COUNTERFEIT HARD GOODS AND
THE PUBLIC’S HEALTH AND SAFETY:
A STUDY OF INTERVENTIONS

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Successful interventions -- that is, actions that interrupt or modify the actions of another or a condition and result in a change towards a status that is preferred or chosen -- rarely happen in a short period of time. In this report we speak about the problem of counterfeit goods that can cause harm and interventions designed to reduce the prevalence of such counterfeits. An intervention is one step in a series of actions that lead to a desired result. These actions can be understood as a series of steps or a process that begin with 1) awareness of a dissatisfactory aspect of a behavior or condition and thus a problem, followed by 2) some form of measurement and study of the problem. These findings are communicated to wider audiences for building awareness and acknowledgement, further study is conducted, and subsequently interventions are begun to address the problem as understood up to that point. Solutions can be of many types – among them, scientific, technical, legal, law enforcement, or regulatory. After an intervention is started, a cycling through these steps or phases continues as none is an end point on its own. The end point is of course when there is a satisfactory reduction of the problem to a tolerable level or the problem is eliminated entirely. Successful interventions are those that work and are measureable and accordingly social consensus is clear that the intervention should be sustained until the desired result is achieved.

The use of seat belts, protection of sand dunes, and cessation of tobacco use, and most other interventions to protect public health all have this road in common. During this process scientific findings, government polices and various observations are translated to legislative, regulatory and law enforcement solutions and actions that are, hopefully, supported by the public at large at the outset and if not, immediately, certainly over time. Unless there is social consensus that the intervention is desirable it is not likely to maintain political support or be sustained. A good example is the use of seat belts, which were mandated after science observed that auto accident trauma was worse if seat belts were not worn. What started as an annoyance became, over time, an effortless act. Regulators, legislators and law enforcement - including civil society and industry - all had a role in the success of seat belts as an intervention. We are now so acclimated to wearing seat belts that we may even feel uncomfortable without them – and in case we forget, we are reminded by “Click it or Ticket” slogans. This intervention is now sustained and maintained by most if not all stakeholders and there are repercussions for compliance failures.

An even more compelling case in point is tobacco cessation. In the mid-20th century, science established a causal link between tobacco use and disease. Still, it took many more years for countries to implement legislative provisions, and to do so against the forces of various lobbies (whose interests lay in not having such legislation) and even against countries where the government itself held the monopoly on tobacco products. A prime legislative example is the Framework Convention on Tobacco Control, entered into force in 2005 some 55 years later than the seminal scientific studies. Over time, a behavior

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associated with sophistication and enjoyment became identified with poverty and lack of education. Now tobacco consumption is in decline in many countries. Moreover, since the adoption of the convention there has been and remains an ongoing process to implement the convention into national legislation and practice.

The point in time when regulators and legislators take up an issue and begin to intervene is clearly not the final phase – indeed, if anything it is but the middle. This middle is characterized by numerous and varied attempts at interventions, such as voluntary standards, guidelines, administrative regulations, regulatory and law enforcement initiatives and new or amended laws coupled with a variety of communications directed at the relevant population. In this context, the status of interventions to combat counterfeit goods in general – not to mention those that can cause harm – is justifiably placed in the middle where it is likely to stay for some years. At this phase, the next steps are therefore to increase the level of study rigor so that existing interventions can be refined and success or failure measured.

The problem of counterfeit goods started to be highlighted in the 1990s at the outset of the last period of expansion in global trade and telecommunications. Being in the middle of this process \textit{in just over 20 years} is a noteworthy achievement. I concluded the 2003 report by referring to the USPTO call to action and observe here that actions in progress are answering that call -- but by no means is the effort in the final phase. However, the steps to maintain and sustain useful interventions are now known and outlined in this report. As these are implemented, their results measured and elements refined, I am confident that the problem of counterfeit goods can be managed to reduce their potential for harm to the health of humans, animals and plants.
EXECUTIVE SUMMARY

Counterfeit goods continue to be a threat to the health of the public, and have been the causal link to injury and death of innocent persons in developed and underdeveloped countries alike in the ten years since 2000 as they were for the ten years prior as reported in "Counterfeit Goods and the Public’s Health and Safety", the first study on this topic published in 2003. What is different now is that there is widespread acknowledgement that counterfeit goods are a threat to the health of humans, plants and animals and, as a result of this observation and other influences, numerous interventions have been directed to stem the problem of counterfeit goods in general and specifically those that can cause harm.

These interventions and their effectiveness in the domains of the legislative, regulatory, and law enforcement branches of government are the subject of the study reported in this paper. The study was designed to find, report on and analyze interventions within the realms of legislation, regulation and law enforcement. Its conclusion made it possible to amalgamate the efforts of many into a snapshot of a comprehensive national strategy to combat counterfeits. This snapshot is portrayed here in the form of an assessment tool (Annex 6) with separate sections for use by each branch of government and suggestions in the companion training materials on how the separate branches can coordinate their separate plans into one national plan.

A comparison of the results of the first study with those from this retrospective study signifies that the five strategy dimensions identified in the 2003 report can be confirmed with minor revisions. These were and remain to shift policy, monitor health status, enforce health and safety regulations, collaborate among interested communities and use health communications strategies. Reflections on and an amplification of these five dimensions form the overall conclusions of this report in Section 7.0. In this executive summary the two most important are highlighted and these are a shift in policy and the need for data.

A shift in policy is essential

Even though a strong IPR policy in the end can be health protective, given the limits of IPR policy and practice, health protection as a rationale for an IPR strategy is not sufficient to protect public health. In the end, it may not protect IP either as fully as desired. Refining some aspects of IPR strategy to be health protective makes sense coupled with an overall comprehensive IPR strategy is an important element in protecting public health. A shift in thinking towards placing the value of health as the primary focus of some IPR interventions will bring a key advancement in how the matter of counterfeits is managed.

This can be accomplished by legislatively empowering regulators and law enforcement to take action against not only counterfeit but also substandard and illegal products. The new acronym SIC products captures the idea of any product from any sector that is substandard, illegal or counterfeit that can cause harm to humans, animals or plants. By this conceptual expansion any regulatory or law enforcement authority can act against counterfeits which are by their very nature often illegal and/or substandard. Adding relevant regulatory principles and standards to the variety of products that when counterfeited might cause harm, such as is the case for foods, toys, and industrial, agricultural, and medical products, health can be protected and so can IP. By no means

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does this suggest that standard approaches to IP protection should be disbanded. It does mean that in addition to standard IP practice, specific actions should be taken against SIC products by the competent authority at national, regional and international levels. By doing so health is protected and along the way IP infringing products will be captured by the regulatory and law enforcement net created by the concept of SIC products. This direction has already been taken by some countries and should be encouraged and expanded.

There is more to a policy shift than data collection however. The topic of counterfeit goods and the public’s health and safety was first understood to encompass the ways in which such goods could -- and did -- cause harm to human and animal health. This acknowledgement of health and safety was instrumental in increasing the attention and resources to combat counterfeit goods that might cause harm. However, to a large extent the initiatives have remained in the purview of the IP community, where IP protection is the top line value rather, than as initiatives, where health is the top line value, so that by protecting health, IP is also protected. An example of this point is ACTA, in which few if any provisions explicitly reflect concern for health even though law enforcement is a key actor in the protection of public health. As itemized in the ACTA section of this paper, some ACTA provisions such as proportionality and destruction among others are devoid of reference to health and safety. These and other provisions could have more explicitly reflected concern for public health without jeopardizing the law enforcement objectives of ACTA. Another example of this observation is found in the protracted debate over the nomenclature of counterfeit medicines. This debate effectively cemented a line between health and IP and silos for the respective communities by adding new nomenclature and a definition claimed to be specific to public health. Each term and related definition has implications for the separate communities that have yet to be understood and as of the date of this report the debate drags on. Even approaches as innovative as the EU Medicrimes Convention (though it now includes the three-dimensional approach of substandard, illegal or counterfeit medicines), missed the opportunity to apply this innovative legislative infrastructure to any product that when substandard, illegal or counterfeit could cause harm. As its scope includes veterinary products, it does a partial job but it leaves out all other types of product. In principle this should be an easy gap to close.

This is not to say that efforts focused on IP alone should be abandoned or otherwise reduced. There is no doubt that all efforts to reduce counterfeits of all kinds, either directly or indirectly, lead to protecting health. This is to say that if the goal is to protect health -- and this is as rightful a goal for the IP community as it is for any other -- then there are steps to be taken to reframe policy and approaches that are highlighted by this research. Simply put, this means to increase regulatory and law enforcement initiatives against any product that can cause harm – even if not counterfeit but also if it is. To do this, the IP community will have to step outside of its comfort zone and work collaboratively with the health, consumer, agricultural, industrial and other product communities. In this sense, this report makes no change to the 2003 recommendation to collaborate among interested communities. And let it be underscored that these other communities, especially health, must also open their agendas to that of counterfeiting and the ways in which collaboration can aid in solving this real public health problem. In sum, IP protection and enforcement is one element of a comprehensive approach to protecting public health; approaches that silo one sector against another will not work. All sectors must work together to efficiently organize and align their respective competencies and responsibilities.
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Data and scientific analysis

Significant and positive observations are enumerated in this study on the specifics of what has been done in the last ten years. There is a tremendous increase in just the number of countries engaging in activities related to counterfeits that it can be said there is widespread acceptance there is a problem. Nonetheless, while there is a plethora of reports on observed and confirmed cases of counterfeits that could or did cause harm to the health of humans, animals or plants that also confirm the existence of the problem, there remains a dearth of valid data that measures what we intend to measure. No more than a handful of studies and no baseline data could be found. Without valid data it is impossible to accurately quantify the prevalence and incidence of counterfeit goods and therefore impossible to evaluate interventions.

Interventions have been based on the empirical observations of regulators, consensus, and stakeholder input. Though these non-scientific approaches do yield interventions that seem to make sense given their grounding in long-established practices (such as theories of criminal deterrence), there is no substitute for rigorous analysis. When the results of the few studies are contrasted with these efforts, the value of rigorous studies is hard to discount. For example, regulators are using the Internet to communicate information to consumers on counterfeits, yet studies show that consumers get their information from newspapers, and in many places people do not have access to the Internet. In the end these less-scientific approaches are simply insufficient given the costs of interventions and the consequences of failure.

Just in the last two to three years, some organizations are finally taking the matter of data collection and scientific analysis seriously and are to be commended, supported and duplicated. Notable are the World Customs Organization (WCO) Research and Strategies Unit (RSU), established in 2009, and The Center for Applied Science and Technology in the UK Home Office, opened in spring 2011. Results of studies from these units are mentioned within but as of yet the research focus of each has not been on the matter of counterfeits. There was some movement towards more sophistication of seizure data fields and categories, although these are not yet harmonized, making comparisons across countries difficult if not impossible. The data field of consumer safety and critical technology (CSCT) was coined by the US, and the European Union (EU) has started to group some products that might cause harm for data reporting. These changes make it a bit easier to determine the percent of all seizures that might have caused harm but do not go far enough. The WCO RSU could and should take on the task of leading a data field harmonization project.

It is only with valid data or data that measures what we intend to measure that the effectiveness of interventions can be measured in a meaningful way. Now the best data is seizure data as it is the only data captured with any level of uniformity. Nonetheless, it measures the quantity of seizures not the quantity of counterfeits. It measures the year to year differences in dollar value and quantity of seizures but not whether as whole there are more or less counterfeits. The topics of data, monitoring and evaluation are so critical to the solution of this problem entire sections of the on-line training materials are devoted to them. These topics are not within the scope of this report but are so important extensive attention is given these in the companion on line training materials. Much more needs to be done in this regard otherwise without data useful to design, measure, and evaluate efforts, hoped-for results are based on little more than guesswork and wishful thinking.
Results

Counterfeiting of products that can harm is a global occurrence now and has been for the last ten years as it was in the ten years prior. This finding and those on what is being counterfeited and their provenance are no surprise. Nor do the findings of this study change our understanding of the problem. Overall, the types of products counterfeited are the same as noted in the 2003 report, including toys, auto parts, cigarettes, foods, electronics, medicines and clothing among others.

Medicines remain in the spotlight and command the most attention, although counterfeit agricultural products are now becoming of great concern and will continue as the world grapples with food shortages. Counterfeit medicines are now traceable to drug-resistant forms of disease, most notably malaria. The dynamics of counterfeit malaria products trade are an archetype for the business opportunity in counterfeit, non-communicable disease products. This comes at a time when these diseases will heavily burden all countries, a fact that led to a high-level UN Summit in September 2011.

A bright spot in the results is that over 50 countries, more than 60% of which are developing countries, have taken some kind of action; if the members of various economic groupings, such as the EU, Andean Community and EAC among others, can be counted separately, the total would be more than 100. This is compared to less than 15 countries for which reports were found in preparation of the 2003 report. This number alone suggests a growing global consensus, among developed and developing countries alike, that this matter should be taken seriously and that it is.

Legislators

There has been significant legislative activity since 2000 at international, regional and national levels. The Anti-Counterfeiting Trade Agreement (ACTA) sets standards for an international law enforcement framework to combat counterfeit products of all types. Several provisions are protective of public health without change at implementation. One is the definition of commercial scale critical to defining when criminal sanctions must be similar to those imposed for crimes of serious gravity and for the application of compulsory licensing in cases of non-commercial public use. Another is the burden of proof when a rights-holder requests a seizure, a step that strengthens rule of law and protects health. At implementation, and even if ACTA is not adopted, there are opportunities to bring the value of health into national legislation without reducing ACTA’s enforcement objectives. This can be accomplished by recognizing society as a participant to be taken into account in calculating proportionality, and mandating destruction and expanding the boundaries of ex officio authority if health is at risk among others noted in this report. Regarding counterfeit medicines, it is unfortunate that no progress was made on a convention to combat counterfeit drugs as called for by the International Conference of Drug Regulatory Authorities (ICDRA) in 2005, and that the International Medical Anti-Counterfeit Task Force and its successor Open Ended Working Group continue to hit roadblocks.

At national and regional levels, counterfeits have been the subject of legislative innovations that empower regulators and law enforcement with multi-dimensional options. Anti-counterfeit laws protect health by several mechanisms: 1) a dual-definition approach - one for all products and one for medicines; 2) by recognizing harm to health as societal harm deserving severe sanctions if injury could have or did occur; 3) adding the crime of corporate manslaughter; and 4) the naming of all existing inspectors as anti-counterfeit officers and granting powers to them, thus filling a gap complained of by regulators.
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Counterfeit labels and packaging and their manufacture are now within the definition of a counterfeit crime, and all the activities of manufacture, packaging, labeling, storage and transport are prohibited. Legislators have also closed gaps in the supply chain by supplier verification requirements, certificates of compliance, mandatory recalls, and the option to block imports of suppliers who refuse inspection – thus an overall increase in the accountability in the supply chain. Many countries have established a counterfeit agency or a focal point in one or more agencies.

Some of the most advanced innovations are found in the EU Medicrime Convention that recognizes actual harm as cause for criminal action and with a scope that includes not only counterfeits but also substandard and unregistered products for humans and animals. This law is one of several that expand the concept of medical products that can harm – whether substandard, illegal or counterfeit or as coined here SIC products. Though limited to human and veterinary medical products, the concepts contained in this new law could be more broadly applied to any product that when counterfeited could cause harm. This comprehensive legislation covers starter chemicals to end-product, all the players in between - even victims and has provisions for witness protection. Especially significant is the adoption of nearly universal jurisdiction across member states. With this change and those that effectively broaden the scope of regulatory and law enforcement capture to substandard and unregistered products along with counterfeits, the playing field for counterfeiters is made smaller.

**Regulators**

The premise that counterfeits flourish in places where regulation is weak remains the standard. This finding from a 1999 study has not been refuted. Legislators in the health products sector confirmed this standard in a 2010 25-country study that acknowledges that weak cooperation between regulators and law enforcement is problematic, and the need for a sufficient legal framework for cooperation. Regulators stated the need for specific legislation on counterfeits, among other elements, as essential to their ability to combat counterfeits. Surprisingly, these results were published after several pieces of legislation were enacted that accord regulators the very powers they describe based on their empirical conclusions. Though medicines have received the most attention in the past ten years, products such as auto parts, children’s and consumer goods, foods, and others are now subject to a wider basis – that of quality and legality - on which to predicate regulatory action. This approach will result in the capture counterfeits even if the basis to do so is not IP. Ultimately this comprehensive approach is health and IP protective.

Regulators have been active in establishing a variety of collaborative initiatives that take advantage of the respective strengths of each cooperating entity. There is still weakness in communications, lack of product-specific regulatory principles on which to establish quality and legality, and failure to assess capacity building to determine if any capacity is built. Some countries are taking the destruction of counterfeits more seriously and are in-line with international law and standards on the destruction of the underlying product type or counterfeits as environmental pollutants. This is important as ACTA has provisions on destruction. But in most countries, the rules are fragmented at best if in place at all. Having good practices on safe handling and destruction of counterfeits as environmental pollutants is critical to the health of the public and the staff of regulators and law enforcement.

