

# Counterfeit CURES

**It is estimated that 300,000 people in China die each year due to fake medicines. Most of these are made in the PRC, the world's #1 producer of phony pharmaceuticals. The only chance of a real cure will come when technology, business and government come together to stop counterfeiters and protect consumers.**





BY BRIAN SCHWARZ AND VENESSA WONG

Just one year after worry sprung up throughout China over a potential large-scale outbreak of avian influenza (H5N1) – which led to the slaughter of millions of ducks and chickens around the country – PRC residents now face another hazard: counterfeit bird flu medication. In late August, Shanghai police broke up a piracy ring that had sold over RMB4.6 million worth of fake Tamiflu, one of two medications found to be effective against the virus. The counterfeiters were selling via the internet to customers in Heilongjiang, Liaoning, Jiangsu and Guangdong provinces and several Southeast Asian countries.

But this was not the first discovery of fake Tamiflu. Last year, U.S. Customs seized 51 shipments of the counterfeit medication suspected to originate from China.

The threat posed by counterfeit drugs is dire as H5N1 becomes a more serious problem worldwide. In the first eight months of this year, China reported 12 human cases of bird flu including eight deaths, according to the World Health Organization (WHO), up from 2005, when eight cases and five deaths were recorded for the year. If a global pandemic were to occur, experts estimate between 2 million and 7.4 million deaths.

The recent Tamiflu instance is only the tip of the iceberg when it comes to the countless counterfeiting schemes in China, some of which have caused serious harm or death to users. In one of this year's biggest domestic scandals, 11 people in Guangzhou were reported dead in May due to kidney failure caused by taking fake *Armillarisni A* (a drug used to treat gallbladder inflammation) produced in Heilongjiang Province. In August, state media reported that the deaths of six Chinese citizens was suspected of being caused by a tainted antibiotic made in Anhui Province.

According to a June testimony by Peter Pitts, president of the U.S.-based Center for Medicine in the Public Interest, an estimated 200,000 to 300,000 Chinese die each year due to

counterfeit or substandard medicine. In the first 11 months of 2005, 461 illegal pharmaceutical facilities in the PRC had been destroyed.

### The counterfeit challenge

The phony pharmaceuticals problem is rampant and growing in China, a fact that is not surprising given that two-thirds of all pirated goods sold worldwide are made domestically. In 2004, the U.S. Food and Drug Administration (FDA) nearly doubled the number of counterfeit drug investigations made in the U.S. to 58 from 30 in 2003 (the number fell to 32 in 2005 for reasons the FDA "cannot identify"). The EU experienced a 1,000-percent increase in seizures of counterfeit prescription drugs between 1998 and 2004 (last year, 75 percent of seized goods came from the PRC). A July report by The Kaiser Family Foundation also revealed that fake malaria drugs produced in China are surfacing in Africa, where the disease claims 1 million lives annually and up to 40 percent of medicines are not authentic.



IMAGINECHINA

**DRUG BUST: US\$32.5 million-worth of fake drugs and medical equipment were seized by Chinese authorities in the first half of this year.**

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Such news is raising grave concern for consumers, who find themselves helpless against well disguised fakes, as well as for pharmaceutical firms, which are struggling to combat Chinese counterfeiters. Recent reports show counterfeit drugs being sold via the internet, pharmacies and hospitals, both intentionally and accidentally, to consumers looking for alternatives to costly medication.

With so many fake pills showing up in medicine cabinets around the world, industry leaders, such as Johnson & Johnson, Pfizer and GlaxoSmithKline are falling behind in the intellectual property (IP) battle, losing billions of dollars in potential revenue and profitability and suffering damage to brand equity. WHO estimates that counterfeits, which now account for a dangerous 10 percent of the global market, cost the pharmaceuticals industry US\$46 billion annually. This value is expected to increase to US\$75 billion by 2010. In many developing countries such as China, the prevalence of fake meds can be more than twice as high. An inspection conducted last September by the China Health Care Association showed that more than 25 percent of health-care products in China were fakes.

