21st-CENTURY TERRORISM
DRUGS COUNTERFEITING CONFERENCE
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Ladies and Gentlemen, we are here today to learn about FALSE PROFITS, the frightening and dangerous growth in international prescription drug counterfeiting.

When asked why he robbed banks, Willy Sutton, the depression-era desperado replied, "because that's where the money is." And, as my former boss Mark McClellan used to say, if Sutton were alive today he'd be selling counterfeit prescription drugs. The bad news is that international prescription drug counterfeiting is on the rise.
The worse news is that pending US legislation could make it even worse.

Two news items crossed the wire late this week that illustrate this growing problem — and its truly global nature. The first story, from China, tells of eleven Chinese nationals and one American arrested in a counterfeit medicine scheme that spanned eleven countries, 440,000 bogus pills and $4.3 million US dollars. The drugs being peddled were Lipitor, Viagra, Cialis and Levitra. The nations involved were the US, Great Britain, Switzerland and Israel. (Note to Senators Dorgan and Vitter: Drug importation from the EU is dangerous.) The second, more frightening news item comes from Hamilton, Ontario where a registered pharmacist, Abadir Nasr, was charged with selling counterfeit Norvasc. Congressman Bernie Sanders and others, when asked about the dangers of drug importation are fond of quipping, "Show me the dead Canadians." Well, the regional coroner in Hamilton is currently investigating the deaths of five people who filled prescriptions for Norvasc at Mr. Nasr's pharmacy. All five died of a heart attack or stroke. Attention must be paid to this very serious problem because it is nothing short of international health care terrorism.

I've just returned from Europe and they've got a lot of problems over there. One of them is that profiteers masquerading as pharmacists are selling unsafe, unregulated, mislabeled, repacked, and co-mingled drugs to unsuspecting consumers. In Europe the cause of this malaise is known as parallel trade.
Here at home we know it as drug importation. Unfortunately, the consequences of this "drug shuffle"are inconvenient for some American politicians and so they parse the truth. That's bad medicine.

Senators Byron Dorgan (D, ND) and David Vitter (R, LA) have both introduced bills that would allow for drug importation from certain nations within the European Union. But they're confused. They don't seem to understand (or they choose not to admit) that you can't cherry-pick drugs from just one or two of the 25 European Union nations. Senators Dorgan and Vitter may only want drugs from Great Britain or France, but that's impossible – because that's the law. According to the Treaty of Rome, parallel trade is completely legal and Articles 30 and 36 prohibit manufacturers from managing their European supply chains in their own or patients' interests. . Sorry Senators, the truth is inconvenient.

Last year 140 million individual drug packages were parallel imported throughout the European Union -- and a wholesaler repackaged each and every one. This means that,

literally, parallel traders open 140 million packets of drugs, remove their contents and repackage them. But these parallel profiteers are in the moneymaking business, not the safety business. And mistakes happen. For example, new labels incorrectly state the dosage strength; the new label says the box contains tablets, but inside are capsules; the expiration date and batch numbers on the medicine boxes don't match the actual batch and dates of expiration of the medicines inside; and patient information materials are often in the wrong language or are out of date. Oops.

This means that drugs purchased from a British pharmacy to an unknowing American consumer (or a blissfully ignorant United States Senator) could come from European Union nations such as Greece, Latvia, Poland, Malta, Cyprus, or Estonia. In fact, parallel traded medicines account for about 20% (one in five) of all prescriptions filled by British pharmacies, the same pharmacies so highly touted by Senators Dorgan and Vitter and Governors Pawlenty (MN), Blagojevich (IL) and Doyle (WI). In the EU there is no requirement to record the batch numbers of parallel imported medicines, so if a batch of medicines originally intended for sale in Greece is recalled, tracing where the entire batch has gone (for example, from Athens to London through Canada to Indianapolis) is impossible. Caveat Emptor is bad health care practice and even worse health care policy. Safety cannot be compromised, even if the truth is inconvenient.
The World Health Organization (WHO) estimates that 8-10% of the global medicine supply chain is counterfeit – rising to 25% or higher in some countries. The largest counterfeit market with close proximity to the EU free trade zone is Russia, where the generally accepted estimate is that 12% of drugs are counterfeit. Now that the Baltic nations of Latvia, Lithuania, and Estonia have joined the European Union, WHO has warned that an increase in the risks of counterfeits entering the EU supply chain is "obvious." Facts are stubborn things.

