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Precommitment Devices: A Defensible Treatment for Opioid Addiction?

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Precommitment is a choice to restrict one's future freedom. This strategy is used to address "weakness of will," when people fear that their later choices will be damaging to their overall well-being.[1] Through precommitment, people can authorize constraints on their freedom to make such choices.[2]

In the past, precommitment has been endorsed as a strategy to treat addiction and mental health problems. Proponents have argued that individuals facing these problems should be authorized to make legally enforceable agreements consenting to treatment and hospitalization that is later unwanted.[3] Yet legal and ethical concerns have presented barriers to implementing such agreements.

Precommitment is in the spotlight again, this time as a potential treatment strategy for people battling opioid use disorder. Implanted devices can automatically

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[1]*See* Kirsten Bell, *Thwarting the Diseased Will: Ulysses Contracts, the Self, and Addiction*, 39 CULTURE MED. & PSYCHIATRY 380, 386-87 (2015).

[2]Precommitment agreements are sometimes called Ulysses contracts, in reference to Homer's story of Ulysses and the Sirens. In the story, Ulysses directed his crew to bind him to the mast so that he could hear the Sirens' song without yielding to temptation. *See generally id*.; Rebecca S. Dresser, *Ulysses and the Psychiatrists: A Legal and Policy Analysis of the Voluntary Commitment Contract*, 16 HARV. C.R.–C.L. L. REV. 777 (1982).

[3]*See generally* Harriet Standing & Rob Lawlor, *Ulysses Contracts in Psychiatric Care: Helping Patients to Protect Themselves from Spiralling,* 45 J. MED. ETHICS 693 (2019) (presenting four reasons why Ulysses contracts should be followed for individuals with certain illnesses); Ryan Spellecy, *Reviving Ulysses Contracts*, 13 KENNEDY INST. ETHICS J. 373 (2003) (arguing that the enforcement of some Ulysses contracts may be justified).

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deliver anti-addiction drugs for several months, with the goal of reducing the impulsive behavior that leads to relapse in many individuals reliant on daily pills or monthly injections to counter their addiction.[4] Accepting an implant is a form of precommitment to long-term use of medication-assisted therapy.

Naltrexone is one of three major drugs used to treat opioid use disorder.[5] In 2019, Columbia University announced that the National Institute on Drug Abuse had agreed to fund research evaluating the safety and effectiveness of a long-acting naltrexone implant called the OLANI.[6] The goal is to determine whether the implants allow more people to achieve long-term sobriety. Although some evidence has been collected on the implant's risks and benefits, authorities in most countries say that more rigorous evaluation is needed to justify its approval for widespread clinical use.[7]

Long-acting naltrexone implants raise some of the same concerns that precommitment agreements raise. Successful use of the implants will require attention to three central issues. First, what constitutes informed and voluntary consent to this form of treatment? What should individuals understand before consenting to receive an implant that could later be unwanted? Second, does a recipient's previous consent supply adequate justification for clinicians and researchers to refuse that person's later request for implant removal? Third, what standard of competency should apply when individuals with naltrexone implants seek to override their previous decisions? Can the cravings associated with addiction compromise a person's competency to withdraw an earlier consent to implantation?

This article analyzes these issues. In Part I, I describe existing treatment options for people with opioid use disorder, as well as the potential benefits and harms of long-acting naltrexone implants. Part II examines precommitment strategies in the context of health decisions. In this part, I consider existing law relevant to the use of precommitment strategies. I also review ethical arguments for and against the use of such strategies in addiction as well as general mental health treatment.[8] I conclude with recommendations for researchers, clinicians, policy officials, and opioid users making decisions about naltrexone implants.[9]

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[4]*See FDA Approves Six Month Implant for Treatment of Opioid Dependence,* NAT'L INST. ON DRUG ABUSE (May 26, 2016), https://www.drugabuse.gov/news-events/news-releases/2016/05/fda-approves-six-month-implant-treatment-opioid-dependence.

[5]*Researchers at Columbia Psychiatry Begin Study to Evaluate OLANI for Treatment of Opioid Use Disorders*, COLUM. U. DEP'T OF PSYCHIATRY (Apr. 15, 2019), https://www.columbiapsychiatry.org/news/researchers-columbia-psychiatry-begin-study-evaluate-olani-treatment-opioid-use-disorders [hereinafter COLUM. U. DEP'T OF PSYCHIATRY].

[6]Australian physician George O'Neil developed the implant (OLANI stands for O'Neil Long-Acting Naltrexone Implant). The first phase of the research will investigate the implant's effects in healthy volunteers. Later investigations will evaluate how the implant works in people with opioid use disorder. *See id.*; Isabella Kwai, *An Australian Doctor's Dream: Curing America's Opioid Curse*, N.Y. TIMES (June 6, 2019), https://www.nytimes.com/2019/06/06/world/australia/opiate-opioid-treatment-naltrexone.html?searchResultPosition=1.

[7]*See, e.g.*, ROYAL AUSTRALASIAN C. OF PHYSICIANS, THE USE OF SUSTAINED RELEASE FORMULATIONS OF NALTREXONE IN OPIOID DEPENDENCE: POSITION STATEMENT 3 (2013), https://www.racp.edu.au//docs/default-source/advocacy-library/the-use-of-sustained-release-formulations-of-naltrexone-in-opioid.pdf?sfvrsn=25aa2f1a_10; Philipp Lobmaier et al., *Sustained-Release Naltrexone for Opioid Dependence*, COCHRANE DATABASE OF SYSTEMATIC REV. no. 2, 2008 at 3.

[8]Precommitment issues arise in the context of health decisions that can be altered over time. Many medical interventions are irreversible, of course. In those cases, it is particularly important for people to understand and appreciate their inability to revoke a choice to accept the intervention.

