

2013

Turn the Beat Around: Deactivating Implanted Cardiac-assist Devices

Lars Noah

Follow this and additional works at: <http://open.mitchellhamline.edu/wmlr>

Recommended Citation

Noah, Lars (2013) "Turn the Beat Around: Deactivating Implanted Cardiac-assist Devices," *William Mitchell Law Review*: Vol. 39: Iss. 4, Article 7.

Available at: <http://open.mitchellhamline.edu/wmlr/vol39/iss4/7>

This Article is brought to you for free and open access by the Law Reviews and Journals at Mitchell Hamline Open Access. It has been accepted for inclusion in William Mitchell Law Review by an authorized administrator of Mitchell Hamline Open Access. For more information, please contact sean.felhofer@mitchellhamline.edu.

© Mitchell Hamline School of Law

TURN THE BEAT AROUND?: DEACTIVATING IMPLANTED CARDIAC-ASSIST DEVICES

Lars Noah[†]

I. INTRODUCTION	1229
II. HOSPITALS ♥ ELECTROPHYSIOLOGY: ASSISTED LIVING MEETS THE ENERGIZER BUNNY.....	1231
III. MEDICAL ETHICISTS FRAME THE DEBATE	1237
A. <i>ICDs and Such</i>	1238
B. <i>Looking Beyond Simplistic Parallels</i>	1243
C. <i>Peculiarities of Pacemakers and LVADs</i>	1248
D. <i>Reaching a Consensus of Sorts</i>	1252
IV. STRADDLING CONSTITUTIONAL AND STATUTORY LINES	1255
A. <i>Tentative Judicial Guideposts</i>	1256
B. <i>Situating Implanted Cardiac-Assist Devices</i>	1264
1. <i>Questions of Ownership and Control</i>	1268
2. <i>Invoking Informed Consent Doctrine</i>	1275
C. <i>Navigating Imprecise Legislative Boundaries</i>	1281
D. <i>“Kill” Switches to the Rescue?</i>	1282
V. CONCLUSION	1284

I. INTRODUCTION

Near the end of the latest edition of my *Medical Technology* casebook, I note the following puzzle:

Imagine that, after the implantation of a left ventricular assist device (LVAD) for a failing heart, an ambulatory but miserable patient asks a physician to deactivate it—would

[†] Professor of Law, University of Florida. I would like to thank those who attended my paper presentation as part of the Grand Rounds in Cardiology series at UF’s Health Sciences Center. This project provided the occasion for my inaugural foray into end-of-life issues. My title alludes to a classic song from the disco era, subsequently popularized by Gloria Estefan among others (and narrowly beating out Sting’s “Be Still My Beating Heart” for my purpose).

that fall within the constitutional right to request the removal of ventilators or other forms of artificial (though external) life-support equipment, or is it more akin to requesting physician-assisted suicide (after all, a heart transplant patient who fares poorly and regrets his choice presumably would have no right to ask a surgeon simply to remove the new organ or perhaps try to “deactivate” it by applying a strong electrical current)?¹

Pacemakers and implantable cardioverter-defibrillators (ICDs) pose similar questions, and medical ethicists have given this conundrum a fair amount of attention,² but the legal academic literature seemingly has had nothing to say about it. In light of likely future increases in the utilization of cardiac-assist devices and continued technological advances, the problem will not conveniently go away.³ My article offers a sustained analysis of this intriguing question, and it also provides an opportunity to consider broader issues about the legality of physician aid in dying from a distinctive angle that none of the participants in that debate has explored.

1. LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 1148 (3d ed. 2012) (adding that pacemakers and implantable cardioverter-defibrillators may pose equally “tricky bioethical questions”).

2. See *infra* Part III. A pair of front-page *Washington Post* articles on the subject included useful summaries of the ethical debate. See Rob Stein, *Devices Can Interfere with Peaceful Death: Implants Repeatedly Shock Hearts of Patients Who Cannot Be Saved*, WASH. POST, Dec. 17, 2006, at A1 (“The problem is an example of the consequences of medical technologies proliferating before the ethical, psychological and logistic issues they raise have been resolved.”); Rob Stein, *Heart Pump Creates Life-Death Ethical Dilemmas*, WASH. POST, Apr. 24, 2008, at A1 (“Most doctors and bioethicists equate [LVADs] to ventilators, feeding tubes and other forms of life support that patients or their families have the right to discontinue . . . , [though] some say that the devices raise unique issues.”); see also Gina Kolata, *Extending Life, Defibrillators Can Prolong Misery*, N.Y. TIMES, Mar. 25, 2002, at A1 (“[ICDs] can fundamentally change the end stages of heart disease, giving years of life to people who would otherwise die. Some experts are asking whether the devices are going to create a new generation of patients who die slow and painful deaths.”); Barry Meier, *Lifesaving Devices Can Cause Havoc at Life’s End*, N.Y. TIMES, May 14, 2010, at B1.

3. See Eugene B. Wu, *The Ethics of Implantable Devices*, 33 J. MED. ETHICS 532, 532 (2007) (“[D]evelopment of a clear ethics for [the] ICD is critical as the massive technological advances in implantable heart failure devices will soon produce an epidemic of patients with implanted devices and end-of-life diseases.”).

II. HOSPITALS ♥ ELECTROPHYSIOLOGY: ASSISTED LIVING MEETS THE ENERGIZER BUNNY

Cardiologists have an ever-expanding range of procedures and medical devices to use with their patients.⁴ For instance, angioplasty using balloon catheters allows physicians to open partially blocked arteries instead of resorting to far riskier coronary artery bypass surgery. The development of stents allowed for the insertion of tiny metal scaffolds to help keep these blood vessels open, and the advent of drug-eluting stents counteracted the risk of clot formation.⁵ Interventional cardiology has become big business, with hospitals opening special “cath labs” to handle the increasing volume of patients.⁶ Heart valve replacement surgery

4. See Earl S. Ford et al., *Explaining the Decrease in U.S. Deaths from Coronary Disease, 1980–2000*, 356 *NEW ENG. J. MED.* 2388, 2390–91 tbl.1, 2396–97 (2007); Keith A.A. Fox et al., *Decline in Rates of Death and Heart Failure in Acute Coronary Syndromes, 1999–2006*, 297 *JAMA* 1892, 1898–99 (2007); Mark A. Hlatky, *Evidence-Based Use of Cardiac Procedures and Devices*, 350 *NEW ENG. J. MED.* 2126, 2127 (2004); Lawrence K. Altman, *Cheney File Traces Heart Care Milestones*, *N.Y. TIMES*, Apr. 24, 2012, at D1.

5. See Sally Squires, *The Selling of the Stent: Costly Drug-Eluting Stents Are Quickly Gaining Market Share—but Research on Their Effectiveness Lags*, *WASH. POST*, Sept. 16, 2003, at F1; see also Neal I. Muni & Thomas P. Gross, *Problems with Drug-Eluting Coronary Stents—The FDA Perspective*, 351 *NEW ENG. J. MED.* 1593 (2004) (discussing some of the regulatory issues presented by the introduction of these devices).

6. See DAVID S. JONES, *BROKEN HEARTS: THE TANGLED HISTORY OF CARDIAC CARE* 13 (2013) (“Together these procedures [bypass and angioplasty] form a \$100 billion industry in the United States alone.”); Reed Abelson & Julie Creswell, *A Hospital Chain’s Inquiry Cited Unneeded Treatment*, *N.Y. TIMES*, Aug. 7, 2012, at A1 (“Cardiology is a lucrative business for [Hospital Corporation of America], and the profits from testing and performing heart surgeries played a critical role in the company’s bottom line in recent years. Some of HCA’s busiest Florida hospitals perform thousands of stent procedures each year.”); *id.* (“HCA has more than 100 catheterization labs across the country and the one at Lawnwood was a financial juggernaut. It accounted for 35 percent of the hospital’s net profits, according to financial documents.”); Jane E. Brody, *More Isn’t Always Better in Coronary Care*, *N.Y. TIMES*, Jan. 6, 2009, at D7 (reporting that some physicians have become “vocal about the overuse of ‘interventional cardiology,’ a specialty involving invasive coronary treatments that have become lucrative for the hospitals and doctors who perform them”); Sarah Kliff, *HCA Probe Shines Light on Heart Care: Many Cardiac Procedures Are Unnecessary, Risky and Costly, Studies Show*, *WASH. POST*, Aug. 8, 2012, at A13 (“Inappropriate cardiac interventions occur so regularly that a term for it has been coined in the medical literature: ‘Oculostenotic reflex’”); see also James C. Robinson, *Hospital Market Concentration, Pricing, and Profitability in Orthopedic Surgery and Interventional Cardiology*, 17 *AM. J. MANAGED CARE* e241, e243–44 (2011) (“These procedures were highly profitable, with contribution margins per patient ranging from . . . 56% for angioplasty, [to] 44% for CRM [cardiac rhythm management]”).

has become more common as well.⁷

Cardiologists also have made growing use of various implants designed to maintain regular beating of the heart, a category sometimes denominated as “cardiovascular implantable electronic devices” (CIEDs).⁸ Cardiologists who specialize in cardiac rhythm management (CRM) using CIEDs are called electrophysiologists.⁹

Pacemakers go back more than half a century,¹⁰ and they combine two components: a pulse generator that produces rhythmic electrical signals and electrodes (commonly referred to as “leads”) that deliver those signals to the patient’s heart.¹¹ Patients with an irregular or abnormally slow heart rate, which can predispose them to heart attack or at least cause inadequate oxygenation of tissues throughout the body, often can benefit from

7. See Matthew Perrone, *FDA Weighs Heart Valve’s Risks in Considering Broader Use*, WASH. POST, June 13, 2012, at A15 (reporting that approximately 50,000 Americans undergo aortic valve replacement surgery each year).

