

TWO GLOBAL FORCES ARE DRIVING INNOVATIONS IN HEALTH TECHNOLOGY

How Digital Technologies are Assisting the Healthcare and Pharmaceutical Industries in Meeting the Challenges of Drug Counterfeiting and the COVID-19 Pandemic

Introduction

Two powerful global forces are accelerating the demand for digital health technologies, and the U. S. healthcare and pharmaceutical industries and related resources are working creatively to meet that demand. The counterfeit drug problem has led to a crisis in drug safety and cost, while the COVID-19 pandemic has created a crisis in hospital operations and unprecedented challenges in healthcare delivery. Together, they have produced a fertile environment for technological innovation, and visionary start-ups as well as established enterprises are actively investing in a wide range of digital health solutions to meet current as well as future needs.

The Global Problem of Counterfeit Pharmaceuticals

We live and work in challenging times, by any standard. In addition to its nearly infinite benefits, the Internet has enabled a rise in fraud at warp speed. Fake consumer packaged goods and counterfeit pharmaceuticals anchor the list of crimes made easier and more profitable through our global connectivity.

Counterfeit goods and pharmaceuticals wreak havoc on national economies, creating extraordinary waste as well as endangering lives. The World Health Organization estimates that counterfeiting costs the global pharmaceutical industry \$75 billion annually.¹ Other recent statistics are equally sobering:

- Counterfeit goods cost the United States between \$29 billion and \$41 billion annually.² A 2017 report by the Commission on the Theft of American Intellectual Property indicates that China, including Hong Kong, accounts for 87 percent of counterfeit goods seized entering the U.S.
- Globally, the problem of counterfeit goods exploded between 2005 and 2016, surging from \$200 billion to \$509 billion in a 154 percent increase, as reported by the Organization for Economic Cooperation and Development.³
- Between 2014 and 2018, known incidents of pharmaceutical counterfeiting and related crimes increased by 102 percent, based on Pharmaceutical Security Institute data.⁴
- Expansion of the counterfeit goods trade to include pharmaceutical products resulted in €16.5 billion in lost sales and lost employment within the European Union, as reported by the European Union Intellectual Property Office in 2019.⁵

Clearly, the problem of counterfeit goods and counterfeit pharmaceuticals is costly, global, and growing. Against this backdrop, the pharmaceutical industry is under pressure from government agencies, health insurers, and consumers to provide greater drug safety, transparency, and accountability.

Contributing to the Scope of the Counterfeit Drug Problem

The flow of foreign counterfeit drugs into the American market increasingly puts patient health at risk, especially as pharmaceutical manufacturers continue to relocate and maintain operations offshore. Multinational pharmaceutical firms must demonstrate that they are meeting U.S. quality standards, are adhering to applicable foreign regulations, and are stepping up to address the patient benefit and drug safety challenges associated with counterfeit medications and medical devices.

In addition, under-regulated wholesalers, repackagers and other third parties involved in the manufacture and transportation of pharmaceuticals are contributing to the rise in counterfeiting, according to Pfizer Global Security.

A report on pharmaceutical counterfeiting compiled by the Fraser Institute identifies the problem succinctly, stating that counterfeiters have no shame, no boundaries, and no limits.⁶ Accordingly, all types of medicines are faked: branded drugs, generic drugs, over-the-counter drugs, and herbal remedies. These counterfeits may contain no active ingredient, harmful ingredients, the wrong drug, the wrong concentration, the wrong dose, or drugs past their expiration dates.⁶ Any one of these may put patients at risk for treatment failure, harmful side effects, and dangerous drug interactions.

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Profit and Cost Factors

There are many reasons why counterfeiting pharmaceuticals has become a lucrative trade on a global scale. Cost and profit are significant factors, from the high cost of many prescription drugs, to the high profitability of their counterfeits. The complex maze of regulations across countries, and the often substantial cost disparities among countries, also play a role. Add to these factors the ease of transporting drugs, and the low risk of detection once they enter the mainstream drug supply, and the collective obstacles are daunting. Counterfeits are also costly in numerous ways, from squandered healthcare resources and increased patient risk to increased costs for government regulatory and enforcement agencies, pharmaceutical firms and distributors⁷, all of which translate to increased costs to the consumer.

For these reasons, it has become imperative that pharmaceutical companies be able to trace every legitimate drug, medication and device throughout the supply chain—which may be multinational or global—from manufacturing, to storage and distribution, to sale and consumption. In addition, seasonal influenza epidemics and pandemics such as COVID-19 demand precise tracking of vaccination delivery mechanisms from manufacture to injection.

