A TOUGH [DIGITAL] PILL TO SWALLOW

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I. INTRODUCTION

While a digital pill that provides compliance information to your health care provider is an innovative technology aimed at resolving medication adherence concerns, it introduces issues encompassing the right to privacy. In particular, psychiatric patients are more at risk of having their right to privacy infringed upon due to this technology.[1]

This paper will analyze the privacy concerns that are associated with this new innovative technology, as well as explore how these concerns relate to individuals with mental illnesses. Section II of this paper will provide background information on how the digital pill will help deal with medication adherence, which is a major problem in today's society. This Section will also describe other initiatives that have been created to combat medication adherence issues, as well as give a detailed description of the initiative in question, the digital pill. Section III will dissect the privacy concerns associated with the digital

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[1] David M. Perry, *Your Pills Are Spying on You*, PAC. STANDARD, (Feb. 1, 2018), https://psmag.com/social-justice/the-pills-have-eyes.

pill, analyzing in particular the privacy concerns of those patients with psychiatric disorders. Section IV will provide insights into potential solutions to maintain patients' privacy rights, while still promoting and advancing technology that solves the medication adherence crisis. Finally, Section V will briefly conclude this paper, recognizing the need for increased medication adherence, while safeguarding patients' right to privacy.

II. HISTORY AND BACKGROUND

A. Medication Adherence Issues

Medication "compliance" is defined as "simply following a treatment regimen as prescribed," which means taking the correct dose at the right time.[2] Medication "adherence" on the other hand, is defined as "continuing to follow the treatment instructions over the correct period of time."[3] Regardless of the term used, "medication adherence" or "medication compliance," both indicate how closely a person's behavior conforms to their treatment instructions.[4] Failure to follow prescribed treatment instructions can have serious negative implications on a patient's health, particularly patients suffering from a chronic illness.[5]

According to the World Health Organization, an estimated fifty percent of patients with chronic illnesses in developed countries fail to take their medications as prescribed.[6] These chronic illnesses consist of cardiovascular disease, asthma, depression, cancer, and diabetes, which affect nearly one in two

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[2] Matt Lamkin & Carl Elliott, *Curing the Disobedient Patient: Medication Adherence Programs as Pharmaceutical Marketing Tools*, 42 J. L. MED. & ETHICS 492, 493 (2014).
[3] *Id.*
[4] *See* Katherine Boshinski Sparks, *Medication Adherence Technology: Medicine of the Future, Emerging Privacy Concern*, 28 J. CONTEMP. HEALTH L. & POL'Y 324, 325-26 (2012)("For example, the patient who never fills the prescription he is given; the patient who fills it but never takes the pills; and the patient who intends to take the pills faithfully but frequently forgets to take them exhibit non-adherent behaviors.").
[5] Lamkin & Elliott, *supra* note 2, at 493.
[6] *Id.*

Americans.[7] Medication non-adherence for those with these chronic conditions negatively affect health outcomes,[8] resulting in relapse and recurrence of symptoms of the chronic disease.[9] For example, non-adherent diabetics are more than twice as likely to be hospitalized than those diabetics who regularly take their medications.[10] Between hospital admissions, emergency room visits, and other various inpatient costs, non-adherent patients with these chronic diseases also have higher health care costs than patients who do adhere to their medication regimens.[11]

Higher expenses for those with chronic illnesses is not the only financial problem; the New England Healthcare Institute explained that "medication non-adherence is responsible for an estimated $300 billion each year in health care expenditures."[12] This figure represents approximately 13% of total U.S. spending on health care.[13] This problem is not only costly for health care providers; the pharmaceutical industry is also affected by non-adherence problems, costing them as much as $564 billion each year in revenue losses alone.[14] Additionally, insurance companies are wasting money on unused drugs when patients do not take their medications.[15]

Failure to adhere to medication instructions can be attributed to a number of factors, including both medical and social issues.[16] External factors such as stigma, cost, and availability are common causes attributed to medication non-adherence.[17] Other non-adherence issues can be traced back to the source—the prescribing physician.[18] By giving complex