8. See Bruce L. Wilkoff et al., *HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations*, 5 HEART RHYTHM 907, 908 (2008). See generally KIRK JEFFREY, *MACHINES IN OUR HEARTS: THE CARDIAC PACEMAKER, THE IMPLANTABLE DEFIBRILLATOR, AND AMERICAN HEALTH CARE* (2001). The Food and Drug Administration (FDA) classification regulations include them alongside other “cardiovascular prosthetic devices.” See *Cardiovascular Devices; General Provisions*, 45 Fed. Reg. 7904, 7906, 7939–47 (Feb. 5, 1980) (codified as amended at 21 C.F.R. pt. 870(D) (2012)). Equipment that delivers electrical pulses through paddles applied to the skin rather than implanted leads gets lumped together with other “cardiovascular therapeutic devices.” See *id.* at 7906, 7967–70 (codified as amended at 21 C.F.R. pt. 870(F)).

9. See Lou-Anne M. Beauregard, *Ethics in Electrophysiology: A Complaint from Palliative Care*, 33 PACING & CLINICAL ELECTROPHYSIOLOGY 226 (2010); Gerald V. Naccarelli et al., *Training in Specialized Electrophysiology, Cardiac Pacing, and Arrhythmia Management*, 51 J. AM. C. CARDIOLOGY 374 (2008); see also Jephtha P. Curtis et al., *Association of Physician Certification and Outcomes Among Patients Receiving an Implantable Cardioverter-Defibrillator*, 301 JAMA 1661, 1669 (2009) (“Nonelectrophysiologists implant 29% of ICDs . . .”); William G. Stevenson et al., *Clinical Assessment and Management of Patients with Implanted Cardioverter-Defibrillators Presenting to Nonelectrophysiologists*, 110 CIRCULATION 3866, 3867 (2004).

10. See Kirk Jeffrey & Victor Parsonnet, *Cardiac Pacing, 1960–1985: A Quarter Century of Medical and Industrial Innovation*, 97 CIRCULATION 1978 (1998). Some authors use the acronym “PM” when referring to a pacemaker.

11. See 21 C.F.R. §§ 870.3610, .3680 (2012); see also *Classification of Permanent and Temporary Pacemaker Electrodes*, 44 Fed. Reg. 13,379, 13,379–80 (proposed Mar. 9, 1979) (discussing the different types of leads and the range of problems experienced with their use). Other components include a polymeric mesh bag to hold an implanted pulse generator; external devices to program the pulse generator, analyze its function, and recharge the battery; and miscellaneous accessories. See 21 C.F.R. §§ 870.3620–.3730.

a pacemaker.¹² By inserting an extra lead, electrophysiologists can pace both the right ventricle and right atrium,¹³ and they also can use pacemakers for “cardiac resynchronization therapy” (CRT) to coordinate beating between the left and right ventricles.¹⁴ Battery life varies but generally averages close to a decade.¹⁵ External pacemakers exist as well, used for instance on a stopgap basis during routine surgery to guard against heart attack.¹⁶

Implantable cardioverter-defibrillators (ICDs) first came into use during the early 1980s and are basically pulse generators with different programming than traditional pacemakers.¹⁷ Not unlike

12. See Fred M. Kusumoto & Nora Goldschlager, *Medical Progress: Cardiac Pacing*, 334 NEW ENG. J. MED. 89, 89–92 (1996) (summarizing the various indications for pacemaker use).

13. See Jeffrey & Parsonnet, *supra* note 10, at 1985–86 (discussing “dual-chamber” pacemakers); Kusumoto & Goldschlager, *supra* note 12, at 89 (noting the popularity of dual-chamber pacing); *id.* at 93–97 (explaining the different modes available with programmable pacemakers); see also Stéphane Rinfret et al., *Cost-Effectiveness of Dual-Chamber Pacing Compared with Ventricular Pacing for Sinus Node Dysfunction*, 111 CIRCULATION 165, 170–71 (2005).

14. See Joshua M. Hare, Editorial, *Cardiac-Resynchronization Therapy for Heart Failure*, 346 NEW ENG. J. MED. 1902, 1903–04 (2002) (discussing “biventricular” pacemakers); see also John G.F. Cleland et al., *The Effect of Cardiac Resynchronization on Morbidity and Mortality in Heart Failure*, 352 NEW ENG. J. MED. 1539, 1546 (2005); Graham Nichol et al., *Cost-Effectiveness of Cardiac Resynchronization Therapy in Patients with Symptomatic Heart Failure*, 141 ANNALS INTERNAL MED. 343, 343–44 (2004).

15. See Michael Kindermann et al., *Longevity of Dual Chamber Pacemakers: Device and Patient Related Determinants*, 24 PACING & CLINICAL ELECTROPHYSIOLOGY 810, 815 (2001); Janet Moore, *Longer-Life Pacemaker Approved*, STAR TRIB. (Minneapolis), May 4, 2007, at 1D (adding that St. Jude’s Zephyr can last 14 years); cf. Janek Senaratne et al., *Pacemaker Longevity: Are We Getting What We Are Promised?*, 29 PACING & CLINICAL ELECTROPHYSIOLOGY 1044, 1050–54 (2006) (finding that batteries last more than a year less on average than projected by manufacturers).

16. See 21 C.F.R. §§ 870.3600, .5550.

17. See Michael Glikson & Paul A. Friedman, *The Implantable Cardioverter Defibrillator*, 357 LANCET 1107 (2001); Zachary Goldberger & Rachel Lampert, *Implantable Cardioverter-Defibrillators: Expanding Indications and Technologies*, 295 JAMA 809, 813–14 (2006); see also Mark A. Hlatky et al., *Evidence-Based Medicine and Policy: The Case of the Implantable Cardioverter Defibrillator*, 24 HEALTH AFF. 42, 48 (2005) (“The ICD field has evolved very quickly, and devices on the market today have much greater capabilities than those of only two or three years ago.”). As described in the FDA’s classification regulation, implanted pulse generators “correct both intermittent and continuous cardiac rhythm disorders. This device [class] may include triggered, inhibited, and asynchronous modes” 21 C.F.R. § 870.3610(a); see also *id.* § 870.3680(b)(1) (providing that electrodes may be used to “transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator”). Nonetheless, because ICDs had not been marketed prior to enactment of the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.), manufacturers must secure full

the old paddle sets used to resuscitate patients in hospitals or at the scene of an accident,¹⁸ ICDs deliver an electrical jolt when they detect cardiac arrhythmias (fibrillation).¹⁹ In addition, ICDs may function as more traditional pacemakers and facilitate CRT as well.²⁰ More familiar than external pacemakers, automated external defibrillators (AEDs) also have become commonplace.²¹

LVADs represent the newest class of cardiac-assist devices, though they provide mechanical circulatory support rather than electrical assistance.²² Sometimes called partial artificial hearts,²³

premarket approval of these devices while most pacemakers still only need to go through an abbreviated premarket notification process to demonstrate “substantial equivalence” to a previously sold device. See Barnaby J. Feder, *Medical Device Ruling Redraws Lines on Lawsuits*, N.Y. TIMES, Feb. 22, 2008, at C2. The FDA recently amended its classification regulations to call for the filing of either a premarket approval application or a notice of completion of a product development protocol for certain pacemaker components. See Effective Date of Requirement for Premarket Approval for a Pacemaker Programmer, 77 Fed. Reg. 37,570 (June 22, 2012) (amending 21 C.F.R. § 870.3700); Effective Date of Requirement for Premarket Approval for an Implantable Pacemaker Pulse Generator, 77 Fed. Reg. 37,573 (June 22, 2012) (amending 21 C.F.R. § 870.3610).

18. See 21 C.F.R. § 870.5300.

19. See John P. DiMarco, *Implantable Cardioverter-Defibrillators*, 349 NEW ENG. J. MED. 1836, 1837–38 (2003); Fred M. Kusumoto & Nora Goldschlager, *Device Therapy for Cardiac Arrhythmias*, 287 JAMA 1848, 1850–51 (2002); Robert J. Myerburg, *Implantable Cardioverter-Defibrillators After Myocardial Infarction*, 359 NEW ENG. J. MED. 2245, 2245 (2008); see also Stevenson et al., *supra* note 9, at 3867 (“Battery longevity is typically 4 to 7 years (dependent on use) . . .”).

20. See Michael R. Bristow et al., *Cardiac-Resynchronization Therapy with or Without an Implantable Defibrillator in Advanced Chronic Heart Failure*, 350 NEW ENG. J. MED. 2140, 2148–49 (2004); DiMarco, *supra* note 19, at 1838, 1842; Alan Kadish, Editorial, *Prophylactic Defibrillator Implantation—Toward an Evidence-Based Approach*, 352 NEW ENG. J. MED. 285, 286 (2005).

21. See Lawrence Altman, *Defibrillators for the Public Aid Survival, Study Says*, N.Y. TIMES, Nov. 12, 2003, at A16 (noting that “the devices have become standard equipment in many airports, malls, convention centers and health clubs”); see also 21 C.F.R. § 870.5310 (FDA classification regulation). See generally Kevin M. Rodkey, Comment, *Medical Technology Meets the Maryland General Assembly: A Case Study in Handling Advances in Automated External Defibrillator Technology*, 12 J. HEALTH CARE L. & POL’Y 81 (2009).

