



SPEECH • DISCOURS • DISCURSO • خطابات

**LAW SYMPOSIUM ON
THE GLOBAL PROBLEM OF COUNTERFEIT PHARMACEUTICALS**

*“CHALLENGES TO FIGHTING PHARMACEUTICAL CRIME GLOBALLY: INTERPOL'S
PERSPECTIVE”*

REMARKS

BY

**RONALD K. NOBLE
SECRETARY GENERAL
INTERPOL**

**UNIVERSITY OF NEW HAMPSHIRE SCHOOL OF LAW
CONCORD, NH, UNITED STATES
19 FEBRUARY 2014**

President Mark Huddleston, University of New Hampshire,

Dean John T. Broderick, Jr., University of New Hampshire School of Law,

Distinguished Members of the Judiciary,

Editors of IDEA,

Distinguished Presenters at this Symposium,

Dear Students,

Distinguished Guests,

Ladies and Gentlemen,

Good evening.

The relationship between a student and the school where he or she has studied is an extremely special one. The memories and friendships connected to that experience lead to the development of a bond, an attachment or an emotional link difficult to describe in words.

Since the day in 1979 (35 years ago) when I graduated from the University of New Hampshire's Whittemore School of Business majoring in Economics and Business Administration – that bond between me and UNH has always been powerful.

When I am asked how did I make it to where I am today or who believed in me when I was young? I humbly and honestly answer "Besides my parents and brother, my professors, classmates and administrators from UNH believed in me; supported me and pushed me to excel as a student and to become a better person."

I simply can never ever say thank you enough to this great university and to all those with whom I had contact here and indeed throughout the State of New Hampshire for having believed in me and for having helped to shape me as a student and as a person.

Chairperson of the Board Diamantis, President Huddleston, Dean Broderick, members of the faculty and student body of the University of New Hampshire School of Law, dear alumni, distinguished guests, ladies and gentlemen, perhaps you can now understand a little better why it is such an honor for me to have been invited to deliver this keynote address today – and why I so enthusiastically embraced this opportunity to be with you and to thank you once again.

I also wish to thank the men and women of law enforcement associated with this great university and this state for the sacrifices they make each and every day and for their professionalism and care in making sure that I get in and out of the Granite State without incident. I've said many times before that the sworn officers and other law enforcement officials with whom I have worked here at UNH are among the best I've seen anywhere!

Simply put, the hospitality and the care I have experienced since my arrival here last night, reminds me yet again...of just how good it always feels to be back home.

I have just spoken about my attachment and bond with UNH.

Yet, I want to turn to another kind of bond that is even stronger and purer. It is the love that binds a parent and a child.

But why would I, as the Secretary General of INTERPOL, a 190 member country police organization, open a Law Symposium on Counterfeit Pharmaceuticals, with a reference to the love that links a parent and a child?

Out of love, parents will do almost anything possible to protect their child, to keep their child safe and healthy. When a child is sick, parents worldwide will consult a doctor whenever necessary and possible to find out what to do to help their child get better. Frequently, a doctor will prescribe medicine for their child. Parents must trust their doctor to prescribe the right medicine; they must have faith – that if they give the child what their doctor has prescribed, then their child will get better.

This is the world that I (and most of you) recognize and understand – A world where we receive the medicines prescribed – A world where parents have faith that these medicines would *not* be something other than that which they purport to be – A world where they would not be ineffective or create another illness – or even worse, where they would not cause the death of their children.

Unfortunately, the real world in which INTERPOL operates and which embraces many of the 177 countries that I have visited as Secretary General is different.

In the real world lurk transnational organized crime groups that ruthlessly exploit the trust and faith that parents and patients place in doctors, pharmacies and medicines.

In many parts of the real world, it is no longer enough that parents' express their love and care for their children by taking them to a doctor when sick and by purchasing and giving their children the medicine prescribed.

Now, more and more parents need to worry whether the medicine that they are purchasing is authentic and is in fact what it purports to be.

They need to take extra steps to assure themselves that they are not purchasing and giving their children fake medicines.

To believe me...you really need to believe that which seems unlikely or even shocking – That there are transnational organized criminal groups that intentionally produce, disguise and sell medicines or pharmaceutical products that they know to be fake –That they do this **even** with medicines and pharmaceutical products created to prevent life threatening diseases or illnesses.

