

Pharmaceutical Counterfeiting, Tampering, and Diversion: Solutions for Addressing a Growing Threat



This paper discusses the threats that pharmaceutical counterfeiting, tampering, and diversion pose to industry, governments, and individuals, and offers a path toward managing these issues using technology and improved security practices.

A good example of tampering occurred in 2004, when \$40 million in counterfeit Viagra was seized at a San Diego warehouse. These drugs were destined for Tijuana pharmacies, and would have been sold to U.S., Mexican, and other international consumers.

In another case, the Pharmaceutical Security Institute (PSI) reported a 2006 sting that discovered a ‘small’ counterfeit drug operation. The equipment seized was capable of creating 200,000 tablets in five hours, for a shipment of 1.3 million phony tablets in a mere 6.5 days of illegal operations. In this criminal endeavor, 20 branded products had been manufactured, matching almost perfectly the color, size, and shape of the original medicines.

One well-known example of pharmaceutical tampering occurred in 1982, when Johnson & Johnson discovered that bottles of its Extra-Strength Tylenol capsules had been laced with cyanide. By the end of the scare, seven people died, and Johnson & Johnson had spent more than \$100 million to recall 31 million bottles of Tylenol.

In another case in 2002, quantities of the antianemia drug Epogen were identified by investigators as having phony lot numbers. Amgen, the drug’s manufacturer, found that the drugs contained only one twentieth of the active ingredient indicated on the drug packaging.

Growing trend threatens safety, corporate brand equity

Pharmaceutical counterfeiting, tampering, and diversion—the three biggest threats to the integrity of the global drug supply are escalating. The advent of inexpensive and sophisticated imaging technologies, and the growth of Internet sales and distribution channels provide criminals with the means to make convincing fakes with little training or capital. The high prices and brand recognition commanded by well-known drugs provide motive for criminals to shift their business away from trafficking in street drugs, which can be less profitable and more risky, to fake ‘legitimate’ drugs. Aside from undermining the profitability and brand integrity of major companies, pharmaceutical fraud has the potential to contribute to a world health crisis, endangering the lives of millions of people who rely on the authenticity of prescription and over-the-counter (OTC) drugs.

Counterfeiting, tampering, and diversion defined

Counterfeiting is the attempt by criminals to gain illegitimate profits or cause harm to consumers or pharmaceutical manufacturers by copying legitimate drugs. Unlike illegal drugs such as cocaine, counterfeit drugs are often sold directly to consumers through mail order catalogues, the Internet, or traditional distribution channels to pharmacies. The World Health Organization (WHO) first acknowledged the problem of pharmaceutical fraud in 1985 at the WHO Conference of Experts on Rational Drug Use in Nairobi, Kenya. Subsequently, the WHO and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), defined counterfeit drugs as those that are “deliberately mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients; without active ingredients, with insufficient active ingredient or with fake packaging.”

Tampering is the criminal manipulation of a pharmaceutical by an unauthorized party. Typical examples include pharmacists who may dilute packaged pharmaceuticals to increase profits, or individuals who wish to inflict pain or death on innocent consumers of pharmaceuticals.

Diversion is the criminal importation and resale of pharmaceuticals intended for use in another country. Diversion typically involves pharmaceuticals donated to a relief organization in a third-world country that make their way to developed nations to be sold at substantially higher prices. Diversion allows practitioners to generate illegitimate profits by diverting drugs from their intended recipients whenever pharmaceutical companies distribute high-value drugs at below-market prices.

Parallel importing and smuggling are two variants of diversion :

- *Parallel importing*, or gray-market importing, is the unauthorized (but not always criminal) importation of patented drugs for resale via conventional distribution channels. A typical example of parallel importing might involve a distributor who sources drugs for a free-market economy from a country in which pharmaceutical prices are fixed at price points below those found in other countries. In such cases, parallel importers rob patent holders of legitimate profits, limiting the incentive for pharmaceutical companies to invest in developing innovative drugs.