22. See 21 C.F.R. § 870.3545; Classification of Ventricular Bypass (Assist) Devices, 44 Fed. Reg. 13,370, 13,371 (proposed Mar. 9, 1979) (to be codified at 21 C.F.R. pt. 870) (noting that LVADs remained investigational at the time); Muriel R. Gillick, *The Technological Imperative and the Battle for the Hearts of America*, 50 PERSP. BIOLOGY & MED. 276 (2007) (recounting the history behind this device’s development); Piera Morlacchi & Richard R. Nelson, *How Medical Practice Evolves: Learning to Treat Failing Hearts with an Implantable Device*, 40 RES. POL’Y 511, 515–21 (2011) (same). Although less common, surgeons instead may implant right ventricular assist devices (RVADs) or biventricular assist devices (BiVADs).

23. Fully implanted total artificial hearts (TAHs) still await final FDA

they help to move blood from the left ventricle—one of the heart’s four chambers—into the aorta, which then circulates oxygenated blood throughout the body. Originally, these mechanical pumps required bulky external power packs and tubing, and they only were meant to serve as a temporary “bridge” while a patient with congestive heart failure awaited an organ transplant.²⁴ LVADs have worked well enough to become “destination” treatments,²⁵ and newer versions utilize a turbine to promote continuous (rather than pulsatile) blood flow through the heart.²⁶ Presently, these implanted devices must remain tethered to external controllers and power-packs, which patients may sling over their shoulders or wear around their waists on belts.²⁷

approval. See David Jolly, *An Artificial Heart Its Makers Say Could Be a Standard Replacement*, N.Y. TIMES, July 14, 2010, at B10 (reporting that the only FDA-approved total artificial heart, SynCardia’s update of the Jarvik-7, “has been implanted in more than 800 patients as a bridge before transplant,” while Abiomed’s fully implantable device enjoys limited distribution under the agency’s “humanitarian use” exemption); Rob Stein, *Artificial Heart Gets FDA Panel Approval; Device Is Interim Before Transplant*, WASH. POST, Mar. 18, 2004, at A1 (noting that SynCardia’s device “could be used only in a hospital and would require patients to be tethered to a large console that powers and controls the heart”). Unlike LVADs, TAH implantation necessitates the complete removal of the patient’s heart. See Renée C. Fox & Judith P. Swazey, *“He Knows That Machine Is His Mortality”*: *Old and New Social and Cultural Patterns in the Clinical Trial of the AbioCor Artificial Heart*, 47 PERSP. BIOLOGY & MED. 74, 81–82 (2004).

24. See Richard Saltus, *Artificial Heart Pumps Are Making a Comeback*, BOS. GLOBE, Aug. 12, 1996, at C1; Ruth SoRelle, *Spare Hearts: Bridges for the Heart*, HOUS. CHRON., Oct. 13, 1997, at A1; Sally Squires, *Putting Heart Failure on Hold: New Devices Keep Blood Flowing While Patients Wait for Transplants*, WASH. POST, July 12, 1994, at F9.

25. See Sally Brush et al., *End-of-Life Decision Making and Implementation in Recipients of a Destination Left Ventricular Assist Device*, 29 J. HEART & LUNG TRANSPLANTATION 1337, 1337–38 (2010); James C. Fang, Editorial, *Rise of the Machines—Left Ventricular Assist Devices as Permanent Therapy for Advanced Heart Failure*, 361 NEW ENG. J. MED. 2282, 2283 (2009); Sheryl Gay Stolberg, *Pump Extends Lives, and Raises Questions*, N.Y. TIMES, July 2, 2002, at F1. In some cases, an LVAD allows a patient’s heart to recover sufficiently so that the device can be explanted.

26. See Farooq H. Sheikh & Stuart D. Russell, *HeartMate® II Continuous-Flow Left Ventricular Assist System*, 8 EXPERT REV. MED. DEVICES 11 (2011); Mark S. Slaughter et al., *Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device*, 361 NEW ENG. J. MED. 2241, 2242, 2244 fig.1, 2249–50 (2009); Daniel Timms, *A Review of Clinical Ventricular Assist Devices*, 33 MED. ENGINEERING & PHYSICS 1041 (2011) (comparing different models).

27. See Yukihiko Nosé et al., Editorial, *The Need to Change Our Objective for Artificial Heart Development: From Totally Implantable Permanent Ventricular Assist Devices to Wearable Therapeutic Ventricular Assist Devices*, 34 ARTIFICIAL ORGANS 1069 (2010); Joseph G. Rogers et al., *Continuous Flow Left Ventricular Assist Device Improves Functional Capacity and Quality of Life of Advanced Heart Failure Patients*, 55 J. AM. C. CARDIOLOGY 1826, 1827 fig.1 (2010); see also Kiyoo Fukamachi & Nicholas Smedira,

As with angioplasty, hospitals and clinics have found CIEDs to be a lucrative source of income.²⁸ Some critics have complained about the inappropriate overuse of such devices—for instance, cardiologists have implanted ICDs in patients who do not really need them or in patients who may need them but suffer from other conditions that make these patients poor candidates for surgery.²⁹ Increasingly, recipients have shorter life expectancies than the batteries in their devices.³⁰ The expanding utilization of these

Smaller, Safer, Totally Implantable LVADs: Fact or Fantasy?, ACC CURRENT J. REV., Aug. 2005, at 40, 42 (“Presently, no continuous-flow pump undergoing a clinical trial is completely implantable, but all are designed for easy conversion of the next-generation model to total implantability.”); cf. Raja Mishra, *Abiomed Poised to Tap Wider Market as Artificial Heart Faces Crucial Tests*, BOS. GLOBE, Apr. 2, 2003, at D1 (“Patients [with fully implanted TAHs] wear batteries in belt pack that transfers energy to the heart via radio waves. No tubes or wires run in and out of patients.”).

28. See Chunliu Zhan et al., *Cardiac Device Implantation in the United States from 1997 Through 2004: A Population-based Analysis*, 23 J. GEN. INTERNAL MED. (Supp. 1) 13, 16 (2008) (“[P]atient admissions for cardiac device procedures might be more profitable than other hospital admissions.”); Barry Meier, *Sales Tactics on Implants Raise Doubts*, N.Y. TIMES, June 1, 2011, at B1; see also Paul A. Heidenreich et al., *Forecasting the Future of Cardiovascular Disease in the United States: A Policy Statement from the American Heart Association*, 123 CIRCULATION 933, 935 tbl.2 (2011) (estimating over \$60 billion in current annual expenditures on care of coronary heart disease and heart failure).

29. See Sana M. Al-Khatib et al., *Non-Evidence-Based ICD Implantations in the United States*, 305 JAMA 43, 47 (2011) (finding a rate of inappropriate use exceeding twenty-two percent); Denise Grady, *Many Defibrillators Called Unneeded*, N.Y. TIMES, Jan. 5, 2011, at A12. But see Douglas L. Packer et al., *ICDs: Evidence, Guidelines and Glitches*, 8 HEART RHYTHM 800 (2011) (responding to the study by Al-Khatib et al.).

30. See Anemona Hartocollis, *Rise Seen in Medical Efforts to Improve Very Long Lives*, N.Y. TIMES, July 18, 2008, at A1 (highlighting the case of a 104-year-old patient who had received an ICD combined with a biventricular pacemaker five years earlier); see also Raymond Cutro et al., *Device Therapy in Patients with Heart Failure and Advanced Age: Too Much Too Late?*, 155 INT’L J. CARDIOLOGY 52, 52 (2012) (“[O]ver 40% of all new ICD and CRT implants [in the United States] are in patients over the age of 70, and 10–20% are in patients over 80 years of age.”); Sharon R. Kaufman et al., *Ironic Technology: Old Age and the Implantable Cardioverter Defibrillator in US Health Care*, 72 SOC. SCI. & MED. 6 (2011) (focusing on use in octogenarians); Ure Mezu, *Effectiveness of Implantable Defibrillators in Octogenarians and Nonagenarians for Primary Prevention of Sudden Cardiac Death*, 108 AM. J. CARDIOLOGY 718, 721 (2011) (“Given the increased probability of death from competing causes in elderly patients, patients older than a certain age cease to extract a survival benefit from an ICD.”). Cardiac-assist devices occasionally get used in much younger patients. See Janet Moore, *Vital Companions: Because They’re Not Just “Little Adults,” Children with Medical Devices Pose Unique Challenges*, STAR TRIB. (Minneapolis), Sept. 3, 2006, at 1D (describing a special camp for children with heart disease, adding that “many are alive today because they were implanted with pacemakers, defibrillators, valves and other devices”); Ron Winslow, *Heart Beat: A*

devices in elderly patients has, of course, depended heavily on coverage under Medicare.³¹

III. MEDICAL ETHICISTS FRAME THE DEBATE

Ethical questions associated with requests to deactivate implanted cardiac-assist devices have drawn sustained attention from clinicians.³² As explained more fully below, the articles published to date generally defend the practice. The medical literature also contains several surveys of various individuals' attitudes about CIED deactivation that document different parties' perspectives in order to help inform the ethical debate, including the views of patients,³³ health care professionals,³⁴ and

New Heart Pump, Just for Kids, WALL ST. J., Aug. 2, 2011, at D1.

31. See Mark B. McClellan & Sean R. Tunis, *Medicare Coverage of ICDs*, 352 NEW ENG. J. MED. 222, 222 (2005) (summarizing the gradual expansion in coverage that has occurred since 1986).

