Witness:
Mr. Graham Satchwell
Proco Solutions, London, UK
Managing Director

Testimony

Mr. Chairman and Members of the Committee

I have been asked to comment on the safety of the drug supply from what has been termed, 'permitted countries' (as defined) and whether it is possible, given the experience of parallel trade within the EU, to truly limit importation to these "permitted countries".

I understand that under the Bill importation will be allowed, subject to the importation of drugs to the United States not adversely affecting public health.

Perhaps I should first tell you why I think I have been asked to contribute to this discussion. I have been involved in the business of investigating counterfeiting and other intellectual property crime, and its links to organised crime for many years.
In addition-

• In 2004, on behalf of the Stockholm Network, a European based organisation, I completed the writing of a book entitled 'A Sick Business – Counterfeit Medicines & Organised Crime'. It has been widely reported upon and Interpol have asked to link it to there internet site.
• I am a member of UK Government's Patent Office Investigative Strategy Group.
• For several years to 1999, I was the official spokesperson (on counterfeiting of branded goods) for Association of Chief Police Officers (ACPO) England & Wales.
• Prior to leaving the Police Service I received personal thanks from four HMG Ministers. I was a detective superintendent for many years in the UK; those thanks included comments from the UK Trade & Industry Secretary in relation to work in anti-counterfeiting of branded goods.
• During my investigative work I have been officially commended by HM Judges, chief constables, the Director of Public Prosecutions and The Lord Lieutenant of London for successful major investigations.
• I have successfully led international and politically sensitive major corporate investigations into counterfeiting, illegal diversion and fraud including the massive re-importation of anti-retroviral drugs from Africa to Europe.
• I was the chief architect and author of the 1999 UK 'Memorandum of Understanding' between all police forces in UK, Customs authorities and other law enforcement agencies, brand-owners and industry groups on the investigation of counterfeiting of branded goods.
• For 3 years I was Director of Security (Europe, Middle East & Africa) for GlaxoSmithKline and took the lead on anti-counterfeiting and unlawful diversion.
• Three years ago I created and led an anti-counterfeiting investigative forum in Europe involving the world's leading pharmaceutical companies.
• Between 1994 & 1999 I was the Metropolitan Police 'Joint Action Group' leader in relation to counterfeiting of branded goods.

• I am currently providing both anti-counterfeiting and diversion strategic input and operational results to several major corporations and doing research into these subjects for another book on the same subject
• I have had items published on counterfeiting, diversion and other crime issues in UK and USA.

I should also mention that I am an Honours Law Graduate.

It is about 10 years since the first case involving counterfeit pharmaceuticals came my way. I have specialised in that area for the last four years.

It was about 3 years ago that I first developed an interest in the supplies of pharmaceutical products being advertised on the internet and purporting to come from Canada primarily to serve the U.S market.

I would like to preface my comments by saying that I am in favour of parallel trade. It seems to me right and fair that those who suffer from the highest prices (USA and Northern Europe) should be able to enter into free-trade with those in less developed countries, to the benefit of both parties and as a result of the differentiation in pricing structures which are imposed.

However, it seems to me to be abundantly clear that in matters such as medicine, special care needs to be taken. It is one thing to buy substandard footwear but quite another to take substandard and potentially life-threatening or life-damaging medicines.

I have read from time to time comments such as, ‘it can be difficult for the layman to identify counterfeit drugs’ or ‘it would need a trained doctor to examine the package to know whether the drugs were genuine’. Such comments completely miss the point and show a lack of experience in handling counterfeit medicines.

The truth is that counterfeit medicines often appear so like the genuine product that no one, not the best specialist can tell the genuine packaging from the counterfeit. And no one, not the best specialist can tell the genuine product from the counterfeit unless the product is subjected to chemical analysis. The result is that everyone, poor, ignorant, rich and smart, all are at risk from counterfeit or sub-standard products – and they probably won’t recognise them when they and if they see them.

Counterfeiters and dealers in substandard medicines do not target particular medicines that we might call ‘life-style drugs’ (such as ‘erectile dysfunction’, or ‘slimming’ products or ‘steroids) they simply act in their own best commercial interests – they target big selling drugs. A little research into the proportion of the world’s top selling drugs illustrates the point perfectly – most have been counterfeited. The threat is therefore neither restricted to those of a certain income, intelligence, nor illness suffered.

