



Winter 2023

Supported Decision-Making and Merciful Health Care Access: Respecting Autonomy at End of Life for Individuals with Cognitive Disabilities

Brenna M. Rosen

Washington and Lee University School of Law, rosen.b23@law.wlu.edu

Follow this and additional works at: <https://scholarlycommons.law.wlu.edu/wlulr>



Part of the [Disability Law Commons](#), [Elder Law Commons](#), and the [Health Law and Policy Commons](#)

Recommended Citation

Brenna M. Rosen, *Supported Decision-Making and Merciful Health Care Access: Respecting Autonomy at End of Life for Individuals with Cognitive Disabilities*, 80 Wash. & Lee L. Rev. 555 (). Available at: <https://scholarlycommons.law.wlu.edu/wlulr/vol80/iss1/11>

This Student Notes Colloquium is brought to you for free and open access by the Washington and Lee Law Review at Washington and Lee University School of Law Scholarly Commons. It has been accepted for inclusion in Washington and Lee Law Review by an authorized editor of Washington and Lee University School of Law Scholarly Commons. For more information, please contact christensena@wlu.edu.

Supported Decision-Making and Merciful Health Care Access: Respecting Autonomy at End of Life for Individuals with Cognitive Disabilities

Brenna M. Rosen*

Abstract

Supported decision-making is a relatively new, powerful, and quickly developing alternative to restrictive guardianships and other draconian surrogate decision-making arrangements for individuals with cognitive disabilities. Its power lies specifically in the protection and affirmation of their autonomy, allowing these individuals to remain central in the planning of

* Recipient, Washington and Lee Law Council Law Review Award; J.D. Candidate, Class of 2023, Washington & Lee University School of Law; B.A., 2016, University of Vermont. Thank you to Professor Alexandra Klein for serving as my Note advisor and for writing a comment to this Note. Your continuing support, encouragement, and contributions to the field are invaluable. Thank you to Professor Beth Belmont for your truly wonderful way of connecting the topic of supported decision-making to the W&L Law community at the *Student Note Colloquium*. Thank you to Amitai Heller for your comment to this Note and your thoughtful and engaging presentation at the Colloquium. Thank you again to Amitai Heller and Jess Pezley for your guidance and expertise, your powerful advocacy in the field, and for intellectually challenging me at every turn. Thank you to Ryan D'Ercole for your role in making this Note a reality and to the entire 2022 *W&L Law Review* Upper Board for giving me the honor of the Law Council Law Review Award. Many thanks to the current *W&L Law Review* editorial board for your edits, suggestions, and hard work. Finally, thank you to my family and friends for your love and support throughout this process, particularly to Brigid O'Donoghue for her citation expertise, to Rich Gilliland for his endless patience and valuable input, and to my dad, Megan, Adam, Bonnie, and Nicole for making the trip to Lexington to support this work.

their lives and affairs. Despite supported decision-making's theoretical promise, it is often unclear whether and how the model interacts with other legislation presiding over how one may make crucial life choices, such as those at end of life.

This Note attempts to bridge the gap by analyzing how supported decision-making may be a valuable tool in effectuating equal access to end-of-life health care. For several reasons, individuals with disabilities are living longer and are subsequently more likely to encounter complex end-of-life treatment decisions. Unfortunately, they also face significant barriers in accessing health services. Their autonomy is often subjugated in favor of paternalistic norms, potentially rendering them ineligible for certain pain-mitigating care and forcing them to suffer needlessly at end of life. It is possible that through the use of supported decision-making, patients may be able to access pain mitigating treatment that may otherwise be unavailable to them. At the same time that supported decision making is gaining legal traction and public favor, laws like the FDA's Expanded Access Program, otherwise called compassionate use, and state medical aid in dying legislation are promoting individual autonomy and the ethical concept of mercy by providing alternative avenues to limit suffering at end of life.

Undoubtedly, those with cognitive disabilities wishing to access medical aid in dying or compassionate use are in unique circumstances, but no individual should be forced to suffer through a terminal diagnosis without access to the health care of their choice. Although more research is needed regarding how supported decision-making agreements are commonly used and how they interact with end-of-life legislation, a continued push for expansion and revision of both supported decision-making statutes and end-of-life legislation may legitimize its application to end-of-life pain management. This would halt foreclosure of individuals' rights to self-determination.

Table of Contents

INTRODUCTION	557
I. AUTONOMY AT END OF LIFE	561
A. <i>Medical Autonomy at End of Life</i>	563

B.	<i>Recognition of Disabled Autonomy</i>	566
II.	END-OF-LIFE DECISION-MAKING	568
A.	<i>Advance Directives</i>	570
B.	<i>Surrogate Decision-Making</i>	574
C.	<i>Guardianship</i>	576
D.	<i>Supported Decision-Making</i>	581
III.	SUPPORTED DECISION-MAKING AND EQUAL ACCESS AT END OF LIFE	587
A.	<i>Medical Aid in Dying: What Is It?</i>	588
B.	<i>Supported Decision-Making and Medical Aid in Dying</i>	591
C.	<i>Expanded Access: What Is It?</i>	594
D.	<i>Supported Decision-Making and Expanded Access</i>	600
	CONCLUSION.....	606

INTRODUCTION

Summer 2020 marked the thirtieth anniversary of the Americans with Disabilities Act (ADA),¹ coinciding with the ongoing COVID-19 crisis and related discussions regarding autonomy and end-of-life healthcare.² The prospect of using the antiviral drug Remdesivir for the treatment of COVID-19 despite its lack of known safety or efficacy reignited ongoing debates about an individual’s “right to try” or “right to die” when faced with a terminal medical diagnosis.³ In December 2019,

1. 42 U.S.C. § 12101.

2. See Press Release, Ctrs. for Disease Control & Prevention, The 30th Anniversary of the Americans with Disabilities Act (July 24, 2020) (reflecting on the successes of the Act on its thirtieth anniversary); Jennifer S. Bard, *Lifting the Barriers Excluding People Living with Disabilities from the Benefits of Inclusion in Research Studies*, 6 U. PA. J.L. & PUB. AFFS. 489, 492–96 (2021) (discussing the role of clinical trials in times of crisis such as the COVID-19 pandemic).

3. See Bret Stephens, *The Story of Remdesivir*, N.Y. TIMES (Apr. 17, 2021), <https://perma.cc/2DFQ-AM7H> (PDF) (“But whether remdesivir turns out to be effective or not—and it’s always wise to curb one’s enthusiasm about supposed miracle cures—the remarkable thing is that it’s available at all.”); Oliver J. Kim, *Trying and Dying: Are Some Wishes at the End of Life Better than Others?*, 41 DALHOUSIE L.J. 93, 94 (2018)

One of the most difficult and controversial issues for policymakers is how to ensure the law respects a patient’s wishes at the end of life. Some

champion Paralympic athlete Marieke Vervoort made headlines when she documented her end-of-life journey under Belgian euthanasia laws.⁴ Soon after, terminally ill patients in the United States fought for the right to legally access psilocybin to ease psychic pain at end-of-life.⁵ In June 2021, New Mexico became the most recent state to legalize medical aid in dying,⁶ while at the same time the Food and Drug Administration (FDA) approved Biogen's Aduhelm on an accelerated approval pathway for the treatment of Alzheimer's disease.⁷ The recent emphasis on mercy and autonomy at end of life⁸ may give hope to some for a peaceful death,⁹ but others remain stuck under

policymakers have proposed granting individuals suffering from terminal illness a "right to die," or to seek medical assistance to end their life. Another policy proposal is the so-called "right to try," or providing a means for terminally ill patients to request experimental drugs that have not completed clinical trials to demonstrate they are safe and effective.

4. See Andrew Keh, *The Champion Who Picked a Date to Die*, N.Y. TIMES (Dec. 5, 2019), <https://perma.cc/R6NF-DZ66> (PDF) (stating that euthanasia has been legal in Belgium since 2002, available to patients who "exhibit a 'hopeless' medical condition with 'unbearable' suffering, including mental illnesses or cognitive disorders").

5. See JoNel Aleccia, *New Legal Push Aims to Speed Magic Mushrooms to Dying Patients*, KAISER HEALTH NEWS (Nov. 24, 2020), <https://perma.cc/VCQ5-UNK5> (discussing the potential for patients to access psilocybin therapy under the Right to Try Act).

6. End-of-Life Options Act, N.M. STAT. ANN. § 24-7C-1–8 (West 2022); see also *New Mexico Governor Signs Historic Medical Aid-in-Dying Bill into Law*, COMPASSION & CHOICES (Apr. 8, 2021), <https://perma.cc/3JQD-4QEK> (stating that as of June 18, 2021, New Mexico is the tenth state and eleventh jurisdiction to allow medical aid in dying).

7. See Jeffrey A. Singer, *Controversy Over New Alzheimer's Drug Challenges FDA Efficacy Requirement*, CATO INST. (June 9, 2021, 11:47 AM), <https://perma.cc/7DF9-V3EM>.

8. See Harold Braswell, *Can There Be a Disability Studies Theory of "End-of-Life Autonomy?"*, 31 DISABILITY STUD. Q., no. 4, 2011 ("The expression 'end-of-life' can include a range of medical conditions, including chronic diseases, terminal diseases, 'severe' disabilities, persistent vegetative states, and brain death.").

9. See Barbara A. Noah & Neal Feigenson, *Avoiding Overtreatment at the End of Life: Physician-Patient Communication and Truly Informed Consent*, 36 PACE L. REV. 736, 739 (2016) ("Patients say that they wish for a 'good death,' but this idea surely must mean different things to different people. Nevertheless, most people's idea of a 'good death' likely have some elements in common, such as avoiding physical suffering.").

traditional medical and legal paternalism, without the opportunity for an autonomous and pain-free passing.¹⁰

Despite the many successes of the ADA, individuals with disabilities¹¹ still face high levels of discrimination in healthcare.¹² Their autonomy is often subjugated in favor of paternalistic norms,¹³ potentially rendering them ineligible for pain-mitigating care.¹⁴ A terminally ill patient with a cognitive impairment who wishes to access treatment through avenues like state medical aid in dying or federal Expanded Access must first find a physician who is willing to help, then navigate complex procedures on the patient's behalf, and finally write the necessary prescription. When physicians are reluctant to extend access to certain health care to individuals with disabilities, these individuals are stripped of their autonomy and may be forced to needlessly suffer.¹⁵ This is a dire reality for the

10. See Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 222–23 (1985) (stating that medical traditions “historically have downgraded patient autonomy” but that doctors have “begun to recognize and accept patient demands for more information and control”).

11. See *Disability and Health Overview*, CTRS. FOR DISEASE CONTROL & PREVENTION (2020), <https://perma.cc/Y57H-F2GE> (defining disability as “any condition of the body or mind (impairment) that makes it more difficult for the person with the condition to do certain activities (activity limitation) and interact with the world around them (participation restrictions)”; see *id.* (noting that the term “people with disabilities” refers to a single population, but is actually a diverse group of individuals with varying levels of function and needs).

12. See Press Release, Ctrs. for Disease Control & Prevention, *supra* note 2 (urging for the American public to address the continued health disparities faced by people with disabilities).

13. See 42 U.S.C. § 12101(a)(5) (“[I]ndividuals with disabilities continually encounter various forms of discrimination, including . . . overprotective rules and policies.”).

14. Megan S. Wright, *Equality of Autonomy? Physician Aid in Dying and Supported Decision-Making*, 63 ARIZ. L. REV. 157, 197 (2021) [hereinafter Wright, *Equality of Autonomy?*] (“Indeed, excluding terminally ill persons with decisional impairments from [physician aid in dying] out of a desire to protect them from harm is paternalistic and reinforces stereotypes of persons with disabilities as weak and incapable of autonomy.”).

15. See Irene Tuffrey-Wijne, *Palliative Care and Intellectual Disabilities*, UNIV. OF HERTFORDSHIRE (2017), <https://perma.cc/42QT-52NV> (“Clinicians may be reluctant to consider and provide the same range of treatment options for people with intellectual disabilities as for the rest of the population,

approximately six-and-a-half million people in the United States who have a cognitive disability and who may eventually face a terminal diagnosis.¹⁶ In times of medical crisis, particularly at end of life, it is imperative that all individuals have equal access to the health care of their choice. Due to advances in medical technology, individuals with disabilities are living longer, increasing the likelihood that they will face complex end-of-life treatment decisions.¹⁷ The law must adapt to the changing medical landscape and support the right to autonomy and self-determination for all.

This Note addresses the importance of individual autonomy in medical decision-making and suggests that the emerging practice of supported decision-making may be a valuable legal tool in effectuating equal access to end-of-life health care for individuals with disabilities. Supported decision-making allows an individual with diminished capacity to freely enter into an agreement with a trusted supporter who assists the principal with life decisions.¹⁸ Part I of this Note provides background on the concept of autonomy and its crucial role at end of life for individuals with disabilities, highlighting the challenges that physicians and patients alike face in effectuating a peaceful—or “good”—death. Part II addresses the existing legal mechanisms that enable individuals to engage in end-of-life decision-making, with a focus on the shortcomings of those tools in relation to individuals with disabilities. Part III argues that supported decision-making may help individuals with disabilities maintain their autonomy and access mercy-promoting treatment to ease suffering at end of life. This Note concludes that supported decision-making offers significant promise as a tool to enhance both autonomy and equal access to emerging end-of-life care for individuals with disabilities.

because of a perceived difficulty obtaining informed consent, or for fear of litigation.”).

16. See CTRS. FOR DISEASE CONTROL & PREVENTION, *DISABILITY IMPACTS ALL OF US 1* (2020), <https://perma.cc/8455-YJXG> (PDF) (stating that of the sixty-one million adults in the United States with a disability, 10.8 percent have a cognitive disability).

17. See Tuffrey-Wijne, *supra* note 15 (stating that reasons for the dramatic shift in life expectancy for individuals with disabilities include reduced childhood mortality, better knowledge and health care, and advocacy).

18. Emily A. Largent & Andrew Peterson, *Supported Decision-Making in the United States and Abroad*, 23 J. HEALTH CARE L. & POL'Y 271, 274 (2021).

I. AUTONOMY AT END OF LIFE

Autonomy in medical decision-making and the concept of self-ownership are crucial to ensuring that individuals retain control over their own lives and values, maintain a high quality of life,¹⁹ and remain integrated in the public sphere.²⁰ Autonomy, or self-government,²¹ is a fundamental principle of bioethics²² and a core “life-affirming value.”²³ Some scholars understand autonomy as being so crucial to American life that it may—or should be—a constitutionally protected value.²⁴ In making autonomous choices, a person uses rational capacities,

19. DIV. OF MENTAL HEALTH & PREVENTION OF SUBSTANCE ABUSE, WORLD HEALTH ORG., WORLD HEALTH ORGANIZATION QUALITY OF LIFE USER MANUAL 11 (1998), <https://perma.cc/6332-XZLW> (PDF) (defining quality of life as an individual’s “perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.”).

