By **Al Scott, CFE, M.S.**

China tackles emerging health care fraud

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In part 1 of two parts in the November/December issue, I described lesser-known emerging health care frauds and U.S. efforts to combat them. In this second part, I describe some of China's plans to tackle similar frauds and joint U.S.-China efforts.

Why China matters

Many have postulated that China is at a crossroads on many levels: politically, economically and socially. This juncture coincides with last year's once-a-decade change in leadership. In recent times, social media users increasingly have uncovered fraudulent activities, which China's government-owned media outlets subsequently reported on. Corruption and other varieties of fraud are now part of an intense national dialogue.

In the aftermath of the U.S.-induced global financial crisis, some in the international community believe China is the world's top economy based on particular metrics, though many in the West adamantly disagree.[1] Regardless, China is the major global supplier of active pharmaceutical ingredients used in drugs, a rising player in the production of finished drugs, a hotbed of research and development for the pharmaceutical industry and an increasingly important source for biological/biomedical innovations and treatments.[2]

China has listed biotechnology as one of the seven strategic emerging industries in its 12th 5th Year Plan (FYP) 2011-2015 — a promotion from its classification as a target industry in the 11th FYP.[3] The 12th FYP's "primary goal of scientific development" is a prominent driver towards achieving "long-term, steady and relatively rapid economic development." (jingji changqi pingwen jiaokuai fazhan)[4]

Despite the trend of American corporations to gradually return some jobs back to the U.S. (or insourcing), high-tech manufacturing and research and development opportunities are still shifting from mature developed countries to emerging countries, including China. Continued construction of state-of-the-art factories and large-scale research industrial parks by multinationals, university-led organizations and Chinese economic development vehicles strengthens this shift.[5]

Increases of procurement and supply chain fraud in Asia

In a relatively brief time, China has become an essential, if not the most important player in the global pharmaceutical supply chain. The abundance of talent, good infrastructure, and relatively low costs (though gradually rising), has enabled China to become a preferred destination for a number of pharmaceutical companies. Fraud is growing, in part, because of more complex supply chain gaps and continual changes in the global economic and regulatory landscape. A noticeable number of Chinese and Southeast Asian respondents in Kroll's 2011/2012 "Global Fraud Survey" acknowledged this type of fraud.[6]

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The Kroll report suggested that 2011 was a challenging year for the health care, pharmaceuticals and biotechnology sector. The accompanying Global Fraud Survey reported that overall prevalence of fraud dropped noticeably (from 88 percent to 73 percent) for the sector, as in every other industry. However, the average loss for the industry, at 2.6 percent of revenue, was the second highest for any sector, behind only financial services. In addition, eight of the 11 frauds surveyed within this sector increased in prevalence in 2011. (See the graph on page 62.)

China's efforts are a work in progress

Fraudulent pharma/biotech practices have a rippling effect inside and outside China because of various dynamics — social, political, technological. Though the U.S. FDA and China's State Food and Drug Administration

(SFDA) are collaboratively making strides to improve quality control of supply chains in China's pharmaceutical industry, health care fraud remains widespread, according to "China Halts Sale of Some Drugs," by Laurie Burkitt, in the April 17, 2012 issue of The Wall Street Journal (http://tinyurl.com/bntfmqv).

The U.S. has recognized gaps in regulatory enforcement, but China has bigger problems because of its huge geographic size and multiple fragmented, intertwined and often opaque regulatiry and commercial relations. For example, the SFDA regulates pharmaceutical companies but not chemical manufacturers, which also produce drug ingredients, taking advantage of a loophole by categorizing Active Pharmaceutical Ingredients (API). The central government isn't equipped to ensure that thousands of drug manufacturers, hospitals, distributors, local government officials and other domestic players comply.

Fraud leading to substandard products

Domestic pharmaceutical companies have supplied bogus or substandard medicines that have been injuring or killing Chinese consumers.

Qiqihar No. 2 Pharmaceutical Co., Ltd. was a medium-size pharmaceutical manufacturer in Qiqihar, Heilongjiang Province in Northern China. In September 2005, Beijing Dongshengyuan Investment Co. acquired the company for 14.42 M RMB (USD$228,160). (See "Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients," prepared by NSD Bio Group LLC, 2010.)

