



# A False Sense of Security:

*The Growing Threat of Counterfeit  
Pharmaceutical Products*

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**Prof. David Taylor**  
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## **About the Speakers**

### **Philip Stevens**

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Philip Stevens is the author of numerous health policy publications, including *The Real Determinants of Health* (2005) and *The 10/90 Gap and the diseases of poverty* (2004). His writings on health policy have appeared in a wide range of international newspapers. Philip has also held research positions at the Adam Smith Institute and Reform in London, and spent several years as a management consultant. He holds degrees from the London School of Economics and Durham University.

### **Peter J. Pitts**

*Senior Fellow, Health Care Studies, Pacific Research Institute*

Peter Pitts is Senior Fellow for Healthcare Studies and Director of the Centre for Medicine in the Public Interest at the Pacific Research Institute. He serves as Senior Vice President for Global Health Affairs at Manning, Selvage & Lee. From 2002-2004 Peter was FDA's Associate Commissioner for External Relations, serving as the agency's "Chief Messaging Officer." He teaches at Indiana University's School of Public and Environmental Affairs.

### **Graham Satchwell**

*Managing Director, Proco Solutions Ltd.*

Graham Satchwell is a former British Police Service detective superintendent, author of the Stockholm Network's publication *A Sick Business* (which examined the counterfeit pharmaceutical trade), and specialist pharmaceutical industry anti-counterfeiting investigative strategy consultant. For several years to 1999, Graham was the official spokesperson (on IPR crime) for the Association of Chief Police Officers (ACPO) England & Wales. He is the chief architect and author of the '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 branded goods counterfeiting.

### **Dr Jonathan Harper**

*Principal Consultant to Council of Europe Counterfeit Medicines Committee*

Dr Jonathan Harper was the author of the Council of Europe's 2005 report on counterfeit pharmaceuticals 'Harmonised provisions for legislative and administrative procedures applicable to counterfeit medicines in the Council of Europe Member States. Since 2004 he has worked as principle consultant to the Council of Europe on Counterfeit Medicines and as adviser to the National Institute of Pharmacy, Hungary. He has undertaken health policy assignments in several other countries including Croatia, Germany, Poland, Romania, Ukraine and Uzbekistan.

### **Prof. David Taylor**

*University of London School of Pharmacy*

David Taylor is Professor of Pharmaceutical and Public Health Policy at The School of Pharmacy, University of London and Chair of Camden and Islington Mental Health and Social Care Trust. In this role he is responsible for the governance of an NHS organisation spending well over £100 million annually. He is also on the Department of Health's Medicines Management Advisory Group, and was recently a member of the joint DTI/DoH Advisory Group on the Reform of NHS Pharmaceutical Services.

### **Dr Michael Tremblay**

*Tremblay Consulting*

Dr Mike Tremblay is a specialist in health policy, and has developed specific ways to help clients develop, assess and improve policy and strategy. His clientele include governments, health providers, payers, pharmaceutical, medical device and information technology companies, retailers, and professional organizations. Mike has over 25 years of international health experience including 15 years in the European Union. He established Tremblay Consulting in 1997.

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## **Transcript**

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### **Peter Pitts**

Good morning and welcome. My name is Peter Pitts, and I am the director of the Centre for Medicines in the Public Interest, based in New York, and we are the co-sponsor with CNE for this conference.

We're here today to learn and discuss and debate False Prophets: the frightening and dangerous growth of international prescription drug counterfeiting.

When asked why he robbed banks, Willie Sutton, the Depression-era American bank robber, said, "Because that's where the money is." And as former FDA commissioner Mark McCollum\* said, "If Willie Sutton were alive today, he'd be selling counterfeit drugs."

The bad news is that international prescription drug counterfeiting is on the rise. Two news items crossed the international newswires recently that illustrate this growing problem and its truly global nature:

- The first story comes from China, and tells of 11 Chinese nationals and 1 American arrested in a counterfeit medicine scheme that spanned 11 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 Great Britain, Switzerland and Israel.
- The second, more frightening, news item comes from Hamilton, Ontario, Canada, where a registered pharmacist was charged with selling counterfeit Norvasc. The regional coroner in Hamilton is currently investigating the deaths of five people who filled prescriptions at this pharmacy. All five died of either heart attack or stroke.
- The recent news that the government of North Korea is in the business of manufacturing and selling counterfeit prescription drugs puts the problem into a dramatic new perspective. It is nothing short of international health care terrorism.

What do counterfeit drug look like? Well, the bad news is that both the product and the packaging look just like the real thing. But looks can be deceiving; let's look at a couple of examples.

Obviously, Pfizer has done quite a bit to promote its efforts to battle counterfeiting, especially for Viagra. Here's an example. [slide] As you can see, unless you're looking very closely and you know what to look for, it's very hard to tell the difference. But it gets worse.

If you look at a pill and you try to point at what it is that makes it counterfeit, you have to look very hard with high-powered imaging equipment to understand that the "G" on one side and the "G" on the other don't exactly match. I know I personally don't have these at home. Or maybe, if you have a calliper, you can measure the precise width and depth of a tablet. These tools are not available at pharmacies. They are not available at border crossings. It points to the dangers – and to the tremendous skill of the counterfeiter.

If you want to look at the packaging, the packaging is superb. An almost perfect counterfeit. And now we're not talking about pills; we're talking about proteins. And these aren't pills that, if you don't take them, you simply don't get the desired effect. These are medicines that people need to live their lives, in many cases to survive.

[slide] One has the degree mark; the other does not. I don't know how many people are looking for it, or even see – the medicine in this form. Tremendous skill. Oftentimes, the people at the manufacturer can't tell by a simple visual inspection. You need a much closer inspection, because it's very hard to tell the difference. And very dangerous. What's also interesting: if you go onto eBay, many times the bottles or the packages for these products are available for sale.

Here [slide], the difference is so close, that it really is a question of how the shrink wrap physically looks and the bottle. And again, the difference between one and the other is so close that you have to know what to look for – and then to look very precisely.

It just gets really scary. Now we're talking about Neupogen. Consider the audience for this product and what happens if they do not get the therapeutic benefit of their medicine.

In the U.S. recently, there was testimony in front of the Congress. There was a young gentleman who was taking Sterostim and had received a counterfeit product; he had almost passed away. But if you look at the packaging, it really is terrific. These slides, by the way, are directly from the FDA web site, which is [www.fda.gov](http://www.fda.gov) if you are in looking at them and looking for additional information directly from the FDA.

To respond to this emerging threat, the FDA formed a counterfeit drug task force in July 2003. At the time, I was FDA associate commissioner and I was proud to serve on that group. We received extensive comment from security experts, federal and state law enforcement officials, technology developers (some of whom are here today), manufacturers, wholesalers, retailers, consumer groups and the general public on a very broad range of ideas for deterring counterfeiters. Those comments

reinforced the need for the FDA to take action in multiple areas to create a comprehensive system of modern protections against counterfeit drugs – something that was necessary before. At FDA we discussed many of these ideas and we developed the beginnings of a framework for a 21st century pharmaceuticals supply chain that would be more secure against 21st century modern counterfeiters.

The specific approach to ensuring that Americans are protected from counterfeit drugs includes the following eight elements from the FDA's task force report:

1. Implementation of new technologies to better protect the American drug supply
2. Adoption of electronic "track and trace" technologies
3. Adoption and enforcement of strong, proven anti-counterfeiting laws and regulations, both by the federal government and by individual U.S. states.
4. In the U.S., the penalty for counterfeiting a package is more severe than counterfeiting the product. This must change.
5. Adoption of secured business practices by all participants in the drug chain. Everybody must step up to the plate and be part of the solution.
6. Development of a system that ensures effective reporting of counterfeit drugs to the FDA and that strengthens the agency's rapid response to such reports. I think you will all realise, certainly those of you in the industry, that the philosophy of – the fear of discussing a counterfeit drug has really changed. Today, I believe that governments and pharmaceutical companies really understand the need to get out the word quickly – and to a broad public; that it doesn't impinge or impugn the reputation of the company and, in fact, in many respects, enhances it.
7. Education of consumers and health professionals about the risks of counterfeit drugs and how to protect against these risks. If we don't know, if we don't communicate with people that the risks exist, it's hard for people to be part of the team solving the problem.
8. Collaboration with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally. Because this is a global problem.

Counterfeit drugs are a global challenge to all nations, and criminal counterfeiting operations are increasingly operating across national borders. FDA will work with WHO, Interpol, and other international public health and law enforcement organisations to develop and implement worldwide strategies to combat counterfeit drugs.

One of the most serious impediments to an allied, transatlantic war against prescription drug counterfeiters is parallel trade. Last year 140 million individual drug packages were parallel imported throughout Europe and wholesaler repackaged. This means that literally parallel traders open and touch about 140 million packets of drugs, remove their contents, put in labelling and language as appropriate to the country they are being sent to. But – these are good people, they're in a solid, legal business, but they are entrepreneurs. They are in the money-making

business. They are not necessarily – strictly speaking – in the safety business, and mistakes happen. For example:

- New labels incorrectly state the dosage strength.
- A new label says the box contains tablets but inside are capsules.
- The expiration date and batch numbers on the box don't match the actual batch and dates of expiration on the medicines inside
- Patient information materials are often in the wrong language or are out of date

This means, from a U.S. perspective, that a prescription drug purchased by an American consumer, from a Canadian Internet pharmacy, that comes from a British chemist, could come from a European nation such as Greece, Latvia, Poland, Malta, Cyprus or Estonia – and, in fact, parallel traded medicines account for about 1 in 5, 20% or so, of all prescriptions filled by British pharmacies. In the EU, there is no requirement to record the batch numbers of parallel imported medicines. So the batch of medicines originally intended for sale in Greece, for example, is recalled. Tracing where the entire batch has gone – for example, from Athens, to London, and through Canada to Indianapolis – is not possible.

"Caveat emptor" is bad healthcare practice and even worse healthcare policy. Safety cannot be compromised, even if the truth is inconvenient.

More dangerous even than the lack of robust quality control is the opening such practices provide to criminal counterfeiters to integrate their phoney products into the legitimate supply chains of Europe and North America. The World Health Organisation estimate that between 8 and 10 per cent of the global medicine supply is counterfeit, rising to 25% or higher in some nations. The largest counterfeit market with close proximity to the EU free trade zone is Russia, where the generally accepted estimate is that about 12% of the drugs are counterfeit. Now that the Baltic nations of Latvia, Lithuania and Estonia have joined the European Union, the WHO has warned that an increase in the risk of counterfeits entering the EU is, "obvious".

Facts are stubborn things. There is a Japanese proverb that bears repeating:

"Don't fix the blame. Fix the problem."

The letter that Cécile showed you from the European Parallel Traders' Association makes a good point: We're not saying that parallel traders are bad people, that they don't take responsibility for what they do, and that they don't want to make things better. But rather than deny that there is a problem, it is time for all people who have a role in this problem to step forward and work together to find solutions to the problem.

Today, we have brought together a panel of some of the world's leading experts on the issue of international prescription drug counterfeiting. They will offer creative,

timely – and, most importantly, practical and functional solutions to this critical issue. Let me tell you who they are:

Doctor Jonathan Harper. Dr. Harper is the principal consultant to the Council of Europe's counterfeit medicines committee. Dr. Harper will speak on the Council of Europe's report on counterfeiting.

Phillip Stevens. Phillip is Health Programme Director at the London-based International Policy Network. Phillip will speak on Intellectual Property rights and counterfeiting.

Graham Satchwell. Graham is a British security expert and a former detective superintendent. Graham led several successful criminal and civil investigations of counterfeit brand name goods, including pharmaceuticals, throughout Europe, Asia and the developing world. Graham will address counterfeiting from an investigatory perspective.

Professor David Taylor. Doctor Taylor is professor of pharmaceutical and public health policy at the University of London School of Pharmacy and was recently a member of the advisory group on the reform of the NHS pharmaceutical services. Doctor Taylor will discuss the economic and regulatory failings of parallel trade.

Doctor Michael Tremblay. Mike is a former adviser to the Council of Europe and to the government of Great Britain, and currently leads Tremblay consulting. Dr. Tremblay will speak on the pharmaceutical safety supply chain.

Let us consider and move forward with the words of a former Canadian prime minister, Pierre Trudeau, who said:

*"Renversez les totems, casser les taboux. Let us overthrow the totems, break the taboos. Or better yet, let us consider them cancelled. Coldly, let us be intelligent."*

Ladies and gentlemen, let me introduce to you Graham Satchwell.