32. See, e.g., Jennifer M. Ballentine, *Pacemaker and Defibrillator Deactivation in Competent Hospice Patients: An Ethical Consideration*, 22 AM. J. HOSPICE & PALLIATIVE MED. 14 (2005); Lofty L. Basta, *End-of-Life and Other Ethical Issues Related to Pacemaker and Defibrillator Use in the Elderly*, 15 AM. J. GERIATRIC CARDIOLOGY 114, 116 (2006); Juan Pablo Beca et al., *Deactivating Cardiac Pacemakers and Implantable Cardioverter Defibrillators in Terminally Ill Patients*, 18 CAMBRIDGE Q. HEALTHCARE ETHICS 236 (2009); Nathan E. Goldstein & Joanne Lynn, *Trajectory of End-Stage Heart Failure: The Influence of Technology and Implications for Policy Change*, 49 PERSP. BIOLOGY & MED. 10, 14–15 (2006); James N. Kirkpatrick & Antony Y. Kim, *Ethical Issues in Heart Failure: Overview of an Emerging Need*, 49 PERSP. BIOLOGY & MED. 1, 6 (2006); Hannah I. Lipman, *Deactivation of Advanced Lifesaving Technologies*, 16 AM. J. GERIATRIC CARDIOLOGY 109, 110 (2007); see also James N. Kirkpatrick et al., *Medical Ethics and the Art of Cardiovascular Medicine*, 376 LANCET 508, 509 (2010) (“Device management at the end of life can be ethically complex.”).

33. See, e.g., Nathan E. Goldstein et al., *“That’s Like an Act of Suicide”: Patients’ Attitudes Toward Deactivation of Implantable Defibrillators*, 23 J. GEN. INTERNAL MED. (Supp. 1) 7, 11 (2008) (“[W]e found that patients were either unwilling or unable to engage in conversations about deactivation.”); James N. Kirkpatrick et al., *Deactivation of Implantable Cardioverter Defibrillators in Terminal Illness and End of Life Care*, 109 AM. J. CARDIOLOGY 91, 93–94 (2012); Daniel B. Kramer et al., *Ethical and Legal Views Regarding Deactivation of Cardiac Implantable Electrical Devices in Patients with Hypertrophic Cardiomyopathy*, 107 AM. J. CARDIOLOGY 1071, 1074 (2011) (“Even this highly-educated cohort expressed substantial uncertainty and confusion about the legal status of CIED deactivation, and more than half could not identify whether variables such as the presence of a terminal illness were required for a device to be deactivated.”); Claire E. Raphael et al., *Implantable Cardioverter-Defibrillator Recipient Attitudes Towards Device Deactivation: How Much Do Patients Want to Know?*, 34 PACING & CLINICAL ELECTROPHYSIOLOGY 1628 (2011); Patricia H. Strachan et al., *Patients’ Perspectives on End-of-Life Issues and Implantable Cardioverter Defibrillators*, 27 J. PALLIATIVE CARE 6, 9–10 (2011).

34. See, e.g., Nathan E. Goldstein et al., *“It’s Like Crossing a Bridge”: Complexities Preventing Physicians from Discussing Deactivation of Implantable Defibrillators at the End*

representatives of device manufacturers.³⁵

A. *ICDs and Such*

Timothy Quill, a general practitioner and professor of medicine and psychiatry at the University of Rochester, became one of the first persons to pen an article about this problem in a medical journal. Dr. Quill, perhaps best known as the name plaintiff in one of the physician-assisted suicide cases to reach the U.S. Supreme Court,³⁶ co-authored a defense of ICD deactivation in 1994.³⁷ This brief article started by offering a first-of-its-kind case study of a patient requesting that his ICD, which had fired regularly, get turned off.³⁸ The authors then simply assumed that

of Life, 23 J. GEN. INTERNAL MED. (Supp. 1) 2 (2008); Paul J. Hauptman et al., *Physician Attitudes Toward End-Stage Heart Failure: A National Survey*, 121 AM. J. MED. 127, 131 (2008) (“[D]iscussions with patients and families about potential device deactivation are very uncommon across all physician specialties.”); Amy S. Kelley et al., *Implantable Cardioverter-Defibrillator Deactivation at the End of Life: A Physician Survey*, 157 AM. HEART J. 702, 706–07 (2009); Daniel B. Kramer et al., “*Just Because We Can Doesn’t Mean We Should*”: *Views of Nurses on Deactivation of Pacemakers and Implantable Cardioverter-Defibrillators*, 32 J. INTERVENTIONAL CARDIAC ELECTROPHYSIOLOGY 243, 248–49 (2011); *id.* at 250 (“Our study offers additional evidence that health professionals view pacemakers and ICDs differently (from each other and from other life-sustaining therapies.)”); Laura J. Morrison et al., *Managing Cardiac Devices Near the End of Life: A Survey of Hospice and Palliative Care Providers*, 27 AM. J. HOSPICE & PALLIATIVE MED. 545, 548–49 (2010).

35. See Paul S. Mueller et al., “*I Felt Like the Angel of Death*”: *Role Conflicts and Moral Distress Among Allied Professionals Employed by the US Cardiovascular Implantable Electronic Device Industry*, 32 J. INTERVENTIONAL CARDIAC ELECTROPHYSIOLOGY 253, 257–60 (2011) (finding significant involvement of industry employees in CIED deactivation requests).

36. See *Quill v. Koppell*, 870 F. Supp. 78 (S.D.N.Y. 1994), *rev’d sub nom.* *Quill v. Vacco*, 80 F.3d 716 (2d Cir. 1996), *rev’d*, 521 U.S. 793 (1997); Jane Gross, *Quiet Doctor Finds a Mission in Assisted Suicide Court Case*, N.Y. TIMES, Jan. 2, 1997, at B1; see also *infra* notes 133–38 and accompanying text (discussing the Court’s decision). Dr. Quill had made headlines a few years earlier after publishing an account about helping one of his patients commit suicide. See Timothy E. Quill, *Death and Dignity: A Case of Individualized Decision Making*, 324 NEW ENG. J. MED. 691 (1991); Lawrence K. Altman, *Jury Declines to Indict a Doctor Who Said He Aided in a Suicide*, N.Y. TIMES, July 27, 1991, § 1, at 1. Jack Kevorkian, a retired Michigan pathologist, drew far less positive press after he began assisting people who wanted to commit suicide. See Lawrence K. Altman, *More Physicians Broach Forbidden Subject of Euthanasia*, N.Y. TIMES, Mar. 12, 1991, at C3; John Schwartz, *A Polarizing Figure in End-of-Life Debates*, N.Y. TIMES, June 5, 2011, at A21.

37. See Timothy E. Quill et al., *Discontinuing an Implantable Cardioverter Defibrillator as a Life-Sustaining Treatment*, 74 AM. J. CARDIOLOGY 205 (1994).

38. See *id.* at 205; *id.* at 206 (“[W]e found no case reports in which an ICD was turned off for a patient who explicitly wanted to die.”); see also TIMOTHY E. QUILL, *A MIDWIFE THROUGH THE DYING PROCESS: STORIES OF HEALING AND HARD CHOICES AT*

the case did not differ from requests for the withdrawal of other life-sustaining treatments at the end of life,³⁹ devoting the bulk of their article to proposing a set of guidelines for handling all such cases without mentioning any special features linked to ICDs.⁴⁰ Fourteen years later, Dr. Quill published an article that made a passing reference to deactivating LVADs, but again with an almost cavalier assumption of equivalence.⁴¹

THE END OF LIFE 72–90 (1996) (elaborating on this case study). It did not take long for other such case reports to appear in the literature. See, e.g., Lofty Basta & Michael L. O’Neal, *Ethical Issues in the Management of Geriatric Cardiac Patients: A Terminal/Dying Patient Endures Repeated Shocks from an Automatic Implantable Cardioverter Defibrillator Unit*, 9 AM. J. GERIATRIC CARDIOLOGY 174, 175 (2000); Yuen Cheng Looi, Letter, *And It Can Go On and On and On . . .*, 31 J. PAIN & SYMPTOM MGMT. 1, 1–2 (2006) (focusing on some of the practical difficulties encountered in deactivating an ICD); Vinod Nambisan & David Chao, *Dying and Defibrillation: A Shocking Experience*, 18 PALLIATIVE MED. 482, 482–83 (2004) (same); Kenneth Plunkitt et al., *Ethical Issues in the Management of Geriatric Cardiac Patients: A Patient Is Asking His Cardiologist to Deactivate an Implantable Cardioverter Defibrillator Device in Order to Allow Him to Die*, 7 AM. J. GERIATRIC CARDIOLOGY 43, 43–44 (1998).

39. See Quill et al., *supra* note 37, at 206 (“Discontinuation of other potentially life-sustaining medical interventions such as mechanical ventilation, renal dialysis, and artificial hydration and nutrition is widely reported and practiced.” (endnotes omitted)); *id.* (“As illustrated in the case presented, life-sustaining medical treatments can save and prolong meaningful life. They are also capable of indefinitely prolonging a life filled with progressive suffering and loss, thereby prolonging an agonizing death.”); see also *id.* at 205 (“A competent patient . . . has the right to discontinue a treatment that has previously been initiated if it no longer meets the patient’s goals.”). Subsequent commentators repeated this mistake. See, e.g., Jeffrey T. Berger, *The Ethics of Deactivating Implanted Cardioverter Defibrillators*, 142 ANNALS INTERNAL MED. 631, 633 (2005); Plunkitt et al., *supra* note 38, at 43–44; Samuel F. Sears et al., *Quality of Death: Implantable Cardioverter Defibrillators and Proactive Care*, 29 PACING & CLINICAL ELECTROPHYSIOLOGY 637, 641 (2006); Debra Lynn-McHale Wiegand & Peggy G. Kalowes, *Withdrawal of Cardiac Medications and Devices*, 18 AACN ADVANCED CRITICAL CARE 415, 416, 419 (2007).