[9]My analysis considers voluntary implant use in the context of research and medical care. I do not address the additional issues that would be raised if implant use were compelled in the context of the criminal justice or mental health treatment systems. *See* Amelia Pang, *Did a Drug Company Illegally*

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I. MEDICATION-ASSISTED THERAPY FOR OPIATE USE DISORDER

Opioid use disorder is a major public health problem, linked to high rates of mortality and morbidity in the U.S. population. Hundreds of thousands of people are now addicted to opioids, and the demand for effective treatment is greater than ever.[10]

Three drugs are currently used to treat people with opioid use disorder.[11] The drugs function in different ways. Methadone and buprenorphine are themselves opioids, but are designed to relieve pain while lowering the risks associated with prescription opioid painkillers as well as prohibited opioids like heroin.[12] Naltrexone is an opioid antagonist, which means it blocks the brain's opiate receptors. By removing the pain-relieving and other positive effects of opioids, naltrexone can reduce the likelihood that individuals will persist in opioid use.[13]

Methadone and buprenorphine have been demonstrated to be effective in preventing relapse among people with substance use disorder.[14] Although people require ongoing treatment to address their cravings and compulsions, they are able to avoid the negative health and social consequences of addiction.[15] Both methadone and buprenorphine are susceptible to misuse, however, including diversion to others seeking the relief the medications can provide. Some people also continue to use other opioids while taking methadone or buprenorphine, which exposes them to the risk of overdose.[16]

Naltrexone has both advantages and disadvantages in comparison with methadone and buprenorphine. Naltrexone is attractive to people whose overriding goal is to eliminate their drug dependence.[17] Naltrexone's biggest disadvantage is that people must undergo complete detoxification before beginning the medication, a process that is so physically and psychologically difficult that many cannot complete it.[18] Some opioid users also say that naltrexone is less effective than methadone and

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Experiment on a Louisiana Prisoner?, NEW REPUBLIC (Oct. 31, 2019), https://newrepublic.com/article/155553/drug-company-illegally-experiment-louisiana-prisoner (raising questions about naltrexone implant testing in prison setting).

[10]*See* Wilson M. Compton & Nora D. Volkow, *Improving Outcomes for Persons With Opioid Use Disorders*, 316 JAMA 277, 277 (2016).

[11]For a description of the diagnostic criteria for substance use disorder, *see* AM. PSYCHIATRIC ASS'N, DIAGNOSTIC & STATISTICAL MANUAL OF MENTAL DISORDERS (5th ed., 2013).

[12]NAT'L INST. ON DRUG ABUSE, NAT'L INST. OF HEALTH, PRINCIPLES OF DRUG ADDICTION TREATMENT: A RESEARCH-BASED GUIDE 42 (3d ed. 2018).

[13]*See* Nora D. Volkow et al., *Medication-Assisted Therapies — Tackling the Opioid-Overdose Epidemic*, 370 NEW ENG. J. MED. 2063, 2064 (2014).

[14]*See generally* NAT'L HEALTH & MED. RESEARCH COUNCIL, NALTREXONE IMPLANT TREATMENT FOR OPIOID DEPENDENCE 4 (2010).

[15]There is a philosophical debate over whether dependence on methadone and buprenorphine is a problem. Although some characterize it as simply another form of drug addiction, others compare it to the long-term maintenance therapy provided to people with chronic conditions like diabetes. *See* Jessica Glenza, *Russia's "Cold Turkey" Approach Highlights Global Divide over Drug Treatment at UN*, GUARDIAN (Apr. 20, 2016 6:22 PM), https://www.theguardian.com/world/2016/apr/20/ungass-russia-drug-treatment-heroin-methadone.

[16]*See* Walter Ling et al., *Buprenorphine Implants for Treatment of Opioid Dependence*, 304 JAMA 1576, 1581-82 (2010).

[17]*See* Maria A. Sullivan et al., *A Randomized Trial Comparing Extended-Release Injectable Suspension and Oral Naltrexone, Both Combined With Behavioral Therapy, for the Treatment of Opioid Use Disorder*, 176 AM. J. PSYCHIATRY 129, 134 (2019). Another positive is that naltrexone is not regulated under the Controlled Substances Act. This law sets demanding requirements for clinicians prescribing methadone and buprenorphine, limiting the drugs' availability. *See* COLUM. U. DEP'T OF PSYCHIATRY, *supra* note 5.

[18]For example, in one study of naltrexone, half the people enrolled were unable to complete the detoxification process. *See* Sullivan et al., *supra* note 17, at 132. The two other drugs can be started at an earlier time, when people are in "mild-to-moderate withdrawal." *See* Joshua Lee et al., *Comparative*

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buprenorphine in reducing their cravings for opioids.[19] Experts warn that naltrexone alone is not a panacea for opioid addiction.[20] Simply removing the pleasant effects of opioids is often not enough to counter what is a "complex syndrome involving a number of genetic, physiological, neurobiological, and psychological factors."[21]

Treatment involving daily naltrexone pills puts extreme demands on people with opioid use disorder. Every day they must resist the temptation to once more experience the pleasurable effects that opioids deliver. The difficulty of maintaining this resistance is a major contributor to high relapse rates among people taking naltrexone on a daily basis.[22]

In an effort to improve naltrexone's effectiveness, researchers have developed methods to reduce the temptation to stop treatment. One such method, a long-acting injection, was approved by the U.S. Food and Drug Administration (FDA) in 2010.[23] Studies have shown that the injection, which patients receive monthly, significantly increases their ability to remain in treatment.[24]

Naltrexone implants are designed to improve on these results. Implants deliver naltrexone over a period of months, further reducing patients' opportunities to stop the medication. Patients often need to receive anti-addiction medication for at least six months to avoid relapse.[25] Different versions of the implant have been developed, although the OLANI device is the only one designed to last for at least six months.[26] The hope is that this device will enable recipients to maintain opioid abstinence for a longer time than they could with other forms of naltrexone treatment.[27]

