

DIGITAL MEDICATION: IMPLICATIONS FOR USE IN THE CRIMINAL JUSTICE SYSTEM

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I. INTRODUCTION

On November 13, 2017, the Food and Drug Administration (FDA) approved the first drug in the United States with a digital ingestion tracking system.¹ The tracking system incorporates several components. First, an aripiprazole tablet, an atypical antipsychotic² used to treat schizophrenia, bipolar disorder, and other mental illnesses, is embedded with an ingestible event marker sensor.³ When the pill is ingested and comes into “contact with digestive fluid, the digital tablet dissolves and activates.”⁴ Upon activation, the sensor emits a time-stamped signal, which is detected by an adhesive sensor patch, approximately 10 cm long, that is worn on the patient’s torso.⁵ Data from the sensor patch is then transmitted and stored in a Bluetooth-enabled device.⁶ If the patient so chooses, the data can be uploaded to a cloud-based, encrypted, HIPAA-compliant record, which can be shared with the patient’s physician and caregivers.⁷ The

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¹ *FDA Approves Pill with Sensor That Digitally Tracks if Patients Have Ingested Their Medication*, U.S. FOOD & DRUG ADMIN. (Nov. 13, 2017) [hereinafter *Press Release, FDA*], <https://www.fda.gov/news-events/press-announcements/fda-approves-pill-sensor-digitally-tracks-if-patients-have-ingested-their-medication>.

² *Aripiprazole (Abilify)*, NAT’L ALL. ON MENTAL HEALTH, [https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/aripiprazole-\(Abilify\)](https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/aripiprazole-(Abilify)) (last visited Mar. 3, 2021).

³ Preetika Rana, *Digital Pills That Talk to Your Doctor Are Here*, WALL ST. J. (Nov. 13, 2017, 11:40 PM), <https://www.wsj.com/articles/fda-approves-worlds-first-digital-drug-1510621146>.

⁴ Dr. Tina Caliendo & Dr. Olga Hilas, *The Promise and Pitfalls of Digital Medication*, U.S. PHARMACIST (July 18, 2019), <https://www.uspharmacist.com/article/the-promise-and-pitfalls-of-digital-medication>.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

captured data includes not only information regarding the date and time of ingestion, but also “physiological metrics such as physical activity, heart rate, skin temperature, and sleep.”⁸ The patient can also choose to self-report data such as mood and quality of sleep.⁹

The impetus behind the digital pill was to improve patient adherence and to allow physicians to provide more effective and collaborative care through increased transparency.¹⁰ Many in the health care community, including the Director of the Division of Psychiatry Products in the FDA’s Center for Drug Evaluation and Research, recognize the value of a system that tracks medication adherence in some patients with mental illness,¹¹ a segment of the medical community with notoriously low rates of non-adherence.¹² Other commentators, however, have proven to be more skeptical of this new technology,¹³ believing the digital pill portends an age of “biomedical big brother,”¹⁴ one in which insurance companies will leverage the technology to strong-arm compliance and potential data breaches threaten patient privacy.¹⁵

Another line of critique focuses on the potential use of the digital pill in the criminal justice sphere. Advocates for the mental health community fear the ethical and constitutional quandaries of monitoring a segment of the population “already disproportionately subjected to

⁸ *Id.*

⁹ *What Is the ABILIFY MYCITE System?*, ABILIFY MYCITE [hereinafter *Product Information*], <https://www.abilifymycite.com/about> (last visited Mar. 3, 2021).

¹⁰ Brian Dolan, *Proteus Biomedical Tweaks Branding, Partners with Abilify-Maker Otsuka*, MOBI HEALTH NEWS (July 6, 2012, 3:55 AM), <https://www.mobihealthnews.com/17831/proteus-biomedical-tweaks-branding-partners-with-abilify-maker-otsuka>.

¹¹ *Press Release, FDA, supra* note 1.

¹² Non-adherence to medication regimes is endemic to the treatment of both schizophrenia and bipolar disorder. Studies have shown that as much as 75 percent of schizophrenic patients will stop taking their medications within 18 months of treatment, and more than 90 percent will miss doses on a regular basis. E. Brown & R. Gray, *Tackling Medication Non-Adherence in Severe Mental Illness: Where Are We Going Wrong?*, 22 J. PSYCHIATRIC & MENTAL HEALTH NURSING 192, 192–93 (2015). Similar rates of non-adherence are documented among patients with bipolar disorder. F. Colom et al., *Identifying and Improving Non-Adherence in Bipolar Disorders*, 7 BIPOLAR DISORDERS 24, 24 (2005).

¹³ *See generally* Cat Wise, *This Digital Pill Wants to Make Following Your Prescription Easier*, PBS (May 23, 2018, 5:31 PM), <https://www.pbs.org/newshour/science/following-a-prescription-is-hard-this-digital-pill-wants-to-help>.

¹⁴ Pam Belluck, *First Digital Pill Approved to Worries About Biomedical ‘Big Brother,’* N.Y. TIMES (Nov. 13, 2017), <https://www.nytimes.com/2017/11/13/health/digital-pill-fda.html>.

¹⁵ Concerns regarding use of the digital pill by insurance companies and privacy considerations are beyond the scope of this Comment.

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coercion and surveillance.”¹⁶ Others fear disproportionate misuse of the technology by judges and probation officers, who stand at the ready to send an offender back to prison for any deviation from his medication regime.¹⁷

This Comment will take the opposite position, arguing that use of the digital pill in our criminal justice system for certain offenders who have a history of either self-injurious or violent behavior when not medicated, coupled with a track record of medication non-adherence, is both constitutional and advisable as a matter of public policy. A special condition of supervised release¹⁸ that requires this small segment of seriously mentally ill offenders to take digital medication and to share the captured data with their probation officers would provide supervision and accountability to those who could benefit from such oversight and would prove valuable to the health care and prison systems, as well as the community at large.

Part II will analogize the digital pill to other utilized forms of enhanced post-release supervision such as forceable medication via long-acting injectable antipsychotics and monitoring devices, such as electronic location monitors or the secure continuous remote alcohol monitor, to make the argument that the imposition of digital medication as a term of supervised release passes constitutional muster.

Part III will first discuss the alarming rates of incarceration of seriously mentally ill offenders and the difficulties correctional institutions face in caring for this population.¹⁹ In light of these realities, Part III will then address why digital medication, for the right patient and in conjunction with other terms of supervised release providing treatment and support services, reflects good policy that would alleviate some of the strain placed on both our criminal justice and mental health systems, in addition to being beneficial to the patient himself. Part III

¹⁶ David M. Perry, *Your Pills Are Spying on You*, PACIFIC STANDARD (Feb. 1, 2018), <https://psmag.com/social-justice/the-pills-have-eyes>.

¹⁷ Wise, *supra* note 13.

¹⁸ Pursuant to the Sentencing Reform Act of 1984, supervised release took the place of parole for federal crimes committed after November 1, 1987. See P.L. No. 98-473, 98 Stat. 1987; see also Charles Doyle, *Supervised Release (Parole): An Overview of Federal Law*, CONG. RES. SERV. (Mar. 5, 2015), <https://crsreports.congress.gov/product/pdf/RL/RL31653>. While there are marked differences between the two, both supervised release and parole represent terms of restricted freedom following a period of incarceration. *Id.* Additionally, revocation of either parole or supervised release could potentially mean a return to prison. *Id.* Therefore, for purposes of this Comment, it is a non-substantive distinction, and any references to parole in the articles or case law cited herein should be considered to apply equally to the system of supervised release.

¹⁹ Jamie Fellner, *A Corrections Quandary: Mental Illness and Prison Rules*, 41 HARV. C. R.-C. L. L. REV. 391, 391 (2006).

will, hopefully, help assuage some of the worst fears of mental health advocates by arguing that both constitutional constraints and the limitations of the technology itself will help ensure that the use of digital medication is both constrained and flexible.

It must be stressed that while this Comment argues that enhanced supervision through digital medication for a small segment of mentally ill offenders is one way to potentially improve recidivism rates for mentally ill offenders, thereby helping to improve overall conditions in penal institutions, this Comment does not suggest that this potential tool should be used in isolation. There are many other methods by which to improve prison conditions, such as decreasing overall rates of incarceration, increasing the number of mental hospital beds, and financing more robust community outreach programs for persons suffering from mental illness both prior to, and upon release from, incarceration. By no means should digital medication be seen as a substitute for these much-needed reforms to our criminal justice and mental health care systems, but rather, as one tool to increase transparency for a select number of offenders who would benefit from closer supervision.

Finally, Part IV will briefly discuss two other areas where the criminal justice system could potentially leverage this technology. First, this Comment will discuss the potential use of digital medication as a discretionary condition of probation and explore how the legal and policy implications of such a condition are both analogous to, and divergent from, a condition of supervised release. Second, this Comment will touch upon the potential for such technology to expand into the treatment of opioid addiction.

II. LEGAL STANDARD FOR CONDITIONS OF SUPERVISED RELEASE²⁰

Digital medication is unique in that it encompasses both a medication and monitoring component.²¹ Because of the novelty of digital medication, this Comment will break down its components, first discussing the legal standard surrounding special conditions of supervised release that compel an offender to take certain medications, and then addressing the standard around monitoring devices. First, however, this Comment will discuss 18 U.S.C. § 3583, the federal statute that addresses terms of supervised release after imprisonment.

²⁰ This Comment will look solely at the federal statutory and constitutional standards governing special conditions of supervised release.

²¹ See *supra* Part I.

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When sentencing a defendant to a term of imprisonment for either a felony or misdemeanor, a district court may require that the defendant be “placed on a term of supervised release after imprisonment.”²² When the sentence of imprisonment exceeds one year, or if the statute so provides, a term of supervised release is compulsory.²³ Moreover, certain conditions, such as drug testing and registration of convicted sex offenders, must be imposed with every term of supervised release.²⁴ In addition to these mandatory conditions, district courts have discretion to impose any appropriate condition of supervised release provided that the condition is reasonably related to the following factors: (1) the nature and circumstances of the offense and the history and characteristics of the defendant;²⁵ (2) the desire to adequately deter criminal conduct; (3) the need to protect the public from future crime; and (4) the aim of providing the defendant with “education or vocation training, medical care, or other correctional treatment in the most effective manner.”²⁶ Additionally, the condition must involve no greater deprivation of liberty than is reasonably necessary for the aforementioned purposes.²⁷ Finally, the condition must be “consistent with any pertinent policy statements issued by the Sentencing Commission pursuant to 28 U.S.C. § 994(a).”²⁸

District courts are afforded wide latitude in crafting conditions of supervised release, which are only reviewed for abuse of discretion upon appeal.²⁹ Special conditions mandating that offenders comply with various treatment programs are not anomalous.³⁰ Rather, the Sentencing Guidelines specifically identify “Mental Health Program Participation” as a special condition of supervised release that may be appropriate if there is evidence that the defendant is in need of

²² 18 U.S.C. § 3583(a).

²³ 18 U.S.C. app. § 5D1.1.

²⁴ 18 U.S.C. § 3583(d).

²⁵ *Id.* § 3553(a)(1).

²⁶ *Id.* § 3553(a)(2).

²⁷ *Id.* § 3583(d)(2).

²⁸ *Id.* § 3583(d)(3).

²⁹ *United States v. Dotson*, 324 F.3d 256, 259–60 (4th Cir. 2003) (citing *United States v. Crandon*, 173 F.3d 122, 127 (3d Cir. 1999)); *United States v. Bee*, 162 F.3d 1232, 1234 (9th Cir. 1998) (stating that district courts have “broad discretion” when imposing terms of supervised release, even when it comes to “restrictions that infringe on fundamental rights”).