Interestingly, governments do not automatically label parallel importing a crime, and the law in this area is unclear. For instance, in a recent U.S. Senate healthcare bill, SA 2793, President Obama endorsed parallel importing from the European Union, pending U.S. Food and Drug Administration (FDA) inspection, to help reduce drug prices in the U.S.

However, the lower prices negotiated by European government agencies create a smaller profit margin, which translates to smaller research and development budgets for European drug companies.

For example, a 12-week course of Serostim, which is used to treat AIDS-related weight loss and build body mass in athletes, can cost \$21,000. This is a significantly higher price point for criminals than comparable quantities of street drugs.

- *Smuggled drugs* enter a country illegally with false documentation, either through the postal system or via couriers. In addition to robbing patent holders of legitimate profits, smugglers also cheat governments out of taxes that would have been earned from legitimate sale of the smuggled drugs.

Factors driving increased criminal activity

While counterfeit drugs are commonplace in developing countries, criminals in the developed world tended to focus on illegal ‘hard’ drugs, which offer high returns on investment. However, several factors are combining to shift criminal activity to counterfeit “legitimate” drugs in developed countries. These include the high cost to develop and market legitimate drugs, the rising demand for prescription (‘lifestyle’) drugs, the declining margins associated with illegal drugs, the increasing accessibility of the tools needed to create and distribute counterfeit drugs, the effect of deregulation and Internet sales channels, and the mild response of law enforcement to counterfeiting.

High cost of drug development

Drug companies spend as much as \$400 billion to develop, patent, distribute, and bring new pharmaceuticals to market.¹ As a result, new drugs can carry high price tags that capture the attention of counterfeiters. For example, a 12-week course of Serostim which, in addition to treating AIDS-related weight loss, is sought by athletes to build body mass, can cost \$21,000. This is a significantly higher price point for criminals than comparable quantities of hard drugs like cocaine, marijuana, or heroin.

Rising demand for prescription and OTC drugs

The global pharmaceutical industry generates approximately \$600 billion in annual sales², with 88 percent of the market located in North America, Europe, and Asia³. An aging population, the ongoing development of new drug-based remedies for many diseases, and the increasing prevalence of direct-to-consumer advertising contribute to the consistent double-digit growth of pharmaceuticals each year. In addition, “the abuse and trafficking of prescription drugs is set to exceed abuse of illicit drugs” as prescription drugs used for ‘recreational’ purposes, such as Oxycotin, increasingly take the place of hard drugs among substance abusers⁴—a trend highlighted by the U.N. International Narcotics Control Board in 2006. Finally, government initiatives to ease the burden of expensive pharmaceuticals, such as the U.S. Medicare prescription drug program, have increased the overall demand for drugs.

¹ *The Price of Innovation: New Estimates of Drug Development Costs*, Journal of Health Economics (Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski), October 2002.

² *The 10 Top Selling Drugs*, Wired Magazine (Matthew Herper and Peter Kang), March 2006.

³ *Industrial Surveys Global Pharmaceuticals*, reportSURE, December 2004.

⁴ *Bogus Medicines Flood Developing World: U.N. Report*, Reuters, March 1, 2007

Involvement of criminal enterprises

In many cases, the profit margin associated with counterfeit prescription drugs far exceeds the margin for illegal drugs, making counterfeiting highly lucrative for the criminals facilitating this growing business. According to David Fernyhough, a counterfeiting expert at the Hong Kong offices of Hill & Associates as reported in the New York Times, criminals attracted to the high profits and relatively low criminal penalties associated with counterfeit drugs are distributing them through networks “that ‘mirror the old heroin networks,’ flowing to Thai distributors, with financing and money laundering arranged in Hong Kong.”