### **Graham Satchwell**

Good morning. Peter said an awful lot there, and we could spend hours just discussing what Peter said. Just a couple of points that Peter made I'd like to pick up on straight away – and, I don't want to be diverted and talk simply about parallel traders, because that's not why I'm here. But Peter said, for instance, that parallel traders are good people – well, guess what, they're not all good people. They're just a mixed bunch like the rest of us, and they're good, bad and indifferent – the issue really there is they perform a vital function, and therefore they need to be regulated properly.

People also say that it is very difficult to tell counterfeits from the real thing, and I can say this: there are occasions when it is impossible to tell counterfeits from the real thing.

And Peter also said that governments now understand the need to get information out quickly when there is a counterfeiting incident. Well, I don't agree with that and I'll tell you why. I'll come on to it later.

So, my name is Graham Satchwell, and of that I'm fairly confident. But who I represent here, I don't know whether it's actually my own little company, whether it's a marvellous idea called the Health Well, or whether it's the Stockholm Network or a group of organisations called Antidote, I don't know – but in a way it doesn't matter because the message is the same.

It was two years ago now that Cécile Philippe, on behalf of the Centre for the New Europe, invited me here to speak. On that occasion it was about the publication of the book, *A Sick Business: Counterfeit Medicines and Organised Crime*. It described the dangers of counterfeit medicines entering the legitimate distribution chain in Europe. The UK regulatory authority the MHRA, disowned the implied criticism, refused to acknowledge any weaknesses or fault in their systems, assured the public that the distribution chain was impenetrable and that there was no realistic threat from counterfeit medicines to the legitimate distribution chain. Well since that time, I thought it best that I illustrate the weaknesses that are present, rather than simply describing them. So I wrote a TV documentary outline based on the following idea:

When the next big counterfeit medicines incident was reported in the UK, I would immediately conduct my own investigation and illustrate how it is possible to identify the supplier of counterfeit medicines very quickly and show how the UK authorities will allow that supplier to continue with his dangerous trade for months and months before acting, notwithstanding the continuing danger to the public. At the same time, I would set up a bogus wholesale pharmaceutical company, apply to get a wholesale dealer's licence, and then enter into negotiations with that supplier of counterfeit products that I had identified. In a nutshell, I would show how any person bent on making a quick buck could get official authority to deal in medicines and then buy from such untrustworthy sources.

I wrote this plan in more detail and took it to the executive producer of a popular British TV documentary filmmakers'. The result was televised approximately three weeks ago in the UK. I think it is now recognised by some that the book did, indeed, draw attention to the extent and nature of the dangers of pharmaceutical counterfeiting and parallel trade in a way that had not been done before. I think the TV documentary illustrates the point completely.

The program had three elements: My investigation to uncover the foreign supplier of fake medicine, which in this case was Lipitor; setting up of a fake business, in getting an official wholesale dealer's licence; and thirdly, showing how to plug the fake

business into the supply of counterfeits, with the continuing opportunity to sell on into the UK National Health Service and elsewhere into Europe.

So how could all that be possible? Why don't governments, regulators and the public care enough to stop this happening? Why isn't there a public outcry? Well, I believe it's as a result of several fallacies:

The first one is this: That counterfeits are not harmful and they often contain active ingredients. Well, the underlying assumption here is that counterfeits are some sort of standard alternative to the real thing. This conclusion is the result of lazy thinking. After a few minutes of reflection, people become aware that counterfeit medicines are produced to all sorts of standards, by all sorts of people, in all sorts of conditions and in all sorts of quantities. Sometimes the counterfeits will contain more 'actives' than the real thing (which, of course, is dangerous), sometimes there's a like amount, sometimes there is less 'active', sometimes there is no active. The contents might be entirely inert, or they might be poisonous. I say "inert" rather than "harmless" – it's obviously not harmless to be taking an inert product when you have a medical condition that requires active treatment.

Second fallacy: The current concern about counterfeiting is just noise made by "big pharma". I've actually got no problem with software makers or car manufacturers making a profit, and no problem with pharma companies doing likewise. However unattractive, over-aggressive capitalism, unfettered sufficiently by legal restraint, is unattractive no matter what the product. Every company seeks to maximize its profits; it's for the law to fairly restrict them in the public good, whether those businesses be software manufacturers, pharmaceutical manufacturers or parallel traders. The politicians, regulators and commentators who turn away from the danger that the public currently is facing, those who smirk and say, "show me the bodies!" – that was a phrase that was about for several years – make it easy for counterfeits to continue to enter our systems. "Show us the bodies" could yet prove not simply cynical; it may prove to be an unwanted and unnecessary prophecy.

Third fallacy: This is just a third world problem. Tens of thousands of people die every year as a direct consequence of taking counterfeit medicines. Yes, they are Chinese people, Asian people, African people. But counterfeiting of pharmaceuticals is not a racist crime. There is no reason to think that the manufacturers of counterfeit products care more about European or North American lives than, say, Korean. In fact, the opposite might well be true. It has been just over two years since my book warned that deaths obviously linked to this trade would occur in the West – I say "obviously" because there was every reason, I think, to believe that deaths had been taking place as a result of this trade, it's just that the deaths in the West have not been obvious. Sadly, of course, that's now been proved to be true with Canadian deaths occurring, but those deaths in Canada will not be isolated deaths unless change takes place. And it's been two years since the book warned that counterfeit medicines would be identified as having entered the legitimate distribution chain, since which time they have been, on at least four occasions. However, the extent to which the

counterfeit Lipitor (referring specifically to the Lipitor investigation in the documentary I referred to earlier) got to the pharmacies' shelves in the UK and elsewhere in Europe has never been fully explored. There seems to have been a general, albeit completely wrong, assumption that it did not reach consumer in the UK or continental Europe – and remember in that case, that for Lipitor, the warning that came to the UK came as the result of a tip-off from mainland Europe. What happened to the Lipitor in mainland Europe? [Inaudible comment from audience.] Exactly. What has changed in the last two years to make us in the West feel that we are now safe, that everything is okay? Well, absolutely nothing has changed.

Fourth fallacy: Pharma companies put holograms on their packs so you can identify the real thing, so what's the problem? Well, the truth is that anyone – pharmacist or consumer – who thinks that the presence of a hologram is surety enough, is a fool. Is it true to say that pharmaceutical companies should know, if they don't, and many certainly do, that some of the counterfeit holograms are more convincing than the real thing. That really is the truth. Many have seen holograms on counterfeit products that are sharper than those put on by the original manufacturer. For the record, a company can introduce a new branded hologram – a really whizzy, flash thing, with about two weeks' turnaround time. If you take a pack of legitimate stuff, send it out to the Far East or elsewhere and say "copy that" including the hologram, you can expect it within two weeks. So, show me a person who says that he can tell from looking at the pack whether it's counterfeit or not, and I'll show you someone who knows nothing about the subject whatsoever. There are much better systems for protecting the supply chain than holograms and microtext. For the pharmaceutical industry has yet to come to terms with the need for increased costs to provide adequate security in the supply chain. Yet they will need to do so.

Fallacy five: Well, the customs pick the stuff up when it comes in, anyway. What's the problem if we've got customs on the borders and so on? When stuff comes in, the customs find it, they seize it, they inquire into its origins – well, they won't. In fact, what happens in the UK – and everything I'm saying here today is provable stuff, not suppositions – customs authorities, if they find one small piece of product coming in (by post, and so on), they will simply ensure that the VAT is paid and then send it on to the address indicated. So it won't be stopped. And I say "small" quantities because it has been at least six years since counterfeiters recognised that if you send whole consignments then it gets quite expensive; they've stopped, and one of the ways of getting counterfeit into the country is to send twenty small packages rather than one big one. So, the reining in of small counterfeit items' quantities is a well-known method of getting large quantities in. Of course that's not to say that container loads don't come in because they do – and, as you well know, when it comes to the examination of containers at our ports in Europe, what is it: less than what percentage – 50 per cent? 25? Less than 10? 5? Well, much less than that. So the chances of getting through alright are really in the counterfeiters' favour.

Fallacy six: If I don't buy off the Internet – if I just get the stuff from the pharmacy or hospital, everything will be okay. It's amazing that intelligent people still seem to

believe that. What it completely avoids focusing on is that those opportunities to buy counterfeit drugs on the net are not simply there to attract consumers – they're there to attract Western businessmen, too. If you go onto the trade sites you will find umpteen adverts directed at wholesalers in Europe, offering to sell counterfeit product from the Far East, particularly China – and those opportunities are taken. Once these opportunities are taken by a Western dealer, then of course the product moves into the legitimate supply chain and into our hospitals and pharmacies. That is what happens.

Fallacy seven. Talk of all organised crime is just scare mongering. Yeah, it is, it's a disgrace. It's scaremongering by the head of Interpol, by the British national Criminal Intelligence Service, by the Food and Drug Administration, by the FBI, by every decent-sized national law enforcement agency in the world including the Chinese authorities – and they are all just making it all up. Of course they are. Why would they? That's the fallacy: If drugs are safe in one part of Europe, then they must be safe in another. In the last 18 months within the UK there have been at least 3 separate cases of counterfeit medicines entering the legitimate chain. Reductil, Cialis and Lipitor. Now, we didn't find them as a result of the UK's monitoring or intelligence systems. In the UK the regulatory agency is not particularly well-resourced and, I might say, not particularly effective, to be kind. But more worrying is the fact that the UK regulatory authority is one of the best in Europe. This "one of the best in Europe" agency is the same one that allowed me to apply for a licence for a company called "Oak Tree Pharmaceuticals" that I just thought up – nothing but a name: I didn't form a limited company, didn't form a partnership, no legal entity whatsoever. I just thought it sounded nice. I applied for the licence in my name, my true Christian names: Graham Edwards. I hired somebody to act as my responsible person, and they were interviewed and talked about football, and then this "best in Europe" agency gave me a license. And this "best in Europe" agency – despite of the fact that last July, it could've, should've and might've had the name of a person who was supplying counterfeit drugs into the UK, continues up to this day not naming that person who has supplied drugs, not naming that person to other UK or European dealers saying, "be aware that this is what's occurred".

Thank you.

### **Jonathan Harper**

Much of the presentation I will be giving you today concerns the subjects of invisibility, biohazard and systems failure, with respect to medicines counterfeiting. What do I mean by invisibility, biohazard and systems failure? Well, hopefully this will be clear by the end.

I'm going to be talking about the background to the Council of Europe anti-counterfeit medicine initiative. An overview of the counterfeit medicine problem in Europe, which includes estimating the scale of the problem, plus I'll give you a brief presentation of one European regional case study based on my personal experience,

a description of medicinal product types counterfeited, counterfeit medicine practices, and factors that facilitate medicines counterfeiting in Europe. And then I'll try to present some potential solution for tackling the counterfeit medicines problem in Europe, and then some general conclusions about the problem and how to solve it.

So, the Council of Europe counterfeit medicine pharmaceutical crime initiative. The origin of the report is based on the Council of Europe objective to protect public health and also its mandate for dealing with crime and trying to install good societal governance. The Council of Europe identified the need in late 2003 for an initiative to look in detail at medicines counterfeiting, and this initiative is based on a number of clearly defined goals and objectives [see slide]. The report is based on a number of surveys that were done between 2003 and 2004. These covered, firstly, relevant national authorities responsible for health, interior affairs and enforcement, police authorities, trade authorities, judicial authorities, and also financial and economic authorities. Secondly, the survey covered responses from stakeholders including all major drug manufacturers in Europe and also major wholesalers and distributors and pharmacists. The information from these surveys forms the basis of the Council of Europe report.

The report covers a number of topics, and these are based on the extensive and detailed primary survey responses as well as a lot of secondary data, and these include: What exactly is a counterfeit medicine, as well as the legal definitions of counterfeit medicines and pharmaceutical crime. Then, the epidemiology behind the counterfeit medicine phenomenon, the counterfeit medicine market in the past, the now and in the future, and also the market analyses split into different geographical regions. Then, the impact of counterfeit medicines on public health, the adequacy of pharmaceutical manufacturing regulations, the adequacy of counterfeit medicine trade and distribution control – which, if you look at point 6, there are a whole number of interrelated issues concerning pharmaceutical trade and distribution, which shows you what an important area this is that needs tackling.

Systems and procedures for counterfeit medicine detection, i.e. who, what and how? Intellectual property rights, legal and enforcement provisions, including legal penalties. Then, cooperation, coordination, collaboration and communication – and that is between relevant national and international authorities and stakeholders. Perception of the counterfeit medicine problem by stakeholders. Perceived adequacy of the European system for tackling medicines counterfeiting. Professional training issues.

Thus hopefully, based on this wide range of topics, the report could be said to be comprehensive, authoritative and evidence-based.

