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Fighting counterfeit pharmaceuticals

New defenses for an underestimated — and growing — menace

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Executive summary

With sales ranging from €150 billion to €200 billion (US$163 billion to $217 billion) per year, according to industry estimates, counterfeit pharmaceuticals are the most lucrative sector of the global trade in illegally copied goods. Fraudulent drugs harm or kill millions around the world and inflict serious damage on the brand names and bottom lines of major pharmaceutical manufacturers. Although less developed markets have long been their stronghold, pharma counterfeiters are now using digital channels to penetrate developed countries, where traditional physical drug distribution networks are well protected. Companies have plowed billions of euros into defensive measures, but their efforts haven't slowed counterfeiters. Common anti-counterfeiting tactics block about half of the fake drugs, at most. New regulatory initiatives, meanwhile, leave large gaps for criminals to exploit.

Yet a new survey by Strategy&, PwC's strategy consulting business, finds that pharmaceutical executives generally aren't inclined to spend more to fight fakes, despite their awareness that current measures don't go far enough. Not only do these executives misjudge their own vulnerability, but they also overlook the opportunities awaiting those that capitalize on rapidly evolving anti-counterfeiting technologies that do more than improve on existing supply chain safeguards. Companies that adopt these technologies will reap a range of new benefits, and gain an edge over rivals relying on yesterday's solutions.

The world's largest fraud market

What comes to mind when you hear the term *counterfeit goods*? Fake Rolex watches? Bogus Gucci handbags? Sure, knocked-off luxury goods grab headlines and generate healthy profits for counterfeiters. But the real money is in plagiarizing pills, not purses.

From falsified Lipitor tablets to imitation Viagra and Cialis capsules, counterfeit pharmaceuticals are a €188 billion (US$200 billion) annual business, making them the largest segment of the €1.6 trillion in fraudulent goods sold worldwide every year (*see Exhibit 1, next page*). Even in the most secure markets in the world, it's estimated that at least 1 percent of all drugs in circulation are counterfeit. Authorities confiscated 4 million counterfeit tablets in 2015 in Germany alone. And in developing regions, such as Africa, the proportion of fake pharmaceuticals can rise to 70 percent.

Roughly one-third of the world's countries lack effective drug regulatory agencies, making them easy prey for counterfeiters. The absence of anti-counterfeiting measures exposes millions of people to potentially lethal chemicals and undermines the growth strategies of companies looking for new markets. More ominously, counterfeiters are moving beyond their traditional focus on "lifestyle" drugs, such as remedies for baldness and erectile dysfunction. Research shows that more than half the counterfeit pharmaceuticals sold today are fraudulent versions of treatments for such life-threatening conditions as malaria, tuberculosis, HIV/AIDS, and even cancer (*see Exhibit 2, page 7*).

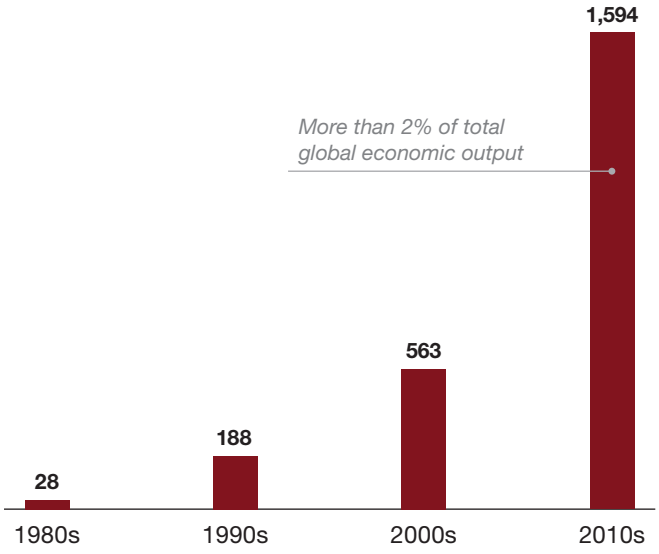
Many of these pirated drugs arrive from illegal online pharmacies based in remote corners of the world, beyond the reach of regulators. Digital channels allow criminals to elude security barriers designed for traditional drug distribution networks. The World Health Organization (WHO) estimates that 50 percent of drugs sold online are fraudulent.