This is an enormous challenge that requires a holistic, real-time system for detecting and reporting existing and potential quality problems at every point in the supply chain. At present, very few companies in the pharmaceutical industry have effectively connected all of the dots in order to create a comprehensive and secure tracking and feedback system.

The Impact of the COVID-19 Pandemic on Healthcare

A second powerful force reshaping healthcare today is the COVID-19 pandemic. In 2020 this force created a crisis in hospital operations and unprecedented challenges in healthcare delivery, and a profound reluctance on the part of individuals to seek any but the most crucial healthcare services and support. In the U.S. alone, as of July 8, 2020, more than

131,000 deaths had been attributed to the pandemic, and as of May 28, 2020, unemployment had peaked at 40 million, representing two of the most concerning results of the pandemic.⁸

In counterpoint, the pandemic has also affected a variety of industries and businesses in positive ways that reasonably can be expected to continue post-pandemic. As an example, patient access to healthcare has become increasingly virtual. Telehealth has gained momentum and is recognized as a logical first step in the diagnosis and treatment of certain health issues, ranging from the common cold and allergies to mild household accidents and sports injuries.

Patient access continues to be the focal point around which healthcare and pharmaceutical innovations are evolving during this historic period. One area particularly ripe for innovation is clinical operations, which are uniquely challenged by the obstacles to live patient access. While decentralized clinical trials have gained traction in recent years, the pandemic is accelerating the move toward and experiments with fully virtual clinical trials. This new reality will drive pharmaceutical companies to adopt innovative information gathering methodologies that will supplement and enhance the knowledge gained from traditional clinical trials.

Patient access continues to be the focal point for healthcare and pharmaceutical innovations

The same issues of patient adherence and engagement exist in virtual trials as well, and will need to be addressed creatively but equally effectively as in the more traditional trials. Re-imagining clinical trials is a step every drug company will want to take in order to succeed in the post-pandemic environment.

Fortunately, proven technologies are available to assist pharmaceutical firms in their initiatives to effectively address the dual challenges of drug counterfeiting and the COVID-19 pandemic. In both cases, digital technologies represent a burgeoning trend in the healthcare industry, powered by ubiquitous smartphones, mobile applications and wireless internet connectivity.

Focus on Health Information Technology

Biotechnology and medical innovations have been evolving at accelerating speed to create a wide range of improvements in drug safety and authenticity, healthcare delivery, and overall patient benefit.

According to an investor survey by KPMG in late 2019, health information technology—including pharma, biotech, medical and diagnostic tools—was ranked as the top subsector of investment interest for 2020.⁹

Addressing the Counterfeit Drug Problem

An article in the U.S. National Library of Medicine at the National Institutes of Health points out that drug counterfeiting creates not only a health concern around the potential for counterfeit drugs to result in negative outcomes and mortality, but also a manufacturing concern related to brand protection and intellectual property rights enforcement for pharmaceutical companies.¹⁰

These concerns have led to new uses of technologies in combatting the counterfeiting problem, from barcodes and 2D datamatrix codes to radio frequency identification (RFID) and near-field communication. By enabling instantaneous remote authentication, these scan-and-send systems make it much more difficult for counterfeits to enter the supply chain.¹⁰ Other

technologies that may be useful in reducing counterfeiting include holograms, embedded images, digital watermarks, chemical and biological tags, and track-and-trace technologies.¹¹

Multifaceted interventions are considered by some to be the most effective strategy in reducing drug counterfeiting.^{11,12} A multilayered approach may leverage a combination of legal action against illicit traders, consumer education, private investigations, cooperation with enforcement agencies, and technological countermeasures.¹¹

The Promise of NFC Technology

Among the health information technologies available to address the rampant counterfeit drug problem, wireless near-field communication (NFC) technology is poised to transform the pharmaceutical industry¹³ and its entire supply chain. NFC tags can be read by smartphones or other NFC-enabled devices at any point in the supply chain, with data automatically sent to a secure data platform. A noteworthy distinction between RFID and NFC technology, which evolved from RFID, is that NFC devices can act as both tags and readers,¹⁴ rendering them two-way communication devices and thereby making them more effective in intelligently tracking pharmaceutical products.

The U.S. Food and Drug Administration, as part of its effort to improve the safety and security of the nation's drug supply, is encouraging pharmaceutical companies to use electronic technology, such as near-field communication, to tag product packaging.¹⁵ Placing more responsibility on the private sector is not a surprising strategy, and may also be an effective one, given that the FDA is able to screen fewer than one percent of drug products that are distributed through the nation's domestic mail system,¹⁵ for example.

