

## **The Fifth Horseman**

The Importation of Counterfeit  
and Unsafe Prescription Drugs:  
A Real Threat to Our Nation's  
Health and Safety

**July 12, 2000**

## Executive Summary

As Congress debates making it easier for American consumers and wholesalers to import prescription drugs into the United States, **policymakers should examine the pernicious tide of counterfeit and unsafe pharmaceuticals coming over our borders every day.**

Hundreds of media reports and government documents as well as anecdotal evidence point to the fact that no community in the nation is safe from counterfeit pharmaceutical products – and globalization has brought the black market to the doorstep of every home in America. **Already 25% of the drugs bought in Mexico by Americans are counterfeit,** according to DEA agent Eric Hill. (San Diego Transcript) Of the remaining 75%, the vast majority of these Mexican drugs are not from approved FDA facilities.

Rows of drugstores line the streets of towns across the border from the U.S. (FDA-OCI) serving many elderly and Hispanic people in search of inexpensive prescriptions.

Many of these medicines are manufactured under standards not acceptable by FDA, and contain adulterated and sometimes dangerous ingredients.

The advent of the Internet (Egan) has opened a new supply chain for American consumers looking for cheaper – but not safer – drugs. E-commerce is supplementing the vast trade in areas near the borders, creating a potentially serious health problem. (Abromowitz)

The Food and Drug Administration – charged with ensuring the safety of our medicines — has been concerned by the size and sophistication of the black market for years. **The U.S. government does not always have the firepower to assure the quality of products imported to the Nation.**

It wasn't until tons of counterfeit active chemicals had been distributed, (Lewis) that FDA stumbled unto a major illegal operation. (Nielsen) In addition, the FDA has remained reactive rather than proactive, not willing to organize a task force to look into the matter of counterfeit bulk drugs coming into the nation "in the absence of actual allegations or cases for such a task force to work." (Henney, FDA Counterfeit Drug Initiative)

On May 8, 2000, Congressman Tom Bliley, in writing to FDA Commissioner Jane Henney, stated, **"the serious weaknesses in the import system appear to leave America largely vulnerable to imported counterfeit, substandard, contaminated or poisoned products."** (Bliley)

**Already 25% of the drugs bought in Mexico by Americans are counterfeit, according to DEA agent Eric Hill. Of the remaining 75%, the vast majority of these Mexican drugs are not from approved FDA facilities.**

While the political pressure to open the market to imports with lower prices is quite serious, health and safety ramifications are more serious. If Congress trades standards of production, distribution and prescription for lower prices, death by ingestion or injection of supposedly prescription pharmaceutical products is likely to be a part of the American way of life for the 21st century.

The principal victims of unsafe imported medicines are the elderly, minorities (Hispanics are dramatically uninsured), the poverty-stricken, (Reuters) and those afflicted with chronic disease, (New York Daily News) or serious medical problems. (Woodcock) **As a nation, America needs to protect our most vulnerable populations rather than expose our poorest and sickest citizens to unsafe or ineffective medicines.**

This paper examines the dangers posed by the import problem and includes an extensive annotated bibliography of supporting information.

## The Danger: Counterfeit & Mislabeled Prescription Drugs

Counterfeiting of pharmaceutical raw material will occur if non FDA approved source material is labeled and packaged as FDA approved material and imported to the United States. Drug counterfeiters can obtain foreign, non FDA approved material, create labels of FDA approved and registered foreign manufactures and affix those labels to the non approved materials and represent that relabeled product as the approved product. Lisa Fairchild, a Customs agent, said, **"A scarier danger is that sometimes the packets don't contain the medicine the label says is inside."** (Los Angeles Times-March)

Patients who take counterfeit or mislabeled imported drugs can have lapses in treatment – a particular concern for the chronically ill. Failure to maintain contact with the medical practitioner prescribing and administering the treatment is also inadvisable.

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In addition to the fact that counterfeit or mislabeled drugs often have no efficacy in treating the purchaser's illness, imported drugs can have unintended and serious side effects. Counterfeit drugs frequently have little or no active ingredients, so mixing them with legal prescription medicines can accelerate the development of illnesses resistant to treatment, prompt treatment failures, and facilitate drug resistance.

The counterfeit drug trade was identified as far back as 1985 as a serious world problem. (Wehrli) But the explosive growth in the black market and the latest sophisticated counterfeiting schemes are a more recent phenomenon. (FDA Consumer-July) According to Customs agents, **"The problem has grown dramatically in the last three years,** but nobody has a handle on how

much is being brought across (the California-Mexico border)." (Los Angeles Times-April)

The danger zone for counterfeit or adulterated prescription drugs stretches across the southern border of the United States. Just as there are Caribbean and Mexican roads for cocaine and, more recently, for heroin, from Colombia and Central America, there is now a "Roid" road from Mexico into Southern California (steroids).

There are numerous known trafficking patterns, vehicles, distribution channels, and retailers, with many as yet to be identified. Gene R. Haislip, deputy assistant administrator of the Drug Enforcement Agency (DEA): "We see factories all over the world producing amounts clearly in excess of any legitimate need, but they're only meeting market demand. This is a consumer-driven operation (Business Week)."

Individuals cross the border to obtain pharmaceutical drugs at a reduced price. According to Charlie Bethea, President of the Texas Board of Pharmacy, "hundreds of thousands, perhaps millions, of dosage units of dangerous drugs enter Texas annually from Mexico." (Medical Economics Publishing Drug Topics) While many consumers are looking for bargain cosmetics or other over the counter purchases, there is an active trade in controlled substances (Shepherd), products for ulcers and other potentially serious conditions.

