COUNTERFEIT GOODS AND THE PUBLIC'S HEALTH AND SAFETY

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EXECUTIVE SUMMARY

Counterfeiting is a recognized problem for the intellectual property legal system and its economic and financial consequences are well documented. Media and industry reports and anecdotal stories often assert that there are public health and safety consequences to counterfeiting but no quantitative or qualitative measures in support are presented nor have studies been conducted. This is the first study to systematically review available materials in an effort to define the problem and begin the scientific study of counterfeit goods as a disease mechanism. Among the findings and recommendations of this study are:

- This work highlights the significance of counterfeit goods as not only an intellectual property and trade problem, but also as an unrecognized public health problem with particular consequences in the area of injury mortality and morbidity.

- Worldwide, children and adults are experiencing injuries, harm and death associated with counterfeit goods, particularly; drugs, alcohol, cigarettes, foods, and personal care items.

- Counterfeit goods are a global public health problem; for developed, developing and underdeveloped countries.

- Counterfeit drugs are a separate category and distinct problem due to the nature of their use and are a part of the problem of substandard drugs. Customs seizure data from the US and the EU indicate that quantities of counterfeit drugs are increasing.

- Injuries and harm from counterfeits include death, blindness, headache, illnesses, swelling and rash, failure to recover from illness, burns, hospital admissions and other adverse reactions. In addition:

    - Counterfeit cigarettes are associated with tobacco related diseases.

    - Crime, terrorism and the attendant mental and physical health consequences are associated with counterfeit goods.

- The types of injuries commonly recognized by the public health information systems are the same or similar to those caused by counterfeit goods. Counterfeit goods are mechanisms of unintentional injury, are associated with other diseases and therefore contribute to the global burden of disease.

- Injury databases and organization that collect public health statistics, with the exception of WHO, do not collect data on counterfeit goods. The US agencies CPSC, FDA, and the NCIPC do not code for counterfeit goods. This lack of

data is a significant impediment to understanding the problem of counterfeit goods.

- With few exceptions, no peer reviewed public health journal, or public health academic institution, nor agency has published materials on counterfeit good related injuries and their consequences to public health.

- The International Classification of Diseases does not provide a code for diseases associated with counterfeit goods, nor for them as a mechanism of injury.

- Citizens in countries with well-developed drug and consumer product safety regulations, border enforcement mechanisms and intellectual property laws have a lower risk of exposure to and harm from counterfeit goods.

- This study recommends as the next steps:

  ►*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.

  Protecting the right to health is a present obligation of governments. There is no deferment timetable for this obligation.

  ►*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*: A key element 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. Good models exist. The US FAA Suspected Unapproved Parts Program is one such model. The outcome is quality assurance.

  - 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. Historical tensions between the fields of public health and intellectual property need not arise with respect to counterfeit goods, as the goal of combating counterfeit goods is common to both.

►*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 are a critical component of an overall strategy as well as training health care workers to recognize and or question for health affects of counterfeits and how to alert any surveillance system in place.

- Efforts to protect public health from injury associated with counterfeit goods can complement and augment strategies to protect intellectual property rights.

- 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 to answer the USPTO call to action is urgent to prevent injury, disease, and death associated with counterfeit goods.

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ACRONYMS USED IN TEXT

AIPM	Association of International Pharmaceutical Manufacturers
CDC	Centers for Disease Control
CIPR	Coalition for Intellectual Property Rights
CODES	Crash Outcome Data Evaluation System
CPSC	Consumer Products Safety Commission
EU	European Union
FAA	Federal Aviation Administration
FAASUP	Federal Aviation Administration Suspected Unapproved Parts Program
FARS	Fatality Analysis Reporting System
FDA	Food and Drug Administration
GATT	General Agreement on Trade and Tariffs
ICC	International Chamber of Commerce
ICD	International Classification of Diseases
ICD10	International Classification of Diseases – Version 10
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICH	International Conference on Harmonization
IFPMA	International Federation of Pharmaceutical Manufacturers
IP	Intellectual Property or Intellectual Property Right
NCHS	National Center for Health Statistics
NCIPC	National Center for Injury Prevention and Control
NEDSS	National Electronic Disease Surveillance System
NEISS	National Electronic Injury Surveillance System
NSTB	National Safety and Transportation Board
PH	Public Health
PRS	FAA Parts Reporting System
STANAG	NATO's Standardization Agreement on Coding
SUP	Suspected Unapproved Part - or SUP Program of the FAA
TRIPS	Agreement on Trade Related Aspects of Intellectual Property

UK	United Kingdom
WCU	World Customs Union
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
YPLL	Years of Productive Life Lost

TABLE OF CONTENTS

INTRODUCTION AND RATIONALE FOR STUDY

Counterfeit goods cause human harm in many ways. Cigarettes, prescription and over the counter drugs, alcohol, foods, personal care products and other goods when counterfeited may induce unsuspected human suffering and even death. Individuals may be at risk if a product is contaminated with ingredients that are injurious or poisonous if consumed. People taking counterfeit drugs, both prescription or over the counter, for example, may also face the risk of not getting better if the required active ingredients are missing. Injuries that occur from counterfeit goods are no different than from injuries routinely seen in medical settings, i.e. burns, blindness, cuts, poisoning, allergic reactions, and other disease conditions. Each time a product is used or consumed, there is a risk that the product or some part of it is not genuine. Instead it may be counterfeit and as a result human injury or death can occur. The public health problem of counterfeit goods is that consumers are unable to assess the safety, efficacy, and quality of products before their consumption. The rationale for this study therefore is to highlight this heretofore-unrecognized risk and public health problem, to discuss the lack of attention and documentation of it, and offer suggestions for how to control the problem throughout the world.

On a worldwide basis, nearly five percent [1] of all products are counterfeit, indicating that the risk of exposure to a counterfeit product is significant. Customs seizures, health and safety regulatory requirements, and intellectual property rights enforcement mechanisms are somewhat in place to stop the movement of counterfeit goods into the stream of domestic and international trade. However, despite these preventive measures, counterfeit goods *do* enter commerce and people are harmed or killed from consuming or using them. Furthermore, in the developing/underdeveloped world where the legal underpinnings of intellectual property rights and a public health and safety system remain nascent, consumers face greater exposure to counterfeit goods now and in the future. Consumers of counterfeit goods are generally unable to assess risk of harm of a product before use. Thus, if a product is harmful or not effective, once it is consumed or used, often it is too late to prevent harm. Actual cases of harm to human health underscore this far-reaching public health problem. Unsuspecting consumers exposed to counterfeit goods include mothers who fed their babies formula

thinking it was soy based; learning it was not when their babies fell ill [2] and Cambodians dying from malaria because the anti-malarial drug they were taking was fake.[3]

Almost any product can be and is counterfeited. Examples include medication, intra-aortic pumps, shampoo, cosmetics, auto parts, helicopter clutches, toys, and sunglasses.[4] Many counterfeit goods are bought with full knowledge of their counterfeit nature: i.e. sunglasses, CDs and pocket books. The knowing purchase of a counterfeit is often referred to as a "victimless crime". However that is not the case for unwitting buyers who only learn of the counterfeit nature of their purchase when it does not function as it should or when they are injured or become ill. An example of innocent victims of the crime of counterfeiting occurred in 1995 when approximately 2500 Nigerians died from receiving a counterfeit meningitis vaccine. [5]

This crime of counterfeiting is also not 'victimless' because a person, although aware that a product may be counterfeit, believes that it is safe, secure and effective. Counterfeit goods may not be manufactured in accordance with established methods that ensure the proper functioning of the item or may just be poorly made. A product may not comply with safety standards such as electric code requirements. Household fans have been made with counterfeit GFI plugs, which would not shut off the fan if it were exposed to water, thus, exposing a consumer to electrocution. In some cases, a product can appear identical; but a changed expiration date makes it possible for a counterfeiter to dupe a buyer into a sale. Forged labels are a frequent counterfeiting strategy. The public health problem of counterfeit goods can most clearly be seen when the health consequences of counterfeit goods are examined in light of the duped or unwitting buyer who is physically affected in a negative manner.

There is extensive economic and business literature and media coverage on counterfeit goods detailing the infringement of intellectual property rights and the consequent economic and financial costs to rights holders, states and localities; including what products are counterfeited, how many, the countries of origin and destination. Documentation by national customs officials, seizure statistics, law enforcement records, the media, and industry sponsored reports indicate the economic losses attributable to counterfeiting are enormous. In the year 2000 alone, over $45 million dollars worth of counterfeit goods were seized at US ports[6], a sum that is just slightly less that the GDP of some Sub-Saharan countries and island

states[7]. Moreover, counterfeiting levels are known to be increasing because of global trade and related global technologies such as the Internet.

However, direct evidence of the costs and public health consequences of counterfeit goods cannot be found. This is the basis for this study. Media and government reports, industry comments and anecdotal accounts indicate that harm, injuries and deaths do occur worldwide, yet public health experts have neither authored nor contributed to these materials asserting that counterfeit goods have public health and safety implications. No scientific studies examining the public health and safety consequences of counterfeit goods have been conducted. Many of the materials from industry and the intellectual property legal system have been compromised by the lack of systematic analysis and a professional method of presenting the findings. Nonetheless, these entities have rightly raised a clarion call to action. This study recommends what actions are essential to answer the call.

