

The Looming Threat of Fake Drugs

By ACSH Staff — May 7, 2004

Recently, I attended a meeting in Trinidad dealing with counterfeiting not of currency, which is what most of us associate with the word "counterfeit." This conference dealt with counterfeit drugs fake pharmaceuticals and I was one of the speakers. I was supposed to speak about "consumer aspects" of drug counterfeiting, but in truth I spoke mainly about the wild and wooly world of the Internet, and its relationship with drugs real, counterfeit, and in-between.

Every day my inbox is filled, repeatedly, with what we affectionately call "spam": unsolicited come-ons for...well, for everything you can imagine, intellectual pursuits, physical pleasures, and anatomical enhancements of every description. Among these annoying ads, about one-quarter or more are devoted to soliciting my purchase of some drug or other. What kinds? You name it: creams and potions, of course, but aids for sexual function are at the top of the list, followed closely by various painkillers (actually, lamely disguised narcotics are apparently available just send in your credit card number).

I was a physician in the clinical practice of internal medicine for over twenty years prior to joining the American Council on Science and Health in 1998. Since medical school, I have known that the responsibility of writing prescriptions is a most serious one. While personal ethics and devotion to patient care normally dictate acceptable boundaries, in cases where prescribing privileges are abused, licensing boards and hospital department heads are not lenient. This is doubly true when the drugs prescribed inappropriately are narcotics or other controlled substances such a pattern may even get the Drug Enforcement folks involved with attendant criminal penalties.

So how can an online "drugstore" purport to sell any pharmaceutical by way of a simple questionnaire filled out online, by a customer answering an e-mail solicitation, and still be considered professional and ethical? Only if an online pharmacy restricted such activity to filling a renewal of a valid prescription written by an M.D. (or other licensed caregiver), which had been faxed or otherwise sent to the pharmacist. But I believe that such transactions represent a tiny minority of Internet drug sales.

Any pharmacy selling medication to an online customer who has filled out a form in lieu of an exam by a physician has abandoned accepted professional ethics; any physician who approves a prescription for a customer I would not call the buyer here a patient in any real sense in this scenario is practicing unethically, is not interested in taking care of the person's health, and is acting unprofessionally. This is not to mention the liability issue: if a person ordering a drug over the Internet had an untoward or allergic reaction, the "prescribing" M.D. would be guilty of malpractice automatically if he or she could be tracked down, of course.

If the site is sending out sugar pills of no efficacy in lieu of bona fide medicine, it is committing outright fraud. On the other hand, if they are really sending, say, vicodin or xanax or percocet, they

are violating narcotics laws and are no different, in essence, from the pushers who sell drugs in schoolyards.

The Internet has been called "a vast flea-market," and anyone ordering drugs from a spammer will get the same level of satisfaction and accountability as from a street merchant selling Rolex watch knock-offs. E-mail pharmacies are an easy way for drug counterfeiters to get their phony wares out into the marketplace but far from the only way: making and selling counterfeit pharmaceuticals is becoming a big business, and will keep growing, according to the immutable laws of supply and demand. Brand-name drugs are expensive, and with income and insurance disparities so great, selling fake drugs that externally are almost identical copies of real pills, such as Lipitor, Viagra, and antibiotics, is highly lucrative blockbuster drugs are in big demand all over the world. Because many consumers demand the latest treatments but can't afford the real stuff, counterfeiters exploit these pressures by supplying cheap, albeit useless, "brand name" drugs.

Adding to the lack of reliability and accountability of Internet shopping is the fact that a number (no one knows the real fraction) of online pharmacies that describe themselves as importers of Canadian products are actually getting their drugs from Thailand, former Soviet republics, India, and other Third World nations, where counterfeit drugs are common.