Accessibility of sophisticated imaging and printing technologies

High-quality graphic design technologies, combined with low-cost scanners and imaging programs, provide the means to create realistic counterfeit packaging and labels. Color printers, capable of printing highly sophisticated images are available for less than \$100, and scanners have become so commonplace that they are given away with many computers. Imaging programs are available as ‘freeware’ or can be purchased for as little as \$25. The accessibility of these tools means that criminals no longer need highly technical computer technology or expensive hardware to create convincing reproductions of packaging materials.

Deregulation and the Internet

The pressure faced by politicians to address mounting healthcare costs is significant, and many politicians see deregulation as a potential tool for combatting rising drug costs. However, if not handled carefully, expansion and deregulation of trade offers greater opportunities, especially through ‘free trade zones,’ to introduce fake products into official channels.

The Internet makes it possible for individuals to “legally” engage in drug reimportation and tampering with little resistance from government regulators. The National Association of Boards of Pharmacy has identified approximately 200 domestic websites that dispense prescription drugs but do not offer an online prescribing service. According to a 2006 Chicago Tribune article cited by the AMA, at least 400 websites both dispense and offer a prescribing service. Additionally, the Fraud Prevention Institute (FPI), agreed with the U.S. FDA and Customs office that approximately 88 percent of Internet and international drug imports are comprised of counterfeit products, many of which are destined for wholesale distributors and retail pharmacies.

With little or no government oversight, and anonymity for buyers and sellers alike, the Internet offers would-be counterfeiters and parallel importers an ideal means for implementing illicit activities.

As a case in point, in 2007 the FDA learned of cases in which consumers ordered the drugs Ambien, Xanax, Lexapro, and Ativan online but received a product that contained, on preliminary analysis, haloperidol, a powerful antipsychotic drug.⁵

⁵ FDA Press Release, February 20, 2007.

Lack of tools for law enforcement

Law enforcement has many tools for catching manufacturers and dealers of illegal drugs. But the criminal code in the U.S. and other countries has not caught up when it comes to putting legitimate drug counterfeiters behind bars. As a result, criminals that traffic in illegal hard drugs see benefits in shifting their operations to counterfeiting. However, in 2006, the U.S. enacted the Stop Counterfeiting in Manufactured Goods Act (HR 32), which amended the federal criminal code by ensuring that the provisions that prohibit trafficking in counterfeit goods and services include prohibitions in the illicit trafficking of labels or packaging. In addition, in 2009 the FDA drafted the Guidance for Industry Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting. The guide provides recommendations for pharmaceutical manufacturers on the use of inks, pigments, flavors, and various taggants used as physical-chemical identifiers (PCIDs) in nonfunctional (immediate release) film coatings. By including these trace amounts of nontoxic taggants or chemical inks and pigments on actual doses, coupled with suggestions to include these same measures on pharmaceutical labeling, the U.S. government took a necessary step toward providing law enforcement the tools needed to prosecute pharmaceutical counterfeiters.

In India, for example, counterfeit drugs manufactured for Indian consumers is unlawful, but legitimate companies are allowed to manufacture counterfeit drugs for export within existing laws.⁶

Another factor compounding the problem faced by law enforcement is the lack of recognition, in developing countries, of the threats associated with counterfeit drugs. Without effective cooperation and communication strategies between relevant global agencies, such as customs, health authorities, police, and pharmaceutical industry representatives, the ability to detect and thwart counterfeiters is limited.