**Law Enforcement**

Basic principles of law enforcement are the foundation of law enforcement intervention strategies to reduce counterfeits overall and those that cause harm to humans,
animals and plants. Increasing law enforcement alone is not enough; it must also be more efficient through the use of coordination within and between national and international agencies, stronger by building capacity and know-how and more specific by adding specialized units and courts. Barriers to success include blurry and incomplete definitions of counterfeits and crimes across all product sectors, and sanctions that are too slight to be effective. Even when these sanctions are severe enough to be a deterrent, they are not imposed with regularity. The lack of ex officio authority, useful data and evaluation studies impede success. Moreover, there is no measurement of capacity building programs to determine if these build capacity.

**In closing**

If this study demonstrates anything it is that much know-how to combat counterfeit goods is in hand. Success depends on building on and sustaining what we now know. There is no magical formula; the means are very familiar -- even mundane and lacking in newsworthy appeal. There is nothing new about ensuring that regulators have the entire mix of authority, regulatory principles, staff, budget and skills; that legislators must provide these; and that law enforcement – both traditional and within regulatory agencies - must be able to stand ready to do its part. The elements of a comprehensive and effective strategy were amalgamated from the interventions studied here. There is not one country that has all the elements in place. But it can be said that the potential for success can be predicted if a comprehensive plan is implemented based on what we now know from available scientific or quantitative studies, empirical know-how and consensus findings and more importantly from what we can learn from such research in the future. Based on this guidance, it is within the reach of all countries to sharpen the focus of interventions, fill in any legislative, regulatory and law enforcement gaps, enhance interventions based upon good social science principles of data, monitoring and evaluation and thus achieve success.
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<tr>
<td>ACTA</td>
<td>Anti-Counterfeiting Trade Agreement</td>
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<td>API</td>
<td>Active Pharmaceutical Ingredient</td>
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<td>BASCAP</td>
<td>Business Action to Stop Counterfeiting and Piracy</td>
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<td>BCC</td>
<td>Behavior Change Communications</td>
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<td>BMJ</td>
<td>British Medical Journal</td>
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<td>CCP</td>
<td>Container Control Program</td>
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<td>CNCP</td>
<td>National Council against Piracy and IP Crimes</td>
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<td>East African Community</td>
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<td>United States Environmental Protection Agency</td>
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<td>Free Trade Zone</td>
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<td>IP</td>
<td>Intellectual Property or Intellectual Property Right</td>
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<td>NEPAD</td>
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<td>PRO-IP</td>
<td>Prioritizing Resources and Organization for Intellectual Property</td>
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<td>Public-Private Partnerships</td>
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<td>SAMMDRA</td>
<td>South African Medicines and Medical Devices Regulatory Agency</td>
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<td>STOP</td>
<td>Strategy to Targeting Organized Piracy</td>
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1.0 INTRODUCTION

In 2003, the problem of counterfeit goods and the public’s health and safety was highlighted with the report “Counterfeit Goods and the Public’s Health and Safety”, the first global study on the subject. Based on the data available at that time, the report (which examined the situation through the ten years prior to 2000) found that many types of goods, not just pharmaceuticals, were being counterfeited, and that those goods that are used or consumed by humans and animals conclusively caused injury, or could have caused injury, had these products been ingested or used. Reports were subsequently released detailing the risk posed by counterfeit agricultural products to plant life. The original study concluded by observing that “To preserve the status quo of ignorance on counterfeit goods and the public’s health and safety is to court disaster.” Taking the steps outlined in this study (see Table A) and to answer the US Patent and Trademark Office (USPTO) call to action is urgent to prevent injury, disease, and death associated with counterfeit goods.”

TABLE A: Steps recommended in the original study (2003) to prevent injury, disease and death associated with counterfeit goods

- **Change policy**: Fundamental to the success of any strategy on counterfeit goods will be to reframe the policy perspective as a matter of public health and within the obligation of governments to protect public health.
- **Monitor health status**: The public health field needs to accurately describe counterfeit related injuries and disease, identify their determinants and develop prevention strategies.
  - The first step to solving the problem is the collection of appropriate data, which requires coding refinements in the International Classification of Diseases and the integration of the changes into the national health statistic and other relevant databases.
  - A common definition, uniform terminology and compatible databases are also critical to developing appropriate data.
- **Enforce safety and health regulations**: Key elements of an effective strategy in counteracting counterfeiting are relevant regulatory authorities, which are able to collect data, disseminate alerts on counterfeits, impose sanctions, and enforce safety and health laws.
  - Effective strategies to combat counterfeiting in the developing world will depend on the development of legal systems that provide intellectual property rights, consumer, drug, health, and safety laws and regulations and the ability to enforce them.
- **Collaborate among interested communities**: Collaboration between government, industry, public health, the intellectual property rights legal system and interested constituencies will lead to effective solutions.
- **Deploy a health communications strategy**: Health communications to empower, inform and educate people so that consumers are aware of counterfeit goods and what to do if injured as a result of counterfeit goods.

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3 supra note 2.
4 If plants used in human and animal food are negatively affected so is the food supply which jeopardizes human health.
1.1 The objectives of the current study

The main aim of this 2011 study is to collect evidence on what works and thereafter duplicate and support successful strategies so that gains are made in strengthening intellectual property (IP) protection and curbing intellectual property theft to protect public health. The approach taken was to synthesize what has been done to address the problem of counterfeits since 2000 to 2010 and from this research highlight successful efforts, offer observations on the effectiveness of interventions that have been or will be undertaken to combat commerce in counterfeit goods that cause harm and seek to understand why some interventions work and others don’t. Resources and a training as noted in Box 1 below complement this report.

Box 1: Training, Website and Resources

A training program based on this report and complementing it are available in several formats. One format is a “Train the Trainer” curriculum for any organization to offer with its own trainer. It can be downloaded or a copy can be requested at no charge in paper or CD Rom format. An asynchronous self paced webinar version of the training program presented by the study author is also available on-line. All formats contain four curriculum modules including a main module for any audience and then separate modules for legislators, regulators and law enforcement.

On the study website www.counterfeitgoodshealth.net, in addition to the report there is a Comments and contributions form for the submission of questions or comments and other materials including archives of training materials, resources on topics of interest and a way to invite the report author to deliver a presentation in person or by a synchronous webinar.
1.2 What is a public health problem and why are counterfeit goods one?

The focus in this report on “the public’s health and safety”, “public health” and the “health of the public” is intended to mean society at large and population health as understood within the discipline of traditional public health. While in most countries, the US being a notable exception, the phrase “public health” encompasses the entire health system, this reference is centrally concerned with public health interventions at the “population level” to improve health – compared to health care or services directed at individuals, such as hospitalization, doctor visits and the like, and the health care system in which care is sought, provided and financed. Population level interventions consider the experiences of groups of persons with a common denominator, such as disease type, age, or residence. Animal and plant health is also part of public health due to the importance of animals and plants for food. Public health is also concerned with sanitation and water quality and quantity.

Public health practice is generally one function of the ministry of health; its main activities are to collect health statistics such as vital statistics. Techniques such as sentinel surveillance are used to monitor and evaluate what is happening with the health of the public or some sub-population. Health statistics are robust data, given their uniformity achieved from global standardization and identified in the International Classification of Diseases (ICD). The ICD groups health data according to just three disease categories: chronic, infectious and injury. From this data collection, causes of death or injury, reasons for hospital and doctor visits, and the costs of health care based on health insurance coding for health care services are quantified, along with other useful information. Increases and decreases in categories are monitored as these data inform health authorities about the status of the health of the public, such as whether there is a new disease, an epidemic or other condition. And these data are used to establish a baseline from which periodic comparisons can be made and interventions assessed.

Thus the public health department can identify a public health problem because it has the capacity to perceive a problem typically when a change is observed. A change can take any number of forms, such as when an unknown disease is identified or when a disease incidence spikes or is no longer treatable by a previously reliable method. In the case of a counterfeit, a person, plant or animal can become “diseased” – typically an injury by a
product that otherwise should not cause harm. Just about any product has the potential to be harmful to individual humans, animals or plants when counterfeited.

Most diseases from exposure to counterfeits would likely fall under the disease category of injury caused by ingestion or use of counterfeit foods, personal care products, medicines, alcohol, and tobacco, or counterfeit auto brakes that lead to crash trauma. The injury could be poisoning, cuts, burns, or wounds from trauma, and fit more precisely in the sub-category of unintentional injuries. The second sub-category, intentional injury, is not likely to yield much data. Counterfeits can also cause chronic diseases or impairments, such as blindness that results from an initial injury or other effect. Theoretically, any product could cause harm directly or indirectly.

Injuries, therefore, are the best window on the problem. Since injuries are not coded by whether there has been exposure to a counterfeit, at best injury data can only be extrapolated to suggest the scope of the public health problem. Nonetheless, injury data present a compelling case that counterfeit goods are a public health problem. Global health data convincingly establishes that all injuries are responsible for 10% of all deaths and 12% of all morbidity or disease.5

Extrapolation of US data on unintentional poisoning data from 2007, the last year for which US national health statistics are complete demonstrates the enormous burden that is in part attributable to counterfeit goods. This injury is the leading cause of death for males and females aged 35 to 54 in the United States.6 The loss of the family wage earners in this age cohort puts surviving family members on a path to poverty. Unintentional poisonings are also a leading cause of death for younger persons, ranking seventh for ten- to 14-year olds, third for 15- to 24-year olds and second for 25- to 34-year olds. Further, the category of all non-fatal unintentional injuries such as burns, cuts, electric shocks, auto and industrial accidents, any one of which could be an injury caused by exposure to a counterfeit, resulted in over 25 million emergency room visits. This number represents

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nearly 22% of all the 115.3 million emergency room visits in 2005, with related medical costs of over $32 billion and costs from lost work of over $98 billion.\(^7\)

Despite this worrisome body of data, as late as 2009, when the US Centers for Disease Control (CDC) conducted a meeting to discuss E-coding issues and make suggestions for improvements, the final report failed to mention injuries related to counterfeits.\(^8\) With no separate coding that identifies injuries resulting from exposure to counterfeit goods, we have no idea how many emergency visits, dollars spent, or lost wages resulted from exposure to counterfeits. Moreover, non-specific “dump codes” for injuries described as “accidental exposure to other and non-specified factors” remain on the books of the tenth version of the ICD, the global standard for coding health data. At a time of tremendous financial pressure on health care systems everywhere, a simple change to coding could lead to significant useful data on which to establish baselines and measure the results of interventions. It is time to code for exposure to counterfeits. Otherwise, measuring the effects of counterfeits on health and any interventions will remain impossible as no baseline can be drawn against which to measure progress.

2.0 METHODOLOGY

A literature review was conducted to locate relevant materials and available data, including anecdotal evidence, media reports, Internet and public press media, industry and trade association releases, organization and government reports and studies of any level of scientific rigor on any type of actual human, animal or plant harm associated with any type of counterfeit good. Overall, this study as a ten-year follow-up to the first study published in 2003 is limited to data for the years 2000-2010 as the 2003 study reported on data up to the year 2000. The search was limited to English-language reports, or reports translated into English, and conducted worldwide. Database searches were conducted under the terms “counterfeit goods and health,” “counterfeit drugs and injuries” or “adverse effects,” “injuries and fakes,” and other synonyms for counterfeit.

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\(^7\) Id. See also Centers for Disease Control, National Center for Health Statistics. (2007, June 29). National Hospital Ambulatory Medical Care Survey: 2005 Emergency Department Summary, Advance Data from Vital and Health Statistics Number 386.

\(^8\) Recommended Actions to Improve External-Cause-of-Injury-Coding in State Based Hospital Discharge and Emergency Department Data Systems. [http://www.cdc.gov/injury/data/ecd_report.html](http://www.cdc.gov/injury/data/ecd_report.html). Retrieved March 11, 2011. E-coding, or external-cause-of-injury coding, is the use of codes to identify the specific cause of death or injury in hospital documentation, etc.
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To the extent possible, the search was for data or other literature that was based on a direct linkage between a counterfeit good and harm to humans, animals or plants. For this purpose health statistics were examined. Law enforcement data in the form of seizure data was also considered; even though this data is problematic, it is better than most data for some purposes. Economic data was not considered. Economic data such the Business Action to Stop Counterfeiting and Piracy (BASCAP) econometric models from which 2008 estimates that counterfeits cost G20 governments and consumers $125 billion and the loss of 2.5 million jobs while significant and troublesome, these data are not capable of being translated in a meaningful way to an effect on health.9

Once resources were collected, the data, findings, and observations were grouped into coherent categories for reporting, discussion and conclusions. A full list of Sources for this study is available at Annex 1.0.

3.0 RESULTS

3.1 What is being counterfeited?

Available data yielded no surprises on the types of products reported as counterfeit for the past ten years. The items are remarkably similar to those identified in the 2003 report, and continue to include a range of products that could cause harm to humans: eyewear, pharmaceuticals, foods, and industrial items such as ball bearings (which are now included in a category of critical technologies). The respective rankings by value and number of cases have changed, and due to more granular data reporting, the provenance of particular items can be charted. It is now also possible to know which countries are the sources of counterfeits, net exporters or leaders in the production of certain counterfeit products. For example, the data clearly indicate that India is a lead exporter of counterfeit pharmaceuticals. There is a greater diversification in the types of goods that are being counterfeited, as well as the production of labels and components for fake products.\(^\text{10}\)

Exactly as reported in the Daily Champion newspaper, one woman’s account alone tells the story.\(^\text{11}\)

“Recounting her experience Mrs. Morufat Shittu said “fake drug almost took away my life, I had catarrh so my father advised that I should go for malaria treatment, as malaria at times come with such symptoms, little did I know that I had taken fake drug. Instead of recuperating, my facial skin started peeling and as day goes by, it was becoming more irritating until I visited the General hospital where it was diagnosed that I took fake drug.” She went on to say, “In order to maximize their profits outside the borders of legality, they use raw materials that are cheap or even prohibited by international laws, materials that are dangerous to the health. That is the reason our homes are flooded with toothpaste containing anti-freeze. There are also toxic tomato sauce and low-quality rice.”

3.2 Counterfeiting is a global problem and plagues every country

That counterfeiting is a global problem is not news. What is news is the increased number of countries, especially developing countries that have taken action or reported


problems. In this review more than 50 countries are actively engaged in counterfeit interventions as compared to about 15 in the 2003 report. If the member states of the various economic communities could be counted the total of countries would exceed 100. It is also significant that of the 50 countries, more than 60% were developing countries. This number of countries listed on Annex 2.0 is proof that there is growing acknowledgment that interventions are being sustained.

3.2.1 Counterfeitingers are found all over the world, but there seem to be more counterfeit products from some countries than others

China continues to be the top source country for Intellectual Property Rights (IPR) violations – as it has been for the last 10 years – accounting in the United States for 66% of all IPR seizure value for FY 2010. It is followed by Hong Kong, Jordan and India. The majority of counterfeit pharmaceutical shipments with values in excess of $1 million that are seized in the US originate in China, Hong Kong and India. The majority of counterfeits entering the European Union (EU) originate in China, United Arab Emirates (UAE), Taiwan, and Turkey. Other notable origin countries include Indonesia, the Philippines, Thailand, Argentina, Brazil, Canada, India, Israel, Korea, Malaysia, Russia, Ukraine, Vietnam and even the United States. These data demonstrate how global a problem counterfeit trade has become.

3.2.2 Seizure data and a new category highlights harmful products

There have been changes to how seizure data are grouped for analysis and reporting. For example, in 2010, the US Immigration and Customs Enforcement (ICE) began to designate some commodities as “consumer safety and critical technologies” (CSCT); these products include cigarettes, electrical articles, critical technical components (such as ball
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bearings), pharmaceuticals, eyewear/parts, exercise equipment and other commodities. CSCT represented 23% of overall seizures by value in 2010.\(^{16}\) Cigarettes represented 21% of this total, electrical articles 19%, critical technical components 18%, pharmaceuticals 13%, eyewear/parts 8%, exercise equipment 7%, and all other commodities 14%. On a positive note, the percentage of the total that pharmaceuticals represented dropped significantly in 2010 from 34% in 2009. However, counterfeit ball bearings increased seven fold in total value of items seized. The statistics for EU seizures of counterfeit goods are fairly similar. Those products that could cause human harm accounted for 18% of all seizures and included foods and beverages, body care items, medicines, electrical household goods and toys.\(^{17}\) Counterfeits are transported via air, post and roads and are most often discovered during import procedures – about 85% of cases. Trademark violations remain the type of right violated most often at 85% of cases.