Given that actual human injuries and death do occur from counterfeit goods, and the enormous quantity of counterfeit goods circulating worldwide, there is a clear imperative to fully understanding the problem of counterfeit goods and to what extent they diminish the public's health and safety. Pursuant to its role to safeguard consumers against confusion and deception in the marketplace, and in recognition that the problem of counterfeit goods is common to the intellectual property (IP) legal system and a public health problem, the United States Patent and Trademark Office (USPTO) sponsored this study to begin to fill the knowledge gap concerning the public health and safety effects of counterfeiting and identify means to protect both public health and intellectual property rights. This study therefore seeks to present the public health and safety implications of counterfeit goods based on a systematic evaluation of available data, anecdotal evidence, available studies, media news, industry and association analysis and reports and to present discussion and recommendations based on the findings.

METHODS

From the onset of this study, it was clear that there is a dearth of public health literature on counterfeit goods. Thus, the approach taken was to identify how human harm and suffering results from the use of counterfeit goods and determine where available data might be found. For the purpose of directing research, it was determined that many of the types of harms described above fall squarely within the meaning of the term injury as used in public health and also within the common understanding of the word injury meaning harm or damage of some kind.

An injury as understood in the field of public health, results as a consequence of the application of a force in excess of body tolerance. The force can be mechanical, electrical, chemical, or thermal. Thus, it was further determined that injuries from counterfeit goods should properly be placed in the public health disease classification of unintentional injury (road traffic crashes, falls, burns, poisonings, cuts and drowning) and not in that of intentional injury (those from war, homicide, violence, and self inflicted injury) nor in the classifications of chronic or infectious diseases.

Counterfeits may also cause harm that are not recognized as injuries in the public health sense, but are injuries in the common understanding of harm or damage. For example, if one were to take birth control pills and have an unwanted pregnancy or take anti-malaria and not recover, it can be said 'harm' occurred. These conditions are "diseases" meaning some ailment or unhealthy condition. As a result of these determinations, data on all forms of 'harm' resulting from counterfeit goods was sought and certain data sources were indicated. In the balance of this paper, when the term injury is used, it is intended to mean both public health injury and other harms or disease conditions, unless otherwise indicated.

A literature review was conducted to locate relevant materials and available data, including but not limited to anecdotal evidence, media reports, industry and association releases and organization and government reports and studies on all types of actual human injury associated with any type of counterfeit good. In an attempt to validate that materials included both actual 'injury' and a counterfeit good, the author devised a six-element screen to filter reports.[8] This was further necessitated by the absence of a common definition of a counterfeit good in the materials or in the law. Further, materials were only assessed to find

an association between a counterfeit good and an injury in the same item. The determination of causation would require analysis far beyond the scope of this study. The elements are as follows:

- First, the product must be named and a statement that the product was counterfeit must be made**.** (Many reports included adjectives such as substandard, shoddy, faulty, cheap, but if a counterfeit good was not clearly indicated as associated with the injury, the report was not included. While there was no attempt made to attribute causation to the counterfeit, there had to be some relationship between the product and the injury through ingestion, use, etc.)
- Second, an 'injury' had to be specified.
- Third, a place where the incident occurred needed to be reported
- Fourth, the number of persons affected,
- Fifth the date of the injury
- Sixth, there must have been a source of the report, which could be traced; this could be a minister of health, a newspaper reporter, industry organization, etc. (Thus a report of livestock steroids being repackaged and sold as human steroids to Australian body-builders is a case of counterfeit goods, but without a report of a human injury related to the steroids and other screen elements, this counterfeit case would be excluded.)

Overall this study was limited to year 2000 data. In order to focus this study, cases were sought in which a reported injury occurred in the year 2000. However, as so few cases were found that met the six-element screen in the year 2000, reports dating as early as 1995 and as late as 2001 were included. 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 injuries; counterfeit drugs and injuries or adverse effects, and injuries and fakes and other synonyms for counterfeit.

Unintentional injury data sources were searched based on an assumption that within the relevant coding categories in the International Classification of Diseases 10 (ICD10), [9] the injurious mechanism or cause could have been a counterfeit good--even though neither the ICD itself nor coding guidelines specify the legal status of the mechanism of injury or disease. Mechanisms and causes according to ICD guidelines can include poison, burns,

cuts, adverse drug reactions, unspecified causes, unknown causes, unknown intent, uncertain diagnosis, multiple burns among other codes.[10] Approximately 20 United States (US) national and international databases on injury, mortality, morbidity and other risk factors were searched for data on injuries associated with counterfeit goods. Databases were selected from a US federal data system list compiled by MacKenzie and Fowler[11] as representing injury data sources and included the US National Center for Injury Prevention and Control (NCIPC), National Safety and Transportation Board (NSTB), US Food and Drug Administration (FDA), Consumer Product Safety Commission (CPSC), and the Centers for Disease Control (CDC).

In the attempt to find materials and relevant information, queries were conducted on the search engines of the World Health Organization (WHO), World Trade Organization (WTO), World Intellectual Property Organization (WIPO), International Chamber of Commerce (ICC), anti-counterfeit associations, and all major public health, news, legal and scientific databases. In addition, government web sites related to trade and intellectual property and national injury, mortality and morbidity databases were searched for the United States, United Kingdom, the European Union, China, India, Pakistan, Brazil and Vietnam; these countries were chosen based on an impression developed during preliminary research that these countries were actively involved in efforts to reduce counterfeiting and their programs might include retrievable data.

A rich source of data is that collected as a result of customs seizures. US and European Union (EU) national seizure data were compared to identify goods most commonly seized as a rough measure of goods most commonly counterfeited. A cross comparison was made between the US and EU to determine goods commonly imported and counterfeited, and to identify any emerging patterns that supported anecdotal data. Table 2 was constructed to display this information. As most countries do not restrict exports based on counterfeit status, there is no comparable data for exports. Furthermore, no data is available for counterfeit goods that are produced locally and traded within domestic commerce.

Based on available seizure statistics and our preliminary research, we concentrated on pharmaceuticals, airplane and auto parts, consumer goods, and tobacco since these appeared to be the most commonly counterfeited products. As several anecdotal and industry reports referenced injuries and deaths related to counterfeit airplane parts, a special search was also

conducted of the US Federal Aviation Administration Suspected Unapproved Parts Program (FAA SUP) database. In order to identify death or injuries related to counterfeit airplane parts, we examined data in the National Transportation and Safety Board's (NTSB) database. Traffic fatalities and injuries also were considered due to the large contribution they make to overall morbidity and mortality totals and the potential that counterfeit auto parts might have played a role.

RESULTS AND FINDINGS

With few exceptions, no major public health journal, organization, academic institution, or government agency had published material on counterfeit goods and injury. No results were available from any major science or public health database, or organizations involved with counterfeits or intellectual property. The following are the results of the searches and analyses conducted in this study.

To report findings from this survey, results have been grouped into four categories:

- Those that meet the search criteria and the six-element screen;
- Injury databases and organizations that collect health statistics;
- Injury databases where counterfeit goods are implicated by other data; and
- Databases or organizations related to intellectual property or counterfeits.

Data meeting requirements of the six-element screen:

From all the databases and materials surveyed for this project, approximately 120 reports, stories or comments were located. Table 1 displays a summary of 21 reports out of the 120 that met at least four of the search criteria employed to screen materials. Thus, only 17.5% of reports, stories or comments could be validated under the criteria of this study: an injury or harm associated with a counterfeit good. The types of harms and injuries disclosed in the materials included death, blindness, headache, illnesses, swelling and rash, failure to recover from illness, burns, hospital admissions and other adverse reactions. Most reports (16) were from anecdotal accounts, media reports and industry comments. Only five of the 21 reports were from a public health agency or journal. Counterfeit goods were reported to injure both children and adults. In nine cases counterfeit drugs were indicated, in six alcohol, two involved food and personal care items, and one each mentioned dietary supplements and cigarettes. Countries that disclosed cases of actual injury included the United States, the United Kingdom, China, Brazil, Russia, Niger, Vietnam, and Egypt.

More than half (11) of the reports indicated that the injury resulted in death. Alcohol was associated with five of the deaths, drugs in four, and food and baby powder in one each. A total of 10 cases involved non-fatal injuries, two had the permanent consequences of

blindness and unwanted pregnancies. Twelve of the cases indicated the number of persons injured; six included 100 or more persons. Appendix C lists all the products mentioned in the materials surveyed, although injuries are associated only with the reports indicated in Table 1.

Results in injury databases and in organizations that collect health statistics:

Generally local and/or national governments are the organizations that capture public health and vital statistics or maintain injury databases. In the US, such agencies include those such as the CDC, NCIPC, and National Center for Health Statistics (NCHS). However, these do not code for counterfeit goods as a mechanism of injury. Ministries of health for the UK, EU member countries, Brazil, China, or Viet Nam do not collect relevant data either. Standard mortality and morbidity data, and other standard summary measures of the burden of disease such as years of productive life lost (YPLL) do not include references to counterfeit goods although their calculation is based on data collected according to ICD coding guidelines. Even the US NCIPC database, which is the database of the national injury agency, can be sorted by several variables, but not for counterfeits. [12]

The US Consumer Products Safety Commission (CPSC) has jurisdiction over 15,000 consumer products (not including food, drugs or cosmetics) and is charged with protecting the American public from unreasonable risks of injury from those products. Each year there are an average of over 22,000 deaths and over 29 million injuries associated with consumer products under the jurisdiction of the CPSC.[13] For nearly thirty years, it has operated the National Electronic Injury Surveillance System (NEISS), which notates when a product is associated with an injury. However, CPSC does not collect data on counterfeit related injuries and the NEISS does not currently code for counterfeit products and related injuries. On an occasional basis counterfeit cases are reported to be involved, thus one report was able to be included, but this is neither a standard nor required practice.