40. See Quill et al., *supra* note 37, at 206 (urging physicians confronting such cases to ensure that the patient’s request is rational and consistent, that the patient’s prognosis is reasonably clear, that the patient understands his alternatives, that depression has been excluded, that specific plans be made for post-withdrawal palliative care, and that a second opinion be obtained).

41. See Timothy E. Quill, *Physician-Assisted Death in the United States: Are the Existing “Last Resorts” Enough?*, HASTINGS CENTER REP., Sept.–Oct. 2008, at 17, 19 (“These [life-sustaining] technologies no longer just mean ventilators and feeding tubes; they now include radical technologies such as ventricular-assist devices. But while the array of medical choices faced by patients and families has grown more complex, ethics and law remain clear that patients have a right both to forgo such treatments and to stop them once started.”); see also *id.* at 18 (prefacing this as a “widely accepted and relatively uncontroversial” option); Brad Stuart, Letter, *On Deactivating Cardiovascular Implanted Electronic Devices (CIEDs): Let Our People Go*, 14 J. PALLIATIVE MED. 1089, 1090 (2011) (“[E]ven patients who are completely device dependent, such as those on destination VAD therapy, should not be prohibited

The problem has gotten the most sustained attention from a group at the Mayo Clinic led by Paul Mueller. Dr. Mueller and his associates first published an article in 2003 detailing half a dozen case studies involving requests to deactivate pacemakers or ICDs,⁴² concluding—based in part on a citation to Dr. Quill’s 1994 article—that such cases do not differ from other instances involving the withdrawal of life-sustaining treatments.⁴³ They elaborated on that conclusion somewhat by invoking causation and intent arguments previously used to justify the withdrawal of other forms of life-sustaining care at a patient’s request: “In PAS [physician-assisted suicide] and euthanasia, a new intervention is introduced (e.g., drug), the sole intent of which is the patient’s death. In contrast, when a patient dies after an intervention is refused or withdrawn, the underlying disease is the cause of death.”⁴⁴

from discontinuing it, any more than they currently are from, say, discontinuing a ventilator.”).

42. See Paul S. Mueller et al., *Ethical Analysis of Withdrawal of Pacemaker or Implantable Cardioverter-Defibrillator Support at the End of Life*, 78 MAYO CLINIC PROC. 959, 959–61 (2003) (only one of the six cases involved an ICD).

43. See *id.* at 962 & n.9; see also *id.* at 963 (“Patients have the right to refuse any and all unwanted medical interventions or to request their withdrawal, including pacemakers and ICDs.”). The authors conceded that new technologies might challenge the settled understandings of physicians and ethicists. See *id.* at 962 (“[A]s medical interventions become less invasive and more effective at prolonging life, . . . clinicians will continue to be challenged by ethical dilemmas involving terminally ill patients who have been treated with new technologies.”). They failed to consider, however, any peculiar features of CIEDs that might distinguish them from other life-sustaining treatments.

44. *Id.* at 962; see also *id.* at 963 (“Unlike PAS or euthanasia, which cause death via an externally implemented means, death after the refusal or withdrawal of unwanted interventions is caused by the patient’s underlying disease.”). The U.S. Supreme Court had relied on just these factors in previously drawing such a line. See *infra* notes 138–46 and accompanying text (discussing and critiquing these arguments); see also Lawrence O. Gostin, *Deciding Life and Death in the Courtroom: From Quinlan to Cruzan, Glucksberg, and Vacco—A Brief History and Analysis of Constitutional Protection of the “Right to Die,”* 278 JAMA 1523, 1527 (1997) (explaining that the Court’s “reasons for differentiating between the two practices fly in the face of a body of philosophic literature examining questions of causation and intention in medicine”); Steven D. Smith, *De-Moralized: Glucksberg in the Malaise*, 106 MICH. L. REV. 1571, 1575–79 (2008) (same). Even die-hard opponents of PAS recognize that this distinction cannot rest on grounds of causation and intent. See Yale Kamisar, *The “Right to Die”: On Drawing (and Erasing) Lines*, 35 DUQ. L. REV. 481, 490–93, 519 n.163 (1996) (defending the distinction on other grounds); see also Norman L. Cantor, *On Kamisar, Killing, and the Future of Physician-Assisted Death*, 102 MICH. L. REV. 1793, 1801–04 (2004) (applauding Professor Kamisar’s “intellectual honesty” in this regard).

Five years later, Dr. Mueller and his associates revisited the subject, reporting the results of a survey about the issue conducted among specialists in electrophysiology.⁴⁵ Although finding somewhat greater discomfort among respondents in deactivating pacemakers as compared with ICDs,⁴⁶ the authors emphasized that more than half of those surveyed saw such cases as indistinguishable from requests to withdraw other life-sustaining treatments such as artificial nutrition and hydration, dialysis, and ventilators,⁴⁷ and they largely reiterated their prior arguments defending the practice based on intent and causation.⁴⁸

A couple of years later, the Mayo team published another survey, this time querying a somewhat broader range of medical professionals plus adding legal professionals and patients to the

45. See Paul S. Mueller et al., *Deactivating Implanted Cardiac Devices in Terminally Ill Patients: Practices and Attitudes*, 31 PACING & CLINICAL ELECTROPHYSIOLOGY 560 (2008). Among other things, they “found that requests to deactivate pacemakers and ICDs in terminally ill patients are common.” *Id.* at 566.

46. See *id.* at 567 (“The practices and attitudes associated with pacemaker deactivation differ significantly from those associated with ICD deactivation.”); see also *id.* at 563 (“11.3% of the respondents described pacemaker deactivation in terminally ill patients as euthanasia, and 1.3% of the respondents described ICD deactivation as euthanasia ($P < 0.001$). Similar numbers of respondents described device deactivation as physician-assisted suicide”); *id.* at 564 (“Among the respondents, 63.6% saw an ‘ethical or moral distinction between deactivating a pacemaker and deactivating an ICD’ in terminally ill patients.”); Mueller et al., *supra* note 35, at 257–60 (documenting similar views among industry personnel).

47. See Mueller et al., *supra* note 45, at 566 (“A majority of respondents did not distinguish between device deactivation and withholding or withdrawing other life-sustaining treatments in terminally ill patients.”). Actually, in all but one of these comparisons, fewer than sixty percent of respondents took that position, see *id.* at 564, leaving a substantial minority thinking that CIEDs raise ethically meaningful differences. For generally comparable findings in a survey of non-electrophysiologists, see Daniel B. Kramer et al., *Ethical and Legal Views of Physicians Regarding Deactivation of Cardiac Implantable Electrical Devices: A Quantitative Assessment*, 7 HEART RHYTHM 1537, 1540 (2010) (“Notably, 25% to 49% of physicians considered deactivation of PMs and ICDs to be morally distinct from withdrawal of other life-sustaining therapies, and cessation of these devices was less frequently supported in clinical scenarios involving stable ambulatory patients with terminal illnesses.”); *id.* at 1541 (“Physicians characterized PM and ICD deactivation as physician-assisted suicide substantially more frequently than previously reported.”); Saadia Sherazi et al., *Physicians’ Preferences and Attitudes About End-of-Life Care in Patients with an Implantable Cardioverter-Defibrillator*, 83 MAYO CLINIC PROC. 1139, 1140 (2008) (“Strikingly, nearly half of the physicians who were not cardiologists or electrophysiologists were uncertain about the legality of withdrawing ICD therapy in terminally ill patients.”).

48. See Mueller et al., *supra* note 45, at 566 (conceding, however, that, “if the intent of the [CIED] deactivation is to cause death of the patient, then deactivation could be characterized as euthanasia”).

mix.⁴⁹ Again they found the respondents more comfortable with ICD as opposed to pacemaker deactivation.⁵⁰ Perhaps because Dr. Mueller relinquished lead-author status on this article, however, their analysis of the underlying question showed some hints of equivocation.⁵¹ First, they noted that all of the available case law related to the withdrawal of “external” devices and treatments.⁵²

49. See Suraj Kapa et al., *Perspectives on Withdrawing Pacemaker and Implantable Cardioverter-Defibrillator Therapies at End of Life: Results of a Survey of Medical and Legal Professionals and Patients*, 85 MAYO CLINIC PROC. 981, 982 (2010); *id.* at 987 (“Although several studies have focused on the attitudes of medical professionals regarding management of ICD therapy at the end of life, few have assessed attitudes regarding PMs, only 2 have looked at patient attitudes, and none have examined the attitudes of legal professionals.”). Their idea of taking the pulse of the legal profession was to survey the faculty at five leading law schools! See *id.* at 982 (adding that they also had mailed questionnaires to judges but all declined to participate); *id.* at 989 (recognizing several possible limitations with this aspect of the survey, and conceding that “it is unclear if the sum of their individual opinions may be extrapolated to a more general legal opinion”).

50. See *id.* at 989 (finding “almost one-third of medical professionals perceiv[e] withdrawal of a PM as physician-assisted suicide or euthanasia and only 1% believ[e] the same about an ICD”); *id.* (“[G]reater than one-third of respondents overall thought that withdrawing PM therapy in the PM-dependent patient was akin to physician-assisted suicide or euthanasia.”); *cf. id.* (“Legal professionals, however, tended to see few differences between withdrawal of ICDs and PMs, perhaps reflecting a different vantage point on the withdrawal of life-sustaining therapies. In fact, legal professionals most commonly thought that there was a lack of clarity in whether turning off an ICD or PM was legal.”).