Today we have brough together a panel of some of the world's leading experts on the issue of international prescription drug counterfeiting …

Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy

Dr. Jonathan Harper, Principal Consultant to Council of Europe Counterfeit Medicines Committee

Julian Morris, Director of the London-based International Policy Network

Graham Satchwell, a British Security Expert. As a former detective superintendent, Graham led successful criminal and civil investigations of counterfeit brand-name goods, including pharmaceuticals, throughout Europe, Asia and the developing world.

Professor David Taylor. Dr. Taylor is Professor of Pharmaceutical and public health policy at the University of London School of Pharmacy and was recently a member of Advisory Group on the Reform of the NHS Pharmaceutical Services.

Jim Thomson. Jim is a patient safety advocate and currently leads the London-based Centre for Mental Health

Dr. Michael Tremblay. Mike is a Former Advisor to the Council of Europe and Government of Great Britain, and currently leads Tremblay Consulting.

Our lunchtime speaker will be **Arif Alikhan**, the Vice Chairman and Executive Director of the U.S. Department of Justice's taskforce on Intellectual Property and former Section Chief of the Cyber and Intellectual Property Crimes Section of the U.S. Attorney's office in Los Angeles.

And our first speaker, **Dr. Scott Gottlieb**, FDA Deputy Commissioner for Policy and Medical Affairs.

Ladies and Gentlemen, Dr. Scott Gottlieb.

Speech by Scott Gottlieb, MD
Deputy Commissioner for Medical and Scientific Affairs
Food and Drug Administration, Washington, DC
September 20, 2005

Ensuring the Safety of America's Drug Supply

At FDA, the growing prevalence of counterfeit drugs, and the growing sophistication of those who make their trade in this illegal business, worries Commissioner Crawford and all of us a great deal.

There is no question that these problems, and the flow of counterfeit drugs around the world, are mounting.

But on the whole, the United States has a very safe prescription drug supply, and FDA is working hard to keep it that way.

This is not something that we can take for granted. If you look around the world, in many countries a quarter or even a half or more of the prescription drugs that people take are not legitimate products.

Studies by the World Health Organization have shown that of developed markets, this is especially true in Europe, where parallel trade has created porous borders and permeable controls that leave many opportunities for counterfeit drugs to enter Europe's supply chain.

This is especially true for drugs taken to treat chronic conditions such as high blood pressure or high cholesterol, which seem to be among the preferred targets of the counterfeiters.

These counterfeit drugs may be contaminated or may not work as intended, and that's a real public health concern.

And although the counterfeiting of drugs is still not as widespread in this country, we have seen a significant increase in counterfeiting activities around the world.

And even more worrisome, we have seen an increase in the sophistication, the cleverness, and the technical capabilities of counterfeiters that are trying to get drugs into the U.S. distribution system.

In 2000 FDA opened 6 counterfeit drug cases, in 2003 we opened 30, and last year we opened 58.

This increased enforcement activity is not only a function of the fact that we are looking harder for these problems. But also, that we are finding many more of these problems crossing our desks during our routine, daily work.

Just this past month, on August 31st, we busted up a Lipitor counterfeiting and smuggling operation that was trafficking almost $50 million worth of the drug.

This is a real public health threat. As we have seen from the counterfeit cases that we've already encountered and in many cases solved and put people in jail, counterfeit drug products may contain only inactive ingredients, they may contain incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or they may be contaminated.

The result is risks to patients' health, either risk to their safety directly if the products are dangerous. Or risks from people suffering from complications from the many diseases that prescription drugs can treat today – but that the counterfeit versions cannot.

So this is a serious concern at FDA.

With these more sophisticated drug counterfeit operations, FDA and all law enforcement activities that are partnering with us need to be even more effective in meeting these new challenges.

One of our proposed remedies at FDA is to strengthen our system for tracking drugs from the assembly line and right to the patient's bedside, by replacing the paperwork that now certifies the integrity of a pill with an electronic track and trace system that cannot be easily forged or forgotten.