The rising tide of counterfeit drugs reveals numerous gaps in governmental and industry efforts to safeguard global pharmaceutical supplies. Even the stricter security regulations taking effect in Europe and elsewhere are far from foolproof. Drug companies are spending

Exhibit 1

Damage from counterfeit goods, by industry

Surging cost of counterfeiting (€ billions, based on average annual estimate of global counterfeiting revenues)



Global counterfeiting market by sector (€ billions) 2013 estimates, not all sectors included

Prescription drugs	188
Electronics	158
Foods	46
Auto parts	42
Toys	32
Clothing and shoes	23
Sporting goods	6
Tobacco	4
Cosmetics	3
Aircraft parts	2
Weapons	2
Alcohol	0.9
Watches	0.9
Diplomas and degrees	0.9
Pesticides	0.7
Money, IDs, and passports	0.3

Source: NetNames, "The risks of the online counterfeit economy," 2016; NetNames, "Counting the Cost of Counterfeiting," 2015; Strategy& analysis

Exhibit 2

The global threat caused by counterfeit drugs

1%–30% of drugs in circulation are fake

and developing countries are more affected than developed countries

1 million patients die annually

from toxic counterfeit pharmaceuticals

450,000 preventable malaria deaths

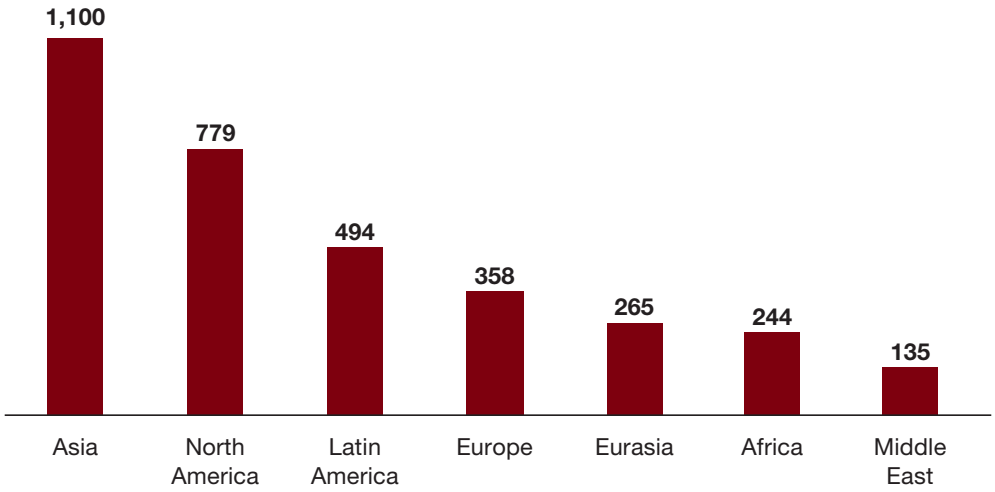
each year are caused by counterfeit pills

4 million tablets were confiscated in 2015

by German customs

Trade incidents

involving fake pharmaceuticals in 2015



Source: Annual press conference of the German Customs Administration, April 2016; Interpol, "The dangers of counterfeit medical products"; Sophic Capital, "A Simple Solution to Protect Consumers and Pharma Companies from Dangerous Fake Drugs," 2014; Lancet, "Rise in online pharmacies sees counterfeit drugs go global," 2015; PwC Strategy& analysis

billions of dollars every year to combat this growing threat to their bottom lines and public health. The Pharmaceutical Security Institute documented 971 customs seizures or police/health inspector raids of counterfeit drugs in 2015, a 34 percent increase over the previous year. Two years earlier, the U.S. Food and Drug Administration identified and shut down more than 13,000 websites run by illegal online pharmacies (*see Exhibit 3, next page*).

Nevertheless, pharmaceuticals industry leaders tend to underestimate the threat even as they acknowledge weaknesses in their defenses. In 2016, Strategy& surveyed executives from the pharmaceuticals industry and related organizations (*see "Survey methodology," page 23*). Executives interviewed by our team showed little appetite for new spending on anti-counterfeiting measures, in part because they've already spent so much to comply with new mandates such as the European Union's Falsified Medicines Directive (FMD).

This cost-centric view of supply chain security misses the opportunity created by a new generation of anti-counterfeiting technologies and related services that offer more than just stronger defenses against fake drugs. Companies that seize this opportunity will reduce harm to patients and ease the financial impact of counterfeiting. What's more, the new technologies hold promise for enhancing manufacturing efficiency and even boosting sales as customers discover that they can buy drugs safely on the Internet.