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[7] Amelia R. Montgomery, *Just What the Doctor Ordered: Protecting Privacy Without Impeding Development of Digital Pills*, 19 VAND. J. ENT. & TECH. L. 147, 155–56 (2016).
[8] *Id.* at 155.
[9] *Id.* at 150.
[10] *Id.* at 155.
[11] *Id.* at 156.
[12] Sparks, *supra* note 4, at 326. One third of that cost is for hospitalizations that could have been prevented by simply adhering to medication instructions. *Id.*
[13] Lamkin & Elliott, *supra* note 2, at 493.
[14] *Id.*
[15] Montgomery, *supra* note 7, at 156.
[16] Leighanne Root, *High-Tech Adherence: Incorporating Smart Pill Technology Into Wellness Programs*, 19 QUINNIPIAC HEALTH L. J. 121, 125 (2016).
[17] *See id.* at 124-125 (discussing different reasons for non-adherence).
[18] *Id.* at 126.

treatment instructions, failing to adequately explain the risks and benefits of the medication, or simply failing to consider the financial burden on the patient, the physician is unwittingly contributing to medication non-compliance.[19] A strong therapeutic alliance is needed between the physician and patient in order for physicians to recognize a non-adherent patient and for patients to properly communicate with their physicians and not "say what they think their doctor wants to hear."[20]

Characteristics of the individuals themselves are also known to contribute to patient non-compliance.[21] Medications are essentially a trade-off between disease symptoms and side effects caused by the drug itself.[22] Therefore, the decision not to take a certain medication may simply be an informed, rational choice based on personal experience.[23] On the other hand, not all patients can make an informed, rational decision and sometimes stop taking their medications to avoid adverse side effects or feel that they have recovered and no longer need the medication.[24] This is a major problem, especially for those individuals being treated for severe mental illness,[25] given that "medication is a key part of treatment for schizophrenia, major depressive disorder, and bipolar disorder."[26]

Non-adherence to medications is a well-established issue that is exceedingly complex; however, there is no single solution

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[19] *Id.*

[20] *Id.* at 125 n.21 (quoting Lars Osterberg & Terrence Blaschke, *Drug Therapy: Adherence to Medication*, 353 New Eng. J. Med. 487, 490 (2005)).

[21] *See* Jaymes V. Fairfax-Columbo & David DeMatteo, *Are Bioequivalents Really Equal?: Generic Substitution in the Context of Mental Illness*, 12 IND. HEALTH L. REV. 281, 309–310 (2015) (including characteristics "such as a lack of insight into their disease, forgetfulness, the severity of the illness, experiencing depressive and psychotic symptoms, low cognitive ability, and substance dependency").

[22] *See* Lamkin & Elliott, *supra* note 2, at 497 (discussing the side effects of certain medications); *see also* Montgomery, *supra* note 7, at 154–55 (stating that patients are reported to be 3.5 times more likely not to take their medications due to adverse side effects of the medication).

[23] *See* Lamkin & Elliott, *supra* note 2, at 497-98 (indicating that factors such as longevity and quality of life are also present in this trade-off calculation).

[24] Rachel A. Scherer, *Toward a Twenty-First Century Civil Commitment Statute: A Legal, Medical, and Policy Analysis of Preventive Outpatient Treatment*, 4 IND. HEALTH L. REV. 361, 380-81 (2007).

[25] *Id.*

[26] Fairfax-Columbo & DeMatteo, *supra* note 21, at 309.

to the predicament.[27] Several initiatives and inventions have been developed in an attempt to solve the medication adherence crisis.[28]

B. Adherence Initiatives

Living in a technologically advanced world, it is no surprise that a vast number of devices and innovative products exist to promote medication adherence.[29] A simple way to help connect our health care providers to our physical health is through the use of Mobile Health (mHealth) applications.[30] mHealth includes everything from medical device apps, fitness apps, and reminder apps that allow patients to receive reminders to take their medications.[31] Some companies, such as HealthPrize and Mango Health, actually reward patients with gift cards when they follow their prescriptions, thereby turning adherence into a game with immediate rewards.[32]