Although experts agree that more testing is needed, some research has been conducted on long-acting naltrexone implants.[28] The existing data on patient benefit are promising. Yet the data also point to concerns that must be addressed before the device becomes widely available. Some of the concerns are related to the harm that can come when people change their minds about wanting the device.[29]

Australian authorities have not approved the OLANI for general clinical use, but a special program permits physicians to prescribe it "to patients at an increased risk

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Effectiveness of Extended-Release Naltrexone Versus Buprenorphine-Naloxone for Opioid Relapse Prevention (X:BOT): A Multicentre, Open-Label, Randomised Controlled Trial, 391 LANCET 309, 310 (2018). For a vivid account of the withdrawal experience, *see generally* TRAVIS RIEDER, IN PAIN: A BIOETHICIST'S PERSONAL STRUGGLE WITH OPIOIDS (2019).

[19]*See* Ed Holt, *Russian Injected Drug Use Soars in Face of Political Inertia*, 376 LANCET 13 (2010).

[20]NAT'L HEALTH & MED. RESEARCH COUNCIL, *supra* note 14, at 5.

[21]*Id*. at 4.

[22]*Cf*. Gary K. Hulse et al., *Improving Clinical Outcomes in Treating Heroin Dependence*, 66 ARCHIVES GEN. PSYCHIATRY 1108, 1113 (2009).

[23]Evgeny Krupitsky et al., *Randomized Trial of Long-Acting Sustained-Release Naltrexone Implants vs Oral Naltrexone or Placebo for Preventing Relapse in Opioid Dependence*, 69 ARCHIVES GEN. PSYCHIATRY 973, 974 (2012) [hereinafter Krupitsky et al. I].

[24]*See, e.g*., Sullivan et al., *supra* note 17, at 129 (after six months, study group receiving injections was twice as likely to remain in treatment as group receiving daily pills).

[25]*See* COLUM. U. DEP'T OF PSYCHIATRY, *supra* note 5.

[26]*See id*.

[27]An FDA-approved six-month buprenorphine implant offers the benefit of long-term drug delivery, but this option doesn't meet the needs of people seeking to avoid dependence on maintenance drugs. *Cf*. Compton & Volkow, *supra* note 10, at 277.

[28]*See generally* Krupitsky et al. I, *supra* note 23.

[29]*Cf id*. at 980 (discussing the limitations of naltrexone implants, including potential implant removal by patients).

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of morbidity or mortality."[30] Investigators in Australia have conducted research on the device, finding the implant superior to daily naltrexone pills in reducing opioid relapse in the post-treatment period.[31] Another study of the OLANI implant conducted in Norway compared it with the usual care provided to people who had undergone opioid detoxification.[32] Investigators in this study also reported benefit in the form of reduced opioid use following treatment.[33]

Yet researchers have also reported risks associated with the OLANI implant. One study found that implant recipients had higher rates of overdose from non-opioid drugs such as amphetamines.[34] Recipients in search of the positive effects they previously experienced from opioids apparently sought those effects from other kinds of drugs. Some implants also had to be removed due to infection and patient dissatisfaction.[35]

Two other noteworthy implant studies were conducted in Russia, where naltrexone is the only anti-addiction medication that is legally available.[36] The Russian studies evaluated an implant that delivers naltrexone for two to three months. A randomized controlled trial comparing the implant to daily pills and placebos found the implant significantly more effective in preventing relapse.[37] A second study evaluated treatment outcomes in people with both HIV and opioid addiction. Study participants receiving naltrexone implants had better HIV and anti-addiction treatment outcomes than those receiving daily naltrexone pills.[38]

At the same time, both of the Russia-based studies documented risks associated with participants' desire to counter the implant's effects. Some implant recipients tried to remove the implants themselves.[39] According to researchers, there was a "higher proportion of patients with surgical infections with naltrexone implants compared with placebo implants, which researchers believe might be a result of addicts trying to take the implant out, possibly so they could get the full effect of an opiate hit again."[40] In addition, one participant "tried to overcome [the implant] by taking vast quantities of heroin to get a high until he finally overdosed, barely surviving."[41] Others have reported similar problems related to implant use.[42]

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[30]Erin Kelty & Gary Hulse, *Examination of Mortality Rates in a Retrospective Cohort of Patients Treated With Oral or Implant Naltrexone for Problematic Opioid Use*, 107 ADDICTION 1817, 1818 (2012).

[31]*Id*. at 1820-21. *See also* Hulse et al., *supra* note 22, at 1108; Hanh T. Ngo et al., *Comparing Drug-Related Hospital Morbidity Following Heroin Dependence Treatment With Methadone Maintenance or Naltrexone Treatment,* 65 ARCHIVES GEN. PSYCHIATRY 457, 457 (2008).

[32]Nikolaj Kunoe et al., *Naltrexone Implants After In-Patient Treatment for Opioid Dependence: Randomised Controlled Trial*, 194 BRIT. J. PSYCHIATRY 541 (2009).

[33]*Id.* at 544.

[34]Ngo et al., *supra* note 31, at 461.

[35]*See* Kunoe et al., *supra* note 32, at 545.

[36]Russian authorities have banned the use of methadone and buprenorphine on grounds that they simply replace one form of drug dependence with another. *See* Krupitsky et al., *Slow-Release Naltrexone Implant versus Oral Naltrexone for Improving Treatment Outcomes in People With HIV Who Are Addicted to Opioids: A Double-Blind, Placebo-Controlled, Randomised Trial*, 6 Lancet HIV e221 (2019) [hereinafter Krupitsky et al. II]; Holt, *supra* note 19, at 13.

[37]Krupitsky et al. I, *supra* note 23, at 973.