While the practice of importing prescriptions is frequently portrayed as a consumer issue, many individuals buying counterfeit or adulterated prescriptions bring them across the border for resale to unsuspecting patients.

"Rat packers" abound in Southern California, scurrying across the border for small amounts of prescription drugs to resell in Los Angeles.

### The Newest Border: The Internet

There are over 400 web sites that offer foreign prescriptions by mail. These sites are frequently unregulated and unmonitored.

"In talking with state and federal agencies and lawmakers over who is responsible for regulating on-line prescription drug sales, we found there seems to be confusion. In fact, it doesn't seem to be against the law. And it is difficult to find out where many of these pharmacies originate." (Behrens)

Medical boards and local authorities do not have the means to monitor these sales, much less to ensure adequate treatment with drugs of unknown origin. (Bernstein)

**"Many Web sites today allow consumers to order prescription medication, often without ever seeing a doctor face-to-face and, sometimes, even without a valid prescription.** Among the concerns is the product quality of these drugs and whether patients may be at risk of serious and even fatal drug reactions due to lack of oversight from a doctor," (Upton) says Congressman Fred Upton.

Lower income persons are not only more likely to buy a prescription or any other pharmaceutical product from a trader in counterfeit products but are also more likely to self-medicate or accept medication by on-line doctors (Catzone) of Internet pharmacies.

### The Root of the Problem Lies Outside the United States

There are thousands of laboratories producing unsafe pharmaceutical products that may be imported to the U.S. In India, there are more 20,000 labs.(Africa News-October) Substandard catheters, HIV and hepatitis contaminated blood, (Agence France Press-August) veterinary products(FDA Consumer-January-February, Kansas City Star, South Florida Business Journal, Interpress Service) and pesticides (The Independent) are also part of the trade. **Corrupt or conniving governments shield bathtub mixers, neighborhood and large laboratories, and distributors.**

***There are thousands of laboratories producing unsafe pharmaceutical products that may be imported to the U.S.***

The principal dangers to the U.S. consumer lie elsewhere, beyond the reach of U.S. law. Countries that do not recognize patents tend to be high producers of mislabeled drugs.

(Newsweek-11/25)

Political change and unrest can create dangerous opportunities for black markets in drugs. Countries that have had very demanding restrictions as in the Central European nations during communism or certain African nations(Africa News-February) have had drug traders capitalize on the cracks in the system.(Business Week) National policies designed to rein in illicit trade in prescriptions can be undermined by local governments who protect the trade in spite of central government actions.(Reuters, Agence France Press-February, FT Asia Intelligence Wire, Daily News Biotechnology and Medical Technology-October)

## U.S. Government Action & Oversight

The U.S. government has not been able to fully gauge the magnitude of this serious issue. "FDA does not collect data to assess the amount of unacceptable or adulterated pharmaceutical ingredients shipped to the U.S. from foreign sources." (Upton-Letter).

The late 1970 media reports of illicit trade in pharmaceutical products spurred Congress into legislation. (Mature Health-October) By 1983, the FDA had hired one hundred new investigators for this one problem (Ladies Home Journal) and was actively monitoring offshore mail-order firms offering the top prescription medicines being shipped to the US from unknown sources, but they have no way to guarantee the quality of these drugs. (The Reuter European Business Report)

In 1992, FDA Commissioner Dr. David Kessler issued an "import alert" designed to stop shipments from a half-dozen Bahamas-based companies. He stated, "In some cases, the drugs are counterfeit - lacking any real similarity to the approved drug. The uncertain character and quality of these drugs constitute an unreasonable risk to the public health." (Chicago Sun Times)

In 1995, Senator Orrin Hatch said "**Perhaps most troubling is the widespread threat counterfeiting poses to public health and safety. Few Americans truly appreciate the significant, scope or consequences of this crime.**" (Hatch) Eleven years after the initial legislative action, Representative Tom Bliley again finds FDA lagging. In a letter detailing nearly two years of investigations by the

Committee, Rep Bliley says that the FDA "has little or no control of imported counterfeit bulks entering the USA, providing no meaningful deterrence to trafficking of these products." (Mature Health-May)

Yet in the year 2000, the FDA was acknowledging that "**The increasingly global nature of pharmaceutical commerce is stretching FDA's safety net — foreign inspections are resource intensive, expensive and more complicated than domestic inspections.**" (Plaisier-May 31)

At another time, FDA states, "Mr. Chairman, FDA does not have in place a regulatory system, which includes requirements for ensuring quality of active pharmaceutical ingredients imported into the United States. It is the responsibility of the manufacturer to ensure adequate dosage of the active ingredient and, FDA as part of its regular drug GMP inspection program, assures during inspections of dosage form manufacturers that these requirements are met." (Plaisier)

It seems that the lack of resources (Plaisier) has cornered FDA into mechanisms geared towards control of less aggressive black marketers and reactionary strategies.

The FDA has not even defined the exact number of foreign drug manufacturers exporting to the U.S.A. that have not been inspected in at least seven years. Nor has it conducted a formal analysis of the effect of not inspecting exports to U.S. every two years. (Plaisier) Foreign sellers pose a difficult challenge for U.S. law enforcement because the seller is not within U.S. jurisdiction. (Woodcock)

**"In some cases, the drugs are counterfeit - lacking any real similarity to the approved drug. The uncertain character and quality of these drugs constitute an unreasonable risk to the public health."**

## Conclusion

There are already many concerns regarding the enforcement of the regulations governing the importation of prescription medicines.

Currently, drugs routinely labeled by importers as for non-pharmaceutical use enter the U.S. market freely. Once in the U.S., they can be redirected for human consumption. "As with drug listing, the Import Alert System is also broken to the point that major basic changes are needed". (FDA-Draft of Work Plan)

Under these circumstances, consuming pharmaceutical products from countries without certified and assured quality control standards in production and distribution is perilous.