The FDA has the responsibility to promote the public health by taking appropriate action on the marketing of regulated products that include foods, human and veterinary drugs, cosmetics, devices intended for human use, and electronic products that cause radiation.[14] The FDA ensures that foods are safe, drugs are safe and effective and that regulated products are properly labeled. To ensure the safety of marketed products, FDA

staff inspects domestic and foreign manufacturers, checks shipments of imported products, and collects and tests product samples for signs of contamination. FDA enforcement powers are available to monitor cases involving adverse reactions to FDA regulated products. In fiscal year 2000-2001, the FDA conducted 18,649 inspections and 25 seizures of FDA regulated products were conducted. [15] Thus in fewer than two per cent of all inspections did cases appear that might have involved counterfeits as the extraordinary enforcement measure of seizure is only used in cases involving illegitimate and wholly uncooperative manufacturers.

WHO maintains a counterfeit database only on drugs and does not collect any data on other counterfeit products that adversely affect human health. It derives reports from member states [16] and less than 5% of the 191 WHO member states report cases of counterfeit drugs. Some members are reluctant to divulge information because of fears of blame, potential for legal liability, and/or expectations that such reporting will have no positive outcomes. The reports are not validated and some do not differentiate between substandard and counterfeit drugs. Between January 2000 and December 2001 WHO received 42 reports on counterfeit drugs from 20 countries. The types of counterfeits reported included: products with no active ingredients (43%), low content of active ingredients (21%), poor quality drugs (24%), wrong ingredients (2%), and wrong source (7%). Counterfeit drugs that do not have sufficient quantities of active ingredients contribute to the already existing problem of drug resistance. Counterfeit products are been cited as one of the many reasons why in the developing world diseases such as shigela, cholera, salmonella, and TB have become resistant.[17]

Russia is an example of a country trying to quantify the problem of counterfeit drugs. The Russian Ministry of Health reported that in 2000 the number of reported cases of counterfeit medicines has increased ten times and that counterfeit medicines were 3.6% of the market--56 medicines that were mostly high volume, low cost antibiotics.[18] This statistic is confirmed by a survey conducted by the Coalition for Intellectual Property Rights (CIPR) and the Association of International Pharmaceutical Manufacturers (AIPM) in 2001 wherein it was reported that ten percent of the drugs on the Russian market are counterfeit; a threefold increase of the 2000 figures.[19]

In one of the very few studies mentioning counterfeits in relation to public health, the WHO conducted research in Myanmar and Vietnam to help develop measures to counteract the counterfeiting of drugs.[20] In the year of the study, 61 inspectors in Vietnam conducted 31,000 inspections as compared to 32 inspections by 2 inspectors in Myanmar. No counterfeit drugs were found in samples from Vietnam whereas they were found in Myanmar. Interestingly, most samples passed lab tests, but many were mislabeled. The study concluded that the prevalence of substandard drugs in general poses a much greater public health problem than counterfeit drugs in Myanmar and Vietnam and that regulatory measures can reduce the availability of counterfeits drugs and enhance the quality of drugs.

Injuries related to counterfeit goods are implicated by other data but databases are not designed to identify counterfeit goods nor link them to injuries:

The International Classification of Diseases, currently revision 10 (ICD 10) provides the basic structure of global health statistics. ICD code data is the basis for a number of public health measures such as costs to health care, the burden of disease and injury, hospitalization rates, and death rates. The nature, outcome and mechanisms or causes of all diseases and injuries are capable of being coded in the ICD; however, currently, it does not provide a code for counterfeit products as mechanism of injury. It is possible to code for antiquated mechanisms of injury such as bayonets and the guillotine, but not for counterfeit goods. [21] Nonetheless, ICD codes are the basis for recording all injuries and diseases regardless of mechanism and thus it does capture some injuries and disease related to counterfeit goods.

Seizure data indicate that auto parts are commonly counterfeited. Since unintentional motor vehicle traffic accidents are the leading cause of injury deaths for all ages 1-85+ in the US and the third leading cause of non-fatal injury in 2000, auto accident databases were searched.[22] In 2000, 41,821 people were killed in the estimated 6,394,000 police reported motor vehicle traffic crashes. [23] There are two data systems, which track US, auto accidents and injuries: the Fatality Analysis Reporting System (FARS) and Crash Outcome Data Evaluation System (CODES). Neither codes for counterfeit parts.

Use of tobacco products accounted for 12.2% of the burden of disease in developed countries and between 2-4% in the developing world in 2000.[24] US seizure statistics

indicated that in 2000, counterfeit tobacco represented 9% of all goods seized at US ports ranking as the fifth highest category of seizures and rising to first position representing a whopping 38% of seized goods in 2002.[25] Quantities of contraband cigarettes are a good proxy measure for counterfeits because world production is closely observed, cigarettes have a short shelf life, and local production and imports are reasonably well documented; differences are thus a measure of counterfeit cigarettes quantities. One third of cigarettes are contraband worldwide and the quantities of contraband cigarettes have increased 73% from 1990-1995.[26] In China, it is estimated that over 50,000 million cigarettes are manufactured illegally each year.

Finally, there also appears to be a relationship between global commerce and global crime. The US Treasury reports instances in which profits from trafficking in counterfeit music, movies, seed patents software, tee shirts, Nikes, drugs and CDs have funded terrorist activities [27] and terrorism has been associated with human health and injury as a result of 9/11 and other events.[28] ICD10 was recently revised to capture data related to mortality and morbidity associated with terrorism.[29]

Databases or organizations related to intellectual property or counterfeits:

No industry association, international organizations such as the WIPO, WTO, World Customs Union (WCU), the International Chamber of Commerce (ICC) or government ministries related to intellectual property maintain data on injuries, disease and death related to counterfeit goods. Governmental customs departments, such as the European Union, and the United States, maintain substantial data sets associated with counterfeit goods but they do not contain codes for injuries. Table 2 was constructed to display intellectual property seizure data collected by United States and European Union Customs in order to explore any commonalities, however it demonstrates that lack of commonalities by which data can be commingled. The seizure category, "other" which includes medicines and auto parts, ranked the 3rd largest contributor to the overall total of goods seized by Customs for Europe and was the largest category for the US. Both increased from 1999-2000, in the US by135% and the EU by 127%. [30]

Only one database, the FAA Parts Reporting System (PRS), captures data associated with counterfeit parts, although it does so incidentally and does not track injuries due to

counterfeit aviation parts. The SUP Program Office developed and maintains the PRS system for informational and statistical purposes. The PRS database can provide reports of comparison for counterfeit parts on a year-to-year basis. According to the FAA's SUP Program Manager, less than 1% of their investigations involve counterfeit parts. The office reported that in the year 2000 only three of 262 closed cases involved counterfeit parts and in 2001, five out of 243 closed cases involved a counterfeit part. None of the counterfeit part cases involved human injury or death.

The NTSB database is the basis for annual accident reports on the civilian aviation and other transportation industries as mandated by Congress. In 1998, 652 million passengers boarded planes of which 4552 individuals boarded Part 121 aircraft (major airlines, cargo carriers or generally large transport category aircraft); of these, 110 persons were injured in incidents or crashes in which unapproved parts were identified.[31] These data indicate that the incidence of all unapproved parts injuries in 1998 was 16/1,000,000 passengers. According to the historical data prior to and including 1996, there are very few accidents, which included multiple fatalities or accidents with at least one fatality or at least one serious injury. The absence of fatalities due to unapproved parts is a testament to the working of this system.

DISCUSSION AND RECOMMENDATIONS

This work highlights the significance of counterfeit goods as not only an intellectual property and trade problem, but as an unrecognized public health problem with particular consequence in the area of injury morbidity and mortality. The principal finding of this study is that for both adults and children, on a worldwide basis, significant prevalence of injuries, disease and death are directly associated with counterfeit goods, particularly counterfeit alcohol, drugs, foods, personal care items and cigarettes.

Literature reviews employing the six-element screen validation process, disclosed cases of actual injury and death associated with counterfeit goods. The types of products that appear to have the highest potential for human injury are those consumed particularly alcohol, tobacco and drugs. Of the cases that were reviewed and could be validated, 21 appear to involve unwitting consumers in both the developed and developing world, including the countries of the United States, the United Kingdom, China, Cambodia, Russia, Brazil, Niger, Vietnam, and Egypt: thus, supporting the reality that counterfeit goods are a global public health problem.

Injuries associated with counterfeit goods are the same as those commonly associated with the recognized unintentional injury mechanisms of poisoning, cuts, burns, and fires and other disease conditions. The injuries reported in this study and summarized in Table 1 include adverse reactions, burns, swelling and rash among others. Unwanted pregnancy, hospital admissions and unsatisfied customers are also included under the more encompassing definition of injury or harm as used in this study. In addition to the aforementioned types of injury associated with a counterfeit, it also apparent that crime and terrorism and attendant mental and physical health consequences can be associated with counterfeit goods. Based on the assumption that at least some persons injured or harmed from counterfeit goods enter a health care system (which captures public health and vital statistics in the normal course), leads to a second key finding that at least some existing data on fatal and nonfatal injury and disease events are associated with counterfeits and that useful data could be available if healthcare professionals asked patients about goods used and/or consumed that might have caused their ill health. As health information systems are the basis for summary health measures, we conclude that morbidity and mortality associated with the use or consumption of counterfeit goods do contribute to the global burden of

disease and that healthcare entities should start monitoring this public health problem worldwide. These conclusions must be confirmed with further research and a detailed understanding of the nature of the public health problem of counterfeit goods must be developed.