20. See Katherine L. Moore, *Disabled Autonomy*, 22 J. HEALTH CARE L. & POL’Y 245, 250 (2020) (stating the need for people with disabilities to be recognized and valued in society); see also Wright, *Equality of Autonomy?*, *supra* note 14, at 170 (stating that everyone should have equal legal capacity and equal power to exercise their legal rights).

21. See Jukka Varelius, *The Value of Autonomy in Medical Ethics*, 9 MED. HEALTH CARE PHIL. 377, 377 (2006) (“Although the notion of autonomy has been used in many distinct senses in different connections, in biomedical ethics there is a common core understanding of the meaning of this notion. According to this idea, autonomy means self-government.”).

22. See Lauren M. Wancata & Daniel B. Hinshaw, *Rethinking Autonomy: Decision Making Between Patient and Surgeon in Advanced Illnesses*, 4 ANNALS TRANSNAT’L MED. 1, 2 (2016) (describing autonomy, beneficence, non-maleficence, and justice as the four main principles of bioethics).

23. See Richard H. Fallon, Jr., *Two Senses of Autonomy*, 46 STAN. L. REV. 875, 875 (1994); see also Moore, *supra* note 20, at 248–49 (“Autonomy is a life-affirming value, in that it promotes the individual self-determination and expression of will that defines our humanity in some ways.”); *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891) (“No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.”).

24. See Fallon, *supra* note 23, at 875 (“A diverse collection of writers has identified autonomy as a central value underlying the First Amendment’s commitment to free expression.”). *But see Personal Autonomy*, LAW INFO. INST. (2022), <https://perma.cc/7EWE-5FRP> (“The Supreme Court does not use the phrase ‘personal autonomy’ very often. Unlike privacy, it is not a fundamental right. As such, it is still a very limited concept regarding its impact on legal jurisprudence.”).

acts as an agent, creates and forms the self, and gives life meaning and purpose.²⁵ Autonomy comprises two abilities: (i) the ability to value, or “espouse a genuine preference”; and (ii) the ability to “enact one’s values in the complex circumstances of the real world.”²⁶ It may be best conceptualized as a two-step process resembling information gathering and action.

While the traditional philosophical notion of autonomy is highly individualistic,²⁷ some scholars argue that comprehensive autonomy must address not only the individual’s inner self, but their social relationships as well.²⁸ Proponents of “relational autonomy” appreciate the benefit of social influence and family involvement in the decision-making process and argue that autonomy may be best understood as a matter of degree.²⁹ Underlying the concept of relational autonomy is the

25. Varelius, *supra* note 21, at 379. *But see* Moore, *supra* note 20, at 247 (stating that an emphasis on rationality can also be used as a weapon to strip certain individuals of their autonomy).

26. See Agnieszka Jaworska, *Advance Directives and Substitute Decision-Making*, in *STANFORD ENCYCLOPEDIA OF PHILOSOPHY* (Edward N. Zalta et al. eds., 2009), <https://perma.cc/PRB5-XT67> (quoting Ronald Dworkin’s interpretation of the capacity for autonomy).

27. See Megan S. Wright, *End of Life and Autonomy: The Case for Relational Nudges in End-of-Life Decision-Making Law and Policy*, 77 *MD. L. REV.* 1062, 1066 (2018) [hereinafter Wright, *The Case for Relational Nudges*] (explaining that this conceptualization occurred at least in part because of how the drafters of the Constitution thought about autonomy and how that was reflected in common law decisions).

28. See John Christman, *Relational Autonomy, Liberal Individualism, and the Social Constitution of Selves*, 117 *PHIL. STUD.: INT’L J. PHIL. ANALYTIC TRADITION* 143, 143 (2003) (defining the concept of relational autonomy as “an alternative conception of what it means to be a free self-governing agent who possibly . . . defines her basic value commitments in terms of interpersonal relationships and mutual dependencies”); *see also* Jose Miola & Roy Gilbar, *One Size Fits All? On Patient Autonomy, Informed Consent and the Impact of Culture*, 23 *MED. L. REV.* 375, 379 (2014) (“Relational autonomy theorists attempt to combine the reality that social relationships constitute an important part of the individual’s identity with the prominence given in Western society to freedom and liberty.”).

29. See Wright, *The Case for Relational Nudges*, *supra* note 27, at 1062 (“On the whole, law conceptualized autonomy at the end of life as an individual making private, personal decisions based solely on their interests and values, independent of others. But ordinary people understand autonomous decision-making at end of life differently, in a way that acknowledges the importance of interpersonal relationships.”); *see also* Fallon, *supra* note 23, at 876 (explaining that individuals with abundant resources are highly

idea that oppressive social conditions threaten one's ability to act effectively on their values.³⁰ Therefore, if autonomy is to be preserved, society and interpersonal relationships must recognize and reinforce—not undermine—individuals' ability to exercise autonomy.³¹ Above all else, autonomy requires liberty and agency.³²

A. *Medical Autonomy at End of Life*

Protection of autonomy assumes particular importance in the context of societal norms regarding death and dying. In the United States, the default treatment method at end of life focuses on preservation of life at almost all cost.³³ This method is often at odds with the dominant preference of most people to avoid physical suffering at end of life.³⁴ Preserving life at all cost may result in avoidable suffering or futile overtreatment, which utilizes significant hospital-based resources with little benefit to the sick individual.³⁵ In popular culture, there is often a depiction of the moral notion of doctors who have “tried everything” to save a patient's life.³⁶ This attitude reflects the

autonomous, while those who are “dictated by economic necessity” may not be very autonomous at all).

30. See 1 TAMAR HELLER ET AL., *DISABILITY IN AMERICAN LIFE: AN ENCYCLOPEDIA OF CONCEPTS, POLICIES, AND CONTROVERSIES* 790 (Tamar Heller et al. eds., 2019) (“[W]hatever the limitations associated with particular disabilities, people with disabilities have been saying for years that their major obstacles are not inherent in their disabilities, but arise from barriers that have been imposed externally and unnecessarily.”).

31. See Miola & Gilbar, *supra* note 28, at 382 (“Thus, the state should not let social structures and relationships undermine the individual's capacities necessary for autonomy. Therefore, autonomy is meaningless without the promotion of equality and justice in the private and the public spheres.”).

32. See Laura Sedig, *What's the Role of Autonomy in Patient- and Family-Centered Care When Patients and Family Members Don't Agree?*, 18 AM. MED. ASS'N J. ETHICS 12, 13 (2016).

33. See Noah & Feigenson, *supra* note 9, at 737 (stating that this preference reflects the opinions of almost a third of Americans who believe that medical staff should do everything to keep patients alive under all circumstances).

34. *Id.*

35. See *id.* at 740 (stating that aggressive interventions are used even when death is imminent).

36. See *Emergency!: Decision* (NBC television broadcast Sept. 16, 1972)

Dr. Larry Sunderline: Well, we tried everything in the book.

historic ethical principle that a physician's main duty is to promote patient welfare.³⁷ While “doing everything” may be helpful in alleviating feelings of helplessness, prolonging an individual's life may not be in the best interest of a patient in pain.³⁸ Even when treatment options are exhausted, terminally ill patients are typically placed under palliative sedation, where they still may experience breakthrough pain.³⁹

Autonomy allows patients to avoid a painful death and make decisions in their own best interests, instead of having to rely on a physician's determinations.⁴⁰ In recent decades, modern ideas about medicine have begun to incorporate autonomy into treatment guidelines and medical legal concepts

Dr. Kelly Brackett: Maybe someday we'll get a better book.

37. See Madison Kilbride & Steven Joffe, *The New Age of Patient Autonomy: Implications for the Patient-Physician Relationship*, 320 *AMA* 1, 1 (2018) (stating that “a central assumption of the paternalistic framework” of medicine was that medical expertise led physicians to believe that they knew what was best for the patient and that the patient was expected to comply with the course of treatment recommended).

38. See Noah & Feigenson, *supra* note 9, at 742–43 (explaining that a growing body of evidence demonstrates that an emphasis on palliative and therapeutic care may actually improve quality and duration of life).

39. See *Medical Aid in Dying and Palliative Care*, COMPASSION & CHOICES (2022), <https://perma.cc/N98A-CR3D> (PDF) (stating that palliative sedation involves being medicated to reduce consciousness, but that the sedation does not completely relieve all pain); see also Giovambattista Zeppetella et al., *Prevalence and Characteristics of Breakthrough Pain in Cancer Patients Admitted to a Hospice*, 20 *J. PAIN & SYMPTOM MGMT.* 87, 91 (2000) (“Breakthrough pain occurs frequently, is short-lasting, is often unpredictable, and is not necessarily related to chronic pain.”).

40. See Tuffrey-Wijne, *supra* note 15 (discussing the transition from medical paternalism to recognition of patient autonomy and the patient's right to decide); see also Maureen Kwiecinski, *To Be or Not to Be, Should Doctors Decide? Ethical and Legal Aspects of Medical Futility Policies*, 7 *MARQ. ELDER'S ADVISOR* 313, 317 (2006) (stating that a myriad of ethical and legal issues arise when physicians unilaterally withhold or withdraw treatment from incompetent patients pursuant to statutory medical futility policies); Carolyn A. Bernstein, *When It Comes to Your Health Care, How Much Autonomy Is the Right Amount?*, *HARVARD HEALTH BLOG* (May 7, 2018), <https://perma.cc/F8WQ-V7BS>

Patient autonomy: The right of patients to make decisions about their medical care without their health care provider trying to influence their decision. Patient autonomy does allow for health care providers to educate the patient but does not allow the health care provider to make the decision for the patient.

more forcefully.⁴¹ For example, individual autonomy is the governing ethical principle of the doctrine of informed consent, which requires physicians to provide information necessary for patients to fully understand the risks and benefits of a proposed intervention, as well as its alternatives.⁴² The informed consent doctrine promotes autonomy by challenging the traditional paternalistic model of medicine,⁴³ empowering patients to take the reins of their own health care.⁴⁴

Recalling the concept of relational autonomy, at the same time that individuals wish to control their own health outcomes, research demonstrates that individuals prefer to make serious end-of-life health care decisions in consultation with their loved ones.⁴⁵ Individuals still view themselves as acting autonomously even when deciding relationally.⁴⁶ Autonomy should be—and in some ways is—seen as a clinical reality that consists of mutual information-sharing, conversation, and decision-making.⁴⁷ It is

41. See Vikki A. Entwistle et al., *Supporting Patient Autonomy: The Importance of Clinician-Patient Relationships*, 25 J. GEN. INTERNAL MED. 741, 741 (2010) (“A principle of respect for autonomy is also invoked in discussions about confidentiality, fidelity, privacy and truth-telling, but is most strongly associated with the idea that patients should be allowed or enabled to make autonomous decisions about their health care.”).

42. See Ben A. Rich, *Advance Directives: The Next Generation*, 19 J. LEGAL MED. 63, 65 (1998) (“The modern view, which pervades the informed consent doctrine, is that knowledge is power, and therefore forthright disclosure of pertinent medical information to patients is empowering.”); see also *Informed Consent*, BOUVIER L. DICTIONARY (2012).

43. See Rich, *supra* note 42, at 64 (explaining the paradigm shift in the nature of the patient-physician relationship).

44. See Braswell, *supra* note 8. For a discussion of state restrictions on medical autonomy including vaccine mandates and penalties for patients without insurance, see Wright, *The Case for Relational Nudges*, *supra* note 27, at 1065–66.

45. Wright, *The Case for Relational Nudges*, *supra* note 27, at 1066.

46. See Wright, *Equality of Autonomy?*, *supra* note 14, at 173 (advocating for the application of relational autonomy to end-of-life health care).

47. See *Are There Limits to a Patient’s Autonomy in Making Health Care Decisions?*, HOSP. NEWS, <https://perma.cc/AJ2F-YGG6> (stating that autonomy should be seen as more than patient control of decision-making); see also JONATHAN PUGH, *AUTONOMY, RATIONALITY, & CONTEMPORARY BIOETHICS* 155 (William Child et al. eds. 2020) (“On this first sense, the relationship between informed consent and autonomy is straightforward; to provide informed consent is just to make a certain kind of autonomous decision, a decision to authorize a particular medical treatment.”).

crucial that physicians and policymakers understand that patient wellbeing and autonomy are closely related.

B. *Recognition of Disabled Autonomy*

Autonomy is integral to ensuring that individuals with disabilities are not excluded from daily life and are recognized as “valuable to society.”⁴⁸ There is a long history of discrimination against disabled populations stemming from, among other reasons, the unwarranted assumption that individuals with cognitive disabilities are incapable of rational thought.⁴⁹ This incorrect assumption profoundly limits respect for disabled autonomy. If an individual is capable of valuing, the wishes stemming from those values should dictate how the individual ought to be treated.⁵⁰

In fact, autonomy is a key policy goal of the ADA, which has challenged incorrect assumptions and expanded economic and social opportunities for individuals living with disabilities.⁵¹ Despite the ADA’s successes, it still falls short in addressing the

48. See Moore, *supra* note 20, at 250 (“People with disabilities must be recognized as valuable to society, both as Kantian ‘ends in themselves’ and as distinct contributors to diversity of thought and experience.”); *cf.* United Nations Convention on the Rights of Persons with Disabilities art. 1, Dec. 13, 2006, 2515 U.N.T.S. 3, 72 [hereinafter CRPD] (defining individuals with disabilities as including “those who have long-term physical, mental, intellectual, or sensory impairments which in interaction with various barriers may hinder their full effective participation in society on an equal basis with others”); 20 C.F.R. § 404.1505(a) (2020) (“The law defines disability as the inability to do any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.”).

49. See Moore, *supra* note 20, at 251 (noting that the assumption is based on stigma, fear, and ignorance); see also Braswell, *supra* note 8 (stating that in order for something to be considered “autonomous,” a patient’s decision must be deemed rational, but a better way to judge rationality would be to determine the decision’s consistency with the individual’s character).

50. See *infra* Part II.

51. See 42 U.S.C. § 12101(b)(4) (addressing discrimination against individuals with disabilities in “such critical areas as employment, housing, public accommodations, education, transportation, communication, recreation, institutionalization, health services, voting, and access to public services”).

needs of individuals with disabilities at end of life.⁵² Due to advances in medical technology, individuals with disabilities are living longer lives and are subsequently more likely to encounter complex end-of-life treatment decisions.⁵³ Unfortunately, they also face significant barriers in accessing health services, including palliative care.⁵⁴ Patients with disabilities experience poor quality of care at end of life because—among other reasons—providers do not always understand or fully consider their needs.⁵⁵ This is especially true if the patient is also facing multiple co-morbidities, navigating complex family and social circumstances, or expressing signs and symptoms of distress in unconventional ways.⁵⁶ Medical professionals may attribute signs of poor health or distress to the disability instead of the underlying illness, a phenomenon known as “diagnostic overshadowing.”⁵⁷

Accordingly, respecting and facilitating these individuals’ autonomous medical decision-making capacity is of heightened importance. End-of-life treatment profoundly affects one’s life, and any decision relating to such treatment should be left to the individual to make with any level of support that they desire.⁵⁸ In recent decades, as medical philosophy has evolved and improved, laws protecting individual choice have also evolved to reflect the growing emphasis on medical autonomy. The following Part describes the legal mechanisms in place that

52. See Harold Braswell, *From Disability Rights to the Rights of the Dying (and Back Again)*, 31 LAWS 1, 12 (2017) (“Indeed, the very nature of ADA litigation arguably precludes dying people from benefitting under it. In the ADA, individuals must bring lawsuits retroactively, after a putative violation has occurred. Such an approach works against the dying.”).