Opening the door for pharmaceutical products that cannot guarantee the FDA standards and controls in production and distribution is an invitation to disaster. Americans should not be held hostage to the unscrupulous, unauthorized black market in prescription drugs.

The principal victims of unsafe imported medicines are the elderly, minorities (Hispanics are dramatically uninsured), the poverty-stricken, and those afflicted with chronic disease, or serious medical problems. As a nation, America needs to protect our most vulnerable populations rather than expose our poorest and sickest citizens to unsafe or ineffective medicines.

While there is serious concern in Congress with the quality of bulk imports, as well as imports by individuals, it seems willing to allow more pharmaceutical imports.

Still, Congressmen on both sides of the aisle are aware that trade in counterfeit and mislabeled, pharmaceutical products is challenging the capacity of U.S. government to protect the population. The political pressure to open the market to imports with lower prices is quite serious.

If Congress trades standards of production, distribution and prescription for lower prices, death by ingestion or injection of supposedly Rx pharmaceutical products is likely to be a part of the American way of life for the 21st century. Ensuring the security of the health system is difficult enough in the

current market without welcoming additional problems.

Pressure to allow more and lower cost pharmaceutical products, even those manufactured under conditions not permitted in the Nation, is overwhelming the saner minds in

Congress. Political pressure, stemming from the price of patented pharmaceuticals, may yet prevail over reason.

Before opening the door to more imports from sources lacking measures and health standards similar to those in the USA, questions on the safety of drugs imported into the Nation must be answered, loopholes must be closed and controls easily circumvented must be strengthened. Congress must resist facile answers to a very complex problem.

BY: CARLOS E. CHARDON  
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***Opening the door for pharmaceutical products that cannot guarantee the FDA standards and controls in production and distribution is an invitation to disaster.***

## Annotated Bibliography of Source Material

**AAP Information Services**, August 5, 1998. Brazil's health authorities have increased jail sentences and fines for medical fraud in an attempt to curb a booming trade in counterfeit pharmaceuticals. Brazil's drug counterfeiters, distributors and drug store owners could now face 30 years in prison if caught, up from just four years. The maximum fine has been raised by 275 per cent to 15,000 reais (\$ A21,558). At least 61 counterfeit brands of pharmaceuticals in the Brazilian market range from general antibiotics to treatments for cancer and AIDS. Estimates suggest there may be 135 million bottles and boxes of fake medicine in Brazil's pharmacies. Three Brazilian patients have died over the past month after treatment with bogus medicine, sometimes provided by cost-cutting government-run hospitals.

**Abromowitz**, Herman. *Oversight Hearing, Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies*, Subcommittee on Oversight & Investigations, July 30, 1999. Prepared Statement of Herman Abromowitz, M.D., Member of the Board of Trustees of the American Medical Association, Representing the American Medical Association.

"Among the concerns with illegal distribution of drugs from foreign sources is the product quality of these 'foreign versions' of prescription drugs and whether patients are at risk of harm due to lack of physician oversight and inadequate directions for use. If obtaining prescription drugs from foreign companies without a prescription through the Internet becomes common, it threatens potentially to render the whole concept of legend (by prescription only) drugs meaningless in the United States. While the FDA has used its authority to prevent this illegal activity by some foreign companies, it has been difficult to stop these and other companies from simply continuing these illegal activities from another web site."

**Africa News**, September 3, 1999. Medicine destined for state hospitals will now also be packaged exclusively, different from that intended for the retail market, in an effort to address overwhelming theft from hospitals and clinics. One company said the company was employing its own investigators in an effort to safeguard business. Special foil, although more expensive, that was more difficult to copy is now being used as packaging.

**Africa News**, October 6, 1999. Tanzania where patients are giving them a wide berth reportedly because of their debased and at times suspect quality. A Dr. Ngiloi, surgeon at the Muhimbili Medical Centre in Dar es Salaam, testified that many patients reject India-manufactured drugs because of their bad reputation and because they were too cheap to be trusted to cure disease. "There have been cases where drugs ordered from India arrive with black spots, or bad smell: In case of capsules, they may arrive melted or virtually empty," Dipen Shah of the Tanzania Pharmaceutical Manufacturers Association said. He claimed that there have been cases where capsule drugs were stuffed with cassava flour instead of the necessary pharmaceuticals. India has 20,000 pharmaceutical manufacturing industries and Tanzanians say that the number is too big for the government of India to control them effectively.

**Africa News**, February 22, 2000. Economic liberalization is to blame for the proliferation of unregistered drugs in the local market, a cabinet minister says. He said this has led to unscrupulous businessmen bringing in unregistered and counterfeit drugs into the local market.

**Agence France Press**, August 1, 1997. In Argentina 7 people were arrested after dozens of raids were made in connection with counterfeit drugs. In addition, laboratories were accused of illegally selling samples of blood contaminated with HIV and the hepatitis virus. Pharmacists have been accused of buying counterfeit drugs in neighboring Paraguay.

**Agence France Press**, February 7, 1997. The WHO estimates the traffic in counterfeit drugs to be \$8 billion per year and have a list of 700 complaints about counterfeit drugs. Corruption in local governments leads to the supply of counterfeit drugs by state health services that prefer to purchase cheap medicine from India or China. Primary ingredients were also purchased in countries such as South Korea or Brazil that have expert chemists, then processed in laboratories in Belgium or Italy. Nobody's ready to denounce the trafficking as there is too much corruption and it's dangerous.

**Agence France Press**, December 21, 1999. (China) The administration acknowledged the country's pharmaceutical trade was "chaotic," with counterfeit and low-quality drugs common on the market, and warned e-commerce could allow illegal business to worsen.