Attention to the problem of injuries associated with counterfeit goods is called for given the significant contribution unintentional injuries alone make to the worldwide burden of disease and disability : 9.3 % of the total burden in the year 2000.[32] Only two other categories can claim a comparable share of the burden of disease: neuropsychiatric disorders (12.3%) and cardiovascular diseases (10.3%).[33] In the United States for the year 2000, unintentional injuries were the primary leading cause of death in persons under the age of 34, the 5th leading cause of death in all age groups, and the cause of 4.1% of all deaths, totaling 97,900 deaths in 2000 alone.[34] In 1996, former Surgeon General C. Everett Koop implored the U.S. Senate that the rates of injury and death attributed to unintentional injuries among just children justified huge public outcry, the sparing of no expense to find solutions to the problem of injury and alacrity.[35] Reducing and preventing injury has been the subject of much research and analysis, including several Institute of Medicine reports, the most recent published in 1999.[36]

Yet, despite the significant contribution injuries make to the burden of disease, no systematic studies have been conducted by public health organizations or government agencies on counterfeit goods. Thus, it is not known in what percent of all unintentional injuries counterfeit goods are implicated as the mechanism of injury, nor do we know the attributable risk of injury associated with counterfeit goods as compared to genuine goods. Further, because counterfeit goods are not coded in ICD as a mechanism of injury or disease, no quantitative analysis can be made to determine for which injuries and deaths counterfeits are involved and which types of counterfeit goods are the mechanisms of injury. Research is clearly needed to reduce injuries related to counterfeit goods. Steps to address this fundamental deficit in our ability to understand the full implications of counterfeit goods and the public's health are suggested here.

There is no public health literature on counterfeit goods, no public health agency such as the US National Center for Injury Prevention and Control, or any public health academic institution that focuses on the health effects from counterfeit goods even though one of the

clearest missions of public health is the prevention, amelioration and treatment of disease and injury. It is thus presumed that the dearth of data has resulted in the public health injury field overlooking counterfeit goods as an injury and disease mechanism. The lack of public health literature on the subject of counterfeit goods indicates that the problem is unrecognized. The fact that public health has not addressed, the problem of counterfeit goods and the public's health, suggests that all current reports on injuries from counterfeit goods should be regarded with caution.

For example, since no base line data on the prevalence and incidence of injuries and death related to counterfeit goods is available, no statements would have been made by public health characterizing the problem as epidemic or otherwise, even though one may exist. We simply do not know. Blatant instances of people allegedly affected by a counterfeit good are summarized in Table 1. Note that more than 100 persons were affected by counterfeit liquor in Vietnam, over 1000 hospital admissions resulted from counterfeit insulin in Russia, and 192,000 deaths allegedly occurred due to counterfeit drugs in China. Such numbers would and should have raised the attention of the public health community. Investigations would have been commenced and a variety of public health alert systems put into effect followed by such reports. This did not happen.

Our observation is that at this time there are virtually no dependable and available data directly linking counterfeit goods and injury, morbidity and mortality, but that available materials nonetheless clearly indicate that were health information systems to collect relevant data, the link would be incontrovertible. In addition, while it is the case that in many developing countries injury surveillance and overall public and vital health data collection is inadequate or non-existent, it is surprising to discover that no data is collected on counterfeit goods and injury even in those countries with developed health information systems such as the US. Nonetheless, a compelling case can be made based on the indirect and circumstantial evidence and analysis as this study discloses. And further, the findings of this study portray a preliminary description of some of the characteristics of the problem and directions for research and prevention.

Based on these findings and analysis, a course of action is proposed; the initial step is that of reshaping public policy regarding counterfeit goods -- to view them as more than just an intellectual property rights problem. Seeing counterfeit goods as a potential public health

problem refocuses the discussion on how to protect the public's health rather than just how to protect individual intellectual property rights and other economic interests. Focusing on protecting public health and quality assurance for goods with the potential to cause harm if counterfeited is essential. The following suggested steps are essential for prevention and protection from counterfeit products.

A Policy to Protect Public Health and Next Steps

The goal of this paper is to begin the process of shifting the policy perspective on counterfeit goods to an understanding that counterfeit goods are not only an intellectual property legal problem, but also a very real public health problem. To reframe the policy perspective is fundamental to the success of any strategy on counterfeit goods. Although the intellectual property legal system has focused considerable attention on the problem of counterfeit goods and is the major contributor of what is known, it was not designed to protect public health or to prevent injury. Rather, it was designed to contribute more safety and comfort to the lives of people by encouraging invention and to protect the interests of right holders.[37] The relevant essential functions of public health of policy development, the enforcement of laws and regulations that ensure health and safety, the assurance of quality in health care, the monitoring of health status, informing, educating and empowering people and the mobilization of community partnerships will be integral to finding solutions especially at this nascent stage. It is necessary at first that the unique expertise of public health be directed at quantifying and qualifying the problem so that appropriate scientific knowledge and guidelines can be developed and integrated with what is known from other fields concerned about counterfeits.

First and foremost, this study, and those to come, should be used to inform policy makers that the problem exists. In addition, it will be necessary for policy makers to comprehend just how counterfeit goods are both an intellectual property legal and a public health problem. It is at the intersection of these two fields that policy reformulation can be understood. The intersection is best seen when viewed in the context of health and safety laws and the ability of governments to enforce them and citizens to interact with the enforcement mechanisms i.e. domestic drug, food and consumer product health and safety regulatory authorities and customs inspectors at international borders. It is also the ability of

customs to inspect efficiently and effectively, as it is simply impossible for inspectors to sample and analyse all products subject to inspection.

Efficiency is therefore largely dependent on the ability of inspectors to rely upon trademarks, labels and other identifying marks, which indicate origin, quality, genuineness and other indicia of compliance with safety and health regulations. Such marks are made possible only within a legal system that includes intellectual property rights and recognizes the right to the exclusive use of a trade name or other identifying characteristics and the ability to control its use and commercialization. These marks are frequently counterfeited as indicated by EU seizure data. Counterfeit goods can be prevented from entering into the marketplace and causing harm as a result of customs and health and safety inspections and seizures as evidenced by the success of the US FAA SUP program for airplane parts and in the low numbers of US FDA seizures of products subject to their jurisdiction. The recent case of fake Lipitor recognized by the label is an excellent example of a system of recall working well to inform and protect the public.[38]

Well-developed drug and consumer product safety regulations and agencies, and intellectual property laws, and customs at borders must deter counterfeiting and enforce health and safety laws. The number of intellectual property seizures of counterfeit goods as indicated in Table 2 is testament to the efficacy of the system where it is operating optimally. In countries where such integrated systems are in place, consumers can in general take for granted that the products they consume or which are prescribed for health are safe. However, consumer blind faith may be compromised if more counterfeit products move into commerce. One could imagine what havoc counterfeits might wreck if these systems were not in place or where they are not or if resources devoted to intellectual property seizures are redirected towards other objectives (such as those within the new US Department of Homeland Security). If the WHO Myanmar-Vietnam study, which demonstrated that inspections are important to the ability of a drug regulatory authority to stop counterfeit trafficking, [39] can be generalized, then reduced inspections at US borders may lead to increased circulation of counterfeit goods. At present, given that no public health information or surveillance system is designed to recognize if there is any increase in injuries, disease or death related to counterfeits, policy makers should consider whether the current risk of this nebulous situation is acceptable. Perhaps this is all the more reason for

public health to be aware of this problem and to begin to aggregate data and formulate solutions.

Often in the developing/ underdeveloped world public health surveillance is inadequate or non-existent, and national legal systems may not have instituted adequate or extensive health and safety regulations common to the developed world; particularly in those with no developed intellectual property legal system and not required to achieve TRIPS compliance as of the date of this study or later. Thus, the ability of public health in these countries to fulfill the essential function of enforcing health and safety laws and regulations is seriously impeded. The risk of exposure to harm from counterfeit goods is elevated and prevalent. Of the 193 member states of the WHO, only one sixth have a well developed capacity to regulate drugs, one half have a limited capacity, and a third have limited or no capacity. [40] According to the World Trade Organization at least 48 countries are recognized as least developed of which 29 have yet to become WTO members and thereafter implement intellectual property laws pursuant to TRIPS. Compounding the danger to the public's health and safety is the fact that many of these countries do not have fully functioning drug regulatory authorities, consumer product safety, transportation and other types of government agencies that can enforce laws if and when enacted. It is only recently that some of these countries such as India and Nigeria are taking action to conduct pre-export bi-lateral inspections and pre-import unilateral inspections to prevent counterfeit drugs. [41]

In the case of a counterfeit product that is identical to the genuine and may even have improved packaging and be less costly than the original, the harm to health may seemingly be nonexistent. Nonetheless, by purchasing a counterfeit product a consumer will have no recourse against the manufacturer or an opportunity for contact for questions or to report adverse reactions.[42] It is the ability of a consumer to connect with the manufacturer or an appropriate regulatory authority that is an essential component of an overall safety enforcement system that alerts other consumers if a product is counterfeit. In addition, in the macro-economic sense, if counterfeiting is not prevented, intellectual property rights holders may decline market participation and innovation in countries where measures to prevent counterfeiting are not available.[43] This is of particular concern for the developing world, the countries of which have yet to become fully compliant with global intellectual property, trade, and anti-corruption norms and other laws. If product manufacturers decline to participate in a

market, consumers will simply have limited product choices. This will be true for all types of products, including drugs the absence of which clearly has dire consequences for public health.