This can be technology as miniscule microchips or "taggants" that go inside pill bottles, or even inside the individual pills. There's been considerable progress made in developing and deploying these sorts of technological tools.

Right now, we have given manufacturers more time to deploy this kind of technology. We have also put a stay on a rule that would effectively require these kinds of measures, a paper pedigree rule, to give people more time to move from paper pedigrees which would not provide the same kinds of protections to electronic pedigrees, which would. New technology would allow for less costly compliance, and better controls. The rule is written broadly enough so that electronic track and trace could be used in place of paper pedigree. We plan to make a decision soon on this stay, which is in place until December 2006, and we could reach a decision before that.

There are already many promising technologies out there such as radiofrequency identification techniques, new applications of bar code labeling, new approaches to doing track and trace technology so that we can reliably, in ways that cannot easily be fraudulently faked, identify whether a product really is a legitimate one, whether it comes from a legitimate source and has not been tampered with along the supply chain.

We've seen new technologies for packaging, new color-based technologies that embed multiple different layers of protection.

We've seen new anti-tampering technologies for drug packaging. Even the tops of injectable drugs that can help keep the product secure.

And we've seen new technologies that can be used on the drugs themselves, from new color technologies to bar codes embedded, not just unit-of-dose packaging but actually on the drug, to other taggant and chemical technologies that are not harmful for patients but that can make it very easy to determine whether a product is safe or not.

These tools do everything from make it easy for us or others to do chemical testing on the product's legitimacy to making it easier for patients to identify whether the product is a legitimate one or not by a distinctive taste.

So there are a lot of potentially valuable technologies out there that are in development right now, and in some cases are starting to be applied to the pharmaceutical industry.

In some ways, the drug sector is behind other industries where secure track and trace approaches and secure anti-counterfeiting technologies have become more widespread.

That needs to change, and it is changing.

These technologies together constitute what we call an electronic pedigree, and we believe that these would go a long way toward starting to meet many of the modern needs of the Prescription Drug Marketing Act, the principal law in this country that protects our domestic drug supply from dangerous foreign imports.

In fact, this law was passed in part, in direct response to a widely reported case where counterfeit drugs that were sub-potent made their way into the U.S. drug supply. But that was a long time ago, the counterfeit drug problem has grown much worse, and so our tools for dealing with it need to advance as well.

Many people believe that FDA interprets our counterfeit drug report that we issued to address this growing threat as saying that we want RFID implemented by 2007. We said that an electronic pedigree should be feasible by 2007, and right now, RFID is the most promising technology to help deliver on that need.

We believe that we can accelerate the development, the testing, the feasibility testing and the cost-effectiveness testing, of many of these technologies that are in development today.

And as we are trying to do in other areas of FDA activities where there are new technologies that can be valuable, we want to bring them to benefit patients as soon as possible.

And while some of these technologies do seem just a short time away from widespread application, others have not been fully tested yet and demonstrated to be feasible, and we would like to see more research applied to this field.

But as our colleagues at other agencies who are also experts on counterfeiting technology have told us, there is no single magic bullet. Not only do many of these technologies need to go through some further developmental steps, counterfeiters are very sophisticated today, so this is a moving game.

We constantly need to be finding ways to update our technologies. We constantly need to be thinking about whether we've got enough layers in place.

There's no one magic bullet.

We need to think simultaneously about a coordinated approach that involves tracking and tracing and product packaging and product-embedded technologies and others.

In short, we need multiple layers to keep our drug supply safe.

Our money supply, just the paper money, has more than 20 embedded technologies, both overt and covert and some that are only known to the Treasury Department that handles the money.

We need multiple layers like that to build more safety and security in prescription drugs as well, and we're going to be working to bring forward proven technologies, and to develop the proof for these other technologies.

We need to bring them forward to improving our drug supply as quickly as possible.

But no one technology is going to assure safety and security. So we need to maintain vigilance over our entire drug chain.

So certainly, this is not a time when we should be going in the exact opposite direction, and weakening the controls we already have over our domestic drug supply.

We need to be adding further measures to ensure the integrity of the supply of vital medicines, not dismantling the measures that we already rely on.

For this reason, it is hard to have a discussion about counterfeiting without also addressing, at least in part, proposals that would increase or legitimize widespread importation of foreign drugs.