53. See *supra* note 17 and accompanying text.

54. Tuffrey-Wijne, *supra* note 15.

55. See *id.*

56. See *id.* (listing “difficulties around insight and the ability to participate in decision-making” and “higher levels of behavioral or psychiatric problems” as other challenges that impede an individual with a disability’s quality of care).

57. See *id.* (listing “lack of staff knowledge, poor understanding of the Mental Capacity Act, and communication problems” as additional barriers to care).

58. See Rich, *supra* note 42, at 65 (“Intimate and important decisions that profoundly affect one’s personal identity and the course of one’s life must be left to the individual if we are going to recognize and respect the authority of the self.”).

govern individual end-of-life decisions and the implications that these mechanisms have on the exercise of disabled autonomy.

II. END-OF-LIFE DECISION-MAKING

At end of life, physicians may respect patients' autonomy by allowing them to avoid suffering by choosing the "time, place, and manner of their deaths."⁵⁹ There are a handful of legal decision-making tools that individuals may rely on to make these choices, but not all support equality for individuals with cognitive disabilities. In making end-of-life decisions, adults are assumed to have capacity, which generally comprises "memory, reasoning, judgment, and decision making."⁶⁰ Competency and capacity are often used interchangeably, but the term "decisional capacity" usually refers to the immediate medical decision to be made whereas "competency" is understood as a legal determination that focuses on the overall status of the patient.⁶¹ To find that an individual is incompetent usually requires a finding that the individual is at risk of harm due to their inability to provide for their needs, and that the individual lacks the cognitive ability to understand decisions.⁶²

When a patient's legal competency is challenged, physicians must assess a patient's capacity.⁶³ While there is no exact consensus on what criteria are used to evaluate capacity, it is typically understood as existing on a continuum.⁶⁴ A physician

59. Wright, *Equality of Autonomy?*, *supra* note 14, at 159.

60. Rachel Mattingly Phillips, Note, *Model Language for Supported Decision-Making Statutes*, 98 WASH. U. L. REV. 615, 617 (2020).

61. See BARRY R. FURROW ET AL., *BIOETHICS* 361 (8th ed. 2018) (noting that a patient may be able to make decisions at some times and not others and that to recognize this variability, many courts and legislatures have switched over to using the term "decisional capacity").

62. See Rebekah Diller, *Legal Capacity for All: Including Older Persons in the Shift from Adult Guardianship to Supported Decision-Making*, 43 *FORDHAM URB. L.J.* 495, 501 (2016).

63. See Christopher Libby et al., *Competency and Capacity*, *STATPEARLS PUBL'G* (Jan. 2022), <https://perma.cc/X8VQ-LLX6> ("Capacity is defined as 'a functional determination that an individual is or is not capable of making a medical decision within a given situation'Competency is defined as 'the ability of an individual to participate in legal proceedings.'").

64. See Jalayne J. Arias, *A Time to Step In: Legal Mechanisms for Protecting Those with Declining Capacity*, 39 *AM. J.L. & MED.* 134, 137 (2013) ("Despite the interrelated attributes of competency and capacity, these

usually bases a capacity determination on the patient's ability to understand the situation, communicate choice, appreciate the potential outcomes of an illness, generally reason or rationalize, and consider the pros and cons of treatment.⁶⁵ Capacity may be affected by conditions such as "mental disorders, neurological disorders, metabolic impairments, or head trauma, or by psychoactive medications and substance abuse."⁶⁶ Some of these conditions may have a significant impact on capacity, while others may only have minimal implications.⁶⁷

Higher degrees of capacity are required for decisions with higher stakes, such as decisions to try experimental treatments or end life-sustaining treatments.⁶⁸ Notably, clinical judgments of capacity can be unreliable and inaccurate, and clinicians do not always engage in formal evaluations before depriving

concepts adhere to different structures. Capacity is a continuum and is context-specific."); *see also* Raphael J. Leo, *Competency and the Capacity to Make Treatment Decisions: A Primer for Primary Care Physicians*, 5 PRIMARY CARE COMPANION TO J. CLINICAL PSYCHIATRY 131, 132 (1999) (stating that a physician determines capacity and refers to an assessment of the individual's psychological abilities to from rational decisions, specifically the ability to understand, appreciate, and manipulate information and form rational decisions). *But see* FURROW ET AL., *supra* note 61, at 361 (stating that courts have been reluctant to articulate a standard for decisional capacity and often invite physicians to testify about the "mental state and, thus, capacity of the patient").

65. *See* Nina Labovich, *Consent, Informed: Rethinking Informed Consent & Competency for Patients with Schizophrenia & Anosognosia*, 62 B.C. L. REV. 615, 632 (2021); *see also* Wright, *Equality of Autonomy?*, *supra* note 14, at 165 (stating that assessing decision capacity requires a "professional clinical judgment as to whether a specific individual has the requisite cognitive, decisional, affective, and practical abilities to be judged to have the ability to complete a specific task . . . or make a specific decision.").

66. MAYO CLINIC HUM. RSCH. PROT. PROGRAM, INFORMED CONSENT & ASSESSMENT OF CAPACITY TO CONSENT TO RESEARCH POLICY 1 (2017) [hereinafter INFORMED CONSENT TO RESEARCH POLICY REPORT], <https://perma.cc/PMV5-KC4R> (PDF).

67. *Id.*

68. *See* Arias, *supra* note 64, at 141 (describing capacity as "risk sensitive" and stating that the "requisite level of capacity will be higher if the decision or action under consideration may expose the individual to significant risk with minimal potential benefit"); *see also* Carl H. Coleman, *Research with Decisionally Incapacitated Human Subjects: An Argument for a Systemic Approach to Risk-Benefit Assessment*, 83 IND. L.J. 743, 748 (2008) (stating that a person in the early stages of dementia may have the capacity to provide informed consent to participate in a focus group, but may lack the capacity to provide informed consent to a study of an investigational drug).

individuals of their autonomous decision-making abilities.⁶⁹ An individual's end-of-life decisions may be effectuated through the use of: (i) advance directives, (ii) surrogate decision-making, (iii) guardianship, and, most recently, (iv) supported decision-making. As illustrated in the following Subparts, determinations of competency and capacity impact the end-of-life decision-making tools that an individual may have access to, and thus how much personal autonomy they may exercise.

A. *Advance Directives*

Competent individuals most commonly exercise their autonomy at end of life by executing advance directives to dictate their wishes should they become incapacitated.⁷⁰ Advance directives are documents that an individual fills out with the assistance of family members and an attorney that allow the individual to expressly state their wishes at end of life.⁷¹ The standard package of advance directives includes a last will and testament, a power of attorney, a health care proxy, and a living will. The health care proxy and living will specifically pertain to medical decision-making. A health care proxy allows an individual to choose who should make decisions for them in the event the individual is unable to make that choice themselves.⁷² A living will states whether an individual wishes to receive or refuse life-sustaining medical treatment if they become incapacitated.⁷³ Physicians only consult and act upon the documents when an incapacitated individual is in immediate danger of dying or needs certain special emergency

69. See Phillips, *supra* note 60, at 619 (stating that in some cases physicians base their decision on factors such as diagnosis, disability, age, appearance, or the simple fact that someone was making an unwise decision).

70. See Carolyn Crist, *Over One Third of U.S. Adults Have Advanced Medical Directives*, REUTERS (July 11, 2017, 5:11 PM), <https://perma.cc/XK8N-3KJU> (stating that as of 2017, nearly thirty-seven percent of Americans have advanced directives for end-of-life care).

71. See generally AM. CANCER SOC'Y, WHAT IS AN ADVANCE DIRECTIVE? (2019), <https://perma.cc/3YJ9-4SCZ> (PDF).

72. See Wright, *The Case for Relational Nudges*, *supra* note 27, at 1113.

73. *Id.*

treatment.⁷⁴ Ultimately, these documents are used as tools to effectuate constitutional principles of end-of-life medical decision-making.

*Cruzan v. Director, Missouri Department of Health*⁷⁵ highlighted the importance of advance directives and established a constitutionally protected liberty interest in the right to refuse unwanted life-sustaining medical treatment.⁷⁶ The Due Process Clause of the Fourteenth Amendment protects a “penumbra” of privacy rights that generally culminate in a right to freedom of personal choice in matters of marriage and family life.⁷⁷ The Supreme Court took a narrow approach to these rights in *Cruzan* and held that while competent individuals have the right to refuse medical treatment under the Due Process Clause, there must be clear and convincing evidence of the patient’s desires.⁷⁸ Since *Cruzan*, the constitutional right to accept or refuse life-sustaining medical treatment has been couched in terms of liberty, privacy, bodily integrity, and self-determination, all of which are components of autonomy.⁷⁹ Advance directives satisfy the clear and convincing

74. See Vicki Joiner Bowers, *Advance Directives: Peace of Mind or False Security?*, 26 STETSON L. REV. 677, 690 (1996); see also *Advance Care Planning: Health Care Directives*, NAT’L INST. ON AGING (Jan. 15, 2018), <https://perma.cc/3FZS-5HKP>.

75. 497 U.S. 261 (1990).

76. See *id.* at 287–88 (O’Connor, J., concurring) (“Because our notions of liberty are inextricably entwined with our idea of physical freedom and self-determination, the Court has often deemed state incursions into the body repugnant to the interests protected by the Due Process Clause.”).

77. See *Eisenstadt v. Baird*, 405 U.S. 438, 439 (1972) (protecting the right to contraception); *Loving v. Virginia*, 388 U.S. 1, 2 (1967) (stating that prohibiting interracial marriages violates due process); *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965) (stating that prohibiting the use of contraceptives violates constitutionally protected privacy interests); *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942) (establishing that the sterilization of “habitual criminals” is unconstitutional); *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 535 (1925) (establishing that parents may direct the upbringing and education of their children); *Meyer v. Nebraska*, 262 U.S. 390, 403 (1923) (protecting the right to learn a foreign language in school).

78. *Cruzan*, 497 U.S. at 282.

79. See Wright, *Equality of Autonomy?*, *supra* note 14, at 162; see also Donald R. Steinberg, *Limits to Death with Dignity*, 1 HARV. J.L. & TECH. 129, 131–32 (1988)

Many state courts also have based a patient’s right to self-determination on state or federal constitutional rights to privacy. These medical rights to

evidence standard for one's end-of-life wishes because the patient expressly states their desires in the document.⁸⁰ After *Cruzan*, Congress passed the Patient Self-Determination Act (PSDA)⁸¹, which requires all healthcare facilities that receive Medicare or Medicaid funding to give their patients written information regarding the right to accept or refuse medical treatment and to provide a patient with an opportunity to execute an advance directive at the facility.⁸² As a result, forty-one states and the District of Columbia now have laws governing advance directives.⁸³

While advance directives allow individuals to state their desires freely and explicitly, they are an imperfect measure of individual autonomy. Only a fraction of Americans have an advance directive.⁸⁴ Advance directives typically apply to situations in which the individual is terminally ill, in a permanent coma, or in a persistent vegetative state.⁸⁵ The directives do not usually provide sufficient guidance for cases in which an individual has only some degree of consciousness but no immediate terminal prognosis.⁸⁶ In such cases, the patient and family may suffer physical, emotional, and financial harm as doctors use exhaustive measures to treat the condition, even if those same exhaustive measures are exactly what the patient

privacy have been expressed as originating in fourth amendment privacy concerns, fourteenth amendment liberty concerns, and as an extension of the penumbral right to privacy recognized in *Griswold v. Connecticut*.

80. See Arthur R. Derse, *Legal and Ethical Issues in the United States, in PALLIATIVE CARE* 343 (Linda L. Emanuel & S. Lawrence Librach eds., 2d ed. 2011).

81. 42 U.S.C. § 1395cc.

82. *Id.* §§ 1395cc(a)(1)(Q), 1395cc(f), 1395mm(c)(8), 1396a(a)(57), 1396a(w).

83. See Larry Gostin & Robert F. Weir, *Life and Death Choices after Cruzan: Case Law and Standards of Professional Conduct*, 69 *MILBANK Q.* 143, 153 (1991) (stating that the constitutional significance of designated proxies received a considerable boost in *Cruzan*).

84. See *Dementia and End-of-Life Care*, COMPASSION & CHOICES (Dec. 17, 2021), <https://perma.cc/LWJ6-9SZ9> (stating that only 36.7% of Americans had an advance directive in 2021).

85. See Bowers, *supra* note 74, at 718.

86. See *id.* (noting that those with severe dementia or immobility may fit in this category).

sought to avoid in their directive.⁸⁷ People may also change their minds regarding treatment without updating their legal documents, and it can be difficult to fully consider and appreciate the hypothetical problems that the future self may face.⁸⁸ As a result, advance directives may lock one into prior, and perhaps no longer appropriate, preferences permanently.⁸⁹

Further, common statutory terms in advance directives like “extraordinary measures” or “artificial hydration” may be too vague and ambiguous to discern the individual’s true desires.⁹⁰ One individual’s extraordinary measure may be another individual’s routine procedure. When a directive appears to be ambiguous, there is a risk that hospitals will ignore it.⁹¹ Even when the directive is unambiguous, healthcare providers may still disregard it, either by accident or due to pressure from the patient’s family.⁹² The clear and convincing evidence standard may impose a heavier burden on those without sufficient means either to: (i) execute an advance directive; or (ii) otherwise provide the necessary evidence of their wishes.⁹³ This barrier forecloses individuals from exercising their rights.⁹⁴ As a consequence, and in accordance with the dominant treatment

87. See *id.* at 719 (“Often those exhaustive measures may be exactly what the patient sought to avoid, but the cost of making a mistake is far too high, and the doctor most likely will not, indeed should not, chance error.”).

88. See *id.* (“A decision made at age thirty may be different from a decision one would make at age eighty. It is extremely difficult, if not impossible, to compose a document to cover hypothetical situations such as future health requirements, especially in an ever-changing world of technology.”); see also Wright, *The Case for Relational Nudges*, *supra* note 27, at 1096 (explaining that a fear of death makes people less likely to plan for it and are unable to anticipate their preferences in every possible scenario).

