A Hard Pill to Swallow: Privacy Implications of Direct-to-Consumer Prescription Drug Services

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PRIVACY IMPLICATIONS OF
DIRECT-TO-CONSUMER PRESCRIPTION
DRUG SERVICES

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ABSTRACT

This case note discusses the emergence and popularity of direct-to-consumer prescription drug services and evaluates their privacy implications on consumers. Minimal regulation exists regarding direct-to-consumer prescription drug services, and patient privacy and data protection laws are also limited. Proponents of these services claim that they allow certain prescription drugs to be available to consumers without the hassle and logistics of health insurance and making and attending medical appointments, effectively empowering individuals to take control of their own health. Alternatively, critics claim that direct-to-consumer prescription drug services are operated by private companies that are not always required to be compliant with patient health privacy and laws, creating the potential for disastrous effects on sensitive health information. This case note evaluates the popularity of these services, analyzes how the way direct-to-consumer prescription drug services are marketed may have an impact on consumer privacy, current and pending litigation surrounding data breaches and privacy issues, and their overarching implications on patient and consumer privacy.

I. INTRODUCTION

Until recently, standard medical practices for patients seeking prescription drugs had largely remained unchanged for several decades. Generally, consumers seeking access to prescription drugs typically were only allotted one choice—to make an appointment to see their physician, explain their ailment, and pick up a prescription from a pharmacy. The COVID-19 pandemic created a demand for an influx of telemedicine services, including the rise of telehealth appointments for both physical and mental health issues, and also caused a significant increase in direct-to-consumer prescription drug services.1

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1. Yasmin Gagne & Burt Helm, Buying prescription drugs online is easier than ever. But there are side effects, FAST COMPANY (Nov. 19, 2019), https://www.fastcompany.com/90396205/buying-prescription-drugs-online-is-easier-than-ever-but-there-are-side-effects [https://perma.cc/W55D-K95L]; Kristen V. Brown
These prescription drug services allow individuals to answer their health-related questions, submit photos or speak to a medical professional over a video conferencing platform, and get prescribed certain prescription drugs without leaving the comfort of their own homes, and in many cases, without having to worry about or even use health insurance. While these services are defined by their ease and general availability of a wide variety of prescriptions, their business model also poses significant concerns for patients and consumers.

II. THE MECHANICS BEHIND DIRECT-TO-CONSUMER PRESCRIPTION DRUG SERVICES

Consumers seeking to use direct-to-consumer prescription drug services have a wide selection of companies to choose from. Several popular companies provide these services, with Hims and Hers Health perhaps being the most notable. These companies provide a diverse range of products from cosmetic-leaning products such as acne medication, and anti-aging cream, to mental health medication, including a variety of generic versions of several anxiety and depression drugs, all the way to Schedule II controlled substances, which are substances with a high potential for abuse such as those meant to treat attention deficit hyperactivity disorder (ADHD). Prescription drugs relating to reproductive health, including medicine for sexually transmitted diseases and contraceptives, have also been increasingly available for consumers to seek through these direct-to-consumer prescription drug services.

Dubbed as a form of “restaurant-menu medicine” by clinicians in the medical field, direct-to-consumer prescription drug companies offer consumers a wide array of remedies for a significant range of afflictions. In the majority of cases, consumers seeking to use direct-to-consumer prescription drug

2. Gagne & Helm, supra note 1.
3. See generally id.
4. See id.
5. Id.
7. Gagne & Helm, supra note 1.
8. Id.
services simply need to create an account on the website of the company they choose, answer a variety of questions pertaining to their health history, and either upload photographs of their condition or schedule a brief appointment to speak with a telehealth provider. These telehealth providers include board-certified physicians, psychiatrists, nurses, and physician’s assistants. After their consultation, the majority of direct-to-consumer prescription drug companies will prescribe the product, as long as the patient qualifies for the drug used to treat their ailment, or instead recommend that the patient see another doctor in person.

This business model has proven to be highly lucrative and popular. Hims and Hers Health, a large direct-to-consumer prescription drug company, boasted over 1.3 million subscribers as of June 2023. In fact, Hims and Hers Health saw a seventy-four percent increase in their user base in just the past year alone, popularity that is quickly being replicated by other direct-to-consumer prescription drug companies through both their business models and prescription drug offerings.