Scope of Problem

The U.S. FDA offers the following assessment of drug counterfeiting:

The extent of the problem of counterfeit drugs is unknown. Counterfeiting is difficult to detect, investigate, and quantify. So, it is hard to know or even estimate the true extent of the problem. What is known is that it occurs worldwide and is more prevalent in developing countries. It is estimated that upwards of 10 percent of drugs worldwide are counterfeit, and in some countries more than 50 percent of the drug supply is made up of counterfeit drugs.⁷

In developing countries, counterfeiters target almost any drug, from children's cough syrup to antimalarial drugs. The WHO estimates that in many parts of Africa, Asia, and Latin America, more than 30 percent of the medicines for sale in a particular area can be counterfeit. Recognizing the unfortunate reality of drug counterfeiting and tampering, healthcare professionals in developing countries must take extraordinary steps to ensure the legitimacy of the drugs they purchase. At AIC Kijabe Hospital in Kenya, for example, before any drug is given to a

⁶ http://en.wikipedia.org/wiki/Counterfeit_drug

⁷ <http://www.fda.gov/oc/initiatives/counterfeit/qa.html>

patient, doctors insist that it be sent to a third party laboratory for testing and validation.⁸ Unfortunately, many hospitals and healthcare professionals in developing regions do not make such expensive and time-consuming efforts to protect their patients against potential adverse effects of counterfeit or tampered drugs.

In developed nations, most counterfeiting activity is focused on “lifestyle drugs,” such as Viagra. And while the U.S. drug supply is more secure than developing nations, there is ample evidence that criminals are becoming more creative in their efforts to take advantage of weaknesses in legitimate production and distribution chains. In recent years, nine recalls of counterfeit medicines have reached the pharmacy level in the UK. Furthermore, according to David Dorsey, acting Deputy Administrator for Policy at the FDA, a record 65 cases of potential counterfeit drug investigations were opened in 2009, and more than 200 cases since 2006.

The FDA has also issued several warnings about counterfeit antiretroviral medicine. Testimony from Randall W. Lutter, Ph.D., FDA acting Associate Commissioner for Policy and Planning, before the House Subcommittee on Criminal Justice, Drug Policy, and Human Resources, outlined several cases dealing counterfeit name brand drugs. The full text of Dr. Lutter’s testimony is available on the FDA website.⁹

- *Lipitor*—In 2005, the U.S. Attorney’s Office for the Western District of Missouri announced that three businesses and eleven individuals were indicted for their involvement in a \$42 million conspiracy to sell counterfeit, smuggled, and misbranded Lipitor and other drugs, and for participating in a conspiracy to sell stolen drugs. As part of this investigation, the FDA initiated a recall of more than 18 million Lipitor tablets.
- *Viagra and Cialis*—In 2005, the U.S. Attorney’s Office for the Southern District of Texas announced the indictment and arrest of an individual from the state of Washington for alleged involvement in the importation from China and subsequent distribution of counterfeit drugs, including Viagra and Cialis. In connection with work on this case, Chinese officials recovered 600,000 counterfeit Viagra labels and packaging, 440,000 counterfeit Viagra and Cialis tablets, and 260 kilograms of raw materials used to manufacture counterfeit drugs.
- *Drugs from Mexican border pharmacies*—In 2004 and 2005, the Office of Criminal Investigation (OCI) received Voluntary Suspect Counterfeit Drug notifications from the drug manufacturers of Zocor, Carisoprodol, Lipitor, Viagra, and Evista. Counterfeit versions of these drugs were being sold to U.S. consumers from Mexican pharmacies along the U.S. border. Analysis of these drugs showed they contained little or no active ingredients.
- *World Express Rx*—In 2005, a San Diego man was sentenced to a 51-month prison term and forced to forfeit substantial cash proceeds for operating a large Internet pharmacy scheme. The drugs distributed included a variety of

⁸ 2006 discussion with Dr. Jon Fielder of AIC Kijabe Hospital.

⁹ <http://www.fda.gov/ola/2005/counterfeit1101.html>

products counterfeited in Mexico and smuggled into the U.S. Some of the ingredients for the drugs were shipped from India and China. In other instances, unapproved and counterfeit drugs made in India and Pakistan entered the U.S. via the Bahamas. At least 14 other individuals were prosecuted in California and Florida as part of this international conspiracy.