So, how extensive is the counterfeit medicine problem in Europe? Is it a real threat to public health and health systems? Secondly, is it a threat to legitimate commercial activity? Well, based upon the evidence provided, I would say the answer is "yes" to both questions. From the surveys conducted, counterfeit medicine cases were

reported from nearly all Council of Europe member states and the indications are that counterfeit medicine is a problem that is on the increase in Council of Europe territory.

Here, I would like to emphasise the invisibility factor behind counterfeit medicine as follows: some member states in the Council of Europe territory don't think they have a counterfeit medicine problem, but in these member states detection capacity is arguably weak – notwithstanding the fact, of course, that counterfeit medicines are clearly harder to detect compared to other types of counterfeit products. Underreporting and detection capability are important issues. Comparison should be made to the well-known situation on underreporting of adverse drug reactions in the pharmaceutical sector. Adverse drug reaction reporting is provided for by regulations Europe (and around the world) while reporting of reactions to suspected counterfeit medicines is not. There is little regulatory provision under European Union pharmaco-vigilance systems for reporting of drug ineffectiveness and adverse reactions that may possibly arise as a result of manufacturing quality problems. Finally, here, as major weakness in European legislative, regulatory and administrative systems were highlighted by the overwhelming majority of survey respondents.

So, can we be complacent and state that Europe does not have a counterfeit medicine problem? No, I don't think so.

Well, the Balkans. This is an area I spent a lot of my life working in; many happy days I had there, as long as I wasn't taking the drugs that were sold in that market. I'd like to use this case from my personal experience and note that the Balkans are part of the European case, if anybody is not sure of that. What happens in the Balkans, given the cross-border trade in drugs, also affects Western Europe as well. The Balkan region is arguably both the "black hole" of European pharmaceutical and trade regulation and also a pharmaceutical dustbin.

Counterfeit medicines in their origins are not just confined to China and India, in fact they may be closer to home than we think. This [referring to slide] is a bit of a complicated slide were that is based on evidence of trade in illicit drugs and counterfeit medicines from that region. From my experience in this region, counterfeit medicines are closely linked with the illicit drug trade, and there are many different trading routes. We do not have the time to go through this in great detail, but to summarize the key points:

- Medicine counterfeiting is clearly linked with the illicit drug trade and organised crime
- All known counterfeit medicine types and counterfeiting practices have been identified in this region of Europe
- The origin of counterfeit medicines coming got this region can be said to be "everywhere", even including the European Union

- What is the public health impact in this region of counterfeit medicine? Well, who knows.
- I think it can be concluded that medicine counterfeiting is a cross-border and cross-authority issue.
- It is easy for the counterfeit medicine criminal business model to exploit the many legislative, regulatory and administrative gaps that exist in the European system.
- Territories such as Kosovo, with limited regulatory and enforcement infrastructure, also suffer from counterfeit medicine problems because of weakness in the great European legal, regulatory and administrative framework.
- Kosovo and some of its neighbours may be the pharmaceutical trashcan and regulatory wasteland of Europe, but this is not entirely their fault.

What drugs are at risk of being counterfeited? Well, the Council of Europe research showed that all drugs are at risk of counterfeiting, but risks vary depending on the market characteristics of a given target country. For sure, counterfeiters are intelligent and know how to exploit market opportunities. There are more examples, but these are the ones highlighted from the surveys done in 2004.

I think that regulatory and enforcement agencies need to understand in detail the various medicine counterfeiting practices. Based on the detailed responses provided by the survey respondents, the report was able to come up with a list of medicine counterfeiting practices with which to demonstrate how sophisticated this pharmaceutical medicines counterfeiting business is. There are two categories: Counterfeit practices identified for finished medicinal products, and then counterfeiting practices for active pharmaceutical ingredients. Practices for active ingredients are pretty creative and highlight the problem of system failure with respect to API manufacturing and distribution regulation, which I think is a serious regulatory black hole in Europe.

A final point on these slides about medicine counterfeiting practices is that there is a need to have a formal international classification system for counterfeiting practices, not least because different authorities either use different classification systems or have no classification system at all.

So, who does the counterfeiting? Graham is probably more qualified, being at the front end of the investigations, than I am to talk about this. But to be sure, medicines counterfeiting is a good business opportunity with a good return on investment. The medicines counterfeiter is organised, experienced, qualified, clandestine, ruthless, and he takes maximum advantage of the deficiencies and loopholes in the international pharmaceutical regulatory, legislative, administrative and trading systems.

So, what factors facilitate medicines counterfeiting, and why is it a good business opportunity? A significant number of interrelated factors contribute to the situation. In no particular order:

- Low awareness among authorities and stakeholders – and there may also be elements of complacency and regulatory denial
- Gaps in pharmaceutical and trade regulation
- Lack of coordination among authorities and stakeholders
- Where systems do exist, they are often unofficial and based on voluntary (as opposed to mandatory) reporting
- Insufficient and inappropriate resources for addressing this issue
- Weak enforcement and sanctions
- The issue of unlicensed medicines – if a particular medicine is not available for legitimate sale in the UK, that is a factor and it encourages medicines counterfeiting.
- Inadequate Internet pharmacy regulation
- Inadequate packaging, labelling and printing regulations
- An increasingly complicated and grey distribution system involving an increasing number of intermediaries
- The rise of "lifestyle" and "embarrassment" drugs
- The age-old human factors of corruption and conflict of interest
- Organised crime's move (or, "business diversification") into medicines counterfeiting
- Increasing sophistication in clandestine manufacturing

The next slides look in more detail at three of the key factors that facilitate medicines counterfeiting in Europe. These are the legislative, regulatory and administrative factors. First the legislative weakness and gaps:

- I think I can safely state with no major objection, that not a single efficient and effective anti-counterfeit medicine piece of legislation exists in any European country.
- Anti-counterfeit medicine legislative measures are currently only indirectly referred to at the national by one or more of the existing pharmaceutical, IPR, customs or penal rules, and very little exists at the European level.
- Furthermore, there is no consistency in member state legal approaches, which confounds the possibility of implementation of effective, cross-Europe anti-counterfeit medicine legislation.
- Another problem is that there are no directly applicable international regulatory guidelines on counterfeit medicines. There are no currently internationally accepted definitions of counterfeit medicines and pharmaceutical crime, and we do need to have some clear definitions to know what we are talking about.
- Finally, the punishment should fit the crime. Sanctions and penalties are inadequate in relation to the public health risk of counterfeit medicines.

There are a number of regulatory weaknesses and gaps as listed on the next slide. Active pharmaceutical ingredients is, I would say the major one. Parallel importation is, I know, a hot topic and a controversial one, but I think some of the other speakers are going to go into that in more detail.

Administrative weaknesses and gaps in Europe; this is one of the main areas of discussion in the report. The complexity of the European administrative system can be equated with system failure in terms of the capacity of Europe to effectively tackle the medicines counterfeiting problem. In Europe there is a lack of recognition of the counterfeit medicine problem, and inadequate systems for counterfeit medicine detection. There is also limited understanding of the counterfeit medicine business model, weak authority, and lacking resource allocation formulas and risk management plans to tackle medicines counterfeiting. There is a strong lack of coordination and weak systems for providing intelligence. And finally, weak inspection and enforcement – although this is often for a lack of formal powers within authorities.

Although the medicinal product traceability and security system is inherently difficult, this is no excuse for the competent authorities to not put adequate systems in place to counteract the increasing sophistication of the counterfeit medicines business.

What is SPOC? It stands for "Single Point Of Contact" and this relates to the fact that the absence of an effective European-level coordinating function, even at a national level, can be seen as a major weakness of the European system.

A fundamental problem for Europe is being able to tackle the emerging public health and health system threat of counterfeit medicines is that Europe is still under administrative construction. The European Union is continually expanding, which causes the system stresses. The pharmaceutical regulatory system in Europe needs to be more unified, more efficient, and the conflicts between the single EU trade market and divergent national health policies and financing systems causes major problems.

What is the Council of Europe's role and function in all of this? They have a leading, advocating role in the need to deal with the counterfeit medicine problem in Europe. Their influence is largely restricted to public health and social governance policy issues.

In conclusion here, Europe suffers from administrative systems failure in its capacity to deal with the counterfeit medicines problem, and this stems from the complex causality behind the counterfeit medicine phenomenon. The fact that counterfeit medicines fall into the gap between trade and public health regulation and control. And thirdly, from fundamental structural and policy problems in Europe.

Is parallel pharmaceutical trade a factor behind the counterfeit medicine phenomenon? Well, I was told by the Council of Europe committee for

pharmaceutical questions to not go into this issue in any great detail in the report, but I kind of ignored that because the evidence is there somewhat, so I did actually include it. Why they didn't want me to include it in the report so much, well, I don't know – but I am sure some of the other presenters are going to elaborate on the issue of parallel trade in more detail.

So are the solutions for Europe? A number of key ingredients are required in order to produce an effective anti-counterfeit medicine solution and these come down to the issues of Who, What, Why and Where. However, a big assumption is that we have an accurate and evidence-based perception that counterfeit medicines may be a problem in Europe. On this point, firstly I would like to say that the Council of Europe report is evidence-based. Secondly, I should make reference to the recent proliferation of reports on the counterfeit medicine issues in Europe – in my experience expert report proliferation on any policy topic is a reaction to some real evidence as well as to, perhaps, without trying to be too demeaning, as well as to authority complacency, reactive-ness and inaction. Of course we should not forget here also today the expert testimony provided on the subject by my presenting colleagues also, which lens further weight to the overall evidence of this problem.

What is the level of political will in Europe to tackle the counterfeit medicine problem? Well, I don't really know. On the positive side, I would say the Council of Europe parliamentary assembly in 2004 accorded high priority to tackling medicines counterfeiting and other forms of counterfeiting that impact public health. But what the Council of Europe (and also the WHO, for that matter) do about the problem – apart from awareness raising – is another issue. One thing that came across in the report from the survey respondents was a desire to have a European coordinating body that dealt with this problem. Many organisations in Europe say they want to tackle the problem, but which organisation in Europe is best placed to coordinate and lead on this issue still needs to be determined. We have a lot of players who potentially have a role in tackling this problem, but who is going to be the leader of the orchestra?

It was also concluded that there was a need to have an implementing framework tool or binding instrument to tackle counterfeit medicines in Europe. The type of tool can take one of several different forms, but whichever form is selected, it should be the highest form of cooperation possible between relevant parties. The important definitions are, obviously: Counterfeit Medicines and Pharmaceutical Crime. The WHO definition of counterfeit medicine appears to be the one that is the most commonly accepted, across the world at the moment, but I would say that in Europe there is no real standardisation of these definitions. The concept of pharmaceutical crimes really needs a lot more work in terms of trying to come up with a proper and comprehensive definition, and I have listed a number of factors that people think should be included under the concept of pharmaceutical crime.

I'm going to skip over this sliding concerning what would be the tasks of a European-level coordinating body, because I think that actually we're not even –

we're still at the stage of defining whether we need a European coordinating body, so I think it's a bit premature to discuss what the tasks should be. At the same time, in terms of model legislative provisions in Europe for dealing with counterfeit medicine, again, I would say this is another step for the future, and this is all covered in the report in great detail.

#### *Major Recommendations of the Report*

The report concluded that multiple implementation measures are required in order to effectively tackle medicines counterfeiting in Europe.

Just to mention that the Council of Europe organised a seminar last September in Strasbourg to discuss the findings of the Council of Europe report, which I wrote. The seminar confirms that the recommendations from the report were more or less unanimously approved by the committee and the various stakeholders who participated in that seminar. The seminar highlighted six key areas that need addressing, namely:

- Legislation
- International cooperation
- Risk management
- Training
- Detection and enforcement
- Supply chain security

This is good work by the Council of Europe, but I would say: What actions can they do apart from making recommendations and raising issues?

#### *Conclusions*

It can be concluded that there is a complex causality scenario behind the medicines counterfeiting phenomenon. Is medicines counterfeiting a transient phenomenon or is it here to stay? To a large extent, this depends how seriously authorities and stakeholders take a proactive approach to dealing with this problem. There is no question that counterfeit medicines are life threatening and undermine health systems, and that pharmaceutical crime is inadequately differentiated from other forms of economic crime.

We have an invisibility problem associated with counterfeit medicines. So how big is the counterfeit medicine iceberg? We don't know. Several factors exist – which are trade, legislative, regulatory and administrative related – that inadvertently facilitate medicines counterfeiting. Certainly the complicated legislative and administrative situation in Europe exacerbates the problem. Medicines counterfeiting is becoming an increasingly sophisticated business activity, and authorities need to be equally sophisticated in dealing with the threat posed.