The internet provides an unstoppable market that can, and is, taken advantage of by private and commercial purchasers of firearms, narcotics, pornography, fraudulent deals

and all sorts of consumer goods. It cannot be stopped nor easily regulated. Governments make increasing resources available to control the adverse elements of online trading and given that individuals in the USA, UK and elsewhere will buy access to goods and services that are harmful to themselves and others, it is apparent that the Internet market needs to be regulated like any conventional one. Of course such regulation must be commensurate with the level of harm that the particular transaction could be expected to cause.

I have read the draft Bill and there many aspects that I am not competent to comment upon. However, I notice that an important distinction is made between the private individual buyer and the commercial importer; the former risks harming himself, the latter risks harming many others. It seems obvious that regulations on business-to-business transactions should be much more tightly controlled. Thus it is surprising that S. 334 attempts to build a regulatory framework for commercial drug importation via domestic importers and their contracts with foreign companies.

You have invited my specific comments on the safety of the drug supply from those 'permitted' countries and whether it is possible, given parallel trade within the EU, to truly limit importation to these "permitted countries." Based on my experience, I have concluded that the regulatory framework as described in this proposal will not afford your citizens the protections they currently enjoy. As it stands, S. 334 does not afford confidence that a drug from a "permitted country" will have originated there or have been subject to appropriate regulation.

It seems to me that there are two particular issues that this committee will be considering that I might be able to assist with; the experience gained from parallel train of medicines within the Europe Community; and secondly, what this experience tells us about how the supply from countries outside of the EEC impacts on this more highly-regulated Community.

The UK now receives some 140 million parallel traded medicines per annum. This is more than 20% of the entire consumption of the British National Health Service. The UK receives much more parallel traded product than any other European country; the reason is obvious – the UK is an expensive market in which parallel traded goods offer the best return for any European importer.

Have there been any problems as a result of this trade? There have been many, and there is now a growing awareness of their significance. Currently the UK Serious Fraud Office (A British Government Agency) is conducting a truly massive investigation into the activities of those responsible for the sale of generics to the UK National Health Service, some of those are involved in parallel trade.

The MHRA has recently admitted a problem with counterfeit medicines. Parallel traded medicines are a proven method of introducing counterfeit and other sub-standard medicines into the distribution chain.

The difficulties surrounding parallel trade arise as a result of several factors:
• The very necessary requirements that medicines marketed in Britain must be packaged in the English language and contain a patient information leaflet in English language- the repackaging of branded goods that follows that requirement (Parallel traded goods will be printed in Spanish or Greek or other language).
• Repackaging standards are not uniformly high and Patient Safety Groups in UK provide many examples of patients being dispensed medicines that 'don't look right' or have accompanying patient information that is incomplete, dangerously translated or otherwise different in effect.
• Repackaging is often conducted in the exporting country or some intermediate country. In such cases the UK regulators are blind to the conditions under which these processes are conducted.
• Repackaging is labour intensive. It is often not a mechanised process. The result is that repackaging is often done in those countries with the cheapest labour. It is just such countries of course that often cannot afford proper regulatory control, spend least on hygiene, and frankly, worry least about U.S or UK concerns.
• Wrappings are taken off, blister packs emptied by hand or cut up (A 'month's supply in Continental Europe is usually 30 days worth, in UK a month's supply is 28 days worth, traders regularly manually remove 2 days supply from each 30 and put them by to create further packs)
• One survey in 2004 revealed that of 300 parallel traded medicines examined, 25% should have failed on 'safety reasons', 50% because of poor quality of product. In addition 80% failed on legal grounds such as IPR infringement.
• Part of the repackaging process involves the removal of the product from the brand owners packaging including batch numbering and anti-counterfeiting features. This in itself provides an ideal opportunity for sub-standard medicine, counterfeit or otherwise to enter the chain.
• Of course much parallel trade and repackaging is conducted in properly, according to the law. However, in reality, those who choose to buy out of date, counterfeit or otherwise substandard medicines and to have them repackaged or stored in totally inappropriate conditions, can do so in Europe with very low risk of detection.
• One potential risk that has not been adequately researched on either side of the Atlantic, is the potential for counterfeiters to copy lawfully repackaged product. This is a low cost and perhaps the most anonymous method of introducing counterfeit in the chain with lowest risk of detection.