The cost of counterfeiting, tampering, and diversion

In most cases, according to the WHO, counterfeit drugs are not equivalent in quality, safety, and efficacy to their genuine counterparts. Even if counterfeit drugs contain high-quality active ingredients, because they are not within the purview of governmental drug regulatory authorities, any associated defects and adverse reactions cannot be easily recognized or monitored. Counterfeiting, tampering, and diversion exact high costs on consumers, healthcare providers, drug manufacturers, and governments.

Counterfeiting, tampering, and diversion harms consumers

- *Illness or loss of life*—Poor quality counterfeit drugs or drugs that are tampered with can cause death and serious illness, as seen in connection with several incidents of counterfeiting in the developing world. According to the New York Times, “estimates of the deaths caused by fakes run from tens of thousands a year to 200,000 or more.”¹⁰ The WHO estimates that a fifth of the one million annual deaths from malaria could be prevented if all medicines for it were genuine and taken properly.¹¹ In Nigeria, 100 children died when a cough medicine was “diluted” with a poisonous solvent; in Haiti at least 59 children died after taking counterfeit syrup labeled to treat fever.¹²
- *Higher costs for pharmaceuticals*—As a result of lost revenue, exposure to huge damage claims, and higher insurance rates, consumers are faced with higher prices for drugs targeted by counterfeiters and diverters.

Counterfeiting, tampering, and diversion can harm drug manufacturers by leading to:

- *Lost revenue*—Counterfeiting, tampering, and diversion sales are made at the direct expense of drug manufacturers who spend millions of dollars developing and promoting their products. The annual cost of counterfeiting to pharmaceutical companies, is estimated at \$35 billion by the U.S. Chamber of Commerce.
- *Liability*—Drug manufacturers can face potentially crippling lawsuits as incidents of counterfeiting, tampering, and diversion pose increasing health and security problems for the public. Plaintiffs hold drug manufacturers accountable for the authenticity of the products they manufacture and the safeguards in place to prevent tampering.

¹⁰ *In the World of Life-Saving Drugs, a Growing Epidemic of Deadly Fakes*, Donald McNeil, Jr., The New York Times, February 20, 2007.

¹¹ *Ibid*

¹² *Counterfeit Medicines - An Unscrupulous Business*, The German Pharma Health Fund, 2001.

- *Brand Integrity*—Pharmaceutical companies invest enormous amounts of resources, time, and money to develop, promote, and maintain their brands. But that investment can be undermined by a single incident or a perception that the product may be fake.

Counterfeiting, tampering, and diversion can harm healthcare providers by leading to:

- *Decline in confidence of public health*—When counterfeit or tampered drugs lead to death or serious illness, public confidence in healthcare systems, healthcare professionals, and government agencies is eroded.
- *Increased liability*—Greater risk of harm to consumers results in greater liability for healthcare providers. In the event of litigation following a consumer illness or death from counterfeit or tampered drugs, healthcare providers must prove they have taken every step possible to protect the integrity of the pharmaceuticals they administer.

Counterfeiting, tampering and diversion can harm governments by leading to:

- *Public health crisis*—Consumption of counterfeit and tampered pharmaceuticals can cause widespread illness that may overwhelm the healthcare system or create healthcare crises worldwide.
- *Lost tax revenues*—Sales of counterfeit or diverted drugs bypass traditional sales channels, thereby depriving governments of tax revenues.
- *Increased enforcement costs*—As counterfeiting, tampering, and diversion grow, governments need to allocate a greater portion of their security budgets toward efforts ensuring the integrity of pharmaceuticals.
- *Funding of criminal enterprises*—The people that benefit most from counterfeiting, tampering, and diversion are criminals who then use their proceeds to fund other criminal activity or to further their own enterprises.