89. See Wright, *Equality of Autonomy?*, *supra* note 14, at 160.

90. Bowers, *supra* note 74, at 720.

91. *Id.*

92. See Wright, *Equality of Autonomy?*, *supra* note 14, at 168 (“There are also reports that advance directives are sometimes disregarded by healthcare providers.”); see also Susan Adler Channick, *The Myth of Autonomy at the End-of-Life: Questioning the Paradigm of Rights*, 44 VILL. L. REV. 577, 641 n.51 (“There is abundant literature, however, that demonstrates that even when individuals exercise these instruments, they are ignored by physicians and family of the incapacitated patient.”).

93. See Gostin & Weir, *supra* note 83, at 168 (“The insistence on “clear and convincing evidence” imposes a particular burden on persons without sufficient education or means.”).

94. *Id.*

model that focuses on the preservation of life, an individual may be forced to endure painful or futile treatments with no options to mitigate the exact suffering that they wished to avoid.

B. *Surrogate Decision-Making*

For incapacitated patients who are unable to or have not provided clear and convincing evidence of their wishes through advance directives, most states recognize end-of-life surrogate decision-making.⁹⁵ A surrogate decision-maker is typically a family member or judicially appointed guardian who is responsible for decisions regarding the initiation or maintenance of medical intervention.⁹⁶ State statutes are designed to allow the surrogate to facilitate decision-making through the substituted judgment standard.⁹⁷ In using substituted judgment, the surrogate makes decisions on the patient's behalf using the patient's values, beliefs, and preferences to guide their decision.⁹⁸ For example, if an observant Catholic individual is incapacitated at end of life and did not execute advance directives, it is relatively easy for the surrogate to make the decision to prolong life-sustaining treatment because it may be clear that the individual would make that same decision according to their religious beliefs. Conversely, decisions like this may be more difficult when the incapacitated individual had private moral beliefs or a more

95. See David Orentlicher, *Cruzan and Surrogate Decision-Making*, 73 S.M.U. L. REV. 155, 156 (2020); see also Nina A. Kohn et al., *Supported Decision-Making: A Viable Alternative to Guardianship?*, 117 PENN. ST. L. REV. 1111, 1115 (2013) (stating that the appointment of a surrogate is also typically made through a guardianship proceeding).

96. See Norman L. Cantor, *The Bane of Surrogate Decision-Making: Defining the Best Interests of Never-Competent Persons*, 26 J. LEGAL MED. 155, 156 (2005).

97. See Megan S. Wright, *Dementia, Autonomy, and Supported Healthcare Decision-Making*, 79 MD. L. REV. 256, 268 (2020) (“To effectuate respect for patient autonomy that survives a loss of decision-making capacity, all states have healthcare decision-making laws designed to facilitate decisions made on the basis of the incapacitated person’s prior wishes.”).

98. See *id.* (explaining that this practice respects the prior autonomy of the presently incapacitated patient); see also *In re Conroy*, 468 A.2d 1209, 1229 (Pa. Commw. Ct. 1985) (“The question is not what a reasonable or average person would have chosen to do under the circumstances but what the particular patient would have done if able to choose for himself.”).

complicated relationship with religion or their family. The substituted judgment standard is typically used for the formerly competent patient—a patient who used to have the relevant decision-making capacity but lost it due to a medical problem that undermines brain function.⁹⁹

For the never-been-competent patient,¹⁰⁰ the best interest standard is a favorable alternative to the substituted judgment standard.¹⁰¹ Under the best interest standard, courts favor the action by the surrogate that produces the greatest net benefit to the individual, or what is in the individual's "best interest."¹⁰² The principle of beneficence guides the best interest standard, with a focus on general comfort, restoration or development of the patient's "physical and mental capacities," and freedom from pain.¹⁰³ Instead of endeavoring to reconstruct the subjective view of the patient through substituted judgment, the best interest standard allows for a more "generic view," without having to rely on the unique values and preferences of the patient in question.¹⁰⁴ Although the best interest standard seems to conflict with the concept of individual autonomy, its use is necessary in some cases.¹⁰⁵ For a never-been-competent patient with a permanent brain deficiency that prevented the patient from ever developing legally recognized decision-making capacity, the best interest standard may be the only feasible option.¹⁰⁶

99. See Jaworska, *supra* note 26 (defining the formerly competent patient and stating that Alzheimer's disease is an example of a medical condition that is common in the formerly competent patient).

100. For the seminal case on substituted judgment for the never-competent patient, see Superintendent of Belchertown State Sch. v. Saikewicz, 370 N.E.2d 417 (Mass. 1977).

101. See Eric C. Miller, *Listening to the Disabled: End-of-Life Medical Decision Making and the Never Competent*, 74 *FORDHAM L. REV.* 2890, 2898 (2006).

102. See *id.* at 2899.

103. See Jaworska, *supra* note 26.

104. See *id.*

105. See, e.g., *In re Grady*, 426 A.2d 467 (N.J. 1981) (allowing parents to sterilize their 22-year-old daughter because the decision was in good faith, with the primary concern being the best interests of the daughter, who could not understand the problem at hand or the proposed solution due to her disability).

106. See Jaworska, *supra* note 26 (stating that the substituted judgment standard is inapplicable if the patient has never been able to make

C. Guardianship

Guardianship is a powerful form of surrogate decision-making in which a court appoints a third party to make decisions for an individual on a longer-term basis.¹⁰⁷ It is an extension of state *parens patriae* power¹⁰⁸ and is primarily governed by state law.¹⁰⁹ Guardianship has historically been used to assist an individual that a court has determined lacks the requisite capacity to manage personal affairs such as finances, health care, and other essential life tasks.¹¹⁰ It is estimated that there are 1.3 million active adult guardianship cases in the United States.¹¹¹ Most individuals living under guardianships are older individuals with dementia or Alzheimer's Disease, individuals with cognitive disabilities, and a smaller but increasing number of young adults with traumatic brain injuries.¹¹²

autonomous decisions because it is impossible to reconstruct what the patient's decision would have been).

107. See Kohn et al., *supra* note 95, at 1113 (describing guardianship as the most powerful form of surrogate decision-making).

108. See *parens patriae*, OXFORD LEXICO (2022) (defining *parens patriae* as a "the government, or any other authority, regarded as the legal protector of citizens unable to protect themselves").

109. See U.S. SENATE SPECIAL COMM. ON AGING, ENSURING TRUST: STRENGTHENING STATE EFFORTS TO OVERHAUL THE GUARDIANSHIP PROCESS AND PROTECT OLDER AMERICANS 10 (2018) [hereinafter ENSURING TRUST], <https://perma.cc/DBK7-3ZXD> (PDF) ("It is primarily governed by laws, regulations, and practices of each of the states and courts therein, and therefore practices can vary greatly from jurisdiction to jurisdiction.").

110. See *id.* at 9 ("[Guardianship] is a legal relationship created by a court between an individual whom it has determined is not capable of making decisions regarding his or her life or property and the person or organization appointed by that court to make such decisions.").

111. *Id.*; see also Sara Luterman, *For Women Under Conservatorship, Forced Birth Control Is Routine*, THE NATION (July 15, 2021), <https://perma.cc/B5KZ-EDTH> (stating that AARP estimates 1.5 million Americans are under conservatorship but that the data is varying in quality and there are no federal regulations for record keeping on conservatorship).

112. See Kristen Booth Glen, *What Judges Need to Know About Supported Decision-Making, And Why*, 58 JUDGES' J. 26, 27 (2019).

Some scholars characterize the imposition of guardianship as a “civil death.”¹¹³ The American Bar Association has criticized guardianship as a commonly abused practice that “deprives an individual of virtually all legal rights.”¹¹⁴ It passed a resolution in 2017 that established a fifty-year commitment to limiting guardianship to only those cases where less restrictive alternatives are unavailable.¹¹⁵ Individuals, their families, and disability advocates have also challenged guardianship in recent years, because in many cases there appears to be a lack of sufficient evidence to support a finding that the individual lacks decision-making capacity.¹¹⁶ Guardianship is further challenged for being inconsistent with Article 12 of the United Nations Convention on the Rights of Persons with Disabilities (“CRPD”),¹¹⁷ which states that “States Parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life.”¹¹⁸ One hundred eighty-one nations have adopted the CRPD, excluding the

113. See Kohn et al., *supra* note 95, at 1116–20; see also *Civil Death Statutes—Medieval Fiction in a Modern World*, 50 HARV. L. REV. 968, 968 (1937).

114. *Guardianship and Supported Decision-Making*, ABA COMM. ON LAW & AGING (Aug. 16, 2021), <https://perma.cc/6HPP-CGFQ>.

115. See ABA Comm. on Disability Rts. Res. 113 (2017)

RESOLVED, That the American Bar Association urges state, territorial, and tribal legislatures to amend their guardianship statutes to require that supported decision-making be identified and fully considered as a less restrictive alternative before guardianship is imposed; and urges courts to consider supported-decision making as less restrictive alternative to guardianship.

116. See Kohn et al., *supra* note 95, at 1117 (stating that in some cases, disability alone appears to be used as sufficient justification for the imposition of guardianship); see also Barton W. Palmer & Alexandria L. Harmell, *Assessment of Healthcare Decision-Making Capacity*, 31 ARCHIVES CLINICAL NEUROPSYCHOLOGY 530, 531 (2016) (discussing a study of experienced physicians showing an agreement rate of only 56% regarding the capacity status of patients with Alzheimer’s disease).

117. See Robert D. Dinerstein, *Implementing Legal Capacity Under Article 12 of the UN Convention on the Rights of Persons with Disabilities: The Difficult Road from Guardianship to Supported Decision-Making*, 19 HUM. RTS. BRIEF 8, 9 (2011) (explaining the importance of Article 12’s insistence on the recognition of the legal capacity of people with disabilities).

118. CRPD, *supra* note 48, at art. 12, ¶ 2; see also *id.* at art. 12, ¶ 3 (“States Parties shall take appropriate measures to provide access by persons with disabilities to the support they may require in exercising their legal capacity.”).

United States.¹¹⁹ In addition to stripping an individual of capacity, guardianship further undermines an individual's physical and psychological well-being by reducing their sense of control over their own lives.¹²⁰ Because guardianship proceedings are treated as a central part of the permanency planning for individuals with cognitive disabilities, placing an individual under guardianship may impose a particularly long-lasting and burdensome degradation of an individual's civil rights.¹²¹

Guardianship may have stark medical implications. Recently, Jamie Spears's past conservatorship¹²² over his daughter Britney Spears has made headlines because of the shocking control that he had over the pop star's finances and personal life.¹²³ Ms. Spears alleged that her guardian forced her to have an IUD to prevent her from having more children.¹²⁴ This highly publicized example of forced treatment goes to the heart of the concerns that guardianship raises about when and how violations of individuals' medical autonomy can be

119. See Bill Alford et al., *How to Strengthen the Americans with Disabilities Act After 30 Years: Promoting Supported-Decision Making for Persons with Intellectual Disabilities*, HARV L. REV. BLOG (Aug. 7, 2021), <https://perma.cc/23BA-VM96> (stating that the CRPD is helping to spread the idea of supported decision-making throughout the world).

120. See Lisa Zammiello, *Don't You Know that Your Law Is Toxic? Britney Spears and Abusive Guardianship: A Revisionary Approach to the Uniform Probate Code, California Probate Code, and Texas Estates Code to Ensure Equitable Outcomes*, 13 EST. PLAN. & CMTY. PROP. L.J. 587, 595 (2021)

Legal commentators note that the legal relationship between conservator and conservatee is not adequate in meeting the needs of the elderly or incapacitated. Commentators argue that a lack of judicial oversight . . . results in a substantial loss of liberty and property for many of the persons that these arrangements are intended to protect.

121. See Kohn et al., *supra* note 95, at 1117–18.

122. See *The Difference Between Conservatorship and Guardianship in California*, GILFIX & LA POLL ASSOCS. LLP (May 13, 2016), <https://perma.cc/N9LA-472X> (clarifying that in California, guardianship refers only to the “court appointment of an individual with the legal authority to represent and manage the affairs of a minor child”).

123. See *Britney Spears: Singer's Conservatorship Case Explained*, BBC (Nov. 12, 2021), <https://perma.cc/RK8E-P5QE> (“The conservatorship has power over her finances and career decisions plus major personal matters such as her visits with her teenage sons and whether she can get remarried.”).

124. See *id.*

justified.¹²⁵ Rightfully, adjudicators and legislators want to protect individuals' end-of-life medical decisions from the influence of others, fearing that outside input has the potential to compromise individual autonomy.¹²⁶

Proposed reforms are pushing guardianship law to be more protective of individual rights.¹²⁷ The Uniform Guardianship, Conservatorship, and Other Protective Arrangements Act calls for expanded procedural rights,¹²⁸ less-restrictive alternatives,¹²⁹ individual guardianship plans,¹³⁰ enhanced

125. See Jan Hoffman, *Is the Forced Contraception Alleged by Britney Spears Legal?*, N.Y. TIMES (June 24, 2021), <https://perma.cc/D9VU-E3CA> (stating that some guardians may ask a court to order contraception for severely disabled children, but preventing Ms. Spears from removing her IUD is a proxy for impermissible sterilization).

126. See Wright, *The Case for Relational Nudges*, *supra* note 27, at 1066 (explaining why the state is interested in end-of-life decision-making); see also U.N. Comm. on the Rts. of Persons with Disabilities, General Comment No. 1 (2014): Article 12: Equal Recognition Before the Law, ¶ 7, U.N. Doc. CRPD/C/GC/1 (May 19, 2014) (stating that the CRPD aims to eliminate guardianships and replace them with other mechanisms that better support individuals with disabilities).

127. See Nina A. Kohn, *Legislating Supported Decision-Making*, 58 HARV. J. LEGIS. 313, 325 (2021)

The international interest in guardianship has unfortunately led to a great deal of advocacy-oriented writing that speaks of guardianship in general and does not distinguish jurisdictions that have reformed their guardianship systems to, for example, require the use of limited guardianships, require guardians to take individuals' preferences into account, or impose guardianship based solely on functional need and not disability status.

128. See Benjamin Orzeske & Diana Noel, *Uniform Guardianship, Conservatorship, and Other Protective Arrangements Act*, AARP (2018), <https://perma.cc/L7BZ-2QST> (PDF) (stating that expanded procedural rights would strengthen the requirement for the respondent to be present at a hearing, require findings before removal of fundamental rights, and include automatic triggers for reconsideration).

129. See *id.* (stating that petitioners must explain why a "less restrictive alternative is not sufficient" and courts ordering guardianship "must include findings explaining why a less-restrictive alternative is not sufficient").