### 3.2.3 Counterfeit agricultural and veterinary products\(^ {18}\)

Since the 2003 report, there has been an increase in cases of counterfeit pesticides, human and pet food, import documentation and stamps and certification of products as organic. Such products are harmful to human and animal health in a number of ways. Like other counterfeit products, there may be too little or too much of the active ingredient – or there may be no active ingredient at all. In other situations, the ingredients may be toxic. These noncompliant mixtures have caused damage to crops and the environment by leaving residue in soils or on plants, which can subsequently have detrimental impacts on human and animal health. Since global food production is under pressure given the growing population, any interference with crop production has implications for public health. Agricultural product-related counterfeiting also extends to counterfeit labeling and packaging.

The US Global Agricultural Information Network (GAIN) Database contains reports on efforts to reduce sales of counterfeit Russian caviar, Italian food and improve Chinese regulations to combat against counterfeit products.\(^ {19}\) In addition, there have been several

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\(^{16}\) Supra note 10.
\(^{17}\) Supra note 14.
\(^{18}\) The materials here on fake veterinary products were contributed by Adam Gibbons, a third year law student at Widener School of Law as part of an externship project at the US Dept. of Commerce.
reports on counterfeit pesticides published by the European Crop Protection Association and the University of Florida Institute of Food and Agricultural Sciences in which the problem is highlighted and solutions are proposed.\textsuperscript{20} Even flea-and-tick collar products included as pesticides are being counterfeited.\textsuperscript{21} Data point to China as the main exporter of counterfeit pesticides, with 60% of seizures originating there.\textsuperscript{22}

Law enforcement has been active in pursing pesticide counterfeiters. In one such case, the offender was sentenced to 41 months in prison and required to pay $45,305 in restitution for selling counterfeit pesticides for mosquito and West Nile virus control.\textsuperscript{23} This case was investigated and prosecuted cooperatively by the US Environmental Protection Agency (EPA), FBI, Justice and the Departments of Agriculture and Industry in the state of Alabama, where the product had been sold. More recently, in early 2011 the USDA released evidence of a Chinese firm’s attempted fraudulent use of a counterfeit certificate to represent products as organic when, in fact, they were not.\textsuperscript{24}

Much like drugs for humans, drugs for animals are counterfeited throughout the world. In 2007, it was estimated that as much as one-fifth of the veterinary drugs tested in China were substandard or counterfeit.\textsuperscript{25} In an investigation by China’s Ministry of Agriculture, it was found that there was a large problem with “underground dens selling fakes.”\textsuperscript{26} This ranged from drugs with fraudulent government approval to drugs already banned in China. Even more dramatic are the counterfeit troubles in Africa. As recently as April 2011, “counterfeit and substandard [veterinary] products [were] still being imported” to Kenya.\textsuperscript{27} The FAO and the WHO estimate that “at least 80 percent of veterinary products sold in Africa do not meet international standards.”\textsuperscript{28} Complicating the global problem with counterfeit and substandard vet drugs are Internet sales where criminals attempt to “sell
unapproved pet drugs and counterfeit pet products, make fraudulent claims, dispense prescription drugs without requiring a prescription and sell expired drugs.”

3.2.4 Counterfeit motor vehicle parts

Due to the extreme damage that can result from the malfunction of a mechanical component when a vehicle is traveling at high speeds – and the fact that this injury can occur repeatedly when that inferior product is installed in hundreds or thousands of cars – counterfeit motor vehicle parts pose a serious threat to human health. Counterfeit parts, such as brakes and brake pads, brake fluid, tires, structural parts and automotive lighting, remain a major global concern and cost the global industry an estimated $12 billion a year. Consumers often have little control over their use of the dangerous product as they rarely see the product they’ve purchased. It is often selected during assembly or repair and goes straight into the vehicle. Most times, drivers do not become aware of counterfeited parts until a warranty claim is submitted. Counterfeit auto part makers have moved from making cosmetic auto pieces to creating fake safety components (e.g., brake pads), which put consumers and other motorists at risk. It has been estimated in Saudi Arabia alone that fake auto parts take 3,000 lives every year.

3.2.5 Counterfeit toys

Toys are yet another type of product that is frequently counterfeited and can cause extreme harm, most often to children. Poor quality may cause toys to break, resulting in sharp edges or small parts that children may swallow and then choke. Toxic chemicals used in production may cause harm following exposure or accidental ingestion. Electronic toys

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33 Supra note 30.
may cause burns or shocks.\textsuperscript{35} Compounding these concerns is the fact that toys are designed to appeal directly to children, increasing their contact with and use of these potentially harmful products.

US Customs and Border Protection (CBP) seizes large quantities of counterfeit toys on a regular basis. In October 2009, CBP officials seized $1.6 million worth of toys found in commercial shipments entering the US. The shipments contained 3,000 battery-operated vehicles. Had these products, which were designed for children to ride, found their way into homes across the country, their poor quality could have significantly injured numerous children.\textsuperscript{36}

\textbf{3.2.6 Counterfeit clothing}

As clothing is worn on the body, there is significant potential for harm when these products are counterfeited. Articles of clothing purchased online – especially those at extremely low prices – may often be counterfeits. These products may be manufactured with toxic or substandard materials, such as counterfeit jackets stuffed with chicken parts. Other times, the performance may be impacted. Jackets that are designed to protect against extreme cold when properly manufactured may result in hypothermia or frostbite when consumers relying on these claims inadvertently purchase a counterfeit version of that jacket.\textsuperscript{37}

\textbf{3.2.7 Counterfeit electronics}

Demand for low-priced electronics is high, and counterfeiters have used this opportunity for flooding the market with substandard goods that can result in serious injury or even death when they malfunction. Due to their popularity with consumers, products like cell phones, iPods, stereos and televisions are frequently counterfeited. Fake electronics may include substandard components and may be labeled with counterfeit

\textsuperscript{37} Cheap knockoffs and counterfeits can be hazardous to your health. Daily Finance. (2011) \url{http://www.dailyfinance.com/2011/06/17/cheap-knockoffs-and-counterfeits-can-be-hazardous-to-your-health/}. 
labels certifying their safety. Resulting injuries may include overheating, fires, and explosions.

### 3.3 Counterfeit Pharmaceuticals and Medical Products

The problem of counterfeit medicines is not limited to lifestyle drugs – which became ready targets once products like Viagra hit the market. Counterfeit essential medicines and medical products, generic, branded and patented medical products such as antibiotics, are discovered from Texas to Hanoi. Generic medicines are not counterfeits. Indeed, unfortunately generic medicines can also be counterfeited from an IP perspective if trademarked and otherwise falsified. Indeed for a well known company such as Cipla, the name itself is a trademark within the common law meaning of the word. If the name is registered as a trademark under Indian law, a falsified Cipla product is also a counterfeit Cipla product in the IP sense. Just as bad if not worse, there are non-IP ways to defraud consumers with the false presentation of information on source or identity. Though not necessarily counterfeit in the IP sense, falsification is as much of a public health problem. This subject of the nomenclature of counterfeit medicines is treated elsewhere in this paper and is the topic of an ongoing global debate.

Medicines, essential or otherwise, are a critical element of a health system because medicines are used to treat and prevent disease. It is axiomatic that counterfeit medicines pose a serious public health problem. Counterfeit medicines were identified by US CBP as constituting the greatest percentage of all seizures in 2009. SiteJabber, a consumer protection service funded by a grant from the National Science Foundation created a graphic (see Annex 4.0) on the size and growth of the international counterfeit drug industry measured in dollars. This graphic supplements industry estimates that the number of counterfeit drug incidents tripled worldwide between 2004 and 2009. In 2002, the WHO estimated that 10% of the global medicines supply was counterfeit, but has not released another estimate since then. As stated by Prof. Dr. Paul Newton, “Even 1% of essential medicines being of poor quality is a severe public health problem.”

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The topic deserves a study of its own given its importance to health. In order to highlight this critical dimension of the subject of counterfeits and health, each part of this paper devotes a section to the topic and how legislators, regulators, and enforcement officials are addressing counterfeit medicines.

### 3.3.1 Why are counterfeit medicines a public health problem?

Medicines are intended for use in prevention, diagnosis and/or treatment. No health system anywhere can function successfully without reliable medical products, including medicines for human and animal health. Medicines include branded and generic products and over-the-counter and prescription items; these products come in a variety of forms, including pills, injectables, solutions, sprays, powders, vaccines, etc. All of these forms can be, and have been, counterfeited. When medical products are counterfeited, patients and consumers do not receive the intended benefit and, in some case, instead are exposed to a toxin that may cause illness or death. There is now sufficient evidence to confirm that counterfeit medicines are associated with multidrug resistance for certain diseases including malaria, TB and HIV among others. Patients facing a multidrug resistance form of some diseases have no alternative medicines to try.

No serious dispute exists regarding the problem that counterfeit medicines pose, yet due to a lack of rigorous data collection efforts, an exact quantification of how much of the medicine supply is counterfeit remains elusive. Industrialized countries with effective regulatory systems and market control (e.g., Australia, Canada, Japan, New Zealand, most of the EU and the US) estimate their incidence of counterfeit medicines as extremely low – less than 1% of market value whereas in many African countries, and in parts of Asia, Latin America, and countries in transition, a much higher percentage of the medicines on sale may be counterfeit.41 To date, no government or other agency has designed a good tracking mechanism. Though current data is not particularly robust, there is enough information to determine that a serious problem exists -- so much so that the matter is referred to as a “crisis” by many. And the number of initiatives related to counterfeit medicines suggests there is consensus that there is a problem, though there is no agreement on what to do about it.

41 World Health Organization. (2010). Fact Sheet N°275 [Fact Sheet].
3.3.2 Focus on counterfeit anti-malaria medicine

The most robust and therefore conclusive studies have been on anti-malaria medicines, in particular artesunate in Southeast Asia. Early studies pointed to a significant presence of counterfeit malaria medicines followed by more recent studies that demonstrate a 15% increase in just three years. Counterfeit anti-malaria medicines are partly to blame for the increased drug resistance in India and Southeast Asia. A January 2011 study by WHO on anti-malaria drugs in sub-Saharan Africa demonstrated that 11.6% of the products reviewed showed extreme deviation from specifications and 28.5% were noncompliant with specifications. Though the type of data collected for this study were insufficient to allow for significant conclusions on how many of these products were counterfeit, results did show that at least 40% of the malaria supply is insufficient to achieve the desired treatment effect. Given all that is known about counterfeit malaria medication, it can be concluded that a sizeable percentage of the drugs that do not meet specifications are indeed counterfeit.

Malaria in and of itself is a disease of endemic proportions. In some regions, such as Southeast Asia and the “malaria belt” in Africa, adults and children suffer the disease several times a year, burdening already strained health systems. Thus, counterfeit artesunate poses a great threat due to the nearly universal resistance to the earlier therapy chloroquine, and growing resistance to sulfadoxine-pyrimethamine, the second treatment mainstay.

This multi-drug resistance has positioned artesunate as the only available anti-malaria drug in some situations. One strain of malaria, Plasmodium falciparum, has become resistant to numerous medicines previously used to treat it. As victims develop resistance to a drug, they are left with fewer and fewer treatment options. Widespread counterfeiting of the remaining option, artesunate, has now caused the death of many people suffering from malaria who would have otherwise survived. Artesunate is a terrific criminal target because of its relatively higher cost and the size of the market in malaria high-burden


\subsection*{3.3.3 The future for counterfeiters is bright if we are not careful}

Malaria is not the only disease for which evidence establishes a link to counterfeit medicines and other products used in health, such as bed nets and repellant products, and those that support health, such as foods. Drug resistance has been charted globally also for HIV, pneumonia, shigella, MDR-TB, and MRSA with documented examples. In fact, the link has become so clear that the WHO has noted that counterfeit drugs are, in part, \textit{the cause of disease resistance in these diseases}.\footnote{Center for Global Development. (2011). Documented Examples of Drug Resistance by Disease. \url{http://www.cgdev.org/section/initiatives/_active/drugresistanceglobalhealth/drugresistance}. Retrieved April 5, 2011. An on-line interactive chart presents data on the prevalence of resistance and demonstrates the widespread nature of this growing problem. See also, World Health Organization. (2011). Regional Director’s message on World Health Day, 7 April 2011. \url{http://www.afro.who.int/en/rdo/speeches/2834-message-of-the-regional-director-on-the-occasion-of-the-world-health-day-2011.html}. Retrieved April 7, 2011.} A similar pattern of necessity and cost exists for these high-burden diseases for which some second- and third-line treatments are available only at higher cost. And for many diseases there is no second- or third-line treatment. On top of this sobering reality now runs another wave of health burden from non-communicable or chronic disease (NCD). An increasing number of countries are facing the double burden of infectious disease and NCDs. There is such great concern about NCDs that the UN held the first summit on the matter in September 2011, taking the topic to the entire General Assembly, rather than just the WHO. The specter of NCDs – such as heart diseases, stroke, diabetes and cancer – now accounts for two-thirds of all deaths globally due to population aging and the spread of risk factors associated with globalization and urbanization, particularly lifestyle factors such as diet. The demand for treatments will continue to rise, making opportunity for a profitable global business for counterfeiters if vigilance is not sustained.
4.0 LEGISLATION

Since 2000 there has been a significant number and variety of international, regional and local legislative initiatives to combat counterfeits. Initiatives have mainly focused on law enforcement measures and counterfeit medicines, adding features that reflect the collective wisdom of regulators and confirming the findings of a recent study on what regulators want. Innovative provisions have been devised in two regions and demonstrate a trend toward a more comprehensive legislative approach that addresses any counterfeit product that can or does cause harm to humans, animals and plants. This approach addresses counterfeits by broadening the legislative scope to encompass substandard and illegal products. Thus, the acronym “SIC” is coined to indicate a product that when substandard, illegal or counterfeit can cause harm to humans, animals or plants.

4.1 International legislation and agreements

The most significant of the international activities has been the international Anti-Counterfeiting Trade Agreement (ACTA), the final draft text of which was completed in November 2010. The agreement establishes an international law enforcement framework to address the global proliferation of commercial-scale counterfeiting and piracy by deepening international cooperation and enhancing enforcement practices. ACTA participants include Australia, Canada, the European Union (EU), EU Member States, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland and the United States of America. [Please see author’s note regarding the status of ACTA and this section of the report at footnote49] The participants represent many of the countries that are key destinations for counterfeit products of all types. Some ACTA measures as they stand now are protective if public health, others could be adapted to be more protective of health without reducing the value of the law enforcement measures of ACTA or integrated into national counterfeit plans even if ACTA is not adopted. The discussion that follows considers these points.

49 Author’s note: On July 4, 2012, the European Parliament rejected ACTA. The rejection precludes any member to separately enter into ACTA. Without EU participation, the likelihood of this agreement entering into full force and effect is unknown. All of this section of the report on ACTA was written before the vote. A decision was made to leave the content in this report for later reference. European Parliament News http://www.europarl.europa.eu/news/en/pressroom/content/20120703IPR48247/html/European-Parliament-rejects-ACTA
4.1.1 ACTA has no role in the absence of IP components

The text states clearly that ACTA only applies to intellectual property rights as they are recognized under the law. Thus, any other product, such as “fake medicines,” that may have a health consequence would not be covered by ACTA if there is no associated IP right. This factor may have little effect on the debate that has raged in the last few years over the nomenclature of counterfeit medical products, the manner in which nations enforce IP rights against medicines, and the scope of the work of the WHO on counterfeit medicines. Currently, a vernacular is proposed to describe products that historically have been called "counterfeit medicines". Terms like “fake medicines” and “adulterated medicines” are either adopted or proposed to describe problematic medicines in ways other than with intellectual property rights references. If health system regulators and related law enforcement officials are sufficiently empowered, in theory they should be able to combat suspicious medical products without reference to an IP dimension and instead rely on marketing authorization, registration, packaging and labeling requirements, and quality standards. The problem is however those regulators are not empowered and are otherwise hampered in their ability to manage the quality of medical products. Fortunately IP Law enforcement measures are available to police suspicious medical products where health regulators fail and it is critical that these remain in place.

Moreover, concerns over IPR seizures may not be quelled even though ACTA does not apply unless an intellectual property right exists under national law. Since trademark violations, which are subject to ACTA, continue to be the predominant type of IP that is counterfeited and generic medicines and other consumer goods can be and are trademarked, products relevant to health will remain in the seizure loop.