[38]Krupitsky et al. II, *supra* note 36, at e225-27.

[39]*Id.* at e227.

[40]Holt, *supra* note 19, at 14. *See also* Krupitsky et al. II, *supra* note 36, at e227.

[41]Holt, *supra* note 19, at 13-14.

[42]Journalists covering the OLANI's use in Australia have reported that "the desire to take drugs while on the implant can be so great that some have even tried highly risky do-it-yourself removals of the implant." *Id.* at 14. In an online comment on a *New York Times* report about the OLANI study, a reader referred to a naltrexone implant that a New Jersey physician had been offering to patients. According to the writer, "the craving to get high was so forceful for some [patients] that they would cut their own implant out

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In sum, the available information on naltrexone implants shows that some implant recipients are likely to regret their initial consent to the intervention, and that they could resort to drastic measures to negate that earlier choice. Investigators conducting the U.S. OLANI study should consider these possibilities in planning their research. Moreover, authorities deciding whether to approve long-acting naltrexone implants for clinical use should acknowledge and respond to the likelihood that some recipients will change their minds about the implants. In the next part, I examine the legal and ethical considerations that should shape their response.

II. LEGAL AND ETHICAL CONSIDERATIONS

A. RELEVANT LAW

Three bodies of law are relevant to the use of long-acting naltrexone implants. First, the U.S. regulations governing research involving human subjects apply to federally funded studies on implants like the OLANI.[43] Second, if the FDA at some point approves the device, rules governing decision making about medical interventions will apply to its use. Third, advance directive laws, particularly those governing future-oriented decisions about mental health treatment, are also relevant to the use of long-acting naltrexone implants.[44]

1. Implants in the Research Context

Federal research regulations require investigators to secure a person's voluntary and informed consent to study participation.[45] Before enrolling an individual in research, investigators must give that individual the facts that a reasonable person would want to know about the study.[46] This includes "any reasonably foreseeable risks and discomforts to the subject."[47] Thus, potential study participants must be warned that they might later regret their decision to try the naltrexone implant.

The regulations also require investigators to tell prospective research subjects that "participation is voluntary . . . and the subject may discontinue participation at any time without penalty . . . ."[48] Furthermore, the regulations prohibit "exculpatory language through which the subject . . . is made to waive or appear to waive any of the subject's legal rights."[49] This provision rules out the possibility of binding precommitment in naltrexone implant research, for it invalidates a participant's waiver of the right to withdraw from study participation.[50]

Decisional capacity is required for participants to enter and withdraw from a study. The regulations fail to define decisional capacity, but authorities generally

to get high. Addiction is a terrible thing and people will go to extremes to get high sometimes, even if it means cutting an implant out." *See* Kwai, *supra* note 6, Reader Comment from Sara.

[43]*See, e.g.*, 45 C.F.R. § 46 (2019).

[44]*See* CHARLES P. SABATINO, ADVANCE DIRECTIVES AND ADVANCE CARE PLANNING: LEGAL AND POLICY ISSUES 7-14 (2007) (discussing the historical development of advance directives).

[45]45 C.F.R. § 46.116 (2019).

[46]45 C.F.R. § 46.116 (a) (4) (2019).

[47]45 C.F.R. § 46.116 (b) (2) (2019).

[48]45 C.F.R. § 46.116 (b) (8) (2019).

[49]45 C.F.R. § 46.116 (a) (6) (2019).

[50]*See generally* Terrance McConnell, *The Inalienable Right to Withdraw from Research*, 38 J.L. MED. & ETHICS 840 (2010) (describing and defending this right); John A. Robertson, *Precommitment Issues in Bioethics*, 81 TEX. L. REV. 1849, 1859 (2003) (noting that a "mainstay of research ethics has been the right of subjects to withdraw from research at any time, regardless of the reason or the cost to researchers").

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agree that the standard requires people to have the capacity to understand important information about the study.[51] The standard also requires people to have the capacity to appreciate how they could be affected by participation, including the personal impact of any harm the study could impose on them.[52]

The regulations do allow studies to include participants lacking decisional capacity in certain circumstances. A "legally authorized representative" is an individual authorized under state law or institutional policy to make health care decisions on behalf of an incapable person.[53] Such representatives are empowered to consent to or refuse study participation, as well as to withdraw the incapable person from ongoing participation. In acting on behalf of the incapable person, representatives are expected to make choices that reflect the values and interests of that person. They are also expected to involve the person in decision making as much as possible, including obtaining the person's assent to the representative's choices.[54]

2. Implants in the Medical Context

If research on long-acting naltrexone implants produces good results, the FDA could approve them for general patient use. State law governs individual decisions about health care, including decisions involving FDA-approved medical devices.[55] The basic rules governing medical treatment are roughly the same as the research rules in requiring a patient's informed and voluntary consent to treatment. Patients also have legal rights to withdraw their consent to treatment.[56] The law permits surrogates, generally family members, to make decisions on behalf of patients lacking decisional capacity. Surrogates are directed to make decisions based on the patient's former values and preferences, as well as the patient's best interests.[57]

In contrast to the federal research regulations, the law governing medical treatment decisions recognizes a form of precommitment. Advance directive statutes authorize people to issue instructions about the treatment they would prefer if they later lose the ability to choose.[58] Individuals may also designate another person as their preferred decision maker in the event of incapacity.[59]

Advance directive laws usually permit people to revoke their previous choices at any time, however, even if they have lost decision-making capacity.[60] But there are exceptions to this approach. A number of states have enacted statutes specifically recognizing mental health care advance directives, and some of these statutes restrict the individual's power to revoke the choices set forth in a directive. [61]

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[51]*See* Michelle Biros, *Capacity, Vulnerability, and Informed Consent for Research*, 46 J.L. MED. & ETHICS 72, 73 (2018).

[52]*Id.*

[53]45 C.F.R. § 46.102 (i) (2019).