³⁰ *See, e.g.*, *United States v. Conelly*, 451 F.3d 942, 944 (8th Cir. 2006) (affirming special condition mandating that defendant “attend, complete, and pay for mental health services as directed by the probation officer”); *United States v. Barajas*, 331 F.3d 1141, 1143–46 (10th Cir. 2003) (mandating that the offender participate in an approved mental health program); *Dotson*, 324 F.3d at 261 (requiring offender submit to penile plethysmograph testing).

psychiatric treatment.³¹ While the Sentencing Guidelines are silent as to whether “Mental Health Program Participation” may include a mandate that the offender take all prescribed medications, numerous courts have seen this as a logical extension of the rationale underlying this special condition and have approved these types of mandates.³² Special conditions that require an offender to submit to electronic monitoring are commonplace³³ and are listed in the Sentencing Guidelines as special conditions that may be imposed in appropriate cases.³⁴

While 18 U.S.C. § 3583 plays into the analysis of whether digital medication may be imposed as a special condition of supervised release, this Comment will primarily focus on potential constitutional challenges. There are three reasons for this. First, the vast majority of our nation’s incarcerated people are held in state prisons and jails.³⁵ Therefore, by concentrating on the constitutional standards, this Comment will identify the overarching limits of this technology, which apply to all federal and state correctional institutions, without wading through myriad state statutory schemes that will add a layer of analysis. Second, from a practical perspective, many of the same factors are pertinent to both a statutory and constitutional review. And third, as will be seen in the discussion of the Fourth Circuit’s decision in *United States v. Holman*, if a term of supervised release passes the more demanding constitutional inquiry, it will often pass statutory scrutiny as well. For these reasons, as will be argued *infra*, the statutory analysis is largely subsumed by the constitutional one, at least in the federal context.

³¹ 18 U.S.C. app. § 5D1.3(d)(5).

³² See, e.g., *United States v. Holman*, 532 F.3d 284, 288 (4th Cir. 2008); *United States v. Larson*, No. 09-1465, 2010 U.S. App. LEXIS 23704, at *6 (10th Cir. Nov. 15, 2010). See generally *United States v. Caluori*, No. 16-354, 2017 U.S. Dist. LEXIS 218650 (M.D.N.C. Mar. 24, 2017), *aff’d*, 2018 U.S. App. LEXIS 4103 (4th Cir. Feb. 21, 2018).

³³ See, e.g., *Pollard v. United States Parole Comm’n*, No. 16-2918-pr, 2017 U.S. App. LEXIS 9004, at *11–13 (2d Cir. May 24, 2017) (affirming special conditions subjecting offender to both GPS and computer monitoring); *United States v. Miller*, No. 12-50238, 2013 U.S. App. LEXIS 11837, at *337–38 (5th Cir. June 12, 2013) (holding that special condition subjecting defendant to active Global Positioning System (GPS) Monitoring was appropriate given the defendant’s propensity for “angry outbursts” and “erratic behavior” that potentially posed a threat to the public).

³⁴ 18 U.S.C. app. § 5D1.3(d)(7)(C) (special condition for sex offenses requiring defendant to participate in program for monitoring of sex offenders); 18 U.S.C. app. § 5D1.3(e)(5) (allowing for use of electronic monitoring to confirm defendant’s compliance with curfew).

³⁵ See Wendy Sawyer & Peter Wagner, *Mass Incarceration: The Whole Pie 2019*, PRISON POL’Y INITIATIVE (Mar. 19, 2019), <https://www.prisonpolicy.org/reports/pie2019.html>.

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A. Potential Constitutional Challenges to Involuntary Medication

The Supreme Court has recognized that prisoners and pretrial detainees possess a “significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause.”³⁶ The origins of this liberty interest can be traced back to a long-standing common law rule of torts that any unauthorized touching by a physician constitute a battery.³⁷

The state is required to show an “essential or overriding [governmental] interest” before depriving an individual of such a fundamental liberty interest.³⁸ In *Washington v. Harper*, the Court found that the state’s interest in administering medication was “legitimate” and “important.”³⁹ And it went on to hold that the Due Process Clause permits the state to treat a seriously mentally ill inmate with medication against his will if the inmate is “dangerous to himself or others and the treatment is in the inmate’s medical interest.”⁴⁰ Thus, the inmate’s valid liberty interest yields to the state’s interest in providing appropriate medical care upon a showing of an “overriding justification and a determination of medical appropriateness.”⁴¹ The test the court applies in determining whether such overriding justification and medical appropriateness exist is dependent on the state’s interest.⁴² If the involuntary medication order is sought out of concern that the prisoner poses a danger to himself or others, the test is whether the medication is “medically appropriate and, considering less intrusive alternatives, essential for the sake of [the prisoner’s] own safety or the safety of others.”⁴³ If the government is seeking such an order to restore a mentally ill defendant’s competency for trial, the court must apply the slightly more onerous test delineated in *Sell v. United States*.⁴⁴

The Court in *Sell* held that for the state to forcibly medicate a mentally ill pretrial detainee for purposes of restoring competency for trial, the court must conclude (1) that there are important government interests at stake, (2) that involuntary medication will significantly further those state interests, (3) that involuntary medication is

³⁶ *Washington v. Harper*, 494 U.S. 210, 221 (1990).

³⁷ *Mills v. Rogers*, 457 U.S. 291, 294, n.4 (1982).

³⁸ *Sell v. United States*, 539 U.S. 166, 179 (2003) (quoting *Washington*, 494 U.S. at 225, 277).

³⁹ *Id.* at 178.

⁴⁰ *Id.*

⁴¹ *Riggins v. Nevada*, 504 U.S. 127, 135 (1992).

⁴² *United States v. Holman*, 532 F.3d 284, 288–90 (4th Cir. 2008).

⁴³ *Riggins*, 504 U.S. at 135.

⁴⁴ *Holman*, 532 F.3d at 289.

necessary to further those interests, and (4) that administration of the drugs is medically appropriate.⁴⁵

The two lines of inquiry consider many of the same factors. The Court, however, has noted that the analysis performed when there is an allegation of danger is both more “objective” and “manageable.”⁴⁶ This is because the reviewing court does not have to analyze the added layer of “quintessentially legal questions of trial fairness and competence” nor weigh such considerations against the competing state interest.⁴⁷

It is unclear which test is applicable when reviewing special conditions of supervised release. The Court in *Washington* noted that the state’s interest in ensuring that the offender was not a danger to himself or others was even more significant in a prison setting because prison officials are responsible for running an orderly institution and ensuring the safety of prisoners and staff.⁴⁸ Thus, an important factual consideration that the Court afforded considerable weight does not exist when analyzing conditions of supervised release. Even more disparate is the *Sell* scenario, which must also account for possible side effects of the medication that could interfere with the defendant’s ability to assist counsel in his defense.⁴⁹

In *United States v. Holman*, the Fourth Circuit was confronted with the question of which test to apply when examining a special condition of supervised release requiring that a mentally ill defendant submit to intramuscular injections of an antipsychotic.⁵⁰ While acknowledging that the “showing necessary to satisfy” the requirements of overriding justification and medical appropriateness is dependent on the “context and reasons underlying the order,”⁵¹ the Fourth Circuit ultimately created a hybrid of the two lines of inquiry, referring to it as the “*Harper-Riggins-Sell* constitutional analysis.”⁵² While referring to it as an amalgamation, the court used the express language from the *Sell* test, suggesting that, at least in the Fourth Circuit, the four-part *Sell* test is the preferred mode of inquiry when analyzing the constitutionality of special conditions of supervised release that implicate a fundamental

⁴⁵ *Sell*, 539 U.S. at 180–81.

⁴⁶ *Id.* at 183.

⁴⁷ *Id.* at 182.

⁴⁸ *Washington*, 494 U.S. at 225 (noting the state’s legitimate and important interest in “combating the danger posed by a person to both himself and others . . . in a prison environment”).

⁴⁹ *Sell*, 539 U.S. at 181.

⁵⁰ *United States v. Holman*, 532 F.3d 284, 286 (4th Cir. 2008).

⁵¹ *Id.* at 289.

⁵² *Id.* at 290.

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liberty interest.⁵³ But other courts, such as the Ninth Circuit, eschew the rigidity of the *Sell* test, instead focusing the constitutional inquiry on whether there has been a “finding of overriding justification and a determination of medical appropriateness.”⁵⁴

The question remains whether this constitutional analysis “supplants or supplements the statutory requirements set forth in 18 U.S.C. § 3583(d).”⁵⁵ When confronted with a constitutional challenge to a special condition of supervised release, some circuits have declined to perform a separate constitutional inquiry, holding that “a court will not strike down conditions of release, even if they implicate fundamental rights, if such conditions are reasonably related to the ends of rehabilitation and protection of the public from recidivism.”⁵⁶ In both *United States v. Schave* and *United States v. Ritter*, the defendant challenged a special condition of supervised release as violative of his First Amendment freedom of association.⁵⁷ While both the *Schave* and *Ritter* courts maintained that the central inquiry was whether the condition furthered the ends delineated in the statute and proceeded to analyze the condition using the statutory framework and terminology, both courts ultimately addressed the constitutional challenges brought by the defendant.⁵⁸ This suggests that, at least in the Sixth and Seventh Circuits, the constitutional inquiry supplements an analysis under 18 U.S.C. § 3583(d).

⁵³ *Id.* at 290–91 (finding that (1) the government’s interest in protecting Holman from himself and the general public are “essential or overriding interests,” (2) the special condition “significantly furthers and is clearly necessary” to further this interest, and (3) that the special condition is medically appropriate, given Holman’s lengthy history of medication non-adherence); *see also* *United States v. Caluori*, No. 16-354, 2017 U.S. Dist. LEXIS 218650 (M.D.N.C. Mar. 24, 2017), at *32–35 (M.D.N.C. 2017) (imposing a condition of supervised release requiring Caluori take antipsychotic medication after finding (1) the defendant posed a substantial risk to the public, (2) antipsychotics were necessary to control Caluori’s symptoms, and (3) such a requirement is medically appropriate).

⁵⁴ *United States v. Williams*, 356 F.3d 1045, 1056 (9th Cir. 2004) (quoting *Riggins v. Nevada*, 504 U.S. 127, 135 (1992)).

⁵⁵ *Holman*, 532 F.3d at 290.

⁵⁶ *United States v. Schave*, 186 F.3d 839, 843 (7th Cir. 1999); *see also* *United States v. Ritter*, 118 F.3d 502, 505 (6th Cir. 1997) (noting that “even though supervised release restrictions may affect constitutional rights such as First Amendment protections, most restrictions are valid if directly related to advancing the individual’s rehabilitation and to protecting the public from recidivism” before reviewing the challenged special condition using the 18 U.S.C. § 3583(d) factors).

⁵⁷ *Schave*, 186 F.3d at 840–41; *Ritter*, 118 F.3d at 504.

⁵⁸ *Schave*, 186 F.3d at 843 (adopting a narrow construction of special condition to avoid any “potential constitutional difficulties”); *Ritter*, 118 F.3d at 506 (finding that condition “intrudes minimally” upon defendant’s constitutional rights).

Conversely, in *United States v. Myers*, the Second Circuit held that when a special condition implicates “a fundamental liberty interest protected by due process,” the court’s “application of the § 3583(d) factors must reflect the heightened constitutional concerns.”⁵⁹ Accordingly, the condition will only be upheld “if the deprivation [of liberty] is narrowly tailored to serve a compelling government interest.”⁶⁰ Thus, the Second Circuit sets a much higher bar than the “reasonably related” standard set forth in 18 U.S.C. § 3583, suggesting that the statute should be interpreted to permit whatever passes constitutional scrutiny. It should be noted that in *Myers*, the court was considering a substantive due process challenge, rather than one brought under the First Amendment. Therefore, it would seem that *Myers*’ holding that the constitutional analysis supplants the statutory requirements would apply to any substantive due process challenge brought to a condition mandating digital medication. Yet, in *Holman*, the Fourth Circuit suggested that this circuit split concerning the interplay between a constitutional and statutory analysis has little bearing when it comes to special conditions mandating antipsychotic medication.⁶¹ As the following Section demonstrates, that may, in part, be attributable to the fact that courts ask many of the same key questions and analyze the same factors when determining whether the condition passes both statutory and constitutional muster.⁶²

⁵⁹ *United States v. Myers*, 426 F.3d 117, 125–26 (2d. Cir. 2005) (considering constitutional challenge to a condition of supervised release that interfered with defendant’s relationship with his constitutionally protected interest in his relationship with his child).