While adherence apps are easily available to everyone with a smartphone, major innovations by pharmaceutical companies include "smart packaging" to remind patients to take their medications.[33] One of the more basic developments that has been around for years and is used today is blister packs—with clear directions and a simple dosing schedule, generally also including calendars and a clear visual for helping patients make adherence easier.[34] More recently, there have been developments in the use of electronic packaging to alert patients when to take their medication through the use of text messages or blinking pill

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[27] Root, *supra* note 16, at 122.
[28] *Id.*
[29] *Id.* at 128.
[30] Anne Marie Helm & Daniel Georgatos, *Privacy and mHealth: How Mobile Health "Apps" Fit Into a Privacy Framework Not Limited to HIPAA*, 64 SYRACUSE L. REV. 131, 132 (2014).
[31] *See* Root, *supra* note 16, at 129 (including apps like DoseCast and MedCoach, which track the patient's adherence to medication regimens).
[32] *Id.*
[33] *Id.* at 128; *see also* Scherer, *supra* note 24, at 381 (noting that researchers are also looking to improve adherence via the chemical structure and form of the medication, such as through the use of extended release capsules and depot injections).
[34] Sparks, *supra* note 4, at 328.

bottles.[35] Some electronic packaging is so advanced that it is capable of storing information about the patient's adherence,[36] or able to transmit adherence data directly to the patient's physician or caregiver.[37] One such invention is the "GlowCap"—an electronic cap for a standard size pill bottle with a wireless transmitter inside that can automatically generate emails to report patients' adherence information.[38]

While these initiatives are a great start toward solving the medication adherence crisis, they leave ample room for human error.[39] Many mHealth applications rely on the patient to enter their own adherence information,[40] and opening an electronic pill bottle cap does not necessarily mean that the patient ingested any of the medication.[41] There is a need for technology that can actually tell when patients took their medications, if they took them at all.[42]

C. The Digital Pill

Although sounding like a topic from a science-fiction novel, advanced pill technology that can transmit real-time adherence information to physicians is already in development[43]—the smart pill. "Smart pill" refers to an ingestible drug equipped with technology that can monitor and control drug release, or even record data related to drug release such as when,

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[35] *Id.*
[36] *Id.* at 328–29 (explaining that some electronic packaging can record the date and time that the medication is opened).
[37] Root, *supra* note 16, at 128. Through the use of this technology, the physician is able to call and remind the patient to take their missed pills if they do not receive a signal that the medication was taken. *See* Sparks, *supra* note 4, at 324–25.
[38] Sparks, *supra* note 4, at 329 (explaining that the pill bottle will send emails or text messages to the patient's physician and family members if the patient does not remember to take their medication).
[39] *See* Root, *supra* note 16, at 140–41 (noting that many of these devices rely on patient input).
[40] *Id.* at 140.
[41] *Id.* at 141.
[42] *See id.* (introducing the idea of the digital pill).
[43] Sparks, *supra* note 4, at 325.

where, drug quantity, body temperature, and heart rate.[44] Already in existence and use are the PillCam, which detects bleeding and other problems in the gastrointestinal tract through the use of an ingestible pill-sized camera, and the SmartPill, another ingestible device that measures pH levels, blood pressure, and temperature as it travels through the body.[45]

On November 13, 2017, Abilify MyCite, the first drug in the U.S. with a digital ingestion tracking system developed by Proteus Digital Health, was approved by the U.S. Food and Drug Administration (FDA).[46] For years, Proteus has been developing this digital ingestion tracking system that consists of an ingestible sensor, an external patch worn on the patient's skin, and an advanced mHealth application.[47]

The ingestible sensor is invisible to patients, having measurements of only one millimeter long and one-third of a millimeter thick,[48] and is embedded in medication,[49] such as Abilify.[50] The sensor is made of silicon, copper, and magnesium, which form a circuit with human stomach acid when the patient swallows the pill.[51] This circuit generates a charge that is detected by the external patch worn on the patient's skin.[52] The patch records and time-stamps the time and date that the pill is digested, while also measuring some other vital signs, such as the patient's heart rate, temperature, activity, and respiration.[53]

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[44] Matthew Avery & Dan Liu, *Bringing Smart Pills to Market: FDA Regulation of Ingestible Drug/Device Combination Products*, 66 FOOD DRUG L. J. 329, 331 (2011).

