



COUNTERFEIT GOODS AND THE PUBLIC'S HEALTH AND SAFETY

Michele Forzley, JD, MPH

July 2003

906 Pennsylvania Avenue, SE
Washington, DC 20003
202-544-6610
www.iipi.org

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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.

ACKNOWLEDGEMENTS

The International Intellectual Property Institute (IIPI) and the author would like to thank the United States Patent and Trademark Office for its support of this study and Mr. Peter N. Fowler for his participation and guidance. IIPI and author would also like to thank Kenneth Reilly, Manager of the US Federal Aviation Administration Suspected Unapproved Parts Program (FAA SUP) for conducting a special search of the SUP database.

The author gratefully acknowledges and thanks Renate Wilson, Ph.D. and Efrat Shadmi RN, Ph.D. candidate and Linda Kenney, MPH candidate, Johns Hopkins School of Public Health, Department of Health Policy and Management for their reading and helpful comments on drafts of this report and Scott Powers, JD, LL.M., Anitha A. Samy, MD, MPH and Nickolas Zaller, Ph.D. candidate, for their thoroughness in searching for data on counterfeit goods and the public's health.

Correspondence should be addressed to: Michele Forzley, JD, MPH, 3120 Lee Street, Capital View Park, MD 20910 U.S.A. Telephone 301-565-1693. Email: mforzley@comcast.net. The contents of this study were developed under the sponsorship of the US Patent and Trademark Office. However, these contents do not necessarily represent the policy of the US Patent and Trademark Office.

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

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