[54]*See* Biros, *supra* note 51, at 76.

[55]Erin S. DeMartino et al., *Who Decides When a Patient Can't? Statutes on Alternate Decision Makers*, 376 NEW ENG. J. MED 2 (2017); *see also* Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) about Off-Label Drug Use*, 87 MAYO CLINIC PROCEEDINGS 982, 986 (2012) (noting that the FDA does not regulate the practice of medicine).

[56]45 C.F.R. § 46.116 (b) (8) (2019).

[57]*See* JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 41-129 (2d. ed. 2001).

[58]*See* Judy A. Clausen, *Making the Case for a Model Mental Health Advance Directive Statute*, 14 YALE J. HEALTH POL'Y, L. & ETHICS 1, 24-25 (2014).

[59]*See generally* Rebecca Dresser, *Autonomy and Its Limits in End-of-Life Law*, in OXFORD HANDBOOK OF U.S. HEALTH LAW 399, 403 (I. Glenn Cohen, Allison K. Hoffman, and William M. Sage, eds., 2017).

[60]*See* Clausen, *supra* note 58, at 29.

[61]*Id*. at 29-33.

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In these jurisdictions, people lacking decisional capacity lack authority to revoke their previous choices.[62]

Virginia's statute illustrates this approach. When a patient loses decision-making capacity, the Virginia law permits the patient's previously selected agent to make a treatment choice over the patient's objection. The patient's advance directive must explicitly authorize the agent to "make the health care decision at issue, even over the patient's later protest."[63] The directive must include a licensed health professional's signed statement confirming that at the time the directive was created, the patient "was capable of making an informed decision" and understood the consequences of permitting future treatment under protest.[64]

The Virginia law defines decisional incapacity as the inability to "understand the nature, extent or probable consequences of the proposed health care decision, or to make a rational evaluation of the risks and benefits of alternatives to that decision."[65] The law directs patients' agents to take into account the risks and benefits of available treatment alternatives and to base "decisions on the beliefs, values, and preferences of the patient, or if they are unknown, on the patient's best interests."[66]

People with opioid use disorder are apparently eligible to make directives under this law, for it covers people whose decisional incapacity is produced by "mental illness, intellectual disability, or any other mental or physical disorder that precludes communication or impairs judgment."[67] Thus, if the FDA eventually approves the OLANI or another long-acting naltrexone implant, states with laws like Virginia's could permit people to engage in a limited form of precommitment to ongoing treatment with the device. Below I discuss whether advance directive laws should permit this or any other form of precommitment to long-term naltrexone treatment.

B. THE ETHICS OF PRECOMMITMENT IN MENTAL HEALTH TREATMENT

Ethicists have debated mental health applications of precommitment for many years. A few writers have considered precommitment in the context of addiction, but most of the debate concerns precommitment in the context of psychiatric disorders.[68] The basic disagreement is over whether the preferences of a person at one point in time should prevail over the person's conflicting preferences at another time.

1. Precommitment in Addiction Treatment

Philosophers defending precommitment for people with addiction disorders emphasize the psychological and physical pressures that reduce the individual's ability to exercise autonomy. According to Chrisoula Andreou, one such philosopher, people

[62] *Id*. at 29-30 (majority of state mental health directive statutes limit revocation to patients with capacity).

[63] VA. CODE ANN. § 54.1-2986.2 (B) (2019).

[64] *Id*.

[65] VA. CODE ANN. § 54.1-2982 (2019).

[66] VA. CODE ANN. § 54.1-2986.1 (B) (2019).

[67] *Id.* § 54.1-2982. Apparently these laws are not used very often. *See* Ron Berghmans & Marja van der Zanden, *Choosing to Limit Choice: Self-Binding Directives in Dutch Mental Health Care*, 35 INT'L J.L. & PSYCHIATRY 11, 15 (2012) (describing low usage rate for legally authorized self-binding mental health directives in the Netherlands); Heather Zelle et al., *Advance Directives in Mental Health Care: Evidence, Challenges and Promise*, 14 WORLD PSYCHIATRY 278, 278-79 (2015) (describing low usage rates of psychiatric advance directives).

[68] *See, e.g.*, Chrisoula Andreou, *Making a Clean Break: Addiction and Ulysses Contracts*, 22 BIOETHICS 25 (2008) (discussing precommitment and addiction).

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with addiction disorders are often preoccupied with preventing the self-destructive behavior that relapse typically triggers.[69] Their "stable" or "considered" preferences are to refrain from such behavior, but their cravings produce a form of incapacity that prevents them from doing so. Andreou contends that in this incapacitated state, they continue to have a preference to refrain from self-destructive actions, but are temporarily unable to act accordingly.[70] According to Andreou, their ongoing preferences supply ethical justification for overriding their immediate desires to resume their addictive behavior.[71] Thus, when people battling addiction enlist another individual to help preserve their considered preferences, it is ethical for that individual to interfere to prevent relapse.[72]

Ethicist Arthur Caplan agrees that addiction produces a compulsion that deprives people of the "full capacity" to exercise autonomy.[73] They may be able to understand relevant treatment information, he concedes, but their lack of control leaves them unable to choose in ways that reflect their values and preferences. Caplan argues that in the context of opioid use disorder, this lack of control can justify imposing a time-limited period of naltrexone treatment to determine whether it restores the capacity to exercise autonomy.[74]

Other scholars, however, question the notion that opioid addiction produces ongoing incapacity to exercise autonomy. One group of critics points to several flaws in Caplan's proposal for coercive naltrexone use. An addicted person who is "intoxicated or experiencing withdrawal symptoms" may be temporarily incapable, they say, but this can at most justify only a short-term compelled intervention like treatment to reverse overdose.[75] Such treatment is warranted because it promotes the individual's best interests. In contrast, they contend, coercive use of a six-month naltrexone implant would constitute an excessive limitation on autonomy.[76] And because the implant hasn't been proven safe and effective, Caplan cannot even cite the user's best interests to justify coercive treatment.[77]

Scholars also challenge the idea that precommitment is the product of the person's genuine preferences, preferences that persist despite the person's later conflicting wishes. Anthropologist Kristen Bell observes that a binding agreement to future compelled treatment relies on the conception of "an 'authentic self' jeopardized by a usurping alien force."[78] This conception merits deeper examination, she suggests, for it is not the only way to understand addiction.[79]

Another challenge comes from philosopher Dan Brock, who believes that identifying which "self" is the substance user's "true self" is a more complex task than

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[69]*Id.* at 27.