**Austin American Statesman**, October 29, 1995. But interviews and a review of dozens of FDA documents raise questions about whether the agency will be able to keep defective drugs from slipping through. "I'm not so sure FDA has the manpower," said William Haddad, chairman of Mir Pharmaceutical Inc. in Brewster, N.Y., and head of the international committee of the Generic Pharmaceutical Industry Association. "The trade is expanding quicker than their ability to respond to it." In general, the concerns are greater with generic products than with branded drugs, because the largest brand name companies either make their own ingredients or use more reliable foreign suppliers. Up to 80 percent of the key ingredients in American-made generics come from foreign suppliers, as do about 60 percent of the components in brand-name drugs.

**Bangkok Post**, September 13, 1999. Food and Drugs Administration secretary-general Mongkhon na Songkhla said Thailand has sought assistance from the World Health Organisation in combating counterfeit drugs, most of which are observed to be coming from countries outside the Asian region. The use of substandard drugs has been one of the main causes of drug-resistant malaria along border areas.

Concern has been raised over the increased smuggling of fake medicines on both sides of the Thai-Cambodian border. The issue was discussed at yesterday's joint meeting of Thai and Cambodian health authorities at the national, provincial and local levels. The counterfeit drugs did not contain active ingredients as specified on their labels. Food and Drugs Administration secretary-general Mongkhon na Songkhla said Thailand has sought assistance from the World Health Organisation in combating counterfeit drugs, most of which are observed to be coming from countries outside the Asian region. The use of substandard drugs has been one of the main causes of drug-resistant malaria along border areas.

**Behrens**, Christine, Reporter, WWMT News 3, Kalamazoo, Michigan.

**Bernstein**, Jody. *Oversight Hearings on Drugstores on the Net: The Benefits and Risks of On-line Pharmacies*. Subcommittee on Oversight & Investigation. Prepared Statement, Ms. Jody Bernstein, Director, Bureau of Consumer Protection, Federal Trade Commission, July 30, 1999.

"State medical boards and state pharmacy boards have both expressed concerns that their existing enforcement tools are not adequate to police the online medium. In many cases it can be difficult, without extensive investigation, to identify the name; location; and state of licensure or registration for the physicians, pharmacies, and website operators involved in these practices.

Our review of almost 100 sites provided by Subcommittee staff found that very few provided adequate identifying information. Even when parties can be located, it can be difficult and costly for a state medical board or a state pharmacy board to pursue law enforcement against an out-of-state physician or pharmacy prescribing or dispensing prescription drugs inappropriately via the Internet."

**Bliley**, Tom. Letter to Jane Henney, M.D., FDA Commissioner, from Congressman Tom Bliley May 8, 2000.

**Business Week**, June 19, 1995. Federal government seizures indicate that Mexico is America's main provider. Personal-use quantities are so available that California drug officials christened the road south from Tijuana to Rosarito Beach and Ensenada, "the Roid Corridor." Dr. Toms Buriil, former director of the Czech Republic's national drug intelligence service, observes that political upheaval in Eastern Europe has allowed clandestine steroid labs to flourish. With privatization of the pharmaceutical industry, Buriil says, many of the rigid controls of the communist regimes have disappeared, and drug traders have capitalized on cracks in the system

**Catizone**, Carmen. Oversight Hearing, *Drugstores on the Net: The Benefits and Risks of On-line Pharmacies*, Subcommittee on Oversight & Investigations, July 30, 1999. Prepared Statement of Mr. Carmen Catizone, Executive Director, National Association of Board Pharmacies, Representing: National Association of Board Pharmacies.

"The prescribing-based sites are often organized into an intricate arrangement of portals and relocater pages designed to increase the accessibility to the services and mislead the consumer into believing that such sites are legitimate simply because of the vast number of similar sites. The system resembles fraudulent 'pyramid operations' where a primary operation is often supported by a varying number of referral or access portals. To the unknowing consumer, the referral or relocater pages appear to be independent and individual sites. In reality, however, such sites are linked and serve only as a means for the primary site to forward sales into its distribution operations."

**CBS News, 60 Minutes**, January 18, 1998. A German company called Helm who refused to be interviewed by "60 Minutes" transported the fake medicine. Helm was described as a well-known European broker with offices in 37 countries, including the US. Ex-employees of Helm provided documents suggesting that Helm had lied to customers about where the drugs were made and when they were due to expire.

**Chemical Market Reporter**, March 15, 1999. To reduce the production of counterfeit pharmaceuticals, the Brazilian sanitary controls agency within the ministry of health is moving toward the adoption of US Food and Drug Administration market control standards. Estimates of counterfeit drugs run as high as 5 percent of the industry's annual sales of nearly R1 10 billion, about \$ 5 billion.

**Chicago Sun Times**, August 3, 1992.

**The Cook Report**, May 12, 1995. In this UK television broadcast, Mr. Cook investigates pharmaceutical counterfeiting including occurrences in Europe and Hong Kong. The investigators set up a front pharmaceutical export/import business in London and discovered numerous wholesalers throughout Europe willing to deal in pharmaceutical products of dubious origin. In Spain the investigators found a "factory capable of offering a complete counterfeiting service." Factory staff stated they were capable of making "capsules, tablets or injectables". In the UK a printer was able to counterfeit a roll of 1,000 Losec labels within 24 hours of the initial request. Counterfeit Losec boxes were manufactured in London after selecting "a London printing company at random from the Yellow Pages." Counterfeit pharmaceuticals were sold in a sting operation to wholesalers in the UK. One wholesaler agreed to import the pharmaceuticals from Asia through Antwerp and to "legitimize it on paper" for import into Europe.