51. See *id.* at 987; *id.* at 989 (“Although existing case law does not specifically focus on ICDs or PMs, extension of case law to these therapies generally supports their withdrawal when the patient requests it.”). In contrast, Dr. Mueller stuck to his original guns in a commentary piece that he solo-authored that same year. See Paul S. Mueller, Editorial, *Clinicians’ Views Regarding Deactivation of Cardiovascular Implantable Electronic Devices in Seriously Ill Patients*, 7 HEART RHYTHM 1543, 1544 (2010) (emphasizing that “no treatment, including a CIED therapy, has unique moral status, i.e., must be continued once started”).

52. See Kapa et al., *supra* note 49, at 981 (“[D]ecisions on many externally provided life-sustaining therapies, including feeding tubes, mechanical ventilation, cardiopulmonary resuscitation in the event of cardiac arrest, and the administration of . . . external pacing, have typically favored the right of the patient or the surrogate decision maker to refuse and withdraw therapy.”). They noted other differences as well:

[M]ost legal cases have focused on withdrawal of life-sustaining therapies that are often more proximate to the end-of-life event (eg, intubation and mechanical ventilation, feeding tubes, and intravenous hydration) or visibly invasive (eg, hemodialysis). Cardiac device therapies, such as ICDs and PMs, are unique in that they dwell within the patient’s body and, except in the case of an ICD shock, are often imperceptible to the patient.

Id. at 987; see also *id.* at 981 (“[T]o our knowledge, no legal cases have focused on the legality of [implanted cardiac] device withdrawal.”).

Second, the authors conceded that certain patients cannot survive without their CIEDs.⁵³ After repeating their previously made points about causation and intent,⁵⁴ the authors focused on the “artificial” nature of CIEDs to buttress their sense that physicians who deactivated these devices upon a patient’s request had acted ethically.⁵⁵

B. *Looking Beyond Simplistic Parallels*

Daniel Sulmasy offered a more nuanced treatment of ICD deactivation.⁵⁶ At the outset, he suggested that the existing ethical defenses may have too quickly dismissed as unfounded the discomfort registered by clinicians and patients when queried about the matter, noting a “discrepancy between ethical analysis and clinical reality.”⁵⁷ Indeed, Dr. Sulmasy wondered whether “there may be more going on here from a moral point of view than the ethics of the 1970s can handle,”⁵⁸ echoing a theme sounded by

53. *See id.* at 988 (discussing pacemaker-dependent patients).

54. *See id.* at 987; *see also id.* at 988 (“[E]stablished case law holds that patients have the right to refuse or request the withdrawal of any treatment and has repeatedly held that no single treatment holds unique moral status, although no single case has focused specifically on management of ICDs and PMs at the end of life.”).

55. *See id.* at 988 (“[I]t is an artificial therapy that a patient can refuse or request the withdrawal of, just as a patient can refuse or request the withdrawal of mechanical ventilation.”). The authors used the term “artificial” five times on this single page without explaining why this made all the difference. *See id.*

56. *See* Daniel P. Sulmasy, *Within You/Without You: Biotechnology, Ontology, and Ethics*, 23 J. GEN. INTERNAL MED. (Supp. 1) 69 (2008).

57. *Id.* (“Several previously published ethical analyses . . . have declared such misgivings to be misguided and have proceeded to analyze the discontinuation of ICD treatment using standard bioethical categories such as patients’ rights, refusal of unwanted therapy, autonomy, futility, and non-maleficence.”); *see also id.* (“[I]ssues long thought settled intellectually by ethicists, such as the difference between withholding and withdrawing life-sustaining treatments, still present lingering doubts for patients and practitioners.”); *id.* at 70 (“[W]hat seems equivalent according to the logic of ethics continues to feel psychologically different to both patients and practitioners.”). For instance, a small study of patient attitudes published alongside Sulmasy’s commentary had concluded that “ICDs are fundamentally different from other interventions that patients might receive at the end of life.” Goldstein et al., *supra* note 33, at 11 (“[P]atients appear to develop a complex psychological relationship with their ICD in a way unlike other interventions. The devices provide a sense of security (‘like an insurance policy’ or like a trusted friend) and the very notion of removing them is ‘like an act of suicide.’”); *id.* (“Participants seem to have developed a symbiotic relationship with the device. If the ICD is seen as a friend, then it is difficult for a patient to believe that the device could actually do them any harm.”).

58. Sulmasy, *supra* note 56, at 69 (“As technology progresses, ethics must keep

his colleague Lynn Jansen a couple of years earlier.⁵⁹ Jansen had proposed that one look at a device's location,⁶⁰ duration of use,⁶¹ and functional role,⁶² but she hastened to add that such a framework would not invariably answer the core question of whether a treatment had become so much a part of a patient that a

pace."); *id.* at 69–70 ("As biotechnological progress marches forward, new interventions are challenging our notions about the difference between killing and allowing to die. . . . [D]o new technologies, such as ICDs, require that the line between killing and allowing to die be redrawn?"); *id.* at 72 ("It is critically important . . . that we begin thinking seriously and carefully about what makes an intervention a part of the patient The rapid pace of technological progress assures us that these sorts of questions will continue to surface in clinical practice.").

59. See Lynn A. Jansen, *Hastening Death and the Boundaries of the Self*, 20 *BIOETHICS* 105 (2006).

With the advent of newer and better life-sustaining devices, some of which will be indwelling and some of which will consist of human tissue, we can expect greater uncertainty over the boundaries of the self in the future. To grapple with the moral issues raised by this uncertainty, we will either need to revise our moral principles or learn to live with the unsettling possibility that they provide no guidance in these cases.

Id. at 111; see also *id.* at 105 ("[I]n end-of-life contexts, when patients are receiving 'artificial' life-support, judgments about where the person or self begins and where he or she ends can become controversial. This can give rise to considerable uncertainty over whether a relevant moral principle applies or not.").

60. See *id.* at 109 ("The fact that an object is under one's skin does not settle the matter of whether it is a part of one's self, but it is relevant to such a determination. . . . [W]e are inclined to view objects that are within our bodies as part of us."). Initially, however, she largely had dismissed this factor as a critical line of demarcation. See *id.* at 106 ("Whether an artificial life-sustaining device is internal or external to the body does not change the fact that it is an artificial life-sustaining device."); *id.* at 108–09 ("[T]he self cannot be defined by spatial boundaries. Our selves are not identical with all that exists under our skins. Some indwelling devices or growths are not part of us.").

61. See *id.* at 109–10 ("The amount of time an object has existed within one's body is relevant to determining whether it is a part of one's self. . . . If the pacemaker had been implanted only days or weeks before the illness, then the case for considering it to be a part of the patient's self would be considerably weaker."). It might make more sense to view this factor as a question about relative permanence, no matter how much time may have elapsed in any particular case.

62. See *id.* at 110. Jansen offered the following illustration to clarify what she meant by the third factor:

If a child swallows a metal penny, and the penny stays inside him his entire life, we would not be inclined to view the penny as part of this person's adult self. But if the metal object is . . . a mechanical heart valve that functions to keep his heart pumping properly, then we will be much more inclined to view it as part of the self.

Id.; see also *id.* at 107–08 (making a similar point about tumors).

physician could not withdraw it.⁶³ Dr. Sulmasy considered—and largely rejected—each of these factors in turn before offering his own (though not altogether dissimilar) test.

Sulmasy started by elaborating on a purported distinction between “regulative” therapies (namely, those that “coax the body back toward its own homeostatic equilibrium,” such as ICDs) and “constitutive” therapies (namely, those that “take over a function that the body can no longer provide for itself,” such as pacemakers).⁶⁴ Although conceding that discontinuation would “raise more questions” in connection with constitutive rather than regulative therapies,⁶⁵ ultimately he concluded that it should make no ethical difference.⁶⁶

Next, Sulmasy wondered about an internal/external distinction: “Does the fact that many new medical technologies are inside the body mean that they have thereby become part of the person so that deactivating an ICD or a pacemaker becomes morally equivalent to discontinuing the function of a natural heart by injecting [potassium chloride]?”⁶⁷ He recognized that, under

63. See *id.* at 110 (“Factors such as spatial location, temporal duration and functional role, then, are relevant to the identification of the boundaries of the self. . . . But these factors do not settle the matter in all cases.”). Indeed, Jansen focused on pacemakers (rather than ICDs) and tentatively concluded (somewhat surprisingly given her framework, especially after also critiquing the common reliance on causation arguments) that it would not amount to active killing. See *id.* at 106–07, 108, 110–11. A different set of authors who focused on ICDs offered an intermediate position: such devices become sufficiently “integral” so that a physician could not unilaterally deactivate them on grounds of futility, but they are not so integral that a physician would have to decline a patient (or surrogate) request for deactivation. See Ruth England et al., *The Ethical and Legal Implications of Deactivating an Implantable Cardioverter-Defibrillator in a Patient with Terminal Cancer*, 33 J. MED. ETHICS 538, 539–40 (2007); see also *infra* note 170 (discussing futility).

64. See Sulmasy, *supra* note 56, at 70; *id.* at 71 (“An ICD is regulative. It does not supply the heart rhythm. Rather, it shocks an abnormal cardiac rhythm back into normal sinus rhythm.”).

65. *Id.* at 70 (“Mimicking physiology, doing what the body no longer can do for itself, seems closer to being ‘a part of the patient’ than does a therapy that nudges the body into healing itself.”).

66. See *id.* (“[W]e still regularly accept the morality of discontinuing constitutive therapies such as ventilatory support. The fact that a treatment is constitutive does not seem to mark a moral difference between killing and allowing to die.”). He also dismissed duration-of-use as morally irrelevant. See *id.* (noting that a request to withdraw ventilator support actually may deserve more serious consideration the longer that the patient has used it).

