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Sproxil: Saving Lives Through Technology and Social Enterprise

As he read the media reports on Sproxil's successful completion of the first phase of the company's work in Nigeria, Ashifi Gogo, founder and CEO of Sproxil, Inc., wondered if the achievement would be one of many for Sproxil or one of a kind. Sproxil now had a proven technology in place and Gogo had identified the regions he would like to enter with his technology. But he was still reviewing data on national markets to determine which markets to enter, as well as the right business model to use: a pure for-profit model or a social enterprise. Sproxil had started making revenue in 2010, but now Gogo had to find sources of commercial investment to build the Sproxil brand and keep it sustainable.

Later that afternoon Alden Zecha, Sproxil chief financial officer and strategist, discussed with Gogo an analysis of their expansion strategy and various options for structuring the Sproxil business model.

A memo from Zecha had identified three categories of customers for Sproxil:

- **Patients:** The company could protect consumers in developing nations from counterfeit medicines. Consumers could receive purchase support via a call center as part of Sproxil's service.
- **Pharmaceutical manufacturers:** Sproxil delivered value to these customers by taking counterfeits out of the marketplace. The counterfeit medicines were costing these businesses billions of dollars in sales. Sproxil was also able to act as a data source for manufacturers and generate a better understanding of the value of their products in the marketplace.
- **Government and law enforcement authorities:** Sproxil provided this set of customers with an additional set of tools and intelligence reports to enable them to find and prosecute counterfeiters as well as those who helped counterfeiters in a timely way.

Sproxil's Mobile Product Authentication MPA[™] was an information intensive product. First, the population had to be taught why it should use the product. Then it had to be taught how to use the product, as well as how the service would enable them to reduce the number of counterfeits in their communities. This process would include information dissemination to consumers on: (1) Sproxil's easy anti-counterfeit solution, using any mobile phone; (2) using the solution only involved scratching, texting, and receiving a response; and (3) if the response indicated the medicine was "fake," how to contact Sproxil or the government to take action. In 2010, the company used posters, fliers, and waybills to disseminate these messages.

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©2013 William Davidson Institute. This case was developed under the supervision of Dr. Prashant Yadav, William Davidson Institute Senior Research Fellow & Director of Health Care Research Initiative, by Research Associate Mary Lowe of the William Davidson Institute. This case was created to be a basis for class discussion rather than to illustrate either the effective or ineffective handling of a situation.

The expansion strategy required Gogo to decide how Sproxil would market MPA. He asked himself: Should the company spend the money to market the product through television, radio, and social media channels? If Sproxil spends on these marketing activities, how will it generate a profit on the product? Should the company work with government regulators and law enforcement agencies to deliver the message? Gogo also thought about the best business model structure to penetrate markets in the regions he identified: Should Sproxil exist as a non-profit organization? Should Sproxil have a purely for-profit model? Or, should Sproxil combine the benefits of a for-profit model with social impact using a social enterprise model?

The Problem of Counterfeit Medicine -

Counterfeit pharmaceuticals were a major threat to the health of populations in developing countries. Counterfeit medicines had become a \$200 billion a year industry by 2010. The World Trade Organization estimated that fake anti-malarial drugs killed 100,000 Africans a year and the black market cost governments around 2.5% to 5% in revenues.¹ One British think tank, the International Policy Network, blamed fake drugs for approximately 700,000 deaths worldwide from malaria and tuberculosis. In regions where regulatory and enforcement environments were weak or ineffective, counterfeiting was rampant. Spurious/falsely-labeled/falsified/counterfeit (SFFC) pharmaceutical cases in the developing world were attributed to several factors, including: ineffective registration of medicines; a large private health sector that was insufficiently regulated; weak law enforcement; a shortage or erratic supply of medicine; ineffective cooperation among stakeholders; high levels of corruption; and inadequate education on health issues. (See Exhibit 1 for distribution chain details and Exhibit 2 for weaknesses in the distribution chain.)