⁶⁰ *Id.*

⁶¹ *United States v. Holman*, 532 F.3d 284, 290 (4th Cir. 2008) (the court held the special condition at issue was properly imposed when analyzed under the *Harper-Riggins-Sell* framework and, thus, declined to weigh in on the question of whether the constitutional analysis supplants or supplements the statutory requirements).

⁶² It should be noted that such a term of supervised release may also be subject to a procedural due process challenge if the offender is not afforded notice and a hearing and if the sentencing judge does not properly articulate on the record that the condition “involves no greater deprivation of liberty than is reasonably necessary.” *United States v. Williams*, 356 F.3d 1045, 1055–57 (9th Cir. 2004) (holding that the “unusually serious infringement of liberty” attendant to special conditions requiring compliancy with antipsychotic medications requires a higher standard of “consideration and justification” on the record than is normally required of sentencing judges when imposing conditions of supervised release); *see also* *Allred v. United States*, No. 2:08-CV-245, 2009 U.S. Dist. LEXIS 112542, at *25–26 (D.C. Utah Dec. 3, 2009) (citing *Holman*, 532 F.3d at 290 and *United States v. Cope*, 527 F.3d 944, 953–54 (9th Cir. 2008) for the proposition that a hearing is required before imposing a term of supervised release requiring medication compliancy).

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B. *The Medication Component of the Digital Pill Passes
Constitutional Muster*

Under the *Harper-Riggins-Sell* framework,⁶³ propounded in *Holman*, a district court considering a special condition mandating digital medication must first determine whether there is an “essential or overriding” government interest at stake.⁶⁴ This requirement closely mirrors 18 U.S.C. § 3583(d), which requires that the condition be related to the following government interests: (1) the desire to adequately deter criminal conduct; and (2) the need to protect the public from future crime.⁶⁵ There is no question that protecting a mentally ill offender from himself and protecting the general public from future crime are essential government interests.⁶⁶ Therefore, once a court decides that medication is essential for the safety of the mentally ill offender or others this prong of the test is satisfied.⁶⁷

The court must then examine whether involuntary medication significantly furthers and is clearly necessary to those interests.⁶⁸ This involves a highly fact-specific inquiry into the history and characteristics of the defendant.⁶⁹ It is not sufficient to speak in generalities as to the importance of psychotropic drugs in the treatment of schizophrenia or bipolar disorder, rather the court must inquire as to the specific characteristics of the defendant before it.⁷⁰ The court must also consider whether there are “any alternative, less intrusive treatments” that are likely to achieve substantially the same results.⁷¹

⁶³ While not the universally accepted standard, it is the most onerous and, therefore, serves as the high-water mark for a constitutional analysis.

⁶⁴ *Holman*, 532 F.3d at 290.

⁶⁵ See 18 U.S.C. § 3583(d) (requiring courts to conform conditions with factors set forth in 18 U.S.C. § 3553(a)(2)(B)–(C)).

⁶⁶ See *Riggins v. Nevada*, 504 U.S. 127, 134–35 (1992); see also *Holman*, 532 F.3d at 290.

⁶⁷ See *Holman*, 532 F. 3d at 290 (finding that “[t]he government’s interest in protecting *Holman* from himself and protecting the general public from *Holman* are essential or overriding interests sufficient to support an order requiring the involuntary administration of antipsychotic drugs”).

⁶⁸ *Id.* at 289.

⁶⁹ For the factors that must be considered under statutory analysis, see 18 U.S.C. § 3553(a)(1) (the history and characteristics of the defendant), and 18 U.S.C. § 3553(a)(2)(D) (the aim of providing the defendant with “education or vocation training, medical care, or other correctional treatment in the most effective manner”); see also *Sell* factors, which require inquiry into the medical history of the offender. *Sell v. United States*, 539 U.S. 166, 184 (2003).

⁷⁰ See *Washington v. Harper*, 494 U.S. 210 (1990).

⁷¹ *Sell*, 539 U.S. at 181.

Two potentially less intrusive means must be considered. First, a district court could simply require an offender to take all prescribed medications. Upon regular check-ins, a probation officer, in partnership with a mental health professional, could assess the offender's mood and cognitive functions to determine if the offender appears compliant. Perhaps the offender could also be required to produce receipts or other documentation proving that he obtained his medications. If the probation officer and mental health professional have reason to believe the offender is not compliant, they could then order him to submit to a urine analysis.⁷²

While this alternative is unquestionably less intrusive, it is unlikely to achieve substantially similar results as a requirement that an offender take digital medication. Even if a urine analysis could deliver proof positive regarding compliance, there is the concern that after abruptly discontinuing medication an offender's thoughts would become too disordered to continue complying with other stated terms of his supervised release, specifically attending check-in meetings with his probation officer.⁷³ Critically, for an involuntary medication order to be *necessary* to further an important government interest it must be predicated upon a finding that the offender has a history of refusing medication.⁷⁴ Thus, there are sufficient grounds to argue that this less intrusive condition is "unlikely to achieve substantially the same results."⁷⁵

The second potentially less intrusive alternative is that a district court could impose a condition, similar to the one that was brought before the *Holman* court, requiring the use of intramuscular injections of an antipsychotic.⁷⁶ Studies suggest that long-acting injectable antipsychotics (LAIAs) have a number of advantages over their oral counterparts.⁷⁷ They were primarily developed to improve rates of medication adherence and to "reduce the high rates of relapses and rehospitalizations in schizophrenia due to treatment discontinuation."⁷⁸

⁷² See generally Joseph McEvoy et al., *Quantitative Levels of Aripiprazole Parent Drug and Metabolites in Urine*, 231 *PSYCHOPHARMACOLOGY* 23 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4221623/#!po=2.38095>.

⁷³ Miriam Larsen-Barr et al., *Attempting to Discontinue Antipsychotic Medication: Withdrawal Methods, Relapse and Success*, 270 *PSYCHIATRY RES.* 365, 371 (2018) (reporting that negative effects of medication withdrawal include "confusion, disassociation, disorientation" and "difficulty with functioning").

⁷⁴ See *United States v. Holman*, 532 F.3d 284, 286 (4th Cir. 2008).

⁷⁵ *Sell*, 539 U.S. at 181.

⁷⁶ *Holman*, 532 F.3d at 286.

⁷⁷ Eduard Parellada & Miquel Bioque, *Barriers to the Use of Long-Acting Injectable Antipsychotics in the Management of Schizophrenia*, 30 *CNS DRUGS* 689, 690 (2016).

⁷⁸ *Id.*

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Despite these significant advantages, there are also drawbacks to LAIAs. Because they are long-acting, it takes a greater period of time to achieve steady levels in patients.⁷⁹ Additionally, it is more difficult for a physician to adjust the dosage level if she feels her patient is not responding well to the medication.⁸⁰ Finally, there are a number of reasons why a patient might be averse to taking an LAIA, including pain at the injection site, the burden of traveling to a clinic for administration of the injections, and the perception of stigma.⁸¹

It is important to bear in mind that in *Holman*, Holman's prison psychiatrist recommended the use of LAIAs.⁸² Additionally, while in prison, Holman received injections of risperidone, the same antipsychotic specified in the condition of supervised release,⁸³ indicating that his psychiatrist knew that he tolerated the medication well. Ultimately, much of the decision around whether an LAIA is an appropriate, less intrusive treatment will bear on the recommendation of the treating physician.

Courts must also consider the patient's preference with regard to medication. Some patients prefer a monthly injection to remembering to take a pill daily.⁸⁴ This concern with missing pills is sure to be compounded by the fact that missed dosages could result in a return to prison.⁸⁵ Moreover, some patients feel burdened psychologically by their daily medication regimen, seeing it as a constant reminder of their illness.⁸⁶

Injections and digital medications are both intrusive in their own ways. In considering which form of "intrusion" outweighs the other, it is important to bear in mind that a term of supervised release does not last indefinitely.⁸⁷ Therefore, it is important to use this period of supervision to develop good habits and to encourage a system that the offender can continue on his own once the period of supervision has ended. If the offender will have difficulty traveling to a clinic monthly to

⁷⁹ Sofia Brissos et al., *The Role of Long-Acting Injectable Antipsychotics in Schizophrenia: A Critical Appraisal*, 4 THERAPEUTIC ADVANCES IN PSYCHOPHARMACOLOGY 198, 201 (2014).

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *United States v. Holman*, 532 F.3d 284, 286 (4th Cir. 2008).

⁸³ *Id.*

⁸⁴ Parellada & Bioque, *supra* note 77, at 693.

⁸⁵ 18 U.S.C. § 3583(e)(3) ("[T]he court may . . . revoke a term of supervised release, and require the defendant to serve in prison all or part of the term of supervised release . . . if the court . . . finds by a preponderance of the evidence that the defendant violated a condition of supervised release. . . .")

⁸⁶ Parellada & Bioque, *supra* note 77, at 694.

⁸⁷ 18 U.S.C. § 3583(b) (authorized terms of supervised release).

receive his injection or believes monthly injections are particularly stigmatizing, then it makes little sense to compel him to adhere to a treatment regime he will likely abandon once the term of supervised release ends. The “least intrusive” condition, therefore, will consider both the treating physician’s recommendation and the patient’s preference.

Finally, the court must determine medical appropriateness by looking at whether the condition is in the patient’s best medical interest.⁸⁸ Because symptoms of schizophrenia can include paranoia and delusions, some mental health professionals fear that forcing patients to use a system that will “monitor their behavior and send signals out of their body” could exacerbate their conditions and be detrimental to their prognoses.⁸⁹ Thus, before any such condition could be imposed on an offender, his psychiatrist must determine that he is an appropriate candidate for digital medication. Additionally, probation officers should make every effort to have a conversation with the offender and his mental health professional to explain the capabilities of the technology and the limited data that it can store and transmit.⁹⁰ Knowing the system is not transmitting any sensitive medical data should hopefully assuage some of the patient’s concerns.⁹¹

C. *The Monitoring Component of the Digital Pill Also Passes Constitutional Muster*

As stated above, the digital pill is more than just an antipsychotic medication, it also contains a monitoring component.⁹² Technologies related to electronically monitoring individuals typically fall into two categories—electronic location monitors and chemical substance monitors.⁹³ Courts routinely impose both types of electronic monitors as a form of enhanced surveillance during probation or supervised release.⁹⁴

⁸⁸ *Sell v. United States*, 539 U.S. 166, 181 (2003).

⁸⁹ *Id.*

⁹⁰ *See* Caliendo & Hilas, *supra* note 4.

⁹¹ While information regarding the patient’s activity levels, heart rate, and body temperature is automatically collected by the system, the patient can decline to share this information with third parties. *Terms & Conditions of Use and Patient Privacy Notice*, ABILIFY MYCITE 11, 14 (Jan. 1, 2018), <https://www.otsuka-us.com/media/static/Abilify-Mycite-Patient-Terms-of-Use-and-Privacy-Notice.pdf>.

⁹² Caliendo & Hilas, *supra* note 4.

⁹³ Erin Murphy, *Paradigms of Restraint*, 57 DUKE L.J. 1321, 1332 (2008).