4.1.2 Burden of proof protects health

The burden of proof requirement of Article 17 will help avoid the seizure of non-counterfeit goods. Under ACTA, before competent authorities may impose a detention

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50 Id. See art. 3(2) that states: This Agreement does not create any obligation on a Party to apply measures where a right in intellectual property is not protected under its laws and regulations.
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procedure at the request of a right holder, a burden of proof must be met to establish a
prima facie case of infringement. This recognition of rule of law principles bodes well for
the protection of public health as preliminary results of a recent study indicate that respect
for rule of law is a predictor of access to medicines.52

4.1.3 Commercial scale defined

Prior to ACTA, there was an insufficient definition of the phrase “commercial scale”
from the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) in its
provisions on compulsory licensing and the application of criminal sanctions. The ACTA
definition brings more clarity to what is or is not commercial scale. This is important as
TRIPS and many national IP laws permit compulsory licenses for non-commercial public
use. Compulsory licenses have been used for medicines and will become more prevalent in
food- and water- saving technologies as food and water become scarcer in the next 20 years,
and debates increase around food and water access -- both even more essential to the
health of the public than medicines. Moreover, in ACTA, commercial scale counterfeit label
and packaging activities are criminal are now defined as a criminal offense. These aspects
of a product are subject to health and safety regulatory control and are the very visual
features used to dupe consumers into buying counterfeit consumer products. Criminalizing
these activities is protective of health.

4.1.4 Recognize society as a participant when implementing ACTA

ACTA Article 2(3) echoes General Agreement on Trade and Tariffs (GATT) Art. 20(b)
and TRIPS Articles 7 and 8, which set the precedent that public health may be considered in
national implementation and practice. When a country considers ACTA Article 6(2) that
states:

“Procedures ….. shall be fair and equitable, and shall provide for the rights of
all participants…..

There is nothing in ACTA that would preclude a state party from interpreting “all
participants” to include the public’s health because actual or potential harm linked
to counterfeits can have a population level health effect. Just as society holds the
position of the aggrieved party in the criminal law system, the public’s health or the

WHO as a research paper. Original manuscript on file with author.
health of society can be so acknowledged in law enforcement measures at implementation. Doing so will strengthen the rationale for implementing the ACTA or any of its provisions. This interpretation is supported by the numerous exceptions for health in trade law such as the GATT 1947 Art. XX (b), the preambles to TRIPS in Art. 8 and in the SPS and in other international instruments and national constitutions that obligate governments to protect the health of the public. Protecting the health of the public is always done at a population level even if a country also is the provider of health care to individuals. Thus all participants refers to the public’s health.

4.1.5 Health considerations and proportionality

ACTA addresses the concept of proportionality. An article 6(3) implementation could reference the public’s health as a party in interest:

In implementing the provisions of this Chapter, each Party shall take into account the need for proportionality between the seriousness of the infringement, the interests of third parties, and the applicable measures, remedies and penalties.

Many products used or consumed by humans and animals are products of low cost or value, and while the right holder may not suffer a great financial loss, the collateral damage to population health from counterfeits can be quite significant. When counterfeited, inexpensive items such as anti-malaria products (bed nets are an example), toothpaste, and food stuffs result in costs to the health care system and to the household, including lost wages and a decline in economic status at the family level as described earlier. A determination of proportionality should include the public’s health within the notion of interested parties. The example of counterfeit vaccines is illustrative of this population
concept.\textsuperscript{53} Thus, whenever a product can or does have a health effect, imposing more severe measures, remedies and penalties can be done without risking claims that these lack proportionality.

### 4.1.6 Mandate destruction if health at risk

The scope of ACTA Article 10.1 can be expanded to support public health. It states:

\textit{At least with respect to pirated copyright goods and counterfeit trademark goods, each Party shall provide that, in civil judicial proceedings, at the right holder's request, its judicial authorities have the authority to order that such infringing goods be destroyed, except in exceptional circumstances, without compensation of any sort.}

If goods have the potential to harm humans, animals or plant life, the destruction of the offending goods should not be at the option of the rights holder. Rather, to protect health, destruction should be mandatory to eliminate the risks the infringing goods pose.

At implementation, Article 10.2 offers another opportunity to enhance protection of public health. It states:

\textit{Each Party shall further provide that its judicial authorities have the authority to order that materials and implements, the predominant use of which has been in the manufacture or creation of such infringing goods, be, without undue delay and without compensation of any sort, destroyed or disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements.}

At the time of legislative implementation of Section 10.2, the provisions of “or harm to public health” could be added. Such an addition would not only prevent the possibility of counterfeits finding their way back into the stream of commerce, it would also eliminate a risk to health and thus be protective of health without reducing the overall benefits of ACTA.

### 4.1.7 Expedited process for health products and consignee compensation

Another appropriate place to consider public health during implementation of ACTA is found in Article 12 on provisional measures. During implementation states will consider whether implementation requires new national legislation, or whether some form of sub-national legal or policy instrument used is necessary to interpret or operationalized ACTA.

provisions. This depends on the situation in each country’s legal system. For example at an operational level, expedited procedural obligations in situations involving suspected counterfeits that have health uses (such as imported foods or agricultural pesticides that may have a seasonal use) would help address concerns. In the case of products used for health, any detention procedures could be fast-tracked to avoid undue delays, the consignee alerted and its needs identified so as to set parameters on how fast the procedure should be conducted. This is because in the case of foods, medicines, or other products that are for health use may have limited shelf life, or the products may be to fulfill a stock-out of essential medicines such as those used for the treatment of chronic diseases such as diabetes or AIDS. The nature of the urgency of the product cannot be determined from shipping documents – rather the consignee or buyer of the goods will have this information and will need to be contacted to obtain it. The recipient of compensation might also be considered so for example if a buyer must obtain the same goods in an urgent situation, and is forced to do so at a higher price, then there is collateral damage to the buyer who is not the IP holder or the defendant and not currently considered in the text.

4.1.8 Consignees of products for health should get assurance

In addition to costs, the other needs of the ultimate consignee should be taken into consideration in the case of products relevant to public health. Article 18 allows for the provision of a security or equivalent assurance to the right holder:

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...... require a right holder that requests the procedures ...... to provide a reasonable security or equivalent assurance sufficient to protect the defendant ......and the competent authorities and to prevent abuse.....
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The security as noted in the text is in favor of the defendant. Such goods may have a short shelf life or other storage requirements. Or the delivery date may be critical to fill a gap in a supply chain, as is the case with foodstuffs, vaccines or drugs. In the event a good has public health consequences, ample reason exists to broaden the scope for determining who are the beneficiaries of the security and the nature of what that security will be. This determination can be made by the same competent authority. Furthermore, not only are expedited procedures in order, but when ACTA is implemented what ever enabling instruments, operational guidance or otherwise are used if any, should require contacting the ultimate consignee in order to determine the relevant public health issues and gather information on how these may be addressed in terms of the security. If the item is an infringing good, the
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ultimate recipient will be able to take immediate action to find a replacement for the shipment. If the item is not an infringing good, it will be possible for the competent authority to establish a timetable and the appropriate actions for security or other assurance to avoid harm to public health.

4.1.9 No return to commerce if health is at risk

In some instances, seized counterfeit goods find their way back into the stream of commerce, a concern that must be more thoroughly addressed with regard to those products that could have negative effects on public health. In Article 20(1), the only harm currently considered is the harm suffered by the right holder:

Each Party shall provide that its competent authorities have the authority to order the destruction of goods following a determination referred to in Article 19 (Determination as to Infringement) that the goods are infringing. In cases where such goods are not destroyed, each Party shall ensure that, except in exceptional circumstances, such goods are disposed of outside the channels of commerce in such a manner as to avoid any harm to the right holder.

The concerns of public health should always be considered when goods are destroyed. At present there is at best a patchwork of applicable law and existing law and practice do not provide guidance on the destruction of counterfeit goods that when destroyed might have negative consequences to public health. Many counterfeit goods are in essence environmental hazards as many are produced with toxic content. If not properly disposed of, there can be serious environmental harm and thus injury to the health of the public when goods are not destroyed in a safe manner. Reference should be made to the relevant authority when disposing of counterfeits. In many countries the relevant authority is the environmental protection agency. The topic of safe destruction has not received much attention in the realm of counterfeits. The online training materials for this project do contain materials on this topic. Therefore, authorities must take into consideration more than just the effects on the rights holder. In the case of goods that can harm health, there should be no return to the channels of commerce, and such goods should be destroyed by methods appropriate to the type and content of the product.

The ACTA already incorporates limitations regarding destruction of goods in terms of environmental concerns in Article 32:
The destruction of goods infringing intellectual property rights shall be done consistently with the laws and regulations on environmental matters of the Party in which the destruction takes place.

Given the patchwork of national practices, it is advisable to require reference to international laws and standards for destruction if those of the Party are not aligned and comprehensive. An example of this patchwork is the US system, where the DEA (the office of national drug control) and FDA (Food and Drug Administration) are responsible for such efforts, but the Consumer Product Safety Commission (CPSC) has no role in the destruction of counterfeit goods. Counterfeit goods are rightly classified as environmental pollutants or hazardous materials and should be treated as such when disposed or destroyed. Oversight of proper handling and disposal of counterfeited goods is best accomplished by a designated officer within a competent authority, likely the environmental pollution agency, who is a technical expert and required to comply with international laws and standards.

4.1.10 Ex officio procedures

An outline of procedures for the investigation of criminal offenses is in Article 26 of ACTA and states:

Each Party shall provide that, in appropriate cases, its competent authorities may act upon their own initiative to initiate investigation or legal action with respect to the criminal offences specified in [previous paragraphs] for which that Party provides criminal procedures and penalties.

Given that actual or potential harm to the health of the public or any individual is a social harm, the addition of ex officio authority to all relevant authorities is protective of public health. Indeed, when there is harm or potential health harm, competent authorities should be required to pursue ex officio action and be mandated to refer for criminal prosecution those instances of counterfeiting that begin as civil matters. How this would be operationalized depends on local practice.

4.1.11 The Internet

Due to the significant use of the Internet as a platform for a large number of transactions, including criminal acts, the ACTA includes a lengthy section addressing
enforcement in the digital environment. There is significant work to be done to slow the
growing use of the Internet as a mechanism of counterfeit trade.

4.2 Regional legislation

Regional bodies have taken legislative actions that have run concurrently with
national legislative efforts. This was the case in particular in the East African Community
(EAC), which developed a draft law and policy on anti-counterfeiting that could supersede
national legislation and harmonize law within its members. Its members have also taken
notable steps in developing national agendas. In 2009, Kenya passed its Anti-Counterfeit
Law, which has been mirrored by Tanzania, Uganda and Zambia.

These laws grappled with the challenge of defining a counterfeit in a way that would
capture all types of goods without risking seizure of generic medicines. Zambia’s draft law
addresses the issue of distinguishing between counterfeit and generic medicines by a clear
statement that generics are not counterfeit— a distinction missing in the Kenyan law that
drew strong complaints from critics and Uganda uses a dual-definition approach starting
with the general definition that counterfeiting means without authority, as does the EAC
draft, and adds another for medicines. It states:

In the case of medicines, includes the deliberate and fraudulent mislabeling of
medicines with respect to identity or source, whether or not such products have
correct ingredients, wrong ingredients, have sufficient active ingredients or have fake
packaging.

Theoretically, this approach gives an extra basis for law enforcement to capture counterfeit
medicines. In comparison, Tanzania’s draft, which creates a specific criminal offense for
counterfeiting, allows the Chief Inspector to refer a case to prosecutors for violations of a
law banning imports and exports that endanger public health or safety. Tanzania is the
only one of the EAC countries that refers to health and safety issues and thus recognizes a

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57 Supra at 46.
59 Tanzania Law: Part VIII - Sanctions and Payment of Fines § 50
risk to health as criminal behavior. This deterrent approach is thought to be useful to combat counterfeit actors. Any deterrence will in the end protect public health.

The provisions of the EAC and national laws as a whole are a comprehensive body of anti-counterfeiting measures. Even if not all are adopted in each country, the trend is positive. Most notable are the designation of inspectors, the grant of powers to them and the scope and definition of a counterfeit. The Kenyan and other EAC regional laws provide these powers to regulators (especially to inspectors), the absence of which has previously impeded their ability to police counterfeits. (A detailed side by side analysis of the EAC and member draft laws is included at Annex 3.) This provision fulfills several of the critical needs identified by regulators in a recent survey.60

Consistent with what regulators said in the WHO study, the EAC region is very active in strengthening its regulatory infrastructure overall giving inspectors and regulators the powers that will enable them to better do their jobs. The new national anti-counterfeit legislations, while not solely focused on medicines, are being enacted as the region also moves towards a harmonized regional medicines regulatory system as organized by NEPAD and the EAC secretariats. The combination of both IP-counterfeit focused and regulatory-strengthening legislation should improve prospects for controlling harmful counterfeits and present a model for others.

4.3 National legislation

4.3.1 The Kenyan 2009 law and related law suit

In the same year it was enacted, a 2009 court case stayed the implementation of the Kenyan anti-counterfeit law. The case involves three persons living with HIV seeking to have the law declared unconstitutional, claiming that the definition of a counterfeit could be confused with generics.61 The main claim was that section 2 of the law could lead to generic medicines being seized as counterfeit goods. On April 20, 2012 the High Court of Kenya struck down section 2 on the basis that the lack of clarity in the definition could lead to incorrect seizures. The Court directed the state to revise the definition of Section 2. This is

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the only part of the law the court overturned. It remains to be seen how the Kenyan government will handle the new definition and whether it will delay the implementation of the other aspects of the law that remain in effect. Otherwise, regulations were issued in August 2010 with forms and refinements to procedures for filing a complaint, seizures and inspection.62

4.3.1.1 Prohibited actions

Kenya’s act begins in Section 2 by defining “counterfeiting” as any one of a set of enumerated actions without the authority of the owner of any intellectual property right existing in Kenya or elsewhere. These actions include the manufacture, production, packaging, re-packaging, labeling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner

- to such a degree that those other goods are identical or substantially similar copies of the protected goods;
- or
- (b) ... the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his license;

4.3.1.2 All inspectors are “counterfeit inspectors” and given authority

One of the impediments to law enforcement in developing countries is that health and safety inspectors may not have a full set of police powers. For example, inspectors may be able to inspect goods, but not be able to seize them, shut down a facility, or otherwise take appropriate actions when counterfeits are suspected. Kenya’s approach eliminates or minimizes possible regulatory gaps and strengthens the ability of local authorities to combat counterfeits. The Act also establishes an anti-counterfeit agency and board that has the ability to appoint inspectors.

The Kenyan law does not refer to any product in particular, allowing for the capture of all kinds of counterfeit products. Rather, it puts a focus on the process of inspection and related procedures and relies upon inspectors from all national agencies. For example, an inspector with subject matter expertise in transportation is appointed by the Act as a counterfeit inspector. The Act identifies existing officers from customs, trade and industrial development; trademark and patent examiners; seed and plant inspectors; public health

inspectors; and those inspectors appointed under the Standards Act, the Weights and Measures Act, the Copyright Act, 2001, the Food, Drugs and Chemical Substances Act and the Pest Control Products Act as inspectors under the Act. Most importantly, the act grants “police powers” to these officers.

4.3.2 United States

The US has been active since 2000 in enacting several pieces of legislation that can protect public health and combat counterfeits. The most recent 2010 Food Safety Modernization Act establishes standards, gives the USFDA the ability to hold food companies accountable for failing to prevent contamination, and requires importers to perform supplier verification, reaching back into the supply chain for better management. In addition, the act authorizes the FDA to require certification of compliance with food safety standards for imported food based on risk criteria, and gives FDA mandatory recall authority over foods and the ability to block imports from facilities that refuse FDA inspections. These new legislative measures follow the global trends of strengthening the supply chain by increasing accountability of all parties – from content producers to intermediaries – allowing sanctions and potentially barring import into the US. These measures enable authorities to more quickly identify reliable and unreliable importers.

In 2008, the Prioritizing Resources and Organization for Intellectual Property (PRO-IP) Act became law. By coordinating enforcement among different agencies under the supervision of an executive-level intellectual property enforcement coordinator known as the IPEC, the Act helps to strengthen US intellectual property laws. A top priority for the IPEC was to develop a national strategic law enforcement plan to address counterfeits by identifying structural weaknesses in the current system; ensuring information sharing across departments; strengthening the ability of other countries to protect and enforce intellectual property rights; working with other countries to develop international standards and enforcement policies; and protecting intellectual property rights overseas by working with other countries to crack down on the sale and trafficking of counterfeit goods. A work plan was issued in 2010. In addition the act enhanced penalties for IP violations.

The act mandates the US Government Accountability Office to evaluate the

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effectiveness of the work of the IPEC in combating counterfeit. As the national strategic plan was just released in 2010, no evaluation has yet occurred. Moreover, given that in 2010 the GAO reported that existing data were insufficient to quantify the problem of counterfeits as a whole, it is likely to be impossible to evaluate the effects of the actions taken under the IPEC plan. Some industry organizations, such as Motor & Equipment Manufacturers Association (MEMA), are concerned that the PRO-IP Act does not address international issues relating to counterfeit goods, including trans-shipment, border and port issues.

In 2007 the US Federal Sentencing Guidelines were amended to comply with the 2006 STOP Counterfeiting in Manufactured Goods Act. The Guidelines now specify that a base level offense is to be raised if the offense involves the conscious or reckless risk of serious bodily injury, but falls short of the broader risk to the public. The STOP act revised prohibitions against trafficking in counterfeit goods to include trafficking in labels and packaging of any type or nature if done with knowledge. This amendment is important as labels and packaging are what consumers look at before purchase.