Start-up tech firm Knecto is creatively using near-field communication technology, in combination with a patented data platform, to enable pharmaceutical companies to track products and capture data from manufacture, packaging and distribution through purchase and consumption. The Knecto data platform integrates with legacy enterprise resource planning programs to connect all of the ecosystems, creating an agile, holistic solution that effectively enables drug authentication. This technology can play a significant role in addressing the dual concerns around health and manufacturing by reducing drug counterfeiting and protecting brand reputation.

Wireless near-field communication technology is poised to transform the pharmaceutical industry

Transforming Patient Care

Technological innovations that have been transforming the delivery of patient care in recent years include electronic patient portals, mobile health applications, wearable biosensors, and home-based systems that can collect and transmit patient-specific health data.¹⁶ These and similar electronic solutions are helpful in enabling patients to self-manage their care from the convenience of their own homes, and are fueling the shift toward patient-centric healthcare. That shift, in turn, is creating consumers who are better informed, more concerned about drug and device safety, and more likely to take an active role in their own healthcare as well as in any physician-prescribed treatment plan.

However, while it has been a growing trend in hospitals and other healthcare facilities for several years, digital health technology is fairly new to at-home patient use. This timing may not be accidental. Millennials now comprise the largest generation in the U.S., having overtaken the Baby Boom generation in 2019; they are tethered to smartphones and mobile

applications and are expected to eagerly adopt new smartphone-enabled healthcare technologies.

Helping to lead the move to digital healthcare, in 2011 the Centers for Medicare & Medicaid Services renamed the Meaningful Use requirement to Promoting Interoperability with the intent of shifting emphasis from electronic health records (essentially a completed project) toward increasing the exchange of health information and facilitating patient access to data.¹⁷ This federal initiative demonstrates to hospitals and other healthcare organizations the importance of empowering patients to manage their own healthcare by providing them with easier access to their health data. This initiative relies heavily on use of digital technologies, a trend that is not going away.

With these and other factors at work, digital technology has also begun to transform the pharmaceutical industry. Rather than general health applications, pharma is focusing on creating disease-specific digital health technologies and innovations, as well as diagnostic applications.¹⁸

Surge in Collaborative Alliances

In addition, leveraging the full range of its constituents, from agile start-ups to firmly established global enterprises, the pharmaceutical industry has witnessed a surge in collaborative alliances. Following are several examples of collaborations that are advancing digital technology in healthcare and pharmaceuticals:

- Sanofi / Happify Health collaboration to design an application to help multiple sclerosis patients manage depression through digital therapeutics.¹⁹
- Eli Lilly collaboration with HealthVoyager to develop an application that allows physicians to create “a personalized and immersive educational experience” for patients with inflammatory bowel disease.²⁰
- UCB collaboration with PatientsLikeMe.com, the world’s largest personalized health network, to improve their website’s ability to educate epilepsy patients on seizure and medication adherence.²¹
- Otsuka Pharmaceutical and Proteus collaborated for further development and commercialization of Proteus’ ingestible sensor pill platform including Abilify MyCite (sensor embedded pill).²² In January 2020, Otsuka acquired full license for Proteus’ mental health treatment adherence technology.²³
- Otsuka and Click Therapeutics collaborated to develop and commercialize a prescription therapeutic treatment for major depressive disorder to address unmet medical needs among this patient population and to improve outcomes.²⁴
- Johnson & Johnson, collaborating with Apple, launched a study to determine whether the Heartline Study application with Apple Watch can help reduce the risk of stroke as well as improve health outcomes through early detection of atrial fibrillation with the ECG and Heartline applications. The application-based approach allows participants to engage in the study remotely rather than at a clinical site.²⁵
- Roche acquired Flatiron Health, a healthcare technology company with a cancer electronic health records platform. The platform captures and normalizes both structured and unstructured oncology data from diverse source systems and addresses how to improve/optimize clinical trial results.^{26,27}

The Value of Direct Patient Feedback

In addition to these and other collaborative alliances that are advancing digital healthcare in innumerable ways, the U.S. Department of Veterans Affairs has developed an integrated web-based application that not only processes adverse reaction reports automatically but also submits them directly to the FDA MedWatch program. One of the advantages of the VA Adverse Drug Event Reporting System is in providing a single portal submission for all VA facilities, which makes it far easier to collect adverse effect information. In turn, this increases the probability of detecting clinically significant adverse effects,²⁸ helps to identify trends in adverse effects, and enables officials to report them sooner to consumers.