Many of the counterfeit drugs were often not registered, while governments lacked appropriate levels of resources to enforce regulations. Governments often faced challenges when collaborating across multiple countries to address problems with counterfeit medications. Law enforcement capacity was weak, and the general public lacked information surrounding the issue of counterfeit drugs. There were, however, exceptions where there were large consumer awareness efforts, typically in response to unfortunate national incidents where SFFC or substandard products had harmed several people, for example, in Nigeria where the "fake drugs kill" message had become widely known after several such incidents.

SFFC pharmaceuticals are medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source. SFFC medicines may include: products with the correct ingredients or with the wrong ingredients; without active ingredients; with insufficient or too much active ingredient; or with fake packaging. All kinds of medicines—from treatments for life-threatening illnesses to inexpensive generic versions of painkillers and antihistamines—were impacted. While regulatory authorities in developed countries had the resources to carry out their anti-counterfeiting duties reasonably well, their counterparts in developing countries often lacked the technical skills and financial capacity to take action. The populations in these countries were overexposed to the risks that counterfeit medicines posed. (See **Exhibit 3** for additional information on the counterfeit problem.)

The problem was especially troubling in Nigeria. According to Director General of the National Agency for Food and Drug Administration and Control (NAFDAC, Nigeria's FDA) Paul Orhii, Nigeria had the largest market of counterfeit drugs in the developing world.² Orhii's predecessor, Dora Akunyili, faced backlash from counterfeiters, who frequently reacted to law enforcement much like cocaine or heroin dealers, after she restricted pharmaceutical imports to two NAFDAC staffed airports and two seaports also staffed by NAFDAC. In 2002, counterfeiters made an attempt on Akunyili's life as she and her family drove down a rural road in Nigeria, shooting at and shattering the back windscreen of the car, piercing Akunyili's head scarf, and grazing her scalp. During Akunyili's tenure at NAFDAC, the enforcement agency also banned a list of 19 Indian and

Chinese companies that had been indicted for manufacturing counterfeit pharmaceuticals, and sent analysts to India and China to recertify any drugs manufactured in the countries prior to entering Nigeria. In Nigeria, NAFDAC executed 800 raids on drug-distribution outlets and 90 destruction exercises for counterfeit and substandard medicines.³

Up to 48% of drugs in Nigeria reportedly were fake or substandard in 2004.4 Borders were porous and corruption in the healthcare sector was rife—drugs were routinely "leaked" from public facilities into the private market. According to the International Property Rights Index 2012, Nigeria ranked 98th out of 130 countries.5 Counterfeit pharmaceuticals were often tainted with highway paint, floor wax, boric acid, and other combinations of toxic and even fatal chemicals. In 2009, 84 infants in Nigeria lost their lives due to kidney failure after using a teething syrup containing chemicals commonly found in antifreeze.6 Groups that may have engaged in traditional drug trafficking entered the prescription drug market—a low-risk/high-reward venture—manufacturing pills for pennies with significantly less risk of exposure to prosecution. When consumers walked into a pharmacy in Nigeria, they largely had no easy way of finding out whether the medicines they purchased were real or fake. The drugs were made and packaged to appear identical to the actual products. Testing the products to determine authenticity was a very time consuming and costly process for manufacturers, and consumers were at risk of exposure to fakes in a system where law enforcement authorities lacked the appropriate resources to catch and prosecute counterfeiters. (See Exhibit 4 for a crime summary.)

The Genesis of Sproxil -

In 2005, Ashifi Gogo was pursuing a PhD in Engineering at Dartmouth College. Gogo was interested in seeing his work make a strong social impact, and he decided that the way to make that impact was to explore entrepreneurial options. "The best way to carry ideas out of the classroom and into the market to see impact is to do it yourself," he told himself. Working with a colleague during his graduate work at Dartmouth, Gogo began his entrepreneurial work with a start-up providing verification technology to the US market in the form of 2D bar codes for organics, with little success. Consumers in the sector already trusted the markets where they purchased their organics to verify the authenticity of the products. The colleagues then began looking at ways to adapt their product verification model to SFFC medicines in the developing world. In addition to 2D bar codes, they explored using radio frequency identification (RFID), but the technology had high infrastructure requirements and was cost prohibitive. They settled on building a solution based on an existing social practice commonly used by local populations: purchasing cell phone minutes on very popular "pay-as-you-go" service plans. The popular existing social practice involved revealing a unique single-use code hidden under a scratch layer and messaging it with a cell phone to get airtime credits.