These kinds of policy proposals mean many different things to the many people that have grappled over this issue over the last five years or more.

But simply put, for the professional staff at FDA that is charged with ensuring the safety of our drug supply chain, in means one thing above all else:

The importation of foreign drugs through middlemen, through storefront pharmacies, and through foreign websites, represents a new and gaping hole in our controls over our drug supply. These holes are already being exploited by those up to no good.

And no amount of well intentioned legislation, to apply a safe way to check the drugs coming in through these different importation schemes, is going to fully guarantee their safety.

All of these schemes are going to weaken our controls, some more than others. And so any consideration of importation needs to come down to a question of how much safety you want to demand, and how many corners you are willing to cut.

And one more thing: These importation schemes are utterly inconsistent with many of FDA's fundamental goals and its fundamental practices.

The same regulatory agency that is called upon to tease apart subtle distinctions about hard to measure risks inherent in certain drugs in one room, is being asked by some to go into another room and open up big holes in the controls over the kinds of drugs that we allow into the U.S., and not be as worried that many of these imported drugs may have co-mingled with counterfeits that are contaminated or sub-potent.

The same agency that is asked to work diligently to write well reasoned, careful labels on newly approved drugs identifying all of their risks and benefits in one room, is asked to go into another room and overlook the fact that there are imported foreign drugs coming into this country with the wrong labels on them, with no labels on them, or with labels written in languages other than English.

The same agency that asks drug developers to sponsor ten thousand patient clinical trials to tease apart the preferred dose of a new drug in one division is being asked by some to formulate a separate division that would allow drugs that are in the wrong formulation or the wrong dosage to be imported.

It is hard to imagine being able to maintain all of these kinds of inconsistencies and still sustain the same kinds of controls on safety that people expect and rely on today.

And so asking the question about drug importation and of whether we want to strengthen our grip over the drug supply in the face of rising counterfeiting or weaken those controls in the name of price considerations is also asking a fundamental question about what we want out of our drug regulatory agency.

These are fundamentally difficult questions, and many people are rightly concerned about the high prices on many drugs, especially people who can least afford to pay for medicines because they lack good health insurance, or have no insurance at all.

And many people are rightly angry about the lower prices that drugs cost in many foreign nations because those countries impose strict controls on the prices that U.S. and other manufacturers can charge for their products overseas.

And so, at FDA and across the government, we are also continuing to champion safe ways to lower drug costs through expanded coverage offered by the new Medicare prescription drug benefit, through more steps to make OTC drugs available, through more steps to lower the cost of bringing safe and effective new drugs to the market and to develop information that guides their smart and appropriate use, and through more steps to allow people to make wider use of safe and effective generic medicines. In fact, Generic drugs represented more than 66 percent of the total prescription doses sold in 2004.

Finally, and in closing, we know that we cannot solve the counterfeit drug problem working alone.

Counterfeit drugs are a global problem. We're seeing an increasing number of cases that involve not just a few people manufacturing a fake product in their garage, but well-organized international criminal operations that are trying to make use of the latest technologies for making a product that looks like the real thing but isn't.

And so we need help of international law enforcement, health and regulatory authorities, as well as private stakeholders internationally to help us address this problem effectively.

We cannot just secure our borders and turn our head to the larger problems that are occurring elsewhere.

So we have consulted with regulatory authorities around the world from Taiwan to Morocco to Malaysia, China, and Sub-Saharan Africa. We continue to build these relationships.

We are also working very closely with Interpol and various law enforcement entities in various countries on specific cases, as well as the World Health Organization on a broader strategy to address the global problem. The WHO had a meeting last year with drug regulatory authorities and we expect to meet again in the coming months.

To those of you who are working on ways to combat the growing traffic in counterfeit drugs, at FDA we want to thank you for your contribution to dealing with this significant emerging public health threat.

At FDA, we are confident that working together we can stay ahead of those who are out to make a fast buck at the expense of the health of Americans.

And we are sure that we will be able to work together to keep our drug supply safe and secure and the safest in the world if we do remain vigilant through steps like this.

Thank you all for your contributions.