A. Positive Implications of Direct-To-Consumer Prescription Drug Services

Advocates of direct-to-consumer prescription drug services assert that these services empower consumers to take their health into their own hands, thwarting and “bypassing” the doctor’s office that exists in conjunction with health care administration in a typical medical setting. Additionally, proponents of direct-to-consumer prescription drug services assert that it allows individuals without health insurance, as well as underinsured individuals, to gain access to prescription drugs that may be deeply beneficial or even life-altering, at a discounted rate. Moreover, advocates of direct-to-consumer prescription drug services tout that these services promote ease, “flexibility,” and
convenience, as consumers do not have to worry about the logistical stress of scheduling a doctor’s appointment, verifying with insurance that they would be covered, and physically picking up prescriptions from the pharmacy.16

III. PATIENT PRIVACY PROTECTIONS RELATING TO PRESCRIPTION DRUGS


In-person healthcare visits are protected by the Health Insurance Portability and Accountability Act (“HIPAA”).17 Passed by Congress in 1996, HIPAA helps to protect patient data by creating and enforcing “national standards” to safeguard “sensitive patient health information from being disclosed without the patient’s consent or knowledge.”18

At the start of the COVID-19 pandemic, the Department of Health and Human Services (“HHS”) expanded HIPAA’s reach to include a variety of telehealth services.19 As defined by HHS, a “health care provider” is considered a covered entity “if it transmits any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard.”20 As a result, “all services that a covered health care provider . . . believes can be provided through telehealth” were covered under and subject to HIPAA.21 This expansion and “flexibility” of HIPAA resulted in the expansion of telehealth services, with the U.S. healthcare market being projected to increase an “80% year-over-year growth in 2020.”22

16. Id.
18. Id.
20. Id.
21. Id.
B. Minimal Regulation Surrounding the Direct-to-Consumer Prescription Drug Business Model

There is minimal legislation and regulation pertaining to the business model adopted by many direct-to-consumer prescription drug companies. In fact, a majority of direct-to-consumer prescription drug platforms “claim to be neither medical providers, pharmaceutical companies, nor online pharmacies,” and, therefore, do not fall into a specific regulated industry like many other medical companies or services do. Additionally, many of the drugs prescribed through direct-to-consumer prescription drug companies are prescribed for off-label use, meaning they are not approved by the United States Food and Drug Administration (“FDA”) to treat the specific condition or ailment that consumers typically want the drug for. This gap in regulation has the potential to create misuse among consumers and may pose significant safety hazards if consumers mistake dosage or administration. Many physicians also question whether the screening process that direct-to-consumer prescription drug companies undertake is sufficient to ensure patient safety.

Moreover, patients’ right to privacy varies drastically based on where they live. While some states have stringent protections on patient and consumer privacy, many states are considered to have a “void within U.S. privacy law with respect to the protection of health information.” Additionally, the federal government has imposed limited restrictions or regulations on the activities of direct-to-consumer prescription drug services because they do not typically fall under a specific regulated industry.

24. Id. at 164.
25. Id.
26. See id. at 167.
27. See id. at 191, 197.
30. Id.
31. See Bitzer, supra note 23, at 164.
C. Leaking of Private and Sensitive Health Information and Other Negative Implications of Direct-to-Consumer Prescription Drug Services

Because direct-to-consumer prescription drug services often advertise their platforms on social media and also utilize social media and marketing analytics services, direct-to-consumer prescription drug companies may generally be at a greater risk for data breaches and leaks of sensitive patient information, including the “impermissible disclosure of personal and health information to third parties.”32 These third parties can include large social media and technology companies including Google and Facebook.33

The majority of health-related data breaches that have occurred over the past several years are the result of hacking or other related IT incidents, while the loss or theft of medical records has declined in recent years.34 As private direct-to-consumer prescription drug companies continue to develop and expand, an increasing number of patients and consumers could grow victim to hacking, theft, or other nefarious incidents relating to their sensitive health information.35

D. Privacy Challenges to Reproductive Health

Direct-to-consumer prescription drug services that sell or infringe upon client data also have the potential to cause disastrous effects for consumers in states that have stringent legal restrictions on reproductive rights.36 Consumers living in states that have banned access to certain types of reproductive care, such as abortion, are not eligible to order drugs such as mifepristone, a commonly prescribed abortion pill.37 However, consumers living in states that have more lax restrictions on abortions have the option to receive prescription

