards;
- Ultraviolet inks, invisible to the naked eye, but detectable with a scanner;
- Chemical protection systems, such as DNA coding;
- Information-encoded micro-crystals and micro-particles ;
- RFID (radio frequency identification) comprising tiny microchips, encoded with product information, than can be fitted to the item. (Tiprus 2004, p.33; Ault 2004, p.714)

Current initiatives, led by the US FDA, favour the introduction of RFID technology, which would enable the tracking and tracing of all pharmaceuticals to their source, allowing the rapid identification of those products without a legitimate 'pedigree' (Thompson 2004, p.1430). However,

such technology-led anti-counterfeiting strategies encounter a number of significant problems. Firstly, the proposals for RFID tagging are on a voluntary rather than mandatory basis (Young 2004a, p.1984). Previous attempts to introduce authentication measures have not fared well, such as the US Prescription Drug Marketing Act (PDMA) that was passed in 1987, requiring that all drugs come with a 'pedigree certificate' in order 'to help stop counterfeit, adulterated, misbranded and expired drugs from entering the supply chain'; it has yet to be implemented, due to resistance from manufacturers on the grounds of its high costs (Young 2004b, p.645-6). Secondly, even if measures such as RFID could be successfully implemented, they would likely be hampered by the unavailability of the tag-reading technologies in those poorest countries where the circulation of counterfeit drugs is highest. Thirdly, the cost issues are likely to recur with new technological solutions (Newton et al 2002, p.801; Strassner and Fleisch 2003, p.10) and so significantly increase unit production costs, which will be passed on to consumers. As a consequence, the price differential between legitimate and illegitimate products may further increase, resulting in unintended incentives for consumers to choose counterfeit goods. Fourthly, technological solutions may only offer a temporary respite, as (to judge by past experience) counterfeiters have proven adept at finding means to circumvent anti-counterfeiting and IP protection mechanism; there is ample evidence that pharmaceutical counterfeiters are becoming increasingly sophisticated in their ability to reproduce authentication devices, making it difficult to spot counterfeits even upon close examination (Watt 2004, p.172)(for other examples from the area of copyright protection technologies, see Rassool 2003, pp.5-6; also Vaidhyanathan 2003, pp.176-7). As one legal specialist in drug counterfeiting cases opined: "any gizmo or gadget that they invent to stop counterfeiting will be beaten by counterfeiters…it's a pipe dream that technology is going to stop the counterfeiting" (Turkewitz, cited in Young 2004a, p.1984).

Conclusions

In this paper I have set out to explore the public health risks generated by the global trade in counterfeit pharmaceutical products. It is clear that this trade serves to exacerbate the crisis of health care delivery in the world's most economically disadvantaged nations. I have further argued, that the emergence and expansion of pharmaceuticals counterfeiting must be situated in the wider social, political, economic and legal contexts of globalisation and neo-liberal market economics, and in the structural organisation of inequalities between the developed and developing worlds. As such, anti-counterfeiting strategies based upon legislation, law-enforcement and technological protection are likely to be of limited utility,

especially in those nations where the public need for protection from dangerous counterfeits is most urgent. Indeed, legislative and enforcement activities based upon recent innovations in intellectual property protection (such as the TRIPS agreement) will likely further curtail the availability of affordable medicines for those most in need. In the final analysis, all such strategies are predicated upon the availability of, and access to, legitimate and safer alternatives to counterfeits. However, for those in the developing world, structural inequalities render access to such resources extremely difficult. For many, counterfeit pharmaceuticals are the only treatment option, even if their use entails taking potentially fatal risks. Until such time as concerted international action is taken to address the global patterns of exclusion from healthcare, the market for dangerous counterfeit drugs is likely to continue flourishing.

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