**Daily News Biotechnology and Medical Technology**, November 26, 1999. An investigation reveals illegal medicine in Vietnam. Two low quality drugs include Pamoxicillin 250-500mg and Ampicillin 250mg. The active ingredients in the two medicines were only 20-50%. They also found B Complex medicine that was made in China but had Belgian and French labels. Counterfeit Kefadim 1g injectable solution was discovered in capsules made by a U.S. based company.

**Daily News Biotechnology and Medical Technology**, October 23, 1998. The Chinese State Drug Administration (SDA) announced that it has revoked the licenses of and suspended production at three pharmaceutical manufacturers due to their sales of fake or sub-standard medicine.

**Egan, Kathy**. Reporter, NBC10/WCAU Philadelphia. "In researching and producing our story, it was difficult to discern who is actually regulating these internet drug companies. We called the U.S. Food and Drug Administration, the Federal Trade Commission, the Pharmaceutical Manufacturers Association, other National Pharmacy groups, and the state boards of pharmacy in our tri-state area. Since we also purchased a controlled substance, we called the U.S. Drug Enforcement Agency. Virtually every agency we talked said they were interested in the problem but referred us to another agency or group. What's more, one government official told us no agency is up to speed on this problem."

**FDA Consumer**, July 17, 1997. A joint investigation by FDA, the Internal Revenue Service, and the Justice Department led to the breakup of one of the largest counterfeit steroid rings in the United States. The suspects manufactured 14 fake steroids and sold them on the black market—mostly to body builders. Federal agents searched nine locations in San Jose and seized hundreds of thousands of dollars worth of fake drugs and manufacturing supplies. FDA and Customs Service seized a quarter of a million-dollar shipment of counterfeit steroids en route from San Jose to Buffalo, and ultimately to Canada.

**FDA Consumer**, July 1990. A joint investigation by FDA, the Internal Revenue Service, and the Justice Department led to the breakup of one of the largest counterfeit steroid rings in the United States. The suspects manufactured 14 fake steroids and sold them on the black market—mostly to body builders...The suspects had a graphics firm design labels, boxes and package inserts that were so authentic-looking even manufacturers of the real products couldn't tell the difference.

**FDA Consumer**, January-February 1998. In the US, individuals in an organization smuggling antibiotics from China into the US were sentenced to prison. Flavine International Inc. of Closter, NJ bought bulk amounts of a veterinary and human antibiotic ingredients from unapproved sources in China and sold them to companies in the US. The case started when it was discovered that for the year 1989, Flavine had officially imported 100 metric tons of ingredients from the authorized supplier while facts demonstrated that Flavine had imported 310 metric tons. The FDA and US Customs seized suspected counterfeit material from 5 end users and warehouses in the US. Flavine was using a North Carolina company to repackage the counterfeit product to hide the fact that it came from unapproved sources. In 1995, a federal grand jury returned an 11-count indictment charging individuals in Flavine with conspiracy, smuggling, misbranding, and other federal drug violations.

**FDA-Counterfeit Drug Initiative**, January 27, 1999. Office of the Commissioner, Executive Summary.

The initiative was terminated for several reasons:

While counterfeit medical products were found to be an issue of significant potential importance, no specific need for a Commissioner's Office initiative was identified.

It was felt that the Centers and ORA were the appropriate FDA components to deal with counterfeits as part of their on-going workload and that they should have the prerogative and responsibility to determine if proposed expenditures were justified in the face of other on-going concerns.

With the passage of FDAMA, substantial new, higher priority, responsibilities were being added to FDA.

**FDA-Draft of Work Plan. Draft of Work Plan of the Counterfeit drug Initiative Working Group of the FDA convened 1995-1998**, April 5, 1999. "the volume of imports dictates that only a small fraction of the entries are examined. Therefore, FDA is not able to sample all entries of product that may not be in compliance with the Act. Moreover, firms do not always withhold products from distribution. ... the violators do not always get caught, and the damages are usually mitigated to a portion of the goods' value. Consequently, ignoring a detention notice is considered by some to be a part of the cost of doing business.

**FDA-OCI**, Case Initiation/Management Report, April 21, 1998. In 1996, the DEA began identifying Tijuana, MX, pharmacies diverting significant quantities of various controlled drugs from southern California Pharmaceutical wholesalers. The continuing identification results from USCS seizures of drugs from trucks headed to Tijuana from the Chula Vista, CA area, as well as through seizures from pedestrians returning from Mexico.

**Federal News Service**, October 21, 1999. In his prepared testimony on the Judiciary Subcommittee on Courts and Intellectual Property, subject hearing on HR 21000, the "Anti-tampering Act of 1999" James A. Dahl states that in a FDA/OCI investigation, counterfeit versions of a drug commonly prescribed to AIDS patients was found in commercial distribution channels.

**Fricke** FCC FDA, Fred. Memo to Liz Berbakos from Fricke of the Forensic Chemistry Center of FDA, n.d.

**FT Asia Intelligence Wire**, November 1, 1998. The Chinese State Drug Administration (SDA) has suspended the import of 21 medicines after they twice failed to reach the required standards during quality inspection at Chinese customs. Since 1996, customs inspections have also detected another 77 foreign medicines with one below-standard batch, the SDA announced. Some 182 batches of medicines in 14 categories from 100 factories failed state standards. Another 79 batches of nine types of medicine produced by 41 units were counterfeit. The prime responsibility of the SDA is to crack down on the manufacture and sale of fake and sub-standard medicines and ensure the safety and effectiveness of medicine for the public.

**FT Asia Intelligence Wire**, November 27, 1998. Indian drug manufacturers have launched a campaign against fly-by-night operators making quick and illegal profits by duplicating leading pharmaceutical brands. In India these fake medicines are made without any drug content — by merely copying the size, color and shape of the dosage and package.