Similarly, a small technology start-up, Knecto, has developed an integrated, single-source solution that enables virtual clinical trials and enhances patient engagement by creating a robust two-way electronic communication between patient and provider. Using their smartphones, patients can provide real-time feedback during the trial by simply tapping their devices near their pre-encoded medication. The interaction literally takes seconds, does not interfere with the trial, and is comfortable and easy for smartphone users, who numbered 3.2 billion worldwide in 2019.²⁹ Companies can readily obtain new, real-world evidentiary data that speaks to daily patient compliance, adherence, and drug safety surveillance. With its strong focus on patient benefit,³⁰ Knecto's digital technology can deliver direct, ongoing feedback from patients related to drug efficacy, side effects and ease of use as well as patient suggestions for product improvement.

Digital Healthcare Rising to Meet Pandemic Challenges

During the COVID-19 pandemic, healthcare providers are challenged to maintain patient-centered care while minimizing the risk of contracting the virus through exposure in healthcare facilities. Digital technology can be particularly useful in helping to manage chronic disease states as well as COVID-19 cases. Consider the following scenarios.

In an article published in *Neurological Science* in April 2020, researchers discuss the challenge of caring for multiple sclerosis (MS) patients, a vulnerable subpopulation, during this pandemic and suggest that digital healthcare technology can play a significant role by enabling triage and assessment surveillance to be conducted remotely. Implementing digital triage and assessment for MS patients can reduce unnecessary visits to treatment centers, maintain patient-centered care for those who live far from treatment centers, and limit the spread of the virus.³¹ The same benefits could apply to patients with various other chronic diseases.

Digital technology can also deliver significant advantages in caring for patients who have contracted COVID-19. According to the Centers for Disease Control and Prevention, patients diagnosed with mild symptoms or discharged early from hospital care can be managed at home and routinely monitored remotely. This enhances patient benefit by reducing exposure to reinfection and returning the patient to a more personally comfortable environment.

At the Sheba Medical Center in Israel, patients are managed in isolated units, with digital health monitors placed under their mattresses. The devices measure patient heart rate, respiratory rate, and physical motion, enabling healthcare providers to observe patients from a remote location in real time and to be alerted if any

Digital technology has enabled the rise of telehealth as a resource for individuals who require occasional treatment

major health events occur.³² Patient benefit is maintained through continuous monitoring while, concurrently, healthcare provider exposure to the virus is substantially reduced.

Growth in Telehealth Solutions

On a broader scale, digital technology has enabled the rise of telehealth as a resource for individuals who require occasional treatment for ailments ranging from the common cold and allergies to minor household accidents and sports injuries, as several examples. Firms such as American Well, MDLive, Doctor on Demand, SnapMD and TeleDoc have been offering telehealth services for several years,³³ including remote diagnoses, proscribed treatments and therapies, and prescriptions for medications. The remote or virtual nature of these services has enhanced their appeal during the coronavirus outbreak.

The use of video in telehealth is a burgeoning trend in facilitating more effective live consultations. Video tools such as Skype or Zoom are being used by many doctors' offices during the current pandemic. In addition, the Amazon Care telehealth application enables employees to connect to physicians or nurse practitioners through a choice of live chat or video, with the option for in-person follow-up services.³⁴

Similarly, the U.S. Department of Veterans Affairs several years ago developed applications, such as VA Video Connect³⁵ and Image Viewing Solution, in order to bring telehealth directly to veterans and ease some of the pressure on its medical centers.

Healthcare providers, health systems, and first responders have been encouraged by the Centers for Disease Control and Prevention to take advantage of the benefits offered by telehealth tools in order to direct patients to the proper level of care.³⁶ In other cases, some health insurers are encouraging patients to utilize telehealth by reducing or waiving co-payment requirements or offering free downloads.

Recent changes in telehealth regulations have enabled freer expansion of digital health services to rural areas, providing better coverage for patients in underserved communities. Pharmacies like Walgreens have been expanding their services to include mobile applications and websites that help patients understand COVID-19 and their risks for contracting the virus—without ever having to leave home or enter a store.