[45] Scott R. Peppet, *Regulating the Internet of Things: First Steps Toward Managing Discrimination, Privacy, Security, and Consent*, 93 TEX. L. REV. 85, 103 (2014).

[46] *FDA Approves Pill With Sensor That Digitally Tracks If Patients Have Ingested Their Medication*, FDA News Release (Nov. 13, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm584933.htm.

[47] Root, *supra* note 16, at 129.

[48] Montgomery, *supra* note 7, at 151.

[49] Sparks, *supra* note 4, at 325.

[50] Montgomery, *supra* note 7, at 153–54 (explaining that Abilify is a drug used to treat schizophrenia, bipolar disorder, major depressive disorder, and Tourette's Syndrome).

[51] *Id.* at 151.

[52] Matthew Avery & Dan Liu, *supra* note 44, at 332.

[53] *Id.*

The information captured by the patch is then sent wirelessly to the patient's smartphone or other Bluetooth-enabled device, where the patient can view the information using an mHealth app.[54] Finally, with the patient's consent, the compliance information can be transmitted to the patient's physician or other caregivers[55] "to better understand how patients are responding to their treatments."[56]

When medical professionals are given the information, they are able to prescribe a treatment regimen that is more likely to result in medication adherence,[57] thereby increasing the therapeutic effects of the drug.[58] The digital pill provides this benefit as well as several other advantages over other adherence technologies, including providing a high level of detail and accuracy regarding medication adherence, building a support system that connects patients and caregivers, and reducing the number of healthcare staff necessary to ensure a patient's compliance with their medication.[59] Also, by increasing patient adherence, overall treatment costs are lowered for both patients and insurers by eliminating unnecessary expenses.[60] Lastly, the digital pill has the ability to greatly improve clinical trials by reducing costs and increasing accuracy because it is crucial that participating patients adhere to the treatment being tested and evaluated.[61]

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[54] Montgomery, *supra* note 7, at 151–52. The Helius mHealth app has additional features that include reminding the patient to take their medication, tracking the effects of the medication by indicating whether the medication is or is not working or is the correct dosage, and prompting the user to take a walk after long periods of inactivity (Root, *supra* note 16, at 130).

[55] Root, *supra* note 16, at 130.

[56] Adam Thierer, *The Internet of Things and Wearable Technology: Addressing Privacy and Security Concerns Without Derailing Innovation*, 21 RICH. J. L. & TECH. 34 (2015).

[57] Root, *supra* note 16, at 141.

[58] *Id.* at 130.

[59] *Id.* at 140.

[60] *Id.* at 139 (explaining that costs associated with skipped doses and emergency room visits are eliminated when patients take their medications as directed).

[61] Montgomery, *supra* note 7, at 156 (eliminating the time-consuming and imprecise methods of pill counts and questionnaires that are currently used in clinical trials).

While this technology has numerous benefits, it also creates a serious threat to patient privacy and the danger of invasive medical surveillance.[62]

III. THE PROBLEM

A. General Privacy Concerns

An ingestible sensor that sends real-time privileged information to others presents a number of concerns regarding personal autonomy and privacy.[63] There is some question about which privacy laws and regulations apply to data that is created and transmitted using digital sensors and whether current approaches to privacy protection apply to this new technology.[64]

The Health Insurance Portability and Accountability Act (HIPAA) is the federal statute that regulates privacy issues regarding health information,[65] including issues related to mHealth.[66] The law provides that entities covered by the statute must "make electronic health information secure, ensure that the information is disclosed properly, and limit the number of people who have access to patient records."[67] Covered entities typically include health care providers and health insurers, not pharmaceutical companies. It is unclear whether HIPAA would apply to the digital pill.[68] Therefore, other privacy remedies are necessary.