Accordingly when governments consider the matter of counterfeit goods as an element of the fulfilment of their obligation to protect public health, they should consider consumer product, drug, food safety and health and intellectual property laws and integrate these with domestic and border enforcement systems. The enforcement of health and safety laws and regulations is what we, as a society through our governments, do to ensure the conditions in which people can be healthy and is a well-accepted and expected role of public health.[44] The obligation of governments to protect public health is clearly established as a matter of customary international law, treaty and national law. The World Health Organization (WHO) Constitution,[45] the International Covenant on Economic, Social and Cultural Rights (IESCR),[46] and many national constitutions such as that of South Africa, recognize the right to health as a fundamental human right. In particular, Article 12 of the IESCR enumerates the steps to be taken by governments in order to achieve the full realization of the right to health; one of those steps is to prevent injury.[47] Unlike the obligation to implement the provisions of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS),[48] the primary agreement related to intellectual property rights, the obligation to protect the right of health is a present one. There are no deferment timetables.

Public health interventions to reduce the exposure to harm related to counterfeit goods are not in conflict with trade law. The General Agreement on Trade and Tariffs (GATT) permits the imposition of trade restrictions and controls if necessary to protect public health and they are asserted in a non-discriminatory manner.[49] WTO members have the right to make full use of the safeguard provisions of TRIPS to protect public health and enhance access to medicines.[50] TRIPS assures that countries may take into account public health and public policy objectives when implementing their intellectual property law.[51] Trade and intellectual property law do not impede the search for solutions to the public health problem related to counterfeits.

Thus, it appears that an integrated system of intellectual property, consumer, drug laws and enforcement mechanisms are integral to the avoidance of harm associated with counterfeit goods. A high profile advocate may be necessary to accomplish the policy

reformulation recommended in this study and to achieve legislative or executive branch mandates to relevant and competent departments to create the impetus to collect data and allocate funds for research. It was the push from former Secretary of Defense Cohn who spearheaded a congressional investigation into suspected unapproved parts in the aviation industry that resulted in the data collection, and legal and regulatory changes that are responsible for the absence of aircraft crashes, injuries and deaths since 1995 due to counterfeit airplane parts. A strong advocate with personal contact with policy makers, armed with relevant research, and available research authors,[52] particularly with the backing and participation of industry can provide the political will to affect a system and garner the necessary financial and public health resources.

Data Collection and Research: The Path to Understanding the Problem

This work highlights the need to collect qualitative and quantitative data and conduct basic research in order to fully define the problem of counterfeit goods and to develop the epidemiology of counterfeit goods and disease. Public health should take the lead in this regard. This study also identifies the need to institute health information coding changes to capture counterfeit goods related injury data and to modify certain injury databases to add elements for counterfeits as injury mechanisms. Also, the need for a common definition of counterfeit, consistent terminology, cross reference systems, and methods to identify a counterfeit is discussed. These activities fall squarely within the public health function to monitor health status.

***Collect data*:** The first task is to develop data collections mechanisms. Data linking counterfeit goods and injuries is an essential tool for injury surveillance, monitoring, prevention and control. It is the starting place for research that would direct future solutions. The finding of this study that there is no data is not new. At least with respect to counterfeit drugs, the WHO has consistently reported on the inadequacy of data in its efforts to improve reporting, as have public health experts.[53] Even Interpol, which collects statistics on counterfeit currency and drugs, maintains the need for robust data.[54]This problem exists in other areas of public health.[55]At a minimum, data sets should be developed for counterfeit products with high potential for injury and disease, including alcohol, drugs, foods, personal care items and cigarettes. Brand owner identity can be delinked from data sets unless the

public release of brand identity is essential to protect consumers. Relevant to the process of data collection are the data aspects of coding changes, existing database refinement, developing a common definition, uniform terminology and methods to identify counterfeits. These sub-topics emerged from this research and discussion of each follows.

Coding changes: The ICD is the basis of global health data and adding a code for counterfeit goods, as the mechanism for injury, disease or death is the *sine qua non* of gathering adequate data. Coding refinements are a constant process and coding for injuries is an issue in general.[56]ICD10 has been amended to contain codes for terrorism related diseases and injuries in recognition of the public health consequences of terrorism;[57] the same should be done for the public health problem related to counterfeits. Once this recommended change is implemented, global data sets and other summary measures of population health would become available. In addition, as non-war related injuries are the leading cause of morbidity and mortality in the military (for example from off duty motor vehicle accidents, falls, poisonings, and athletics), an ICD code for counterfeit goods would allow the commingling of data on injuries in the military with that of the civilian population.[58]

Refine databases: Several well-developed databases can be refined to add data elements for injuries related to counterfeits including NCPSC, NEISS, NCIPC, USFDA, CODES and FARS. The National Electronic Disease Surveillance System (NEDSS) is a new initiative created to advance the development of surveillance systems at state, local and federal levels. NEDSS could provide the basic platform for the collection and dissemination of data to alert and notify the public, professionals, industry, and government agencies that a particular counterfeit good is circulating and has caused injury. If any of the above databases provided alerts for counterfeit goods, it would be an invaluable resource in the prevention and control of counterfeit related injuries.

Common definition: This research indicates that unless a common definition of a counterfeit good is developed the reliability and usefulness of data and any reports will be limited. Differing definitions in the law and practice were cited by WHO as a problem with counterfeit drug statistics.[59] A pattern appeared in the surveyed materials whereby terms such as unapproved, substandard, shoddy, cheap, contraband, and fake were used interchangeably with the word counterfeit to describe products, which may or may not have

been counterfeit. However, the materials drew conclusions as if the goods were in fact counterfeit; thus the veracity of certain reports is placed in question. This is particularly troublesome when deaths or injuries are attributed to alleged counterfeit goods if, in fact, they are not.

The deaths in Haiti due to the ingestion of diethylene glycol (DEG) contaminated glycerin[60] are an example. In 1995-1996, over 90 children died from anuria (inability to urinate) and renal failure after exposure to contaminated drugs. After an extensive epidemiological investigation, it was discerned that a local producer of two drugs, Valodon and Afebril had used imported contaminated glycerin without confirming the safety and potency of the raw ingredient. Although, it was not possible to trace the origin of the contaminated glycerin, the glycerin had probably moved through several countries. And the Haitian manufacturer of the drugs had not tested its quality prior to its use. The epidemiological investigation concluded this was not a case of counterfeit drugs; however, at least three reports referred to the glycerin and drugs as counterfeit. [61]According to WHO, other cases in Nigeria, Bangladesh, Argentina, and Haiti mentioned in various reports were cases of substandard drugs, not counterfeits since the product manufacturer had unknowingly used the incorrect ingredient. With respect to another example regarding airplane parts the terms unapproved and counterfeit are used interchangeably with respect to injuries and deaths reported in the media and industry releases,[62] even though FAA data does not support the conclusion that counterfeit airplane parts are associated with air crashes as the term unapproved has specific meaning.

Uniform terminology: Media, advocates and trade and industry groups have been carrying the responsibility of warning consumers and informing policy makers of the dangers of counterfeit goods and have authored the majority of reports. It is critical for the government to take a role in developing common definitions, uniform terminology and report guidelines. Existing groups should be invited and involved in this governmental initiative because their current input and cooperation will assure the breadth, accuracy and ultimate value of the data. Focusing on health-related counterfeit terms, data, reporting validity (anecdotal and evident) in terms of date, quality of data, and who, how, where, when and why should be included in governmental studies and open-sourced to all interested parties.

Additionally, it became clear while constructing Table 2, that if it were possible to compare seizure data from one country to that of others, it could be more useful in counterfeit goods surveillance. In the EU where member state data is capable of being commingled on a regional level it is possible to determine that in 2000 of all intellectual property rights counterfeited, 78% were trademark violations, 15% were copyrights, and the balance designs and patents.[63]From this data, it is clear that interventions in Europe should be directed at stemming trademark violations. Unfortunately, in US and EU customs data, there is no common terminology used to describe categories of seized data. The EU places eyeglasses in the category of wearing apparel; the US does not. Correcting impediments to a full cross comparison and sharing of seizure data would enhance the ability of law enforcement to intercept counterfeit goods, as well as to establish global alert systems,[64] trace products to their origin, and detect global trends.