Exhibit 3
Online purchases of counterfeit drugs

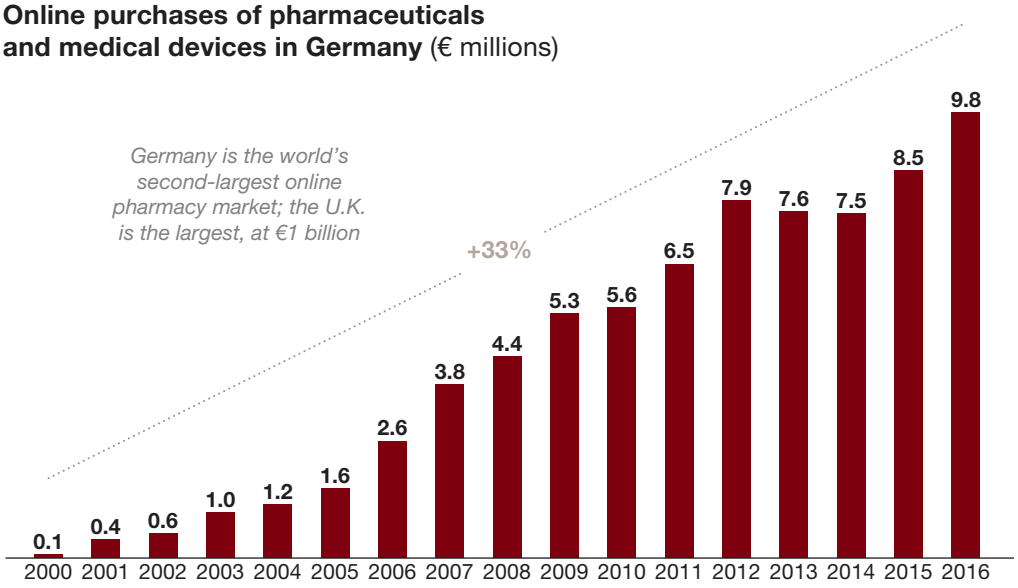
The World Health Organization estimates that **50% of the drugs for sale on the Internet are fake**

90% of drugs purchased online **come from a different country** than the website claims

Up to **50,000 online pharmacies** are in operation, about **95% of which don't comply with the laws** and industry standards created to protect patients

In 2013, the U.S. Food and Drug Administration identified and shut down more than **13,000 websites hosted by illegal online pharmacies**

Online purchases of pharmaceuticals and medical devices in Germany (€ millions)



Source: IfD Allensbach (ACTA 2015 and ACTA 2016); James Dudley newsletter, Jan. 2017; NetNames, "The risks of the online counterfeit economy," 2016, Access Rx 2013

An unaffordable vulnerability

Counterfeit pharmaceuticals exact a devastating human toll. Some 1 million people die annually after taking fake drugs, according to WHO estimates. Some are killed outright by counterfeits containing toxic ingredients such as rat poison or floor wax. In one well-publicized case from 2008, adulterated heparin from China killed hundreds in the U.S. and elsewhere.

Even when fake drugs don't kill people, they can cause serious harm. Some 25 percent of physicians who responded to a survey conducted in the United Kingdom in 2009 said they have treated patients suffering adverse effects from a drug purchased on the Internet, a primary conduit for counterfeit drugs in developed countries. And buyers continue to risk receiving drugs that can be damaging.

Just as harmful are bogus remedies that do nothing. Many contain few or no active ingredients, allowing patients to suffer and sometimes die from preventable or curable illnesses. Malaria researchers estimate that some 450,000 people die of the disease every year after taking ineffective counterfeit pills.

Less tragic but equally real are the financial consequences of counterfeiting. Along with suffering about €188 billion annually in lost sales, drugmakers are spending big money on marginally effective anti-counterfeiting measures. Eli Lilly, for example, recently spent more than US$100 million on a new system to thwart reproductions of big-name remedies such as Cialis, Cymbalta, and Zyprexa.

Sales lost to fraudsters and money spent to combat them pinch profits, leaving less to invest in new drugs and increasing the pressure on companies to cut back in other areas — including head count.

Harder to quantify is the reputational cost. Yet there's no denying that counterfeiting damages a company's brands. When a pill masquerading as one of your products hurts — or fails to help — a patient, guess who takes the blame. Not the unknown counterfeiter. Customers rarely realize they've taken a fake drug. But they remember the name on the bottle: yours.

An inadequate response

Increasing public awareness of drug counterfeiting has spurred regulators around the world to action. Working with the industry, they're implementing stricter measures to protect pharmaceutical production and distribution systems. Unfortunately, the new rules leave some doors open, and rely on methods that counterfeiters already know how to subvert.

A new mandatory method called "mass serialization," often combined with "track-and-trace" requirements, is becoming the worldwide standard for regulators working to stem the tide of fake drugs (*see Exhibit 4, next page*). Although it is not an authentication method, mass serialization can be used to trace products.