In 2009, Gogo struck out on his own, forming Sproxil. He planned on taking his SMS MPA technology to market first in Nigeria, and then modifying and scaling his model to meet the needs of consumers, manufacturers, and regulators in other regions of West Africa, East Africa, and India. MPA allowed product verification at the end-user level and linked legitimate manufacturers directly to consumers. MPA worked through an easy-to-use, scratch-off tag with a unique product code identifier, which was attached to a medicine bottle or blister pack for pennies per unit. Consumers scratched off the coating on the label to reveal the code, and then sent the code via SMS text for free to Sproxil's phone number. They instantly received back a text message alerting them as to whether the product was genuine or potentially counterfeit (Exhibit 5). Important and useful market data was gathered and provided to legitimate manufacturers, who could monitor both purchasing trends and suspicious activity through Sproxil's proprietary Web portal. Authorized employees of these companies could see where drug hot spots were in real time by tracking the counterfeit drug incident reports in a geographic region over time. The technology replaced ineffective and inefficient

random sampling methods, and allowed manufacturers to not only track counterfeit pharmaceuticals, but also administer product recalls quickly and cheaply. MPA could be applied to any tangible goods, so there also was the potential for donors to Sproxil and others to leverage the MPA solution to provide assurance that mosquito nets and other life-saving items were reaching intended populations, among other applications.

"By looking at the existing trust relationship between manufacturer and purchaser, we've designed a solution that allows greater trust to be built in regions that inherently have low levels of trust in many commercial transactions," Gogo said.⁷

Sproxil's Competitors -

Sproxil had three main competitors in the regions and markets it was seeking to penetrate. The competitor business models were non-profit and for-profit. None of the competitors had used a social enterprise business model. Sproxil's competitors were:

Kezzler

Founded in 2001, Oslo, Norway-based Kezzler was a privately owned company that sold code generation engines to brand owners for their internal serialization needs. The Kezzler business model evolved over time to include consumer facing authentication using SMS, and provided this service in partnership with a local firm in Kenya.

Like Sproxil, Kezzler provided consumer verification and track and trace software solutions via the cloud.8 Kezzler offered consumers the ability to verify their products prior to purchase by sending an SMS, mobile phone app, or using the Internet. Hundreds of millions of products ranging from over-the-counter medicines to high value oncology drugs had been serialized with the Kezzler system worldwide. When the products and SKUs either reached or left a "touch point," the location and time was recorded and stored.9 The company operated in Europe, the Americas, Asia, and Africa.10 Kezzler had the advantage of operating much longer than Sproxil, and specifically in pharmaceutical brand verification since 2005. The company also was inside the regions it served using local sales representatives to find partners at local companies to distribute its solution.

PharmaSecure

PharmaSecure was a Lebanon, New Hampshire-based company that was founded in 2007. PharmaSecure provided drug authentication technologies and software to pharmaceutical manufacturers and consumers in emerging markets. It was a rapidly growing company with operations in the US, Europe, India, Africa, and Southeast Asia. PharmaSecure's core products and solutions included:

- **Integrated serialization systems:** Hardware integration services that printed unique codes directly onto drug packages for regulatory or authentication purposes.
- **Mobile authentication:** The company's mobile authentication technology allowed consumers to verify if their medicines were genuine or fake by mobile phone.
- **Customized market data:** PharmaSecure provided its partners with real-time and historical visualizations of consumer needs and opportunities to address these needs.
- **Customized intuitive software and hardware solutions:** These were user-driven solutions to support marketing decisions and secure partner supply chains.¹¹