33. See id.
34. Id.
35. See generally id. (citing the “increasing digitalization of healthcare data” as one reason for the steady uptick of HIPAA breaches).
37. See Ashley Lopez, Prescribing abortion pills online or mailing them in Texas can now land you in jail, NPR (Dec. 6, 2021, 1:42 PM), https://www.npr.org/sections/health-shots/2021/12/06/1060160624/prescribing-abortion-pills-online-or-mailing-them-in-texas-can-now-land-you-in-j [https://perma.cc/8QN8-RQ9R].
medication such as mifepristone.\textsuperscript{38} As such, these restrictions, coupled with issues related to sensitive health data and privacy, have potential challenges concerning criminal liability for either obtaining or aiding in abortion that some states have implemented.\textsuperscript{39}

Because this topic is a sensitive, ever-evolving area of the law that varies by jurisdiction, the leak of confidential health information relating to reproductive care could cause significant ripple effects in the future on reproductive rights as a whole.\textsuperscript{40}

\section*{IV. PRIVACY IMPLICATIONS, LAWSUITS, AND DATA BREACHES THAT HAVE ARISEN DUE TO DIRECT-TO-CONSUMER PRESCRIPTION DRUG SERVICES}

\subsection*{A. The Use of Social Media and Influencers to Target Younger Consumers}

Many direct-to-consumer prescription drug companies advertise and promote their services through social media.\textsuperscript{41} TikTok, Meta Group (including the Instagram and Facebook platforms), and X (formerly known as Twitter) make up the bulk of platforms on which direct-to-consumer prescription drug companies advertise their services.\textsuperscript{42} In addition to content and posts that advertise their services, many direct-to-consumer prescription drug services employ social media influencers to advertise their products, which has the potential to target and influence younger consumers.\textsuperscript{43} Additionally, the use of influencer

\begin{itemize}
  \item \textsuperscript{38} See Eleanor Klibanoff, \textit{Abortion Drug Remains Approved, with restrictions, appeals court rules}, \textit{Texas Tribune} (Apr. 13, 2023, 10:00 AM), https://www.texas-tribune.org/2023/04/13/texas-fda-abortion-drugs/ [https://perma.cc/KEH4-25X6].
  \item \textsuperscript{39} See generally Lopez, supra note 37 (“Texas already has the most restrictive abortion laws in the U.S.—and they got tougher on Dec. 1. That’s when a new law went into effect that adds penalties of jail time and a fine up to $10,000 for anyone who prescribes pills for medication abortions via telehealth and the mail.”).
  \item \textsuperscript{40} See generally id.
  \item \textsuperscript{43} See Marshall, supra note 42.
\end{itemize}
marketing has the potential to dilute the gravity of safeguarding personal and sensitive health data because younger consumers may misunderstand, dismiss, or undervalue the importance of their personal information, rendering them more susceptible to breaches of privacy.\textsuperscript{44}

Referred to as “digital natives,” younger consumers, including “Gen Z,” are already more likely to have a substantially increased internet and social media presence than their millennial, Gen X, or Baby Boomer counterparts.\textsuperscript{45} As a result, a great deal of individuals in Gen Z, many of whom are still in their teenage years, are likely “to curate their online selves,” including personal information relating to their day-to-day lives.\textsuperscript{46} This, in conjunction with younger individuals being more likely to utilize direct-to-consumer prescription drug services, puts consumers with lower digital and health literacy at a higher risk of falling victim to data breaches or other privacy risks related to their sensitive health information.\textsuperscript{47}

**B. The Promotion of Direct-to-Consumer Prescription Drug Services by Medical Professionals**

Additionally, several medical professionals, including board-certified physicians have also promoted direct-to-consumer prescription drug services on social media apps, most notably on TikTok.\textsuperscript{48} Advertising to tens of millions of followers, many of whom are under the age of eighteen, TikTok amplifies the voices of physicians and allows them to monetize their brand partnerships with direct-to-consumer prescription drug companies.\textsuperscript{49} A significant portion of the products advertised on TikTok include beauty products, and physicians also advertise forms of skin care products and apparatuses through “brand deals and endorsements.”\textsuperscript{50}

\textsuperscript{44} See id.


\textsuperscript{46} Id.

