

RFID Tagging of Pharmaceuticals

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INTRODUCTION

Pharmaceuticals play a more prominent role in American health care than in any other nation. The North American market today comprises 47% of the global prescription drug market, which now exceeds half a trillion dollars, with Americans spending approximately \$251.8 billion annually on pharmaceuticals. This is up significantly from a decade earlier, when American consumption represented approximately one-third of the world market (IMS Health, 2006a). America's insatiable demand for prescription drugs has led to serious cracks in the drug supply chain of the world's leading pharmaceutical market.

This chapter examines the size and scope of the problem of counterfeit pharmaceuticals, both globally and in the United States. It looks at the impact this crisis is having both on public health and the pharmaceutical industry. Today, leaders in both the pharmaceutical industry and government are looking to more stringent regulations and radio frequency identification (RFID) tagging of pharmaceuticals as a way to head off the problems associated with an increasingly leaky drug supply chain. This chapter outlines the steps being taken in the United States to help secure this vital supply chain. Finally, an analysis is given of the impact the shift to electronic pedigrees of pharmaceuticals will have both on the pharmaceutical and RFID market spaces.

BACKGROUND

The World Health Organization (WHO) estimates that as much as 10% of the global pharmaceutical market—a half-trillion-dollar marketplace—is counterfeit. In some countries, the WHO estimates that 25% or more of the entire drug supply is counterfeit. The New York City-based Center for Medicines in the Public Interest recently predicted that by 2010, counterfeit drug sales will reach \$75 billion worldwide, almost doubling from the estimated counterfeit sales in 2005. The Federal Bureau of Investigation (FBI) estimates that the financial

impact of counterfeit drugs on U.S. companies is \$30 billion a year (Brooks, 2006; Eban, 2006).

Today, the toll of counterfeit drugs is mounting worldwide. Consider these recent news headlines from around the globe:

- In Hamilton, Ontario, Canada, Abadir Nasr, a registered pharmacist, was arrested by the Royal Canadian Mounted Police. Mr. Nasr, who was working at a retail drug store, dispensed counterfeit doses of Norvasc® to heart patients—pills filled with only talc. The local coroner investigated five patient deaths—all caused by a heart attack or stroke—that may have been brought about by the substitution of the counterfeit drug (Pitts, 2005).
- Within the last year, counterfeit versions of three popular drugs—Lipitor® for cholesterol, Cialis® for erectile dysfunction, and Reductil® for obesity—have surfaced in England. One British expert, Graham Satchwell, has estimated that 100,000 counterfeit drug imports are dispensed by the U.K.'s National Health Service annually (Eban, 2006).
- In China, a counterfeit drug smuggling ring was recently broken up that involved almost a half-million fake pills, including Lipitor® and all three major erectile dysfunction drugs (Cialis®, Levitra®, and Viagra®). Eleven Chinese nationals were arrested in the scheme, along with one U.S. citizen. The American had only recently been released from a New York State penitentiary for his involvement with counterfeit drugs in his home country, and he was drawn to the lucrative China market upon his release from jail due to the considerable money involved.
- Lipitor® is a cholesterol-reducing medication taken by more than 600,000 Americans, making it the most widely prescribed drug in the country. The U.S. Food and Drug Administration (FDA) announced on August 31, 2005, that it had busted a Lipitor® counterfeiting and smuggling ring that

was trafficking almost \$50 million worth of the drug (Gottlieb, 2005).

There is already evidence that counterfeit drugs are worsening public health in general around the globe. For instance, in many Southeast Asian countries, more than half of the drugs sold do not have the correct formulation or levels of the active ingredient (National Drug Intelligence Center, 2005). This is especially telling in the case of malaria. Deaths from the dreaded disease are on the rise, despite the introduction of the latest and most effective antimalarial drug, Artemisinin®. Because of the poor quality of Artemisinin—both legitimate and illegitimate outlets—drug resistance to antimalarials is rapidly increasing. In fact, it has been estimated that more than 100,000 people die annually directly as a result of counterfeit antimalarial medications in the region (Stevens, 2006). Likewise, new drug-resistant forms of the HIV virus that causes AIDS have been largely attributed to the use of counterfeit medications for HIV-positive individuals (Gaul & Flaherty, 2003). In the United States, customs agents recently seized a large quantity of Tamiflu®, which is highly sought after today due to fears of avian flu. Epidemiologists fear that fake Tamiflu® could actually exacerbate any H5N1 outbreak, as the counterfeit treatment could actually help the virus mutate into new drug-resistant strains (Stevens, 2006).

Scott Gottlieb, M.D. (2005), the FDA's Deputy Commissioner for Medical and Scientific Affairs, recently outlined the negative health outcomes that may occur directly from the use of counterfeit pharmaceuticals. These include actual cases where the fake drugs have contained ingredients that were:

- Inactive
- Incorrect
- Improperly dosed
- Subpotent
- Superpotent
- Expired
- Contaminated

Gottlieb (2005) summarized, "The result is risks to patients' health, either risk to their safety directly if the products are dangerous or risks from people suffering from complications from the many diseases that prescription drugs can treat today—but that the counterfeit versions cannot."

Why is there such unfortunate growth in counterfeit pharmaceuticals? The answer is multifaceted and complex, but the causal forces can be captured in the following:

- Profitability of the activity
- Relative ease of the activity
- Demand for drug products
- Cost of prescription drugs
- Web of country-specific regulations
- Vast cost disparities among countries on products
- Ease of transporting pharmaceuticals (which are generally shipped in cases, not pallets)
- Practice of relabeling, repackaging, and reimporting controlled substances
- Low prospect of being caught once the counterfeit pharmaceuticals are integrated into the drug supply (Pitts, 2005).

Indeed, according to the U.S. Department of Justice, the lure of counterfeit pharmaceuticals is so enticing that both organized crime and rogue entrepreneurs around the world are increasingly turning to the production and trade of fake, legal pharmaceuticals over narcotics and other illegal drugs (Gaul & Flaherty, 2003). The global pharmaceutical industry's counterfeiting problem is only exacerbated by the nature of its supply chain. In fact, the industry has been characterized in a recent *CIO Magazine* article as having "one of the world's most complex and opaque supply chains," producing "a web of legitimate, quasi-legitimate and illegitimate trade" (Patton, 2006, n.p.). With that, the sourcing of counterfeit drugs is now global, as fake pharmaceuticals have come from not only China and India but also from Central and South American as well as African and European countries (Stevens, 2006).

The United States has long thought of itself as being immune from the type of counterfeit drug problems found "over there" in areas of the world such as Southeast Asia and Africa (Pitts, 2005). This is because in the United States, 90% of all prescription drugs pass through the systems of just three drug wholesalers on their way to retail and hospital pharmacies. These are:

- AmerisourceBergen
- Cardinal Health
- McKesson (Navas, 2005)

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