PharmaSecure provided a cheaper solution than Sproxil by eliminating the scratch-off component. The company paid only for the ink. Sproxil paid for both the ink self-adhesive and scratch-off coating. PharmaSecure had taken its business model to India, however, many consumers there had stopped using the solution due to new regulatory guidelines. Under the guidelines, companies were required to print the 2D bar codes on the product.

mPedigree

Launched in 2007, mPedigree was a non-profit initiative based in Accra, Ghana, that had partnered with leading telecom operators, pharmaceutical industry associations, and technology provider Hewlett Packard to empower African consumers to receive safe, effective medicines. Since 2007, beginning with the West African country of Ghana, the mPedigree program strived to establish an "Electronic Resource System" for Africa's under-resourced health sector. The non-profit organization's leaders were also exploring ways to take the initiative to the Indian sub-continent and East Asia. MPedigree sought to build an electronic resource system to boost transparency in the marketplace, as well as efficiency in the regulatory process. It acted to facilitate the promotion of common standards and regional economies of scale for the manufacturers and marketers of medicines.¹²

The initiative acted as an information resource, emphasizing to consumers the importance of querying the origin of their medicines to establish whether they were genuine or potentially dangerous imitations through basic text messaging, using mPedigree's mobile phone platform. To cultivate a sound marketplace for medicines, mPedigree sought partnerships with drug manufacturers, marketers, pharmacists, and regulators.

Sproxil's Business Model -

Sproxil's Mobile Product Authentication™ (MPA™) solution enabled consumers to verify a drug's authenticity. Sproxil provided specially encrypted scratch-off labeling to pharmaceutical manufacturers that attached the labels to each package. When consumers purchased the medicines they used a scratch card, similar to those used to replenish cellular talk time, to reveal a one-time-use code. They then sent the code via SMS to a free number that was identical on all cellular networks within a country. Sproxil's servers sent a message to the consumer immediately, indicating whether the drug was real or fake. If the product's identity could not be authenticated (it was fake) consumers were provided with a hotline number via text message to call and report the suspicious medication. The message to the consumer confirming the product's identity in some cases also included advice on how to take the product and other useful information. Sproxil charged the pharmaceutical manufacturer for the labeling/encryption technology, call center services, and the encrypted scratch-off labels. Sproxil also offered value-added services such as Stolen Product Investigator®, a service that helps legitimate brand owners identify pharmacies selling stolen products with the help of vigilant consumers.

Operational and Cost Structure

Sproxil's process of identifying counterfeit medicines included the following costs:

- A scratch panel that was attached to the pharmaceutical product at 10 cents or less per unit
- Built-in SMS service for 1 cent to 2 cents per message. The service allowed users to text the
 medicine's 12-digit code to Sproxil, and receive a text message back verifying whether the
 medicine was real or fake. Consumers sent text messages for free.

Call center employees. The cost for an agent for eight hours a day, five days a week, was
approximately \$1,000/month; and 24/7 coverage for one seat, seven days a week, would
be approximately \$3,000-\$5,000. (At least four agents at this cost per day were required to
maintain 24/7 coverage, but call center operators could provide discounts on fees as the number
of agents increased)

As Gogo went about deciding which regions to enter and how to modify, adapt, and scale his business model specific to the point of entry, he looked at the data by region. (See **Exhibit 6** for potential sources for this information.)

What next? Expansion, Scale-up, and Revenue Models for Sproxil

Gogo had a great deal of data to review. He knew that he wanted to take his MPA technology to market in West Africa, East Africa, and India, but he was not sure which region he should enter first. The capital requirements for the venture were relatively high. Gogo would have to generate revenues and attract commercial investment to sustain and build his organization. He asked himself which regions he should enter first. He then questioned himself as to which business model would be the most appropriate—non-profit, for-profit, or social enterprise? He also asked himself how he would adapt and scale the business model once he had entered a region?

Exhibits

Exhibit 1 The Drug Distribution Chain

The pharmaceutical supply chain was complex. Medicines were made from ingredients sourced from different countries. Final formulations were then exported, and packaging, re-packaging, and sale could happen in many other countries. Drugs changed hands many times between the manufacturer and patient; every transaction was an opportunity for falsified and substandard products to infiltrate the market. Drug quality around the world could be improved with changes to the drug distribution system.