Efforts so far

Following congressional pressure and heightened public awareness of issues relating to fake drugs in the aftermath of 9/11, the FDA established an internal U.S. Counterfeit Drug Task Force. This task force issued its report, “Combating Counterfeit Drugs: A Report of the Food and Drug Administration” in 2004, which recognized the threat of counterfeit drugs and offered recommendations for government and industry to improve the security of the U.S. drug supply. The FDA’s Dr. Randall W. Lutter summarized the findings with the following recommendations¹³:

- Securing the actual drug product and its packaging
- Securing the movement of the product as it travels through the U.S. drug distribution chain

¹³ <http://www.fda.gov/ola/2005/counterfeit1101.html>

- Enhancing regulatory oversight and enforcement
- Increasing penalties for counterfeiters
- Heightening vigilance and awareness of counterfeit drugs
- Increasing international collaboration.

While the FDA report highlighted the benefits of RFID as a track-and-trace solution for improving drug companies' ability to monitor and police drugs as they move through the supply chain, the task force was also clear in its view of the value of authentication technologies (which it listed as holograms, color-shifting inks, and covert taggants) to address the issue of securing the actual drug product and its packaging:

“Existing authentication technologies have been sufficiently perfected to serve as a critical component of any strategy to protect products against counterfeiting. ... The use by manufacturers and repackagers of one or more authentication technologies on their products, particularly those likely to be counterfeited, would protect the public health and diminish counterfeiting.”¹⁴

Furthermore, to mobilize awareness and action in the fight against counterfeit medicines, the WHO created the International Medical Products Anticounterfeiting Taskforce (IMPACT) in 2006. IMPACT is comprised of all 193 WHO member states, and also includes international organizations, enforcement agencies, national medicine regulatory authorities, customs and police organizations, nongovernmental organizations, associations representing pharmaceutical manufacturers and whole-salers, health professionals, and patients' groups. These groups joined together to improve coordination and harmonization between countries to combat the production and distribution of counterfeit medicine.¹⁵

Additionally, PSI created the PSI Counterfeiting Incident System, which records incidents of counterfeiting, theft, and illegal diversion of pharmaceutical products worldwide. The various incident reports come from a variety of sources, including open media reports, PSI member company submissions, and public/private sector partnerships.

Fighting the problem

Pharmaceutical counterfeiting, tampering, and diversion demands a new mindset for drug manufacturers and regulators alike: they must recognize the need to treat pharmaceutical packaging like a valuable currency, and secure it with robust security and authentication features.

The solution

To generate the best solution, authentication solution providers should consider all appropriate technologies and match the best features and techniques with their

¹⁴ *Combating Counterfeit Drugs*, U.S. Food and Drug Administration, February 2004.

¹⁵ <http://www.who.int/impact/FinalBrochureWHA2008a.pdf>

customers' particular challenges. In many cases, only a combination of technologies will meet customer requirements. While it is difficult to establish specific rules across various challenges and issues, strategies that incorporate an amalgamation of overt, covert, and forensic security technologies provide the most functionality to deliver the optimal level of authentication.

Layers of security

The Authentication Solutions group of JDSU uses a multitechnology approach, that includes layers of overt, covert, and forensic technologies, to address counterfeiting, tampering, and diversion through a strategy of interdiction, authentication, and digital verification. The goal is a layered solution that can interdict counterfeit products at the source starting with AuthentiTrak™, the JDSU digital verification system for securing the supply chain. This level of verification helps prevent the entry of the counterfeit products into the supply line. In addition, AuthentiTrak™ can educate consumers via product authentication through an online database.

Overt, covert, and forensic authentication solutions

JDSU authentication solutions incorporate overt and tamper-evident, covert, and forensic, and digital tracking security features and techniques for multiple layers of authentication.

Overt technologies

Overt authentication technologies are designed to be easily recognizable to the public and difficult for counterfeiters to simulate. These features are generally authenticated visually, without the aid of a special device or training. Holography and color-shifting technologies are the most widely used overt authentication technology, and provide the first layer of protection against fraudulent products.