The U.S. Supreme Court has long recognized that both the right to privacy and the right to autonomous medical decision making[69] are fundamental rights,[70] although not expressly written in the U.S. Constitution.[71] The right to privacy involves

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[62] Sparks, *supra* note 4, at 325.
[63] Montgomery, *supra* note 7, at 150.
[64] *Id.*
[65] Montgomery, *supra* note 7, at 157.
[66] Helm & Georgatos, *supra* note 30, at 152.
[67] Sparks, *supra* note 4, at 336.
[68] Montgomery, *supra* note 7, at 163.
[69] Fairfax-Columbo & DeMatteo, *supra* note 21, at 311.
[70] Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990); Roe v. Wade, 410 U.S. 113 (1973); Griswold v. Connecticut, 381 U.S. 479 (1965); Union Pac. Ry. Co. v. Botsford, 141 U.S. 250 (1891).
[71] Sparks, *supra* note 4, at 331.

two different provisions: "the first is a due process right to make certain personal decisions without government's intrusion" and the second, as "stated in the Fourth Amendment, is the right 'of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures.'"[72] The digital pill could only be considered an unlawful "search" under the Fourth Amendment if the medical information generated by the pill was received by the government without the consent of the patient.[73]

Privacy unrelated to government action is protected through common law privacy torts, such as intrusion on seclusion and publication of private facts.[74] The intrusion tort imposes liability for an intentional act that intrudes "physically or otherwise upon the solitude . . . of another or is of private affairs or concerns."[75] The digital pill would likely meet this threshold requirement due to its invasive nature.[76] The second tort is only of concern if the patients' private facts, such as their medical information and data, are widely circulated to the public.[77]

Medical information, in particular, is exceedingly personal to patients and can be valuable to businesses,[78] such as insurers in setting insurance premiums.[79] This is especially true with respect to the information collected and transmitted by the digital pill.[80] Patients need to trust that their private medical information will be protected, especially with a medication that itself "tattle-tales" to those who receive the information.[81] Informed consent[82] is of vital importance with adherence technology, especially when considering the intrusiveness of the

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[72] *Id.* at 332.
[73] *Id.* at 333.
[74] *Id.* at 334.
[75] *Id.*
[76] *Id.*
[77] Sparks, *supra* note 4, at 335.
[78] Montgomery, *supra* note 7, 170.
[79] *Id.* at 170–71.
[80] *Id.*
[81] Sparks, *supra* note 4, at 336. Individuals' fears include hackers using their health data to steal patient identities, as well as using patient data to conceal its seriousness or issue false alarms. *See* Root, *supra* note 16, at 148–49.
[82] *Id.* at 345 (defining "informed consent" to mean when "a person 'allows something to happen with full knowledge' of the risks and the possible alternatives to the course of action.").

digital pill.[83] Physicians should provide patients with as much information as possible, describing how the technology works, indicating the privacy risks that are associated with the technology, and reciting the steps taken to minimize those risks.[84] The patients would then have all the information necessary to make a decision about whether or not to use the digital pill. Deciding when and if to take medications is a personal matter that is crucial to the right to privacy.[85]

B. Privacy Concerns of Psychiatric Patients

In addition to the fundamental rights of privacy and medical decision making, the Supreme Court has also held that "persons with mental illness have a right not to be coerced into treatment or into taking a medication."[86] Although non-adherence to antipsychotics has been a long-endured problem,[87] the decision remains with the patient. A problem arises when the patient is deemed incompetent to make the decision.

If the patient lacks insight, awareness, or understanding, he or she lacks the requisite competence needed to make a voluntary decision.[88] Research suggests that about half of the patients with severe mental illnesses lack the necessary insight, awareness, or understanding that they suffer from mental illness.[89] Taking medication is difficult to justify when you believe there is nothing to treat.