Advances in digital health and the use of Bluetooth, a wireless technology for exchanging data over short distances, have allowed individuals who are not infected with the virus to track their recent interactions and obtain real-time updates infected populations in the U.S. For example, Google's recently released GPS Mobility Reports document anonymous reports of civilian movements and behaviors related to COVID-19.³⁷

Other trends in digital healthcare include mobile health and fitness applications for smartphones, and personal health tracking devices

Additional Trends in Digital Healthcare

Other trends in digital healthcare include the development of mobile health and fitness applications downloadable to smartphones; the development of websites to track individual health progress and facilitate online support communities; and the increasing use of personal health tracking devices such as Apple Watch, Google Fitbit, blood glucose sensors such as Dexcom that offer mobile apps enabling patients to send their data directly to doctors, and wireless blood pressure monitors such as MOCACuff.

Artificial Intelligence (AI) is on the forefront of healthcare advances and is being used to monitor hospital visitors and patients to protect

staff, to monitor patient health conditions, and most recently to monitor and treat COVID patients.³² AI is being used to improve clinical trials by making them more efficient and less expensive³⁸ as well as to support clinical decisions, predictive analytics, and chronic disease management. AI-based diagnostics are also in development, such as IDx-DR, an AI algorithm that analyzes images of the eye taken with a retinal camera.³⁹

Digital healthcare is also being reinforced with technologies like 5G, which can transmit large volumes of data at much greater speeds than 4G⁴⁰ and can even accommodate remote surgery or telesurgery.⁴¹ 3D printing is proving useful in printing medical supplies during the current pandemic as well as structures for isolating infected patients.³² And blockchain technology, which by design is resistant to the modification of vital data once recorded and hence highly secure, is being employed to improve interoperability and the availability and integrity of healthcare information. As two examples of its innovative uses, IBM Watson Health partnered with the FDA to research the use of health data transfers from personal healthcare wearables and other devices⁴¹, and a global-scale control and communication system called MiPasa powers rapid, more precise early detection of COVID-19 carriers and infection hotspots by feeding big data on infection routes and occurrences to AI processors. Blockchain enables MiPasa to ensure the privacy of health records and location data of its users without the need for government surveillance.⁴²

In due course, it is anticipated that the U.S. healthcare and pharmaceutical industries will be able to effectively leverage and further enhance the various innovative digital health technologies that are being developed to improve healthcare throughout the pandemic.

These innovations do not come without cost, however. And although the healthcare industry historically has been slow to adopt new healthcare technologies, the digital health market is expected to reach \$206 billion this year.³⁹ Aside from the costs associated with the research, development, and deployment of digital health technologies, there are several other challenges in play as these innovations evolve.

Although the healthcare industry has been slow to adopt new technologies, the digital health market is expected to reach \$206 billion in 2020

Challenges Facing Digital Healthcare

One of the challenges facing the ongoing development and deployment of digital health technologies involves the protection of personal health information (PHI) and other HIPAA compliance requirements. Privacy and communication regulations may require review and updating to reflect new techniques for the transfer and storage of health data digitally or in the cloud.

In addition, the current consent to use patient data likely does not include all possible future uses of the data⁴³ and may require frequent updating. Further, absent stringent security measures, digital technologies may increase the vulnerability of data to cyberattacks, database hacks, and ransomware.⁴³

The sheer scope of digital health technology innovations may demand new cost structures and payment plans. Services called into use for any given case could include video, text, email, mobile apps, and personal healthcare wearable devices, for example. In addition, health insurers may be reluctant to justify coverage and patients could be reluctant to justify payments, if significantly higher.

Still other challenges might arise from WiFi and network connectivity issues, and the potential difficulty of obtaining regulatory approvals of specific individual monitoring devices.

As with most technological advances, the real and potential benefits to be derived from innovations in digital healthcare will, no doubt, ultimately outweigh the challenges to widespread adoption.

Conclusion

Two of the most powerful global forces in healthcare and pharmaceuticals today are drug counterfeiting and the COVID-19 pandemic, both of which have cost nations and businesses around the world hundreds of billions of dollars. Innovations in health information technology, particularly in digital health technology, continue to be developed to address and mitigate these forces. They range from electronic patient portals to mobile health applications, from wearable healthcare devices to 3D printing, from unique uses of near-field communication and RFID technologies to artificial intelligence. These and other exciting innovations in the healthcare and pharmaceuticals industries are being further advanced by evolving federal policies as well as numerous strategic alliances among established leaders and technology start-ups.

All of these factors have set the stage for a paradigm shift in the provisioning of patient healthcare going forward, and in the delivery of legitimate pharmaceuticals through the supply chain to the patient. Characterized by the complementary objectives of patient benefit and drug safety, the environment for technological innovation in healthcare has rarely been more fertile, nor the opportunities more abundant for those with the vision to understand and pursue them.

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