The systems differed markedly between developed and developing countries, however. A few, large firms controlled the manufacture and wholesale drug markets in developed countries, where most patients obtained medicines from licensed pharmacies or dispensaries. In low- and middle-income countries, multiple parallel distribution systems of varying efficiency ran in the same country. It was also difficult and expensive to transport medicines over poor roads to remote villages, as supply chain managers in poor countries did.

The first step on the drug distribution chain was the wholesale market. There were two kinds of drug wholesalers: primary wholesalers, who had written distribution contracts with manufacturers and bought directly from them, and secondary wholesalers, who bought from other intermediaries. Both kinds of wholesalers bought and sold medicines to accommodate market demand. When they saw a medicine was scarce in one region, they could buy the same medicine from other wholesalers. The markets were constantly fluctuating; products changed hands many times. Wholesalers many times repackaged products repeatedly, and in the repackaging, fake products could gain authentic labels.

In the US, thousands of secondary wholesalers could trade medicines, causing drug shortages and exploiting them for profit. Limiting the secondary wholesale market to vetted firms would improve US drug supply. The National Association of Boards of Pharmacy (NABP) wholesaler accreditation process required criminal background checks on senior staff and proof of professional standards in record keeping and drug storage and handling. Some states required NABP accreditation of wholesalers, but unscrupulous businesses could seek out states with lower standards to set up operations. And, because the wholesale trade was national, weaknesses in one state's system could become vulnerabilities in another.

Source: Institute of Medicine: Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products. Board on Global Health.

Exhibit 2 Weaknesses in the Drug Distribution Chain

- A few national firms controlled most of the primary wholesale market in rich countries. In developing countries hundreds, sometimes thousands, of firms controlled tiny shares of the primary market.
- Drug distribution chains in developing countries were often fragmented and complicated.
- The final leg of the drug distribution chain was exceptionally expensive and inefficient in developing countries.

Figure 1 describes the drug distribution chain in developed countries, where most patients get medicine from a doctor's office, or a licensed pharmacy or dispensary. For example, in the US about three-quarters of all pharmaceuticals were bought in retail pharmacies, about half of which were national chains or food stores with an internal pharmacy. These vendors handled a wide variety of products sold in an even wider variety of packaging. Retailers in developed countries would find it logistically impossible to buy their stock, in its many different packages, directly from manufacturers. Most vendors consequently bought their inventory from pre-wholesalers and wholesalers.

Supplier(s)

Manufacturer

Wholesale Distributor
(Primary)

Repackager

Wholesale Distributor
(Secondary)

Figure 1
The Drug Distribution Chain in Developed Countries

Source: Institute of Medicine: Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products. Board on Global Health. National Academy Press.

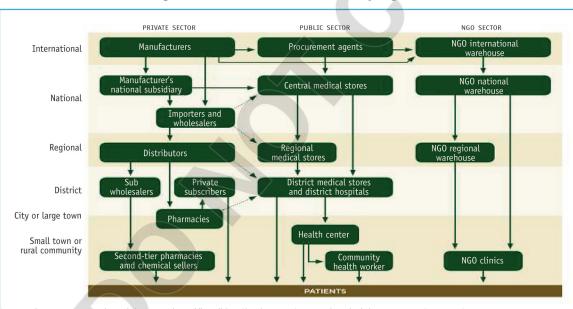


Figure 2
The Drug Distribution Chain in Developing Countries

Source: Yadav, P., H. L. Tata, and M. Babaley. 2011. The World's Medicines Situation 2011: Storage and supply chain management. Geneva: WHO.

Exhibit 3 The Counterfeit Problem

International trade and manufacturing systems obscured connections between the crime and the criminal; in modern supply chains, medicines could change hands many times in many countries before reaching a patient. To complicate the problem, medicines were mostly for sick people. The effects of inactive, even toxic, drugs often went unnoticed or were mistaken for the natural course of the underlying disease. This was most true in parts of the world with weak pharmacovigilance systems, poor clinical record keeping, and high all-cause mortality, where friends or relatives of those who died were saddened, but not shocked.