Fake medicines and medical products are found in **each** country in the world. Organized crime is involved with counterfeits of both branded and generic medicines.

My experience over the last 25+ years has taught me that many transnational organized crime groups worldwide do not care about a child's health or your health. Instead, they care about making profits irrespective of what the cost might be to children or to you. Their greed and desire for more and more money are without boundaries and limitations.

Law Enforcement's and INTERPOL's Challenge:

Understanding INTERPOL's and law enforcement's task in combating fake medicines and pharmaceutical crime is fairly clear and straightforward: It is to identify medicines that are fake, counterfeit or illicit; get them off the streets; shut down those entities knowingly selling such products; identify the group(s) and person(s) that produced and transported these fake or illicit medicines and bring them to justice – so as to shut down these illegal supply chains and dismantle these transnational crime groups and deter others from engaging in this criminal conduct.

Unfortunately, accomplishing this task globally and systematically is not as straightforward as understanding what needs to be done.

Is accomplishing this task something that can be brought about just by passing and enforcing the right laws?

I recognize that I am speaking at a law school ranked among the top 10 in the US in intellectual property.

Therefore, it is natural that this symposium will discuss and debate how the right laws targeting medical product counterfeiting and pharmaceutical crime and their proper application can assist society, governments and law enforcement – in their collective desire to prevent consumers and patients from purchasing or taking fake medicines for example.

But, I need you to keep in mind that the real world outside these doors is quite complex and having and applying the right laws in one country is only a small part of the solution. If you keep in mind what I said about transnational organized crime groups, you'll better understand what I mean.

These groups can manufacture fake or counterfeit medicines in one country on one continent; disguise and transport them through a range of countries over other continents; repackage and redistribute them and then resell them in new packaging or out of the packaging all together.

Even with authentic medicines, they can repackage medicines that have expired or just remove the medicines from their packaging and sell them in other forms.

They can redirect authentic medicines from the original country of destination to a different country. They can conceal or disguise medicines in violation of the relevant national laws so as to avoid strict regulatory oversight.

Such medical products are commonly called illicit.

For INTERPOL, the daily challenge we confront in helping our 190 member countries fight medical product counterfeiting and pharmaceutical crimes is overwhelming at times.

Simply put, the opportunities for transnational criminals to profit from the sale of fake, counterfeit or illicit medicines and pharmaceutical products are huge.

Transnational criminals are experts in finding and exploiting the gaps in regulatory regimes for such products or the weak enforcement capacity of governments to prevent the illegal manufacture and sale of fake, counterfeit and illicit medical products.

Let me give you a few statistics to help you better understand the regulatory gaps that exist and that are currently being exploited by transnational organized crime groups:

Just this January, 2014, Dr. Margaret Chan, the Director General of the World Health Organization (WHO), gave a report to the WHO's Executive Board the WHO's Executive Board wherein she estimated that:

"For medicines, only around 20% of our Member States (194) have a well-functioning regulatory authority, 50% have variable regulatory quality, and 30% have virtually no or only very limited capacity."

As soon as you think globally, you can easily see why having as high as 80 per cent of WHO countries with variable, limited or no regulatory capacity for medicines presents significant hurdles for governments and law enforcement worldwide.

Imagine a medicine is produced legally in country A for export to country B, but is sent to country B via countries C and D, from where it is diverted to countries X, Y and Z for sale.

Imagine that in countries X, Y and Z, they have limited or no regulatory capacity, where it is not illegal to sell medicines that were manufactured for export to country B.

Imagine a simpler case...a fake anti-malarial medicine is produced in country A. It is then transported through countries B and C until it finally ends up in country Z where it is taken out of its original packaging; broken down into smaller units and sold at local pharmacies or stalls in outdoor markets throughout the country.

Imagine children consumed this fake medicine and hospitals are reporting an increase in the number of children with symptoms including fever, headache and vomiting. Eventually children and even adults are found in comas or die.

When INTERPOL is called upon by country Z for help, what would be the crimes that INTERPOL would be asked to help investigate and prosecute?

Where did they occur?

Where can they be prosecuted?