67. See *id.* Others have noted perceptual differences that result. See Goldstein et al., *supra* note 34, at 5 (“Both hemodialysis and ventilator support also require large machinery, which creates a physical reminder that advanced technologies

conventional approaches, “deactivating an external pacemaker is morally equivalent to deactivating an internal pacemaker, and deactivating an external defibrillator is morally equivalent to discontinuing an ICD.”⁶⁸ Even though he conceded that a heart transplant patient would have no right to demand withdrawal of that treatment, Sulmasy rejected the internal/external divide on the strength of little more than a straw man argument.⁶⁹

Having largely dismissed the factors emphasized by Professor Jansen,⁷⁰ Dr. Sulmasy instead tentatively suggested that only a subset of what he had called “constitutive” therapies might become sufficiently integral to a patient that their withdrawal would amount to physician aid in dying: treatments that fully “replace” (as opposed to simply “substitute” for) a diseased function.⁷¹

are being used to sustain life. . . . Because the ICD is so small and innocuous, its size does not create a daily interference with a patient’s quality of life”); *see also* Cruzan v. Dir., Mo. Dept. of Health, 497 U.S. 261, 288 (1990) (Stevens, J., dissenting) (“Highly invasive treatment may perpetuate human existence through a merger of body and machine that some might reasonably regard as an insult to life rather than as its continuation.”).

68. Sulmasy, *supra* note 56, at 70–71; *see also id.* at 71 (“But is this correct? Does not having a device inside a patient make it a part of the patient, part of her physiology, so that stopping its function is killing?”).

69. *See id.* at 71. Taking “internal” to mean “under the skin” (taking Jansen too literally), he imagined a severe burn victim with a skin graft who demands withdrawal of this “external” life-sustaining treatment. *See id.* (“Most plastic surgeons would refuse to do this on the grounds that they would be mutilating, if not killing, the patient, even if she were otherwise dying from some other comorbid disease.”). Sulmasy contrasted this situation with the following one, where he thought that physicians clearly should honor a request for withdrawal: an implant delivering a hormonal treatment to the site of prostate cancer. *See id.* Although more clearly internal, I fail to see how that qualifies as life-sustaining.

70. *See id.* (“[W]hereas Jansen’s insight is correct—that some treatments must truly be considered within the ontological boundaries of the patient’s ‘self—I do not think the criteria she has suggested fully capture the distinction.”).

71. *See id.* (offering this admittedly imprecise distinction as a “preliminary hypothesis,” and concluding that “the more an intervention can be understood as a replacement therapy, the less it seems morally appropriate to withdraw it”); *id.* at 72 (“Whereas there is no absolute standard for judging whether something is a replacement or a substitute, the more clearly a technology can be classified as a replacement therapy, the greater the case for judging that its discontinuation would constitute an immoral act of killing.”). Under his approach, “regulative” therapies such as ICDs would never cross the line. *See id.* at 71 (“These interventions are distinct from the organism and extrinsic to its function, whether administered inside or outside the body.”); *id.* (“Regulatory therapies, no matter how sophisticated, and whether located inside the body or not, can be thought about just as one would think about withholding or withdrawing more standard forms of therapy at the end of life.”); *id.* at 72 (“[D]eactivating an ICD can be ethically distinguished from killing and considered a part of good palliative

What I mean by a replacement therapy is a technological intervention that participates in the organic unity of the patient as an organism. . . . A replacement therapy is one that has become part of the patient's restored physiology. The most important feature of a replacement therapy is that it provides the function that has been pathologically lost, more or less in the same manner in which the patient was once able to provide this function when healthy.⁷²

As potentially relevant factors, Sulmasy mentioned responsiveness to its surrounding environment, capacity for growth and self-repair, freedom from external power sources and expert control, immunologic compatibility, and physical integration into the body.⁷³ After having subjected Jansen's factors to a pointed rebuttal, however, Sulmasy never provided any account for why one or more of his factors should count in the ethical analysis—for

care.”).

72. *Id.* at 71 (“Thus, for instance, a renal transplant is a replacement therapy, whereas peritoneal dialysis (although it also takes place inside the body) is a substitutive therapy.”). His explanation for the ethical relevance of this distinction strikes me, however, as question-begging:

Replacement therapies become part of the restored physiology of the patient, part of the integrated unity of the patient as an intact individual organism. To discontinue such therapies is better understood as introducing a new lethal pathophysiological state rather than discontinuing a treatment that is merely substituting for a preexisting lethal pathophysiological lack of that function.

Id. at 72.

73. *Id.* at 71–72. He added that “[t]he paradigmatic replacement therapy is thus a well-functioning organ transplant from an identical twin,” *id.* at 72, but that is only because he made immunologic compatibility relevant—why exactly would it raise less serious ethical concerns to discontinue an organ transplanted from an unrelated donor that required more aggressive immunosuppression? Would an artificial version of the same organ get pluses for immunologic compatibility to offset minuses for an inability for growth and self-repair? Although Sulmasy repeatedly emphasizes that he envisions a sliding scale without any “bright line” or indispensable factors, *see id.* at 71–72, he still needs to provide some account for why (and how much) one or more of these factors count in the ethical calculus, *cf. id.* at 72 (“[T]his conclusion will doubtless prove challenging for persons unaccustomed to philosophical thinking.”). Sulmasy closed by offering an extended illustration of the difference he had in mind: a diabetic patient receiving either insulin injections (clearly a “substitution” therapy that could be withdrawn at the end of life) or islet cell transplantation (clearly a “replacement” therapy that could not be destroyed by injecting streptozosin). *See id.* To use a harder case between these two extremes that comes closer to the CIED deactivation question, what about an implanted insulin pump, which in the near future may become fully automated? *See* Natasha Singer, *Insulin Dose More Finely Calculated*, N.Y. TIMES, Feb. 5, 2010, at B1; “Artificial Pancreas” Shows Real Promise, ORLANDO SENTINEL, June 26, 2011, at A6.

instance, why exactly would fully implanted mechanical replacement organs not make the cut (is he relying on a natural/artificial distinction that others have rejected)?⁷⁴ Although he never said so explicitly (and sought mainly to defend ICD deactivation), Sulmasy evidently would exclude pacemakers and LVADs as well.⁷⁵

C. Peculiarities of Pacemakers and LVADs

Requests for pacemaker deactivation appear to pose trickier ethical questions.⁷⁶ First, unlike ICDs that may fire repeatedly in dying patients (adding to their pain and distress),⁷⁷ pacemakers

74. For instance, FDA officials have rejected the natural/artificial distinction in regulating medical devices. See *Ala. Tissue Ctr. v. Sullivan*, 975 F.2d 373, 378 (7th Cir. 1992) (dismissing a challenge to the agency's decision to treat heart valve allografts as devices); see also 21 C.F.R. pt. 1271 (2012) (outlining the FDA's approach to human cells, tissues, and cellular and tissue-based products). For more general flaws with the natural/artificial distinction, see Jansen, *supra* note 59, at 107 (concluding that instead it is "the distinction between what is a component of the self and what is alien or extrinsic to the self"); Robert D. Truog & Thomas I. Cochrane, *Refusal of Hydration and Nutrition: Irrelevance of the "Artificial" vs "Natural" Distinction*, 165 ARCHIVES INTERNAL MED. 2574, 2575–76 (2005).

75. In contrast, one pair of commentators used Sulmasy's framework to argue that pacemaker deactivation in pacemaker-dependent patients would differ from the permissible deactivation of ICDs. See G. Neal Kay & Gregory T. Bittner, *Deactivating Implantable Cardioverter-Defibrillators and Permanent Pacemakers in Patients with Terminal Illness: An Ethical Distinction*, 2 CIRCULATION: ARRHYTHMIA & ELECTROPHYSIOLOGY 336, 338 (2009). But see Richard A. Zellner et al., *Deactivating Permanent Pacemaker in Patients with Terminal Illness: Patient Autonomy Is Paramount*, 2 CIRCULATION: ARRHYTHMIA & ELECTROPHYSIOLOGY 340, 342 (2009) ("Using Sulmasy's criteria, if an ICD is substitutive, with its continuous sensing capacity, so too is a pacemaker. . . . Implanting the device under the skin does not change the nature of the device, only its location. Like pacemakers, [LVADs] are likely to become internalized.").

76. See Ron Shasby et al., *Ethical Issues in the Management of Geriatric Cardiac Patients: A Family Member with Power of Attorney for an 87 Year Old Patient Is Requesting Removal of the Patient's Pacemaker*, 7 AM. J. GERIATRIC CARDIOLOGY 48 (1998); Case Study, *Retiring the Pacemaker*, HASTINGS CENTER REP., Jan.–Feb. 1997, at 24 (focusing on collateral issues); see also Tia P. Powell, *Life Imitates Work*, 305 JAMA 542 (2011) (offering a bioethicist's first-hand account of struggling over whether to consent to the implantation of a pacemaker in her cognitively impaired mother); Katy Butler, *My Father's Broken Heart*, N.Y. TIMES MAG., June 20, 2010, at 38 (offering a personal perspective after a frail parent received a pacemaker).