**FT Asia Intelligence Wire**, February 9, 1999. Eight medicine marketing companies and drugstores in China had their business licenses revoked for selling fake products, sources with the State Drug Administration (SDA) said. It reflects the country's determination to root out marketing and manufacturing of fake and sub-standard medicines, said Cao Wenzhuang, spokesman for SDA. Results from a nationwide inspection on medicine quality in the last quarter of 1998 indicated that 24 batches of medicines in 62 categories were fake products or below minimal standards, making up 13.1 per cent of the total tested.

**Gazeta Mercantil**, June 26, 1998. (Brazil) After issuing a ministerial directive limiting the action of the medicine drugs counterfeiter "mob", the government's strategy to combat adulteration of drugs is to make inspection stricter on companies distributing pharmaceutical products. The Sanitary Surveillance Bureau has indications that some of the more than seven thousand distributing companies spread across the national territory could be used by counterfeiters to insert adulterated drugs in the market.

**Hatch**, Sen. Orrin. Press conference, August 9, 1995.

**Henney M.D.**, Jane. Letter of Jane Henney, M.D., Commissioner of FDA., to Congressman Tom Bliley, May 31, 2000.

**Hill**, Eric. Quoted in the San Diego Daily Transcript, February 27, 1998. "Warnings issued on misbranded or phony drugs sold in Mexico."

**Idaho Falls Post Register**, December 2, 1998.

**The Independent**, December 27, 1999. In Bangladesh the local pharmaceutical companies are facing a serious challenge in as the market here is flooded with lower quality and cheaper smuggled Indian medicines and pesticides. According to sources, fake medicine producers have produced some of those drugs. Consumers are facing a serious threat due to the consumption of these medicines and pesticides. According to different sources, the smugglers can deliver inferior quality Indian medicines and pesticides within 24 hours of getting orders. The smugglers also found it easy to carry medicines in place of heavy goods from India. Doctors in India are not prescribing these low-quality medicines. Sometimes the date expired smuggled medicines are updated with new expiry dates. Ranitidine, Femotidine, Canesten-V and other essential drugs are smuggled into the region

**Inter Press Service**, November 25, 1997. Zimbabwe authorities have introduced new measures aimed at curbing the import of counterfeit medicines. In June 1997, the government recalled more than 14 million contaminated antibiotics. Antibiotics such as tetracyclin and veterinary drugs are often counterfeited.

**Journal**, May 11, 2000. "Makers of AIDS drugs agree to slash prices for developing world." Michael Waldholz.

**The Kansas City Star**, October 4, 1995. Four persons in the US were charged with smuggling counterfeit antibiotics and anti-microbial drugs into the US from 1985 until 1991. While primarily sold to manufacturers of veterinary pharmaceuticals, the counterfeit drugs were also supplied to makers of drugs destined for humans. The bulk product was purchased from unapproved drug manufacturers in China. They were then relabeled to appear as if they were from FDA-approved manufacturers and sold to US pharmaceutical companies that processed them for use in finished medications.

**Ladies Home Journal**, September 1993. The FDA has hired 100 additional investigators to investigate drug counterfeiting and other illegal activities.

**Legget**, Don (LEGGETT@cder.fda.gov) E-mail to John Taylor (JohnTaylor@ACRA@FDAORAHQ), April 12, 1999. Legget gives his thoughts about "drug listing". "About a dozen years ago, I conducted an internal regulatory audit of the activities of the Drug Listing Branch. Accordingly, I agree, 'anyone can obtain a drug listing' the illegality of those drugs notwithstanding. Since such activities subsequently were contracted, the dismal record of using it as an import gatekeeper continues. Thus the use of EES to 'partially deal with this shortfall' may even be optimistic - compounded with the workload and lack of sophistication in much of the import investigar domain - the agency will need major changes in order to hope to cope with this growing problem."

**Lewis**, James L. Operation CDI (Counterfeit Drug Investigations) Special Project Proposal FY97, Resident Agent in Charge, U.S. Customs Service, Kansas City, Missouri, July 29, 1996.

**Los Angeles Times**, March 5, 1999.

**Los Angeles Times**, April 23, 1999.

**Mature Health**, March 13, 1995. News of the World, reported that counterfeit drugs of almost any kind available from a Barcelona-based supplier. A broker offered to supply a container-load of inexpensive counterfeit drugs. He boasted that he had already supplied such products to the United Kingdom, Asia and the Far East, and could even copy Glaxo Wellcome's holographic seal. He also offered to cut the price by further reducing the dosage. The counterfeits were versions of well-known products, such as SmithKline Beecham's Amoxil and Tagamet, and Glaxo Wellcome's Zantac. These counterfeits only contained a fraction of the normal active ingredient. They were manufactured in illicit factories in Spain, Italy, Greece, and Turkey.

**Mature Health**, May 22, 2000. A lack of leadership at the US Food and Drug Administration and weakness in its import system has left the USA vulnerable to potentially counterfeit, substandard, contaminated or poisoned imports of bulk drugs, House Commerce Committee chairman Tom Bliley has told FDA Commissioner Jane Henney. US News and World Report, June 9, 2000 so reported the story.

**Mature Health**, October 1989. The counterfeiting is widespread; when congressional investigators questioned legitimate drug manufacturers, they learned 36% had experienced problems with bogus copies of their products. And big bucks are involved.