130. See *id.* (stating that a guardian must file a plan within sixty days of appointment and update that plan annually, and stating the requirements of the guardianship plan).

monitoring,¹³¹ respect of the right to social interaction,¹³² and informal grievance procedures.¹³³ The Act has been enacted in Washington and Maine.¹³⁴ The focus on person-centered terminology has replaced terms like “ward” and “incapacitated person” with language such as “individual subject to guardianship.”¹³⁵ This language shift reinforces the idea that individuals with disabilities must be recognized as valuable members of society above any other characterization.¹³⁶ Unfortunately, because each state handles its own guardianship cases, there is wide variation in how data is collected and monitored, which makes it difficult to track guardianship rates and abuses.¹³⁷ While reform efforts offer some hope, it is nonetheless difficult for policymakers and advocates to understand guardianship’s problems and properly address them due to the lack of comprehensive data on the subject.¹³⁸ Considering the complexity of these issues and the rights at stake, incomplete information may halt changes in

131. *See id.* (stating that the court can compare annual reports to the guardianship plan to ensure compliance).

132. *See id.* (“Without court approval, a guardian for an adult may not indefinitely restrict interaction with another person unless the guardian has good cause to believe interaction poses a risk of significant physical, psychological, or financial harm.”).

133. *See id.* (stating that any interested person may submit a grievance to the court in writing, no formal petition is necessary, and the court is required to review and respond as appropriate).

134. ME. REV. STAT. ANN. tit. 18-C, art. 5, pt. 6 (LexisNexis 2023); WASH. REV. CODE § 11.90.010 (2022).

135. *See Orzeske & Noel, supra* note 128 (stating that other “new” terms include “adult” and “minor” and “respondent”).

136. *See RES. FOR INTEGRATED CARE, USING PERSON-CENTERED LANGUAGE* 1 (2020), <https://perma.cc/KVY8-J65H> (PDF) (“Using person-first language avoids the assumption that a person’s disability or condition is a characteristic of their personal identity, placing these as secondary to who the person is.”).

137. *See Exclusive: Elizabeth Warren, Bob Casey Ask for Data on Conservatorship After Britney Spears Testimony*, TIME (July 1, 2021, 1:02 PM), <https://perma.cc/WC4H-JF62>.

138. *See id.* (stating that Senators Elizabeth Warren and Bob Casey have requested more federal oversight of guardianship to remedy this problem); *see also ENSURING TRUST, supra* note 109, at 6 (calling for better data and stating that few states are able to report accurate or detailed guardianship data).

guardianship laws, resulting in continued poor health outcomes for individuals with disabilities.¹³⁹

D. *Supported Decision-Making*

As a supplement or alternative to guardianship, supported decision-making may provide a solution to some of the problems embedded in traditional medical decision-making models and may be best situated to respect the autonomy of individuals with disabilities. The term “supported decision-making” has been used to refer both to a legal framework that enables people with cognitive disabilities to exercise legal capacity, as well as a process for providing supporters to individuals with cognitive disabilities to enable them to achieve maximal participation in decisions about their lives.¹⁴⁰

Under the supported decision-making model, individuals with cognitive disabilities can choose to enter into agreements with “supporters.”¹⁴¹ Instead of a surrogate making decisions for the individual with the disability, the supporter assists the individual in decision-making by gathering information, weighing healthcare options, and communicating decisions to others, among other activities.¹⁴² Supported decision-making ensures that individuals with cognitive disabilities are their own decision-makers, and preserves their right to self-determination.¹⁴³ The model can be used both informally and through a formal written agreement,¹⁴⁴ and may involve a single supporter or multiple supporters that may work

139. See Bard, *supra* note 2, at 499 (stating that individuals with disabilities “receive less care, have less interaction with medical professionals for conditions unrelated to their disability, and have worse health outcomes”).

140. See Karrie A. Shogren et al., *Supported Decision-Making: A Synthesis of the Literature Across Intellectual Disability, Mental Health, and Aging*, 52 EDUC. TRAINING IN AUTISM & DEV. DISABILITIES 144, 145 (2017).

141. See Wright, *Equality of Autonomy?*, *supra* note 14, at 170.

142. *Id.*

143. See Kohn et al., *supra* note 95, at 1111 (“According to its proponents, supported decision-making empowers individuals with cognitive challenges by ensuring that they are the ultimate decision-maker but are provided support from one or more others, giving them the assistance they need to make decisions for themselves.”).

144. *Id.*

separately or together as a “circle of support.”¹⁴⁵ Supported decision-making challenges the harmful notion that individuals with disabilities need to be protected from making poor decisions¹⁴⁶ and goes beyond providing support and care for individuals by instead facilitating individual capacity.¹⁴⁷ Importantly, due to the weight given to an individual’s support systems, the model is compatible with the theory of relational autonomy.

Advocates for supported decision-making describe the practice as inclusive and preventative of the harms imposed on individuals under guardianship.¹⁴⁸ Supported decision-making preserves the civil rights that guardianship strips away from individuals, providing an opportunity to “re-imagine the disabled legal subject.”¹⁴⁹ In addition to allowing an individual to retain legal rights, supported decision-making also promotes and supports self-advocacy.¹⁵⁰ It reduces stigma by demonstrating that individuals with disabilities are capable of contributing to society and overseeing their own lives,¹⁵¹ and increases self-esteem and self-worth, allowing for meaningful personal growth.¹⁵² Above all else, empowering individuals with

145. See Kohn, *supra* note 127, at 316.

146. See *id.* at 319 (stating that supported decision-making is actually not a novel concept and has important implications for individuals with disabilities).

147. See *id.* at 320

For example, it is consistent with Martha Nussbaum’s capabilities approach to social justice in that it treats individuals with cognitive disabilities as equal citizens and responds to their needs not simply by providing protection and care, but by actively facilitating individuals’ abilities to make their own choices and make use of their own capabilities.

148. See *id.* at 322 (explaining how supported decision-making may improve the lives of individuals with disabilities).

149. See Kohn et al., *supra* note 95, at 1127.

150. See Dinerstein, *supra* note 117, at 10 (discussing identification of the key elements of a supported decision-making system).

151. See ROYAL COLL. OF SURGEONS, CONSENT: SUPPORTED DECISION-MAKING, A GUIDE TO GOOD PRACTICE 4 (2018), <https://perma.cc/Q9X5-YMEW> (PDF).

152. See *About Supported Decision-Making*, CTR. FOR PUB. REPRESENTATION (2022), <https://perma.cc/3HWR-AA55>; see also Miola & Gilbar, *supra* note 28, at 381 (stating that self-trust, confidence, and esteem are crucial components of one’s autonomous capacity, and people close to the individual have a large effect on the development of these qualities).

disabilities improves physical and psychological well-being for stronger health outcomes.¹⁵³

Supported decision-making is not without criticism. Some scholars argue that it is in fact antithetical to autonomy because it emphasizes dependency, prohibits the autonomous actor from making isolated decisions, and exposes individuals with disabilities to exploitation.¹⁵⁴ Some statutes allow a supporter to enforce the supported decision-making agreement independently.¹⁵⁵ This may lead to abuses when a supporter requires a third party to act on a decision that the principal disagrees with—or worse, is unaware of.¹⁵⁶ Informal or private arrangements may fail to provide adequate accountability.¹⁵⁷ Even when a supporter has good intentions, undue influence may still occur because, naturally, individuals value their loved ones' opinions.¹⁵⁸ Some limited safeguards exist to protect against these concerns, however, such as restricting the scope of a supporter's authority to decisions relating to one particular matter.¹⁵⁹

Moreover, if autonomy is understood relationally, it is incorrect to characterize supported decision-making as

153. See Kohn et al., *supra* note 95, at 1127.

154. See Kohn, *supra* note 127, at 320

Supported decision-making also moves from a model of an autonomous actor whose needs and abilities can be considered in isolation from others to a model where the actor is embedded in a web of dependency and the actor's needs and abilities must be considered in a social context.

see also Robert A. Burt, *Self-Determination and the Wrongfulness of Death*, 2 J. HEALTH CARE L. & POL'Y 177, 206 ("But I must reiterate my conviction that we fool ourselves if we think that patient control—that the self-determination ideal—is an adequate correction to these abuses.").

155. See Kohn, *supra* note 127, at 334 (stating that the most "disempowering provisions" allow the supporter to enforce decisions independently).

156. See *id.*

157. Kohn et al., *supra* note 95, at 1137.

158. See *id.*

159. See Wright, *Equality of Autonomy?*, *supra* note 14, at 171

Such safeguards include prohibiting some persons from acting as supporters, such as those who have committed certain types of crimes, limiting the scope of a supporter's authority; and advising third parties to contact the state agency responsible for ensuring the welfare of older persons or persons with disabilities if they suspect abuse or neglect of the person with a disability.

promoting dependency. Many individuals, regardless of disability status, prefer to consult with others when making serious healthcare decisions and may face challenges due to cognitive biases, power imbalances, limited options, or inability to understand and navigate complex medical systems.¹⁶⁰ Civil rights and elder law scholar Nina Kohn argues that advocates for supported decision-making over-assume the limits of guardianship and emphasizes that most courts impose only limited guardianships that allow an individual to retain certain legal rights, including the right to challenge the guardianship.¹⁶¹ Although accurate, this perspective may fail to consider the social factors that may prevent an individual from challenging the arrangement, such as dependent family relationships and lack of resources.¹⁶² Further, much of the literature on supported decision-making is focused on individuals with “static impairments” that do not change significantly over time.¹⁶³ The focus on static impairments ignores the reality that dynamic impairments, such as Alzheimer’s disease, also impact an individual’s legal decision-making capacity over time.¹⁶⁴ For these reasons, supported decision-making is not necessarily antithetical to guardianship or surrogate decision-making. Instead, the two may exist and overlap on a continuum.¹⁶⁵

160. See Wright, *Equality of Autonomy?*, *supra* note 14, at 173 (discussing empirical studies on the preference for relational autonomy and its application to supported decision-making).

161. See Kohn, *supra* note 127, at 323.

162. See Carter Barrett, *Britney Spears Left Her Guardianship, But Others Who Want Independence Remain Stuck*, NPR (Jan. 9, 2022, 7:00 AM), <https://perma.cc/2FAH-S65S> (stating that people challenging their guardianship face a “catch-22” when they need money to speak with a lawyer for legal advice but the guardian controls their finances).

163. See Largent & Peterson, *supra* note 18, at 273 (noting that examples of this type of static impairment include young adults with intellectual and developmental disabilities who are transitioning from being in the care of their families to independence).

164. See *id.* (stating that dynamic impairments are “characterized by clinically and practically significant neurodegenerative diseases” and that supported decision-making must account for fluctuating ability).

165. See Kohn *supra* note 127, at 326–27 (stating that guardianship would be on the more controlled end of the spectrum and supported decision-making would be closer to the middle, existing as neither an independent nor a controlled process); see also Largent & Peterson, *supra* note 18, at 273

Texas was the first state to implement supported decision-making in 2015,¹⁶⁶ followed by Alaska, Colorado, Delaware, the District of Columbia, Illinois, Indiana, Louisiana, Nevada, New Hampshire, North Dakota, Rhode Island, Washington, and Wisconsin.¹⁶⁷ All existing legislation provides legal recognition of formalized decision-making agreements and many include a model form that individuals can use.¹⁶⁸ Even in states without specific supported decision-making statutes, the practice is often mentioned in other state laws relating to least restrictive environments or support for individuals with disabilities. State legislation differs, and some states may have statutory provisions that are better suited to address end-of-life healthcare concerns. For example, thirteen of the fourteen existing statutes state that the mere existence of the supported decision-making agreement should not be interpreted as evidence that the individual lacks capacity, which is crucial when access to certain medical treatments require a capacity determination by a physician. Louisiana, Nevada, North Dakota, Texas, and Wisconsin have no restrictions on who may act as a supporter, while other states do have such restrictions.¹⁶⁹ Additionally, in several states, the person with the cognitive impairment may act independently of the

(explaining that supported decision-making cannot fully supplant surrogate decision-making).

166. TEX. ESTATES CODE ANN. §§ 1357.001–.102 (West 2022).

167. ALASKA STAT. ANN. §§ 13.56.010–.195 (West 2021); COLO. REV. STAT. ANN. §§ 15-14-801 to -806 (West 2023); DEL. CODE ANN. tit. 16, §§ 9401(a)–9410(a) (West 2023); D.C. CODE ANN. §§ 7-2131 to -2134 (West 2022); 755 ILL. COMP. STAT. ANN. 9/1–9/9 (2022); IND. CODE ANN. §§ 29-3-14-1 to -13 (West 2023); LA. STAT. ANN. §§ 4261.101–.302 (2023); NEV. REV. STAT. ANN. §§ 162C.010–.330 (West 2021); N.H. REV. STAT. ANN. §§ 464-D:1–D:16 9 (West 2021); N.D. CENT. CODE ANN. §§ 30.1-36-01 to -08 (West 2021); 42 R.I. GEN. LAWS §§ 66.13-1 to -10 (West 2019); WASH. REV. CODE ANN. §§ 11.130.670–.755 (West 2022); WIS. STAT. ANN. §§ 52.01–.32 (West 2021).

168. See Kohn, *supra* note 127, at 328.

169. See Zachary Allen & Dari Pogach, *More States Pass Supported Decision-Making Agreement Laws*, 41 J. ABA COMM. ON L. & AGING 159, 160 (2019) (explaining that in Delaware, Alaska, the District of Columbia, and Rhode Island, employers and employees may not be decision-makers, nor can a person who is providing paid support services to the decisionmaker). *But see* Kohn, *supra* note 127, at 336 (stating that the current wave of supported decision-making statutes do not provide limitations on who may serve as supporters or mandate any minimum training requirements).

agreement.¹⁷⁰ Restricting who may act as a supporter and allowing for freedom of the principal outside of the agreement may help protect against the risk of exploitation present in end-of-life decision-making for individuals with cognitive disabilities. Still, supported decision-making should not—and likely cannot—replace surrogate decision-making entirely. Supported decision-making is unavailable to those with severe cognitive disability, and some state statutes may require full capacity to enter into an agreement.¹⁷¹

For those that can benefit from supported decision-making, the practice is particularly useful in the medical context. Consider a hypothetical patient, Jen, who has mild cognitive impairment and just received a terminal cancer diagnosis. If Jen works with a supporter throughout the course of her illness, the supporter would understand her wishes at each step and be able to track those wishes relationally to apply them appropriately in context. The supporter could monitor Jen’s status over time, effectively communicate with her physician about her needs and behavioral patterns, and ultimately assist her in ensuring that she receives the treatment that she desires according to her values at the time of diagnosis or as her values and capacity change and evolve. The recognition of this relationship as a legal one preserves Jen’s autonomy and protects her right to decisional assistance, even if her supporter is not her healthcare proxy, and would allow her to give informed consent to treatment she might not otherwise be able to. In this example, supported decision-making reinforces an optimal society that values quality of life, while also empowering Jen to make her own decisions about her well-being. Yet, she cannot maximize her well-being without equal access to health care.