⁹⁴ *Id.*

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Electronic location monitors typically work by either setting parameters for where an individual can or cannot go or by giving precise information about an offender's location that can either be reviewed later or in real time.⁹⁵ All fifty states, the District of Columbia, and the federal government use electronic location monitors to track the movements and activities of either pretrial defendants or offenders on probation or supervised release.⁹⁶ Many of the state provisions are based on broad categories, such as the nature of the offense, rather than on an "individualized determination of the dangerousness or likely recidivism" of a particular offender.⁹⁷

One of the most prevalently used chemical substance monitors is SCRAM, the secure continuous remote alcohol monitor.⁹⁸ Often imposed as a condition for incorrigible drunk drivers, the monitor attaches to the offender's ankle and tests the alcohol concentration levels in the person's sweat on an hourly basis.⁹⁹ It then date and time stamps the data before storing it for transmission, typically to the offender's probation officer, via the offender's home phone.¹⁰⁰

Given the purpose and functionality of the SCRAM device—to monitor the ingestion of certain substances and to transmit relevant data regarding same to the offender's probation officer via the offender's phone—it would appear that digital medication can be most closely analogized to this type of monitoring device. This would suggest that the monitoring component of the digital pill is on solid constitutional footing. In *Diehl v. Parole Bd.*,¹⁰¹ for instance, Magistrate Judge Joseph G. Scoville of the Western District of Michigan found the SCRAM device to be "just another method to monitor a parolee's alcohol use, no different in kind from random urine testing."¹⁰² Reasoning that parolees have no Fourth Amendment right to be free from random drug testing¹⁰³—indeed, in the federal context, it is a required term of

⁹⁵ *Id.* at 1332–33.

⁹⁶ Stephanie Fahy et al., *Use of Electronic Offender-Tracking Devices Expands Sharply*, PEW CHARITABLE TRUSTS, (Sept. 7, 2016), <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2016/09/use-of-electronic-offender-tracking-devices-expands-sharply>.

⁹⁷ Murphy, *supra* note 93, at 1333.

⁹⁸ *Id.* at 1334.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ No. 1:12-cv-402, 2012 U.S. Dist. LEXIS 91059 (W.D. Mich. May 4, 2012), *adopted*, 2012 U.S. Dist. LEXIS 90182 (W.D. Mich. June 29, 2012).

¹⁰² *Id.* at *7.

¹⁰³ *Id.* at *7–8 (citing *Skinner v. Railway Labor Executives' Ass'n*, 489 U.S. 602 (1989)).

supervised release¹⁰⁴—Magistrate Judge Scoville found that the imposition of SCRAM did not violate the offender’s Fourth Amendment right to be secure from unreasonable searches and seizures.¹⁰⁵ Applying the same reasoning to digital medication, because the same results could be achieved through random urine testing, it would follow that the monitoring component of the digital pill would not violate an offender’s Fourth Amendment rights.¹⁰⁶

Indeed, if a special condition requiring compliance with digital medication were to survive the demanding strict scrutiny test that governs challenges brought on substantive due process grounds, it is an almost foregone conclusion that the condition would also survive a challenge under the Fourth Amendment. In the Fourth Amendment context, the state merely needs to show that the search was “reasonable” after considering the individual’s right to privacy, on the one hand, and the government’s legitimate interests, on the other.¹⁰⁷ This highly deferential standard is rendered even more so in the context of a condition of parole or probation. The Court has held that parolees do not enjoy “the absolute liberty to which every citizen is entitled.”¹⁰⁸ A parolee’s expectation of privacy is even further diminished when he is clearly informed of the condition of parole that infringes on his privacy interest.¹⁰⁹ Given this deferential standard, compounded with the wide latitude district courts are afforded when crafting special conditions of supervised release,¹¹⁰ it is not surprising that, while relatively common, Fourth Amendment challenges to terms of supervised release are by and large unsuccessful.¹¹¹

¹⁰⁴ 18 U.S.C. § 3583(d) (a presumptive mandatory condition of supervised release is that the offender submit to at least three periodic drug tests).

¹⁰⁵ U.S. CONST. amend. IV.

¹⁰⁶ Additional challenges focus on whether SCRAM evidence is sufficiently reliable to be admitted. *See, e.g.,* *People v. Dorcent*, 909 N.Y.S.2d 618 (Kings Cty. Crim. Ct. Oct. 22, 2010). Evidentiary standards are beyond the scope of this Comment.

¹⁰⁷ *Samson v. California*, 547 U.S. 843, 848 (2006).

¹⁰⁸ *United States v. Knights*, 534 U.S. 112, 119 (2001) (quoting *Morrissey v. Brewer*, 408 U.S. 471, 480 (1972)).

¹⁰⁹ *Id.*

¹¹⁰ *United States v. Dotson*, 324 F.3d 256, 259–60 (4th Cir. 2003) (citing *United States v. Crandon*, 173 F.3d 122, 127 (3d Cir. 1999)); *United States v. Bee*, 162 F.3d 1232, 1234 (9th Cir. 1998) (stating that district courts have “broad discretion” when imposing terms of supervised release, even when it comes to “restrictions that infringe on fundamental rights”).

¹¹¹ *See* Naomi M. Weinstein, *The Legal Aspects of Conditional Release in the Criminal and Civil Court System*, 32 BEHAV. SCI. & L. 666, 672 (2014).

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Certain instruments of monitoring, such as the electronic location monitoring of sex offenders or registry statutes, are also commonly challenged¹¹² under the Ex Post Facto Clause.¹¹³ The Ex Post Facto Clause bars application of a law “that changes the punishment, and inflicts a greater punishment, than the law annexed to the crime when committed.”¹¹⁴ To prevail on an ex post facto claim, a defendant must show (1) that the law operates retroactively, and (2) that the law works to increase the penalty from what it was at the time he committed the crime.¹¹⁵ More often than not, these challenges fail, as reviewing courts have repeatedly held that even the most draconian civil statutes¹¹⁶ are regulatory in nature—not punitive—and, therefore, not ex post facto laws.¹¹⁷ To determine whether a law is regulatory or punitive, courts first and foremost look to the intent of the legislature.¹¹⁸ If it is clear the intent was to impose punishment, “that ends the inquiry.”¹¹⁹ If the intention was to enact a “civil and nonpunitive” regulatory scheme,¹²⁰ the courts will apply the multifactor test elucidated in *Kennedy v. Mendoza-Martinez*¹²¹ to ensure that the purpose or effect of the regulation is not so punitive as to overcome the deference extended to the legislature.¹²² Key to this analysis is an inquiry into the principal

¹¹² See John Kip Cornwell, *Sex Offender Residency Restrictions: Government Regulation of Public Health, Safety, and Morality*, 24 WM. & MARY BILL OF RTS. J. 1, 16 (2015); see also Murphy, *supra* note 93, at 1347.

¹¹³ U.S. CONST. art. I, § 9, cl. 3.

¹¹⁴ *Johnson v. United States*, 529 U.S. 694, 699 (2000) (quoting *Calder v. Bull*, 3 U.S. 386, 390 (1798)).

¹¹⁵ *Id.*

¹¹⁶ This Comment does not address the use of digital medication outside the confines of the formal criminal process. Accordingly, further exploration is needed regarding the potential uses of digital medication in the civil preventative outpatient commitment context. See generally John Kip Cornwell & Raymond Deeney, *Exposing the Myths Surrounding Preventative Outpatient Commitment for Individuals with Chronic Mental Illness*, 9 PSYCHOL. PUB. POL’Y & L. (2003).

¹¹⁷ See, e.g., *Smith v. Doe*, 538 U.S. 84, 105–06 (2003) (holding that the Alaska Sex Offender Registration Act was designed to be a civil, nonpunitive way of identifying past offenders for the purpose of protecting the public from the risk of recidivism); *Belleau v. Wall*, F.3d 929, 937 (7th Cir. 2016) (finding a Wisconsin law that imposed a condition of lifetime electronic monitoring for sex offenders released from civil commitment to be prevention and not punishment).

¹¹⁸ *Smith*, 538 U.S. at 93.

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ 372 U.S. 144, 165–66 (1963) (factors include whether the sanction “has historically been regarded as a punishment;” whether its operation will further the traditional aims of punishment, namely retribution and deterrence; “whether the behavior to which it applies is already a crime;” and whether it appears to be excessive in nature).

¹²² *Smith*, 538 U.S. at 93.

aims of the condition of supervised release, as evidenced by the number of courts that have consistently held that conditions of supervised release should not be regarded as punishment if they “further the deterrent, protective and rehabilitative goals of sentencing.”¹²³ Additionally, the Supreme Court in *Kansas v. Hendricks*¹²⁴ found that for a law to be punitive it must further punitive goals: either “affix culpability for prior criminal conduct” or deter future crime.¹²⁵ While a special condition requiring digital medication compliance does potentially deter future crime, it also furthers nonpunitive goals, such as ensuring proper mental health treatment and the safety of the offender and the community at large.¹²⁶ Given this precedent, it is probable that a condition imposing digital medication would be regarded as regulatory and, therefore, would not be an ex post facto law.

Assuming arguendo that a special condition of supervised release requiring compliance with digital medication is punitive,¹²⁷ such a condition is subject to scrutiny under the Ex Post Facto Clause. It is unlikely that such a claim will succeed, however. First, the Court has held that the Clause “looks to the standard of punishment prescribed by a statute rather than to the sentence actually imposed.”¹²⁸ While digital medication introduces another mode of ensuring compliance with antipsychotic medication, the standard that governs when a court could impose such a condition remains unchanged. Additionally, courts have held that there is no ex post facto prohibition on laws that change only the procedures by which a case is adjudicated while leaving unchanged the “substantive law of crimes.”¹²⁹ A change in the methodology by

¹²³ *United States v. Jackson*, 189 F.3d 820, 824 (9th Cir. 1999) (citing *United States v. Eyler*, 67 F.3d 1386, 1393 (9th Cir. 1995)); *see also* *United States v. Winston*, 850 F.3d 377, 382 (8th Cir. 2017); *United States v. Hook*, 471 F.3d 766, 776 (7th Cir. 2006).

¹²⁴ 521 U.S. 346 (1997).

¹²⁵ *Id.* at 362.

¹²⁶ *See Winston*, 850 F.3d at 381–82 for the proposition that a finding that a condition furthers goals of deterrence is not necessarily determinative that a law is punitive in nature.

¹²⁷ Certain factors support a finding that such a special condition would be punitive, including: (1) 18 U.S.C. § 3583, the statute addressing terms of supervised release after imprisonment, is codified in Title 18, Crime and Criminal Procedure, evincing a legislative intent that the statute should be construed as penal in nature; and (2) courts and commentators have discussed supervised release as being an integral part of the penal sentencing scheme. *See United States v. Larson*, 402 Fed. Appx. 349, 354 (2010); *see also* Byran R. Diederich, *Risking Retroactive Punishment: Modifications of the Supervised Release Statute and the Ex Post Facto Prohibition*, 99 COLUM L. REV. 1551, 1554 (1999) (commenting that supervised release is an integral part of federal sentencing scheme).

¹²⁸ *Lindsey v. Washington*, 301 U.S. 397, 401 (1937).

¹²⁹ *Collins v. Youngblood*, 497 U.S. 37, 45 (1990).

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which courts oversee medication compliance can be analogized to a procedural alteration, rather than a substantive one. As stated above, the “substance” of this additional form of punishment—if indeed, that is what it is—namely, the statutory and constitutional constructs that govern when a court can impose such a condition, remains unchanged. Therefore, even if a special condition mandating use of digital medication can be properly considered punitive, it does not offend the Ex Post Facto Clause.