Some overt features offered by JDSU include:

- SecureShift®—color-shifting that can be visually verified
- MetaSwitch—highlights color-shifting effects with a static, non-shifting color
- Phantom™—gives the appearance of distinctive color motion and shadow effects to shapes or logos
- 3D imagery—gives the illusion of depth at varying distances
- true color—holographic images that produce the illusion of color at specific angles
- parallax—images created on different planes appear to move in relation to each other
- secondary flip image—an image appears and disappears when viewed from different angles
- diffractive mercurial—bright, sharp, color-shifting, two-dimensional images

- animation—2D or 3D images give the illusion of motion
- stereogram—displays recording of an image with extensive color or motion
- demetallization—makes printed materials underneath a hologram visible and protected.

Tamper-evident technologies

JDSU offers a wide range of optical security packaging solutions, such as laminates and seals, that immediately indicate if a product has been opened, refilled, or otherwise modified. These include:

- fugitive ink—JDSU is developing fugitive inks that would immediately dissolve and clearly alter their appearance if tampering occurs
- frangible film—a layer on the surface of packaging that fractures into small pieces when damaged.
- HoloSeal™—a holographic authentication label featuring a tamper-apparent break pattern built into its adhesive layer that self-destructs if tampering occurs.

Covert and forensic technologies

Covert and forensic authentication technologies contain hidden features that can only be detected with commercially available microscopes or specialized readers. These sophisticated technologies can be incorporated into overt authentication solutions or can function on a standalone basis to protect against counterfeiting and diversion. Current covert technology features a broad spectrum of authentication solutions, including machine-readable technology, microtext, nanotext, imbedded images in holographic images, and a mix of machine readable technology and holographic imagery.

Some covert features offered by JDSU include:

- Charms™—microstructured taggants that incorporate customized logos in a specific shape
- HoloScan™—hidden, machine-readable code within a holographic image
- microimagery—microscopic text or logo within a holographic image
- nanoimagery—microscopic printed text
- latent image—images visible with hand-held readers
- taggants—unique features added to holographic films or inks that are machine readable and verifiable.

In addition, JDSU has the capability to perform laboratory tests of the chemical and optical components of its products to conclusively determine the authenticity of its products.

Digital authentication technologies

A JDSU proprietary digital authentication platform, Authentitrak™, enables brand owners to track products and validate authenticity throughout the entire supply chain. Accessed through a password-protected web portal hosted by JDSU, key elements include:

- variable printing—each item, box, or sleeve is encoded with a different serial number
- database tracking—each serial number is registered in a database and is accessible via a web portal
- field verification—investigators can authenticate products using proprietary, closed systems or commercially available open systems.

Using Authentitrak, manufacturers can view the name, date, and address of the original shipping location through the serialized link to an individual product. This technology not only authenticates each individual product but also illustrates the lifecycle of the entire shipment.

Robust technology

JDSU specializes in creating and implementing product security solutions that are extremely difficult to copy or falsify. While no technology is completely immune from counterfeiters with infinite resources, many thought product security thought leaders—from issuers of major credit cards to central banks to leading consumer brands—recognize that because of the complexity involved in JDSU holography, ink, and printing technology, counterfeiters find it nearly impossible to copy our authentication solutions. This fact has been recognized by U.S. Secret Service, Interpol, U.S. Department of Homeland Security, and other law enforcement entities, who have worked with us to train their agents in the security features embedded in JDSU products.

Application Methods

When the appropriate authentication solutions technologies are chosen, there are several ways to implement them. JDSU supports many application methods through its dedicated commercial holographic and ink manufacturing facilities, as well as its state-of-the-art printing plant.

Holographic applications can be delivered as high-security foils or films that are stamped or laminated onto paper or plastic substrates. A wide range of holographic products are available including, foils, labels, hang tags, shrink sleeves, induction capseals, textiles, and molded plastics.