170. Wright, *Equality of Autonomy?*, *supra* note 14, at 171.

171. See *id.* at 173 (“For example, if someone is in a chronic vegetative state where they lack awareness, they will not be able to make their own decisions.”); see also NEV. REV. STAT. ANN. §§ 162c.010–.330 (West 2021) (stating that an adult must be “capable of making decisions about such matters” to be able to participate in a supported decision-making agreement); Phillips, *supra* note 60, at 637 (stating that if one has full capacity, they already have the legal ability to make decisions about their life and supported decision-making will therefore provide “minimal benefit” in such a context).

III. SUPPORTED DECISION-MAKING AND EQUAL ACCESS AT END OF LIFE

It is possible that through the use of supported decision-making, patients like Jen may be able to exercise their autonomy and access specific pain-mitigating treatment. At the same time that supported decision-making is gaining legal traction and public favor,¹⁷² laws like the FDA's Expanded Access Program¹⁷³ and state medical-aid-in-dying legislation are promoting individual autonomy and the ethical concept of mercy by providing alternative avenues to limit suffering at end of life.¹⁷⁴ Physicians may be hesitant to provide individuals with disabilities the same range of healthcare options they provide to the general population due to a perceived difficulty in obtaining informed consent.¹⁷⁵ Individuals with disabilities are still entitled to equal treatment under the law and the opportunity to seek medical treatment of their choice. Considering the breadth of the "penumbra" of privacy rights discussed earlier in this Note,¹⁷⁶ the right to freedom of personal choice should be read more broadly and include a fundamental right to make one's own autonomous medical decisions.¹⁷⁷ Although there is no

172. See Kohn, *supra* note 127, at 314–15 (“Fueled by the adoption of the Convention on the Rights of Persons with Disabilities, polities around the world are rewriting their laws to encourage practices termed ‘supported decision-making’ and to curtail more restrictive interventions such as guardianship.”).

173. 21 C.F.R. § 312.

174. See Kim, *supra* note 3, at 115

On one hand, if the individual is allowed access to an experimental drug, at least he will know whether that drug would have made any difference. Many advocates for a right to try noted that their advocacy was driven by not knowing the answer to that question. On the other hand, if an individual is seeking medical aid in dying, she will achieve closure in ending a struggle with a terminal illness or condition on her own terms, rather than on the disease or condition's progression.

175. See Tuffrey-Wijne, *supra* note 15.

176. See *supra* note 77 and accompanying text.

177. See Steinberg, *supra* note 79, at 132 (“Decisions as to medical treatment fundamentally affect an individual and primarily involve only the individual, making the decision extremely private. Also, these decisions are very personal, involving an individual's choice as to how to lead his life and, therefore, are especially appropriate for protection under a right to privacy.”). *But see* Jacobson v. Massachusetts, 197 U.S. 11, 39 (1905) (emphasizing public

constitutional right to medical aid in dying or treatment through Expanded Access, the following Subparts examine how supported decision-making may help individuals with disabilities achieve—at minimum—the same right to exercise autonomy and explore health care options as the rest of the public.

A. *Medical Aid in Dying: What Is It?*

When confronted with a terminal illness, many view medical aid in dying as the greatest expression of autonomy and life ownership.¹⁷⁸ In the United States, where it is legal, terminally ill, competent adult patients may voluntarily request a prescription for medication that the patient will self-ingest to hasten death, subject to specific safeguards.¹⁷⁹ Medical aid in dying is available in almost one in five U.S. states.¹⁸⁰ California, Colorado, Hawaii, Maine, New Jersey, New Mexico, Oregon, Vermont, Washington, Montana, and the District of Columbia all have medical-aid-in-dying statutes.¹⁸¹ Safeguards for

health and stating that an individual does not have the right to refuse a smallpox vaccination without a stronger medical justification).

178. See Susan M. Behuniak, *Death with “Dignity”: The Wedge that Divides the Disability Rights Movement from the Right to Die Movement*, 30 POL. LIFE SCI. 17, 18 (2011)

On the side supporting physician assisted death, “dignity” is the emblematic justification as to why competent, terminally ill adults should be allowed to hasten the process by ingesting prescribed lethal drugs For opponents within the disability rights movement, this reference to dignity assumes that living with a disability is per se an indignity.

179. Wright, *Equality of Autonomy?*, *supra* note 14, at 159; see also *Medical Aid in Dying*, COMPASSION & CHOICES (2021), <https://perma.cc/NSV3-KY5R> (defining medical aid in dying as a “trusted and time-tested medical practice that allows a terminally ill, mentally capable adult with a prognosis of six months or less to live to request from their doctor a prescription for medication they can decide to self-ingest to die peacefully in their sleep”).

180. See Wright, *Equality of Autonomy?*, *supra* note 14, at 159 (stating that the success of the medical-aid-in-dying movement is in part due to the efforts of right-to-die advocates); see also Jeffrey M. Jones, *Prevalence of Living Wills in U.S. Up Slightly*, GALLUP (June 22, 2020), <https://perma.cc/Q34H-7PX4> (showing that Americans have consistently favored medical aid in dying for the past twenty-five years).

181. End of Life Option Act, CAL. HEALTH & SAFETY CODE §§ 443.1–.22 (West 2022); End-of-Life Options Act, COLO. REV. STAT. ANN. §§ 25-48-101 to -123 (West 2022); Death with Dignity, D.C. CODE ANN. §§ 7-661.01–.16 (West 2022); Our Care, Our Choice Act, HAW. REV. STAT. ANN. §§ 327L-1 to -25

medical aid in dying limit access to: (i) adults; (ii) with decision-making capacity; (iii) who are terminally ill; and (iv) reside in the state in which they receive the prescription.¹⁸² Additional process requirements may require that the attending physician conduct a mental health assessment if the physician has concerns regarding a patient's requisite capacity.¹⁸³ The physician must obtain informed consent,¹⁸⁴ ensure that the patient knows that they may change their mind at any time, and offer the individual the opportunity to rescind their request.¹⁸⁵ Medical-aid-in-dying advocacy groups believe that the implementation of a "good death"—that is, one that halts pain and suffering—is ethical, and that the right to autonomously control the manner of one's death is a human right.¹⁸⁶ Seventy-four percent of Americans support medical aid in dying,¹⁸⁷ and many believe that the practice avoids the overtreatment and unnecessary suffering that can result from traditional end-of-life treatment models.¹⁸⁸

(West 2022); Death with Dignity Act, ME. REV. STAT. ANN. tit. 22 § 2140 (West 2022); Baxter v. State, 224 P.3d 1211, 1221–22 (Mont. 2009) (holding that medical aid in dying is not contrary to public policy); Aid in Dying for the Terminally Ill Act, N.J. STAT. ANN. §§ 26:16-1 to -20 (West 2022); End-of-Life Options Act, N.M. STAT. ANN. § 24-7C-1 to -8 (West 2022); Death with Dignity Act, OR. REV. STAT. ANN. §§ 127.800–.897 (West 2023); Patient Choice at End of Life, VT. STAT. ANN. tit. 18, §§ 5281–5293 (West 2022); Death with Dignity Act, WASH. REV. CODE ANN. §§ 70.245.010–.901 (West 2022).

182. Thaddeus Mason Pope, *Medical Aid in Dying: When Legal Safeguards Become Burdensome Obstacles*, ASCO POST (Dec. 25, 2017), <https://perma.cc/4LQW-MWB5>.

183. *Id.*

184. See COMPASSION & CHOICES, MEDICAL AID IN DYING: A POLICY TO IMPROVE CARE AND EXPAND OPTIONS AT LIFE'S END 2 (2022), <https://perma.cc/F62G-3YMY> (PDF).

185. See *Medical Aid in Dying*, *supra* note 179.

186. See Behuniak, *supra* note 178, at 24 (stating that groups such as Compassion & Choices adopt "the liberal vision of the individual as autonomous, independent, and capable of actualizing choices").

187. See *Medical Aid in Dying*, *supra* note 179 ("Support is high across all demographic groups surveyed.").

188. See *Medical Aid in Dying and Palliative Care*, *supra* note 39

A New England Journal of Medicine study of hospice nurses and social workers in Oregon reported that symptoms like pain, depression, anxiety, extreme air hunger, and fear of dying were less pronounced among hospice patients who requested aid-in-dying medication, indicating a strong

A common criticism of the concept of “death with dignity”¹⁸⁹ is that by enacting medical-aid-in-dying statutes, a state communicates to the public that disabled lives are undignified and unworthy.¹⁹⁰ Allowing medical aid in dying for individuals with disabilities may perpetuate stereotypes, such as the idea that individuals with disabilities are inferior or lack dignity.¹⁹¹ Others argue that instead of promoting autonomy, medical aid in dying endangers personhood by exposing vulnerable populations to coercion to end their lives.¹⁹² For example, disability advocates believe medical aid in dying may entice individuals with disabilities to choose death to avoid burdening their families.¹⁹³ Accordingly, some opponents have called for a total ban on medical aid in dying, citing additional concerns regarding exploitation and misdiagnosis.¹⁹⁴ Opponents’ skepticism is reasonable in light of the nation’s history of harmful treatment of individuals with disabilities.¹⁹⁵ Research

palliative care benefit for having aid-in-dying prescription on hand regardless of whether it ever gets filled.

189. See Death with Dignity Act, OR. REV. STAT. ANN. §§ 127.800–.897 (West 2022).

190. See Eric A. Johnson, *Assisted Suicide, Liberal Individualism, and Visceral Jurisprudence: A Reply to Professor Chemerinsky*, 20 ALASKA L. REV. 321, 323 (2003)

Further, because a right to assisted suicide would have to be based on an objective determination that the disabilities accompanying terminal illness make life less worthy of protection, recognition of that right would have the effect of reinforcing the common misperception that life as a disabled person is “undignified” or “degraded.”

191. See Behuniak, *supra* note 178, at 27 (“In a culture where health is a virtue, and fears of disability are exploited to win support for physician assisted death, pervasive biases lead to the conclusion that the lives of those with disabilities are inherently bad, unfulfilled or partial, and lack dignity.”).

192. See Johnson, *supra* note 190, at 323 (challenging Professor Erwin Chemerinsky’s critique of the Alaska Supreme Court’s decision to uphold the state’s ban on assisted suicide in *Sampson v. State*, 32 P.3d 88, 100 (Alaska 2001)).

193. See Wright, *Equality of Autonomy?*, *supra* note 14, at 180 (“But importantly, not wanting to be a burden on family and friends was listed as an end-of-life concern by over half of persons who sought [physician aid in dying] in Oregon in 2018.”).

194. Moore, *supra* note 20, at 272.

195. See *id.* at 253 (discussing the eugenics movement that spanned from 1890 to the early 1940s and had a goal of creating a superior society by “eradicating the reproduction of those deemed ‘unfit’”); see also *Buck v. Bell*,

has, however, overwhelmingly found that patients in vulnerable groups are not hastening death at a higher rates than other patients.¹⁹⁶

B. *Supported Decision-Making and Medical Aid in Dying*

Due to the requirement that a patient accessing medical aid in dying be “[m]entally capable of making their own health care decisions,”¹⁹⁷ individuals with disabilities may be excluded from access, again because of the harmful assumption that they are incapable of autonomous decision-making.¹⁹⁸ Scholar Megan Wright argues that supported decision-making, in honoring relational autonomy, challenges the assumption that medical aid in dying is unavailable to individuals with cognitive disabilities.¹⁹⁹ She champions the position that if a person with decisional impairments can decide autonomously with intention and understanding, there is no reason to exclude them from accessing medical aid in dying.²⁰⁰ Wright argues that in some cases, “despite decisional impairments, a person will be able to communicate their preferences and act autonomously in

274 U.S. 200, 206 (1927) (upholding a Virginia law that permitted involuntary sterilization of individuals with disabilities).

196. See Kathryn L. Tucker, *Building Bridges Between the Civil Rights Movement of People with Disabilities and Those with Terminal Illness*, 78 U. PITT. L. REV. 329, 344 (2017) (“The Oregon data, and, more recently, similar data from other states, shows that the dire predictions of those initially opposed to the Dignity Act were unfounded and that the option of aid in dying has not been unwillingly forced upon those who are poor, uneducated, uninsured, or otherwise disadvantaged.”).

197. *Medical Aid in Dying*, *supra* note 179.

198. See Wright, *Equality of Autonomy?*, *supra* note 14, at 160 (stating that scholarship has neglected the convergence of supported decision-making and physician-aid-in-dying laws); see also Richard K. Scotch, *Models of Disability and the Americans with Disabilities Act*, 21 BERKELEY J. EMP. & LAB. L. 213, 216 (2000) (“Such stigmatizing assumptions can result in exclusion and social isolation, including lack of access to employment, public facilities, voting, and other forms of civic involvement.”).

199. See Wright, *Equality of Autonomy?*, *supra* note 14, at 161 (“The option of supported decision-making combined with understanding autonomy as relational troubles this assumption, however.”).

200. See *id.* (“If a person with decisional impairments can decide autonomously—intentionally, voluntarily, and with understanding—when they are assisted in decision-making, it is not obvious that such persons should be excluded from [physician aid in dying].”).

relation to others.”²⁰¹ When an individual wishes to make such a serious decision with a supporter, a physician’s confidence in the patient’s informed consent to receive medication for medical aid in dying may depend on the patient’s prior ability to understand death, along with years of experience making their own decisions.²⁰² There may be less confidence if the patient “has had lifelong difficulty understanding various medical treatments or concepts such as death, has had lifelong difficulty engaging in causal inference, or has not had as much experience or skill in making their own decisions.”²⁰³ Nevertheless, advocates who support medical aid in dying assert that denying access to the treatment perpetuates a paternalistic view of individuals with disabilities.²⁰⁴

Currently, the only jurisdictions with both medical-aid-in-dying legislation and supported decision-making legislation are the District of Columbia, Colorado, and Washington. The District’s supported decision-making law²⁰⁵ permits individuals with decisional impairments to access support in healthcare decision-making but does not identify specific capacity requirements.²⁰⁶ Colorado and Washington’s supported decision-making laws, on the other hand, presume capacity.²⁰⁷ The medical-aid-in-dying statutes in these

201. *See id.* at 173.

202. *See id.* at 175.

203. *Id.* at 176.

204. *See supra* note 14 and accompanying text.

205. D.C. CODE § 7-2131 (2023).

206. *See id.* § 7-2131(11)

“Supported decision-making” means a process of supporting and accommodating an adult with a disability in order to assist the adult with a disability in understanding the options, responsibilities, and consequences of life decisions; and enable the adult with a disability to make life decisions, without impeding the self-determination of the adult with a disability or making decisions for the adult with a disability.

see also id. § 7-2132 (including the statement “[n]othing in this document prevents my supporter from also serving as a power of attorney or as a healthcare decision-maker” in the model supported decision-making agreement).