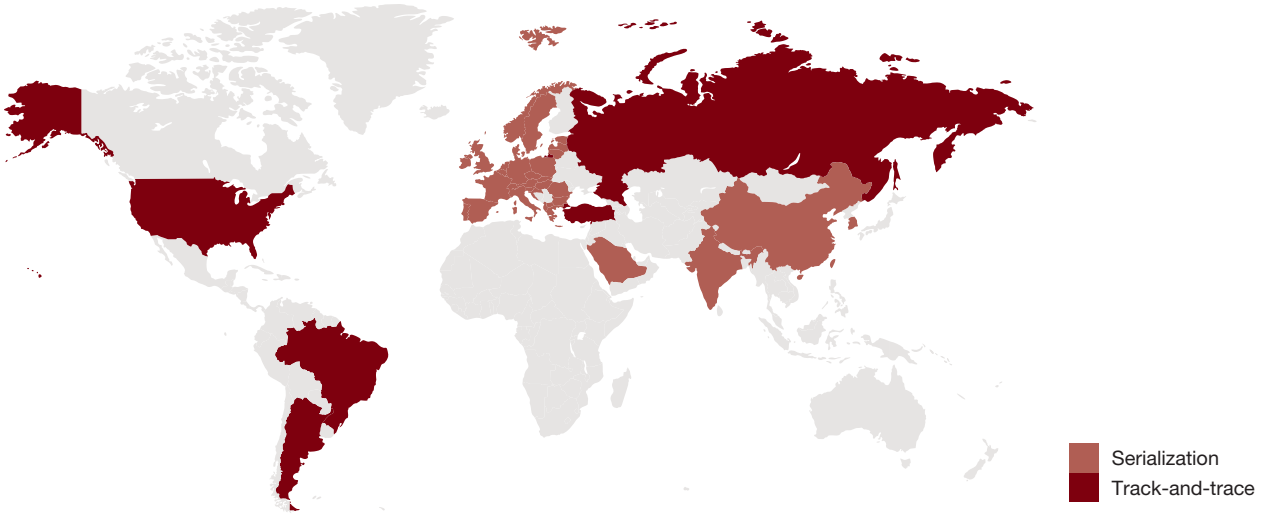
Mass serialization encodes each drug package with a unique identifier, usually a scannable barcode. Manufacturers can use linear, two-dimensional, or radio frequency identification (RFID) coding. As each package comes off the production line, its identifying code is entered into an online database. With track-and-trace technologies such as handheld scanners, drug containers can be monitored and checked against the database at each point in the value chain, from manufacturer through wholesaler, repackager, and pharmacist. Unfortunately, weaknesses in the system leave the supply chain vulnerable to counterfeiters.

The E.U.'s Falsified Medicines Directive requires drug companies to adopt mass serialization and other anti-counterfeiting measures starting in 2019. Manufacturers operating in the E.U. will have to add unique identification numbers to the outer packaging of all prescription drugs, and equip containers with tamperproof seals.

To steer customers away from illegal online pharmacies that supply large amounts of fake drugs, the FMD requires authorized legal Internet pharmacies to display a logo identifying them as E.U.-approved drug retailers.

Exhibit 4

Mass serialization and track-and-trace around the world



Country	Deadline for implementation[1]	Type of protection
Argentina	In place	Track-and-trace
Brazil[2]	In place	Track-and-trace
China	December 2015	Serialization
E.U. & Switzerland	Enforcement begins in 2019	Serialization
India	In place	Serialization
Russia[3]	2019	Track-and-trace
Saudi Arabia	Expected in 2017	Serialization
South Korea	In place	Serialization
Turkey	In place	Track-and-trace
U.S.	Serialization by 2019, full track-and-trace by 2025	Track-and-trace

Notes: 1. For pharma industry; 2. Situation in Brazil unclear; 3. Regulatory requirements in Russia not yet clearly defined.

Source: "Pharmaceutical Serialization Track & Trace," Infosys, 2014; TraceLink

The directive also imposes tougher controls and inspection requirements for companies that make active pharmaceutical ingredients, and it strengthens record-keeping standards for drug wholesalers. Similar regulatory initiatives are under way in the United States and elsewhere.

However, both the technology and the regulatory controls are porous. Counterfeiters usually crack today's systems in two to three years, forcing companies to shell out regularly for expensive upgrades. Even at peak effectiveness, conventional mass serialization catches only 35 to 50 percent of fake drugs.

A glaring weak spot is the barcode attached to exterior drug packaging — boxes with blister packs of tablets, and bottles containing loose pills. This might allow a counterfeiter with a smartphone camera and access to production or distribution facilities to compromise codes on external containers. Counterfeiters could snap photos of legitimate, package-specific barcodes, and use the images to create forgeries. They could then slap the forged codes on packs of falsified drugs, and slip them into distribution channels with little chance of detection, provided the fakes arrive at dispensation points before legitimate products bearing identical codes. Counterfeiters typically move fast, improving the chances that fraudulent drugs will reach customers long before duplication is detected (which will happen when the genuine article generates a "second scan" error).