Qiqihar No. 2 Pharma's counterfeit Armillarisin A injection was responsible for 14 deaths in Guangdong Province between 2006 and 2008. This incident exposed flaws in China's drug administration and business licensing administration infrastructure. Chemical dealer Guiping Wang forged his business and pharmaceutical production licenses plus his pharmaceutical approval certificate. He then sold the fake pharmaceutical excipient (a pharmacologically inactive substance used to stabilize or deliver a drug's active ingredients) diglycol or diethylene glycol

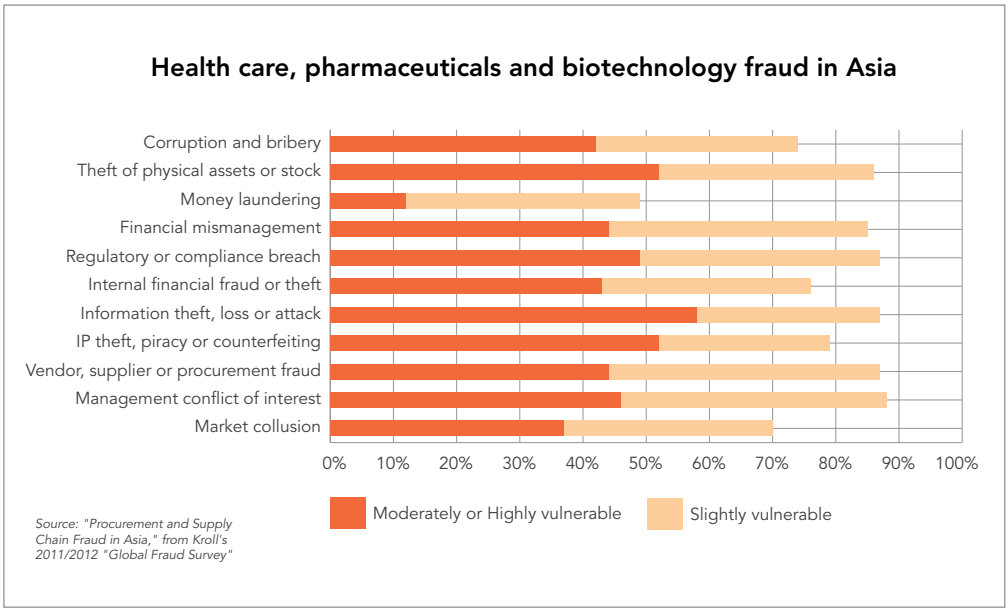
— an industrial solvent and component of antifreeze — as propylene glycol to Qiqihar No. 2 Pharma.

Qiqihar No. 2 Pharma, an official pharmaceutical manufacturer certified by the SFDA and supposedly adhering to SFDA's Good Manufacturing Practice for Drugs (GMP), allegedly failed to test their purchased excipients according to GMP standards. Quality control supervisors at the company did a basic test of the fake propylene glycol and were aware that its relative density "did not meet the requirements." However, they didn't conduct a further analysis and passed the fake excipient forward to production of Armillarisin A Injections. Eventually, the Guangzhou Intermediate People's Court sentenced five key executives at Qiqihar No. 2 Pharma from four to seven years in prison on charges of "negligently causing serious accident crime."

The vice general manager received seven years; the supervisor of the assay lab, six years; the purchaser, 5½ years; and the vice general manager, four years.

The Jiangsu Provincial Supreme People's Court sentenced Guiping Wang, the illegal chemical dealer, to life imprisonment and fined him 400,000 RMB ($63,305).

In April of 2012, the Ministry of Public Safety announced the arrest of nine suspects and the confiscation of approximately 77 million capsules made with industry-grade gelatin (instead of food-grade gelatin) containing toxic chromium from scrap leather by 254 pharmaceutical companies or 12.7 percent of all capsule makers. The Chinese government has attempted to restore public confidence by announcing a blacklist systems of substandard drug makers.[7]



In September of 2012, companies were alleged to have used "gutter oil" (reprocessed oil manufactured from waste oil and animal fat collected from restaurants, fryers, drains, grease traps and slaughterhouses) in their production processes. Huikang Grease reportedly sold 16,200 tons of gutter oil to Jiaozuo Joincare Biological in 2010 and 2011, which used it to produce an antiobiotic intermediate, 7-aminocephalosporanic acid (7 ACA), a component of the cephalosporin class of antibiotics. Two other companies, Qilu Pharmaceutical and Charoen Pokphand, also reportedly bought gutter oil to make this intermediate. (See "Chinese drugmaker accused of using cooking oil in antibiotic production," by Peng Tan, Sept. 10, 2012, in *Chemistry World*, http://tinyurl.com/ctrwh4.)