So, what are the solutions? Well, problems with complex causality do require multifaceted, coordinated solutions. What is clear, though, is that uncoordinated national and international approaches in Europe are not likely to be effective in tackling this global problem. An effective solution requires the necessary political will, cross-sector and cross-border coordination, collaboration, cooperation and communication, a united European state approach, possibly a European-level coordinating body, a binding legal instrument, and insurance that appropriate enforcement and sanctions are put in place. Also, I believe there is a large score for the authorities concerned with the counterfeit medicine problem to learn from the experience of other related sectors such as the authorities responsible for dealing with the illicit drug trade and other types of product counterfeiting.

I should briefly just mention here that tomorrow, the WHO is organising a conference entitled "Building effective international collaboration in combating counterfeit drugs", and this is obviously a very important meeting. The objective of the meeting is to draw up a global convention on counterfeit medicines with input from all stakeholders. WHO plays a very important role in global health, and I really have high respect for the work they do but, let's be honest, they are not an implementing body. Authorities and players in Europe still have a job to do, and cannot expect organisations like the WHO to do the job for them.

In conclusion, the three problems with medicines counterfeiting are, in my opinion,:

- 1) Its invisibility, i.e. its relative undetectability
- 2) Its serious biohazard potential – and let's not forget that. Although, Graham was saying at the start that the relative number of known cases of deaths from this problem may be quite small at the moment, but one death is one death too many. Plus, the systems that we have in Europe are not adequate to detect the problem. So we don't actually know how many deaths have been caused by this problem. Notwithstanding the direct impact on public health let's not forget also the impact that medicines counterfeiting has on the credibility of the health systems that we operate in Europe – surely we cannot afford to be complacent and let counterfeit medicine undermine the value and important role that health systems play in our society.
- 3) The complex causality scenario that leads to the failure of systems to adequately address the issue. "System failure" may be a strong thing to say, but you can draw your own conclusions from that.

Solving the problem and protecting public health requires political will, proactiveness and non-complacency. Also the "Four Cs" Coordination, Communication, Collaboration and Cooperation. And risk management: do we have a risk management plan in Europe for counterfeit medicines? Do we have one for bird flu?

Coming back to my friend SPOC again, I think it's important to have a designated SPOC at the national and European level to tackle the counterfeit medicine problem. As Spock from *Star Trek* would say, the objective in society is that we can all "live

long and prosper". When I say "all", of course I mean law-abiding citizens and not pharmaceutical criminals. So, finally, let us in Europe try to get real with counterfeit medicines and pharmaceutical crime, and let's hope that we won't have to make the same presentations here again in one year's time.

Thanks you very much for your kind attention.

### **Michael Tremblay**

What I'm going to focus on is what I call "finding common ground". In trying to characterise the problem of counterfeit medicines is to identify a variety of factors, some of which – many of which Jonathan and Graham have raised and will be raised by other speakers. What I'm going to try to do is to address the context of the problem, perhaps put it into a policy and regulatory context and try to steer your thinking toward specific European Union competency issues in this respect.

The basis for this work and this approach – I was retained by the pharmaceutical industry to look at the problems of counterfeit medicines trade, and how it ought to be dealt with, and I came up with this idea called the "Pharmaceutical Safety Chain". It's implicit and underlies a lot of the material that I am going to cover.

As Jonathan said, counterfeiting is characterised by complexity. However, there is no consensus in fact on what the counterfeiting problem is. Is it about patient safety and public health threats? Is it about criminal activity? Or is it about intellectual property rights and patents? In many cases the crime committed is theft of an idea and illegal reproduction of an image. Rarely is it understood and seen to be the behaviours Graham has so clearly identified of systematic, organised intent to penetrate a secure medicine system. But I'd like to suggest that the only way to understand it is that it is a patient safety issue – or, more broadly, as an issue of safety. Because that implies, and is implicated by, the problems that lie elsewhere. Unfortunately, a considerable amount of the debate has focused around the intellectual property issue, and some of the European language has been steered toward treating counterfeiting as an issue of intellectual property rights, which the pharmaceutical industry has to enforce rather than the regulators dealing with the penetration of a secure system.

The other point to keep in mind because counterfeiting is a complex issue. Some of you may be familiar with a concept called "wicked problems" – it's characterised as a wicked problem in that no solution easily solves it. What is particularly important about counterfeiting is it may be evidence of problems and gaps elsewhere. and so by looking at the counterfeiting problem and addressing it, you actually miss that the problem may lie someplace else. I think Jonathan has clearly shown, we do have fragmented and absent rules and systems, broadly speaking. We do have gaps in regulation. We clearly have failure of oversight of the whole pharmaceutical supply chain (and I'll illustrate that in a minute), and we have clear failure of international action.

When you squeeze the balloon at one end and you go after the criminals, as Graham has put it, they actually pop up someplace else under another name, with a different licence, in a different country. And that information never circulates back to people. I would like you to think, too, that counterfeits may be incentivised. There may actually be incentives within countries that enable counterfeiting to take place – and I'm going to return to that, but I'd like to suggest that the EU single market may actually incentivise counterfeits (I mean this within the context of the Treaty of Rome). This means that no one group can own the problem. We can't just give it off to regulators, we can't say, "okay, go on and solve it".

The problem crosses boundaries of knowledge. Manufacturing processes, science, the fine art of substitution of one inert element for another inert element. It crosses jurisdictions; is it a customs problem? Is it the police? Is it the health care systems? Who, if you like, controls the jurisdiction? It crosses organisations. Jonathan's list is very long and its length is part of the problem, and it crosses national borders.

What I like to say is that we have regulatory denial. What that means is the regulators deny there is a problem. We have weak cross-border collaboration with the European Union. There is no concerted action, because there is the absence of a cross-border focus on the problem of counterfeit trade and counterfeit medicines. National regulators within the EU do not have jurisdiction to deal with the problem. They do not talk to each other; they lack harmonised procedures. Looking at Jonathan's report in great detail, you get told "there isn't really a problem" and this is what Graham has also said.

Regulatory systems fail to prioritise the problem. So, why? They fail to prioritise the problem because they don't have any of the information that is reliable about the problem. For example, hospitals do not have to detect whether or not a medicine that leads to an adverse drug reaction was counterfeit. They don't inspect the medicine, they don't detect it. In the case in Hamilton, Ontario, they have been doing autopsies on the people who died, and the people doing the autopsies have not been able to determine whether the causal factor was the counterfeit medicine, because the problem is that the medicine itself, as was said, is inert. Does the absence of an active ingredient cause a death or not? So we don't actually have good information on the medicine side, so we cannot actually quantify the problem. And since regulators deny the problem – I've spoken to regulators about the problem, and they say there isn't a problem, we don't think it's an issue, we don't really have anything to talk about... "Has anybody died?" is usually the way it's put.

I think it's important to realise that regulatory actions are often punitive. In Ontario, the RCMP investigating the case of the pharmacy wrote a letter to all of the other pharmacists in Ontario asking if they had counterfeit drugs in their inventories. None of the pharmacists replied; the reason was that when the pharmacist in Hamilton was discovered to have counterfeit medicines, within about a week he had lost his licence and had his pharmacy taken away from him before he was charged. So if I'm a pharmacist and I think I might have some counterfeit medicines in my

inventory, the best thing for me to do is keep quiet, because if I tell somebody I have them I'll lose my licence. I think Graham should share the story he was telling me earlier about a journalist who went undercover to show how easy it is to pass off counterfeit prescriptions. She was arrested and charged. So, we have to understand that health care problems are complex problems, and we do not solve them by being punitive. There is enough evidence that errors in health care systems are complicated by the fact that we punish people who tell you there's a problem. We have a punitive, fault-finding system. Rather than saying, "How we can deal with this systematically?".

So the evidence of a problem means you have a problem. It doesn't mean, well, as was put so eloquently: You fix the problem, not the blame. And I think it's clear from what Jonathan has said that regulators cannot agree on what they should do. Perhaps more importantly, they don't even know if they should do anything. My point is this one, though: public confidence has yet to be shaken. That no event of significance has taken place within the EU should not be seen as justifying complacency. The loss of public trust in the safe supply of medicines is not an option. If the public thought that the medicines in their pharmacy were not safe, can you imagine how they would deal with prescribing, how they would deal with the pharmacy? "How do I know this is safe?"

Think of the problem with BSE. And the labelling of cattle carcasses. We track a cattle carcass more accurately than a medicine, as though somehow a fake medicine is less dangerous than a poisoned steak. So we have to think about it as a patient safety issue, because we may fix a lot of the regulations; we may fix a lot of other issues. But if public confidence is shaken, in that moment when the doctor concludes the consultation with a prescription and says "I would like you to take this, because you've got a serious problem and you need to take a statin or you will die," and the patient says "Well how do I know this is something that I want to do?" Is the risk understood?

Some of you who work in policy may be familiar with the precautionary principle used in environmental areas. We have to think ahead of the problem and we have to act before there is a crisis. I don't mean counterfeit drugs all over the place. I mean a few publicised incidents that make the public question whether or not anybody is in charge, knows what's going on, takes responsibility and acts. One can never, ever – in healthcare – be complacent about standards of safety and security. There are vulnerabilities in the trade in medicines, we know that. And we know that the supply chain is not secure.

We have to think of it in this context: it's broadly called "systems thinking" – for those of you who like to look at these sorts of things, a safety chain is a voluntary assurance system of everyone involved in the trade of medicines, to enable consistent safety practice through high standards of safety. The transparent exchange of

information from surveillance and monitoring of trading practices all designed to enhance public confidence. That's it.

We must have a common purpose; I suggest that patient safety is the trick.

We have to be pragmatic. There is a lot of intellectual energy that is being expended that is not leading us towards a solution. We have to understand and create interlocking accountability. These will be achieved through harmonised regulations and rules that lock suppliers, distributors, and wholesalers together. And we must make sure we learn from this process.

This is the safety chain: People who make the drugs, people who trade in the drugs, people who regulate the system, people who dispense the drugs and people who use them. The weak link is in the middle, the government and the regulators.

Let's take a look at the European context. It's very clear that Europe needs a cross border solution. There's absolutely no question in my mind that this is the only way to go. The EU single market rules complicate tackling counterfeiting. Because we're dealing with the cross border movement of illegal and dangerous products, it's very clear to me that there are perverse incentives operating to the benefit of counterfeiters in the fact that different member states have different drug reimbursement policies. This acts to create an incentive for counterfeiters to move drugs from one jurisdiction into another to take advantage of regulatory reimbursement systems.

In the United States, this is the system that is often used to move drugs from one state to another, to take advantage of differential reimbursement pricing systems. The question in my mind is, by what authority do member states hijack the agenda for drug management and drug regulation when clearly it is a European Union agenda issue? Because there isn't single market in medicines. It is clear that we have – from Jonathan's work again – inconsistencies in regulation between the member states of the European Union. It is clear that there are gaps in the European supply chain. How do drugs move around the European Union? It is clear that the European Union's external border is porous to the entry of counterfeit drugs. They are coming in. How do they come in? It doesn't matter where they come from in a sense, but the European Union's external border is porous to the entry of counterfeit products that are a risk to public safety. Importantly, no one regulator has jurisdiction. And it's clearly not something that EMEA is able to deal with.

So my suggestion is to think of it something like this: If we have this system in place, we have to be able to identify rogue traders. We have to find the bad guys. We know they are there because we know the problem is there.

We have to create a consistent policy environment. For example, we have to have European approach to Internet pharmacy. That's one way of moving drugs around. We have to have consistent industry and trading practices in all the member states.

They may differ in terms of the actual practice in terms of how distributors work, but if I have a licence to trade in one country, that licence should be accessible to people in all the other EU member states, so they can examine it – not a blurry copy or a fax transmission in a language they don't read, but something that is clear, concise, centrally regulated and centrally documented. And clearly we need common regulatory and trading standards for the movement of drugs across EU member state borders. It's clear to me that there has to be consistent supply chain standards right across the EU. Dealing with the entry of products into the EU, whichever country they happen to come into – common entry standards. The fact of the porosity of the border is evidence that this is not the case.

We have to be able to tell people what is going on. Industry is very interested in exploring "track and trace" technology, the use of radio frequency ID tags on packages, that sort of thing. We have to figure out how to make sure that the tracking of medicines is consistent across the EU and within it.

We have to build and test our response capability. We don't know what to do when a medicine is detected. Who else do we tell? How do we deal with it? Who goes and finds the problem? In fact, we don't know who owns the problem yet.

We have to monitor safety compliance. There has to be reporting. There has to be accountability. When there is an incident, people have to know about it. We should learn from what other people do. Health care is not unique; it can learn from what other jurisdictions do. We have to have some sort of alerting system.