Local jurisdictions have not been quiet on the issue in the US. New York City is considering a bill to make buying a fake a crime. Led by Councilwoman Margaret Chin, whose district includes Chinatown, the effort is designed to prevent the area from being known as a prominent source of counterfeit goods. Consumers interviewed regarding the pending legislation stated they thought it was their decision whether or not to buy fakes. If the bill passes, violators could face $1,000 fines, a year in jail, or both.

### 4.3.3 Brazil

In October 2004, Brazil created the National Council against Piracy and IP Crimes (CNCP) within the Ministry of Justice. Its objective is to implement the Council’s National Plan for Combating Piracy, based on four distinct approaches: enforcement, education, economic, and institutional policies.

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68 Efforts to criminalize the distribution of misbranded and adulterated drugs failed when introduced in the Counterfeit Drug Enforcement Act H.R. 2345 or S. 1978.
4.3.4 India

Taking steps to strengthen its often-violated intellectual property laws, India passed The Patents (Amendment) Act 2005 and The Patent Amendment Rules 2006. The new legislation introduced a product patent regime that affords protection to pharmaceuticals and agrochemicals by recognizing the end result (i.e., an actual product).70

4.4 Changes to customs laws

Some legislators have chosen to address the problem of counterfeits through non-IP-specific legislation, such as customs laws. The EAC Customs Management Act 2004 was amended in 2008 to prohibit trade in counterfeit goods with a simple amendment that added counterfeit goods to the list of prohibited and restricted good.71 Not only did Russia effect updated legislation that provides Customs Authorities with broader jurisdiction and more discretion in apprehending counterfeit goods, it joined Belarus and Kazakhstan in a Customs Union in 2010.72 Members are currently working to combine the national trademark registries into a large combined registry that is expected to be operational by 2012. Thailand has proposed legislation to address landlord liability for infringement and to enhance the authority of Thai Customs to take enforcement actions ex officio.73 The EU continues to look for ways to avoid seizure of Indian generics passing through an EU member state to Africa or Latin America. The EU has agreed to refrain from seizures of these goods in transit and to amend its Customs regulations.74

4.5 Changes to punitive measures

By strengthening penalties for counterfeiters, some countries have taken measures that aim to increase deterrents. A new Czech Republic criminal code raises the maximum penalties for IPR-related crimes from two to eight years imprisonment. The law, which came into effect January 1, 2010, also criminalizes the manufacture and storage of counterfeit items.\(^{75}\) India passed the Drugs and Cosmetics (Amendment) Act of 2008 that increases penalties for spurious and adulterated pharmaceuticals.\(^{76}\) Russia has also seen amendments of a criminal law that changed the categorization of IPR infringements (copyright and trademarks) to "serious gravity crimes."\(^{77}\)

Taking penalties even further, Vietnam, the UAE, Oman, Bahrain, Kuwait and Qatar have incorporated provisions for the death sentence into their national laws as punishment for counterfeit drug-related offences.\(^{78}\) In a landmark legislative achievement, Britain passed The Corporate Manslaughter and Corporate Homicide Act 2007, providing for corporate liability for deaths resulting from gross breaches of duty of care, including actions that contribute to fatal incidents resulting from counterfeit products.\(^{79}\)

4.6 Changes to Internet laws

Due to the increase in counterfeit trafficking over the Internet, legislators have turned their focus to this arena. These provisions encourage ISPs to cooperate with authorities in fighting counterfeit sales of harmful products online and reduce the avenues for trade available to counterfeiters.

\(^{75}\) Supra note 71.


4.7 Changes to standards laws

In 2009, the EU passed the Directive on the Safety of Toys. The new directive replaces the 1988 directive and updates safety standards to address the evolving technology in toy production. The directive places the burden of preventing the entry of counterfeits into commerce on the shoulders of manufacturers, importers and distributors. It also includes provisions to require transparency of operators and procedures. Chapter IV of the directive establishes assessment procedures to ensure that all toys being placed on the market have met the applicable standards.

4.8 Legislators and counterfeit medicines

Numerous actions taken by legislators relate to medicines or medical products and range from creating new, specific legislation to refining existing laws to better manage the problem within regulatory and law enforcement systems. There seems to be a trend, somewhat confirmed by the initial results of criminal law study, to create counterfeiting crimes in which causation is described in minimum terms of (at least) palpable dangers to life and/or health. Brazil and others chose to call this “the crime of medicines falsification”.

4.8.1 A framework convention on counterfeit medical products

In 2005, the International Conference of Drug Regulatory Authorities (ICDRA) voted favorably to take the next steps towards a framework convention to combat counterfeit medicines. A proposal for such a convention was circulated in a background paper during

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both the pre-conference and main meeting. The main elements of the proposed convention were focused on enhancing regulatory authority for the National Medicines Regulatory Agency (NMRA), ministries of health (MOH) and consumer product safety commission (CPSC). The proposal covers specific enumerations for a single point of contact within drug regulatory authorities; regulation of the supply chain; a code of good practice for drug inspections; adoption of a uniform or harmonized definition for counterfeit medicine; and enforcement of good manufacturing practices. From the law enforcement perspective, the proposal included the establishment of offenses and increase of sanctions when the public’s health is harmed. Members would also be obligated to maintain data and provide for cooperation between law enforcement and regulatory agencies. Despite the favorable reaction of medicines regulators to the convention, the idea lost in favor of a task force approach for political and other reasons that cannot be explained logically.

In 2006 the International Medical Anti-Counterfeiting Task Force (IMPACT) was formed and, despite its substantial and costly effort to illuminate a variety of good practices, it came under tremendous political pressure -- particularly in the 2010 World Health Assembly -- and has again morphed. It is now a Working Group of the World Health Assembly. It met in spring 2011 and, ironically, the idea of a legally binding instrument was raised again by some Member States. The 2011 WHA voted to have the working group continue and

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Some academics also raise a call for an international convention on the criminal counterfeiting of medicines.86

4.8.2 Standardizing the definition of “counterfeit”

The debate within the public health community regarding solutions has frequently focused on the definition of the phrase “counterfeit medicines” and, more specifically, the use of the term “counterfeit.” Opponents of the term “counterfeit” are concerned that it is an intellectual property law term and its use may place undue emphasis on the IP issues rather than public health. In response to this debate, Dr. Margaret Chan, Director General of the WHO, sought clarification in November 2009 by asking what terms Member States actually use. Member States were asked to supply their definitions of counterfeit medicines (or equivalents) as used in national legislation; a total of 65 definitions were collected and assessed.87 Not surprisingly, out of 65 country definitions, the majority (42 of 65) fell within the drug regulatory authority (DRA). Fourteen States had no definition, and ten had an IP-based definition that was independent of the type of product.88

The result of this debate at the WHO is new nomenclature: “falsified medical product.” This new terminology is public health-specific and without reference to an IP concept, although a companion definition of “counterfeit medical product,” meaning a falsified medical product with a counterfeit trademark, is included in the background document.89 Although this public health definition narrows the scope of authority of health sector authorities, it accords a wider scope of wrongs associated with the sector than what is associated with a counterfeit trademark, including misleading statements with respect to manufacturer, country of origin, marketing authorization holder, steps of distribution, name, composition, strength, or other elements. None of these elements has reference to any IP concept. This dual-definition approach had been adopted by some countries and there seems to be a trend toward this direction, as is the case in the EU discussed next.

89 EC Council Regulation 1383/2003 of 22 July 2003 Concerning Customs Action against Goods Suspected of Infringing Certain Intellectual Property Rights and the Measures to be taken against Goods Found to Have Infringed Such Rights. (See Article 2 (1) a and b)).
4.8.3 Amending existing and adding innovative legislative frameworks

The European Commission defines counterfeit good under Article 2(1) (a and b) of Directive 1383/2003, a customs regulation on the entry of products into the legal supply chain in terms of trademarks and copyrights. To distinguish infringements of intellectual property rights from medical products in customs legislation, the Commission introduced the phrase “falsified medical product” in a December 10, 2008 Proposal to amend Directive 2001/83/EC, which lays out the regulatory framework for pharmaceutical regulation. The Europeans considered this change and more to protect public health interests after an extensive study of the shortcomings in member state and European Union legislation.

In 2010, The Council of Europe Committee of Ministers adopted an innovative solution in a convention that criminalizes not only counterfeiting, but also the manufacturing and supplying of medical products placed on the market without authorisation or without being in compliance with quality requirements. Thus, the convention governs counterfeit, substandard and unregistered medicines creating a law enforcement framework that could capture all unacceptable forms of medical products.

In line with best practices, the Convention provides a framework for national and international co-operation and coordination across and between government agencies. It adds preventive measures and provides for protection of victims and witnesses, a monitoring body, and a central information point to oversee the implementation of the Convention by the States Parties.

The Convention is innovative in several other ways. Medical products are defined in Article 4 to include medicines for humans and veterinary use. The addition of veterinary products to this act is very important as good health relies on safe food sources, which are constituted in large part by animal meats and dairy. Specifically included in the Convention are excipients, active substances and medical devices. In addition, accessories, documents, parts and materials fall within the Convention’s scope. Even the term victim now includes the natural person who suffers as a result of exposure to a counterfeit, substandard or...

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unregistered product. Thus, the Convention directly demonstrates the concept that actual harm is cause for criminal action.

The Convention adopts nearly universal jurisdiction in Art.10 as it expands the jurisdiction of Member States to locations where acts are committed by Member nationals. The illegal activities typically seen in relation to counterfeits are made criminal under the Convention, including warehousing or keeping in stock and exporting counterfeit medicinal products.

The Convention also incorporates new prevention measures. The regulatory measures mandated by the Convention call for Members to establish quality and safety requirements for medical products. It also requires Members to legislate safe distribution (supply chain management). In addition to these mandates, it calls for members to take measures to train healthcare professionals, protect witnesses, promote awareness campaigns to the public, and implement methods of preventing illegal supply of counterfeit medicinal products. Members are committed to integrate measures for prevention and combating counterfeits into development assistance programs. Victims are now accorded care, compensation, and access to information about any criminal proceedings in which the perpetrator of their injury is involved.93

4.8.4 Singapore – a case study in counterfeit medicine-specific legislation

As early as 2007, Singapore had taken the same approach as the Medicrime Convention and amended its Health Products Act. The amendments include specific provisions for counterfeits, criminal and civil penalties for supply of same, and include unregistered and poor quality products.94 Health products are defined by a schedule and include pharmaceuticals, medical devices and cosmetics. Some key provisions of the Act include prohibiting the supply of health products unless registered, and fines of up to $100,000 and prison up to three years for the knowing supply of adulterated, counterfeit, or tampered-with health products.

93 Id.
5.0 REGULATORS

Of all the interventions regarding counterfeits, most fall squarely on the shoulders of regulators. As the operators of national policy and law, regulators can also be seen as the keystone between law enforcement and legislators. They refer cases to law enforcement at the limit of their adjudicatory powers but do not prosecute and inform legislatures about what legislation is needed to do their jobs. Despite their critical role, there are few studies on what regulators need to intervene in combating counterfeits and on what would be the components of a set of optimal regulatory powers.

Although medicines are not the main focus of this study, counterfeit medicines have received the most attention from all directions as the link between counterfeit medicines and health is most clear. The only studies on factors that lead to a reduction in the prevalence of counterfeit goods have been in the medicines arena, so the premise that more counterfeits are found in countries with weak regulatory and enforcement systems remains the standard. Regulators have taken actions based on their intuitive sense, professional expertise and empirical experience even if unfamiliar with the few study results. In fact, all of the innovative developments in the last ten years have occurred in advance of the release of study results. The main innovations are to capture counterfeits along with illegal and substandard products and to enhance the powers of inspectors. There have been regulatory interventions in the traditional sphere of IPR as well such as the establishment of a national IP enforcement office and cooperation arrangements between customs, finance, and/or law enforcement with common database access as examples.

5.1 What regulators need

A recent study considered what regulators need. A survey of national medicines regulators (NMRA) from 25 countries in Africa and the Middle and Near East show that regulators favor and call for specific legislation that empowers them, criminalizes behaviors around counterfeit medical products, and for legislation to control pharmaceutical trade within free trade zones. A clear majority (Annex 5) -- 23 of the 25 countries -- would welcome specific legislation on counterfeit medicines. Regulators noted weak cooperation

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55 Supra note 37.
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between them, plus police and customs as problematic; the reason for this being a lack of a legal framework for cooperation. High on the list of items that regulators indicated would improve their ability combat counterfeits were 1) more information sharing between regulators; 2) police and customs authorities; 3) more joint efforts; and 4) the identification of a single point of contact to facilitate information exchange between agencies.

There are examples of recent legislative changes that provide regulators with the powers they identified. Both the study and the legislative changes were made before the study findings were released, and are testament to the capacity of regulators to empirically determine their needs and confirming of study results. As mentioned in more detail in the legislative section of this paper, one example is Kenya’s Anti-Counterfeit Act, which establishes a regulatory agency to implement the law and grants appropriate powers to a variety of actors, such as inspectors from all product sectors. This regulatory agency will also be responsible for increasing public education and awareness, as well as to coordinate efforts to combat counterfeit trade within Kenya and with regional and international organizations.97

5.2 A three-dimensional approach to regulation

The interventions considered in this study suggest that the next phase of anti-counterfeit measures must include empowering regulators to act against any product when its IP feature is counterfeited and it can or does cause harm to humans, animals or plants. They must also be empowered if the item is substandard and illegal according to sector or products specific requirements. There is already movement in this direction in terms of auto parts, children’s goods and foods, and recent solutions, such as the EU Medicrimes Convention, to the problem of counterfeit medicines, which have criminalized substandard, illegal and counterfeit medicines. By doing so, regulators can focus on dimensions within their technical and subject matter expertise. Auto parts in Nigeria are an example. According to the Nigerian Automotive Council (NAC), the country sees some of the highest occurrences of auto accidents in the world – 66% of which are caused by tire or component failure due to substandard parts.98

There is a big market for auto parts as in Nigeria; one of

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Every four brand-new cars is abandoned or resold as a result of spare part problems. In response, the Lagos State Motor Vehicle Administration Agency (MVAA) will now rely on the dimension of legality, and has stated its policy to immediately revoke the operational license of any seller or distributor of fake auto parts.\(^99\)

The US Consumer Product Safety Improvement Act (CPSIA) has a focus on children’s products and now mandates third-party testing to ensure quality for certain children’s products and toy safety standards. These are significant advances in protecting the health of one of the most vulnerable populations – children. Also governed by the Act are labeling requirements, standards for durable nursery products and mandates for inspection of laboratories that certify products as meeting the standards. Absent these certifications, the agency can act against products as illegal. The CPSIA has other noteworthy provisions -- some of which are related to law enforcement but noted here.\(^100\)

Among them are those noted in the following text box.

- States that the legal authority of the US CPSC to halt unsafe consumer product imports,
- Requires the Comptroller General to provide legislative recommendations related to the inspection of foreign manufacturing plants and requiring foreign manufacturers to consent to the jurisdiction of US courts with respect to enforcement actions by the Commission,
- Grants State attorneys general authority to enforce certain federal product safety laws and gives them powers to stop the sale of products that violate CPSC safety standards, such as children’s products that have not been certified as tested by third-party laboratories and unauthorized use of those safety marks,
- Requires the Commission to develop a risk assessment methodology for the identification of shipments of consumer products intended for import into the US that are likely to include consumer products in violation of the Act, and
- Mandates the commission to develop a plan for sharing information and enhancing coordination with the US CBP to allow for quicker and more efficient identification of harmful products.

A 2011 law related to food granted similar regulatory powers to the USFDA in the Food Safety Modernization Act (FSMA). The agency now has more power to prevent potentially unsafe food from entering commerce by allowing it to administratively detain human or animal food the agency believes has been produced under unsanitary or unsafe conditions – both illegal and substandard.\(^101\) The previous law required a finding of credible evidence of contamination or mislabeling in such a way as to have adverse health consequences or to


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cause death to humans or animals. Now, adulterated or misbranded foods can be blocked from entering commerce whether counterfeit or not. Thus, counterfeits will be captured along with other substandard or illegal products.  

Under the FSMA, food importers are required to notify the FDA if the food they are seeking to import has been denied entry into another country.

**5.2.1 Closing gaps in regulatory powers**

In addition to intuition and empirical reflection, another strategy to identify gaps in regulatory powers and underlying legislation is to conduct assessments. However, to do this assessment tools must be based on some understanding of what should be in place. Here again, there are too few studies on which to base an understanding of what are the essential components of a comprehensive body of regulation to generally manage a regulatory agency and then to specifically address issues such as counterfeits. The US Institute of Medicine (IOM) is conducting a consensus study to identify the core elements of regulatory systems in developing countries. When done, the report could be very useful. There is an urgent need to strengthen regulatory infrastructure and for this standards are critical. To this end, an assessment tool (Annex 6) has been created based on the findings of this study. It is an outline created by assembling the elements of regulatory, legislative and law enforcement interventions from the past ten years and organizing them logically.