Another very serious concern is to establish that drugs have been distributed legitimately from verified sources..

First and foremost, how can a parallel trader trust the bona fides of the trader from whom he purchased his product? If a UK parallel trader wishes to buy from another European dealer then he must first ensure that that foreign dealer is licensed within his own country. The mechanism for doing so is sloppy. It is not sloppy only in UK but elsewhere in Europe.
Currently the UK dealer might receive an unsolicited email from a business which

advertises a particular drug at an attractive price. The UK dealer might email back and a price be agreed. The UK dealer should then ensure that the seller is licensed. He will therefore ask for evidence from the seller. The seller will then fax or post a document that purports to be a licence to conduct such trade. There is no one European body with which the UK dealer can verify his sellers' credentials, and the UK regulatory authority do not see it as their duty.

It should be no surprise that this is seen as something of a loophole. It is impossible for a UK dealer to be aware of the origin of the product in his warehouse. He might have been told that it originated from Greece, but in Greece it could easily have been repackaged from India or Pakistan or China.

In the course of my work I have myself negotiated to buy counterfeit medicines from China, Germany, Poland, India, Pakistan and other countries. It is extremely easy for anyone to find a foreign party willing to counterfeit medicines (without active ingredients) and present those medicines in packaging that will easily pass as genuine.

This is not hypothetical. There have been well-publicised cases in USA and UK to illustrate the point. In the USA the recent Lipitor case is but one example amongst many. You will recall that one of the several defendants in that case was a convicted cocaine dealer. Parallel trade in its current form provides ideal opportunities for the unscrupulous. In the UK in 2004 there were several counterfeiting cases but the most informative were those involving the medicines Reductil and Cialis. Counterfeited products entered the legitimate distribution chain in Holland and were shipped to UK dealers for onward sale into the (innocent) market.

Parallel trade in Europe has led to a situation where medicines often change hands more than twenty times before reaching the dispensary. They are manufactured in one country, shipped to the country in which they were intended to be marketed, bought and sold from there by wholesalers and then into the parallel trade market where they typically pass through many hands into the more expensive markets and then frequently moved on again.

No doubt the creation and use of such a long distribution chain is often in itself innocent, but it makes product recall extremely difficult; the manufacturer and regulatory authorities do not and cannot know where the relevant batch is. In addition, such long and convoluted distribution exposes medicines to the increased likelihood of inappropriate storage, provides anonymity for those at the top of the chain, and gives an easy excuse for those downstream should the goods prove sub-standard (they claim not to know of their origin and movements).

Product recall is of course a vital patient safety issue. In the UK it is currently not working properly and I have no reason to think that things are much better elsewhere in Europe. Apart from the problems that arise from repackaging, we simply do not have a system that can cope with having so many different bodies holding medicines from so many other bodies. Currently, if there is a product recall then a notice is faxed by the

MHRA to amongst others primary health trusts, to those listed as having imported the batch if indeed it is a batch rather than whole product issue. However, the overwhelming number of wholesalers and parallel traders are not advised. In a very fluid market such as has been created in pharmaceuticals, this means that those who are in possession of what has become 'unsaleable' stock are able, innocently or otherwise, to sell it forward to innocent recipients. Following a product recall in UK last year, incidents occurred where chemists attempted to sell products that had been subject to official recall.

Like any profession, lawyer, policeman, stevedore, parallel trader, there is a dishonest element. The harm that can be caused by a dishonest importer of pharmaceuticals is extreme. Proper regulation and enforcement are both needed if parallel trade in medicines is to be safe. But a clear distinction needs to be made between the writing of legislation (and regulations) and the practical enforcement of the same.
In the UK there are adequate regulations, these are more or less mirrored across the E.U. However, the matter of enforcement of those regulations is another matter. It must be extremely difficult to adequately 'police' parallel trade, and the movement of such products within the UK, when the number of licences issued has increased tenfold in 10 years (from 300 to 3000) without any corresponding increase in staff. It currently takes about 18 months to obtain a parallel trade licence. You can imagine the opportunity that this small regulatory agency has to conduct audits on premises (without notice).