Deaths from fake drugs went largely uncounted. The toll of the excess morbidity as well as wasted time and money mounted. The illegal manufacture and trade of fake pharmaceuticals were impossible to measure precisely. Even crude copies could blend in with legitimate products in the market. The camouflage succeeded because drug quality was not something consumers could accurately judge. This imbalance, also called information asymmetry, made the medicines trade vulnerable to market failure. At every step of the supply chain there was unequal knowledge.

Market controls and oversight aimed to correct the information imbalance in the medicines market, but supervising sprawling multinational distribution chains was a regulatory nightmare. National drug regulatory agencies were responsible for assuring drug quality, a job that increasingly required cooperation with counterpart agencies around the world. The World Health Organization had worked to facilitate such cooperation since 1985, but advancing the public discourse on this topic had proven more difficult than anyone would have predicted.

Source: Institute of Medicine: Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products. Board on Global Health.

Exhibit 4 The Crime

Making fake medicine was not difficult. The least sophisticated operations managed with empty capsules bought in the open market or a hand-held pill press and any powder. Production costs on fake drugs were low. And, because the licit and illicit supply chains mixed in unregulated markets, the odds of getting away with the crime were good. The global burden of falsified and substandard medicines was borne disproportionately by low- and middle-income countries. There was wide evidence that criminals frequently targeted inexpensive anti-infective medicines, mostly because they were bought often and by the largest segment of the population. The United Nations Office on Drugs and Crime described making falsified medicines as "opportunistic crime, emerging where regulatory capacity is low, not where profits would be highest."

Source: Institute of Medicine: Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products. Board on Global Health.

Exhibit 5 How to Use Sproxil's System







Source: Sproxit.com

Exhibit 6 Relevant Information Sources

Population and Economic Characteristics	World Bank http://www.worldbank.org/
	West Africa Club Secretariat http://www.westafricagateway.org/topic/demographic-trends
	 UNOWA http://www.humansecuritygateway.com/documents/UNOWA_Urbanization InsecurityWestAfrica.pdf
	Economic Community of Western States (Ecowas) http://www.ecowas.int/
	African Economic Outlook http://www.africaneconomicoutlook.org/
	India Online www.indiaonlinepages.com/population/india-current-population.html
	• Export.gov http://export.gov/india/eg_in_028850.asp
	CIA factbook https://www.cia.gov/library/publications/the-world-factbook/
Counterfeit Pharmaceutical Information	• WHO http://www.who.int/en/
	 International policy Network http://www.policynetwork.net/
	 International Property Rights Index http://www.internationalpropertyrightsindex.org/
	 Center for Medicine and the Public Trust http://www.cmpi.org/
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Counterfeit Pharmaceutical Information	All Africa http://allafrica.com/
continued	AfricanLiberty.org. http://www.africanliberty.org/content/counterfeit-drugs-kill-over-700000-people-every-year-new-report
	The Independent http://www.independent.co.uk/news/world/africa/tainted-teething-syrup-kills-84-babies-in-nigeria-1570715.html
	• 60 Minutes, CBS News www.cbsnews.com/video/watch/?id=7359537n
	WDIMichigan http://www.youtube.com/watch?v=6oxStlI6H-0
	United Nations Office on Drugs and Crime http://www.unodc.org/documents/data-and-analysis/Studies/West_Africa_ Report_2009.pdf
Regulatory Environment	All Africa http://allafrica.com/stories/201207180698.html
	United Nations Office on Drugs and Crime http://www.unodc.org/ NAFDAC
	www.nafdac.gov.ng/ West African Regulatory Authority Network (WADRAN healthmarketinnovations.org/
	India Today http://indiatoday.intoday.in/story/government-cracks-down-on-fake-drugs-menace-in-india/1/201183.html
Cell Phone Use	International Telecommunications Union http://www.itu.int/en/Pages/default.aspx
	CIA Factbook https://www.cia.gov/library/publications/the-world-factbook/ rankorder/2151rank.html
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