Regulation is strengthened by product-specific regulatory principles. Though when assembled, these principles may not result in a comprehensive package of regulation, their importance should not be underestimated. Veterinary products are an example. Here, the World Organization for Animal Health (OIE) has developed regulatory principles and continues to promote their adoption by regulators. The Terrestrial Animal Health Code also sets responsibilities of the regulatory authorities in terms of counterfeits as follows in Article 6.9.3.4

> Regulatory authorities of importing countries should request the pharmaceutical industry to provide quality certificates prepared by the Competent Authority of the exporting and manufacturing country as appropriate. All countries should make every effort to actively

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102 US Food Safety Modernization Act. Section 207 amends criteria for ordering administrative detention of human or animal food in section 304(h) (1) (A) of the US Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(h) (1) (A)).

Global standard setting is a most efficient means of translating scientific understanding into regulatory principles and standards. This is despite the difficulty in achieving standards strong enough to do anything and flexible enough to take into account the different levels of development. More importantly, global standards eliminate the need for any one nation to determine good practices -- especially if it lacks scientific capacity or political will. Ultimately, each regulator will place these principles and standards into its local context. When industry organizations, relevant international governmental or non-governmental organizations establish relevant standards these can be incorporated by reference into national regulatory schemes. In so doing, the qualities of a product – whether finished, raw material, or a component, are established. If a product when counterfeited does not meet the standard, regulators and law enforcement are better able to identify counterfeit products that most often meet few if any standards. This use of standards provides one more basis on which to take action against counterfeit goods.

The absence of regulatory standards has been a clear link to counterfeits and harm. In one instance, nearly 100 people died and thousands around the world were sickened by what authorities believe was an intentionalcounterfeiting of the blood thinner heparin. An active pharmaceutical ingredient (API), heparin costs manufacturers around $900/lb. to produce. In this instance, oversulfated chondroitin sulfate, a contaminant that costs about $9/lb. to produce, was imported as a bulk chemical by the counterfeiters and substituted to produce fake heparin. A regulatory standard that required importers to declare whether a bulk chemical is intended for use in pharmaceutical products might have prevented this situation. The legality and quality of the chemicals would have to be monitored by a national regulatory body such as the NMRA in reliance on supply chain management techniques, such as requiring API manufacturers to register with the agency. Accordingly, a manufacturer could check to see if its API vendors are authorized, increasing the likelihood that products are genuine. Had there been a standard integrated into local practice in this

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106 Supra note 71.
situation, the product would have to be produced according to it, Ensuring such a level of production could be done by a certification or inspection or other mechanism in which case an absence of proof of meeting this standard would have been an indication to the heparin manufacturer in this story that there was reason to suspect the raw material. Even if the manufacturer could not have determined the IP status, it might have been able to avoid the use of the counterfeit API by having had a reference to a standard that was enforced by some required documentation or other approach.

5.3 Counterfeits as environmental pollutants, and safe destruction methods

Many counterfeits are made in such a manner that when their disposition is considered they are rightly classified as environmental pollutants. The materials used in counterfeits are harmful because of their toxicity, reactivity, ignitibility, or corrosiveness. They might even be a material listed as an environmental pollutant, such as an off-specification chemical or industrial waste. Pollution occurs when a contaminant is introduced into a natural environment and causes instability, disorder, harm or discomfort to the ecosystem (i.e. physical systems or a living organism – humans, animals or plants).

Accordingly, in order to protect health, the nature of a counterfeit must be understood before selecting a destruction method. There are destruction methods known to be safe means for the final disposition of a polluting material, and these must be followed when counterfeits are destroyed. There are some basic principles for the safe management of waste when it is hazardous or polluting or otherwise defined under relevant laws. Procedures include: recycling, mixing into cement to render the material inert, neutralization, incineration, destruction, waste to energy uses, sequestering/landfill, and others. Appropriate methods do not include flushing down a toilet or dumping in a landfill! Counterfeits should be tracked from seizure to final disposition, records kept, their destruction done by a permitted facility only, and witnessed by an independent third party.

Regrettably, applicable international and national laws, standards and guidelines on destruction exist are a patchwork, as noted. Even these depend on the nature of the material and what is planned for the item, such as whether a country is considering the export of the waste. Therefore, basic principles of waste management apply, the first of which is to appoint a designated officer who is responsible for the process, and to comply with applicable laws and standards. It is important to note that the process starts at the crime
scene itself, where an accumulation of component materials and the product may be found. Just as these materials can be toxic to consumers, they can also be toxic to law enforcement and regulatory officers who must handle them. The designated officer may be the same person who is the counterfeit focal point, or the officer may be part of the national environmental protection branch of government. Whoever this person may be, it is the regulators who hold the scientific and subject matter expertise that should be lead destruction and do so according to written standard operating procedures.

It is recommended that standards be adopted by each country. Some countries – Russia among them -- have already adopted guidelines, such as for the destruction of counterfeit and substandard drugs. The new law will require that the destruction of all fake drugs be handled by organizations that are licensed for the collection, transportation and disposal of grade I-IV waste. The legislation also recommends that such organizations should have access to specialized facilities where the counterfeit drugs can be disposed of with the proper equipment. These changes reflect the international legal and scientific standards regarding environmental pollutants.

5.4 Inter-ministerial cooperation

Coordination between ministries increases efficiency and better utilizes resources while leveraging the strengths of each. Several countries have engaged in cooperative initiatives between such as Singapore that has joined with INTERPOL, in the first alliance between a national health authority and the international law enforcement organization. The main goals are to collaborate on new programs to facilitate training on prevention and suppression of counterfeit medical products. There remains much room for cooperation to evolve between regulators and law enforcement, whether the efforts start or are led by IPR-focused ministries or by non-IPR ministries of health, agriculture, consumer safety and industry. What is important is that all anti-counterfeit activities are conducted collaboratively, cooperatively and in a coordinated manner for efficiency. In the end this will lead to the protection of public health and safety.


108 Id.

The US has actively implemented a national strategy though an inter-ministerial approach since 2004, when it announced its Strategy to Targeting Organized Piracy (STOP).\textsuperscript{110} Four agencies joined the campaign, including the departments of Justice, Commerce, and Homeland Security (which includes the Customs and Border Protection Bureau). This regulatory initiative moved to its next phase with the passage of the 2008 PRO-IP Act that established the office of the White House IP Czar. No evaluation has yet established whether STOP or the PRO-IP Act initiatives have reduced counterfeits and thus protected health. And although the IPEC office issued its first annual report in June 2011, this report does not evaluate the effectiveness of the national strategy.\textsuperscript{111}

The US is joined by Kyrgyzstan, Uganda, India and Nigeria in centralizing and coordinating anti-counterfeit efforts. The Kyrgyzstan Patent Office and the State Customs Service produced a joint action plan for 2010-2011, outlining cooperative efforts to identify and interdict against methods used by counterfeit products traffickers.\textsuperscript{112} This approach to border controls brings Kyrgyzstan more in line with international standards, and serves to ensure utilization of all available resources in preventing the entrance of counterfeit products into the country. In Uganda, the Ministry of Trade, Industry and Tourism and the National Bureau of Standards are working together to increase personnel at national borders to stop more counterfeits from entering the market.\textsuperscript{113} This initiative is part of an overall scheme Uganda recently announced to fight the entrance of counterfeits into the country.\textsuperscript{114} Another example of cooperation between national ministries is India, where the Ministry of Finance and the Department of Revenue implemented IP Rights (Imported Goods) Enforcement Rules in 2007, giving the Customs Authority the power to adjudicate issues involving the import or export of infringing products.\textsuperscript{115} A rapid product evaluation and infringement determination by Customs will help protect public health, eliminating

\begin{itemize}
\item \textsuperscript{110} Krim, J. Anti-counterfeiting initiative launched, and four US agencies team up for effort Washington Post. October 5, 2004, p E5.
\item \textsuperscript{111} 2011 US Intellectual Property Enforcement Coordinator Joint Strategic Plan One Year Anniversary, http://www.whitehouse.gov/sites/default/files/omb/omb/IPEC/ipec_anniversary_report.pdf
\end{itemize}
delays in taking steps to prevent potentially dangerous products from entering the stream of commerce.

5.5 Does training build capacity?

Substantial resources are directed at training to build capacity. It seems common wisdom that training is the intervention that is best to strengthen the skills and abilities of the various branches of government involved with counterfeits. There is no doubt that the ability of regulators and other branches of government to perform their duties can be improved, but it has not been until very recently that sponsors of capacity building have begun to assess the results of these efforts. Such assessment initiatives have been noted at national and international levels, although these are too few and too recent to offer insights into the effectiveness of capacity building. In January 2011, the World Intellectual Property Organization (WIPO) and World Customs Organization (WCO) conducted a Multi-Stakeholder Roundtable on Technical Assistance against Counterfeit Medicines. The Roundtable was comprised of participants from other international organizations – including the WHO, the World Trade Organization (WTO) and Interpol – as well as pharmaceutical and non-governmental organizations.116 Apart from being one of the few efforts taken to consider the assessment of capacity building, at this point the meeting’s outcomes are unclear.

In another study conducted by the USPTO, surveys of participants in IP trainings demonstrate that desired training outcomes could be measured.117 Data such as these informed the structure of the training developed under this project and suggest that the following learning objectives are achievable: 1) develop a new policy document; 2) implement new policies or procedures; 3) establish a better working relationship with another ministry; 4) initiate a new program; 5) adopt an innovative IPR strategy; 6) propose an amendment to legislation; and 7) establish a procedure to manage data and for publishing statistics on enforcement.

Nigeria also conducted an internal review by hosting a meeting with national and international stakeholders – including the USFDA, US Environmental and Occupational

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Health Science Institute (EOHSI), South African Medicines and Medical Devices Regulatory Agency (SAMMDRA) – to improve staff training procedures and information sharing techniques.\textsuperscript{118} Much more needs to be done to measure the benefits of capacity building.

5.6 Communication

One of the main regulatory functions of any ministry is to educate its particular audience, whether they are consumers, industry or other persons including other branches of government. In the health sector, this educational function is called health promotion and prepares messages such as “Wash your hands during flu season.” Rightly so, many regulators launched communications campaigns, especially on websites, to educate their audiences on counterfeit goods and to provide a place to report encounters with counterfeits. Here again examples abound and can be as simple as in this text box.

**Simple Guide for Consumers**
- Scrutinize labels, packaging, and contents.
- Seek authorized retailers.
- Insist on secure transactions.
- Report questionable spam and faulty products.
- Teach your kids about counterfeits.
- Warn friends and family of illegitimate product sources.
- Trust your instincts.

The Netherlands Health Ministry launched a website that includes warnings and an informative film with quiz.\textsuperscript{119} In Nigeria, NAFDAC has implemented awareness and enlightenment campaigns in all 36 states of the Federation.\textsuperscript{120} For consumer goods, SaferProducts.gov is a platform where consumers can report incidents of unsafe products, including counterfeits. There, businesses can register and review reports about their products before publication. The portal just went live in the spring of 2011, so the value of its data and effectiveness is not yet known. Health leads the way again in the United Kingdom (UK) where the Medicines and Healthcare Products Agency (MHRA), an executive


agency of the UK Department of Health, has dedicated a 24-hour hot line, an email address and a "postal address for reports of counterfeit medicines and devices.\textsuperscript{121}

Japan's Patent Office (JPO) commenced an "Anti-Counterfeiting Campaign" in December 2010, in cooperation with the Intellectual Property Policy Headquarters and related ministries to raise public awareness of the issues. As consumers purchase more products online, the JPO is ramping up efforts to warn consumers of the risks of counterfeits due to the increased distribution of counterfeit goods via the Internet, says the Ministry. As part of the initiative, 6,000 posters will be displayed across Japan in government offices, companies and institutions. In addition, a major media campaign involving print, television and web media will be instituted.\textsuperscript{122}

Trade associations, such as the US National Association of Boards of Pharmacy (NABP), are adding their communications campaigns. NABP recently announced the purchase of AWARxE, a website and campaign that seeks to educate the public about the dangers presented by illegal online pharmacies. Using the AWARxE consumer protection program as a vehicle, NABP aims to educate and raise public awareness about counterfeit medications, rogue Internet drug outlets, and prescription drug abuse, among other serious issues."\textsuperscript{123} The question is whether these communications campaigns are sending the right messages and in the right medium. Section 7.3 considers these questions.

5.7 Public-private partnerships and technology

Despite the breadth and depth of actions taken at the governmental levels, the likelihood that every single counterfeit good will be identified and seized prior to entering the stream of commerce is very small. Consumers and industry are part of the equation for finding a solution to eliminating harmful products, and now regulators are turning to them both to help combat counterfeits. Consumers are considered in Section 7.3 on communications. Cooperation between industry players and government officials significantly increases the effects realized by anti-counterfeit initiatives. Technology and trainings/conferences appear most frequently as the mainstays of these cooperative efforts.

\textsuperscript{123} AWARxE is at \url{http://www.awarerx.org/counterfeitMeds.php}.
Nigerians and Ghanaians are now able to use mobile phone codes to determine the authenticity of their medicines through an African social enterprise network called “mPedigree”.124 Nigerians can also participate in a pilot program that is testing the use of mobile phones, one that shows promise due to its simplicity. A patient simply scratches off a label, sends an image via cell phone, and gets back a text indicating whether or not the product is genuine.125 Cell phones are also being used in India to text a set of code numbers to a pharmaceutical database, where they will be cross-referenced and, if a duplicate is identified, the customer is instantly warned.126 Unichem Laboratories, a major Indian drug manufacturer, has retained a New Delhi company, PharmaSecure, to print random code on approximately 70 million pill packets. These types of initiatives are particularly effective in developing nations, where citizens rely heavily on the use of cell phones in their daily lives.127

India, which it is known as the world’s pharmacy but also the largest net exporter of counterfeit drugs, has also adopted another technological solution to combating counterfeits in the pharmaceutical area. The Indian Commerce Ministry passed regulations requiring all medicine exports to carry bar codes with serialization, as per global standards, on primary, secondary and tertiary packaging levels. The rules will be implemented in phases and mandatory coding of all medicinal exports is expected by July 2012.128 Indian industry has expressed concerns that, while the system may work for capturing exports, it will not aid importers unless they have access to the database developed to house the bar code information. Another regulation on exporters will require that a copy of the Certificate

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of Analysis be filed with the government and product samples retained for later reference.129

Recognizing the benefits of public-private partnerships (PPP), the UAE Ministry of Health and Pfizer organized a conference aimed at protecting patients from the dangers of counterfeit pharmaceutical products.130 The conference brought together senior officials from Bahrain, Egypt, Iraq, Jordan, Kuwait, Lebanon, Libya, Saudi Arabia, Syria, Yemen and the UAE to share best practices and discuss transnational cooperation in areas such as legislative and regulatory reforms. PPPs are another important element of the strategy to combat counterfeits because no government alone can manage all the dimensions needed to succeed.

When it comes to determining quality, or whether or not a product meets standards, there is an enormous need for good laboratories. These facilities are valuable for monitoring or conducting quality control checks for all locally manufactured and imported medicines and other products to ensure they meet international or national quality standards.131 A real impediment to combating counterfeits is the determination of authenticity, a step that may require more than a visual inspection and for which good labs and other technological devices are essential. This has been an area in which PPPs have been active and should be applauded and encouraged.

5.8 Conclusion

It is encouraging to note that since 2000, regulators have been granted new powers and new inspectors to combat counterfeits, as well as given a broader basis by which to capture counterfeits: that of quality and legality. Also, the nature of the products that are the focus of anti-counterfeit efforts is being broadened to include more products that, when counterfeited, can cause harm. As a result, in addition to medicines and consumer regulators, other sector regulatory agencies can focus on counterfeits. There is still room to improve data capture to measure the impact of interventions and trainings.

131 Nsimbe, SE. Problems Associated with substandard and counterfeit drugs in developing countries: a review article on global implications of counterfeit drugs in a free market economy. East Afr J Pub Health, 2008, Dec; 593); 205-10.
The variety of regulatory interventions noted in the Assessment tool derive from sections of this paper other than this one, as many are new and only just established in legislation. As these are regulatory in nature they are included in the section of the tool on regulation.
6.0 LAW ENFORCEMENT

Since the 2003 report was released, law enforcement has worked actively to combat all counterfeit products -- not just those that could cause injury. Reliance on basic principles of law enforcement remains the primary strategy to stop the manufacture, import, export, transit, warehousing, and distribution of counterfeit goods. The plan is simple: have laws, enforce the laws and enhance the deterrent effects of penalties by imposing their maximums. These basic tactics directed at all counterfeits – not merely products that can harm humans, animals, and plants -- have been deployed over the past years. The basics are protective of health even if the fundamental reason they are deployed is to enforce IP rights. In some instances, law enforcement has focused especially on products that can harm health such as the addition of the new seizure category of goods that can cause harm. Additionally, law enforcement has coordinated and collaborated between national, regional and international agencies, built capacity, added specialized IPR-focused police units and courts and, many countries have increased sanctions. In this section, the term law enforcement refers to customs, the courts, regulatory inspectors, and police.