Methods to identify a counterfeit: Lastly, valid methods must be developed by which health care workers, laypersons and others can identify a counterfeit. Once ICD is refined to code for counterfeits as the mechanism of injury or the suspected one, protocols and training thereon must be developed for health care workers and researchers to identify counterfeits or to question injured or ill persons as to the circumstances which may give rise to a suspicion or confirmation of a counterfeit. The same issue arises with respect to counterfeit auto parts. Currently, the CODES system does not provide a mechanism to capture the cause of the accident. It is simply not possible for emergency workers and police at accident scenes or in hospital emergency settings to make this determination. However, providing the coding mechanism so that the cause can be entered later is very possible and allows for statistical compilation. The EU tax data collection process is a good model in this regard because the right holder must confirm the counterfeit nature of the goods before the statistics are included.[65]

Research: Injury epidemiology has provided a reliable framework to identify the key biologic, epidemiological, socio-cultural, economic, legal, and political determinants of counterfeit goods in relation to public health. Whether there is insufficient and inadequate enforcement of existing laws[66] and/or a lack of attention to the damages caused by counterfeit goods[67] as some have maintained, theories to form the basis for future research must identify key determinants of the problem which ultimately become the targets for

interventions. Table 3 is a conceptual framework known as a Haddon Phase-Factor Matrix [68] prepared in order to present potential key determinants implicated by this study. Potential key determinants are arranged at the top under the larger order categories of biology, epidemiology, socio-cultural, economic, political and legal factors. Table entries are categorized as pre-injury/event stage, injury event or post-injury event. Through examination of the information on this chart, (i.e. noting potential interventions such as poor manufacturing practices, lack of data, lack of enforcement of laws, and little collaborating experience between public health and trade as pre-event determinants), models to test effective intervention strategies can be devised. Research is ultimately needed to test the validity of the determinants implicated by this study and other appropriate prevention and intervention strategies.

Community Collaboration and Possible Intervention Strategies

A collaboration of communities will be needed to solve the problem of counterfeit goods. Here the term community is used in the broadest sense and will include global, national and local communities in public health, policy, industry, intellectual property, trade, government, donor, law enforcement, and consumer groups among others. Public health expertise in data collection and analysis, injury epidemiology and prevention is unique and will be critical to defining the problem, measuring it, determining key determinants, searching for solutions and testing outcomes. However, no 'one' solution exists within the competence, parameters and resources of public health or any other interested community. Thus, a collaboration of communities will be necessary in order to achieve success.

Answering the USPTO call to action, and accomplishing the task of protecting both public health and intellectual property rights goals, is a unique undertaking and will require collaboration between two fields that have different purposes and some historical animosity. The intellectual property legal world has traditionally focused on the implementation of laws, policies and regulations to create and enforce intellectual property rights, which essentially protect a small limited class of rights holders. The intellectual property legal system is intended to also encourage invention by protecting the rights of those who innovate by according control over the commercialization and use of inventions once documented according to relevant laws. Public health on the other hand is what we, as a society, do

collectively to assure the conditions in which people can be healthy[69] and emanates from a population-based perspective seeking to implement population-wide strategies to prevent or ameliorate morbidity and mortality. The derivation of the tensions that have arisen in recent years on the issue of drug access is in part a result of this difference in perspective.

Progress has been made, although not smoothly at times, in the last twelve or more years in resolving the differences between the fields of intellectual property and public health. Along with the growth in international trade and globalization, awareness and acceptance has grown that economic and trade prosperity is greatly influenced by overall public health.[70] Drafters of international trade rules and national intellectual property laws must develop greater appreciation of their impact on health. In fact, drafters are advised that intellectual property laws do not supplant a nation's obligation to protect public health, which can take primacy over property rights.[71] Exactly how these two domains influence and interact with each other and how public health concerns can be integrated into the intellectual property legal system will evolve over the next ten or more years. Solving the problem of counterfeit goods and public health will occur in this environment.

Unlike the drug access problem, however, counterfeit goods are a problem shared by each now and are a subject where collaboration between these disparate realms can result in solutions to the common problem. This is so because the intellectual property field is opposed to counterfeit goods and the field of public health should be given the fact that counterfeit goods are the mechanism of injuries and disease. The subject of counterfeit goods is therefore an area in which health and trade overlap; the solution to which requires collaboration from each.[72] Efforts to protect public health from injury associated with counterfeit goods can complement and augment strategies to protect intellectual property rights. The fact that some interventions protect intellectual property rights does not negate their importance to the protection of public health and safety.

An excellent example of a collaboration of communities is that surrounding the global epidemic of tobacco related diseases. The Framework Convention for Tobacco Control Draft Protocol on Smuggling is indicative of an international framework based on the global recognition that the public health problem of tobacco and counterfeit cigarettes can be controlled through law and public-private collaboration.[73] The international public health community has made a clear case that counterfeit cigarettes pose a public health problem.[74]

Counterfeit cigarettes undermine government efforts to reduce smoking and maintain the non-smoking status of citizens; they are targeted primarily at low-income consumers, evade the prohibitions on sales to minors and evade regulations on additives and labeling. The smuggling protocol includes penalties, product markings to make contraband products easier to detect and trace, licensing of members of the supply chain, and labelling requirements, such as health warnings.

Another clear opportunity for collaboration is between the media and industry and public health. The content of available reports suggests that public health was not consulted prior to the publication as lawyers often are. Consultation prior to publication of reports might have permitted the addition of the unique perspective of public health and thus the utility of their messages enhanced. Consultation on term definitions, government data, checking report validity and the relevance and implication of evidence in terms of date, quality, and how and where it is reported would be a valuable point of collaboration between media and public health.

Potential strategies: A number of actual or potential strategies described in the materials surveyed are worth mentioning. Generally, they are regulatory and legal, but some are trade procedures or quality standards designed to reduce the circulation of counterfeits or to enhance the ability of law enforcement, to intercept, capture and punish counterfeiters.[75] These strategies are presented here; organized by whether they affect international trade or can be implemented at a national or local level.

Strategies affecting international trade: Intervention strategies such as pre-import or export inspections are successful in reducing the number of counterfeit goods and should be continued. If some of these had been in place in 1995-6, the deaths in the Haitian DEG case in which a local manufacturer unintentionally used contaminated glycol in children's medication, might have been prevented or the original source of the toxic ingredient might have been discovered. Measures to combat counterfeit goods can be integrated into overall measures to improve security at international borders.

It may be possible to develop global or uniform laws and harmonized standards as additional strategies, such as worldwide frameworks for the control of pharmaceuticals to prevent substandard and counterfeit drugs. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) may be

a step in that direction. Globally standardized testing, analysis and laboratory accreditation can be developed at least for products with the potential to harm humans. For example, ISO recently announced a guide to conformity assessment to improve the efficiency of international trade.[76]This may be accomplished more easily on an industry-by-industry basis and is ongoing in the tobacco,[77]chemical, and pharmaceutical excipients industries.[78] Global standards on the accreditation of labs, types of tests and analysis on all products with the potential to be harmful to humans may reduce the opportunity to forge certificates of quality. Identification, tracking and recording systems, licensing and technology can also be useful. These are described in Appendix B.

National or local laws: National and local laws can authorize the establishment of a regulatory authority which can be the central collection point for data and its analysis, communication of alerts and the imposition of sanctions. This type of alert and surveillance system is what makes the SUP program so successful in combating counterfeit airplane parts. Ideally, an alert system would be integrated with law enforcement, customs and the public health system, to provide a place for consumers to furnish information on purchases and injuries. The Myanmar-Vietnam study demonstrated that increased inspections stopped counterfeit drugs from crossing into Vietnam. Enhancing the roles of drug regulatory agencies with legal authority particularly in the developing world is an essential step.[79] (See the WHO Essential Drugs and Medicine Policy, Drug Regulation and Quality Assurance Systems developed in consultation with IFPMA and industry groups for other strategy elements.[80]) A central regulatory authority is necessary not only for pharmaceutical regulation, but also for other industries that produce products having a potential for human harm.

Local and provincial governments can also play a role. For example, North Carolina enacted a law in1991 which requires products to be safe, to be manufactured from approved ingredients, and to be labeled truthfully. The legislature is currently considering tightening a loophole that permits an in-state wholesaler to accept a shipment from an out-of-state wholesaler not licensed to do business in the state. [81] North Carolina is not alone in addressing the consequences of the wholesaler-retailer network and the opportunities it presents for counterfeiters; Nevada, Florida, Georgia and Minnesota among others are grappling with legislative remedies.[82]

A full analysis of jurisprudence that may have the potential to reduce the risk of exposure to counterfeit goods is beyond the scope of this study. However, some examples might include the criminalization of trafficking in counterfeit labels or participation in any act related to counterfeiting, requirements for post-market surveillance on drugs to identify adverse reactions due to counterfeiting, imposing liability on right holders for failure to take action on a counterfeit alert, regulating the internet sale of drugs, and settling the rules on importation of drugs for personal consumption.

Health Communications

To date it does not appear that the channel of health communications has been utilized to address counterfeit goods. Health communications programs and research, which focus on how to inform, persuade, and mobilize overt behavior change, should be leveraged to determine the best approaches. Health communications campaigns can address two issues raised by the problem of counterfeit goods. First is the perception that counterfeits present a victimless crime and therefore no harm occurs if one knowingly purchases a counterfeit. Second is the need for consumers to be aware that they may be buying or have purchased a counterfeit and what to do if they become ill. A 1998 poll reported that 40% of the public would consider buying a counterfeit good with knowledge of fakeness, thus, there appears to be a perception that buying counterfeit goods is a victimless crime.[83] This is not surprising since many products, which are counterfeited and are knowingly purchased, such as perfume, watches, jeans, pocketbooks and other luxury goods or wearing apparel, are not associated with reports of injuries, disease or death. Thus, research on the behavior of knowingly buying counterfeit goods would be a useful tool to first confirm the public perception of buying counterfeits, whether it is perceived as a victimless crime, and then to identify factors that might reduce this behavior. One possible hypothesis to test via this health communication research is whether information regarding the potential harm of counterfeits will affect purchasing behavior; and ultimately whether changes in the intentional buying of counterfeit goods would effect the overall production and circulation of counterfeits.