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The Parallel Importing of Medicines in Europe
Private Concerns and Public Interests

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Most public discussion about the parallel importing (or in US parlance re-importation) of medicines in the EU illustrates the fact that it is difficult to communicate in balanced ways about complex issues, involving conflicting policy goals. There is a natural tendency to simplify, and to focus on what for each particular group of 'stakeholders' are 'key' facts. But all too often this approach leads to an unsatisfactory debate, which is partisan and confusing. This serves to prevent rather than promote the understanding and protection of the public's best interests.

In the European context the proponents of PIs (that is, medicines provided via parallel importers) argue that if cheaper forms of a given medicine are available in one part of the single EU market as opposed to another, it must make sense for pharmacists and other care providers to purchase at the lower cost. This will – PI advocates suggest – allow other forms of care or service to be afforded, or taxes and fees to be lower than otherwise would be the case.

Against this PI opponents say that its savings are exaggerated and that its costs, to not only innovative companies but also the wider public, outweigh its benefits. Permitting parallel importing may, they believe, raise the risk of harm resulting from causes such as medication errors associated with factors like patients not recognising their treatments and the problems of drug counterfeiting. Although the latter are most acute in less developed countries, where vulnerable populations are often open to exploitation and hazard on a large scale, they should not be ignored in Europe and the US[1]. Recent work for the Council of Europe has emphasised this point[2].

However, the 'real world' is more complex than simplistic claims about parallel importing being unequivocally harmful or beneficial may imply. In the EU pharmaceutical parallel importing has (to date at least) taken place without significantly undermining standards of patient care, or the integrity of the pharmaceutical supply chain. However, any assumption that parallel importing is economically beneficial to countries such as the UK would be deeply questionable.

In fact, the research available offers fairly robust evidence that the savings to the public purse achieved as a result of PI use have been small as compared with total European drug outlays[4]. They have also been significantly less than the income losses as a result incurred by research based pharmaceutical companies and their subsidiaries located in this country.

Even discounting all harm caused to patients (and partly hidden costs such as those associated with the purchasing of PIs by NHS pharmacists, and the resources needed to maintain complex regulatory safeguards over product quality) the impact of parallel importing on UK pharmaceutical industry interests has been significant. This factor was one of the reasons why an independent ESRC funded group led by Professor Stefan Szymanski of Imperial College recently found its net UK value to be negative[3].

The long-term balance of gain and loss for EU nations that export PI products is also less certain than might at first appear. For instance, supply problems can occur when medicines are diverted away from domestic to external markets. Over time a shift to more standardised medicines pricing across EU states might also disadvantage countries which have traditionally set lower than average drug prices in their home markets, while still enjoying full access to the fruits of modern research.

Europe's long-term goals

Such observations need to be informed by an appreciation of the economics of pharmaceutical development and supply, and the political imperatives underpinning the creation of the European single market.

Normally, the average selling *price* of a patented medicine is many times the cost of its basic ingredients. This is because 'sunk' costs associated with research, manufacturing and marketing must be recouped within a narrow window of time. Patented medicine prices must also be high enough to allow adequate returns to investment (and/or attract further investment for the future) to be generated before generic competition ensues. As recent events surrounding medicines such as Vioxx demonstrate, the pharmaceutical industry faces high levels of commercial risk. Investment returns should compensate for this fact.

But the marginal production *cost* of a new medicine will by definition be much closer to its ingredient cost, and its eventual generic price. Just making one additional batch of a product will typically require very little extra spending. Many economists would argue that in such circumstances, and particularly when health or similarly vital 'customer' concerns are at stake, better-off communities ought to pay more per unit of consumption than poorer ones. Provided that losses are not incurred as a result of any one sale, strategies based on this type of price discrimination ('Ramsay pricing') help maximise both private returns and the welfare of all sections of the public.

However, the free movement of patented medicines between richer and poorer EU nations today tends to obviate this option. The European situation is also complicated by the fact that formal (as opposed to voluntarily discounted) medicine price differences within the Union are imposed by member state based regulators, rather than resulting from the freely made decisions of the innovators holding intellectual property rights for the products concerned.

Agencies such as the European Commission may, it can be conjectured, wish to see a gradual removal of national level controls over all sectors of the European economy, and the emergence of stronger pan-European regulations and institutions. The establishment of a single European 'free market' could be regarded as key step towards achieving the long-term political goal of establishing more comprehensive central competencies in fields such as the health sector.