And finally, I guess I'm the only one that talks about the public in all of this – I don't mean that negatively, I'm saying that's the point that I began with, that the issue is about the public. If we lose the public's confidence, we have a very, very big problem. And it's a lot bigger than the counterfeiting problem. Because the health care system, the way they work, they depend on trust. We trust doctors, we trust nurses, we trust physiotherapists, we trust the pharmacists to protect us from these bad things.

Medicines – legal medicines are dangerous. Taken in inappropriate doses they will kill you. If you've had friends on chemotherapy, you know the consequences of medicines. So we know we are dealing with something that is very dangerous. But if you ask the public and talk to the public about what they think is going on, they haven't a clue. We have to think about how we can engage the public in this debate without undermining public confidence and public trust. We have to tell them there are counterfeits out there. We have to help them become confident in identifying counterfeit medicines. It's hard to do. Pill identifiers are a way.

But we have to help people solve this problem as well. They are part of the safety chain – in fact, the medicines in Hamilton were found by a patient, because the medicine crumbled in his hands, and he went back to the doctor and he said, "should it do this?" and his doctor said no. Thank you.

**Peter Pitts**

Last September, just prior to the Strasbourg meeting that Jonathan mentioned, many of us on the panel today also were at a conference in Washington, D.C., and at that time Jonathan promised everybody that the Council of Europe report would be published imminently. I would like to tell you that it is currently online if you would like to go to the web site, which is [rxcmpi.org](http://rxcmpi.org).

Jonathan raised an interesting point that I think is worth going into in a tad more depth, and that's the issue of invisibility. Jonathan, when we were in Washington, do you mentioned the number of adverse event reports that happened in Hungary?

**Jonathan Harper**

Some countries in Europe really have a problem establishing whether or not they actually have any adverse drug events. And the fact is, as most of you may well know there is no such thing as a completely safe drug. In Hungary, well, according to the regulatory authority, Hungarians are the iron men of Europe, and that's why they have no reports of adverse events. So, for a drug agency to state that they don't have any problems with adverse events – well, how can they say then that they have no problems with counterfeit medicines? What else can you say, really?

**Graham Satchwell**

Can I just say that in the UK, of course, we are much better informed than that. In 1993, Liverpool University did research on this to show – and reassure us – that there are 10,000 deaths in hospitals in a year in the UK from adverse drug reaction. The point there is, well, what was just said. Of course the adverse drug reaction reporting system in the UK is not designed or adapted to cope with the reporting of suspected counterfeit medicines.

**Peter Pitts**

Graham has a very interesting way of portraying the way to admit that there is a counterfeit medicine problem relative to what WHO says could be the maximum type of problem versus what we are actually capable of, I think, cognitively accepting as a potential problem.

**Graham Satchwell**

The Scotsman newspaper contacted me a few months ago and said they were doing a feature on this and asked me: How many counterfeit medicines are there in the UK? I said "No one knows, that's part of the problem" and they said "can you help us with a figure; we need something". So I said "okay, if the WHO say that 10 per cent of the world's pharmaceutical products are counterfeit, let's look at how many million that would be in the UK". Well, let's just talk about 25% of UK medicines, about 120

million that we import to the UK – I shouldn't use the word "import" of course, it's one market. That we "take in" to the UK, then from overseas every year. Just 25 per cent of the total into National Health Service, not of all. So, let's just take the figures that the UN provide us there, let's say 10 per cent of those are counterfeit. Then you've got 12 million counterfeit products in the UK every year. But of course that's ridiculous, so let's forget about 10 per cent of the 25 per cent and, say, let's take 10 percent of that. So now it's only 1.2 million counterfeit medicines in the UK – and this is one-tenth of one-tenth of 25 per cent.

But that's too many, too, so let's say 10 per cent of 10 per cent of 10 per cent of 25 per cent, and now it's only 120,000 counterfeit medicines, okay? So, Mr Scotsman, I don't know. Three days later, The Scotsman had the headline that I said there were 120,000 medicines counterfeited in the UK. So, I don't know how many there are, but it seems to be that even if you take a miniscule percentage of what the UN says, potentially there is still an awful lot.

### **Peter Pitts**

Thanks, Graham. I think another important point to reinforce is – Jonathan spoke of invisibility relative to the ability to measure the problem. But it's also, in many respects, an invisible problem from the effect on the patient, the consumer. As Graham had mentioned, "show me the bodies" or, as we hear in we are fond of saying in the U.S., "show me the dead Canadian bodies" – but the truth is, counterfeiters are businesspeople, and it is not good business to kill your customers. If you are taking a fake drug for a chronic condition, as Graham mentioned, the product could be super potent, it could be sub-potent, or it could have no active ingredient at all. The patient will not keel over and die, but they will not be receiving the therapeutic effect from that medicine to treat a serious condition. So as in the Canadian example, did the people die because of the fake medicine, or did they die because they had an inherent health condition – in this case, a heart condition – which was not being appropriately treated? Any way you slice it, it's nasty business.

That being said, let me open up the floor to questions for any of this morning's speakers.

### **Question**

I had a technical point. I missed Graham Satchwell's presentation so maybe you dealt with this already. I saw the letter from the EAEPC, and I understand that parallel traders do not want to get associated with dirty business. But, you do need to raise the issue of parallel trade as such, since perpetrators have the right to – indeed, are mostly required to – interfere with the trade dress (meaning packaging). So it is clear that manufacturers are not in control of the supply chain. And so, I don't see how you can deny the fact that this is a safety issue from the parallel traders' side. I'm sure

the industry people here know a lot more about this than I do, but I know that parallel traders are required to supply the modified trade dress back to the manufacturers – but I know this happens very rarely. So before you deal with the parallel trade issue, I don't see how – well, this implies dealing with the whole regulation of pharmaceutical pricing in Europe.

**Peter Pitts**

Thank you for that question. Actually we dealt with it a little bit in the morning session, and we're going to talk about it quite significantly more after the upcoming coffee break. But Graham, would you like to touch on the issue of the organisations, member control and everybody else?

**Graham Satchwell**

To be fair, it's not a subject you can "touch on", is it? And that's why I've chosen to keep away from it, generally. Because once you get sucked into that – it ends up, this is sort of a debate – the whole counterfeiting thing can be corrupted by a suggestion that it's actually about an argument between parallel traders and manufacturers. But to go down that way, then, for certain I think the European Association is not doing itself any favours by not being clear that it does not represent the majority, numerically, of parallel traders. So when it makes statements about its own membership, fine. But what no one parallel trader or parallel trade association can do in Europe is claim that all parallel traders are really good guys and none of them are involved in corrupt practice. Or that the industry itself is adequately regulated, because it is not. But I really don't want to get sucked into that thing. T

he real constructive way forward would be for parallel traders, the association of European parallel traders – who call themselves manufacturers for some reason I don't quite understand – if they were to get together with the pharma industry, with people who represent public health, and say: Okay, how do we identify and get rid of bad practice in relation to the movement of pharmaceutical goods around Europe?

The presence of counterfeit products in Europe does not depend on parallel trade. The presence of parallel trade, though, does assist – facilitate, potentially – and in actual cases, the presence of counterfeit products in the legitimate distribution chain as a result of repackaging, etc.

**Jonathan Harper**

I'd just like to add a few brief words on the issue of parallel trade in pharmaceuticals, and whether they actually contribute to – or are a factor behind– the counterfeit medicine problem. As I mentioned in my presentation, this was a very controversial issue when discussed at the level of the Council of Europe committee on counterfeit medicines. I'm not going to go into a great deal of detail here because I know that

David Taylor is going to be speaking after the coffee break, and he has a lot more to say on this issue...information with a large degree of evidence.

Only to say here that quite clearly, and also from what Mike was saying earlier in his presentation, that there is clearly a conflict in a single European market in goods and the way that drugs are priced and financed in Europe. Thank you.

### **Peter Pitts**

I think I'll pick up on Jonathan's point. In the U.S., talking about counterfeit drugs – this came up at our event in Washington, D.C. last year. The American response is that the reason this is a problem in the U.S. is because of the issue of prices being so much higher in the U.S. than other places in the world. I think it's interesting that that is not the issue in Europe. It is an issue of availability and pliability, and that price really becomes a secondary point of discussion. Next question, please.

### **Question**

I have a question for Peter Pitts, if he could explain: I've heard about initiatives at the FDA level for the use of RFID mandatory for pharmaceuticals. This kind of technology, in my view, would give a good argument without getting into the discussions of the parallel traders themselves, whether it's good or bad. But saying "we need such a device on all of our packaging" and, whether repackaging or not, that it should stay there in order to have an error-proof supply chain and be able to track the product all the way through the supply chain. I think, when I listen to the information on this type of track and trace system, that it is a good preventive methodology, and if we can act on the prevention side more than the "curative" or "punitive" side of the counterfeiting, we may get further ahead, so I'd like to see what the idea was behind that.

### **Peter Pitts**

Well, early on in the FDA's counterfeit task force, we discussed quite seriously the issues relative to RFID, and the first thing that we realised we could do was not get in the way. But we let RFID technology continue to advance and support it, from the bully pulpit in many respects, as the direction that we feel the industry should go. And a lot has been happening the past 2-3 years on RFID. One thing that's also important to understand, which Graham mentioned earlier, is that you're always only just one step ahead of the counterfeiters and there is no one magic bullet, there's no one technology – not RFID, not taggants not holograms – that's really going to solve the problem. It's going to make it more difficult. One of the things that came up in the FDA's task force report talking with experts is that it's so easy now to bring counterfeit drugs to market, and the penalties are so light that the risk-benefit analysis on the part of the criminal is very much in favour, that if you get caught in the U.S. selling counterfeit medicines you pay a fine. If you get caught selling cocaine, you go to prison. The question becomes: When are we going to understand

that both of those things are very serious business. The FDA began, at least when I was still there, initial conversations with the department of justice to adjust the penal code more appropriately. What FDA can do relative to moving RFID forward is, again, not get in the way. And also not allow industry in the U.S. to get away in many respects with creating a "paper pedigree". If we allow the paper pedigree requirements to go into effect – and currently that's law' the FDA has not allowed it to be implemented because it would forestall more advanced and more efficacious track and trace supply chain initiatives.

### **Michael Tremblay**

To pick up on the RFID issue, it's also important to understand that there are other technologies as well of embedding chemicals in the pills themselves. I've seen the language from the FDA that says that pharma companies have to prove that the additions made to medicines to identify medicines with the addition of a chemical in the pill itself will have to be clinically tested to show that it isn't chemically active in the patient. But this type of technology is used other areas. It's used in munitions to identify the origin of Semtex for example when there is an explosion there are small particles that remain and they can be identified. All [unclear] uranium, for example, has a unique fingerprint that identifies how and where it was produced. And it may be worth looking at the regulations on the addition of inert counterfeit track and trace molecules within the pills themselves, because it's very easy to repackage, and the RFID tags could be removed, could be resubstituted. It's pretty easy to fake a credit card; I can't imagine it being terribly difficult to fake a tag. The problem is, the industry has often approached the problem of counterfeiting as a packaging problem, over packaging or creating another layer of security around the package itself.

But to go back to the patient: The patient, generally, does not know who can interfere with the package. They think they are the ones breaking the seal. They don't always understand that the pharmacist can break the seal. That there are other people that can break the seal. This could be worrisome to people who are concerned. Think about the reaction to genetically modified products. Insertion, if you like, in a natural product of something "inappropriate" and the public's reaction to that. If the industry says, "well, we're sort of dealing with the package, but we're not actually dealing with the substance itself, the public might get quite concerned. Again, coming back to helping the public understand the problem.

### **Peter Pitts**

Actually, Mike raises a very interesting point. I want to just clarify one other thing, that in the U.S., a patient leaving a pharmacy with their pills – or receiving their pills from an Internet pharmacy – are not receiving blister packs. They are receiving pills in bottles that have been removed from the blister packs – at which point any RFID technology, any hologram, and packaging security is not worth anything. Again the issue of taggants, the one Mike was referring to, is very important and the FDA has

said – obviously they need to understand the bioactivity of the taggants, but they're not going to put any really intrusive mechanisms in place to stop it from happening.

### **Question**

In this debate we have constantly gone back to drugs which are imported through parallel trade. Is there any evidence, for instance in the United Kingdom, that counterfeits are also produced in the United Kingdom itself, for the United Kingdom market – and what is the potential size of that problem?