[70]*Id.* at 27-29.

[71]*Id.* at 28.

[72]Andreou does not offer a defense of legally binding precommitment, instead focusing on informal precommitment agreements, *see generally id.*

[73]Arthur Caplan, *Denying Autonomy in Order to Create It: The Paradox of Forcing Treatment Upon Addicts*, 103 ADDICTION 1919, 1919 (2008). *See also* Berghmans & van der Zanden, supra note 67, at 11 ("compulsory force resulting from addiction" can interfere with autonomy).

[74]Caplan, *supra* note 73, at 1919. *See also* Arthur Caplan, *Ethical Issues Surrounding Forced, Mandated, or Coerced Treatment*, 31 J. SUBSTANCE ABUSE TREATMENT 117 (2006).

[75]Wayne Hall et al., *The Use of Depot Naltrexone Under Legal Coercion: The Case for Caution*, 103 ADDICTION 1922, 1922 (2008).

[76]*See id.*

[77]*See id*.

[78]Bell, *supra* note 2, at 395.

[79]For an alternative conception of addiction, s*ee* Hanna Pickard, *Responsibility Without Blame for Addiction*, 10 NEUROETHICS 169, 171-72 (2017) (describing evidence that addiction fails to deprive people of control over their harmful behavior).

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precommitment advocates have recognized.[80] In cases involving repetitive behavior like substance addiction, he suggests, "two selves alternate over time."[81] And each self might resort to precommitment to bind the other self. Brock describes how this could work for people with drinking and gambling problems: "we can perfectly well imagine the self who is in the throes of drink or gambling seeking a precommitment strategy to prevent his sober or nongambling self from making it more difficult or impossible for him to drink or gamble."[82] Brock contends that precommitment demands an explanation of why the choices of one self should prevail over the other, and that explanation should clearly identify a defect in the other self's reasoning.[83]

According to Andreou and Caplan, that defect lies in the addicted person's cravings, which deprive the person of the capacity to exercise autonomy.[84] But there is no agreed-upon test to determine when cravings substantially diminish a drug user's decision-making capacity.[85] The absence of such a test presents a serious challenge to writers like Andreou and Caplan, for their defense of precommitment agreements assumes that evaluators can reliably differentiate the capacity of the self that is authorizing future unwanted treatment from the capacity of the self that is refusing such treatment.

2. Precommitment in General Mental Health Treatment

a. Ethical Arguments For and Against Precommitment

Writers endorsing precommitment in mental health treatment focus on psychiatric conditions like bipolar disorder that produce periodic episodes of self-destructive behavior.[86] Much of the analysis is also relevant to addiction. Some supporters think that enforcement of precommitment agreements can be justified for any individual who previously agreed to compulsory treatment. Others defend enforcement only when individuals have lost decision-making capacity. As in the addiction context, however, defining and assessing incapacity can be complicated.

Scholars defending precommitment for mental illness offer different justifications for honoring a person's advance treatment choices. Some follow Andreou in arguing that the stable and well-considered preferences expressed in a precommitment agreement continue to exist during illness episodes. For example, Julian Savulescu and Donna Dickenson believe that the preferences in mental health treatment directives represent enduring, "dispositional" preferences.[87] Momentary departures from those preferences should not, they argue, take priority over the dispositional preferences expressed in a treatment directive.[88] John Davis presents a related argument, contending that enforcing precommitment agreements can help to ensure that the "circumstances of the agent's life are consistent with his or her

[80]*See* Dan W. Brock, *Precommitment in Bioethics: Some Theoretical Issues*, 81 TEX. L. REV. 1805, 1816-17 (2003).

[81]*Id.* at 1818.

[82]*Id.*

[83]*Id*. at 1821. "Different selves" questions can arise in other contexts, too, such as criminal punishment. *See* Rebecca Dresser, *Personal Identity and Punishment,* 70 B.U. L. REV. 395 (1990).

[84]*See* Andreou, *supra* note 68; Caplan, *supra* note 73.

[85]*See* Peter J. Cohen, *Untreated Addiction Imposes an Ethical Bar to Recruiting Addicts for Non-Therapeutic Studies of Addictive Drugs*, 30 J.L. MED. & Ethics 73, 76 (2002).

[86]*See, e.g.*, Brock, *supra* note 80, at 1805, 1818.

[87]Julian Savulescu & Donna Dickenson, *The Time Frame of Preferences, Dispositions, and the Validity of Advance Directives for the Mentally Ill*, 5 PHIL. PSYCHIATRY & PSYCHOL. 226, 233-34 (1998).

[88]*Id.* at 232-35.