Compounding these technical shortcomings is the loose language of the FMD. Despite the good intentions of its drafters, the regulatory framework is a negotiated compromise between regulators and industry representatives. The give-and-take watered down stricter requirements that would have been costlier to implement. The FMD establishes broad mandates, delegating details and enforcement to individual E.U. member countries, which leaves room for variability that counterfeiters could exploit.

Most worrisome is the fact that provisions for implementing the directive at the wholesale level are still under discussion. Manufacturers are required to attach unique identifiers to product containers and enter the codes in a digital database, and pharmacists must scan each drug container, check its code against the database, and record the final sale online. But at intermediate distribution points, vague FMD language mandates only random container-level scanning. Comprehensive product tracing occurs only in limited cases, such as product returns. For most products, wholesalers and other middlemen record only batch numbers and expiration dates of pallets, as required by good distribution practice. This creates a potential opening for counterfeiters at the wholesale level.

Despite the good intentions of the Falsified Medicines Directive's drafters, the regulatory framework is a negotiated compromise between regulators and industry representatives.

A U.S. anti-counterfeiting protocol that also takes effect in 2019 has its own strengths and weaknesses. The Drug Quality and Security Act requires authentication at every supply chain juncture, including wholesalers. But like the FMD, it doesn't require product-level coding. And it lacks the E.U. directive's requirement of tamperproof packaging.

Then there are geographic shortcomings. Anti-counterfeiting regulations apply only in a single country or group of countries. The FMD, for example, governs drugs produced and distributed within the European Union. As a result, global drug manufacturers based in Europe shouldn't expect the FMD to deter counterfeiting of products they sell outside the European Union.

Complacency in the face of risk

To assess industry attitudes toward the counterfeiting threat, we interviewed 38 executives at companies or agencies in the pharmaceutical value chain, including manufacturers, wholesalers, hospitals, payors, and regulators. Our conversations revealed little enthusiasm for additional anti-counterfeiting measures, despite widespread awareness of significant vulnerabilities in current security systems (*see Exhibit 5, next page*).

A large majority of interviewees said they're satisfied with their companies' supply chain integrity protections. Only a few saw much need for major improvements in anti-counterfeiting technology.

This complacency seems at odds with executives' acknowledgment that today's security tools fall short in important areas. Many recognize that adding barcodes to exterior drug packages provides far less protection than encoding products at the blister pack or even pill level. Several also expressed frustration with the short shelf life of traditional anti-counterfeiting systems.