Ink applications are generally delivered as high-security inks that can be incorporated into a range of printing methods, including silkscreen, flexography, gravure, and offset for documents, labels, hang tags, shrink sleeves, induction capseals and in molded plastic. Each of these applications (and others that may be required to meet customer needs) demand an applications team with a high level of expertise in material science, engineering and design in order to deliver such applications in a manner that is both cost effective and will not complicate or slow down the supply chain.

Printing applications are delivered using our state-of-the-art electronic prepress, specialty materials, unique constructions, and the industry's highest-quality flexographic printing plant. The JDSU collection of high-security facilities hold certifications from the International Organization for Standardization (ISO) and the North American Security Products Organization (NASPO).

Applications engineering

JDSU capabilities include mechanical, electrical, software, facilities, process, and quality engineering. We take responsibility for overseeing the design and construction of proprietary manufacturing equipment and all supporting infrastructure. An in-house model shop and electronics shop provide the capability to design and build custom proprietary devices and equipment as needed. Equipment is qualified and software is validated according to written procedures that meet the requirements of US CFR 21 Part 211 and ISO 9001:2000. Software used to plan and commission building, equipment, and automation projects includes MS Project, SolidWorks, and proprietary applications.

Leverage existing infrastructure and vendors

In addition to in-house label converting capabilities, JDSU offers many of its products through leading label converters and packaging companies. JDSU has worked with label converters to supply customized security material for inclusion in finished labels and in other packaging elements for their customers.

Cost Impact

In most cases, the total cost for a JDSU solution would not exceed a few pennies per unit, including any application cost.

Testing capabilities

In connection with product development efforts, and to support ongoing customer trials and quality requirements, JDSU maintains extensive in-house testing capabilities, including a precision microscopy laboratory that examines the fine optical details of holographic security images, pigments, and inks for inspection and forensic purposes. In addition, sophisticated procedures and testing equipment examine physical, durability, and adhesion issues that may arise in connection with JDSU products. These capabilities enable short run jobs that allow for initial trials and testing before launching major programs.

Educational impact

Some security features offered by JDSU are intuitive and require no consumer education. For example, holograms can incorporate tamper-evident features that render any manipulation of a holographic security device obvious to consumers. In addition, consumers can identify holograms and ink solutions with the naked eye, without using expensive or complicated tools. In extreme cases, consumers or merchants who doubt the authenticity of a JDSU label can use AuthentiTrak™, the JDSU online database for verifying serial numbers located on product labels.

Program management

Program management is an often overlooked element of successful authentication solutions. Authentication solutions providers must manage their applications in several locations around the world. This includes coordinating concept and color design, customer support, and security, sometimes all in entirely different locations. A program manager must integrate the proposed solution and application with the current supply chain tools; create a convenient order-entry system that considers cost and anticipates problems that may occur in a complex, global delivery matrix; and implement a just-in-time delivery system to prevent excess inventory. Delivering program management on such a global scale requires expertise in account management, customer service, technical support, logistics, and software development.

JDSU: solutions for every aspect of product authentication

The counterfeiting, tampering, and diversion of pharmaceuticals is on the rise due to the wide availability of sophisticated printing and imaging technology needed to replicate pharmaceutical packaging, the emergence of alternative distribution channels, and the high cost of developing name-brand pharmaceuticals. Counterfeiting, tampering, and diversion are a threat to public health and create potential financial liabilities to the pharmaceutical companies, healthcare providers, and governments who share a common interest in fighting threats to the authenticity of pharmaceutical products.

With decades of experience in integrating technology, applications, and program management, JDSU has pioneered a true solutions approach to product authentication. In-house designers and engineers are dedicated to meeting customer needs for sophisticated prototypes and applications using best-in-class holography and color-shifting ink technology. In addition, web-based order-entry portals make supply chain integration easy and convenient. Implementing the optimal technology and applications, managed by JDSU, will assist pharmaceutical companies in improving security to protect their financial interests and help preserve public safety.