207. *See* COLO. REV. STAT. ANN. § 15-14-801(c) (West 2022) (“Adults with disabilities are presumed competent and have the capacity to facilitate the exercise of decisions”); WASH. REV. CODE ANN. § 11.130.710 (West 2022) (“All adults are presumed to be capable of managing their affairs.”).

jurisdictions²⁰⁸ likely did not contemplate supported decision-making²⁰⁹ and it is difficult to predict how these laws would interact.²¹⁰ Access to medical aid in dying in these states requires two witnesses to declare that the person making the request is either “mentally capable,”²¹¹ “[a]ppears to be of sound mind and not under duress, fraud, or undue influence”²¹² or that the patient is “competent, acting voluntarily, and is not being coerced to sign the request.”²¹³ In some instances, it may be difficult for witnesses to make such important determinations with confidence.²¹⁴

Further, the D.C. Death with Dignity Act²¹⁵ provides that “[a] provision in a contract, will, or other agreement executed on or after the effective date of this act, whether written or oral, is not valid if the provision would affect whether a person may make or rescind a request for a covered medication.”²¹⁶ Colorado and Washington’s statutes contain almost identical provisions.²¹⁷ As Wright points out, these provisions may be interpreted to mean that the supported decision-making agreement bars access to medical aid in dying because the

208. D.C. CODE § 7-661 (2023); COLO. REV. STAT. ANN. §§ 15-14-801 to -806 (West 2022); WASH. REV. CODE ANN. §§ 70.245.010–.901 (West 2022).

209. See Wright, *Equality of Autonomy?*, *supra* note 14, at 188 (noting that despite the absence of contemplation, the plain meaning of D.C.’s statute suggests that the laws may not be compatible).

210. See *id.* at 172 (“A question that has not yet been addressed by scholars, legislators, or judges is how [physician aid in dying] and supported decision-making laws interact.”).

211. COLO. REV. STAT. ANN. § 25-48-104(2)(III)(A) (West 2022).

212. D.C. CODE § 7-661.02(c) (2023).

213. WASH. REV. CODE ANN. § 70.245.030 (West 2022).

214. See Wright, *Equality of Autonomy?*, *supra* note 14, at 187 (“It is unclear whether two witnesses would be willing to attest that a person with moderate dementia, for example, who was seeking to use [physician aid in dying] was of ‘sound mind.’”).

215. D.C. CODE § 7-661 (2023).

216. D.C. CODE § 7-661.08(a) (2023).

217. COLO. REV. STAT. ANN. § 25-48-114(1) (West 2022) (“A provision in a contract, will, or other agreement, whether written or oral, that would affect whether an individual may make or rescind a request for medical aid in dying pursuant to this article is invalid.”); WASH. REV. CODE ANN. § 70.245.160(1) (West 2022) (“Any provision in a contract, will, or other agreement, whether written or oral, to the extent the provision would affect whether a person may make or rescind a request for medication to end his or her life in a humane and dignified manner, is not valid.”).

agreement may be a “contract” or “other agreement” that alters the legitimacy of the individual’s request.²¹⁸ Despite the uncertainty surrounding how these laws would interact, if supported decision-making continues to gain traction, legislators should re-visit state medical-aid-in-dying statutes to incorporate guidance for its use to ensure that medical-aid-in-dying laws continue to promote intersectional patient autonomy with appropriate protections. Still, both the ethical considerations²¹⁹ and the limited jurisdictional access to medical aid in dying through supported decision-making demonstrates the difficulty that patients, supporters, and providers may face in attempting to utilize this option. In comparison, supported decision-making may be better suited to help patients access treatment through Expanded Access as a way to preserve their autonomy and avoid suffering.

C. *Expanded Access: What Is It?*

The Expanded Access Program, also called “compassionate use,” has existed for approximately thirty years and serves as a pathway for patients who have an immediately life-threatening disease or condition²²⁰ to access investigational drugs²²¹ that treat conditions for which there are no other options available outside of clinical trials.²²² The program is largely a result of the

218. See Wright, *Equality of Autonomy?*, *supra* note 14, at 187–88 (“This is because the supported decision-making agreement permits a person who otherwise would be ineligible to make their own decisions (because of their cognitive disability) to make decisions with assistance from supporters, which may then make the person eligible for [physician aid in dying].”).

219. See Moore, *supra* note 20, at 245 (“An anti-subordination perspective might seek to limit a right to physician-assisted suicide, for example, because of concerns about exploitation and the messaging that disabled lives are not worth living.”).

220. See 21 C.F.R. § 312.300 (2022) (defining “immediately life-threatening disease or condition” to mean “a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment”).

221. See *Expanded Access: Information for Patients*, FDA (May 20, 2019), <https://perma.cc/EYL3-7BD7> (defining an investigational medical product as a drug, biologic, or medical device).

222. See Ori Rozenberg & Dov Greenbaum, *Making it Count: Extracting Real World Data from Compassionate Use and Expanded Access Programs*, 7 AM. J. BIOETHICS 89, 89 (2020) (stating that Expanded Access was enacted in 1987 in response to the Aids epidemic); see also AGATA BODIE, CONG. RSCH.

work of HIV advocates in the 1980s and 1990s, who successfully forced an unwilling presidential administration to address the stigmatizing medical crisis facing their community.²²³ To apply for compassionate use, the patient must first consult with their physician.²²⁴ At this stage, the patient and the physician explore alternate treatment options or clinical trials together, ensuring that all other options have been exhausted before endeavoring to request treatment through compassionate use.²²⁵ If all reasonable or feasible treatment options have been exhausted and the patient consents to pursuing treatment, the physician contacts the medical product manufacturer and files paperwork with an Institutional Review Board (IRB).²²⁶ The physician is responsible for patient care and reporting, and must conclude that the experimental drug does not pose a greater risk to the patient than the disease itself.²²⁷ The physician is also responsible for obtaining the informed consent of the patient or the patient's legally authorized representative.²²⁸ After

SERV., R45414, EXPANDED ACCESS AND RIGHT TO TRY: ACCESS TO INVESTIGATIONAL DRUGS 2 (2021), <https://perma.cc/3SKL-TG7U> (PDF) (stating that individuals may be excluded from clinical trials because they are full or because enrollment may be limited to patients with particular characteristics).

223. See Patricia J. Zettler, *The Implications of Post-Phase 1 and "Off-Label" Treatment Use of Experimental Drugs: How Expansive Should Expanded Access Be?*, 18 KAN. J.L. & PUB. POL'Y 135, 136 (2009) (stating that cancer patients first lobbied for Expanded Access in the 1970s before the efforts of HIV/AIDS patients formalized Expanded Access programs).

224. See *Expanded Access: Information for Patients*, *supra* note 221.

225. *Id.*

226. See *Information Sheet: Institutional Review Boards Frequently Asked Questions*, FDA (Jan. 1998), <https://perma.cc/Y828-5Z8H> (defining an Institutional Review Board as "an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects" that has the "authority to approve, require modifications in (to secure approval), or disapprove research").

227. See U.S. DEPT. HEALTH & HUM. SERVS. ET AL., EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE—QUESTIONS AND ANSWERS: GUIDANCE FOR INDUSTRY 11 (2017) [hereinafter EXPANDED ACCESS GUIDANCE FOR INDUSTRY], <https://perma.cc/NE29-GARK> (PDF).

228. 21 C.F.R. § 50.20 (2023)

Except as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider

physician clearance, the product manufacturer must then agree to provide the treatment.²²⁹

If the manufacturer agrees, it submits an Expanded Access request to the FDA after consulting with the physician and obtaining all the required information for the request.²³⁰ The IRB must then assure that all protocols have been followed to protect the patient's rights,²³¹ including a review of the compassionate use plan and the patient's informed consent.²³² This is a triple-check to ensure that the patient understands the nature of the product and the proposed treatment.²³³ Finally, the FDA determines whether treatment can proceed.²³⁴ Once the patient begins treatment, the physician must report any adverse drug effects to the manufacturer.²³⁵ Manufacturers must also submit safety reports to the FDA, and the FDA in turn outlines specific responsibilities that each party must follow.²³⁶

The Right to Try Act was passed in 2018 and closely resembles Expanded Access, but is critically distinguishable.²³⁷ Right to Try serves as another way for patients who have been

whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

229. *Expanded Access: Information for Patients*, *supra* note 221; *see also* Zettler, *supra* note 223, at 166 (stating that pharmaceutical companies are often reluctant to make an investigational drug available due to concern that an adverse event would prevent their drug from receiving full FDA approval).

230. *Expanded Access: Information for Patients*, *supra* note 221.

231. *Id.*

232. *Id.*

233. *Id.*

234. *Id.*

235. *See* Robert Romanchuk, *What's the Difference Between Right to Try and Expanded Access?*, ADVARRA BLOG (July 12, 2018), <https://perma.cc/9FHT-5R8N>.

236. *See* 21 C.F.R. §§ 312.32, 312.33.

237. *See* *Advanced Integrative Med. Sci. Inst. v. Garland*, 24 F.4th 1249, 1252 (9th Cir. 2022) ("Because of restrictions on clinical investigations and difficulties associated with the expanded access program, Congress passed the [Right to Try] Act in 2018 to give certain patients access to investigational new drugs under certain circumstances, outside of a clinical trial setting.").

diagnosed with life-threatening conditions to access treatment that the FDA has yet to approve.²³⁸ Right to Try, however, bypasses FDA involvement and only requires the approval of the treating physician, approval of the manufacturer of the drug, and notification to the FDA by the physician within a year after the treatment has taken place.²³⁹ Unlike compassionate use, physicians do not need to submit any additional reports to the FDA.²⁴⁰ The emphasis on safety under compassionate use is crucial, especially in considering the needs of vulnerable populations.²⁴¹ Given the shameful history of eugenics and mistreatment of individuals with disabilities, the absence of FDA oversight is dangerous and creates a heightened risk of exploitation.²⁴² Right to Try should not be a viable treatment option for individuals with disabilities, even with the theoretical assistance of a supporter.²⁴³ Because more than 99 percent of all

238. See *Right to Try*, FDA (Jan. 14, 2020), <https://perma.cc/Z3N8-8U6F>.

239. See Jennifer Byrne, *Right to Try: A 'Well-Intentioned' But 'Misguided' Law*, HEMONC TODAY (March 10, 2020), <https://perma.cc/6C9C-U5L9> (explaining that Right to Try's "striking similarity" to the FDA's Expanded Access Program has led clinicians to view the Act as a "politically motivated attempt to undermine and jettison the FDA").

240. See Rozenberg & Greenbaum, *supra* note 222, at 90 (stating that researchers have questioned the ethics of providing a streamlined process to "not yet proven remedies"); see also 21 C.F.R. § 312.310(c)(2) ("At the conclusion of treatment, the licensed physician or sponsor must provide FDA with a written summary of the results of the Expanded Access use, including adverse effects.").

241. See *Institutional Review Boards (IRBs) and Protection of Human Subjects in Clinical Trials*, FDA (2019), <https://perma.cc/YD94-V3CU> (stating that the job of the IRB is to "assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research").

242. See Byrne, *supra* note 239 (quoting a physician objecting to Right to Try because "the inclusion of the FDA provides for a number of important patient protections").

243. See Bard, *supra* note 2, at 516–17 (stating that individuals with disabilities had been experimented on without their consent and were subject to torture at the hands of the Nazi regime in the 1930s and 1940s); see also Jeremiah Stout et al., *Oncologists' Reflections on Patient Rights and Access to Compassionate Use Drugs: A Qualitative Interview Study from an Academic Cancer Center*, 16 PLOS ONE 1, 1 (2015) ("Physicians struggled with a 'right-to-try' framing of patient access to experimental drugs, noting instead their own responsibility to protect patients' best interest in the uncertain and risky process of off-protocol access.").

Expanded Access requests are approved, the streamlined process of Right to Try is also largely irrelevant.²⁴⁴

The ethical justification for compassionate use is that it demonstrates compassion for individuals with terminal illnesses and respects their right to autonomy.²⁴⁵ Most law and policy justifications for compassionate use programs are grounded in justice, autonomy, or beneficence, but physicians tend to root their decision to grant Expanded Access in the principle of beneficence.²⁴⁶ Physicians must always consider patient safety and balance their duty of beneficence and nonmaleficence with respect for individual autonomy.²⁴⁷ When it comes to compassionate use, physicians and the FDA make these determinations, as courts have traditionally shied away from engaging in such balancing inquiries.²⁴⁸ Compassionate use may appropriately strike the balance between respecting patient autonomy and adhering to principles of beneficence and nonmaleficence. The process implements physicians' knowledge and guidance and allows them to adhere to the dominant treatment protocol without explicitly causing undue suffering.²⁴⁹ It does not empower a patient with the "right to try"

244. See Byrne, *supra* note 239 (explaining that the FDA approves nearly all Expanded Access requests within days, requiring changes in only about 10 percent of cases for patient protection); See *Expanded Access (Compassionate Use) Submission Data*, FDA, <https://perma.cc/MSW3-UVYD> (noting that both the American Cancer Society and the American Society of Clinical Oncology have criticized Right to Try).

245. See Stout et al., *supra* note 243, at 2 (discussing the complex ethics of providing experimental medication outside of clinical trials); see also Jonathan J. Darrow et al., *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 NEW ENG. J. MED. 279, 283 (2015) (stating that patients should have a right to mitigate extreme suffering and "deference to the assumed capacity of patients to thereby make appropriate treatment decisions should be greatest when the stakes are highest").

246. See Stout et al., *supra* note 243, at 11 (illustrating that a preference for beneficence ensures that the decision to pursue compassion use is the option that physicians believe is best for their patient's wellbeing).

247. See *supra* note 37 and accompanying text.

248. See *Abigail All. for Better Access to Developmental Drugs v. Von Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007) ("Arguments about morality, quality of life, and acceptable levels of medical risk are certainly ones that can be aired in the democratic branches, without injecting the courts into unknown questions of science and medicine.").

249. See Stout et al., *supra* note 243, at 9 ("Several participants suggested that because a physician's knowledge and guidance is necessary for patients

any drug that they wish when faced with a terminal illness.²⁵⁰ Unlike the process of obtaining treatment for medical aid in dying, there appears to be a larger institutional safety net—or more ethical gatekeepers involved—in compassionate use.²⁵¹ The physician, drug manufacturer, IRB, and FDA all oversee the process and monitor patient comfort and safety, each with their own ethical obligations and goals.

Critics of compassionate use fear that patients may have unrealistic expectations regarding the outcome of their treatment, although many patients understand that treatment largely serves as a way to help prolong or improve the quality of their life.²⁵² Still, when confronted with terminal illness, patients may feel that they have nothing to lose by trying investigational treatment, but the risk always remains that the medication may hasten death or increase pain.²⁵³ Those who seek to limit access to compassionate use argue that the probability of a clinically meaningful benefit from early stage experimental trials may be slim, and that “informational asymmetries can lead to patient vulnerability.”²⁵⁴ Yet, even if an experimental drug does not work as hoped, the individual may feel closure and empowerment that they were able to advocate for themselves to really “try everything.”²⁵⁵ In a recent study, the majority of physicians utilizing compassionate use reported that the investigational drugs prescribed were used for palliative care for patients.²⁵⁶ They were offered largely to help

to access investigational drugs, patients should have a right to ask for experimental therapies or discuss them with their oncologist instead of a right to try any drug they wish.”).