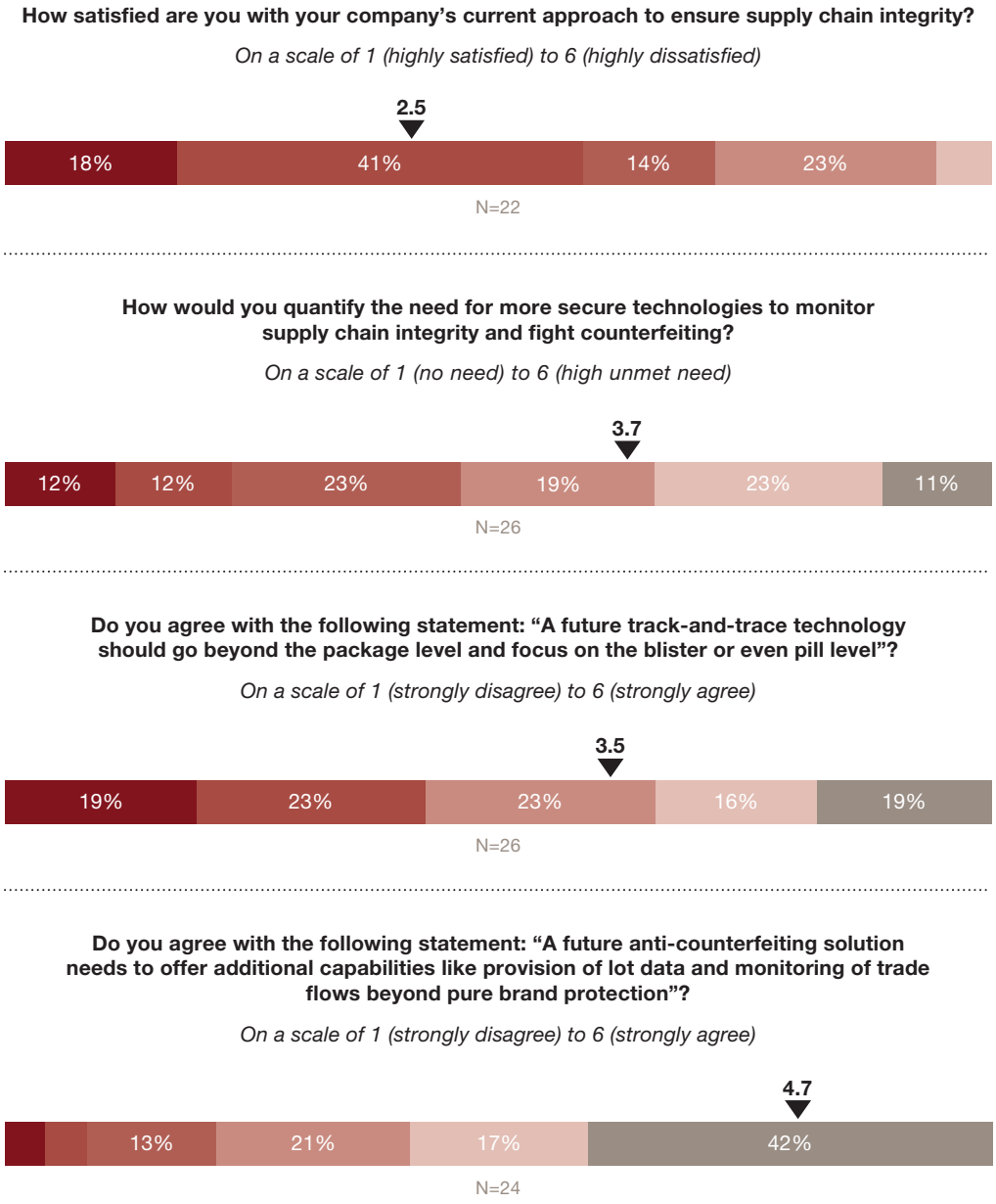
Their willingness to live with these flaws is understandable in light of the large sums many companies already have spent fighting fakes. FMD compliance alone has cost drugmakers an estimated €500 million, according to estimates from our survey. Additional measures would have to show significant cost-benefit value to attract support.

Another factor in the executives' indifference may be an incomplete understanding of the potential perils of counterfeiting. Though lost sales and security expenditures can be calculated with a degree of certainty, it's harder to quantify the damage to brands that are widely counterfeited.

Nevertheless, interviewees anticipated a range of benefits from next-generation anti-counterfeiting solutions. High on the list was data protection, a concern for almost all executives interviewed. Most also expressed a desire for systems that would provide information on downstream sales, "lot data," chemical contents, and other drug-related data.

Exhibit 5

How pharma executives view their anti-counterfeiting protection



Note: Entire group (N = 38) was asked every question, and some answers are not quantifiable.

Source: Strategy& analysis

Mobility was seen as a key benefit; smartphone-based anti-counterfeiting apps would help extend a company's security system to all players in its value chain. Some showed interest in purchasing comprehensive anti-counterfeiting services from an outside supplier that would provide everything from encryption materials to a data backbone.

Next-generation anti-counterfeiting

New technologies under development promise the enhanced anti-counterfeiting protections and higher risk/reward payoff that executives say they want. These systems are harder to crack, so they don't require frequent, costly overhauls. And they fill a critical gap by enabling companies to embed identifiers below secondary packaging. If regulatory obstacles can be removed, direct labeling of pills will be possible in some cases.

What's more, advanced anti-counterfeiting systems go beyond thwarting fake drugs to create value in other ways. The same capabilities that enhance detection of counterfeits also drive supply chain efficiencies. For example, new tracking technologies that follow high-value products through production and distribution — within applicable legal bounds — gather information that can be used to reduce costs in many areas.

- Recalls become less expensive and more efficient when the manufacturer knows exactly where to find all of the affected products.

- The availability of better insights into the amount, timing, and location of demand for various drugs makes it possible for manufacturers to forecast sales more accurately, manage production more efficiently, and avoid product shortages. Inventory costs decline by as much as 15 percent, freeing capital for other uses.

- The ability to effectively "lock" a supply chain for extremely costly products or controlled substances can help reduce expenditures for the special security measures these products currently require.

The new technologies can also yield opportunities on the revenue side, particularly by making it possible for manufacturers to generate more sales through digital channels, as improving security boosts customers' confidence in online pharmacies. Data flowing from tracking technologies can also enable a first-to-market manufacturer to differentiate itself in the marketplace, by offering customers valuable

data they can't get from suppliers as long as most of the industry is still using older anti-counterfeiting systems. Product codes can include much more than a unique serial number. They also can provide information on a drug's chemical makeup, side effects, and other characteristics important to a doctor or pharmacist.