It has become accepted knowledge that counterfeits flourish in locations and sectors where there are significant variations and/or weaknesses in law enforcement capabilities or regulatory authority, such as when there is no substantive crime of counterfeiting or no law on consumer protection. Free trade zones (FTZs) and transshipment ports also exemplify the points where counterfeitors exploit these gap opportunities.132 Products move more freely, as the ability of local law enforcement to police such sites is limited, allowing counterfeitors to establish a growing and global trade. Often, counterfeitors will ship the components of counterfeit products separately to FTZs to be assembled and then shipped once again to be distributed in another country.133 New mediums for counterfeit trade complicate matters, leaving law enforcement in a catch-up mode. This is especially true with the emergence of the Internet as a “transit” point or “trade route”. Other technologies, such as those that enable counterfeiters to make labeling and packaging so alike the genuine, makes spotting counterfeits ever more difficult.

133 Supra at note 13.
Legislators have strengthened law enforcement by clarifying and expanding the definition and scope of counterfeit crimes, adding all the activities from start to finish, such as packaging, labeling and warehousing, and giving law enforcement more powers, such as the right to seize equipment used to make counterfeits, among others. However, problems particular to IPR enforcement continue, especially lack of *ex officio* authority and the inability to collect and share information fast enough to enforce certain provisions, such as detention of specific goods. Data collections, and therefore monitoring and evaluation, still suffer from inattention. On the demand side, law enforcement officers are underutilized as effective carriers of behavior change messages, and data is not used to demonstrate or improve the effectiveness of law enforcement strategies.

### 6.1 Enforcement and deterrence are primary reduction strategies

Since 1999, there has not been another study confirming or refuting the principle that stronger and more effective criminal and border enforcement reduces the flow of counterfeit product into a country and between neighboring countries.\(^{134}\) National success stories continue to confirm the validity of the principle established by the 1999 study and demonstrate that consistency and targeted law enforcement coupled with public awareness campaigns and training of enforcement personnel, is the road to law enforcement success in reducing counterfeits. This strategy resulted in the closure of Hungary’s notorious Verseny street market, a major selling outlet for a wide range of counterfeit and illicit products.\(^ {135}\) When law enforcement succeeds and tells the story, criminals take notice and move on, as did many website owners who voluntarily took down sites in response to the US Operation in Our Sites effort.\(^ {136}\) In the end, law enforcement is a key dimension in protecting public health, but only when it is strong and effective. The nature of criminal behavior is such that, without robust law enforcement, no amount of regulation and legislation will be sufficient to accomplish goals.

The main value of strong law enforcement is deterrence; by reducing the profitability of the crime there is less incentive to counterfeit. The reason why it works is simple. Counterfeit profits are high because of several factors, including the poor quality of


\(^{135}\) Supra note 13.

the counterfeit products, evasion of customs duties and taxes or national pricing regimes or business regulatory requirements, such as labor laws. Unfortunately, the potential profit margin for counterfeits far outweighs the penalties that most countries have in place. 137 Thus when penalties are too low -- or maximum penalties are not imposed or counterfeiters are not prosecuted at all, as is the case too often -- the benefit of strong enforcement is lost.138 There are too many stories demonstrating this principle. One is the case of Indonesian IPR enforcement, which is significantly weakened by impediments to the successful prosecution of IPR crimes – delayed proceedings, infrequent convictions and minimal fines that fail to act as a deterrent for repeat infringers.139

6.2 Initiatives to Enhance Law Enforcement Basics

6.2.1 International, regional, and national cooperation and coordination

As the value of cooperation and coordination to strategies to combat counterfeits has become clear, a number of national, regional and multilateral initiatives have been undertaken in the past decade. By this cooperation, inefficiencies and duplication are avoided, gaining the benefits of the respective strengths of all the various parties. Many of the initiatives did focus on medicines counterfeiting but, nonetheless, exemplify collaborative approaches. For example, in 2009 The Economic Community of West African States (ECOWAS) received support to develop a regional action plan to combat drug trafficking and organized crime from The United Nations Office of Drugs and Crime (UNODC), the United Nations Office for West Africa Department of Political Affairs and Peacekeeping Operations and INTERPOL. Additionally, the Central Asian Regional Information and Coordination Centre (CARICC) has improved the flow of information and intelligence used to identify and disrupt transnational trafficking networks. The Centre produced trainings on basic methods of counterfeit product detection, identification of persons and entities involved in the crimes, and techniques of investigation. The successful results of the partnership led to agreement by the Gulf States to establish a similar network

138 Supra note 13.
139 Id.
built on the same model.\textsuperscript{140} UNODC has also been active in cooperation with the WCO by initiating in 2003 the Container Control Program (CCP) to assist governments in building enforcement capacity in seaports susceptible to trafficking via maritime containers. In 2005, Ecuador became the first pilot country to join the CCP. Similar initiatives have since commenced in Ghana, Pakistan, Senegal, and Turkmenistan.\textsuperscript{141}

Operations Jupiter and Pangea are examples of multi-jurisdictional approaches to stem cross border counterfeit traffic. “Operation Jupiter – South America,” a cooperative effort between Argentina, Brazil and Paraguay facilitated by INTERPOL, successfully blocked a major anti-counterfeiting operation in the tri-border area.\textsuperscript{142} Operation Pangea III, in which 45 countries participated, is an INTERPOL-organized campaign to combat online counterfeit drug crime that demonstrated success. The results included recovery of US $2.6 million worth of illicit and counterfeit drugs, 76 arrests, and the investigation of 694 websites – 290 of which have already been shut down.\textsuperscript{143} Pangea IV, its fourth phase, targeted online sales and resulted in a seizure of $6.3 million of potentially harmful medicines.\textsuperscript{144}

\textit{6.2.2 Creation of specialized police units and courts}

Recognizing the special dimensions of IPR crime and related activities, some nations are creating specialized enforcement mechanisms to address the problem. This movement comes as nations acknowledge the threat that counterfeit products pose for human and animal health and the critical need for dedicated resources to combat them. The Indian ministerial committee on IPR enforcement created specialized IPR police units and implemented the 2007 IPR (Imported Goods) Enforcement Rules.\textsuperscript{145} The Indian courts are

\textsuperscript{145} Supra note 13.
successfully upholding these new rules; they have issued a series of rulings protecting rights in trade dress and product markings, two elements of IPR that are frequently counterfeited.\textsuperscript{146} In July 2008, Taiwan established a Specialized IPR Court.\textsuperscript{147} The Supreme Court of Russia issued a resolution on the application of article 146 of the Criminal Code of Russia (copyright infringements) that provided guidelines for judges and summarized national court practices.\textsuperscript{148} These efforts to clarify the rules relating to counterfeit offenses, and specialized courts to impose them, improve the likelihood that law enforcement will successfully prosecute and punish counterfeiters.

\textbf{6.2.3 Using additional laws to stop counterfeiters}

Law enforcement continues to rely on alternative means to successfully prosecute criminals who promote counterfeits. In Operation Smoking Dragon, US law enforcement agencies waited to break up a counterfeiting ring until the smugglers brought illegal weapons and counterfeit currency into the country, despite having monitored the illegal cigarette trade for several years.\textsuperscript{149} Another example is the arrest of fake drug spammer Oleg Nikolaenko, a 23-year-old Moscow resident, and the alleged mastermind behind the Mega-D botnet, a spam disperser that promoted counterfeit materials. The disperser was allegedly used to deceptively market and sell herbal products and generic prescription drugs falsely advertised as FDA-approved. In a collaborative enforcement effort, the US FBI and Federal Trade Commission began following Nikolaenko in 2007. In 2010, he was indicted for violating the Controlling the Assault of Non-Solicited Pornography and Marketing Act, a law unrelated to counterfeiting but effective nonetheless for capturing this counterfeit criminal. In November 2009, an undercover federal agent purchased Viagra from Nikolaenko via the Internet and received herbal supplements disguised as Viagra. The pills were subsequently deemed to be counterfeit. On November 16\textsuperscript{th}, 2010, Nikolaenko


\textsuperscript{147} Supra note 13.


was arrested and charged on several counts, one being the execution of a scheme to defraud by failing to send purchased prescription drugs. He is currently awaiting trial in Milwaukee, Wisconsin.150

6.2.4 Capacity building

Even the best plans and strategies are worthless if they cannot be implemented due to insufficiencies in capacity – including adequate personnel, with appropriate skill sets, equipment, and financial resources. There have been and are many training programs in the last ten years. Regrettably, little to no study has been directed to design these programs or to determine if they have actually augmented any capacity.

Training and capacity building examples abound. Interpol, WCO, WIPO, and regional and national IPR offices have been active in generating training programs. Interpol, for example, offers an annual IP training program that is now in its seventh year. Attendance at these programs is substantial. In 2010, 500 delegates from nearly 50 countries attended, reflecting the quality of the program and the desire for increased capacity. Interpol also offers an online International IP Crime Investigators College at www.iipcic.org plus other regional and topic specific programs.

Another training example is the 2009 WCO program that established a Regional Working Group on Human Resources Management. This program enabled the countries of West and Central Africa to build capacity in their customs administration by strengthening their national training programs and improving their operational management. Hungary has implemented numerous public awareness-raising campaigns and training as well as educational seminars for police, prosecutors, and judges.151

In 2009, the UNODC issued the Serious Organized Crime Threat Assessment Handbook, providing policymakers with much-needed tools for identifying threats, trends, and future challenges to implementation of effective strategies. When published by an international organization, this type of compilation of best practices is extremely useful. Creating such tools requires collecting comprehensive information – efforts that few national governments or local organizations have the necessary resources to fulfill. Yet all authorities can benefit from this type of resource when building local capacity.

151 Supra note 71.
What’s more, with the wealth of options readily available, there is no need to create a training program. These include many online programs, as well as global and regional conferences and manuals. A list of organizations offering training is included at the study website. The curriculum designed under this study does not duplicate the content of these existing training programs, but rather focuses on materials these programs are not offering. In particular, topics included in the law enforcement sections are on what can be done to protect public health and safety, how to improve the quality of data for its several uses, including the design of interventions, targeting enforcement resources, and monitoring and evaluation.

6.3 Law enforcement and counterfeit drugs

6.3.1 Increasing regulatory efficiency leads to stronger law enforcement

Recognizing the need to improve law enforcement, many countries have taken steps to strengthen regulatory infrastructure. An example is simply having a list of approved medicines -- or any product subject to regulation. Creating such a list is the responsibility of the regulatory agency - this is not merely a bureaucratic action. Absent a list, law enforcement has difficulty in verifying the status of a product so it can determine whether to allow entry, refuse entry, or impose other measures. Organizations like Nigeria’s NAFDAC are addressing this regulatory gap by establishing procedures to increase efficiency, reduce delays in medicines registration, and increase organized surveillance and monitoring activities at factories and points of sale known for counterfeit medicines violations. These regulatory actions should assist law enforcement to do its work to apprehend counterfeiters.

6.3.2 Functional definitions in civil and criminal law

Many counterfeit products do not satisfy legal requirements, such as quality specifications or product registration requirements, and are thus illegal without reference to any IP infringement. If IP violation cannot be sufficiently established at an inspection point to be caught, it is essential to have other functional definitions as the basis of law enforcement, and to empower any inspector to take action under any of one or more definitions. As described in the legislation section of this paper, some countries and regions

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have taken steps to create a series of crimes and civil acts of wrongdoing, capturing not only counterfeits but also substandard, illegal or unregistered products. Counterfeits are also substandard and illegal. This approach is now seen in health, consumer, agricultural and industrial product laws and is an approach that is not inconsistent with TRIPS.

### 6.3.3 Combating online sales of counterfeit drugs

The Internet has emerged as an area of special focus and concern. Medicines sold over the Internet seem to get the most attention, given their potential to cause such harm when counterfeited. Some estimates claim that over 50% of pharmaceuticals purchased over the Internet from sites that conceal their physical address are counterfeit. The difficulty in tracing the manufacturing and distribution channels of these products makes eliminating their circulation in national markets a challenge. Despite the obstacles, significant steps are being taken to address this new transit point for counterfeits. Several major regulatory and law enforcement initiatives have taken hold, such as the previously noted "Operation Pangea."

In 2011, the European Union ambassadors approved an agreement to regulate medicines sold over the Internet and protect legal suppliers of medicine by requiring Internet pharmacies to register with authorities in their home country and ensure that products sold are licensed for sale in the country of purchase.\(^{153}\) As stated by Marisa Matias, a Portuguese delegate who led the negotiations on the proposal: "The absence of a legal framework encourages not only counterfeiting but also counterfeiters, who are organized in highly profitable criminal networks." \(^{154}\)

Major American Internet companies are helping to establish a non-profit organization targeting illegal Internet pharmacies. The participants are credit-card payment networks, advertisers and companies that control domain names – in other words the building blocks of any online business, including illegal online pharmacies. The National Association of Boards of Pharmacy has also joined the online fight against counterfeits, and

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developed a certification mechanism for Internet sites called Verified Internet Pharmacy Practice Site (VIPPS) that can be used for both human and pet medications.155

6.4 Conclusion: Moving Forward; Enhancing Law Enforcement

6.4.1 Barriers to and gaps in successful enforcement

Despite the known value of the deterrent effect of enforcement, barriers remain. Due to long waits for authorities to process counterfeit claims through criminal procedures, rights holders are hiring private investigators to “bring down” drug counterfeiters by pursuing them through civil channels.156 In some cases, enforcement authorities hesitate to conduct enforcement actions due to the heavy presence of organized crime gangs in well-known selling outlets.157 Seizure procedures still suffer from a lack of cooperation with rights holders, such as former US CBP policies that prevented the release of product identification information to the rights holder – either via samples or photographic evidence – when detained products are suspected of infringement. This procedure was reported to have prevented the rights holder from making a definitive statement regarding the product’s authenticity.158 Fortunately in the US, CBP has changed its regulations in this regard. Due to a lack of ex officio authority, coupled with the inability of rights holders to submit the documentation within the legal timeframe following notification from Customs, a large number of identified counterfeit goods are released into the marketplace.159

In most legal systems only imported counterfeits are subject to law enforcement based on international principles as found in TRIPS, whereas domestic source counterfeits are subject to national laws. Exported counterfeited products are not generally subject to either set of laws. However, some countries are now imposing counterfeit laws on exports to fill this gap.

155 Verified Internet Pharmacy Practice Site. Available at http://vipps.nabp.net.
157 Supra note 13.
Another gap in law enforcement arises in those countries that are not yet members of the WTO (approximately 40 states). For these nations, law enforcement is based on national laws that may not be in alignment with international standards. The fact remains, however, that in many countries (including WTO members) existing national health and safety consumer protection laws either are inadequate or do not exist at all. Thus, if a law enforcement official cannot make a case based on a potential IP infringement, in the absence of health and safety laws to which the officer can refer, law enforcement cannot take action. The result is counterfeits of all types enter markets. Therefore, closing regulatory gaps so that law enforcement can take action on any and all grounds is a critical step and is to be included in any national plan.

6.4.2 Trade facilitation and avoiding erroneous seizures of health products

The experience of health products procurement, whether donor or government funded, demonstrates that trade facilitation failure is a major reason that shipments are delayed or incorrectly seized. These trade facilitation failures can be remedied by implementing expedited procedures for medical or other product with a health-related use, and training for inspectors to reduce the potential for occasional incorrect tagging of products as suspected counterfeits.

6.4.3 DATA – Improvements and use

There is tremendous room for improvement in the collection and use of data. Targeted enforcement and trend analysis become possible when countries collect data on type, volume, origin, provenance, and other aspects of counterfeit products. These data become significantly more robust and useful if collected and categorized according to standards that result in the ability to compare across countries, within national borders and around the globe. This requires harmonious (if not uniform) data fields, categories and reporting periods for any product that, when counterfeited, can cause harm. The category of CSCT is a start but, being limited, is not sufficient.

Since 2009, there have been some encouraging developments in this area with the establishment of the WCO Research and Strategies Unit that has already published useful

Counterfeit Hard Goods and the Public’s Health and Safety: A Study of Interventions

In light of the WCO theme of “Knowledge as a catalyst for customs excellence”, this new research office with its social science expertise should take the lead on harmonizing seizure data fields. As recently as 2011, the UK Home Office also began an office of research and statistics. The office has already demonstrated the importance of applying social science techniques to the design of interventions and measuring their success.