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concurrent wishes over the longest period of time."[89] For Ryan Spellecy, it is the planning process that elevates one set of preferences over another. Spellecy portrays precommitment agreements as the product of a deliberative planning process governed by a person's stable intentions.[90] According to Spellecy, such agreements carry greater moral weight than any immediate desires that conflict with the person's precommitment choices.[91]

These writers assume that observers can accurately distinguish between a person's legitimate and illegitimate choices. They support upholding precommitment agreements even in the face of a legally competent individual's conflicting choices. According to existing law, however, individuals who remain capable of independent medical decision making remain free to alter their previous treatment choices.[92] Moreover, as John Davis observes, "it is not unheard of for people to impulsively abandon carefully-considered plans."[93] As in the addiction context, precommitment supporters must show why the law should give priority to the competent person's advance choices. They must also explain how observers could detect when a legally competent person's desire to revoke a precommitment agreement stems from suspect, rather than genuinely autonomous, preferences.[94]

In light of these problems, some precommitment supporters would limit enforcement to cases in which the individual has lost decision-making capacity.[95] On this model, surrogate decision makers acting on behalf of individuals whose mental disorder impairs their ability to understand and appreciate treatment information could turn to a precommitment agreement to guide medical decision making. This approach is easier to reconcile with existing law, as long as the usual legal standards for capacity assessment are applied.[96] Certain precommitment supporters argue for a different capacity standard in precommitment situations, however, proposing that a person's refusal of previously chosen treatment is itself an indication of the person's incapacity.[97] This would be a novel capacity standard, unrecognized under current law. Such an approach would face obstacles similar to those who say precommitment

[89]John K. Davis, *How to Justify Enforcing a Ulysses Contract When Ulysses is Competent to Refuse*, 18 KENNEDY INST. ETHICS J. 87, 98 (2008).

[90]*See* Ryan Spellecy, *Reviving Ulysses Contracts*, 13 KENNEDY INST. ETHICS J. 373, 384 (2003).

[91]*Id.* Other scholars justify binding treatment agreements on different grounds. *See, e.g.,* Standing & Lawlor, supra note 3 (presenting four reasons why Ulysses contracts should be followed); Guy Widdershoven & Ron Berghmans, *Advance Directives in Psychiatric Care: A Narrative Approach*, 27 J. MED. ETHICS 92, 93 (2001) (directives are a highly significant "part of a process of finding ways of living one's own life").

[92]*See* Clausen, *supra* note 58, at 22 (person with decision-making capacity "should always be able to revoke her Ulysses arrangement").

[93]Davis, *supra* note 89, at 93. *See also* Brock, *supra* note 80, at 1820 (notion that precommitting "evaluative self" presents best picture of person's wishes and behavior doesn't leave room for people to change their minds).

[94]*See* Berghmans & van der Zanden, *supra* note 67, at 14 (describing difficulties in applying this criterion to cases considered under Dutch mental health directive law).

[95]*See, e.g.,* Tania Gergel & Gareth S. Owen, *Fluctuating Capacity and Advance Decision-Making in Bipolar Affective Disorder – Self-Binding Directives and Self-Determination*, 40 INT'L J. L. & PSYCHIATRY 92, 95 (2015).

[96]*See* Biros, *supra* text accompanying note 52 (describing this definition).

[97]*See* Clausen, *supra* note 58, at 33 ("When a patient's irrevocable directive consents to treatment that the patient refuses when he arrives at the hospital, the refusal itself is evidence of incapacity"); Widdershoven & Berghmans, *supra* note 91, at 95 (patient should be able to determine what counts as later incompetency sufficient to overrule wishes in favor of directive).

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should be sufficient to override the conflicting wishes of a legally competent individual.[98]

b. Therapeutic Arguments For and Against Precommitment

Besides arguing that precommitment agreements embody the most important preferences of their makers, supporters cite the therapeutic benefits that can come from creating such agreements.[99] Planning for future treatment "creates the opportunity for an important conversation and education about the future among the client, his or her doctors, caregivers, and family members."[100] Furthermore, the very process of making an agreement can increase the person's motivation to follow the precommitment plan, reducing the likelihood of later resistance to that plan.[101] Making a directive can also enhance a person's feeling of personal responsibility and control in coping with a psychiatric problem.[102] In these ways, supporters say, precommitment promotes the shared decision making that should govern medical choices.[103]

Not everyone presents such a positive picture, however. There will always be some people who resist the treatment they previously agreed to, and these individuals will experience the now-unwanted treatment as coercive.[104] Moreover, "[b]eing responsive to the patient during a crisis requires that refusals are taken seriously."[105] Efforts to persuade patients to follow their previous choices may be acceptable, but coercion damages trust and the odds of long-term treatment success.[106] In light of these concerns, clinicians and surrogate decision makers should think seriously about the potential negative impact of imposing a medical intervention on any refusing patient. In such circumstances, a better outcome could come from seeking a resolution the patient can accept, rather than imposing a now-unwanted intervention on that patient.

III. PRECOMMITMENT AND NALTREXONE IMPLANTS

At this point, naltrexone implants are investigational devices requiring further evaluation to determine their risks and potential benefits. As long as they remain under study, their use will be governed by the federal rules protecting human subjects. The rules require researchers to permit subjects to withdraw from studies at any time.

[98]Some endorse a less drastic approach in which a person's refusal of previously accepted treatment would trigger a capacity evaluation. *See*, *e.g.*, Gergel & Owen, *supra* note 95, at 95 (behaviors person names as triggering precommitment agreement are "key indicators that [decision-making capacity] may have been lost and requires assessment").

[99]Lisa Brodoff, *Planning for Alzheimer's Disease with Mental Health Advance Directives*, 17 ELDER L.J. 239, 294 (2009). *See also* Gergel & Owen, *supra* note 95, at 96 (advance directive "would create an opportunity for detailed reflection and engagement between the patient and their clinical team").

[100]Brodoff, *supra* note 99, at 294. *See also* Gergel & Owen, *supra* note 95.

[101]*See* Zelle et al., *supra* note 67, at 278. There is some empirical support for this claim. One study found a lower rate of involuntary medication and other coercive interventions among people who had completed a psychiatric advance directive than among those who had not. Jeffrey W. Swanson et al., *Psychiatric Advance Directives and Reduction of Coercive Crisis Interventions*, 17 J. MENTAL HEALTH 255 (2009).