Companies including Merck KGaA and Clariant are incorporating new technologies into end-to-end anti-counterfeiting solutions with differentiating capabilities such as monitoring of high-value product flows, creation of custom-tailored data sets, and automatic reporting of counterfeiting attempts. Merck KGaA's ecosystem comprises three primary elements.

The first element is a unique chemical marker, or taggant, that uses special nontoxic pigments to inscribe product identifiers on outer containers, primary packaging, and, in the future, pills themselves. Proven to be forgery-proof when used on valuable documents, the taggants are invisible to the human eye. They come with a virtually unlimited number of unique security codes, making them much harder to crack than conventional encryption tools. Taggants printed on the two-dimensional barcodes required by the E.U.'s FMD would provide an extra layer of security by preventing counterfeiters from photocopying the codes. However, adding taggants to pills or primary packaging would pose a challenge in regions where pharmacists are not allowed to open secondary packaging. In such cases, patients would have to authenticate their own drugs after opening the outer container.

Product codes can include much more than a unique serial number. They also can provide information on a drug's chemical makeup, side effects, and other characteristics.

The second component is hardware, in the form of handheld scanners that link information embedded in taggants to a database maintained in the cloud. Inexpensive and easy to use, these scanners distinguish fakes from genuine products within seconds.

Finally, Merck KGaA is working with an independent data administrator to create a cloud-based repository of supply chain data that allows users to track products from manufacturers through every distribution point. The database enables the design of individualized data templates for various entities in the value chain, supporting data analytics and real-time decision making.

The ecosystem that results is just one of the taggant-based anti-counterfeiting solutions under development. It entails a significant up-front investment. A single company may find it impractical to incur such expense to create an ecosystem solely for its own products. As more manufacturers buy into the new technology, however, costs for each participant will decline, and the system will grow more effective against counterfeiters. On the other hand, the competitive advantages of advanced anti-counterfeiting capabilities will diminish as more

companies become part of the ecosystem. Other covert authentication solutions, such as security inks or security printing, can be implemented more easily by a single company, but they are also easier to crack.

Drug companies won't necessarily have to build their own anti-counterfeiting ecosystems. Manufacturers can avoid the high up-front costs of developing an anti-counterfeiting system by handing off all or part of the work to external providers.

Outsourcing reduces development time and expense, fixed costs, and sourcing complexity. An outsourced track-and-trace system also shields manufacturers from potential liability for privacy violations by limiting the drug company's access to confidential patient information.

External providers may offer new anti-counterfeiting solutions under several potential business models. In some cases, pharmaceutical companies, depending on their strategic priorities and capabilities, might also develop similar anti-counterfeiting services of their own or acquire companies in the business. Possible business models range from materials supply relationships to brand protection and consulting services (*see Exhibit 6, next page*).