Because we in the U.S. have a strong regulatory, investigative, and enforcement system, the problem is not yet as massive as in poorer and less well-policed regions. Pharmaceuticals are a \$400 billion business worldwide. According to a speaker at the Trinidad conference, the percentage of the world drug market made up of fakes is approximately 5%-8% that's about \$28 billion in underworld profits. In eastern Europe, the figure is closer to 40%, and in central Africa, over half of the anti-malarial treatments are phony and therefore useless (or worse) and quite likely contribute to the increasing prevalence of drug resistance there, with its frightful accompanying death toll. India probably represents the worst case at this time, given its huge population, its many thousands of drug companies, and the fact that around 35-40% of certain popular, brand-name drugs there are now fake. In Russia, the figure is more like 10%, although some have made higher estimates.

Those whose life's work is investigating counterfeit pharmaceuticals several of whom also spoke at the meeting I attended (sponsored by the Caribbean Industrial Research Institute, CARIRI) reported that the counterfeiting of drugs has been taken up by terrorist organizations in recent years, as their other funding sources have been squeezed by laws designed to counter money-laundering and covert "donations" to terrorist front groups. What better way to poison a large population with little chance of detection than by substituting toxic ingredients in apparently life-saving medications? And you can make a substantial profit at the same time.

A representative of the pharmacists of Trinidad denounced "suitcase importation" (also called "parallel trade") of fake pharmaceuticals from Guyana and Venezuela, which has predictable adverse effects on public health. Drug counterfeiting is not merely an economic crime: victims abound when heart, blood pressure, diabetes, and even cancer medicine is substituted with wheat flour, starch, or sugar. In the U.S., the FDA recently launched a multi-pronged campaign entitled "Combating Counterfeit Drugs," with seven separate areas to be addressed: technology, business practices, legislation, regulation/enforcement, public awareness/education, a "Counterfeit Alert

Network," and international cooperation.

In America, the public has no idea of the seriousness of this problem. The FDA, at least, seems to understand: even under pressure from Congress, the FDA continued to urge against letting in foreign drugs as a short-term "fix" for the problem of high drug prices here. The FDA has always held the position that drugs coming in from abroad would be difficult to monitor for purity, efficacy, and safety, while pro-importation senators dismiss this argument as merely an excuse for supporting drug industry profits against competition. In fact, inspections last year by the FDA with the assistance of U.S. Customs confirmed that over 80% of samples of imported drugs were not up to FDA standards. And this survey was restricted to imports from Canada. If Congress gets its way, in one year imports from countries as remote as Slovenia and Estonia will be permitted. Whatever degree of fake and defective drugs we have now and no one really knows the problem will increase tenfold or more when these floodgates open.

Even now, the problem of counterfeit pharmaceuticals is growing insidiously within our own borders. The sad truth is that even reputable pharmacists in well-established chains may easily be fooled by clever, technically-sophisticated counterfeiting organizations. In many cases, the phony drugs are almost identical, container and pill, to the originals they mimic. Only when unique identifiers are embedded in each batch of medications, with rapid product identification available at the retail outlet (similar to the way credit card information is available now), will we get a satisfactory degree of protection even at a real, walk-in drugstore.

To summarize: counterfeit drugs have been a problem for many years recall the character Harry Lime, who diluted penicillin in 1945 Vienna in the movie *The Third Man* with Orson Welles. But now crooks are getting more sophisticated, and we are only in the early stages of detecting their newer methods and formulating counter-technology to foil them. At the same time, increased calls for importing cheap drugs and the increasing use of the Internet have exposed weaknesses in our system of protection against phony pharmaceuticals. We can prepare for this by increasing our awareness, by having manufacturers and wholesalers use unique identifiers (individual product codes, like bar codes), and by avoiding obvious traps such as buying from anonymous "pharmacists" and "physicians" online.

I would go so far as to warn anyone interested in getting bargain-priced drugs that even a reputable-appearing Internet site, seemingly affiliated with a well-known retail pharmacy chain, may be merely a front for fraud. A crook with no scruples against selling counterfeit drugs would surely have no inhibitions about fooling consumers into thinking they are visiting a drug chain's site. I can say the same about companies who break laws against spam, and companies who mass-market with medical data obtained through a questionnaire, or with no medical history at all. Thus, here's a word to the wise: *Don't order drugs on the Internet!* This is the best way to protect yourself against counterfeit drugs.

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