Rules of purity and safety

The SFDA has recently created new regulations on excipient quality and supervision, consistent with the International Pharmaceuticals Excipients of the Americas.[8] In addition, the SFDA issued new rules to govern the safety of drug excipients. These new regulations place responsibility for the safety of excipients on the drug companies that use these ingredients and also require excipient makers to test their products and prove they meet all specifications. (See "SFDA Published Regulation of Strengthening Supervision on Pharmaceutical Excipients," Aug. 1, 2012. http://tinyurl.com/bb5u6bj.)

As articulated at the 65th World Health Assembly — the annual World Health Organization (WHO) meeting — the spread of substandard drugs is a major global concern. Conversely, according to the WHO, companies will make substandard APIs as long as drug makers continue to buy them. (See "Substandard APIs will be made as long as Pharmas keep buying them, says WHO," by Gareth MacDonald, Sept. 3, 2012, in-PharmaTechnologist.com, http://tinyurl.com/aov8m86 and "Special Report: China's 'wild east' drug store," by Melanie Lee and Ben Hirschler, Aug. 28, 2012, http://tinyurl.com/cwe6mdq.)

On the surface, we can argue that those in China who are apprehended for conducting potentially egregious life-threatening behavior and actions affecting public health are dealt with more harshly and appropriately than those who are "fortunate" to oversee similar direcgives and outcomes in the U.S. However, several factors are in play here — not the least is the enormous, but tenuous "social infrastructure" to which China obligates its new leadership to further develop and strengthen maintenance of social stability.

Health care fraud impacts all citizens through higher pass-through costs, dangerous unregulated therapies or unapproved compromised drugs. Both China and U.S. governments suffer these cross-border dilemmas. Health care fraud evils are plentiful: They diminish public confidence in the health care system, deprive consumers of needed treatments, undermine the judgment of health care practitioners and, in many cases, put patients' health and safety at dire risk.

As was witnessed and experienced during the recent U.S. financial crisis — in which the U.S. Department of Justice determined it was easier to prosecute small banks than large influential banks (a viewpoint vehemently opposed by the general public) — accountability is the social glue of society. If individuals and for-profit entities aren't held accountable, then they can and will do anything — as history has repeatedly shown. ■ FM

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[1] "Growing Concerns in China about Inequality, Corruption." Pew Research Center Global Attitudes Project, Oct. 16, 2012 (http://tinyurl.com/8c9bm2l).

[2] NSD Bio Group, LLC, "Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients." 2010. Prepared for U.S. China Economic and Security Review Commission.

[3] "Backgrounder: China's 12th Five-Year Plan." U.S. China Economic and Security Review Commission, June 24, 2011 (http://tinyurl.com/agqnjsj). Additional sources in public domain.

[4] For the full text of the 12th FYP, see: "People's Economy and Social Development 12th FYP Outline." Central People's Government (http://tinyurl.com/b7hph6q) "China's Eleventh Five-Year Plan (2006-2010): From 'Getting Rich First' to 'Common Prosperity.' " C. Cindy Fan. *Eurasian Geography and Economics.* 47:6 (2006): 718 (http://tinyurl.com/ce4pavd).

[5] "China's pharmaceutical industry – Poised for the giant leap." KPMG. 2011. http://tinyurl.com/agdsudf; "Beyond borders: global biotechnology report 2011." Ernst & Young. http://tinyurl.com/68hmbbj.

[6] "China's growing presence in the global supply chain," by Shannon Bennett. *Chemistry Today.* Vol. 30 No. 1 January/February 2012. http://tinyurl.com/coy4boh; "Procurement and Supply Chain Fraud in Asia," by Tadashi Kageyama and Charlie Vilasenor, Regional Analysis: Asia-Pacific from Kroll Global Fraud Report Annual Edition 2011/2012. http://tinyurl.com/ansg9sb.

[7] "Unsafe Capsules," by Li Li. Beijing Review. com.cn. April 27, 2012. http://tinyurl.com/afcn7k6; "China may blacklist substandard drug manufacturers," by Eric Palmer. June 4, 2012. Fierce Pharma Manufacturing. http://tinyurl.com/bh8j8ux.

[8] "IPEC Americas backs new SFDA excipient regs; English translation available," Aug. 9, 2012. in-PharmaTechnologist.com. http://tinyurl.com/a4n82mo; "SFDA draft excipient guidelines place quality burden on pharmas," by Gareth MacDonald. July 3, 2012. in-PharmaTechnologist.com, http://tinyurl.com/byetmrl.