Examining how products arrive is a good example of how data collection can be used to determine where to place resources. An analysis prepared by Hungary for the EU shows that irrespective of quantity, the most significant proportions of seizures are those transported by mail, vehicle, vessel and air. Thus, placement of law enforcement officers at ports of entry or passage for these types of transport would be in order. The use of data has led to big changes in the UAE, a primary point of transshipment and origin for products headed to the EU. The EU data showing that 73.7% of counterfeit medical products entering Europe arrive from the UAE may have pressured the Dubai customs authority to begin cracking down on counterfeiting by launching an e‐gate for IPR enforcement in 2001.

Yusuf Mubarak, Senior Director of the IPR Department at Dubai Customs, said the project aims to develop awareness on intellectual property rights; protect the national economy, customers, investors and traders; and boost legal trade for the benefit of the society: "The online portal to be open to the public would feature detailed information on the intellectual property rights as well as the relevant local, regional and international laws," he stated in 2001. “Statistics on the IPR violations and seizures by every participant ministry, authority and department will also be displayed.”

6.4.4 Behavior change communications

Law enforcement communicates to several external audiences: the public, criminals and to policy and lawmakers. There are numerous examples of such communications, many of which inform this report and the suggestions that follow here on improving external

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164 Dubai Customs to launch e‐gate to crackdown on IPR violations. Saturday, January 08, 2011 8:52 PM http://www.istockanalyst.com/article/viewiStockNews/articleid/4795841
communications as part of an intervention strategy. Communications are a mechanism to reduce consumer demand and to let counterfeiters know that there are real consequences to such crimes. Moreover, like any other stakeholder, law enforcement must make its case to legislators that its budget requests are justified because it can show that what it is doing is working.

Perhaps as important a role for law enforcement as capturing counterfeit criminals, is carrying the message to consumers about why it is important to refrain from buying counterfeit and what do to do if a counterfeit is encountered. As mentioned, recent studies demonstrate that police are effective messengers of the two main reasons why consumers should refrain from purchasing counterfeits: the health and safety dangers, and the risks of prosecution.\textsuperscript{165} Law enforcement plays a role in reducing the demand side of the counterfeit equation, thus any strategy should contain a communications component.

The supply side of the equation is also influenced by law enforcement. Each time a case is won -- and even better if it is a high-profile case -- publicity about the case sends the message that law enforcement is serious about combating counterfeit crime and that there are significant consequences. High-profile cases make clear to counterfeiters that such crimes can carry significant risks. Prime examples are the sentencing of six Chinese citizens to death for importing fake drugs into Nigeria, and the sentencing to death of the former head of China’s Food and Drug Administration for taking bribes to approve untested medicines. When these cases are reported in newspapers, law enforcement reaches the largest audience compared to placing articles in other media.\textsuperscript{166} This remains the situation even though the Internet is a widely used medium of communication. An extension of this type of communication is directed to trading partners and audiences at international meetings. The presentation of materials on health and safety in annual reports, in data fields, in discussions in bilateral consultations, FTAs, and at meetings of international organizations by law enforcement is, by extension, more effective than when presented by other speakers. This should be kept in mind when speakers are selected for such meetings.

Finally, perhaps law enforcement’s toughest job is to garner the budget it needs to adequately conduct its business. By employing established social science techniques of data


collection and monitoring, as well as by evaluation, law enforcement will improve its ability to demonstrate its success and show why budget support should be continued and increased.
7.0 CONCLUSIONS

This report began with a reflection on the five dimensions of a strategy to combat counterfeit goods while protecting public health, as recommended in the first global study on this topic. Based on this follow-up research, this report concludes that the same five dimensions are as valid today as in 2003. These are discussed next and as the overall conclusion of this report.

7.1 Change policy and collaborate

In 2003 the policy recommendation was to “reframe” the policy perspective as a matter of public health. Since then, senior officials at all levels of government and other public figures have spoken about the health implications of IP-infringing goods as the rationale for stronger law enforcement. As recently as early 2011 officials such as John Morton, ICE Director, remarked in his statement to the 6th Counterfeiting Congress that it was necessary to change the terms of the debate and to refrain from the use of legal terms. Rather, Morton advocated using terms like jobs, health, and taxes, and to talk about organized crime, aircraft parts, airbags, honey and medicines. Moreover, he suggested that health and safety resonates with the public and judges, so that more sanctions would be imposed and the support of business gained.\(^{167}\) Even the outcome statement of the Congress referenced “protecting consumer safety - a critical driver to fight counterfeiting.”\(^{168}\) These statements continue the idea that health harm is a rationale for action. Indeed it is but it needs to be and can be more.

In 2011 it is clear that counterfeit goods remain a public health problem -- and by some accounts a growing one -- so it cannot be said that policy has as yet been successfully

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reframed. There are obvious reasons for this, and others that reflect the need for acceptance of certain realities and a substantive shift in thinking. The most obvious proof that policy has not shifted is that, to date, robust data on injuries related to counterfeits does not exist, and there are no common seizure data fields or statistics that allow for comparison between countries, and therefore no reliable trend data. No one measures the effectiveness of interventions: without data this cannot be done. Thankfully, these actions are relatively easy to do and can still be undertaken. Indeed, there are exceptions, such the country Singapore, which has started to collect data to link counterfeit goods with health, demonstrating that it can be done. In 2008 and 2009, Singapore’s Health Sciences Authority recorded a total of 302 adverse reaction reports associated with the use of counterfeit products in the country -- including 11 deaths and 24 coma cases.\(^{169}\)

There is more to a policy shift than data collection however. The topic of counterfeit goods and the public’s health and safety was first understood to encompass the ways in which such goods could -- and did -- cause harm to human and animal health. This acknowledgement of health and safety was instrumental in increasing the attention and resources to combat counterfeit goods that might cause harm. However, to a large extent the initiatives have remained in the purview of the IP community, where IP protection is the top line value rather, than as initiatives, where health is the top line value, so that by protecting health, IP is also protected. An example of this point is ACTA, in which few if any provisions explicitly reflect concern for health even though law enforcement is a key actor in the protection of public health. As itemized in the ACTA section of this paper, some ACTA provisions such as proportionality and destruction among others are devoid of reference to health and safety. These and other provisions could have more explicitly reflected concern for public health without jeopardizing the law enforcement objectives of ACTA. More proof is found in this phase of the protracted debate over the nomenclature of counterfeit medicines. This debate effectively cemented a line between health and IP by adding new nomenclature and a definition claimed to be specific to public health. Each term and related definition has implications for the separate communities that have yet to be understood. Even approaches as innovative as the EU Medicrimes Convention (though it now includes the three-dimensional approach of substandard, illegal or counterfeit

medicines), missed the opportunity to apply this innovative legislative infrastructure to any product that when substandard, illegal or counterfeit could cause harm. As its scope includes veterinary products, it does a partial job but it leaves out all other types of product.

This is not to say that efforts focused on IP alone should be abandoned or otherwise reduced. There is no doubt that all efforts to reduce counterfeits of all kinds, either directly or indirectly, lead to protecting health. This is to say that if the goal is to protect health -- and this is as rightful a goal for the IP community as it is for any other -- then there are steps to be taken to reframe policy and approaches that are highlighted by this research. Simply put, this means to increase regulatory and law enforcement initiatives against any product that can cause harm – even if not counterfeit but also if it is. To do this, the IP community will have to step outside of its comfort zone and work collaboratively with the health, consumer, agricultural, industrial and other product communities. In this sense, this report makes no change to the 2003 recommendation to collaborate among interested communities. And let it be underscored that these other communities, especially health, must also open their agendas to that of counterfeiting and the ways in which collaboration can aid in solving this real public health problem. In sum, IP protection and enforcement is one element of a comprehensive approach to protecting public health; approaches that silo one sector against another will not work. All sectors must work together to efficiently organize and align their respective competencies and responsibilities.

Reframing the policy discussion will also demand some new ways to approach the problem. Indeed, some realities will force a shift. Opposition to ACTA and what we know about consumer behavior highlights some of these factors. A main criticism of ACTA with regard to public health is less about particular provisions and more about fundamental differences between developing and developed economies. In developing and underdeveloped countries where counterfeits are marketed and produced, government resources for any purpose (including IPR enforcement) are limited. Such governments may not devote resources to IPR enforcement as it is not the main concern of nationals. It is observed that in developing countries more non-nationals want their rights enforced than nationals.170 This observation is important because recent evidence shows that people

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knowingly buy counterfeits due to constraints on financial resources. A person in a low-income country may choose a counterfeit product (even though he or she knows it may have a negative health or safety effect) due to the inability to afford the genuine item. Also, it may be more desirable to have some product rather than none.

The evidence suggests this is a correct observation – that cost trumps safety for many consumers. Low cost also trumps the rights of others as purchasers of counterfeit luxury goods demonstrate. A shift in thinking here might take the form of finding ways to make such products affordable, such as establishing health finance systems that work or devoting resources to fundamental regulatory infrastructure in which counterfeits can be captured, rather than channeling resources to the narrower focus of IPR enforcement.

Approaching IPR as part of the larger system in which it fits, and with a view towards development, might improve prospects for mainstreaming respect for IP. Moreover, if the estimates on food and water shortages and the potential for crisis surrounding access to these are true, absent strong fundamental regulation, legislation and law enforcement, no amount of single-topic interventions will be of much use.

This point leads to the lessons to be taken from the realm of counterfeit medicines, which have without doubt been given the most attention in the last ten years. When Margaret Chan, Director General of the WHO said,

"The WHO approach to address the problem in developing countries is the same as that used successfully by wealthy nations to protect their populations. That is: strict regulatory control of medicines on the market, strict enforcement of quality standards, and diligent pharmacovigilance. Nothing suggests the need for a double standard."

she was referring to this same idea of enhancing the entire regulatory system -- not just the pieces related to counterfeit medicines. This same idea was endorsed in 2005 by the International Conference of Drug Regulatory Agencies when they voted in favor of a framework convention to combat counterfeit medicines, the first element of which was to build strong health, safety and consumer regulatory agencies.

The realm of counterfeit medicines is responsible for another important idea. Inadvertently, the disruption caused by the debate over counterfeit medicines nomenclature has led to the innovation of the three-dimensional approach to protect health

171 Supra note 164.
and safety. This has already been adopted by the EU and was in place in some countries, such as Switzerland and Egypt, which focus on substandard, illegal and counterfeit products. To protect health from counterfeit goods, counterfeits must be grouped with illegal and substandard products and captured within a comprehensive and coherent regulatory environment that is supported by civil and criminal law enforcement. To the extent that the IP enforcement system misses goods on entry to a market, whether across a border or domestically produced, the health and safety regulatory system must function well and be strong enough to get the job done. These systems are not limited to consumer and health products, and must include the regulatory systems surrounding any product that, when counterfeited, can cause harm. For this to happen regulators must have the entire mix of authority, regulatory principles, staff, budget and skills -- and legislators must provide these. Law enforcement – both traditional and those in regulatory agencies - must also stand ready and be prepared to do its part. This means adequate budget, staff, legal authority, such as ex officio, a range of substantive crimes, and the other details noted in the specific sections of this paper related to each branch of government.

7.2 “Monitor health status” means collect data, monitor and evaluate

“What you don’t measure you don’t change.”

The irony in the policy and attitudinal split regarding counterfeits and health is that, despite all the evidence of what works to stem the problem, it is still death and morbidity that leads to changes. Let us hope that we need not remain blind to the need for useful indicators and we continue to let humans, animals and plants be our canaries in a coal mine. Rather, let us hope that we can establish useful measures to tell us if what we are doing is working.

The scope and nature of the counterfeit goods problem is still reported most often in the popular press, by international NGOs, and specialized agencies such as the WHO, rather than in national health and other statistical databases. The dollar value and number of shipments are most closely monitored through seizure data. However, the different methodologies employed in the collection of these statistics make comparative analyses difficult or impossible, due to a lack of standardization and uniformity in data. This difficulty remains even though the number of reports, articles and popular press items has substantially increased since 2003. Government agencies and organizations have taken
significant steps in establishing programs, projects and initiatives to combat the problem, but the data are lacking and no indicators are established, thus making it impossible to measure effectiveness. In 2011, some data collections tools, such as the US CPSC database, are just coming into use; some offices to assess and collect data have only begun in 2009 – the WCO office -2011 – the UK office; and others, such as the EU Observatory, are yet to begin. These developments are most encouraging and should be supported and engaged with as often and as soon as possible.

It is particularly frustrating to report this data gap, since some minor changes to existing systems could make a big improvement. One change is for the WCO to take the lead on harmonizing seizure data and set standards for categories, such as the CSCT in use by the US and EU and other countries. Perhaps the WCO Research Office will take on this task with the full support of the WCO Secretariat. Another is to amend the ICD to define disease conditions that reflect exposure to counterfeits. Seven updates since 2003 have added codes, but none have been added for anything related to a counterfeits. Sufficient funding and attention must be devoted to the matter of data and related activities of monitoring and evaluation. This is an opportunity to collaborate with non-IP communities where relevant expertise can be found, or the IP community should add this expertise to its cadres.

### 7.3 Deploy a health communications strategy

**Supply and demand**

The supply side is typically managed by regulation, law enforcement and legislation. The other side of the equation is demand or that of the buyer or consumer. This demand is managed by behavior change communications.

Behavior change communications (BCC), or what is referred to in the 2003 report and in the health field as health communication strategy, has been successfully deployed to influence people to change personal and even intimate behavior, such as condom use to prevent HIV transmission or seat belts in cars. Outside the field of health, it is relied upon to change human behavior to protect beach dunes, animal habitats and more. The science of BCC, also known as risk communication, has identified steps essential to successful

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173 Available at [www.saferproducts.gov](http://www.saferproducts.gov).

behavior change. These are analysis, strategy design, develop, and pretest, implement and monitor and evaluate. This know-how can be deployed to reduce demand for counterfeits and to refine communications from regulators and law enforcement.

The need for BCC is as great now as it was in 2003. Recent studies tell us that public opinion may be no different today than in 2003. And worse, there seems to be a widespread public attitude that counterfeiting is a “victimless” crime, and that consumers do not hesitate to knowingly buy counterfeits for several reasons, the first being cost. Even if consumers are told of the dangers of counterfeits, a recent study on recalled products and consumer behavior shows that consumers failed to take steps to respond to recall notices for products they own. Only one-fifth of US adults were even aware of having purchased food, medication or another product (excluding automobiles) that was recalled in the last three years, despite more than 632 injuries and 26 deaths in the US at the end of fiscal year ending September 30, 2010. While not all recalled products are counterfeit, the fact that they are dangerous to consumers makes them analogous to counterfeits for this discussion.

This study shows that many countries have established websites and are attempting other means of communications to various audiences as noted in Section 5.6. Surely, significant resources have been spent to design and develop these sites; however it is not so clear that the science of BCC was applied. A full exploration of BCC is beyond the scope of this paper but, given its importance, a few comments are made here, and components of the project training and website resources are devoted to it.

The science of behavior change has learned that change is rarely achieved without highly tailored and carefully crafted messages, as well as a keen understanding of audiences and their situations. Some quantitative proof is now available that shows that knowledge about the potential negative health and safety consequences would have the most impact on buying decisions, and that a reduced supply of product and the threat of prosecution for buying an illegal product would also influence behavior. The question of what to say to

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177 Supra note 164.
audiences is somewhat now understood – but targeted research is needed to pinpoint the right messaging. Much is now known about the best medium for delivery of information and who will deliver it. This is important, because most regulators are relying on the Internet, but many people (particularly in developing countries) do not have access to the Internet. Even if they do, we know that consumers are most likely to learn of a recall from traditional news outlets, such as newspapers and the radio, more than any other source. One article alone can contain precise guidance on what to do to protect oneself, and detail the extent to which counterfeit goods have permeated the local marketplace. Finally, there is the matter of who should deliver these messages. Should it be the ministry of health? A recent study found that victims of harm were the most effective messengers, followed by medical experts and then police, judges and corporate executives. Thus, messages by celebrities or action figures, such as Jackie Chan and Arnold Schwarzenegger (the “Governator”), may not be as effective as they are entertaining. Thus, if the demand side of the counterfeit equation is to be managed BCC must be deployed by regulators with the support and collaboration of law enforcement and the legislature.

In closing, it can be said that, if anything, this study demonstrates that the know-how to combat counterfeit products of any type -- and certainly those that can harm humans, animals and plants -- is in hand. There is no magical formula; rather, the means are familiar and within reach. To some extent, the means are so mundane or lacking in newsworthiness that some of this available know-how has not yet been implemented. Yet these are the very actions – policy shifting, data collection, monitoring and evaluation, capacity building, regulatory infrastructure strengthening and applying fundamental regulatory principles, keeping law enforcement strong and efficient and calling on the legislature to authorize whatever is missing – that will lead to a moment when it can be said that the incidence of harms related to counterfeits have indeed been reduced.