III. A CONDITION OF RELEASE MANDATING USE OF DIGITAL MEDICATION REPRESENTS GOOD POLICY

As the previous Part showed, a district court must first make a finding that an offender is a danger to himself or others before imposing a condition of involuntary medication, whether it be digital medication or otherwise.¹³⁰ Thus, the requisite condition for any such term of supervised release reflects what is perhaps the primary benefit of compulsory medication—keeping people, both the offender and the public at large, safe.

Separate and apart from ensuring the health and safety of the offender and those individuals he comes into contact with, digital medication could also be an important and effective tool to ameliorate some of the intense strain placed on both our criminal justice and mental health systems. The hope is that digital medication will help ensure that offenders on supervised release remain stable, thereby reducing the very high rates of recidivism among the mentally ill offender population¹³¹ and hopefully preventing mental health crises that divert critical resources away from a severely underserved population.¹³²

¹³⁰ See *supra* Section II.A.

¹³¹ Matthew E. Hirschtritt & Renee L. Binder, *Interrupting the Mental Illness-Incarceration-Recidivism Cycle*, 317 J. AM. MED. ASS'N. 695, 696 (Feb. 21, 2017) (noting that the rate of recidivism for mentally ill offenders is nearly twice the national average; 53 percent for mentally ill offenders compared to 30 percent for offenders without a history of mental illness); see also JENNIFER BRONSON & MARCUS BERZOFKY, U.S. DEP'T. OF JUSTICE, INDICATORS OF MENTAL HEALTH PROBLEMS REPORTED BY PRISONERS AND JAIL INMATES, 2011–12, 7 (2017) (finding that prisoners with multiple arrests were more likely to have a history of a mental health problem than prisoners with one arrest and that almost half of those surveyed with a history of a mental health problem had been arrested 11 times or more).

¹³² TREATMENT ADVOCACY CTR., EMPTYING THE 'NEW ASYLUMS:' A BEDS CAPACITY MODEL TO REDUCE MENTAL ILLNESS BEHIND BARS 5–6 (Jan. 2017) [hereinafter EMPTYING THE NEW ASYLUMS], <https://www.treatmentadvocacycenter.org/storage/documents/emptying-new-asylums.pdf>.

A. *Schizophrenia and Bipolar Disorder*

Many Departments of Corrections, including the Federal Bureau of Prisons (BOP), classify a wide spectrum of mental disorders as “serious mental illnesses.”¹³³ This Comment will focus on two specific diagnoses, both of which are treated with the digital pill—schizophrenia and bipolar disorder.¹³⁴

Schizophrenia is a chronic mental illness characterized by “delusions, hallucinations, disorganized speech and behavior, and other symptoms that cause social or occupational dysfunction.”¹³⁵ Schizophrenia requires long-term treatment, which is usually comprised of both antipsychotics and therapy.¹³⁶ Similarly, bipolar disorder is a chronic mental illness, typically treated with medications.¹³⁷ Those who suffer from bipolar disorder, also referred to as manic-depressive illness, experience dramatic fluctuations in mood and energy levels.¹³⁸ Symptoms of bipolar disorder include alternating periods of depression and “mania,” characterized by increased activity, racing thoughts, and impulsive behavior.¹³⁹

As noted *supra*, non-adherence to medication regimes is endemic to the treatment of both schizophrenia and bipolar disorder.¹⁴⁰ “Non-

¹³³ OFFICE OF THE INSPECTOR GEN., U.S. DEP’T OF JUSTICE, REVIEW OF THE FEDERAL BUREAU OF PRISONS’ USE OF RESTRICTIVE HOUSING FOR INMATES WITH MENTAL ILLNESS 5 n.18 (2017) (BOP policy lists schizophrenia, bipolar and related disorders, and major depressive disorder as diagnoses generally classified as serious mental illnesses. Other diagnoses such as anxiety disorders, autism spectrum disorders, and personality disorders, to name but a few, are additional diagnoses that can be classified as serious mental illness, particularly if the condition is “sufficiently severe, persistent, and disabling”).

¹³⁴ Bipolar disorder is a category that encompasses three related diagnoses—bipolar I, bipolar II, and cyclothymic disorder. *What Is Bipolar Disorder?*, AM. PSYCHIATRIC ASS’N [hereinafter *What is Bipolar Disorder?*], <https://www.psychiatry.org/patients-families/bipolar-disorders/what-are-bipolar-disorders> (last visited Apr. 3, 2021). The digital pill is only indicated to treat bipolar I disorder, however, many of the statistics regarding offenders with serious mental illness lump these diagnoses together referring to them, collectively, as “bipolar disorder(s).” Therefore, it should be noted that only a segment of this offender population could potentially be treated by the digital pill. *See Product Information, supra* note 9.

¹³⁵ *DSM-5 Fact Sheet: Schizophrenia*, AM. PSYCHIATRIC ASS’N, <https://www.psychiatry.org/psychiatrists/practice/dsm/educational-resources/dsm-5-fact-sheets> (last visited Sept. 19, 2019).

¹³⁶ Xiang Cong Tham et al., *Factors Affecting Medication Adherence Among Adults With Schizophrenia: A Literature Review*, 30 ARCHIVES OF PSYCHIATRIC NURSING 797, 797 (2016).

¹³⁷ *What Is Bipolar Disorder?*, *supra* note 134.

¹³⁸ *Id.*

¹³⁹ *Press Release, FDA, supra* note 1.

¹⁴⁰ Brown & Gray, *supra* note 12, at 192; *see also* Colom et al., *supra* note 12, at 24.

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adherence is the most powerful predictor of relapse,”¹⁴¹ which can have profound ramifications, not only for the individual patient but for the health care system as a whole. It is estimated that non-adherence to medication costs approximately \$100 billion per year, attributable to the increased cost of treatment and hospitalization.¹⁴² Use of the digital pill allows for transparency and accountability to help ensure that the patient is regularly taking his medication. This is not only imperative to treating the patient’s mental illness but is also beneficial to our strained mental health care system.

B. Prisons and Jails as the “New Asylums”¹⁴³

The mid-twentieth century saw a movement toward the deinstitutionalization of the mentally ill.¹⁴⁴ Advancements in psychotropic medications and psychotherapy shepherded in a dramatic shift away from “warehousing” the mentally ill in hospitals and institutions to treating them in comprehensive community mental health centers.¹⁴⁵ With the passage of the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, community-based care became the standard of mental health treatment.¹⁴⁶ The Act provided for the construction of 2,000 community health centers by 1980 and anticipated a growth rate of one center for every increase of 100,000 to the population.¹⁴⁷ As of 2017, there were approximately 2,500 such community mental health centers.¹⁴⁸

While the construction of community centers has not kept pace with the growing need, the number of state hospital beds for the mentally ill has sharply declined over the past sixty years.¹⁴⁹ The dire

¹⁴¹ Brown & Gray, *supra* note 12, at 193; *see also* Tham et al., *supra* note 136, at 797 (citing the main reason for relapse in schizophrenics to be non-adherence to antipsychotics).

¹⁴² *See* Belluck, *supra* note 14.

¹⁴³ EMPTYING THE NEW ASYLUMS, *supra* note 132.

¹⁴⁴ *See, e.g., Deinstitutionalization, Mental Illness, and Medications: Hearing Before the Comm. on Finance*, 103rd Cong. 1 (1994) [hereinafter *Hearing*] (statement of Sen. Daniel Patrick Moynihan, Chairman, S. Comm. on Finance).

¹⁴⁵ NATIONAL COUNCIL FOR BEHAVIORAL HEALTH, <https://www.thenationalcouncil.org/about/national-mental-health-association/overview/community-mental-health-act> (last visited Sept. 20, 2019).

¹⁴⁶ Pub. L. No. 88-164, 77 Stat. 282 (1963).

¹⁴⁷ *Hearing, supra* note 144, at 2 (statement of Sen. Daniel Patrick Moynihan, Chairman, S. Comm. on Finance).

¹⁴⁸ DEPT. OF HEALTH & HUMAN SERVICES, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMIN., NATIONAL MENTAL HEALTH SERVICES STUDY (N-MHSS): DATA ON MENTAL HEALTH TREATMENT FACILITIES 36 (2017), https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/2017_National_Mental_Health_Services_Survey.pdf.

¹⁴⁹ EMPTYING THE NEW ASYLUMS, *supra* note 132, at 5.

lack of space and resources means that “[i]n 44 states and the District of Columbia, a prison or jail holds more individuals with serious mental illness than the largest remaining state psychiatric hospital.”¹⁵⁰ This translates to almost 400,000 men and women, suffering from a mental health condition, being held in U.S. jails and prisons.¹⁵¹ Put in the context of the entire prison and jail population, approximately 37 percent of state and federal prisoners and 44 percent of jail inmates, respectively, reported a history of a mental health problem.¹⁵² Of those respective populations, 18 percent of prisoners and 25 percent of jail inmates reported a history of bipolar disorder, and 9 percent of prisoners and 12 percent of jail inmates reported a history of schizophrenia or another psychotic disorder.¹⁵³ When compared to the paltry percentages of the U.S. general population who have received these diagnoses—2.8 percent for bipolar disorder and 0.25-0.64 percent for schizophrenia¹⁵⁴—it is evident that persons suffering from these serious mental health diagnoses are severely overrepresented in our nation’s jails and prisons. The staggering rate of incarceration in the mentally ill community is exacerbated by the very high rates of recidivism that characterize this population.¹⁵⁵ The digital pill can help stem the tide of recidivism, and thereby reduce rates of incarceration, by providing a mechanism to help ensure that mentally ill offenders remain stable on their medication.

*C. Improving Mental Health Outcomes for Mentally Ill Offenders
Will Help Close the Revolving Door of Prisons*

The mentally ill are particularly susceptible to the physical, emotional, and psychological stresses of incarceration, which lead them to further decompensate.¹⁵⁶ The stresses of institutional life can manifest in myriad ways, including violence. A 2017 special report from

¹⁵⁰ TREATMENT ADVOCACY CTR., GOING, GOING, GONE: TRENDS AND CONSEQUENCES OF ELIMINATING STATE PSYCHIATRIC BEDS 9 (June 2016), <https://www.treatmentadvocacycenter.org/storage/documents/going-going-gone.pdf>.

¹⁵¹ EMPTYING THE NEW ASYLUMS, *supra* note 132, at 1.

¹⁵² BRONSON & BERZOFKY, *supra* note 131, at 1.

¹⁵³ *Id.* at 3.

¹⁵⁴ *Mental Health Information: Statistics (Schizophrenia)*, NAT’L INST. OF MENTAL HEALTH, https://www.nimh.nih.gov/health/statistics/schizophrenia.shtml#part_154880 (last visited Nov. 3, 2019); *Mental Health Information: Statistics (Bipolar Disorder)*, NAT’L INST. OF MENTAL HEALTH, https://www.nimh.nih.gov/health/statistics/bipolar-disorder.shtml#part_155460 (last visited Nov. 3, 2019).

¹⁵⁵ See Hirschrift & Binder, *supra* note 131, at 696.

¹⁵⁶ See Fellner, *supra* note 19, at 391 (2006); see also *Jailing People with Mental Illness*, NAT’L ALL. ON MENTAL ILLNESS, <https://www.nami.org/learn-more/public-policy/jailing-people-with-mental-illness> (last visited Oct. 25, 2019).