In addition, health communications and education programs could be created to inform consumers how to identify a counterfeit, what steps they can take to prevent purchases, and what to do if one is injured or made ill by a counterfeit. Events sponsored by

industry in which counterfeit goods are displayed and educational materials and programs are offered are a useful component of overall strategy to educate the public.[84] However, given the apparent perception that there are no victims of counterfeit goods, this type of program may be more effective if offered by a public health department or other non-industry related entities. Other educational messages that can be tested and delivered in a manner based on solid health communications theory, include: guidance to shop only at solid "stationary" pharmacies; locating reputable online venues with well known and traceable ownership, how to recognize suspicious packaging, labeling, and printing, locating information on the producer, ingredients and expiration dates, what to look out for when buying at kiosks, and individuals on the street. Cultural differences and sensitivities must be taken into consideration when developing health communications and education programs, as should the capacity differences implicit in the distinctions between the developed, developing and underdeveloped countries.

CONCLUSION

Even though the data on counterfeit goods and the public's health and safety is limited it is enough to declare a problem exists and this is enough to create the impetus to begin scientific study on counterfeiting as a potential source of injury, disease and death and what to do to reduce the risk of exposure. Actual reported cases of injury and death around the world have indeed established that counterfeit goods are a very real global health concern. The absence of sufficient data prevents a full quantitative and qualitative description of the problem, at this time. However, the preliminary findings and description developed in this study provide clear direction for data collection and ample opportunities for the generation of hypotheses for research to find solutions to the problem.

This study serves the essential purpose of raising awareness and thereby launching the process of creating international policy standards whereby counterfeit goods are seen as a public health problem to be dealt with globally and nationally. People are being injured and sickened. If current legal enforcement resources at local, national and international levels are insufficient or redirected, opportunities increase for crime and terrorism groups to escalate trade in counterfeits. We cannot let our guard down. Seizure statistics indicate that the

quantities of counterfeit goods are increasing and thus the potential for harm to public health escalates accordingly.

To take no further action means that public health and governments will fail to fulfill their current obligation to protect the public's health. Without data and research leading to effective interventions, populations worldwide are at risk of harm and decidedly unaware of the dangers of counterfeit goods. Although no data appears to indicate a public health epidemic that does not mean that one does not exist. The matter at hand is now to determine how many of the persons entering health care systems worldwide are ill or dying or not getting well as a result of consuming/using a counterfeit product and to implement appropriate intervention strategies. To proceed otherwise is to blindly court disaster. This study heralds that it is time to answer the call to action the US PTO has placed before us with all the knowledge and resources at our command.

LIMITATIONS OF THE STUDY

The methods used to identify available data relied upon readily available published reports searchable through electronic databases. This precluded any studies and data that governments may have conducted but have not made available for searching in electronic databases or library search systems. No effort was made to collect this type of report or to determine if any available; however, it is highly doubtful such reports exist. The data are so limited that no statistical analytical tools could be employed to conduct a meta-analysis or other techniques commonly used to evaluate data. Several assumptions were made to connect heretofore-disconnected information in order to construct the preliminary conclusions of the study. These will need to be tested and further evaluated.

There is also no way to determine if we have identified the universe of injury events related to counterfeits, nor even the universe of available published literature. As a result, certain stories and other reports may have been missed. However, as four independent researchers conducted the research, we are confident that all significant reports, databases and relevant literature have been identified and searched. We did not include materials we reviewed but that did not meet our search criteria.

Since there were no reports of actual injuries related to media, wearing apparel, and vanity products and for many other commonly counterfeited products, this report does not address them. These products comprise more than 60% of products seized by US customs and therefore represent a major proportion of counterfeited goods. No conclusions can be drawn on the public health effects of these products.

Emotional and financial harm, societal cost of crime, the attraction of organized crime to a community, tax revenue and job loss, and costs to health care budgets are potential costs of counterfeiting, but these are beyond the scope of the survey.

TABLE 1: SUMMARY OF REPORTS OF COUNTERFEIT GOODS RELATED TO INJURIES

Product	*Place*	*Injury*	*# People*	*Source of report*	*Date of injury*
Insulin	Volograd, Russia	Hospital admission	1000	PBN Co[85]	2001
Dietary supplements	Texas, US	Adverse reactions	Complaints	Metabolife[86]	2000
Enfamil	US	Ill	2	USFDA[87]	2000
Birth control pills	Brazil	Unwanted pregnancy	12	Brazzil [88]	1998
AIDS triple cocktail	Brazil	Panic	120	Brazzil	1998
Androcur	Brazil	Death	10	Brazzil	1998
Fake drugs-unspecified	China	Death	192,000	Washington Post[89]	2001
Viagra	China	Unsatisfied customers	On-line customers	CNN.com	2001
Serostim	US	Swelling/rash	Some patients	BMJ [90]	2000
Meningitis vaccine	Niger	Death	2500	WHO counterfeit drug reports[91]	1995
Baby powder	Vietnam	Death	300 children	AP-Dow Jones	1997
Liquor	Vietnam	Death	100 adults	AP-Dow Jones	1997
Medicines	Vietnam	Death	27adults	AP-Dow Jones	1997
Vodka	Russia	Death	22	ACG	
Wine	Egypt	Death	One	ACG	1996
Washing powder	UK	Can cause burns	None cited	Dept. of Trade and Industry	2000
Vodka	UK	Blindness	One	ACG [92]	1999
Food sprayed with banned pesticides	China	Death	69	Christian Science Monitor[93]	1999
Beer bottles	China	Death	Dozens	Same	
Alcohol	China	Death	Dozens	Same	Each year
Cigarettes	China	Headache	Unspecified	Business Week[94]	--

TABLE 2: COMPARISON OF US AND EU 2000 CUSTOMS DATA ON SEIZURE FOR TYPE OF PRODUCT, RANKING OF PRODUCTS, COUNTRY OF ORIGIN AND TREND DATA FOR PRODUCT TYPE FROM 1999-2000.

2000 Customs Seizure Data Comparison for US and EU	*US Top Commodities 2000 -rank* Noted by % of total seizures	*Trend 1999-2000 US*	*US Top Countries of origin*	*EU Top Commodities 2000- rank noted by #*	*Trend 1999-2000 EU*	*EU Top Countries of origin*
Media	17%	-56%	China	2nd	+3311%	Thailand
Toys, electronics	13%	+160%	Taiwan	5th	+94%	China
Computer/hardware	10%	No change	Malaysia	8th	--	Hong Kong
Wearing Apparel	10%	+142%	Hong Kong	1st	+144% [95]	Thailand
Cigarettes	9%	No rank in 1999	Singapore	--	--	--
Watches/Parts	9%	+450%	Korea	4th	+629%	USA
Handbags, wallets, backpacks	4%	+200%	Panama	1st	--	Thailand
Consumer electronics	3%	No rank in 1999	Mexico	7th	-29%	Hong Kong
Sunglasses	3%	-80%	Italy		--	Thailand
Footwear	3%	No 1999 rank	France	1st	--	--
Other- medicine, auto parts	19%	+135%	--	3rd	+127%	USA
Foodstuffs, alcoholic and other drinks	--	--	--			Turkey, Poland
Perfumes and cosmetics				6		

Data source: US Customs Top IPR Seizure by Commodity and Country of Origin[96] and European Commission Taxation and Customs Union Data on Counterfeit, for 2000.[97]

TABLE 3: CONCEPTUAL FRAMEWORK TO IDENTIFY KEY DETERMINANTS OF THE PUBLIC HEALTH PROBLEM OF COUNTERFEIT GOODS

Determinants► Event stage▼	***Biology/ Technology***	***Epidemiology***	***Socio-Cultural Factors***	***Economic Factors***	***Political Factors***	***Legal Factors***
Pre-event defined as making the counterfeit good	Poor manufacturing practices Safety innovations	Temporal relationship between increases and decreases in production and interventions Lack of data Lack of a common definition	Organized crime[98] and terrorism Criminal infiltration into law enforcement Easy for counterfeiters to relocate[99] Little experience in the relationship between trade and health	Counterfeiting is profitable Cost benefit and cost effectiveness regulation EU principle of free movement of goods[100] VAT tax[101]	Lack of enforcement or sporadic enforcement of existing IP laws[102] Lack of global and central data base Obligation to protect public health not fulfilled	Temporal relationship between increases and decreases in imported and exported and intervention Lack of chain of custody markings or deterrence Obligation to protect public health not fulfilled
Event defined as placing the good into commerce where it can cause injury or injury	Lack of resources and techno-logical sophistication to detect fakes	Not on public health radar screen	Public health education and health promotion campaign	Channels of distribution; clandestine or commercial[103] Price of drugs	Border sampling strategies Gov't corruption Lack of uniform testing standards Lack of IP laws	Lack of a common definition Lack of IP laws Lack of harmonized standards
Post-Event defined as consumer, industry and government actions after the event	Assay tests to ID contents	No epidemiological studies, No public health summary measures-	Little health communication campaigns on what to do if one is injured, how to avoid counterfeits	No measures of costs to national health budgets		Compen-sation for injuries Punishment for infringers who harm humans

APPENDIX A: ORGANIZATIONS, KEY PLAYERS, AND OTHERS INVOLVED IN INJURY PREVENTION AND CONTROL AND ACTIVITIES RELATED TO COUNTERFEIT GOODS.