Spearheaded by U.S. Rep. John Dingell (D—Mich.) and his Subcommittee on Oversight and Investigations, the Prescription Drug Marketing Act was adopted by Congress and went into effect late last year. The new law:

- 1) Severely curtails re-importation of any prescription drugs into the U.S.
- 2) Requires doctors to sign for samples and specify the quantities received, giving the drug companies a paper trail to those who order quantities too large to use
- 3) Prohibits resale of excess drugs ordered by hospitals and other health care facilities
- 4) Requires licensing of drug wholesalers under federal standards; and
- 5) Makes many of the black market activities federal felonies with stiff prison sentences.

Throughout investigation of this international consumer swindle, it has been obvious that the FDA, which is charged with protecting Americans from unsafe or ineffective drugs, has fallen down badly on the job.

The new law now has been in effect for nearly a year. What has the FDA accomplished? Mike Shaffer, a spokesman for the agency, says a special office has been established to deal with the problem, but admits it could take considerable time to get up to speed. The FDA also has sent letters to pharmaceutical companies, providing guidelines as to what they must do the reports.

**Medical Economics Publishing Drug Topics**, March 17, 1997.

**Newsweek**, November 5, 1990. Often, the point of origin is a nation that does not recognize international drug patents, like India or Thailand for example.

**Newsweek**, November 25, 1990. Counterfeiters range from bathtub chemists in Southeast Asia to high-tech manufacturers in countries like Argentina and Greece, working with chemicals freely available on the open market.

**New Scientist**, March 29, 1997. A study by Philip Lee and his colleagues at the University of California's Institute for Health Studies in San Francisco identified a false antibiotic being sold to hospitals and clinics in Indonesia that contained only a fraction of the required dosage. People with life threatening infections, such as peritonitis, died even though they and their physicians thought they had completed the prescribed course of treatment.

**New York Daily News**, June 13, 1993. The anti-AIDS drug AZT and other vital medicines—watered-down or tainted—are being sold at full price to unsuspecting patients through a thriving New York-based black market. Authorities say that the medicine—bought cheap from Medicaid patients or stolen from samples intended for doctors—may be outdated and change hands a half-dozen times with no regard for proper storage or sanitation as it passes from street-level dealers to re-packagers to sophisticated black marketers. By the time AIDS patients buy AZT—from seemingly legitimate pharmacies as far away as Puerto Rico—expiration dates have been altered and packages refitted with forged labels and counterfeit instructions so they have no clue they are not receiving safe, effective medicine. In some cases, “drugs in capsules have been replaced with talcum powder or other substances, a circumstance that can be proved only by laboratory analysis,” said FBI Special Agent Jaclyn Zappacosta.”

**Nielsen S.A.(FDA), Carl.** Memo of Carl Nielsen, SA to Frank Forgione, SAIC May 15, 1999, *Counterfeit imported Human Rx Bulk Drugs*. "Counterfeit bulk drugs were first discovered in the U.S. marketplace in May 1991, by CSO Michael Spangenberg. He discovered the counterfeit Long March oxytetracycline because he had first hand knowledge of the authentic product which he obtained during an inspection of the Long March facility in China. FDA systems of operation did not detect the counterfeit. He found the counterfeit product .... while conducting unrelated official business."

**Nielsen, Carl.** Memo from Nielsen@OCI@FDAOCIMET to Fred Fricke, Frick@FCC@ORAMAR.

**Plaisier-March 5,** Melinda K. Associate Commissioner, FDA. Letter to Congressman Fred Upton. March 5, 1999. The statement originates in a February 12, 1999 letter to Commissioner Henney from Congressman Upton. In the letter answering several statements by the Congressman, Plaisier answers to this particular one, "The statement is accurate."

**Plaisier-May 12,** Melinda K. Associate Commissioner for Legislation, FDA. Letter of May 31, 2000 letter, to Congressman Tom Bliley. "The increasingly global nature of pharmaceutical commerce is stretching FDA's safety net - foreign inspections are resource intensive, expensive, and more complicated than domestic inspections."

**Plaisier,** Melissa K. Associate Commissioner of FDA. Letter to Congressman Tom Bliley (June 2, 2000).

The agency has a plan to confront certain aspects of this criminal activity but "Continued and full implementation of the initiative is dependent on identification of additional funds and Full Time Equivalent (FTE) for Fiscal Year (FY) 2001."

**Reuters,** December 27, 1994. Fake medicines are sapping the health of Asia's poor, claim doctors and health care advocates. Counterfeit drugs are prevalent in India. "The extent of counterfeits is still guesswork, as there is no central monitoring agency" states a spokesman for the Bombay-based Association for Community Action in Safety and Health. Fake drugs continue to be sold in China thanks to local government protection. In Tianjin, city authorities closed down a factory making counterfeit pharmaceutical products.

**The Reuter European Business Report,** October 6, 1993. The FDA has been monitoring offshore mail-order firms often offering the top 100 or 200 prescription products. There is no way of guaranteeing the quality of drugs being shipped to the US from unknown sources and counterfeits could be found. The FDA has taken action against companies in the Bahamas, Switzerland, Germany, Mexico, and Britain.

**San Diego Daily Transcript,** February 27, 1998. "Warnings issued on misbranded or phony drugs sold in Mexico."

**The San Diego Union-Tribune**, April 12, 1989. A well-known professor of chemistry in Mexico was arrested for counterfeiting drugs that were smuggled into the US. Twelve people were arrested. Laboratories Milano, S.A., were involved. There are many such clandestine labs manufacturing bogus prescription drugs. Many of these labs operate in big cities such as Guadalajara and Monterrey, where they manufacture great quantities of low-quality drugs they claim are the same as drugs produced by reputable pharmaceutical companies.

**Sheperd**, Marvin D. and Kristin McKeithan, R.Ph., February 28, 1996. "Examination of the Type and Amount of Pharmaceutical Products Being Declared by US Residents returning to the U.S. from Mexico at the Laredo, Texas Border Crossing."