The phenomenon of pharmaceutical parallel importing within the EU can be seen in this context. It is not purely associated with a movement towards freedom of trade, away from local protectionism towards greater efficiency. It is arguably more an artefact (or even 'side effect') resulting from competition for bureaucratic power and political legitimacy between regulatory and governmental interests in the EU member states and their counterparts in Brussels, the ultimate costs and benefits of which remain uncertain. In such circumstances it is in the overall public's interest to promote awareness of its possible hazards, not least to try to ensure that European industry does not suffer irretrievable long term damage.

Global lessons?

EU policy makers could, if they wish to, continue to permit the parallel trading of pharmaceutical goods within the expanding EU single market for an indefinite period. Challenges associated with the entry of Eastern European member states will make it harder in future to ensure drug quality and safety, and prevent crimes such as medicine counterfeiting. So too may an increased use of the internet for medicines purchasing, especially in the absence of high quality publicly funded health services. Yet the fact remains that the European record since the 1970s indicates that, if enough effort and money were invested in regulating parallel trading in medicines in the expanded EU, it could be conducted ethically and relatively safely.

However, policy questions remaining to be answered include:

- what relevance does the European example have for the wider world? And

- even if safety can in most instances be assured at a cost, what in future will be the overall balance of the European public's interest in relation to the trading of locally priced patented medicines across its internal borders?

Neither can be answered simply. In relation to the first question the European Union is in many ways a special case. What has worked in the (pre 2004) EU would not necessarily be viable in the US, or in less advantaged regions of the world. Indeed, if improving global health and reducing world wide health inequalities is taken to be one of the most important challenges of the twenty first century, Europe's experience with promoting medicines parallel importing is largely irrelevant. It may well prove much more beneficial to find ways of better controlling the international movement of pharmaceutical goods, both to protect the integrity of their supply and to allow poorer populations to benefit selectively from the lowest possible prices.

With regard to direct European interests, it can be concluded that the most important concerns at stake relate to maintaining and further developing knowledge based industries, and creating beneficial new health and other technologies. The short term value of making even minor savings in pharmaceutical/health service outlays should not be ignored, especially in communities which do not see themselves as direct beneficiaries of more sophisticated forms of research based industrial activity. Nevertheless, maintaining the long-term living standards of Europeans demands adequate investment in just such forms of enterprise. Informed public discussion of the positive and negative aspects of parallel trading of medicines in the EU ought (whatever the private interests of entrepreneurs, taxpayers and social security recipients) in the final analysis serve to highlight this economic reality.

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Counterfeit Medicines – A Challenge to European Pharmaceutical Care?

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Ensuring the safe use of medicines is central to pharmacy's mission. To date patients in the European Union have not suffered significant harm as a result of counterfeit drugs entering the legitimate pharmaceutical supply chain. But there are concerns that this risk is now growing. Any avoidable factors likely to make the EU's member states and their peoples vulnerable to harm from fake pharmaceuticals should be addressed early, before patient welfare is seriously undermined.

To professionals working in the orderly environment of pharmacy in Western Europe, dangerous worlds such as that of 'the Russian maffia' may seem to present no more of a real threat than that posed by reports of children dying of treatable diseases in remote parts of Africa. But the global community is changing fast.

Comfortable assumptions of immunity from the hazards experienced elsewhere may prove false. The increasing risk of illicit drug smuggling in today's Europe is now becoming widely recognised. In its 2005 Annual Report the UN's International Narcotics Control Board[1] warned that the porosity of the extended EU's new Eastern borders has opened the way to a rapid increase in the amount of heroin flowing into the Union from Afghanistan.

Some experts also believe that where illegal drugs have led, high value modern medicines (or at least counterfeit and sub-standard copies of such products) will inevitably follow. They argue that if the leaders of Europe and its pharmacy community are unduly complacent, the cost will ultimately have to be measured not merely in terms of lost revenues for European industry, but in patients' lives.

A rising trend

In 2004 the Stockholm Network published a study entitled *A Sick Business*[2]. In it, its author Graham Satchwell documents a series of serious instances involving pharmaceutical counterfeiting. His work reveals how sub-standard and fake products ranging from contraceptives to antibiotics have entered legitimate pharmaceutical supply chains around the world.