\textsuperscript{47} Marshall, supra note 42.


\textsuperscript{49} KC Ifeanyi, Your doctor has a side hustle on TikTok as an influencer, FAST COMPANY (Mar. 31, 2022), https://www.fastcompany.com/90735760/your-doctor-is-moonlighting-on-tiktok-as-an-influencer [https://perma.cc/K3U5-GEYG].

\textsuperscript{50} See id.; see also Kelly Kovak, Marketing Beauty Products Might Be Tiktok’s Superpower, BEAUTY MATTER (Sept. 11, 2022), https://beautymatter.com/articles/tik-toks-superpower-might-be-marketing-beauty-products [https://perma.cc/UVH6-WTL9].
For example, Dr. J. Mack Slaughter, a board-certified emergency room physician in Texas who has over half a million followers on TikTok, partnered with Curology, a direct-to-consumer skin care company that specializes in prescription serums and creams to combat acne and promoted its product to his follower base.51 Similarly, Dr. Muneeb Shah, a board-certified dermatologist in North Carolina with a staggering 18.2 million TikTok followers,52 and Dr. Lindsey Zubritsky, a board-certified dermatologist in Mississippi who has over one million followers on TikTok, have both accepted sponsorships from and advertise Apostrophe, which is a direct-to-consumer skin care company that sells prescription acne and anti-aging creams.53

While consumers must be eighteen years or older to contract with direct-to-consumer prescription drug companies, young adults who have grown up fully immersed in the digital age of social media often lack appropriate social media literacy, particularly pertaining to privacy.54 In fact, many individuals in Gen Z prefer TikTok to Google as a search engine,55 making them more susceptible to falling for online misinformation, and by extension, privacy issues.56 As a result, many of these individuals grow up inundated with advertisements from board-certified medical professionals that normalize prescription anti-aging and beauty products on social media apps and will often flock to direct-to-consumer prescription drug services when they come of age.57


53. Dr. Lindsey Zubritsky (@Dermguru), #ad What does a derm really think about @hi_apostrophe?, TikTok (Feb. 01, 2023), https://www.tiktok.com/@dermguru/video/719518280569023854 [https://perma.cc/H5N7-R7AA].

54. See Marshall, supra note 42.


56. See generally Jennifer Neda John, Why Generation Z falls for online misinformation, MIT TECH. REV. (June 30, 2021), https://www.technologyreview.com/2021/06/30/1026338/gen-z-online-misinformation/ [https://perma.cc/2EAF-CSA4] (“I’ve found that young people are more likely to believe and pass on misinformation if they feel a sense of common identity with the person who shared it in the first place.”).

Direct-to-consumer prescription drug companies employing board-certified physicians who are wildly popular social media influencers creates a false sense of security amongst consumers.\textsuperscript{58} Moreover, this practice dilutes the historically stringent privacy rights available for patients receiving health care services because many of these services do not have the traditional safeguards required by medical offices and some are not required to be HIPAA compliant.\textsuperscript{59}

\textbf{V. LITIGATION SURROUNDING PRIVACY BREACHES INVOLVING DIRECT-TO-CONSUMER PRESCRIPTION DRUG COMPANIES}

\textbf{A. Current and Pending Litigation}

Recently, many direct-to-consumer prescription drug companies have found themselves involved with lawsuits pertaining to data breaches.\textsuperscript{60} In an effort to shield their clients from litigation ranging from individual plaintiffs bringing claims to class action lawsuits, law firms are advising their healthcare clients to be increasingly cognizant of data protection and third-party management relating to healthcare information.\textsuperscript{61}

Wisp, a direct-to-consumer prescription drug company that provides sexual and reproductive health services, was listed as the defendant in a class-action lawsuit for allegedly sharing “personal, sensitive health data” with third parties without the “knowledge or consent” of patients.\textsuperscript{62} The class action lawsuit alleges that Wisp “collected, tracked, and shared sensitive personal information, including personal reproductive and sexual health data, of its online health platform users with third parties” and “failed to comply with its users’ reasonable expectations of privacy,” thereby breaking California privacy laws.\textsuperscript{63} Individuals whose claims are approved may be entitled to up to one thousand dollars in damages.\textsuperscript{64}

\textsuperscript{58} See Ifeanyi, supra note 49.


\textsuperscript{61} Id.


\textsuperscript{63} Id.