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the U.S. Department of Justice stated that prisoners and jail inmates with a history of severe mental illness were more likely to have been charged with assault compared to prisoners and inmates with no such history.¹⁵⁷ A strong argument could be made that at least some of this violence is preemptive, as the mentally ill all too often find themselves the targets of both sexual and physical violence.¹⁵⁸ Sadly, but perhaps not surprising given these realities of life behind bars, prisoners with mental illness are more likely to attempt or complete suicide, which is the leading cause of death in U.S. jails.¹⁵⁹

Additionally, the disorganized thought processes and poor impulse control that characterize schizophrenia and bipolar disorder also make it difficult for mentally ill prisoners to conform their behavior to the strict requirements of institutionalized life.¹⁶⁰ Consequently, mentally ill prisoners are more likely to receive disciplinary infractions while in prison.¹⁶¹ And it is not just the symptoms of mental illness that make incarceration particularly hard on these prisoners, but also the rigid and punitive characteristics of incarceration itself, which are inherently at odds with the mental health needs of this population.¹⁶²

Perhaps most troubling, all of these factors that characterize a mentally ill offender's experience in prison—the increased likelihood of victimization, the difficulty in adhering to the rigidity of incarceration, and concerns that the offender may be a risk to himself or others—are also all reasons why offenders find themselves in solitary confinement.¹⁶³ Solitary confinement is shown to have devastating

¹⁵⁷ BRONSON & BERZOFKY, *supra* note 131, at 9.

¹⁵⁸ Marshall T. Bewley & Robert D. Morgan, *A National Survey of Mental Health Services Available to Offenders with Mental Illness: Who is Doing What?* 35 LAW HUM. BEHAV. 351, 352 (2011).

¹⁵⁹ EMPTYING THE NEW ASYLUMS, *supra* note 132, at 1.

¹⁶⁰ Kenneth Adams & Joseph Ferrandino, *Managing Mentally Ill Inmates in Prison*, 35 CRIM. JUST. & BEHAV. 913, 917 (2008).

¹⁶¹ Bewley & Morgan, *supra* note 158, at 352.

¹⁶² Fellner, *supra* note 19, at 391 (noting that it is “nearly impossible” to coordinate the needs of the mentally ill with rules and goals reflecting “staff concerns about security, safety, power, and control”); *see also* Adams & Ferrandino, *supra* note 160, at 914 (quoting a report from the Oregon Department of Corrections acknowledging that “finding safe, humane, and non-punitive methods for handling inmates who are experiencing the symptoms of mental illness is an ongoing challenge for prison administrators”).

¹⁶³ *See Reassessing Solitary Confinement: The Human Rights, Fiscal and Public Safety Consequences: Hearing Before the Subcomm. on the Constitution, Civil Rights, and Human Rights of S. Comm. on the Judiciary*, 112th Cong. 712 (2012) (statement of Michael Jacobson, President & Director, Vera Institute of Justice) (noting that solitary confinement is most commonly used in the United States: (1) “to punish prisoners for rule violations;” (2) to isolate those prisoners believed to be a risk to the safety of others

consequences for a person's mental health.¹⁶⁴ BOP's policy "recognizes that an inmate's mental health may deteriorate during restrictive housing placement."¹⁶⁵ Symptoms such as social anxiety, depression, a decline in cognitive abilities, and instances of self-harm and suicide, have been exhibited by even those prisoners who entered solitary without a diagnosis of mental illness.¹⁶⁶

The psychological harm endemic to solitary confinement is why, in 2011, the U.N. Special Rapporteur of the Human Rights Council issued an interim report stating that imposition of solitary confinement on persons with mental disabilities constitutes "cruel, inhuman or degrading treatment," which violates the Convention against Torture.¹⁶⁷ Despite those recommendations, a 2017 investigation of federal prisoners conducted by the Office of the Inspector General found that even though the BOP's official policy denounces solitary confinement, prisoners, including those with mental illness, were housed in single cells for extended periods with very little human contact.¹⁶⁸ And the problem of the mentally ill being held in solitary confinement is not unique to the federal penal system; similar observations have been noted in state systems as well.¹⁶⁹

The mental decompensation that is an almost inevitable byproduct of solitary confinement is deeply disconcerting, not only for the health of the individuals who must endure such conditions but for the safety and security of the community at large. Particularly problematic are reports that inmates with mental illness are released directly from solitary confinement into the community, some of whom have spent

or to the security of the institution; and (3) to protect those thought to be at risk from other members of the general population).

¹⁶⁴ OFFICE OF THE INSPECTOR GEN., *supra* note 133, at 1.

¹⁶⁵ *Id.* (citing BOP Program Statement 5310.16, Treatment and Care of Inmates with Mental Illness (May 1, 2014)). Restrictive housing, often a euphemism for solitary confinement, consists of the placement in a locked room or cell for twenty-two hours or more a day; however, under the U.S. Department of Justice's definition of restrictive housing, it could include being housed under such conditions with another inmate. *Id.*

¹⁶⁶ Sarah Childress, *Craig Haney: Solitary Confinement is a "Tried-and-True" Torture Device*, FRONTLINE, PBS (Apr. 22, 2014), <https://www.pbs.org/wgbh/frontline/article/craig-haney-solitary-confinement-is-a-tried-and-true-torture-device>.

¹⁶⁷ Juan E. Méndez (Special Rapporteur), Interim Rep. of the Special Rapporteur of the Human Rights Council on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, 21, U.N. Doc. A/66/268 (Aug. 5, 2011), <http://solitaryconfinement.org/uploads/SpecRapTortureAug2011.pdf>.

¹⁶⁸ OFFICE OF THE INSPECTOR GEN., *supra* note 133, at i.

¹⁶⁹ See Childress, *supra* note 166 (commenting on being "taken aback" by the number of seemingly mental ill offenders housed in solitary confinement in Pelican Bay State Prison in California during the early 1990s).

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years in isolation.¹⁷⁰ Both experts and prison officials maintain that failing to re-socialize inmates before release into the community is troubling,¹⁷¹ and can have disastrous consequences.¹⁷²

All of these are reasons why the criminal justice system should utilize innovative tools, such as the digital pill, to ensure that mentally ill offenders are receiving proper treatment once released and help stem the likelihood of recidivism.¹⁷³

D. *Reducing Recidivism Improves Prison Conditions for All*¹⁷⁴

There are approximately 2.2 million people incarcerated in our nation's jails and prisons, which equates to a 500 percent increase over the last forty years.¹⁷⁵ Concurrent with this increase in the overall population, the number of people with serious mental illness entering the criminal justice system has also increased exponentially.¹⁷⁶

Some jurisdictions have tried to mitigate this disturbing trend by instituting mental health courts to provide more specialized attention to this vulnerable population.¹⁷⁷ While the number of mental health courts has been slowly increasing over the past twenty years, and

¹⁷⁰ OFFICE OF THE INSPECTOR GEN., *supra* note 133, at 27.

¹⁷¹ *Id.*; see also Childress, *supra* note 166.

¹⁷² See Rick Raemisch, *Why We Ended Long-Term Solitary Confinement in Colorado*, N.Y. TIMES (Oct. 12, 2017), <https://www.nytimes.com/2017/10/12/opinion/solitary-confinement-colorado-prison.html> (remembering Tom Clements, the former executive director of the Colorado Department of Corrections who, in 2013, was assassinated by a former prisoner who had been released directly into the community after spending seven years in solitary confinement).

¹⁷³ This Comment does not suggest that digital medication should curtail the important work being done to restrict the use of solitary confinement. Rather, it recognizes that while this uphill battle ensues, the criminal justice system should explore all alternatives to reduce the numbers of mentally ill people in our prisons and jails and, in turn, solitary confinement.

¹⁷⁴ The author would like to reiterate that nothing in this Comment proposes that digital medication is a quick fix for the myriad shortcomings of our criminal justice and mental health systems. There is no question that comprehensive reform is needed to reduce our staggering prison population, particularly with regard to diverting vulnerable populations, like those suffering from mental illness and substance abuse disorders, away from the criminal justice system and into programs that provide them with holistic care. This Comment merely suggests that the digital pill may help a small segment of offenders who may benefit from closer supervision while adjusting to life in a non-institutional setting.

¹⁷⁵ THE SENTENCING PROJECT, FACT SHEET: TRENDS IN U.S. CORRECTIONS, <https://www.sentencingproject.org/wp-content/uploads/2020/08/Trends-in-US-Corrections.pdf> (last updated Oct. 2020).

¹⁷⁶ See Fellner, *supra* note 19, at 392–94.

¹⁷⁷ Desmond Loong et al., *The Effectiveness of Mental Health Courts in Reducing Recidivism and Police Contact: A Systematic Review*, COMMUNITY MENTAL HEALTH J. (June 2019), <https://doi.org/10.1007/s10597-019-00421-9>.

although recent data suggests that these courts help reduce rates of recidivism and improve offender outcomes,¹⁷⁸ state and federal correctional systems remain overwhelmed with staggering numbers of mentally ill inmates.¹⁷⁹ While mentally ill prisoners are omnipresent throughout both state and federal correctional institutions, a recent study suggests that only twenty percent of mentally ill offenders reported receiving any mental health treatment while incarcerated.¹⁸⁰

In 2014, BOP attempted to address the failings of the federal system to provide mental health treatment, issuing a new policy that provided for more comprehensive care and treatment for mentally ill offenders.¹⁸¹ This well-intentioned and much-needed policy, however, may have had a perverse effect. A 2017 report from the Office of the Inspector General found that BOP had not provided sufficient resources to implement their new policy and, consequently, mental health staff at federal prisons may have deliberately reduced the number of prisoners classified as seriously mentally ill to alleviate some of this additional workload.¹⁸² The report went on to find that, even when prisoners were properly classified, mental health staff shortages resulted in some inmates with mental illness not receiving adequate care.¹⁸³

Not only is this extremely troubling for the individual patients who are not getting the care they need, but this failure to provide proper treatment could have ramifications for the prison system as a whole. In the seminal case, *Estelle v. Gamble*, the Court held that “deliberate indifference to serious medical needs of prisoners constitutes . . . ‘unnecessary and wanton infliction of pain,’” prohibited by the Eighth

¹⁷⁸ *Id.*

¹⁷⁹ See Adams & Ferrandino, *supra* note 160, at 913; see also Fellner, *supra* note 19, at 394.

¹⁸⁰ Jane C. Daquin & Leah E. Daigle, *Mental Disorder and Victimization in Prison: Examining the Role of Mental Health Treatment*, 28 CRIM. BEHAV. AND MENTAL HEALTH 141, 149 (2018).

¹⁸¹ OFFICE OF THE INSPECTOR GEN., *supra* note 133, at 37.

¹⁸² *Id.* (finding that while the number of inmates requiring some level of mental health care remained relatively stagnant over the course of four years, the number of inmates classified as needing such care decreased approximately thirty percent in the year after the new policy was issued).

¹⁸³ *Id.* at 37, 41 (quoting interview with BOP Chief Psychologist where he admitted that mental health staff shortages resulted in people “reducing care levels in order to survive”); see also Christie Thompson & Taylor Elizabeth Eldridge, *Treatment Denied: The Mental Health Crisis in Federal Prisons*, THE MARSHALL PROJECT (Nov. 21, 2018), <https://www.themarshallproject.org/2018/11/21/treatment-denied-the-mental-health-crisis-in-federal-prisons> (statement from BOP psychologist that psychologists were often required to man gun towers or perform prisoner escorts, lamenting, “[w]e’re not really devoted to treating”).