Which jurisdictions would be willing to devote the human and financial resources necessary to investigate the relevant crimes?

Could the individuals in the supply chain be identified?

If so, could they be found in the same jurisdiction where the laws have been violated?

Would they speak the same language?

Would it be possible to establish the necessary mental state for prosecution?

If so, would the crimes for which these criminals are sought – be extraditable offences in the countries where they are located?

Do extradition treaties exist between the country where the criminals are located and the country seeking their extradition?

Could the country seeking to prosecute these transnational criminals afford to finance a multi-country investigation, prosecution and extradition process?

Are the countries where these transnational criminals are located and are citizens ones that will extradite their citizens to another country?

Assume that during the investigation, it is learned that in this country's market places, one could easily purchase fake, counterfeit and illicit medicines and it is not even clear whether malaria was contracted before or after some or all of the above medicines had been consumed.

With these questions in mind, you can see how complex it is globally to investigate and prosecute one case of fake medicines and how difficult it is to identify one transnational organized crime group engaged in producing fake, counterfeit and illicit medicines.

There is more at issue here than having the right set of laws; regulatory scheme and enforcement powers in one country.

Even where adequate regulations exist at the national level, they present problems when one tries to enforce them across national borders where different countries have different laws or even no laws concerning medicines. Unless laws are harmonized and unless there are no gaps in regulatory and enforcement schemes globally, organized criminals will exploit these gaps at their weakest points.

Let me give you concrete examples where countries or a group of countries are trying to tackle a global problem nationally or regionally through important legislative efforts.

In 2010, the European Union promulgated guidelines to ensure that by 2017, packaging of medication bears a security code, enabling identification and tracing of products.

Here in the United States, the "Drug Quality and Security Act" was recently passed in November 2013. One of its directives mandates *"a manufacturer or repackager to affix or imprint a product identifier on each package and homogenous case intended to be introduced in a transaction into commerce."* This would theoretically enable easy tracking and tracing all the way through the supply chain.

India – the third largest manufacturer of pharmaceutical products in the world - has issued guidelines for implementation of bar coding on all pharmaceutical products intended for export.

I have just cited a few examples – over three different continents – to reinforce a point that is probably already obvious to all of you. Each country or grouping of countries is concerned about passing laws that first and foremost protect citizens or persons within its, or their, jurisdiction. While this makes sense at the national level, internationally it presents significant opportunities for transnational organized crime groups.

When there are existing laws in place, they are often not enforced.

This lack of harmonization means that regulatory, customs and law enforcement authorities around the world need to become familiar with many countries' regulatory schemes and need to have tools that allow them to screen any and all pharmaceutical products to see if they are what they purport to be and are where they are supposed to be.

Now, think about the varying kinds of border control regimes and different levels of sophistication and resources available to regulatory, customs and law enforcement authorities – all around the world.

Add the element of different languages and legal frameworks in which these customs and regulatory authorities operate.

Think about it practically, under the specific legislation what is being uniquely marked in a traceable way? the pallets? Cartons? Packages? And/or the pills/tablets/bottles themselves?

Finally, think about the transnational organized crime groups that have been so successful at exporting or importing illegal *drugs*, and are able to use the same supply chains for fake or illicit medicines. That is, irrespective of how harmonized the laws are, transnational crime groups have supply chains that are never exposed to law enforcement or regulators.

This is the real world in which INTERPOL and law enforcement in its 190 member countries operate each and every day.

For INTERPOL, it is not enough that one country like the US might have great laws; an effective regulatory scheme and a robust law enforcement regime, nor is it enough that a group of countries have great laws; an effective regulatory scheme and a robust law enforcement regime.

With responsibility for helping 190 member countries keep their citizens safe from crime and harm, we need to be concerned about all countries' laws as well as their regulatory and enforcement capacity.

But, how can INTERPOL possibly achieve such a lofty goal?

By targeting countries, crimes, transnational organized crime groups whose prosecution will reverberate around the world; sometimes one country; one case; one organized group at a time; sometimes multiple countries and crimes at a time.

By putting in place training and capacity building programs.

By being available 24/7 to respond to any member country's call for help.

By understanding what the needs and capacities of our member countries are.