### **Graham Satchwell**

There have been several cases. There was one just outside Liverpool a few years ago, for instance – the guy got five years' prison for that. In Wembley, in northwest London, a chap got five years' prison for that last year. There have been about three or four cases of manufacturing of counterfeit products in the UK of any size. But they absolutely pale – in terms of their potential to do harm – when you compare it with the massive manufacturing capability of, say, China, and their willingness to manufacture counterfeit goods. You know that situation with the origins of counterfeit products – whether they be pharmaceutical products, car tyres or DVDs – it's basically the same: it's only a question of economics. When you have cheap labour and technical ability and a lack of political will to do anything to stop it, there will be counterfeiting of products. And you know that China is a particular problem and you know that India is also – there are also issues in Russia where, allegedly, ten per cent or more of the pharmaceutical product in circulation is counterfeit. There are problems with counterfeiting of pharmaceutical products also in South America. So it is a global problem, but, you know, that pharmaceuticals are typical of the general counterfeiting situation where you have massive amounts of counterfeit product coming from China and the rest of Southeast Asia.

### **Philip Stevens**

Today I'm going to talk about the problem of counterfeit medicines in less-developed countries (that's what LDC stands for, for those who are not in the development field). It hasn't really been said today that 60 per cent of all counterfeit medicines in circulation around the world today originate from developing countries. So I think this is an important issue that needs to be addressed, how we incentivise these countries to reform their own systems in order to make the lives of counterfeiters that little bit more difficult than it is at the moment, because in many countries, they are able to operate with some impunity.

So, just a quick overview of the problem. 25% of all medicines in LDCs are fake. If you get to China, the figure rises to about 40 per cent in some Chinese cities. Now, Malaria – one of the greatest problems facing many LDCs – 53 per cent of all Artemisinin antimalarial drugs are fake. That's over half. And in Thailand, about a third of all antibiotics and antimalarials are fake as well. The problem gets worse in

Africa; between 20 and 90 percent of all antimalarials fail quality testing, which means that they are probably not doing the job that they are supposed to be doing. In Nigeria and Pakistan, two of the worst afflicted countries, between 40 and 50 percent of the total supply are fake.

In less developed countries, antimalarials and antibiotics that are being knocked off by counterfeiters, they span the entire range of therapeutics and drugs. Take, for example, the Philippines. The top five counterfeit medicines? Firstly, antihypertensives; secondly, anti-asthma medicines; thirdly, anti-diarrhoea; fourthly, vitamins; fifth on the list, globulin. More generally, we have experience with a whole range of drugs, including those for anaemia, HIV, schizophrenia, and even growth promotion hormones which are used in the treatment of people suffering from HIV.

But it's not just medicines. It's also things like sterile medical gauze being manufactured by counterfeiters. The problem with this is that they are not manufactured under sterile conditions, so you're not actually getting sterile conditions. You're not actually getting sterile gauzes. You're getting gauzes which are far from sterile and not doing the job that they're supposed to be doing.

We also have a big problem in public health institutions in a lot of LDCs. Theft, for example. This is not quite counterfeiting, but medical staff have been known to steal drugs from their own hospitals and put them on to the black market. The problem with that is they are often not stored at the correct temperature, making them practically useless. For example, in South Africa, at one hospital 46 medical professionals were imprisoned in 2003 for stealing and reselling medicines on the black market.

So what does this actually mean in these countries? Well, deaths, most obviously. 2500 people died from fake meningitis vaccines in 1995. One of the most notorious cases, which happened a few years ago, 119 died after diethylene glycol – which is a toxic analogue of antifreeze – was added to fake cough syrup. The same thing happened in 1995 in Bangladesh when 100 people died after diethylene glycol was added to a knockoff painkiller. The Chinese media reported in 2001 that 192,000 died in China alone in one year due to counterfeit drugs. And as this figure was reported by a state-controlled newspaper, we can safely assume that there was a degree of suppression of the real figure. We could probably assume that it is much higher in real life.

There are also some problems with fake veterinary pharmaceuticals – which is actually a human public health issue, as well, especially with regard to the current bird flu epidemic. Especially in China, a lot of poultry vaccines are being knocked off by counterfeiters, meaning that large numbers of flocks are not being vaccinated against avian influenza – which is hastening, perhaps, the spread of the HN51 virus, which has turned up in Europe this week.

Now another massive problem with this – not just deaths – is the development of drug-resistant diseases. For malaria, for example, there is a drug called Artemisinin which has, until fairly recently, been a pretty foolproof way of treating malaria. Unfortunately, now scientists are beginning to report cases of resistance developing to this drug. Which means that if the problem gets much worse, there will not be any new drugs available on the market to combat malaria, which is a massive threat to many millions of people around the world who are threatened by it. And the same thing is true for antiretroviral drugs used to treat HIV sufferers; there are worries from scientists that even third-line antiretroviral drugs are facing this problem. Again, due to counterfeiting.

So where in the world are all of these being made? We have heard some talk already today of China, most obviously. India, as well. But also Southeast Asia is a bit of a hotspot. In 2001, China had 500 illegal medicine factories. Again, that figure is probably much higher today. Southeast Asia: Cambodia has 2800 illegal sellers of medicines, and about 1000 unregistered medicines on the market. But Latin America is also a bit of a culprit: Colombia, Mexico, Ecuador – as well as African countries such as Nigeria. And in India, 9 per cent of all drugs tested were of poor quality, and there are some 25,000 generic manufacturers operating in that country; we can safely assume that not all of them are adhering to the highest of standards.

So, it's not just a problem for people who live in less developed countries. We over here in the West are also suffering from drugs that are manufactured over there and then imported by various illicit means. Lifestyle drugs, such as anti-impotency drugs, as well as anti-obesity drugs, cholesterol, anti-anaemia, and globulin. Also, we are beginning to see fake Tamiflu consignments turning up in both Europe and the United States – which, in the event of the transference of avian flu from chickens to humans, could be a disaster if there are a lot of ineffective drugs floating around the market.

We've covered a bit of ground about the problems with these drugs. They are ineffective. If they contain little or none of the active ingredients, patients who think they are getting treatment are in fact not – and they can die from the diseases for which they are supposed to be being treated. They can contain ingredients that are harmful for health, as in the examples of the antifreeze cases; there are many more.

Also, there is a wider R&D issue: If you have near-perfect copies of on-patent medicines circulating around the market, they actually cause harm by competing with legitimate supplies of medicines from branded R&D companies, which reduces revenues and undermines incentives to invest in future research and development. So this is a problem of innovation as well as public health.

Why is the developing world such a source of these counterfeit medicines? Firstly, the biggest point to make is that this is a question of weak law in general in these countries. And where the law does exist, weak implementation of the law. This is the

fundamental reason why – not only why there's a lot of economic backwardness in these countries, but also a reason why it's very easy for counterfeiters to operate.

Now, weak intellectual property legislation. Trademarks are very important in showing people the quality and origin of a drug. If you buy something with a trademark you can be certain that what you're getting is what it says it is – and you know you can pretty much rely on it. Unfortunately, in many less developed countries, there is no enforcement of trademark law – even in countries that are signatories to TRIPs (the WTO-administered Trade Related Intellectual Property agreement). Also, there's very weak civil liability law in many countries. Civil liability provides liability between private parties and protects the consumer against the sale of fraudulent goods. But if civil law is adequate, there should be no need for the intervention of criminal law. Someone harmed by counterfeits should be able to sue in order to gain redress. But again, civil law is rarely implemented properly in a lot of countries. This largely due to the fact that courts are weak and under-resourced; sometimes there is an inability to resolve disputes over intellectual property rights and contracts. The judiciary is often not independent; it can be corrupt. Police can be corrupt. Sometimes courts can be under-resourced, they can even lack electricity, they may not have computer systems – which makes bringing cases through the court very slow, even next to impossible. It can take many years, if a case is both criminal and civil, to get through the courts – which, all of the time, makes the lives of the counterfeiters very easy.

So, this becomes a broader issue of the absence of the rule of law. Intellectual property legislation is just not implemented because the judiciary is not effective. It also explains the economic underdevelopment of many countries; entrepreneurs are unable to trade with the certainty that their contracts will be respected. There's very little chance that legitimate economic development will take place, which unfortunately is what we have seen in many countries in Africa for many decades.

So all of this means that consumers are powerless to gain redress from people who actively harm them through counterfeiting. The pharma companies are unable to protect their own brands. The lack of the rule of law means we are unable to enforce the control of drugs through the supply chain, which means that products are less likely to be stored and sold in the appropriate manner, harming both consumers and the reputation – and profits – of pharmaceutical companies.

Price controls are another issue. Many LDCs have very rigorous price control, which creates distortions in prices between markets, which encourages parallel trade within continents as well intercontinentally. Also, price controls can often lead to an undersupply of drugs as people become less willing to supply a price-controlled market – which again gives another opportunity for counterfeiters to fill that demand supplying fraudulent goods. If the rule of law is very weak, counterfeiting becomes a very easy pastime and moneymaking activity, incentivising criminals to move their activities from, say narcotics or weapons trading, into pharmaceutical counterfeiting. It's a much easier and less risky way of making money.

What can we do in these countries in order to starve the counterfeiters of oxygen and really get to the root of the problem? Well, firstly, we could ask countries to define their property rights more clearly. We should make a more simple and clear processes for the registration of trademarks. Perhaps we should ask these countries to apply patents to drugs that are under patent in other countries.

Secondly, we should encourage countries to enforce the law more rigorously. Encourage courts adopt greater independence and not bow to pressure from the legislature or executive to make decisions go an arbitrary way. We should make it so that the executive cannot interfere with judicial decisions. Also it is vital to address corruption within law enforcement agencies, the police and the courts. One way, perhaps, is to ensure that law enforcement and the law in general is a priority for aid spending or government spending. Because with the framework of these institutions, most of the aid money will probably be swallowed up in corruption.

Bad regulation is probably worse than none at all, and again presents a lot of opportunities to counterfeiters. In South Africa, for example, drugs that have already been registered in the United States, the European Union or Japan, can wait for 39 months before they can be approved in South Africa. This creates a massive unmet demand within the country, which – again – provides incentives for counterfeits to meet that demand with fraudulent goods.

Finally, taxes and tariffs on important medicines. Many less developed countries artificially inflate the cost of imported medicine with a host of import tariffs and local taxes – in some cases, increasing the cost of medicine by up to 50 per cent. A lot of south Asian countries in particular are "baddies" at this, and Nigeria is another one. It cannot be any coincidence that Nigeria and Pakistan have the highest taxes and tariffs on imported medicines – and they also have the highest levels of counterfeits circulating within those countries. If the medicine is artificially expensive, it creates incentives for people to fill the gaps with cheaper medicines; this would be the criminals.

What can we do internationally, apart from what we have heard earlier on? Very little, until we solve these problems of the rule of law within poor countries. We could ask that countries who have signed TRIPs actually enforce it properly. Many countries just pay lip service to the implementation of this agreement, China being one example – India as well, and also countries like Thailand. The problem with this is enforcement is often through trade sanctions, in which both parties lose on the trade – and also raise complex and very delicate public relations and political issues, and that should be kept in mind as well.

Countries like the United States and the European Union can offer carrots in the form of offering actual trade agreements, which could spur the signatories to beef up their own intellectual property law and to look more closely at the rule of law in general in order to make the environment less friendly to pharmaceutical counterfeiters.

The rule of law in many poor countries is the fundamental reason why they remain underdeveloped and not economically competitive – and also a reason why they are the largest source of counterfeit medicines circulating around the world. The basic point is that counterfeiters have a bigger incentive to do what they do than law enforcement agencies have to enforce the law in dribs and drabs in richer countries. We really need to get to the basic problem of why these people are allowed to operate with such impunity in poorer countries. Otherwise, I'm afraid the future looks rather bleak. Thank you.

### **David Taylor**

One of the difficult things in a situation like this is that a lot of the things I wanted to say have already been said; perhaps what I should be doing is emphasizing some of the more important points of the other speakers. The strap line of this presentation, "What could and should stakeholders be doing?" – I think my initial reply is "take the issue seriously" – not exaggerating the problem of counterfeiting in Europe, because that would obviously be silly. But at the same time, focus on it and respond appropriately.

I wanted to talk about the wider global, social, economic political context in which counterfeiting takes place and to think about some issues related to the European medicines market in particular: The integrity of pharmaceutical supply, and this vexed issue of the parallel importing and the context of that. I had some sympathy with the parallel importers – they are clearly not crooks. They're clearly not involved in moneymaking any more than the research based pharmaceutical industry, any more than doctors, nurses, even academics – although perhaps academics aren't so good at it. I also wanted to talk about stakeholder responsibilities.

First of all, as a declaration of interest, at one time I was director of economic and public affairs for the association of the British pharmaceutical industry. I know most research based pharmaceutical companies well and have received funding from them, including for example, at the moment, Pfizer. In my defence, I also receive funding from the National Institute of Clinical Excellence in the UK. My salary and earnings are guaranteed by the state and come via the Higher Education Funding Council in the UK. I don't think they can fire old professors until they are 65, but I'm crossing my fingers on that. I am also the chairman of an NHS trust, which provides mental health care in London; it's looking at a 5 billion pound structural deficit at the moment, so I don't think I am motivated to give extra money to the pharmaceutical industry or anybody else. So what I've got to say is what I genuinely believe.