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Amendment.¹⁸⁴ Subsequent circuit court decisions have held that when analyzing whether the level of care meets constitutional standards, there is to be no distinction drawn between physical and mental health care.¹⁸⁵ Additionally, federal courts have held that maintaining mental health staff in “sufficient numbers to identify and treat in an individualized manner those treatable inmates suffering from serious mental disorders” is essential to constitutionally adequate mental health care.¹⁸⁶

In *Coleman v. Wilson*, the Eastern District of California found that the California Department of Corrections’ “significant” and “chronic” understaffing of its mental health care services violated the Eighth Amendment.¹⁸⁷ This chronic understaffing was only one of the myriad constitutional violations that led to the appointment of a Special Master to oversee the implementation of remedial measures designed to cure these violations.¹⁸⁸ “In 2007, 12 years after his appointment, the Special Master in *Coleman*” issued a report detailing the “deteriorating” state of mental health care in California’s prison system, ascribing this decline to the severe overcrowding in the prison system.¹⁸⁹ Confronted with a similar scathing report from the Receiver in *Plata v. Brown*, a related case concerning the condition of medical care in California prisons, the *Coleman* and *Plata* plaintiffs moved their respective district courts to convene a three-judge panel to order the California Department of Corrections to reduce the state’s prison population.¹⁹⁰ The three-judge panel, under power of the Prison Litigation Reform Act, ordered California to reduce its prison population to 137.5% of design capacity, a reduction which equated to approximately 38,000 to 46,000 prisoners within two years.¹⁹¹ On appeal, the Court, while recognizing that the potential release of such a large number of prisoners “is a matter of undoubted, grave concern,”¹⁹² upheld the panel’s order, finding that the “mental health care provided by California’s prisons falls below the

¹⁸⁴ *Estelle v. Gamble*, 429 U.S. 97, 104 (1976) (citing *Gregg v. Georgia*, 428 U.S. 153, 173 (1976)).

¹⁸⁵ *See Doty v. Cty. of Lassen*, 37 F.3d 540, 546 (9th Cir. 1994); *Torraco v. Maloney*, 923 F.2d 231, 234 (1st Cir. 1991); *Greason v. Kemp*, 891 F.2d 829, 834 (11th Cir. 1990); *Smith v. Jenkins*, 919 F.2d 90, 93 (8th Cir. 1990); *Bowring v. Godwin*, 551 F.2d 44, 47 (4th Cir. 1977).

¹⁸⁶ *Balla v. Idaho State Bd. of Corr.*, 595 F. Supp. 1558, 1577 (D. Idaho 1984) (citing *Ruiz v. Estelle*, 503 F. Supp. 1265, 1339 (S.D. Tex. 1980)).

¹⁸⁷ 912 F. Supp. 1282, 1307–08 (E.D. Cal. 1995).

¹⁸⁸ *Id.* at 1324.

¹⁸⁹ *Brown v. Plata*, 563 U.S. 493, 507 (2011).

¹⁹⁰ *Id.* at 509.

¹⁹¹ *Id.* at 509–10.

¹⁹² *Id.* at 501.

standard of decency that inheres in the Eighth Amendment. This extensive and ongoing constitutional violation requires a remedy, and a remedy will not be achieved without a reduction in overcrowding.”¹⁹³

As the Court’s order in *Plata* makes clear, constitutional levels of care are irreconcilable with overcrowded correctional institutions.¹⁹⁴ Thus, reducing rates of recidivism, particularly among offenders with serious mental illness who require additional care and services, helps ensure that all prisoners and jail inmates receive a constitutional level of care.

E. *Ensuring Medication Adherence Helps Alleviate the Strain Placed on Mental Health System*

In many states, detainees deemed incompetent to stand trial can remain hospitalized “even though they are not ill enough to qualify for involuntary hospitalization under civil commitment laws.”¹⁹⁵ Given the grossly inadequate number of mental health beds in state hospitals, this often leaves more critically ill members of the community out on the streets.¹⁹⁶

Digital medication addresses this problem by identifying non-adherence early, before an offender can decompensate to the point where he may need to be hospitalized to restore competency.¹⁹⁷ Take, for example, the offender in *Holman*.¹⁹⁸ When he was first released from prison, the conditions of his supervised release contained no requirement that he receive mental health treatment or take all prescribed medications.¹⁹⁹ It was only upon recommendation of his probation officer that the conditions were modified to contain such requirements; however, by then, it was too late.²⁰⁰ *Holman* had left his home, leaving his medication behind.²⁰¹ He was found several weeks later, “wandering aimlessly and in a partially catatonic state.”²⁰² It took

¹⁹³ *Id.* at 545.

¹⁹⁴ *Id.* at 502 (stating that “overcrowding is the ‘primary cause’ . . . [of] the severe and unlawful mistreatment of prisoners through grossly inadequate provision of medical and mental health care”).

¹⁹⁵ EMPTYING THE NEW ASYLUMS, *supra* note 132, at 17.

¹⁹⁶ *See id.*

¹⁹⁷ *See* Larsen-Barr et al., *supra* note 73, at 372 (studies evidence that withdrawal from antipsychotic medications can be severe enough to require hospitalization).

¹⁹⁸ 532 F.3d 284 (4th Cir. 2008).

¹⁹⁹ *Holman*, 532 F.3d at 286.

²⁰⁰ *Id.*

²⁰¹ *Id.*

²⁰² *Id.*

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several months before he was stabilized and deemed competent to stand trial for violating the terms of his supervised release.²⁰³

While the opinion in *Holman* is silent as to where he was held while his competency was restored, it is reasonable to assume that it was in a hospital. Thus, if digital medication had identified his non-adherence earlier, before he decompensated to the point of hospitalization, a member of the community could have used this mental health bed. This is especially poignant when one considers the unknown number of patients who are turned away from hospital care, unable to get the medical treatment they so desperately need, who then go on to commit crime, “typically misdemeanors and nuisance offenses,”²⁰⁴ thus perpetuating the cycle of incarceration, decompensation, and recidivism.

F. Potential Counterarguments

Opponents of digital medication might argue that such technology could actually increase rates of recidivism by imposing yet another condition that offenders would have to comply with upon penalty of revocation of their term of supervised release.²⁰⁵ There is some evidence that suggests mentally ill offenders are returned to prison more often for technical violations of parole than for committing a new crime.²⁰⁶ Moreover, the nature of mental illness, particularly schizophrenia, can make compliance with conditions of supervised release more difficult.²⁰⁷ The concern is that a condition mandating digital medication would be setting mentally ill offenders up for failure and effectively criminalizing their mental illness.

Compounding this concern of an overly rigid condition that does not account for the compliance challenges inherent to mental illness is the reality that the technology itself is not perfect. It is possible that a

²⁰³ *Id.*

²⁰⁴ EMPTYING THE NEW ASYLUMS, *supra* note 132, at 6.

²⁰⁵ 18 U.S.C. § 3583(e)(3) (“[T]he court may . . . revoke a term of supervised release, and require the defendant to serve in prison all or part of the term of supervised release . . . if the court . . . finds by a preponderance of the evidence that the defendant violated a condition of supervised release. . .”).

²⁰⁶ Jennifer Eno Loudon et al., *How Do Probation Officers Assess and Manage Recidivism and Violence Risk for Probationers With Mental Disorder? An Experimental Investigation*, 37 LAW & HUM. BEHAV. 22, 22-23 (2013).

²⁰⁷ Tham et al., *supra* note 136, at 807 (noting that “[p]sychotic symptoms have been linked to declining memory and executive function[,] . . . [t]herefore, those with severe symptoms cannot make appropriate decisions to take medications, leading to medication non-adherence”).

taken dose might not be reflected in the transmitted data.²⁰⁸ For these reasons, it is apparent that this condition cannot be absolute. One missed pill cannot be a reason to revoke an offender's supervised release.²⁰⁹ Several missed pills in a week would be a red flag to have an intervention with the probation officer and a mental health professional to prevent further non-adherence. Only after a subsequent pattern of missed dosages after such a meeting would a probation officer be warranted in revoking the offender's supervised release. Just because the realities of the illness and the technology demand flexibility does not suggest that digital medication is without value. Research indicates that parole supervision decreases the likelihood that mentally ill offenders will recidivate.²¹⁰ Moreover, there is evidence that adherence behavior engenders a healthy and proactive attitude toward preventing relapse and "enjoy[ing] the advantages of being adherent," which in turn fosters adherence in the future.²¹¹ Thus, a condition imposing digital medication could reduce recidivism through increased supervision and improved medication adherence, even after the term of supervised release expires.

Another argument against the imposition of digital medication is that medication alone will not keep the seriously mentally ill from recidivating because the question of why the mentally ill recidivate at rates that far exceed their non-mentally ill counterparts²¹² is far more nuanced. Studies suggest that a confluence of factors contribute to high rates of recidivism, including high rates of substance abuse,²¹³

²⁰⁸ *Product Information*, ABILIFY MYCITE, <https://www.abilifymycite.com/about> (last visited Jan. 9, 2020).

²⁰⁹ Given the limitations of the technology, not only would such a stringent condition be inherently unfair, it would also be unlikely to meet due process protections that attach to supervised release revocation. See *Vitek v. Jones*, 445 U.S. 480, 488 (1980); see also *Morrissey v. Brewer*, 408 U.S. 471, 484 (1972) (noting that both the parolee and society have "an interest in not having parole revoked because of erroneous information").

²¹⁰ Jason Matejkowski & Michael Ostermann, *Serious Mental Illness, Criminal Risk, Parole Supervision, and Recidivism: Testing of Conditional Effects*, 39 LAW & HUM. BEHAV. 75, 77 (2015).

²¹¹ Tham et al., *supra* note 136, at 807.

²¹² U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-18-182, REPORT TO CONGRESSIONAL COMMITTEES, FEDERAL PRISONS: INFORMATION ON INMATES WITH SERIOUS MENTAL ILLNESS AND STRATEGIES TO REDUCE RECIDIVISM, 2 (2018).

²¹³ Samantha Hoke, *Mental Illness and Prisoners: Concerns for Communities and Healthcare Providers*, 20 ONLINE J. OF ISSUES IN NURSING (Jan. 2015), <http://ojin.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol-20-2015/No1-Jan-2015/Mental-Illness-and-Prisoners.html>; see also KiDeuk Kim et al., *The Processing and Treatment of Mentally Ill Persons in the Criminal Justice System* (Mar. 2015), <https://www.urban.org/sites/default/files/publication/48981/2000173-The-Processing-and-Treatment-of-Mentally-Ill-Persons-in-the-Criminal->

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unemployment,²¹⁴ homelessness,²¹⁵ and a lack of access to mental health services.²¹⁶

The federal and various state governments have enacted legislation aimed at reducing rates of recidivism by targeting these sociological and criminogenic risks.²¹⁷ Other federal and state programs are aimed at providing mentally ill offenders with employment opportunities, educational opportunities, and substance abuse treatment—all of which have proved to be successful in reducing recidivism rates.²¹⁸

A term of supervised release that mandates digital medication should not be viewed as supplanting these programs but rather as an integral complement to them. Stabilizing a patient on medication is an important precursor to psychotherapy, vocational training, or substance abuse treatment.²¹⁹ In particular, there is a high correlation between mental illness and substance abuse.²²⁰ Moreover, research shows that offenders with both mental illness and a history of substance abuse are more likely to recidivate than those with serious mental illness alone.²²¹ Evidence suggests that the high rates of substance abuse among the mentally ill can be attributed to a desire to treat, or at least lessen, the symptoms of mental illness.²²² Thus it follows that

Justice-System.pdf (stating that nearly three-quarters of state prisoners with a history of mental health problems reported a co-occurring substance dependence).

²¹⁴ See Hoke, *supra* note 213.

²¹⁵ Hirschrift & Binder, *supra* note 131, at 695 (lifetime arrest rates of homeless individuals with serious mental illness at a staggering rate of 62.9 to 90 percent).

²¹⁶ EMPTYING THE NEW ASYLUMS, *supra* note 132, at 15.

²¹⁷ See Hirschrift & Binder, *supra* note 131, at 696 (discussing bills passed in Montana, Nevada, and Virginia in 2013 which provide funding to support community-based organizations that provide substance abuse services, employment and housing resources, and medical care to ex-offenders with serious mental illness); see also 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033, § 14022(l)(2)(c)(i) (Dec. 13, 2016) (permitting the Attorney General to award grant monies to applicants for the development of “post-release transition plans for eligible inmates that, in a comprehensive manner, coordinate health, housing, medical, employment, and other appropriate services and public benefits”).