This past Saturday, I completed a 5-day mission to five countries in West Africa (Togo, Guinea, Gambia, Sierra Leone and Liberia). In my 13+ years as Secretary General, I have visited 177 INTERPOL member countries to see and understand for myself the issues they face.

In the last of these five countries, Liberia, the Ministry of Health had just announced a "major crackdown on counterfeit drug sellers throughout the country, but Liberians say they have no choice but to buy such drugs, given their low cost and availability even in rural areas."

I have seen where medicines are sold and purchased. They are often nothing like the pharmacies you see here and probably not like the pharmacies you could imagine.

In many countries, medicines can be sold in roadside stalls – no longer in their original packaging. Even where pharmacies or hospitals are used for the sales, such medicines are often not purchased in original cartons or packaging.

The differences between wealthy and poor countries are huge in terms of the risk of purchasing and consuming fake, counterfeit or illicit medicines.

The poor in these countries cannot afford expensive medicines, nor can they afford to buy medicines in large quantities. Sometimes, the poor knowingly purchase counterfeit or illicit medicines.

Some governments even discourage prosecution of these crimes because they consider the cost of certain authentic medicines prohibitive.

If you recall my reference to parents' love for and desire to care for their children by purchasing the medicine prescribed by their doctors, then imagine yourself as a parent living in Africa.

How can any parent in Africa take comfort in purchasing and giving their child prescribed medicine?

When they are so poor that they can only afford cheap medicines, how can they ensure that they are buying authentic medicines?

A frequently stated estimate, credited to the World Health Organization (WHO) – is that about as much as 30 per cent - almost ONE THIRD of all medicines sold in Africa are fake or counterfeited.

Not only is it about massive quantities – equally important is the *type* of medicines. In Nigeria, for example, lifesaving medicines form the majority of such counterfeits – such as antibiotics, anti-malarials and anti-infectives.

In most countries citizens have very few tools with which they themselves can compare medicines they purchase to determine whether they are authentic or counterfeit. The quality of counterfeit packaging has gotten so good that even experts from the authentic manufacturers themselves cannot tell the difference without testing the packaging in their labs.

You must recall that police worldwide are not specialized in this domain. One can count the number of specialized units worldwide with two hands.

One need not focus only on parents and children. Adults also do not want to consume fake medicines. I for example have been to 45 countries in Africa and to Nigeria on several occasions. I have run out of anti-malarial medicine during a few trips; I have become sick and needed to purchase medicine. I have been to outdoor markets or non-descript markets to purchase medicine, and it is an unsettling experience.

As you can see from these examples, the opportunities the real world presents for transnational crime to exploit are many, and this is the world in which INTERPOL and our member countries must operate now. We can't wait for laws to be harmonized; for all countries to have a sound regulatory and enforcement scheme in place. There are too many lives at risk right now.

So what is INTERPOL's approach?

INTERPOL's approach is about health and safety. We are interested in saving lives and keeping fake and illicit drugs away from unsuspecting consumers.

We think globally; plan regionally and execute locally.

Using this approach, we have launched anti-counterfeiting operations and operations against fake medicines all around the world, and have done so on a consistent basis. Our primary goal with these operations is to protect the public through seizures of fake, counterfeit and illicit medicines; to disrupt criminal conduct by shutting down operations and arresting persons involved and to use our operations as opportunities to raise awareness and educate the public about the problem presented by fake and illicit medicines.

Through our operations, some of which have included 16 countries across Western, Eastern and Southern Africa – we have been able to make concentrated efforts to seize counterfeit medicines, arrest suspects and to dismantle transnational organized crime networks.

With each operation, we have collected more names; telephone numbers; email addresses; business addresses; and intelligence about who is doing what and where. It has made us become more and more effective at disrupting these criminal networks and removing fake and illicit medicines from the market.

Let me share just one recent example of an INTERPOL operation.

Operation Giboia was held across Southern Africa last October. It involved more than 900 officers from five participating countries - Angola, Malawi, Swaziland, Tanzania and Zambia.

550 coordinated raids and inspections were conducted across 30 cities and different border points under Operation Giboia, in just three days. We checked marketplaces, pharmacies, clinics and illicit sites.

In all, the seizures of illicit and counterfeit medicines were approximated to be worth USD 3.5 million. We shut down unauthorized outlets for selling medicines.