\textsuperscript{64} Id.
Similarly, a 2023 lawsuit filed in the Southern District of California alleges that Hims and Hers Health is in violation of the California Invasion of Privacy Act for “sharing and data-mining online chat transcripts.” The lawsuit alleges that Hims and Hers Health “(1) secretly wiretaps the private conversations of anyone who communicates through the chat feature at www.forhims.com; and (2) allows at least one-third party to eavesdrop on such communications in real-time and during transmission to harvest data for financial gain.”

Additionally, Nurx, a direct-to-consumer prescription drug company that specializes in acne and anti-aging treatments as well as contraception and mental health services, recently discovered that it had been involved in a data breach where patients’ sensitive health information was leaked. Nurx claimed that it uses an “online information tracking pixel” that inadvertently provided protected health information to “the third parties providing the technology, including Google, Meta, and TikTok” within the time span of over a year. The type of data that was collected included the name, contact information and medical information of patients, as well as their IP addresses and page views. Individuals affected by Nurx’s data breach may have the opportunity to receive legal remedies for a potential violation of their rights.

With the “line between patients and consumers” becoming increasingly “fuzzy,” common themes between these lawsuits include data breaches, inappropriate sharing of patient health data, and the dissemination of patient health data to third-party vendors providing unrelated services. The aforementioned lawsuits and data breaches make up only a small fraction of the potential harm that may result from private and sensitive health data being leaked to and by private companies.

Many of these companies, including Hims and Hers, are not required to be HIPAA compliant in the same way as traditional medical providers because

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68. Id.

69. Id.

70. Id.

71. Zuppello, supra note 42.

72. See generally Murray-Watson, supra note 32 (providing regularly updated healthcare data breach statistics).
they are not considered a “covered entity” under the Act. As direct-to-consumer prescription drug companies continue to expand, gain more customers, or expand into different types of prescription drugs, instances of data breaches, security incidents, or the inadvertent disclosure of sensitive health information of patients may increase.

B. California Privacy Laws

Notably, many current legal cases surrounding privacy and data breaches relating to direct-to-consumer prescription drug companies take place in California. With arguably one of the strictest consumer data protection laws in the United States, privacy regulation in California protects consumers victimized by data breaches and other information leaks. The California Consumer Privacy Act allows consumers the right to delete personal information collected by companies. Similarly, the California Confidentiality of Medical Information Act, (“CCMIA”) augments the protections and rights available through HIPAA and specifically defines who is eligible to release certain types of medical information and under which circumstances. These protections help consumers of direct-to-consumer prescription drug companies have better control over who can access and share their data as well as provide stronger remedies for breaches. If other states follow in suit of California’s patient and health protections, privacy issues of the breach of confidential or sensitive patient health information may be ameliorated.

VI. CONCLUSION

Because of its ease and simplicity, direct-to-consumer prescription drug services have seen and will likely continue to experience widespread popularity.

73. *HIMS & HERS HEALTH, INC. PRIVACY POLICY*, supra note 59.
74. See generally Zuppello, supra note 42; see generally Murray-Watson, supra note 32.
79. See generally id.
amongst consumers. By cutting out the proverbial middle man of having to schedule and attend in-person health care appointments, as well as the logistics of having to verify insurance and other administrative health care tasks, direct-to-consumer prescription drug services offer consumers the individual agency to be able to address their health care needs in an efficient and flexible manner, within an increasingly complicated health care system. However, direct-to-consumer prescription drug companies are subject to very minimal regulation and in some cases, are not required to comply with HIPAA and other patient protection and health privacy requirements. This, in conjunction with the marketing and social media advertising mechanisms through many third parties that several direct-to-consumer prescription drug companies utilize, may be a significant cause for concern, as patients’ sensitive health care data and information have the potential to be breached or leaked at greater rates. Many direct-to-consumer prescription drug companies have also been involved in lawsuits regarding data privacy, an occurrence that may see an increase in the future. Overall, direct-to-consumer prescription drug services have the potential to be an advantageous business model for both companies and consumers but may pose significant risks relating to patient privacy.

81. See generally id.
82. Bitzer, supra note 23; HIMS & HERS HEALTH, INC.: PRIVACY POLICY, supra note 59.
83. Friel et. al, supra note 60.
84. See Wisp Online Healthcare User?, supra note 62.