A couple of introductory points. Political communication, as you know, requires a simple message – sometimes, almost simplification to the point of half truth. It's easy to communicate. Graham's wonderful television programme – I had members of staff and patients coming to me after that, saying: Are our medicines genuine? Should we be taking them? A woman with blood pressure and several people taking

antipsychotic, for example. And so I assured them that our system is, as far as I know, pretty safe.

Substantive arguments about welfare are often very complicated. MPs tell me all of the time – European MPs, British MPs – "You cannot transmit politically complex arguments. Just don't bother, David. Don't try." But there is a linkage, I think, between the safety issue (as Mike has emphasized along with John) about counterfeiting as a patient safety issue and the context of parallel importing – which I think is in many ways changing the environment and in some ways making it more vulnerable – although that's not to say that parallel imports have been a substantive source of major harm in Europe as yet at all.

The fundamental issue, which we were discussing over the coffee break, about research in the future. We have one job about distributing today's medicines safely, fairly and effectively while getting the benefit that we can nationally, internationally, globally.

We have another job, about preparing for the next 50 years, of living through this biomedical revolution which will take people like me who have had cancer and ensure life expectancy well into old age. Insure active life expectancy, which is presumably what all want. The definition of productivity has moved on from manufacturing warships – we are about manufacturing longer lives. Does Europe have a role to play with that? We have globalise, pushed out manufacturing of pharmaceuticals and everywhere else, mostly out of Europe. If we don't have a role in research – we're talking about the welfare of our children and of the global society, about these benefits to come. And so what I really think about counterfeiting is in that very complicated context – but I realize it's virtually impossible to communicate politically. That's our trouble with this.

And with another general point: health services users are becoming empowered, where if you like, normalising medicines as goods, and I think that's a deeply desirable long term trend. Europe may be resisting that to some extent with its attitudes towards information and of course part of that is buying political support. Buying political support from professional groups for the European project. And professionals – like every other industry – have vested interests they want to preserve. But in the long term, we are going to normalise medicines consumption considerably. The trouble is, of course, insuring integrity of supply when we set free information, when we accept things like the Internet, when we encourage consumers to really make decisions for themselves – this is going to create problems. That's just another background factor. It doesn't mean to say that we shouldn't accept those risks, but they are there.

Back to the message of not exaggerating. Exaggerating problems can be extremely counterproductive and can get you into all sorts of conflicts that might have been better avoided. Ignoring them can be catastrophic, and that's the fundamental message. Americans don't always make mistakes. Taking this issue seriously – as

Peter described, the FDA's efforts – is important. It's just a question of balance, honesty and integrity.

*Stakeholder perspectives*

The Transparency International report, which came out just a few weeks ago, was about corruption and health. One of the issues it raised – along with many others, for example about in the U.S. and other markets, providers overcharging, mis-billing, causing grief that way. I'll talk about it a little bit more later, but the point being that there are all sorts of corruption. One sort of corruption is to sell an obviously counterfeit drug. Another form of corruption is to accept intellectually invalid arguments. So I think that's a background point.

Service users have all sorts of interests in pharmaceuticals: One is that they are universally available and that we can get them cheaply. Another is that they work. Another is that they work better in the future. We've got complex interests as consumers, and we seek those sometimes conflicting aims – we live in a society where on one hand we are encouraged to be individualistic – you know Mallow's hierarchy of needs, we're near the top of that, self-actualisation. But, paradoxically, we also want better regulation. We want safety. A big task for the pharmaceutical industry and for regulators is to put those two things together: consumer choice, greater safety and regulation. How do we do that? The task of regulators – well, it is awfully

easy to badmouth regulators. I worked for a trade association, I know how easy it is to badmouth trade associations and politicians. But I do think there are issues there that sometimes might mention regulatory denial i looking at this issue of counterfeiting. There are also some issues of denial around parallel importing, which I'll get back to. It's just the background feeling that sometimes – it's obvious across Europe: you've got the EMEA on one hand, you've member state regulatory agencies on the other. Some people might be worried about their jobs. One thing you might think funds your jobs is the apparent savings made by parallel importing. There are complex political themes running through this, which may make us a little insensitive to the risks associated with sort of pharmaceutical market that we have established in Europe at the moment.

The same thing goes for the Commission: Obviously the people who work in the Commission want to do a good job for Europe. They're focused in the long term, many of them, about a closer European Union. There are tensions between national-level regulation and that bigger European view – which I think colour this area considerably. It might be, for example, for the moment, that we look away from a productive environment which is safe for consumers to live in and is really conducive to industrial development for the sake of a Union, for the pressures you have to apply to achieve that.

Pharmacists, drug wholesalers, of course people working in every – most people, most of the time, want to do good. Do pharmacists, to my knowledge, often make quite a lot of money out of buying cheaper drugs – whether it's in the generics

market or whether it's in the parallel imported patented drugs market? Yes, of course. Do you sometimes run some risks? Yes. We need to look at that. Might we be diverting time with all of this activity away, for example, from useful clinical activity? These are questions which need to be asked about that wider background of counterfeiting.

The industry, obviously, has incentives to maximise its income, maximise its research productivity. There are even people in the pharmaceutical industry, though, whose jobs depend on complex regulatory structures, on unnecessarily complex market structures. If you've got too many Eurocrats, you also need too many "industry-crats" to deal with them. There are conflicting incentives there. Criminal incentives are obvious. Law enforcement agencies face considerable challenges in this area. John said that he was warned off by the Council of Europe from looking at some areas. Of course regulatory agencies, criminal law enforcement agencies, have to operate in a political environment – and that leads back to these political imperatives. What do you want if you're a politician? You want power. How do you get power? You need votes. How do you get votes? You communicate clearly. And what's easy to communicate isn't always quite what's right.

So, to push home that point, it would obviously be irresponsible to argue that people working in the Commission or regulatory agencies are not concerned about protecting the public; of course they are. Or indeed, that medicines parallel import, to date, has caused certain counterfeit medicine-related therapeutic risks; there's not much evidence of that and, in the grand scale of things, the level of harm done so far is very small compared with, say, the toll of road traffic accidents each year. However, it would be silly to suppose that people working in any bureaucracy don't have any vested interests of their own, just like people working in pharmaceutical companies, just like professionals. I believe, in the case of the EU, that political drivers have encouraged us to take a view of parallel importing and the obvious conflicts it creates: on the one hand, you grant European patents. On the other hand, you say member states can impose price levels. And then on the other hand, you say you must then have free movement of goods. It's back to that word "corruption" with a small "c" – there's obviously something wrong with that. It potentially, of course, undermines principles of intellectual property, and Europe should be the last region on Earth to be thinking of doing that now.

So, I think we need a precautionary approach, as Mike has said. We need to think very carefully about protecting the integrity of the European medicine supply chain and, thank you very much, the integrity of the environment in which we are trying to support research-based industry.

So, back to Transparency International. They argue that the world spends an enormous amount of money, about 3 trillion dollars a year now, on health. But the corruption is widespread at all levels, in all regions, and it is significantly undermining health outcomes. I remember it's that definition of "corruption" which goes well beyond simply activity that is obviously criminal, much more to what most

of us are part of all the time. There's no doubt that improper medicines marketing causes harm, no doubt about that at all – especially in poor environments. There is similarly no doubt that medicine counterfeiting causes significant harm. We know, since we have heard from Phil earlier on, it is widespread in India China, and other nations. The director of Nigeria's equivalent of the FDA at the launch of "Corruption in Health" in Berlin, described how their heroic efforts in some ways to rationalise a market – in some ways I thought Phil was rather hard on developing countries. I think there are tremendous issues and complexities. Remember that 80 per cent, by value, of the world's medicines are consumed by us: Europeans, Americans and Japanese, the world's richest, healthiest, most protected people. It's not just a simple lack of law and order which accounts for the poverty of the mass of the world's population who don't have access to allopathic medicine at all, almost 40 or 50 percent of the world's population, effectively. There are huge problems there. What's interesting is that at the launch of "Corruption in Health" it was emphasised that China had not been very helpful to Nigeria in trying to restrict these problems of counterfeit medicines. In a sense, Europe's responsibility is now – it was a great thing, wasn't it, to create systems like the NHS or the German or French health care system – that was the achievement of the 20th century. The achievement of the 21st century – Victorians only had to look out of their windows to see the poor making their goods in front of them. Now we have to look into our television sets to see the poor making our goods in China, in India, et cetera. That means, of course, we have moral responsibility to create a world health care system. So the idea of drug counterfeiting being not our problem because it is largely "out there" is actually profoundly absurd for the 21st century in my view.

So, key messages:

We need to take those issues of people dying needlessly – of malaria, for example, in sub-Saharan Africa – deeply seriously. There is a threat to global public health which will ultimately affect us all. There's no doubt that in the old, secure, rather cosy EU of the 1980s and 1990s, there were far fewer reported problems with drug counterfeiting in the U.S. To some extent I am tempted to believe the size of an internal market – its total value and total volume – is the key potential driver. Once you are in a large market, of course you've got huge incentives to produce counterfeit products. And in some ways, the fragmentation of the old EU market might have been protective – it's a thought worth thinking about.

What's clear now is that we've got no reason for complacency. John's work has clearly showed that counterfeiting is taking place in Europe, that counterfeit drugs are accessed in the market. As the EU continues to change its structure, the risks will – I think, plausibly – increase. These risks are not all due to parallel importing, very clearly. But I think the environment that creates confusion – professionals are used to packs being opened and they are used to going out on the market and buying from wherever they can the most cheaply – and at the same time the parallel use and generic drugs in the UK consumers – my parents-in-law, both of whom are now survived to over 90 – so it must be quite a safe system. But they're used to having

medicines that look different every time they have their prescriptions filled. That combination of consumer disempowerment, and that of the incentives acting on professionals – and they're used to just not accepting a simple supply chain, a protectable one. I think it's potentially dangerous.

To put things into a policy context: Back to that issue that an easy political message might, well: *You're sitting in the States, you're an older person, do you realise, notwithstanding the changes to Medicare going on at the moment, you can get cheaper medicines elsewhere? They're got to be ripping you off, haven't they? It's obvious!* It's a very easy message to transmit. These two politicians wonderfully – in English eyes, anyway – are named Byron Dorgan and Olympia Snow; Olympia is the female lead. They're arguing that if you can't get the American domestic act together to have a price control system, what you might do is import other people's price controls, because you should have an equivalent system to the European system in the States. Buy cheaper drugs from Canada controlled by the price in Canada, but you do it in the name of free trade. Now there are some people across the world who rather like the thought that Americans cutting their own throats because it would save them the job. But this really would be the U.S. economy cutting its own throat; I think if they went down that path we would see the research that John referred to done by the University of London School of Pharmacy and the London School of Economics on the impact of parallel importing in Europe. It suggested, in fact, the savings to taxpayers – the savings to public health systems – when you stripped away the additional earnings of pharmacists, when you stripped away the additional earnings of traders involved, is reasonably limited, probably on the order of one billion euro per year (on early 2000 figures). Even if you dispute that, even if you jack it up a bit – when you think the total market is worth something like 130 or 140 billion euros, that's small beer. The issue is, what's it costing you? Where is that savings going to? Is it, for example, costing you additional [unclear] costs. If we looked at the system carefully, you could – with a more rationalised system – reduce.

So, some policy research questions. Will an expanded, more diverse European market be able to maintain supply integrity? We need to understand this and really get into the issues being raised today about "how do you do that?". Practice. What does it look like? What are the full costs and benefits of parallel importing across the EU? One minor thing that I'm concerned about is in the UK we're trying to shift the pharmacy to do something more useful than it did in the past; not just dispensing but being a clinical professional. If people's attention is diverted too much by buying cheaply in markets and all of the rest of the things you do with that, I don't think that's terribly helpful. How do we build that into real cost/benefit analysis? If Europe spends a billion euros of public expenditure on parallel imported medicines (if that's the right figure, I'm not fighting for it either way), that costs the research based industry three times as much. But we want the research based industry. What's the real cost and benefit of that? Who does the actual sums? It hasn't really been approached very rationally yet, largely because we haven't wanted to look, because there have been such strong political boundaries. Like John being warned off: Don't go there, people don't want you to go there. Under what circumstances could it be

shown that exempting pharmaceutical goods from provisions like those in Article 28, i.e. you don't have free movement because you've price controlled them locally, so keep them locally. Would it benefit European public health and other interests? Logically, I think there's a case to argue for that. For one thing, smaller markets may be less subject to counterfeiting anyway. The alternative is, could we have single pricing for patented pharmaceuticals across the EU? What are the barriers to this, and what would be the advantages or disadvantages? Might it, paradoxically, promote counterfeiting if you really have a larger, single European market? There are scenarios, you could say that would happen – so we need to look at these options – but on the other hand it would reduce the repackaging and parallel importing-associated risks.