C. Comparison to Other Initiatives

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[83] *Id.*
[84] *Id.* at 345–46.
[85] *Id.* at 337.
[86] *See* O'Connor v. Donaldson, 422 U.S. 563 (1975); *see also* Washington v. Harper, 494 U.S. 210 (1990); Riggins v. Nevada, 504 U.S. 127 (1992); Sell v. United States, 539 U.S. 166 (2003).
[87] Lamkin & Elliot, *supra* note 2, at 497 (indicating that the antipsychotics non-adherence issue began in the 1950s when these drugs became an available treatment for schizophrenia).
[88] Scherer, *supra* note 24, at 375–76.
[89] *Id.* at 375 (indicating that a person's insight into their illness varies based upon their age, duration of the illness, and possibly the tendency towards violence).

Due to the Supreme Court's holding that those with mental illness have a right not to be forced into treatment, including into taking a medication, the digital pill could appear problematic as a solution to medication adherence in those with mental disorders.[90] Therefore, other means of medication adherence have been created to achieve a proper balance of adherence and patient autonomy.[91]

In order to protect the public from harm potentially caused by severely mentally ill people, and to help protect the mentally ill themselves,[92] states developed involuntary outpatient commitment ("IOC") programs.[93] These programs allow mentally ill individuals to live safely in the community, while receiving court-mandated treatment,[94] which includes psychopharmalogical drugs along with vocational counseling and a variety of therapies.[95] The first state to enact such a program was North Carolina in 1983, allowing an order to issue if the court finds that the mentally ill individual "is dangerous to others, dangerous to himself or herself, or requires treatment to prevent 'deterioration that would predictably result in dangerousness.'"[96]

Currently, there are two principal IOC statutes in existence: Kendra's Law (New York) and Laura's Law (California).[97] Both laws were named after innocent victims who were subject to the violent actions of schizophrenic individuals who had sought treatment in the community,[98] but were denied due to insufficient resources.[99] Individuals are only subject to the court-mandated treatment under Kendra's Law or Laura's Law if

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[90] Fairfax-Columbo & DeMatteo, *supra* note 21, at 313.
[91] *See generally id*. at 310–16 (explaining various court rulings which outline patient rights against mandatory medication).
[92] *See* Scherer, *supra* note 24, at 362 (referring to these "civil commitment" statutes as "preventive outpatient treatment" ("PVOT")).
[93] Bernfeld, *supra* note 88, at 352. Similar names for these laws include: "assisted outpatient treatment" ("AOT"), or simply, "outpatient commitment" ("OPC"). *Id.* at n.1.
[94] Bernfeld, *supra* note 88, at 352.
[95] Scherer, *supra* note 24, at 370.
[96] Bernfeld, *supra* note 88, at 358.
[97] Scherer, *supra* note 24, at 385.
[98] *Id.*
[99] Bernfeld, *supra* note 88, at 356.

they meet several eligibility requirements.[100] If the person meets these requirements, the court orders a treatment plan created by the treating physician and the individual. Allowing the individual to participate creates a higher probability of patient adherence.[101] This order cannot be changed by the court and lasts for an initial six months, to be extended for one year at a time.[102] IOC statutes have been challenged due to their intrusion on the autonomy of the mentally ill, but the New York Court of Appeals has held that "the intrusion is not sufficiently great to overcome the government's interest in treating mentally ill people before their condition may deteriorate."[103]

These statutes have had abundant positive effects on rates of homelessness, incidences of harmful behaviors, and even victimization of the mentally ill,[104] but of utmost importance are the positive therapeutic outcomes for patients under a court order.[105] Statistics revealed that for 3,766 IOC recipients in New York, the medication adherence rates doubled after six months of treatment.[106] Other statistics revealed an 89% increase in case management services participation, a 47% increase in group or individual therapy participation, as well as a 77% reduction in

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[100] Bernfeld, *supra* note 88, at 357. Kendra's law requires the following seven requirements be met: (1) the person is eighteen years of age or older; (2) the person has been diagnosed with a mental illness; (3) the person is "unlikely to survive safely in the community without supervision"; (4) the person has a history of lack of compliance with treatment that has resulted in (5) either two or more hospitalizations within the last thirty-six months or one or more acts or threats of violence within the past forty-eight months; (6) the person is "unlikely to voluntarily participate in outpatient treatment"; and (7) the person must be in need of outpatient treatment to prevent "relapse or deterioration" and would likely benefit from the outpatient treatment. *Id.* Laura's Law requires these seven criteria as well as two additional requirements: that the person's condition must be "substantially deteriorating" and that "the IOC must be the least restrictive placement for the person." *Id.* at 359.