Your much larger country will I believe, because of the attractiveness of the U.S market (both size and cost), face an even more formidable challenge. Without a good number of regulators and inspectors on European soil, it is impossible to conclude that the US will be able to do any meaningful verifications of drug pedigree, much less in Japan, Australia, New Zealand, or other "permitted countries.

Before the commercial importation is permitted I strongly urge you to weigh your confidence that you have created and funded a system that not only provides adequate measures to restrict the type of person who can be involved in the supply of those drugs, restricts involvement of particular businesses (by providing criteria for licensing and minimum operating standards), the country of origin of drugs, but also provides adequate inspection and enforcement provisions. Simply relying on the fact that the drugs have come from a European (or permitted country) dealer will not do that.

There is of course great difficulty in relation to enforcement. Importers in USA, should they receive counterfeit or substandard product will no doubt (honestly or otherwise) claim that they had no idea that the goods were other than genuine. It will be for the public authorities to show a guilty mind. The same defence will be offered by those who export from abroad, out of reach of but US regulators. Reliance on the law of contract will only extend to 'parties to the contract'. That is hardly sufficient within a complex and lengthy distribution chain, abroad.

In many countries, including the UK, the involvement of major law enforcement agencies (as opposed to regulatory ones) is something that can be achieved – though it has been only rarely and invariably after the fact. The setting up of thorough investigations after

counterfeiting incidents is not a satisfactory means to protect public health, neither will the law of contract (with foreign companies) enforce public safety in the USA. Stronger measures are needed to prevent counterfeiting incidents.

Of course it is impossible to consider the issue of S. 334 without thinking about 'Online' sales from Canada. It is a vital experience upon which to call. The opportunities to make a fast buck from the Canadian online pharmaceutical business were quickly pursued by both legitimate businessmen and others. More than two years ago advertisements were placed on the web purporting to come from Canada and yet when drugs were ordered they frequently came from Malaysia, Vanuatu or Eastern Europe. Rates of counterfeiting in such places are high, but that aside, the likelihood of drugs being time-expired or incorrectly stored are extremely high.

I have maintained an interest in this issue and it is clear that some of those who are actively seeking to supply, and indeed now actively supplying the U.S market are dealing with foreign entities that are, known or unknown to them, at very least questionable. Of that I have clear evidence.

Even now some Online Canadian business to business traders are actively advertising to supply pharmaceuticals from India and elsewhere.

The pharmaceuticals market is of course a huge one and will no doubt continue to increase. There are fortunes to be made, and I can understand why there is a push towards this type of legislation in order to reduce the cost of drugs to the U.S. consumer.

I have often been asked, Why should the industrialized world worry about drug distribution issues when so few people appear to be hurt by them? To an increasing extent the developed world is becoming more aware of the dangers that counterfeit and other sub-standard medicines. Cases of harm in the USA have been recorded. However, if one looks at the global picture it is clear that tens of thousands of people die annually from using such medicines. Those who perpetrate such crime do so for one reason – money. Providing sub-standard medicines is not a race crime, there is no reason to believe that those who kill those in the developing world by these means would think any more of taking American or European lives, indeed the opposite might be true.

Very often counterfeit drugs contain some active ingredient but in lower dosage, or contain an alternative active, in both cases the user of those drugs might suffer gradual deterioration of health as the disease overcomes the lesser treatment. The results might be simply greater suffering or death. Now one knows, and there is little chance of finding out.

The UK's Criminal Intelligence Service recognises these threats, so too does Interpol. It has only been 5 months since I published (via the Stockholm Network) my book on this subject, and there has been a great deal of interest since. Still however, despite all the evidence some people fail to see the potential for widespread harm. For those who wish to see the dangers, they are clear. Those who call upon Europe in support of allowing

easier access to the U.S. market ignore the evidence most blatantly.

Before legislation is introduced in the USA, given the potential for serious public harm, it is fundamentally important that the risks are fully understood and weighed, and then an importation system designed and properly policed in order to achieve and maintain compliance. I would most strenuously recommend that you consider establishing an international framework with regulators, law enforcement, and public health officials of the “permitted countries” in order to establish a system that affords adequate protection.