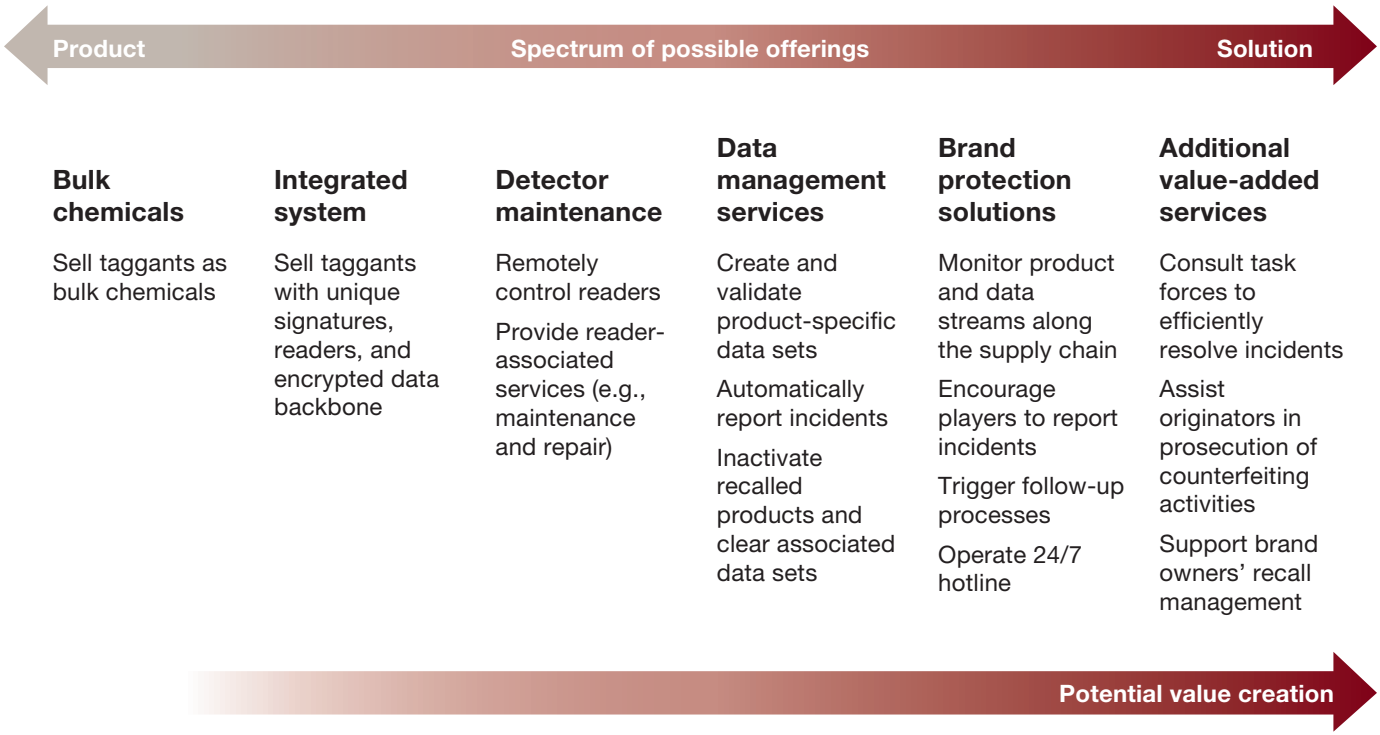
In the most basic model, a supplier would simply sell taggants as bulk chemicals to drug manufacturers. At the next level, a service provider might offer an integrated system including taggants and unique identifiers, scanners, and an encrypted data backbone. Repair and maintenance of scanners could be offered separately or as part of a service package.

A data services specialist would offer not only database management but also customized, validated data sets, flagging of recalled products, and automatic reporting of counterfeiting incidents. At the brand level, a service provider might monitor products along the value chain; encourage distributors, pharmacists, and others to report counterfeiting incidents; and staff a hotline for such reports. There's also room for a consulting model, with experts providing advice on preventing counterfeiting and on prosecution of counterfeiters by law enforcement authorities.

Manufacturers can avoid the high up-front costs of developing an anti-counterfeiting system by handing off all or part of the work to external providers.

Exhibit 6

External providers' offerings arising from next-generation anti-counterfeiting technologies



Source: Strategy& analysis

From threat to opportunity

Pharmaceutical companies underestimate both the threat posed by counterfeit drugs and the potential benefits of new technologies that do much more than block spurious products. Fake pills are pouring into markets around the world, as online pharmacies penetrate countries with well-defended physical distribution channels. Fraudsters easily sidestep many of the traditional snares laid down by industry and government, leaving a trail of suffering and death in their wake. The financial toll spirals upward as counterfeiters siphon off billions in sales from legitimate companies and inflict lasting reputational damage on major brands.

Yet pharmaceutical executives take a cost-centric view of counterfeiting. They acknowledge shortcomings of conventional anti-counterfeiting measures, while expressing satisfaction with their own systems. After absorbing significant costs to comply with regulatory directives such as the FMD, few are willing to take greater precautions and spend more on new technologies that would seal the cracks in their defenses.

The general indifference toward new anti-counterfeiting solutions represents an opportunity for companies with the foresight to invest in a broader vision of supply chain integrity. Today's technologies go beyond catching counterfeiters and mitigating losses. They also enable new capabilities that set a company apart in the marketplace, and set the stage for new business models that create value in many different ways. The opportunity won't go unnoticed for long.

Survey methodology

During March and April 2016, Strategy& interviewed 38 executives at organizations involved in the manufacture, distribution, or dispensing of prescription drugs. Interview subjects included 20 executives at pharmaceutical companies, six at wholesalers or pharmacies, four at hospitals, two at payors, and six regulatory officials. Participants held senior-level positions such as senior vice president of global manufacturing and supply, executive vice president of global product supply, senior director, head of global strategic marketing, chief operating officer, and company director.

All key functions were represented, including marketing and sales, supply, operations, quality, medical, and security. Geographically, the survey spanned Europe, the U.S., Africa, and China.

In structured 60-minute telephone interviews, we covered a range of issues relevant to anti-counterfeiting measures in the pharmaceuticals industry. Participants were asked a series of standard questions, augmented by questions tailored to the interests of each panel. The interviews elicited both qualitative and quantitative information.

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