China, the world's largest counterfeiter, is also the fifth-largest pharmaceutical market, worth US\$24 billion. It is predicted by Boston Consulting Group to become the largest by 2010, due mainly to the growth of its elderly population by 3.02 million people annually. Latest figures show average annual spending on drugs in China comes to only US\$10 per capita versus US\$623 in the U.S., but foreign companies are prepping for the inevitable upsurge of the industry. Already, multinational drugmakers have created more than 600 joint ventures with local players since the country's 2001 entry into the

World Trade Organization (WTO), according to *Forbes*.

The challenge for ambitious multinationals will be protecting their brands in China's poor intellectual property (IP) environment. Pfizer, for example, has identified a large number of counterfeits of its leading brands in China. Authorities in China seized 2 million tablets of fake Viagra, 1 million tablets of fake Lipitor and 500,000 tablets of fake Norvasc last year. Despite the large amounts of counterfeits found in the market, Pfizer has become more optimistic about the China business outlook in recent years. "Are there IP challenges? Yes. But we have great expectations for the Pfizer China operation," says the firm's Director of Public Affairs (Asia) Christopher Costigan, adding that the company still plans to make available 20 new medicines in the PRC over the next five years.

### State solutions

Costigan is hopeful that the company can work with the Chinese government to jointly find solutions. "The Chinese government is taking our issues seriously and looking for opportunities where we can share our expertise to enhance their efforts." Pfizer currently organizes roundtable discussions and seminars with Chinese ministries, including the State Administration for Industry and Commerce (SAIC), State Food and Drug Administration (SFDA), Ministry of Public Security and China Customs to exchange information and experiences on battling drug counterfeiters.

"We're working with many ministries to protect our own rights," says David Benner, Pfizer's Director of Global Security (China), about the company's "multi-pronged" approach to the problem. "It's not just dealing with law enforcement. They play a very important role for us, but we can't stop there. We must continue to work with all levels of government, locally and internationally, to ensure that counterfeiting is stopped."

Among the Ministry of Public Security's IP initiatives is Operation Mountain Eagle, a crackdown campaign launched in 2005. According to Wang Zhiguang, deputy director of the IP Crimes Bureau, China saw a 70 percent increase in the number of criminal IP cases last year as a result of this program. During the first half of 2006, China

uncovered 167,000 cases of illegal production and trade in medicines and medical equipment worth US\$32.5 million and shut down 200 underground drug production sites, according to the SFDA.

Officials say that this is only the beginning: China's *Action Plan on IPR Protection 2006*, released in March by the National IPR Protection Working Group Office in conjunction with other departments, states that seven crackdown campaigns (such as Mountain Eagle, Sunshine and Blue Sky), eight regular enforcement initiatives and twelve specific measures will be deployed to improve IP protection. Also as part of the 2006 plan, a nationwide IP complaint hotline (call 12312) was completed this August, allowing individuals and companies to report incidents for inspection.

Looking ahead, the SFDA is planning to launch a one-year national campaign that will target malpractice and poor supervision in drug research, production, distribution and application.

"There's an IP issue for sure, but, more importantly, the Chinese government rightly recognizes that this situation is unique because there's also a health and safety issue," says Costigan. "That's why you're seeing so many government agencies acting with great cooperation. People can become sick or die from taking counterfeit drugs, so there is real motivation to act."

### Technology to the rescue?

According to some analysts in the United States, hope may be on the technological horizon. A growing number of pharmaceutical firms are starting to

adopt new Radio Frequency Identification (RFID) technology that may help limit commercial damage and save lives. Simply defined, RFID is an automatic identification technology that employs "tags" (devices comprised of an integrated circuit and antenna) to transmit radio waves to a reader that can analyze the data according to the unique needs of the user. RFID is similar to conventional bar code technology, although it uses radio waves to eliminate the need for line-of-sight reading. While costly, RFID tags are more durable and harder to fake than bar code. It helps companies keep better track of goods during the shipping process and ensure that they are receiving genuine goods.