Nearly 200 suspects were either arrested or put under investigation.

Most importantly, we alerted parents and communities to the problem presented by fake medicines and illicit drugs, and ... we made organized crime groups worry whether the next operation would lead to their arrest.

I could continue with citing examples, but I want to make another point here: I want to highlight how complex it is to investigate and prosecute fake or illicit medicines across borders globally.

To make such multi-country operations successful, INTERPOL must take a multi-pronged approach.

To coordinate all our initiatives, INTERPOL has a dedicated 'Medical Product Counterfeiting and Pharmaceutical Crime' unit, a team with multiple nationalities working together – ranging from analysts to specialized police officers.

Our multi-pronged approach requires that those participating in operations are educated and trained about what constitutes a fake or illicit medicine. We hosted such a training in India just last October, 2013. We work closely with regulatory bodies and experts in identifying fake, counterfeit and illicit medicines.

We also organize conferences and meetings where the problems confronting us can be discussed and best practices can be shared. We held such a conference in Ethiopia just two months ago with the participation of 20 countries.

But despite the successes we have had launching operations at the micro level – we know that the problem of medical product counterfeiting and pharmaceutical crime cannot be dealt with by law enforcement alone.

Law enforcement could never fully understand how to distinguish a fake medicine from an authentic medicine, like a manufacturer.

Law enforcement does not understand the supply and distribution chains like the manufacturers.

Law enforcement does not have the links to medical and pharmaceutical communities like the manufacturers.

We therefore needed to forge strong partnerships with the drug manufacturers—both brand name and generic drug manufacturers.

In March last year, INTERPOL entered into an agreement with 29 (now 30) pharmaceutical companies to foster greater cooperation between the private sector and law enforcement, in fighting pharmaceutical crime collectively. This is called the Pharmaceutical Industry Initiative to Combat Crime (or PIICC).

This initiative brings greater focus on both branded and generic drug counterfeiting, as well as providing further impetus to law enforcement in cracking down on organized crime networks.

Similarly, INTERPOL works alongside numerous other active players in the international arena – World Health Organization (WHO) and European Commission, to name a couple.

Here in the United States, we are grateful for the support of the Office of Criminal Investigation of the Food and Drug Administration (FDA).

Internationally, much needed support has also been received from entities such as Global Fund and US AID.

Let me give an example of how such partnerships help. In April last year for an operation in the Republic of Congo, INTERPOL engaged expertise from one private manufacturer in delivering a training just before the operation – and sought this manufacturer's

assistance with helping us to identify some of the over 30 tonnes of fake medicines seized.

All such partnerships have truly helped bridge information or intelligence gaps where they exist and strengthened cooperation across borders.

But borders are no more merely physical in our world.

I am sure you understand and are very well acquainted with the challenges I speak of – those of the virtual world.

Transnational, organized and other criminals regularly profit from the sale of counterfeit medicines online to unsuspecting, innocent citizens across the globe.

They understand the ease with which anonymity can be used to commit cybercrime. And they know how to circumvent customs and regulatory authorities in many countries to deliver the – possibly ‘deadly goods’ – to wholesalers, street traders or retailers, or even right to people’s doorsteps – all, at just the click of the proverbial mouse or the tap of a finger.

INTERPOL and our member countries have been aware of and fighting this ongoing problem on a regular basis. We have been going after them again, and again.

Let me share with you the continuing saga of “Pangea”.

A story which began over half a decade ago, when the first Pangea operation was conducted in 2008, with only eight participating countries. It was initiated with the simple aim of protecting innocent customers from transnational criminals preying over the Internet by selling counterfeit and illicit medicines.

In June 2013, INTERPOL’s Pangea-VI was conducted in cooperation with nearly 100 countries. From eight to 100 countries. It lasted about one week and was coordinated from the Command and Coordination Center at INTERPOL’s headquarters in Lyon, France. It brought together their Customs, Police and National Regulatory Authorities – to simultaneously target Internet Service Providers (ISPs), electronic payment systems and delivery services.