Most of the documented cases illustrative of this trend have occurred in United States and the less developed countries. But research undertaken under the auspices of the Council of Europe is indicative of an emergent problem in the EU[3]. Recently, for instance, a counterfeit batch of the erectile dysfunction drug Cialis was discovered in Holland[4]. Although this incident was not life threatening, it is unlikely that it was a unique. Other forms of counterfeiting could have more serious outcomes.

Satchwell is a former British police superintendent who has specialised in the areas of brand forgery and illegal medicines supply. In the European context he particularly stressed the avoidable risks that the parallel importing of medicines may create, as products are repackaged and resold in ways that create opportunities for not only accidental error, but also improper substitution.

The policy recommendations Satchwell offers reflect his experience in policing, and knowledge of the realities of organised crime. They range from introducing sophisticated tracking technologies into medicines packaging to further controlling re-packaging activities within the EU's borders. The purpose of the latter would be to ensure that safeguards designed to protect medicine pack integrity cannot be removed by parallel traders, after products have left their original manufacturers' factory gates.

Critics of the EU's policies point to the fact that the fake Cialis found in Holland was a parallel import. However, the Union's record of regulating parallel importing has so far been good, in that its inherent risks have in the main been controlled. PI's advocates say that it has saved money for taxpayers and health care providers in countries like the UK and Germany, albeit that most of the financial resource freed seems to have gone to the traders involved[5]. They can also argue that although individual patients may have had problems with medicines recognition or information provision, this has not compromised safety at a population level. And the spectre of counterfeit drugs, they may claim, is more one of future possibility than of present substance.

Care perspectives

Leading hospital pharmacists in Western Europe can be relatively confident that the systems of medicines purchasing and quality control for which they are accountable act as an additional check against sub-standard medicine use, over and above the controls provided by national and Union level regulatory bodies. If adequate investments continue to be made in pharmacy, sufficient to allow it both to protect drug supply standards and further strengthen the profession's clinical care contributions, patients being cared for in European hospitals are very unlikely to be treated with fake or otherwise grossly inferior medicines.

But as the expansion of the EU continues it should not blindly be assumed that this will always be the case, especially in less well funded and sophisticated institutions. Nor should it be forgotten that recovering patients leave hospital, to return to their lives in the community. Modern pharmacists are concerned with the totality of pharmaceutical care available to their patients. It is in the community setting that threats such as that of drug counterfeiting deserve the most rigorous consideration.

One likely future trend is towards an increased emphasis on self-care. The availability of comprehensive tax or universal social insurance funded services in the established EU countries has to date ensured that virtually everyone in need of drug treatments has had good access to professionally facilitated pharmaceutical care. That is in large part why

phenomena like consumer initiated internet medicines purchasing from uncertain domestic and foreign sources have not developed as they have in the US. But as countries with less comprehensive public services join the Union, and at the same time patterns of treatment shift more towards life style modification and consumer choice led strategies, this situation may well change.

Another underlying reason why the risks of medicines counterfeiting associated with practices such as parallel importing deserve ongoing and careful attention relates to the viability European industry. While the net health service savings generated by PI medicine use have been relatively small, there can be doubt that its costs to research based companies are higher[6]. Hence the price of parallel importing may eventually have to be counted in terms of economic harm to Europe as a whole, in addition to the direct damage that could in time be done to the Union's pharmaceutical supply chain.

Conclusions

In many less fortunate parts of the world medicines counterfeiting is already a major cause of harm. Most pharmacists do not, of course, regard avoidable deaths amongst children or adults in regions as sub-Saharan Africa as unimportant, even if in the welfare of European or American citizens is not immediately affected by them. Seen from this perspective, the global problems caused by the supply of fake drugs demand urgent attention and coherent action today.

From a purely EU stand point, medicines counterfeiting may not be so serious a hazard as it is in other regions. Yet the logical conclusion to draw is that it would be unwise for anyone involved in European pharmacy to dismiss out of hand the potential threat it poses. A precautionary approach would demand that this should be confronted before significant harm results. Pharmacists have an important part to play in conveying this fact to managers and policy makers, while communicating the vital importance of maintaining public and patient confidence in all aspects of the safe and effective use of medicines.

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