What should U.S. policymakers learn from Europe's experience? And what should we learn from the U.S. experience? Really, that the momentary level of debate is pretty simplistic – there's opportunity for us to take that forward.

So, to conclude, what should we be doing? Answer: taking counterfeiting seriously. And the first thing, beyond my ramblings about wider economics, there's a patient safety issue. I was in India earlier this year trying to develop a joint project relating to pharmaceutical development and pharmacy development in India and the UK. 1.1 billion people in just India, which is pretty small, in fact: it's only about 3 million square kilometres; it's not that huge. If you take what – politically, deeply incorrectly – what used to be called "British India" (include Pakistan, include Burma, include Nepal and Sri Lanka), you're talking about a population bigger than China. I never believe statistics if anybody gives me too many, but it appears that in volume terms India is now the world's fourth largest pharmaceutical producer. Since the 1970s, the Indians removed product patents – not process patents, but you can always find new processes to produce things. And that's created a huge market: tens of thousands of different brands of very cheap pharmaceuticals. Interestingly, perhaps to the dismay of some groups like Oxfam in the UK, India has recently reintroduced pharmaceutical patents. Why? Well, immediately because its academic and industrial infrastructure is getting strong enough to compete with Europe. This is the future. In a way, India is where Victorian Europe and Britain were; India has a large, growing middle class – 100, 200 million educated people – and it's got a pool of 800 million very cheap labourers. Same as with China. That's the real competition that we have to think of. What's in our health and welfare interest over the next 50 years? The immediate reasons for India reintroducing patents are not only developing their own research based product and taking part in world research more effectively – they are also about organising that chaotic, low-cost generic market. The effect of that is to have a market of very cheap drugs where an awful lot is still spent on promotion of different brands, kickbacks to professional, etc. Very unstructured, very high risk of counterfeiting – this needs to be stabilised as you develop.

That's also a lesson for Europe. In our context, we've got very complex, and sometimes competing, interests in regulation, investment in research. What you notice: Taxpayers – we were talking about Switzerland and how Swiss had voted for

reducing taxes at the expense of publicly funded research. So we really want to do that in Europe? When I worked in the industry I was always aware of a symbiosis between the industry charging and the government paying. And the government knowing if it wanted to invest in research, that was politically one of the only viable ways forward. These are difficult areas for most people to understand. EU policies on pharmaceutical trading are conflicted, I have no doubt about that. And I think the Council of Europe work has shown there is a risk from medicines counterfeiting. Regardless of the causes of that and the extent to which parallel importing may or may not be a contributing risk factor, I think the case is that we need a precautionary approach, and if it does go wrong, remember: I think you mentioned diethylene glycol – it was a tragedy just before the second world war in which over 100 people were killed the States from the same mis-ingredient in medicine, only that time it wasn't known, which led to the 1938 Food, Drug, and Cosmetic Act. Small tragedies can lead to huge consequences in the world of pharmaceutical legislation. Thalidomide did disable several thousand people across the world, many of whom have lived [unclear] with the side effects of that medicine. In the grand scheme of things it was quite a small event, but it changed the history of medicines and the pharmaceutical industry. If we don't get this right – and if there is a significant, but not necessarily huge, tragedy involving counterfeit medicines (however they are traded), I think that all the stakeholders' interests whether they are regulators, whether they are industry, whether they are professionals will be severely affected. So I think there's a very strong case, and ultimately, of course, a political case. There's a very strong case for paying due attention and trying to get this right.

### **Peter Pitts**

David raised the issue of the simple statement, the simple message. Panel, what is the simple message that these people in the audience should take away with them? Graham?

### **Graham Satchwell**

That means doing proper evaluation. A proper evaluation, conducted by all of the stakeholders, would be the key message.

### **Michael Tremblay**

Good policy needs good data; we don't have good data.

### **Jonathan Harper**

The problem of counterfeit medicines in Europe is clearly a very complicated one. I don't think it should be oversimplified, and I agree with what Michael said as well, and Graham, that there is a big gap in data. I'd like to emphasise that the Council of Europe report is evidence based, but it does not cover everything. There is a need now for a lot more work to be done to actually dig out more facts and figures on this

whole issue. As David Taylor was saying, this issue of parallel importation needs looking at in much more detail. I'm looking forward to seeing more of David's work with the London School of Pharmacy and London School of Economics on this issue.

**Philip Stevens**

I think counterfeiting is part of a wider development issue and it should be recognised as such by development agencies and NGOs working in the field. Also, people haven't made enough of the linkages between the wider reasons for economic underdevelopment and counterfeit medicines.

**David Taylor**

Well, the university message is of course that "nothing is simple and you need an extra degree in it" [laughter], but against the messages which Graham and the others have already said, I'd say: If Europe founds its policy in the pharmaceutical, or any other sector, on lies or half-truths, we're ultimately all in trouble.

**Peter Pitts**

Thank you. My takeaway message is: Ignoring prescription drug counterfeiting is ignoring an important public health issue.

Jonathan, to your point on importation as it's known in the U.S., H.L. Mencken wrote that for every complex problem there's usually a simple solution, and it's usually wrong. To echo what some of the other panellists said, this is not a problem that is going to go away. It's not a problem that can be ignored. It's not a problem that can be easily solved. It's complicated, it's hard, and that's all the more reason to focus resources and time on it.

**Michael Tremblay**

I wanted to ask the audience a question. How many here have ever been a patient? How many of you have ever been sick? How many of you have ever taken a medicine? So you have any view of whether or not we have made the case? Are there any doubts in your mind that we haven't covered your hot buttons, your concerns and your issues? Have we left anything out?

**Question**

My first point would be that I have been sick in some developing countries. I won't say that I have been scared, but I have been very concerned by what I would be taking. That's number one.

Number two is that I believe we haven't spoken perhaps enough about the consequences of the trend to promote generics. I have nothing against generics, but the fact is that when you have one drug that is called, let's say "Viagra", you have one

problem of counterfeiting the Viagra. When you have Viagra plus  $x$  generics, you have one plus  $x$  problems. And actually, it is compounding. I think this is a major issue for the immediate future.

### **Graham Satchwell**

I think that's absolutely wrong. What's more, if you look at the efforts that are made to counter the counterfeiting problem, they are made primarily by members of the pharmaceutical industry – particular companies have staff that they engage in anti-counterfeiting activities globally. The generic manufacturers, whilst they represent a large percentage of the volume of sales of pharmaceutical products, I know of no generic manufacturer that gets engaged in anti-counterfeiting work.

Another add-on: At the moment there are people selling very large computer systems to health care systems and telling them that "you'll save those 10,000 deaths a year because the computer is so wonderful". There is very little evidence to support that, and the extrapolations from hospital experience to community experience on drug safety are normally false. The evidence is that safety is supported at many tiers, and it depends on the integrity and ability of both ordinary professionals and ordinary consumers to spot things which are different and unusual. If we created a situation with patented drugs where it's usual to see odd packaging or different arrangements – or it looks as though something has been opened, but it's usual because this is the way we're making a bit of extra money. At if at the other end of the equation, with consumers, they are used to their pills looking different, they're used to generics, and they've been told it's all good because that wicked pharmaceutical industry charges too much, so we shouldn't be asking questions. We obviously risk, at most – damage from counterfeiting and everything else – probably won't be even – most counterfeiters don't want to do harm, they want to make money. But if you do make mistakes, if you do have accidents like a toxic ingredient, or if it's just suboptimal – that's how harm gets done, and potentially gets done on a large and invisible scale.

### **Question**

I have been sick in the United Kingdom, and I was very afraid there, because I got all sorts of infections from so-called "sterile environments" and they weren't that sterile. I can honestly say I probably would have received better treatment in a few of the less developed countries. But there are two things: One is, I think that David Taylor's call for what might be an "international National Health Service" is something I really do not want to see. I want to see more choice, not less choice, and a global standard of health care is something I really do not want to see, because the chances of it being better than the European average is unlikely on a global scale; if anything it's going to be quite a bit worse than that. I really think that's going to be a tough sell.

It occurs to me on the serious issue of how we deal with counterfeits: Patients, of course, have a huge interest in this, and the big problem (which I feel a couple of the

speakers have touched on) is the degree to which restrictions on information to patients is a killer. I think if you want a simple message, it is: Not being able to address the problem of counterfeit medicines in Europe is literally putting patients at risk. There's your simple message, I think.

### **David Taylor**

I'm sorry, on behalf of the NHS, that you had these problems. What it does show is how difficult communication is. The bit that I was selling there was not the NHS but the idea of universal availability. And what I was suggesting was that we start off with a subsection, almost a community level: "our class deserves good health care". You expand it to "our nation" – one way or another – deserves safety and universal [unclear] access. And I think we expand it again to globally, we have mutual responsibilities to try to make sure these products of the pharmaceutical industry and other medical interventions are reasonably and fairly available. I wouldn't necessarily say you do that by extending the NHS franchise.

### **Question**

On the issue of pharmaceutical companies being unable to communicate directly with patients in Europe, can I say: We should not afford any pharmaceutical manufacturer the opportunity to hide behind that as an excuse for not conveying information of potential counterfeit medicines. Merck, Sharp & Dohme took the initiative and shared some stuff about Propecia. Now I cannot imagine any court prosecuting a case of a pharmaceutical company drawing attention to a potential harm to European citizens. I don't think that's a real issue for pharmaceutical companies – it'd be nice to tidy it up, but let's not let anybody hide behind that.

### **Peter Pitts**

I think another point as well, to your question, is that in the U.S. – David showed a slide with Senator Dorgan and Senator Snow on it, and what they are saying is that the European system is much safer than the American system. Now, that's a whole other conference, but the point is: both systems are very well run and both systems are very safe. To defer sovereignty to another system because of some things you don't like about your system, I think that falls into the category of a simplistic solution. All systems, whether unified or by themselves, need to 'fess up to the problem and have the resolve to address those problems.

### **Jonathan Harper**

I'd like to follow up on that point and make a point about communication. This is an issue that was very much discussed within the Council of Europe, and there was a large degree of feeling that there wouldn't be so much communication to the general public about what potential problems there are with counterfeit medicines in Europe, because they felt there was a serious risk of undermining, in the public's eye, how effective health systems are. It is an issue, and I think it comes down to an issue of

risk management, for dealing with counterfeits. What is the right risk management strategy, what is the right level of communication? As David had on one of his slides, we don't want to over exaggerate the problem but we don't want to under-exaggerate it, either. What is the right message to be saying to the general public? Therefore, I see very much the work that we did with the Council of Europe report is just a start. I think there needs to be a lot more work done in terms of digging out the evidence – how much of a problem is there in Europe? And I do believe that the public has a right to know, but we have to avoid the wrong information and we have to be very careful that the information we do impart is actually based on really thorough and validated evidence.

### **Michael Tremblay**

Just to show you an example of where even the Council of Europe gets it confused, the work I did for the council was on how patients should have access to information on health care over the Internet, and it produced a particular recommendation. I take a strong view that there are no good reasons to withhold information from patients about their health care. There are people who believe that the less you tell patients, the better, because it is important to maintain sort of a climate of fear amongst patients in the sense that if they don't do something, there are going to be terrible consequences. Informed patients have to have a variety of sources in order to arrive at an opinion. That countries would nationalise health care information would worry me, too – that there are official sources of information is equally disturbing because we know that governments can misuse and misrepresent information. We had the boy who cried "wolf". So we know that governments do not always act in the public interest because they have their own interest as well. When we start looking at withholding information about risks that the public faces in health care, we get it wrong. The Commission took a view on BSE that the British government did not act quickly enough in informing the British public about the problem; these kinds of cases create conflict in policy, and I think the counterfeiting issue raises a very important issue about who has to inform, how, and under what circumstances? What are the "trigger points"? The simple solution, of course, is that information wants to be free. People who try to package it up and contain it and manage it massage it and control it are the people that we have to avoid. We have to let the information be available to a nuanced, informed public. I think there is a real potential conflict in terms of how we get the information about counterfeiting out to the public. I would say within the EU these are intertwined issues, which I think in other jurisdictions are less intertwined because European governments have taken the view that if they act in a protective, with sort of an *in loco parentis* type of relationship to the patient – and it's kind of time to grow up: let the patient have an "adult" relationship with health care information, even if it's scary, even if it's dangerous. Because if they don't know, you have a worse situation.

– end –



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