In June, the U.S. FDA released its *Counterfeit Drug Task Force Report 2006*, strongly encouraging the use of RFID technology. "We continue to believe that RFID is the most promising technology for electronic track and trace across the drug supply chain," the report stated. In the U.S., the FDA is encouraging the tagging of all shipments of Class 1 pharmaceuticals with the hope of one day being able to track all pharmaceuticals transported within the country.

"We absolutely agree with the FDA that an electronic product code will help fight counterfeit drugs. But this technology still requires development of industry-wide standards so that we can share information in a meaningful way," said David Pulman, president of global manufacturing and supply for GlaxoSmithKline, to the press. The company announced plans two years ago to use RFID technology on an unnamed drug deemed susceptible to counterfeiting.

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## FAKE DRUGS IN CHINA

2001

**57** → Value (in US\$ million) of counterfeit medicines investigated

**1,300** → Counterfeit drug factories closed

**192,000** → Deaths in China due to fake drugs

**480,000** → Cases of counterfeit drugs investigated

2004

**691** → Counterfeit drug factories closed

**1,300** → Pharmaceutical firms forced to halt sales after SFDA issued the Good Manufacturing Practice Policy in July

2006 (H1)

**32.5** → Value (in US\$ million) of counterfeit medicines and medical equipment seized

**200** → Underground drug production sites shut down

**167,000** → Cases of illegal drug production and trade uncovered

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Purdue Pharma last year began shipping the painkiller OxyContin in bottles with RFID tags within the U.S., and Pfizer began doing the same with Viagra in the U.S. last December. “You know precisely where the unit is at all times and you exclude other products from entering that market unless they can prove their pedigree,” said Aaron Graham, vice president of corporate security for Purdue Pharma, to *CNN Money*.

Health-care firms are also exploring a variety of RFID-related technologies. Jacobi Medical Center in New York, for instance, now uses RFID tags on patients’ wrist bands to match with bar-coded information on individually packaged medication to ensure accurate administration and improve efficiency for nurses.

RFID is also becoming a big deal in a variety of other industries, as it reduces labor costs by automating the process of tracking goods. It is already in widespread use overseas. For example, Wal-Mart deploys RFID in their global supply chain

to reduce out-of-stocks, and Boeing announced last October it would use RFID “smart labels” on a number of maintenance-significant parts of its B-787 Dreamliner airplanes. According to a 2003 report by global IT research firm Gartner, by 2012 most “enterprises will be forced to redesign their value chain processes as a result of RFID changing the storage, collection and use of data concerning goods in the supply chain.”

### RFID in China

The PRC is presently a major user of RFID technology, although not yet in the pharmaceuticals industry. China placed a US\$6-billion order for RFID tags – the largest order to date – for a nationwide initiative that would give all 1.3 billion Chinese citizens an RFID identification card over the next few years. The technology is already used by mass transit systems in most major cities and Guangshen Railway Co. signed a deal in late August for 125 million RFID tickets for use on rail lines in Guangdong Province.

However, RFID for item-level tag products such as pharmaceuticals is still in an early stage of development in China, says Mark Gu, Texas Instrument’s (TI) marketing manager in China. Only a few Chinese companies so far have tried to use the technology, although market demand is expected to increase as more Chinese firms learn about it.

According to Gu, China’s pharmaceutical solution providers are closely studying successful benchmark pilot projects currently undertaken in the U.S. For example, Ross Systems, a subsidiary of China-based CDC Corp., this March released a new service called RFID-to-Go, which allows RFID tags to be placed on products during various stages of shipping and storage to improve traceability.