[102]Clausen, *supra* note 58, at 20. *See also* Pam Belluck, *Now Mental Health Patients Can Specify Their Care Before Hallucination and Voices Overwhelm Them*, N.Y. TIMES (Dec. 3, 2018), (interviews with people experiencing this benefit).

[103]Gergel & Owen, *supra* note 95, at 99.

[104]John Q. LaFond & Debra Srebnik, *The Impact of Mental Health Advance Directives on Patient Perceptions of Coercion in Civil Commitment and Treatment Decisions*, 25 INTL J. L. & PSYCHIATRY 537, 552-54 (2002). *See also* Gergel & Owen, *supra* note 95, at 97.

[105]Widdershoven & Berghmans, *supra* note 91, at 95.

[106]*See* LaFond & Srebnik, *supra* note 104, at 547.

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In implant research, the right to withdraw would include the right of a person with decision-making capacity to have the implant removed before the study ends.[107] In theory, a legally authorized representative would have the power to block withdrawal by an objecting study subject who has lost decision-making capacity. However, the risks and unproven nature of the implants, together with the absence of subject assent to ongoing study participation, make this an ethically questionable outcome. Thus, it is unlikely that binding agreements will become an issue while implants remain in the research phase.

If studies eventually show that implants can safely and effectively reduce relapse rates, the FDA could approve the devices for clinical use. However, the legal obstacles and ethical concerns I have described are likely to undermine efforts to incorporate binding precommitment agreements into implant use.

Proposals to allow clinicians to deny legally competent opioid users' implant removal requests would be highly controversial, likely to encounter strong opposition. Certainly, there would be challenges to such a serious infringement of patient autonomy. Opponents would also challenge claims that denying removal requests would promote the best interests of recipients deemed incapable of making the removal decision. Research in Russia and Australia documents the harm that could come from denying removal requests, including infection caused by attempted self-removal and overdose from opioid and non-opioid drugs.[108] To prevent such harm, denials of removal requests would have to be accompanied by confinement or some form of close monitoring of the protesting individual. Risks and complexities like these have reportedly made enforcement of psychiatric advance directives a relatively rare occurrence.[109] Efforts to enforce precommitment to long-term naltrexone use are likely to suffer a similar fate.

At the same time, the ethical debate over precommitment offers guidance to policymakers, clinicians, and individuals considering naltrexone implants. Although precommitment enforcement would be problematic, features of the precommitment process could be valuable in decision making about implants. Advance planning could have therapeutic benefits similar to those seen in the mental health context, possibly increasing recipients' feelings of control and investment in the treatment plan, as well as reducing the chance that they will change their minds about the device.

The precommitment debate highlights the need for researchers and clinicians to promote genuine informed consent to treatment with naltrexone implants. This includes preparing people for the difficulties they could face after the device is implanted. Before deciding on implantation, prospective recipients should not only understand and appreciate the burdens associated with long-term naltrexone treatment, they should also confront the possibility that they will want the implant removed once they experience those burdens.[110] Clinicians and prospective recipients should discuss what should happen if this occurs, creating a plan for responding to the recipient's objections to continued naltrexone treatment. The plan should include ongoing

[107]In line with this requirement, researchers conducting the most recent naltrexone implant study in Russia included the right to withdraw in the disclosure materials given to prospective subjects. Krupitsky et al. II, Supplementary Appendix, *supra* note 36, at 3.

[108]*See supra* notes 40-42 and accompanying text.

[109]*See* Zelle et al., *supra* note 67.

[110]The consent form for the most recent implant study in Russia addressed removal requests as follows: "We strongly advise you not to try to remove the implant after it is inserted. . . . If you wish to have it removed, please make an appointment with the research staff to discuss the situation." Krupitsky et al. II, Supplementary Index, *supra* note 36, at 8. Study investigators also required prospective study participants to pass a quiz measuring their understanding of study information before signing the consent form. *Id.* at 2.

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clinical and social support for implant recipients, which experts and opioid users say is crucial to maintaining the motivation to continue treatment.[111]

If a recipient does request early implant removal, clinicians should discuss the previously agreed-upon plan and try to persuade the person to adhere to it. They should also discuss the reasons for the recipient's change of mind, exploring alternatives to removal that might help the recipient deal with the distress and other problems underlying the removal request. If these efforts are unsuccessful, clinicians should remove the implant and encourage the individual to begin another type of treatment for opioid use disorder. Methadone and buprenorphine are safe and effective alternative therapies that would be reasonable options for people who find naltrexone treatment too difficult.[112]

Naltrexone implants could be a welcome addition to the treatment options available to people seeking medication-assisted therapy for opioid use disorder. Implants could make it easier for people to maintain their commitment to long-term sobriety. As researchers and clinicians point out, people choosing naltrexone are a relatively motivated group, able to complete full detoxification and willing to try a particularly challenging form of treatment.[113] Researchers and clinicians should build on this foundation, creating an alliance with implant recipients. Imposed treatment, even with advance consent, is unlikely to contribute to the long-term success of naltrexone implants.

[111]*See*, *e.g.*, Krupitsky et al. II, *supra* note 36, at e223 (counseling for study subjects "focused on providing support, encouraging adherence to prescribed medication, dealing with craving, avoiding situations associated with drug use and behaviours that spread HIV, providing help for psychiatric and psychosocial problems, and documenting adverse events").

[112]Herbert D. Kleber, *Pharmacologic Treatments for Opioid Dependence: Detoxification and Maintenance Options*, 9 DIALOGUES IN CLINICAL NEUROSCIENCE 455 (2007).

[113]*See* NAT'L HEALTH & MED. RESEARCH COUNCIL, *supra* note 14, at 5, 15 (long-term benefit of naltrexone treatment greatest for "highly motivated patients").

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