²¹⁸ Hoke, *supra* note 213.

²¹⁹ Glenn D. Walters & Gregory Crawford, *Major Mental Illness and Violence History as Predictors of Institutional Misconduct and Recidivism: Main and Interaction Effects*, 38 LAW AND HUM. BEHAV. 238, 245 (2013) (Psychotropic “[m]edication should . . . be supplemented by a multidimensional approach designed to address the manifold mental health- and criminal justice-related problems experienced by [seriously mentally ill] offenders”).

²²⁰ James A. Wilson & Peter B. Wood, *Dissecting the Relationship Between Mental Illness and Return to Incarceration*, 42 J. OF CRIM. JUST. 527, 528 (2014).

²²¹ U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 212, at 2.

²²² Hoke, *supra* note 213.

focusing on medication adherence would abate one of the key drivers of substance abuse and, therefore, recidivism, which is the desire to obtain relief from one's symptoms through self-medication.

Another potential counterargument is the cost of digital medication, which opponents would suggest is prohibitive.²²³ In addition to the cost of the drug itself, users will also need access to a Bluetooth-enabled device for the monitoring system to function.²²⁴ While there is no question that the digital pill is a more expensive alternative, certainly more than generic antipsychotics, there are several reasons why this factor alone does not defeat an argument that digital medication should be considered a useful tool for the right patient. First, courts would only mandate digital medication for those patients for whom a traditional oral antipsychotic would not be a viable alternative because of a history of non-adherence.²²⁵ Thus, the appropriate comparison would be between digital medication and LAIAs. When comparing these alternatives, the price differential is less stark.²²⁶ And after factoring in the additional administrative costs, this price differential becomes even more negligible.²²⁷ It should also be noted that digital medication is in its infancy.²²⁸ Venture capitalists have been pouring a tremendous amount of money into new digital technologies,²²⁹ suggesting that competitive products are likely to enter the market and drive the price down.²³⁰

Additionally, there is some question as to which party would shoulder this cost—the criminal justice system or the individual offender. Most likely it would be the individual, who will then be left to

²²³ Zoë LaRock, *Smart Pills Aren't Living up to the Hype Yet—But They're Not Doomed*, BUS INSIDER, <https://www.businessinsider.com/abilify-mycite-smart-pill-lacks-evidence-of-benefits-2019-7> (July 23, 2019) (digital medication is currently priced at \$1,650, while the generic alternative costs \$20).

²²⁴ Caliendo & Hilas, *supra* note 4.

²²⁵ See *supra* Section II.B.

²²⁶ See CAN. AGENCY FOR DRUGS AND TECH. IN HEALTH, ARIPIRAZOLE PROLONGED RELEASE SUSPENSION FOR INJECTION, (*Abilify Maintena*) (300 mg and 400 mg Vial) tbl.1, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (Feb. 2017), <https://www.ncbi.nlm.nih.gov/books/NBK447758/table/pe1.t1/> (manufacturer's submitted price of vial of long-acting atypical antipsychotic ranges from \$78 to \$635).

²²⁷ See Parellada & Bioque, *supra* note 77, at 694 (patients often cite loss of time spent on travel to the clinic for monthly injections and high direct and indirect costs as significant drawbacks to LAIAs).

²²⁸ See *Press Release, FDA, supra* note 1.

²²⁹ Belluck, *supra* note 14.

²³⁰ Despite Proteus's June 2020 bankruptcy filing, analysts remain enthusiastic about the future of this technology. See THE MED. FUTURIST, *The Present and Future of Digital Pills* (July 21, 2020), <https://medicalfuturist.com/the-present-and-future-of-digital-pills>.

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navigate the murky waters of how his private health insurance or Medicaid process requests for court-ordered treatment.²³¹ For this reason, it is essential that, prior to release, prison officials aid the offender in enrolling for Medicaid benefits, a service that many correctional systems have already recognized the value of.²³² It should also be noted that if a patient is successful in getting Medicaid coverage for the digital pill, he may also qualify for a loan of a limited-functionality smartphone, necessary to receive and transmit the adherence data.²³³

Alternatively, digital medication could be analogized to electronic monitoring services, which many states assume the cost of when it comes to indigent defendants.²³⁴ When considering the question of cost from the perspective of a state-payer system, one must compare the cost of digital medication to the cost of incarcerating seriously mentally ill offenders. Studies suggest that state prisons spend upwards of \$5 billion annually to incarcerate non-violent mentally ill offenders.²³⁵ Specifically, research indicates “[t]he economic impact of recidivism and psychiatric relapse among patients with schizophrenia is substantial from a state government perspective.”²³⁶ Viewed in light of the alternatives, the cost of digital medication becomes more palatable.

Finally, it should be noted that the high cost associated with digital medication could actually be a good thing. A primary critique of monitoring technologies is that the “economics of technological control

²³¹ See MARSHA REGENSTEIN & LEA NOLAN, GEO. WASH. UNIV. DEP’T HEALTH POLICY, IMPLICATIONS OF THE AFFORDABLE CARE ACT’S MEDICAID EXPANSION ON LOW-INCOME INDIVIDUALS ON PROBATION (Feb. 2014), https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1296&context=sphhs_policy_facpubs (The Centers for Medicare and Medicaid Services has deferred from issuing a ruling as to whether state Medicaid programs must cover court-ordered treatments. Absent guidance from the federal government, states are free to either include them among covered benefits or exclude them wholly from coverage.).

²³² See Kim et al., *supra* note 213, at 34 (research indicates that enrolling seriously mentally ill offenders in Medicaid at the time of release from jail has proven to be an effective policy and one that has become common practice across a number of jurisdictions).

²³³ See Dep’t of Health and Human Servs., Office of Inspector Gen., OIG Advisory Opinion No. 19-02 (Jan. 29, 2019).

²³⁴ Deeanna M. Button et al., *Using Electronic Monitoring to Supervise Sex Offenders: Legislative Patterns and Implications for Community Corrections Officers*, 20 CRIM. JUST. POL’Y REV. 414, 427 (2009).

²³⁵ Wilson & Wood, *supra* note 220, at 528.

²³⁶ I. Lin et al., *General Model for Estimating Medical and Criminal Justice Costs Among Patients with Schizophrenia After Release From Jail/Prison*, 17 VALUE IN HEALTH A218 (2014), [https://www.valueinhealthjournal.com/article/S1098-3015\(14\)01326-6/pdf](https://www.valueinhealthjournal.com/article/S1098-3015(14)01326-6/pdf) (estimating that a 20 percent increase in the proportion of ex-offenders treated with antipsychotics following release decreased total cumulative costs to the state of Florida by almost \$600 per patient over three years).

enable the regulation of greater numbers of persons under less stringent conditions for a longer period of time and to a greater degree than an equivalent physical intrusion.”²³⁷ Therefore, the higher costs associated with digital medication serve as added insurance that this condition will be reserved only for those offenders for which there are not less intrusive, and less expensive, alternatives.

IV. POTENTIAL EXPANSION OF DIGITAL MEDICATION

There are two primary areas where this technology could have useful implications and, therefore, should be explored further. The first is in the realm of probation. Similar to terms of supervised release, a district court may attach discretionary conditions to a sentence of probation.²³⁸ As in the context of conditions of supervised release, the court is authorized to impose a condition that an offender undergoes “available medical, psychiatric, or psychological treatment.”²³⁹ This determination must further the same statutory factors that govern conditional terms of supervised release.²⁴⁰ Additionally, such conditions must “involve only such deprivations of liberty or property as are reasonably necessary” to further such ends.²⁴¹ Therefore, a court would analyze a condition of digital medication using many of the same factors in the probation context as it would in the context of supervised release.

There are key distinctions, however. First, if a court attaches the condition to the sentence without the consent of the offender, the prosecution may have difficulty proving the requisite history of non-adherence to overcome an argument that a less intrusive alternative, namely a condition requiring the offender to take an oral antipsychotic as prescribed, is unlikely to achieve the same result.²⁴² Alternatively, if the defendant voluntarily consents to the condition as part of a plea agreement, there will be a question of whether the defendant’s consent is valid or was coerced.²⁴³ Voluntariness is predicated upon the “plea of guilty [being] entered by one fully aware of the direct consequences . . .

²³⁷ Murphy, *supra* note 93, at 1367–68.

²³⁸ See 18 U.S.C. § 3563(b).

²³⁹ *Id.* § 3563(b)(9).

²⁴⁰ *Id.* § 3563(b); § 3553(a)(1)–(2) (“the nature and circumstances of the offense and the history and characteristics of the defendant” and considerations of punishment, deterrence, rehabilitation, and the need “to protect the public from further crimes of the defendant”).

²⁴¹ *Id.* § 3563(b).

²⁴² See *supra* Section II.B.

²⁴³ Richard J. Bonnie, *Judicially Mandated Treatment with Naltrexone for Opiate-Addicted Criminal Offenders*, 13 VA. J. Soc. POL’Y & L. 64, 81 (2005).

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of any commitments made to him by the court.”²⁴⁴ Therefore, depending on the defendant’s mental health at the time of prosecution, it may not be possible for him to voluntarily consent to such a condition. If such voluntariness can be established, such a condition would greatly further the goals of preventing further mental decompensation while incarcerated and alleviating the strain placed on the criminal justice system through overcrowding.²⁴⁵

The second area where the criminal justice system could potentially leverage this technology is the treatment of those struggling with opioid addiction. An ingestible sensor could be embedded in a naltrexone tablet. Naltrexone blocks specific receptors for opiate drugs, thereby preventing these narcotics from producing a high in users.²⁴⁶ The potential advantages of such a drug are self-evident; whether a district court could impose such a condition of either supervised release or probation is less clear. It is unlikely that the prosecution could make a sufficient showing of medical necessity, especially when there are much less intrusive alternatives, such as substance abuse treatment programs. But, applying the *Harper-Riggins-Sell* framework, it is not inconceivable that—presented with a defendant who had repeatedly failed to comply with treatment programs and who had previously overdosed or had a history of committing violent acts while under the influence of opioids—a district court may mandate involuntary medication of digital naltrexone.

In the probation context, when such a condition is being attached to a plea agreement, it is more likely that a condition mandating digital naltrexone would be upheld. As long as the defendant was fully aware of the consequence of his commitment and his promise was not induced by “threats,” “misrepresentation,” or by “promises that are by their nature improper,” the district court is likely to find such a condition voluntary and, therefore, enforceable.²⁴⁷

V. CONCLUSION

The mid-twentieth century witnessed a profound shift in the way mental illness was viewed and treated in the United States. With the most benevolent of intentions, this movement away from institutionalization had an insidious effect—the mass incarceration of

²⁴⁴ *Brady v. United States*, 397 U.S. 742, 755 (1970) (internal quotation marks omitted) (quoting *Shelton v. United States*, 246 F.2d 571, 572 n.2 (5th Cir. 1957) (en banc), *rev’d on other grounds*, 356 U.S. 26 (1958)).

²⁴⁵ See *supra* Sections III.A–B.

²⁴⁶ See *Bonnie*, *supra* note 243, at 67.

²⁴⁷ *Brady*, 397 U.S. at 755 (quoting *Shelton*, 246 F.2d at 572 n.2).

those with serious mental illness. A swelling population of prisoners with serious mental health needs not only jeopardizes the physical and mental health of the offenders at issue but also compromises the ability of the criminal justice system to deliver a constitutional level of care to all offenders. Reducing rates of recidivism among mentally ill offenders is an important step in alleviating the pressures placed on our criminal justice system, and digital medication, in conjunction with other terms of supervised release aimed at addressing the myriad sociological and criminological factors that contribute to recidivism, may well be a useful tool to achieve this end.