Before RFID becomes widely used in China, industry standards first need to be clarified. China currently follows ISO approved standards created by EPCGlobal, which are considered defacto in the industry. However, as Beijing is currently in the process of drafting its own national RFID standards, Western experts are voicing concerns, saying that it is too little, too late: The Chinese government’s 18-page document says the new standards will “correspond to international standards,” but does not detail how they would correspond with RFID tags manufactured in other countries.

## RISKS OF RFID TECHNOLOGY

Experts warn: RFID technology is promising, but not risk-proof. Companies using RFID technology should have a clear understanding of the security risks, such as eavesdropping or inventory jamming. A rival or an angry staff member could alter, corrupt or even delete the information inside RFID tags.

RFID tags also can be copied or “cloned.” Ari Juels, manager and principal research scientist for RSA Laboratories, a provider of digital security products, tells the story of the VeriChip tag, made by VeriChip Corp. “I’d suspected for some time that the VeriChip was susceptible to cloning attacks,” he recently was quoted in the *RFID Journal*.

Among industry insiders, the most talked about risk of RFID involves the so-called “Big Brother” controversy. All new technologies run the risk of being abused if they fall in the wrong hands. Criminals or possibly even governments could use these “spychips” to track people as they move from place to place.

There are currently over 100 companies in China involved in supplying RFID solutions, of which 30 percent are domestic firms with their own IP and 40 percent are resellers for companies from Europe and the U.S. The remaining 30 percent represent companies from other Asian countries. According to a report by internet-based business information provider Analysys International, China’s RFID market grew by 8.6 percent during the fourth quarter last year to reach RMB617 million, and is expected to expand by 33 percent annually to reach RMB5 billion by 2009.

— Brian Schwarz



IMAGINECHINA

**CRACKDOWN:** Shanghai police seize RMB2 million-worth of phony pharmaceuticals, including medicines and other health-care products (2002). Pharma companies are now working more closely with officials to find solutions.

As global standards are adopted and used by more companies in China, TI's Gu predicts the number of pilot projects and roll-outs of item-level tagging for both pharmaceuticals and high value goods will accelerate, ultimately providing a safer and more secure supply chain.

### Other tactics

Despite the hype surrounding RFID, significant limitations persist, including competing international standards, privacy concerns and a variety of technology barriers. Moreover, many Chinese manufacturers are deterred by the short-term costs of setting up an RFID system, which requires implementing expensive technology infrastructure that far exceed the costs of hiring extra labor.

In these early stages of implementation in the supply chain, questions also remain about its usefulness in the pharmaceuticals industry. Says Pfizer's Benner: "[RFID] has proven its value in inventory control, logistics and supply chain management. So companies such as Wal-Mart are seeing it as helpful and worth the investment. It still has yet to be seen if it has a valuable anti-counterfeiting aspect."

Gregg Metcalf, an industry market manager for U.S.-based Nosco Security Protection, a consultancy to pharmaceutical and medical device manufacturers, recommends that in the meantime

pharmaceutical firms use a variety of tactics such as mass serialization and optical watermarks in addition to RFID technology, in their fight against the counterfeiters. In the *Pharmaceutical & Medical News* last January, he concluded the more technologies that are in place, and periodically rotated, the more likely a counterfeiter would be discouraged from an attempt to duplicate the package, or try to generate a fake pedigree.

In the *Counterfeit Drug Task Force 2006*, the FDA reaffirms this view: "[W]e recognize that the goals can also be achieved by using other technologies, such as 2D-barcodes. Based on what we have recently heard, we are optimistic that this hybrid environment of electronic/paper and the use of RFID/bar code is achievable in the very near future. We believe that efforts to ensure that hybrid pedigrees are secure and verifiable should be a priority consideration."

In the near term-future, there will be no magic pill to cure the global problem of fake drugs. To fight against China's counterfeiters, companies and consumers must continue to use a strategic combination of technology and public-private cooperation to ensure safe medicine for now. 🇺🇸

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