Pangea-VI saw the support of the World Customs Organization (WCO), the Permanent Forum of International Pharmaceutical Crime, the Heads of Medicines Agencies Working Group of Enforcement Officers, the Pharmaceutical Security Initiative, Europol and the Center for Safe Internet Pharmacies. From the private sector, we cooperated with major payment service providers such as Visa and Mastercard, PayPal and also with Microsoft.

In the virtual space, over 13,700 illegal sites were shut down under Operation PANGEA-VI.

On the ground, raids were conducted across addresses linked to such websites – over 500,000 packages were inspected and over 200 suspects arrested.

Right here in the US, nearly 6000 websites were monitored – leading to the shut down of over 1600 of them. This was *after* over 4,700 websites had been shut down the previous year, as a part of Operation Pangea V.

Overall, as a direct outcome of Operation Pangea VI, the value of seizures stood at an approximate USD 41 million. This included the confiscation of more than one million potentially dangerous medicines.

I repeat: more than ONE MILLION, in five days.

While investigations and leads generated continued to facilitate further arrests and seizures long after the operation, our thoughts also went towards: what if...

What if, those medicines had been consumed by unsuspecting, innocent persons anywhere in the world?

What if, even after the arrests, the shutting down of websites and breaking down of criminal networks, other criminals posing similar challenges to people's health and safety sprang up?

What if, after the seizures, they looked up different sources for obtaining illicit medicines...such as the *diversion* of medicines intended for different purposes or markets?

Many of you might even remember one such case which saw the seizure of such "second hand drugs" worth over USD 16 million by the Federal Bureau of Investigation, in Manhattan. It was in 2012, when 48 people were charged with diverting prescription drugs.

Or what if, organized crime started focusing more on citizens making purchases online in countries with fast growing internet penetration rates? Countries that might not yet have strict regulations and laws in place to deal with such criminal activity? For example, Sub-Saharan Africa is one of the world's fastest growing regions for mobile phones' internet penetration.

INTERPOL believes that one of the *absolutely necessary* things to do for fight this and other global crimes in the 21st century...is to innovate.

I have already spoken about the importance of partnerships among all stakeholders – law enforcement, customs, non-governmental organizations, international organizations, payment providers and delivery service providers – indeed, across both public and private sectors.

But INTERPOL wants to innovate – by involving and empowering one more, very important stakeholder.

The private citizen.

We want to give the private citizen – the choice, the freedom to know for him-or-herself – whether what he or she is buying is genuine or not, by simply *checking* its authenticity.

This is how the concept of “I-Checkit” was born.

In simple terms, through INTERPOL’s I-Checkit initiative, the aim is to provide common citizens with a one-stop mobile application that could scan products, such as medicines, and help establish their authenticity.

This form of verification would certainly require the use of unique identification for packaging of medicines.

As I had highlighted earlier, laws to ensure traceability of medical products are being introduced by a lot of countries at the national level, or even at a regional level. However, multiple kinds of technologies or solutions are under consideration or in use. In India for example, Pharmasecure has already been contracted to work with certain drug manufacturers.

INTERPOL aims not to duplicate, but only provide a coherent platform for leveraging the existing efforts of manufacturers, or national regulatory authorities.

The application would help users in identifying medicines that could potentially be illicit or counterfeit. It would do so by checking against information that could be provided by the pharmaceutical industry, both brand name and generic, through the secure channels of INTERPOL.

I-Checkit would be designed for use across borders. It would give an equal opportunity to consumers, regardless of whether their national authorities might have the technology or equipment to carry out expensive laboratory testing of medicines, or not.

Through I-Checkit, INTERPOL believes that manufacturers also have the option of voluntarily joining INTERPOL’s fight against pharmaceutical crime.

Ladies and Gentlemen, let me close my formal remarks with the inspirational words of a Nobel Peace Prize recipient, the late Albert SCHWEITZER who said:

“The purpose of human life is to serve, and to show compassion and the will to help others.”

That is why great institutions like the University of New Hampshire’s School of Law and INTERPOL exist.

This Law Symposium on the Global Problem of Counterfeit Pharmaceuticals will contribute to our collective desire for a safer world by helping us to better understand the problem and the myriad ways in which we can reduce the threat it poses.

This is the real world that INTERPOL and I want us all to experience...one in which we can lead long, prosperous, healthy and of course law abiding lives.

Thank you.