[101] Bernfeld, *supra* note 88, at 358.

[102] *Id.*

[103] *Id.* at 367; *see also In re* K.L., 806 N.E.2d 480 (N.Y. 2004) (raising several arguments about the constitutionality of Kendra's Law, under which K.L. (diagnosed with schizoaffective disorder and a history of noncompliance with treatment and psychiatric hospitalization) was involuntarily court-order to receive psychiatric treatment).

[104] Scherer, *supra* note 24, at 371.

[105] Bernfeld, *supra* note 88, at 366.

[106] Scherer, *supra* note 24, at 411.

hospitalization rates for those who had previously been hospitalized.[107] These impressive results demonstrate the success of such IOC statutes and their ability to enhance the lives of mentally ill individuals.

The addition of the digital pill to these IOC statutes would have a drastic effect on cutting program costs and further increasing medication adherence. Psychiatrists, or others who are administering medication, would no longer need to physically be with the IOC participant when they are taking their medication. The digital pill would allow for remote monitoring while still ensuring that the patient is following treatment instructions. New York has devoted $32 million dollars a year to support programs under Kendra's Law;[108] an incredible expense which could be decreased by the introduction of the digital pill into these programs.

IV. SOLUTION

A balance must be struck between the privacy risks presented to patients by the digital pill and the risks of overregulation that could end any benefits offered by the digital pill before they begin.[109]

Because informed consent is essential to medical decision making, particularly in the realm of adherence technology, federal legislation regarding informed consent should be strengthened and reinforced.[110] Providing a written privacy policy to a potential consumer of the digital pill would not be an effective means of offering the patient the best privacy protection available. Just as a user glances through a privacy policy on a downloaded app on their device without reading and merely clicking "accept," a consumer of the digital pill would be inclined to do the same. Informed consent obtained by a physician allows the patient a better opportunity to pay attention and learn of the privacy issues associated with the technology and to discuss concerns with their doctor before they use or pay for the digital pill.[111]

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[107] *Id.*

[108] Bernfeld, *supra* note 88, at 368 (ensuring every patient gets individual case management through this funding).

[109] Montgomery, *supra* note 7, at 172.

[110] Sparks, *supra* note 4, at 345.

[111] Montgomery, *supra* note 7, at 173.

One possible solution would be an explicit opt-in approach to the use of the digital pill, as well as other related innovations.[112] No one should be forced to use the digital pill without their full informed consent. One way to prevent such forcible use is to ensure that pharmaceutical companies continue to develop and produce pharmaceuticals without the addition of the adherence technology in it. If the only drug option is the digital pill, it is not truly an option at all. In addition, only those that can competently opt-in and consent should be allowed to make the choice to do so. The elderly, children, and those with mental incapacities should not be forced to take such medication.

Additionally, because it is unclear whether HIPAA, or other patient privacy laws, would apply to the digital pill, such laws should be strengthened and updated to specifically address this new technology. Adherence technology has the potential to be used against patients as a prerequisite for insurance coverage, employment, or school admission. Therefore, federal restrictions on mandatory use of such technologies is needed to prevent this.

V. CONCLUSION

The digital pill is an incredible innovation that has an endless list of benefits. But if precautions are not taken, the digital pill also presents serious risks to our fundamental rights to privacy and autonomy. By passing appropriate statutes, strengthening existing protections, and creating proper safeguards, the digital pill can be seamlessly introduced to the market where we can enjoy all of its advantages.

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[112] Sparks, *supra* note 4, at 345.