250. *Id.*

251. See Kim, *supra* note 3, at 97 (“Today, the FDA serves as a ‘gatekeeper’ to protect public health by using its regulatory authority over the drug approval process.”).

252. See Stout et al., *supra* note 243, at 7–8 (“The majority of oncologists reported that they thought their patients had realistic expectations and a good understanding of the experimental nature of the drug while also having hope that it would improve their condition and/or quality of life.”).

253. See Byrne, *supra* note 239 (quoting a physician stating that “the unknown effects of the drugs can worsen outcomes of even those with poor prognoses”).

254. Darrow et al., *supra* note 245, at 284.

255. Kim, *supra* note 3, at 115–16.

256. Stout et al., *supra* note 243, at 8.

patients reach “a specific milestone, ease symptom burden, or improve quality of life.”²⁵⁷ As such, a significant cohort of oncologists reported that offering access to investigational treatment was arguably part of their professional obligation to patient care.²⁵⁸

D. *Supported Decision-Making and Expanded Access*

Supported decision-making may help patients access treatment through compassionate use by (i) facilitating thorough and effective informed consent, and (ii) helping a patient navigate and fulfill certain requisite soft requirements for access. Although compassionate use is different from clinical trials,²⁵⁹ the informed consent provision in Expanded Access requires no more than what is generally required for clinical trial participation.²⁶⁰ Under this general provision, a guardian could give informed consent on behalf of a patient.²⁶¹ Because guardianship largely strips an individual of legal decision-making capacity, it is likely not best practice for a guardian to have such power.²⁶² Compassionate use advances personal autonomy, so a guardian’s decision to subject an individual to treatment is at odds with the purpose of the program and may undermine an individual’s right to self-determination.²⁶³ Advance directives similarly are not conducive to accessing treatment under compassionate use due to the impossibility of predicting one’s future health challenges or the subsequent availability of investigational treatments for the condition.²⁶⁴

257. *Id.*

258. *See id.* at 9–10 (quoting oncologists stating that the effort of accessing investigational drugs is part of their professional obligations for patients that could benefit but noting that the same physicians clarified that compassionate use is only appropriate in “rare clinical cases”).

259. *See* EXPANDED ACCESS GUIDANCE FOR INDUSTRY, *supra* note 227, at 3 (clarifying that the main purpose of a clinical trial is to obtain information about the safety or effectiveness of a drug, while the purpose of compassionate use is to diagnose, monitor, or treat a patient’s condition).

260. 21 C.F.R. § 50.20 (2023).

261. *See id.*

262. *See supra* notes 113–114 and accompanying text.

263. *See supra* note 245 and accompanying text.

264. *See supra* note 88 and accompanying text.

Many physicians require that compassionate use requests have a “clear scientific rationale, a strong ratio of risk to benefit, and a solid safety profile” and that patients have “good functional status” and “high motivation to pursue [Expanded Access].”²⁶⁵ These additional soft requirements go beyond what regulation requires.²⁶⁶ Given the procedural complexity and relative unpredictability of access, research into compassionate use has demonstrated a need for enhanced shared decision-making tools.²⁶⁷ Both physicians and patients are often confused about terminology and the correct process to follow.²⁶⁸ Physicians experience difficulty managing patient expectations in balancing hope and realism, especially when patients are in a fragile emotional state.²⁶⁹ The sheer complexity of the process may deter both patients and physicians from attempting access entirely.²⁷⁰

Supported decision-making may help effectuate the enhanced communication necessary to make compassionate use possible for patients with disabilities. Proponents of compassionate use have advocated for expanding informed

265. Stout et al., *supra* note 243, at 10; *see id.*

Together with our participants’ prioritization of function status over the terminal nature of their patients’ conditions, this rationale provides important nuance around the factors physicians may use to qualify patients to receive unapproved drugs and suggest substantial differences between regulatory and clinical standards for making unapproved therapies available to patients.

266. *Id.*

267. *See id.* at 12

Tools designed to enhanced shared decision-making and facilitate conversations about both on- and off-trial medications with patients are needed, and may bridge the gap amount discordant views between patient and oncologist . . . Tools to foster dialogue between patient and oncologist and support systems for oncologists to navigate non-trial [Expanded Access] are needed so that patients can receive the best care at a crucial juncture late in their illness.

268. *See id.* (stating that oncologists were unclear on Expanded Access terminology and could benefit from “training about preapproval access and need institutional infrastructure to help navigate the application processes”).

269. Byrne, *supra* note 239.

270. *See* Kim, *supra* note 3, at 100 (explaining that the complexity of the process and its effectiveness has garnered criticism from both the public and Congress); *see also* BODIE, *supra* note 222, at 8 (discussing an editorial that was published leading up to the passage of Right to Try that called FDA’s procedures “‘bureaucratic absurdity, daunting’ and ‘fatally flawed’”).

consent requirements to include a thorough discussion of the patient's assumed risk and the involvement of a third party to help explain that risk.²⁷¹ A supporter may assist the patient in giving complete and meaningful informed consent by translating all the criteria and concerns from the physician into terms that the patient can understand and appreciate.²⁷² This would minimize information asymmetries. The supporter may help the patient self-advocate and satisfy some of the physician's soft requirements, and may also assist the physician in monitoring patient status and emotional condition. This "process of collaboration between researchers, participants, and surrogate decision-makers is well developed in the U.K., where it is necessary to comply with the mandate of including people who are not legally competent as participants in research."²⁷³ Again, although compassionate use differs from research trials, supported decision-making could work equally as well in the United States to facilitate assent to treatment under compassionate use. A supporter would likely be a welcome additional ethical gatekeeper, and would support the patient's relational autonomy along the way.

The Mayo Clinic has stated that for its clinical trials involving individuals with diminished decision-making capacity, special procedures should be implemented to protect patient welfare.²⁷⁴ The additional procedures it suggested include: (i) the "timing of study procedures to avoid periods of heightened vulnerability where possible;" (ii) "advance directives to document the participant's intent and attitude toward research participation at the time the research

271. See Meghan K. Talbott, *Currents in Contemporary Ethics: The Implications of Expanding Access to Unapproved Drugs*, 35 J.L. MED. & ETHICS 316, 318 (2007). The FDA recently responded to this need in draft Expanded Access Guidance containing a model informed consent form. See U.S. DEPT. HEALTH & HUM. SERVS. ET AL., EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE—QUESTIONS AND ANSWERS: GUIDANCE FOR INDUSTRY 29 (2022), <https://perma.cc/9EN9-PDE3>.

272. See Coleman, *supra* note 68, at 748 ("The relationship between capacity and understanding also means that persons who initially appear to lack decision-making capacity can sometimes be rendered capable through education.").

273. Bard, *supra* note 139, at 519.

274. See INFORMED CONSENT TO RESEARCH POLICY REPORT, *supra* note 66, at 6 (explaining the procedures for patients with "fluctuating capacity").

participant is capable of decision-making”; or (iii) “the use of an independent monitor.”²⁷⁵ There is no reason that these same procedures could not be used when a patient desires investigational treatment through compassionate use. Having a supporter involved to help effectuate heightened informed consent and to assist in complying with additional procedural and ethical safeguards will better educate patients and advance their rights without depriving them of autonomy.

While risk of exploitation is always a valid consideration, there has never been a lawsuit brought against a physician in the entire lifetime of Expanded Access.²⁷⁶ The fear that a supporter may act unilaterally is further alleviated because at least where the Mayo Clinic is the IRB of record for clinical trials, “any meaningful objection by the potential participant regarding study participation must be taken as a refusal or withdrawal and be honored, even if the [legally authorized representative] or the person obtaining consent disagrees with the decision.”²⁷⁷ Even if the Mayo Clinic’s IRB is exceptional rather than typical,²⁷⁸ the patient’s physician, the product manufacturer, and the FDA all serve as additional monitors of the validity of genuine informed consent.

Much like Death with Dignity laws, Expanded Access has not contemplated supported decision-making.²⁷⁹ Because Expanded Access is a federal program, the jurisdictional limit on access through supported decision-making is not as restrictive as it is for medical aid in dying. Still, some state statutes better support the application of supported

275. *Id.*

276. *See* Byrne, *supra* note 239 (explaining that a clause that exempts healthcare workers from liability related to treatment is unlikely to be the thing that entices oncologists to offer investigational drugs to their patients).

277. INFORMED CONSENT TO RESEARCH POLICY REPORT, *supra* note 66, at 4.

278. *See* Kelly McBride Folkers & Alison Bateman-House, *Will New FDA Regulation on IRB Review Speed Patient Access to Experimental Drugs?*, HEALTH AFFS. (Dec. 11, 2017), <https://perma.cc/YT9X-CPEK> (noting the lack of information on IRB protocol for single-patient requests but noting its crucial role in protecting patient welfare).

279. *See* Zettler, *supra* note 223, at 136 (discussing the origins of Expanded Access and stating that cancer patients first lobbied for it in the 1970s, long before supported decision-making was passed in Texas); *see also* Talbott, *supra* note 271, at 318 (stating the absence of detailed provisions on providing informed consent, indicating a lack of consideration for those with diminished capacity hoping to access).

decision-making to compassionate use than others. In theory, anyone with requisite capacity under supported decision-making statutes should be able to use a supporter to access compassionate use, but in practice, varying capacity requirements and practical considerations have significant impact on who may exercise the option.

Alaska, Colorado, Illinois, New Hampshire, and Washington's supported decision-making statutes may be the most conducive to access, as they appear to extend supported decision-making to the widest population of individuals. These states' statutes explicitly declare that an individual utilizing supported decision-making is presumed to have capacity.²⁸⁰ Other states have more limitations. For example, Delaware's statute appears to presume capacity, but allows "a judicial determination that the principal lacks the capacity to engage in the making of specific decisions covered by the agreement despite the assistance of a supporter" as grounds for limiting the terms of the agreement.²⁸¹ Nevada's statute states that "[a]n adult should be able to live in the manner in which he or she wishes and to accept or refuse support, assistance or protection as long as the adult does not harm others and is capable of making decisions about such matters."²⁸² It appears that the phrase "capable of making decisions about such matters" requires a subjective capacity determination as a prerequisite to entering a supported decision-making agreement.²⁸³ The phrase

280. See ALASKA STAT. ANN. § 13.56.150(d) (West 2020) ("In this chapter, a principal is considered to have capacity even if the capacity is achieved by the principal receiving decision-making assistance."); COLO. REV. STAT. ANN. § 15-14-801(c) (West 2023) ("Adults with disabilities are presumed competent and have the capacity to facilitate the exercise of decisions . . ."); 755 ILL. COMP. STAT. ANN. 9/15(a) (2023) ("All adults are presumed to be capable of making decisions regarding daily living and to have capacity unless otherwise determined by a court."); N.H. REV. STAT. ANN. § 464-D:3 (2022) ("All adults are presumed to be capable of managing their affairs and to have legal capacity."); WASH. REV. CODE ANN. § 11.130.710 (West 2022) ("All adults are presumed to be capable of managing their affairs.").

281. DEL. CODE ANN. 16, § 9405A(i) (2022).

282. NEV. REV. STAT. § 162C.100(2)(a) (2023).

283. See Phillips, *supra* note 60, at 628 (noting this consideration and asking whether the principal "[n]eed . . . only have capacity to decide to accept or refuse support, or [the capacity] to decide the manner in which they wish to live").

“about such matters” may limit the scope of capacity needed depending on how “such matters” is understood.²⁸⁴

Notwithstanding state nuances, capacity-affirming statutes open the door for potential access to compassionate use through supported decision-making. Yet, because of the inconsistency in state statutes regarding the level of capacity that is required of an individual to enter into a supported decision-making agreement, it may be difficult to determine just how wide that door may open to expand access to compassionate use.²⁸⁵ Even in jurisdictions that are conducive to access, dynamic impairments may eventually progress to invalidate a supported decision-making agreement, and supporters may also be hesitant to take on such a high-stake emotional and time commitment. Accordingly, although supported decision-making derives its value from the power of human relationships and the ways that those relationships may support autonomy and wellbeing, the complexity of human relationships can sometimes limit the model’s potential as well.

Ultimately, there is a noticeable lack of empirical evidence on both the use of supported decision-making agreements and compassionate use.²⁸⁶ To accurately predict and assess how the two laws work together, much more information is needed about the effectiveness of each, and the impact that each has on patient wellbeing.²⁸⁷ Still, supported decision-making may be

284. *Id.* at 629.

285. *See id.* (stating that existing statutes are inconsistent, but that “the majority view is that the principal must have, at a minimum, the limited capability of understanding the agreement”).

286. *See* Kohn et al., *supra* note 95, at 1128 (“Indeed, a number of recent discussions of supported decision-making note the lack of, and need for, empirical evidence that evaluates the different models of supported decision-making.”); Zettler, *supra* note 223, at 153–54

Without more comprehensive data, it is unknown how many patients currently are being treated with investigational drugs through expanded access, how many patients want to be treated with investigational drugs but are denied access by the FDA, how often sponsors refuse to participate in expanded access options, and whether patients who do gain access are being treated with drugs that are eventually found to be safe and effective. The FDA does not make this data readily available to the general public, and patient advocacy groups, like Abigail Alliance, have not yet pushed the FDA to publish such data.

287. *See* Kohn et al., *supra* note 95, at 1129 (“Nevertheless, this lack of evidence is unfortunate not only because it means that we do not know

highly effective in addressing some of the challenges that access to compassionate use poses for individuals with cognitive disabilities. Because the formalized Expanded Access program is largely a result of the needs of a population that was once one of society's most vulnerable,²⁸⁸ the program should continue to adapt and change to reflect the needs of those whose voices are often silenced in healthcare today.

CONCLUSION

“Cautious support” for mechanisms that improve individual autonomy, with safeguards, accurately serves the needs of individuals with disabilities.²⁸⁹ Undoubtedly, those with cognitive disabilities wishing to access medical aid in dying or compassionate use are in unique circumstances, but no individual should be forced to suffer through a terminal diagnosis without access to the health care of their choice. Supported decision-making may provide a legal framework that bolsters autonomy while supporting access to merciful end-of-life care. Although more research is needed regarding how supported decision-making agreements are commonly used and how they interact with end-of-life legislation, a continued push for expansion and revision of both supported decision-making statutes and end-of-life legislation may legitimize its application to end-of-life pain management and halt foreclosure of individuals' rights to self-determination.

whether supported decision-making is achieving its goals but also because it makes it difficult to develop and support effective evidence-based supported decision-making practices.”).

288. See *supra* note 223 and accompanying text.

289. See Behuniak, *supra* note 186, at 18 (highlighting the differences in how activists and individuals with disabilities view medical aid in dying).