Anti-Counterfeiting Group
PO Box 578,
High Wycombe
Buckinghamshire, HP11 1YD
United Kingdom
Tel: +44 (0) 1494 449165
Fax: +44 (0) 1494 465052

American Public Health Association
(Injury Control & Emergency Health Services)
800 I St., N.W.
Washington, D.C. 20001-3710
Tel: 202 777-APHA
Fax: 202 777-2534
www.apha.org

Beijing Dahai Consultants - Wang Hai- China's Ralph Nader
http://www.csmonitor.com/durable/2000/01/25/fpls5-csm.shtml
www.csmonitor.com/durable/2000/01/25/p155.htm

Car Fax
Tel: 518 348-1042
email: Garen@carfax.com

Coalition for Intellectual Property Rights - Russian
www.cipr.org

Commerce Department
Herbert C. Hoover Bldg.
14th & Constitution Aves.
Washington, D.C. 20230
Tel: 202 482-2000
www.doc.gov

National Science Academies (National Science Foundation)
2101 Constitution Ave., N.W.
Washington, D.C. 20418
Tel: 202 334-2000
Fax: 202 334-2158
www.national/academies.org

US Consumer Products Safety Commission

Headquarters: U.S. Consumer Product Safety Commission
Washington, D.C. 20207-0001
Address:
4330 East West Highway
Bethesda, MD 20814-4408
Tel: 301 504-6816
Fax: 301 504-0124 and 504-0025
email: info@cpsc.gov
Web:http://www.cpsc.gov
Hot Line: 800-638-2772

US Food and Drug Administration

5600 Fishers Lane
Rockville, MD 20857-0001
Tel: 1 888 INFO-FDA (1-888-463-6332)
www.fda.gov

GACG Global Anti-Counterfeiting Group

16 rue de la Faisanderie
75116 Paris, France
Attn: Mrs. Elisabeth Ponsolledes Portes
Vice Chairman John Anderson
www.gacg.org

International Generic Pharmaceutical Alliance

P.O. Box 193 B-1040
Brussels 4, Belgium
Tel: +32-2-736 8411
Fax: +32-2-736 7438
www.EGAgenerics.com

International Federation of Pharmaceutical Manufacturers Association

30 rue de St.Jean
P.O. Box 758
Geneva 13 1211, Switzerland
Tel: +41 223383200
Fax: +41 223383299
email: admin@ifpma.org
www.ifpma.org

International Anti-Counterfeiting Coalition

1725 K Street N.W.
Suite 1101
Washington, D.C. 20036
Tel: 202 223-6667
Fax: 202 223-6668
www.iacc.org

International Chamber of Commerce

Counterfeit Intelligence Bureau
Maritime House, 1 Linton Road, Barking, Essex IG11 8HG
United Kingdom
Telephone +44 (0)20 8591 3000 Fax +44 (0)20 8594 2833
e-mail: cib@icc-ccs.org.uk
Peter Lowe, Assistant Director

Intellectual Property Institute

1st Floor, 36 Great Russell Street
London
WC1B 3QB
Tel : +44 (0) 207-436-3040
Fax: +44 (0) 207-323-5312
www.ipinstitute.org.UK

International Organization for Standards

www.iso.org

INTERPOL

Interpol IP Advisory Group - Erik Madsen
Financial & Hi-Tech Crime Sub-Directorate
200 Quai Charles de Gaulle
69006 Lyon, France
Tel: +33 4 72 4471 90
Fax: +33 4 72 4472 21
email: e.madsen@interpol.int
www.interpol.int

Investigative Consultants

Investigative Consulting Group
6401 Golden Triangle Drive
Greenbelt, MD
301 220-3230

Johns Hopkins Center for Injury Research & Policy
624 N. Broadway
Room 554
Baltimore, MD 21205
Tel: 410 614-4025
Fax: 410 614-2797

National Criminal Intelligence Service UK
P.O. Box 8000
London SEII 5 SEN
Tel: 020 7238 8000
Tel. for publications: 020-7238-8431
email for publications: press@ncis.gov.UK
www.ncis.co.uk

Oxford University
Centre for Tropical Medicine & Infectious Disease
The University of Oxford
United Kingdom

NCIPC National Center for Injury Prevention and Control
Mailstop 565
4770 Buford Highway N.E.
Atlanta, GA 30341-3724
Tel: 770 488-1506
Fax: 770 488-1667
email: OHCINFO@cdc.gov
www.ncipc.gov

US National Transportation Safety Board
490 L'Enfant Plaza, S.W.
Washington, D.C. 20594
Tel: 202 314-6000
Fax: 202 314-6148
Web: www.ntsb.gov

Proctor and Gamble
Cincinnati, Ohio 45203
Corporate Web: www.pg.com
Tel: 800 879-8433 General Information

Packaging Solutions Advice Group
www.psag.co.UK

Recording Industry of America
1330 Connecticut Ave., N.W.
Suite 300
Washington, D.C. 20036
Tel: 202 775-0101
Fax: 202 775-7253
http://www.riaa.org

Underwriters Lab
Government Liaison Office
1850 M St., S.W.
Suite 1000
Washington, D.C. 20036-5833
Tel: +1-202- 296-7840
Fax: +1-202-872-1576
email: gillermang@aol.com
www.ul.com

UNECE
Economic Commission for Europe - Intellectual Property Group
www.unece.org

WHO
Avenue Appia 20
1211 Geneva 27
Switzerland
Tel: (+41 22) 791-21-11
Fax: (+41 22) 791-311
www.who.int

APPENDIX B: TRADE AND TECHNOLOGICAL SOLUTIONS TO PREVENT COUNTERFEITING

Identification systems: A system that permits the tracking or tracing of goods as they move through the chain of custody to identify the manufacturer, country of origin, final destination, date of manufacture, the distributor, wholesaler and exporter would accelerate investigations when injuries or counterfeit goods are detected. Unique serial numbers and UPC codes are examples that can provide not only pricing and inventory control, but also a basis on which to trace a product. The technology of bar code scanners, product tags that send radio signals to manufactures, downloadable product information from bar codes, 96 bit ID numbers are available. Minimum package design and labelling may also be used to permit tracing to the origin of a product.

Tracking and recording systems: The onus to prove that products actually arrive at intended destinations can be placed on shippers or manufacturers and can be enabled with a computerized control system, such as is readily available now to track exports. This type of system is already under consideration in response to the illegal diversion of donated and subsidized drugs to the developing world. This EU plan incorporates tracking of consignments, differential packaging and a public awareness campaign.[104]

Licenses: Licensing fine chemical and drug excipient manufacturers, tobacco growers and manufacturers, and other product manufacturers, can be required. The potential to loose a license can be an incentive for a manufacturer to analyse product before repackaging and shipping outsourced orders. This is particularly important if a manufacturer commingles product and may have prevented the Haitian DEG incident.

Technology: Each private company can also consider the use of technology to combat counterfeiting. For example, Schering AG uses specialized high tech packing equipment in Western Europe and then ships product to Russia. Schering reports their products are not counterfeited in Russia as a result. [105]

APPENDIX C: COUNTERFEITED PRODUCTS ENCOUNTERED IN THIS RESEARCH

Airline tickets
Alcohol
Apparel
Auto parts
    brake pads, engine, steering and suspension components, tires
Aircraft parts
Baby formula
Cable/telecommunications
Children's clothing
Clothing
Cigarettes
Cosmetics
Drugs
Education credentials
Electric products-
    Christmas tree lights, GFI plugs, TVs and videos
Fertilizers
Food products-
    health drink
Internet piracy- fraudulent products offered on the net
Jewelry
Medical devices-
    intra-aortic pumps
Perfume
Purses
Shampoo
Software
Sunglasses
Toiletries-
    toothbrushes, washing powder
Tools-
    screw drivers
Toys
Watches

APPENDIX D: ABSTRACT AND MESH HEADINGS

Background: Little has been done to describe the link between injury, disease and counterfeit goods despite the fact that in the US alone unintentional injury was the 5th leading cause of death in the year 2000 and contributed 10.6% of the total worldwide burden of disease in disability. This study was the first to be conducted to determine if a public health problem associated with counterfeit goods could be quantified, whether there is data linking counterfeit goods and injury and, if possible, to identify and understand its determinants.

Methods: A literature search was conducted of public health data sources, media, government, national databases, and industry reports for cases actual human injury occurring in the year 2000. A six-element screen was developed to validate materials.

Results: Sufficient data exists to establish that worldwide adults and children are experiencing injury and death associated with counterfeit goods. Data is insufficient to quantify the problem. Limited data suggest that injuries related to counterfeit goods are associated with terrorism, tobacco, drugs, alcohol, personal care products and foods. The public health information system does not identify disease related to counterfeit goods, ICD does not code counterfeits as a mechanism of disease.

Discussions and Implications: Policies, programs and laws to control counterfeits can be assisted by timely and reliable information about the extent, patterns, and trends in injuries related to counterfeit goods, their use in populations, health and socio-behavioral factors that underlie counterfeit purchasing behavior. The government and public health community need to work with the intellectual property legal system and industry to measure the problem, conduct research, and create strategies for the prevention of injuries related to counterfeit goods.

Conclusions: Changes to data collection, data coding, national health statistics, policy and legal changes, research, and public health promotion campaigns are recommended. Recommended interventions are compatible with and complementary to efforts to enforce intellectual property rights and the obligation of sovereign nations to protect public health and safety. To permit the status quo of non-attention to the public health aspects of counterfeits is to court potential disaster.

Medical Subject Headings (MeSH): injury, national health statistics, causes of death and injury, counterfeit goods, injury prevention, intellectual property, International Classification of Diseases, quality assurance, international trade, customs, health care quality and health system reform.

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