**South Florida Business Journal**, June 11, 1993. A European terrorist organization was implicated in counterfeiting Merck's Ivomec that was sold in the US. The fake veterinary product contained no active ingredient. The US Attorney in South Florida prosecuted the case.

**Taylor** ORA FDA, John. Memo of Taylor to several FDA officers (Famulare and others), on Counterfeit Drugs, April 5, 1999. Taylor identifies the strategies to ensure the drug products meet the requirements of the Food and Drug Act. "the first strategy is to evaluate the conditions under which drugs are manufactured, packed, tested, and held, though on-site inspections, and the second strategy is to monitor the quality of the drug products through PMS programs." FDA ensures that good manufacturing practices prevail (GMP)

PMS means Post Manufacturing Strategy.

"A key aspect of the PMS strategy is the Drug Product Surveillance program. The program provides the agency with information about the quality of drugs marketed in this country through the sampling and analyzing of imported and domestic drug products. The volume of products dictates that only a small fraction of the entries are examined. Therefore, FDA is not able to sample all entries of product that may not be in compliance with the Act."

Since then the process has been reviewed and changes allow for five batches per year for the last five years for each source of API at each finished dosage manufacturer. (Approved Pharmaceutical Imports)

On drug listing, Taylor says "The system does not ensure that authentic sources or authentic material as described in the new drug applications is in fact being offered for admission."

**Upton**, Fred. *Oversight Hearing, Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies*, Subcommittee on Oversight & Investigations, July 30, 1999. Prepared Statement of Congressman Fred Upton. July 30, 1999.

**Upton**, Fred. Letter of Congressman Fred Upton to FDA Commissioner Jane Henney, March 5, 1999. FDA does not collect data to assess the amount of unacceptable or adulterated active pharmaceutical ingredients shipped to the US from foreign sources. Further, FDA does not collect data that would allow it to track trends or catalog the quality of products coming from abroad. "Manufacturers are not required to report adulterated or substandard material, and therefore there is no systematic means for FDA to retrieve this data.

...the ordinary testing performed by U.S. manufacturers would not necessarily deter cross contamination from ingredients such as pesticides or penicillin, nor would ordinary testing necessarily detect counterfeit ingredients.

**The Washington Post**, "Antibiotics: Handle with Care", Michael F. Jacobsen and Patricia Lieberman, April 22, 2000.

**Wehrli**, Agathe. Division of Drug Management and Policies, World Health Organization. Counterfeited and substandard active pharmaceutical ingredients. PIC-PIC/S Seminar. June, 1997. Finland.

**Widup**, Richard. Memo to Frank Forgione and Stephen Haynes on "Counterfeit Drug Matters", January 26, 1999.

**Woodcock**, Dr. Janet. Prepared Statement of Dr. Janet Woodcock, representing the FDA, Oversight Hearing, Subcommittee on Oversight and Investigations, July 30, 1999.

**World Health Organization/41**, Press Release, "Drug Resistance Threatens to Reverse Medical Progress." 12 June 2000. "We currently have effective medicines to cure almost every major infectious disease," said Dr Gro Harlem Brundtland, Director-General of WHO. "But we risk losing these valuable drugs - and our opportunity to eventually control many infectious diseases - because of increasing anti-microbial resistance."

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## *About the Author....*

*From 1995 to 1996, Carlos E. Chardon was advisor to the Governor of Puerto Rico on a sweeping reform that transformed a government based and led public health system to one based on a private health provider system based on health insurance covering the majority of the population. The publicly funded health insurance card currently serves the medically indigent (including the working poor) and has already been extended to certain public service groups (state police) as it expands into a system that will eventually serve employees of small businesses. The aim of the program is to preserve choice of providers independently of ability to pay for services.*

*Mr. Chardon returned to government because of his expertise in business and small business administration developed from 1988 to 1995 as District Director for the Caribbean of the U.S. Small Business Administration. During the seven years in SBA, Chardon increased loans from 125 a year to 1200, and reduced personnel by more than fifty percent. He became the principal spokesperson for small entrepreneurs against government overregulation and a legal system favoring large corporate concerns over family and privately owned businesses.*

*Before joining SBA, he was a consultant on business development and fund raising. At the same time, he was the Executive Director of the Ponce Museum of Art, the most important regional museum on western art in the Americas, outside the U.S.A. His role was the institutionalization of Board leadership in a closely knit family foundation, and securing new sources of funds.*

*Carlos E. Chardon completed his doctoral course work in cultural anthropology at Syracuse University, from whence he returned to Puerto Rico as aide to Governor Luis A. Ferré in charge of education and culture in 1969. He was Executive Director of the Puerto Rico Board of Education (1970-1971) and Liaison Representative of the Department of Health Education and Welfare (1972-1976). On leaving DHEW, he became Secretary of Education, leading the third largest school district in the Nation (1977-1980) into a massive continuing education program for school personnel and a reexamination of the criteria for building schools.*

*Currently, Mr. Chardon is involved with a group proposing a pilot project on tele-medicine for Puerto Rico, with possibilities for growth in the Caribbean and Latin America. On a similar venue, he has been active in promoting the organization of a distance-education center for training in large industries and government. He is also consultant on development to a rural hospital as well as for the state Work Incentive Act Board and for the Commercial Development Administration on the redevelopment of traditional business centers.*

*Mr. Chardon has been twice honored by the U.S. Hispanic Chamber of Commerce, as regional award winner (1990) and national winner (1993). He was decorated by the government of Spain with the Order of Isabel la Católica, and was the first American to receive the Gold Medal on Education from the Oficina de Educación Iberoamericana. He is a former member of the Board of the Academy of Arts and Sciences (Puerto Rico).*