77. See Nathan E. Goldstein et al., *Management of Implantable Cardioverter Defibrillators in End-of-Life Care*, 141 ANNALS INTERNAL MED. 835, 836 (2004) (finding that more than a quarter of dying patients received ICD shocks during their last month); *id.* at 837 (reporting that "the next of kin found it distressing to witness the patient being shocked at the end of life"); William R. Lewis et al., *Withdrawing Implantable Defibrillator Shock Therapy in Terminally Ill Patients*, 119 AM. J. MED. 892,

generally continue to function unnoticed, maintaining a steady cardiac rhythm. Thus, pacemakers in no way interfere with the dying process apart from possibly prolonging it.⁷⁸ Second, pacemakers are not as easily deactivated as ICDs—health care personnel cannot simply shut them off with a programming device or a strong magnet.⁷⁹ Instead, the programmer must dramatically reduce the pacing rate and voltage.⁸⁰ Third, unlike recipients of ICDs that may never fire (making their deactivation of little practical consequence),⁸¹ some patients become pacemaker-dependent,⁸² leading a few commentators to view deactivation in such cases as amounting to active euthanasia.⁸³ Although these

892–93, 895 (2006); Michelle A. Mullen & Robert M. Gow, *Understanding Ethical Issues, ICD, and DNR Orders: An Obstacle to Imminent Death?*, 7 HEART RHYTHM 858, 859 (2010) (“[R]epeated discharges of the ICD can dramatically exacerbate suffering during the dying process.”).

78. See Jill A. Rhymes et al., *Withdrawing Very Low-Burden Interventions in Chronically Ill Patients*, 283 JAMA 1061, 1062 (2000) (“[T]here is no clinically significant iatrogenic burden in allowing the pacemaker to continue to function.”); see also Beca et al., *supra* note 32, at 237 (“[T]he patient’s agony was extended for more than a week only by the pacemaker’s action. . . . [T]he presence of a [pacemaker] can actually postpone death.”).

79. See Michael Thomas Beets & Edward Forringer, *Urgent Implantable Cardioverter Defibrillator Deactivation by Unconventional Means*, 42 J. PAIN & SYMPTOM MGMT. 941, 945 (2011); Stein, *Devices Can Interfere*, *supra* note 2, at A1 (“Large, specialized doughnut-shaped magnets can disable ICDs in an emergency. And programming devices can permanently deactivate ICDs wirelessly.”).

80. See Ted C. Braun et al., *Cardiac Pacemakers and Implantable Defibrillators in Terminal Care*, 18 J. PAIN & SYMPTOM MGMT. 126, 127 (1999); Wilkoff et al., *supra* note 8, at 919–20. Conversely, ICDs need not get shut off completely. See James E. Russo, *Deactivation of ICDs at the End of Life: A Systematic Review of Clinical Practices and Provider and Patient Attitudes*, AM. J. NURSING, Oct. 2011, at 26, 33 (noting that intermediate options exist for reprogramming ICDs, “such as lengthening the detection interval, limiting the number of shocks, or deactivating the shock function while retaining antitachycardia pacing”).

81. See Goldstein et al., *supra* note 34, at 5 (“The interval between ICD deactivation and patient death may be much longer [than happens upon the withdrawal of hemodialysis or ventilators] given the unpredictable nature of malignant arrhythmias.”); see also Sulmasy, *supra* note 56, at 70 (“[T]he very fact that it functions only intermittently might make it psychologically easier to deactivate an ICD than to deactivate the pacemaker of a patient with complete heart block.”).

82. See Classification of Implantable Pacemaker Pulse Generators, 44 Fed. Reg. 13,373, 13,373 (proposed Mar. 9, 1979) (to be codified at 21 C.F.R. pt. 870) (noting that “patients may be totally dependent upon this device for their continued survival”); Panagiotis Korantzopoulos et al., *Pacemaker Dependency After Implantation of Electrophysiological Devices*, 11 EUROPACE 1151, 1154 (2009) (“Pacemaker dependency is observed in an appreciable number of paced patients after implantation . . .”).

83. See Basta, *supra* note 32, at 116 (An ICD may be inactivated at the end-of-

features explain why some clinicians hesitate when pacemaker patients request device withdrawal, most ethicists view these differences as inconsequential and would allow for pacemaker deactivation on the same grounds as ICD deactivation.⁸⁴

Only rarely have ethicists given LVADs more than passing attention. As Dr. Quill had done before him,⁸⁵ Dr. Mueller extended his defense of ICD deactivation to such implanted heart pumps.⁸⁶ In 2008, a brief case study published in the *Hastings Center Report*—a prominent bioethics journal—provided the competing views of Jeremy Simon and Ruth Fischbach.⁸⁷ Dr. Simon thought it

life because it “may interfere with the natural process of dying peacefully. However, this is not true with a pacemaker, since it is considered to have become an integral part of the heart. Therefore, changing pacemaker parameters to hasten the patient’s death is a form of euthanasia”); Lofty L. Basta, *Ethical Issues in the Management of Geriatric Cardiac Patients: A Patient Asks to Put an End to the Nightmare of Living with a Lifesaving AICD*, 11 AM. J. GERIATRIC CARDIOLOGY 326, 327 (2002) (“In a pacemaker-dependent patient, disabling or removing the pacemaker represents an active intervention, the intent of which is to cause death.”); Lofty L. Basta, Reply to Letter to the Editor, *When Is Deactivation of Artificial Pacing and AICD Illegal, Immoral, and Unethical?*, 12 AM. J. GERIATRIC CARDIOLOGY 275, 275–76 (2003) (elaborating); Kay & Bittner, *supra* note 75, at 338.

84. See Ballentine, *supra* note 32, at 18; Beca et al., *supra* note 32, at 239 (“If the [pacemaker] sustains the patient’s life by means of an artificial cardiac rhythm, its deactivation should be considered just a way to avoid therapeutic obstinacy, not a way to cause death.”); Berger, *supra* note 39, at 631 (“[T]he ethical considerations in decisions to deactivate ICDs may similarly apply to . . . pacemakers.”); Kapa et al., *supra* note 49, at 988; Rachel Lampert & David Hayes, Letter, *Pacemakers and End-of-Life Decisions*, 305 JAMA 1858 (2011); Mueller et al., *supra* note 45, at 566; Edmund D. Pellegrino, *Decisions to Withdraw Life-Sustaining Treatment: A Moral Algorithm*, 283 JAMA 1065, 1067 (2000); Rhymes et al., *supra* note 78, at 1063 (“[D]eactivating this patient’s pacemaker is not killing in the sense of introducing a new pathology that causes death.”); Jeffrey Spike, Commentary, *Retiring the Pacemaker*, HASTINGS CENTER REP., Jan.–Feb. 1997, at 25, 26 (“[A] pacemaker is more like an implantable defibrillator than any other medical device, and turning that off should be as acceptable as signing a DNR [Do Not Resuscitate] (or a DNAR, Do Not Attempt Resuscitation) order since they are functionally and ethically isomorphic.”); Sandra N. Whitlock et al., *Is Pacemaker Deactivation at the End of Life Unique?: A Case Study and Ethical Analysis*, 14 J. PALLIATIVE MED. 1184, 1185–87 (2011); Wiegand & Kalowes, *supra* note 39, at 421–22; Zellner et al., *supra* note 75, at 341–43.

85. See *supra* note 41 and accompanying text.

86. See Paul S. Mueller et al., *Ethical Analysis of Withdrawing Ventricular Assist Device Support*, 85 MAYO CLINIC PROC. 791, 795–97 (2010) (discussing causation, intent, and similarity to withdrawal of ventilators). Unlike Quill, these authors had reviewed several case studies in detail, and they did recognize that LVADs appeared to raise some special concerns before dismissing these as ethically irrelevant. See *id.* at 794–95.

87. Case Study, “Doctor, Will You Turn off My LVAD?,” HASTINGS CENTER REP., Jan.–Feb. 2008, at 14 (including commentaries by Jeremy Simon and Ruth

“tantamount to removing the patient’s heart.”⁸⁸ Although cognizant of the limitations in drawing this parallel,⁸⁹ he focused on the functional similarities between such a mechanical implant and a transplanted organ insofar as both become “integrated” in patients so that they then can function independently.⁹⁰ Professor Fischbach dismissed Dr. Simon’s effort to equate LVADs with transplanted organs,⁹¹ emphasizing instead the device’s similarities

Fischbach, both of whom now serve on the medical school faculty at Columbia University). Five years earlier, a similar exchange (though focused on TAHs rather than LVADs) had appeared in the pages of the wonderfully obscure journal *Death Studies*. Compare Robert M. Veatch, *Inactivating a Total Artificial Heart: Special Moral Problems*, 27 DEATH STUD. 305, 307–10 (2003) (expressing some reservations), with Katrina A. Bramstedt, *Replying to Veatch’s Concerns: Special Moral Problems with Total Artificial Heart Inactivation*, 27 DEATH STUD. 317, 318–19 (2003) (defending deactivation), and Katrina A. Bramstedt, *Elective Inactivation of Total Artificial Heart Technology in Non-Futile Situations: Inpatients, Outpatients and Research Participants*, 28 DEATH STUD. 423, 427–29 (2004) (same).

88. Jeremy R. Simon, Commentary, “*Doctor, Will You Turn off My LVAD?*,” HASTINGS CENTER REP., Jan.–Feb. 2008, at 14, 15; *see also id.* at 14 (“We would not remove a patient’s biological heart, transplanted or native, simply because the patient was suffering greatly from heart failure and did not want to go on; nor should we disable his LVAD.”).

89. *See id.* at 14 (“Although LVADs are neither fully implantable nor a full replacement for a heart, they share many ethically relevant features with true artificial organs.”). The hypothetical case had stipulated that “many of the device’s controls, as well as its power source (a rechargeable battery), are outside the patient and connected to the pump by tubes and wires that pass through the patient’s abdominal wall.” *Id.* These differences added to Dr. Simon’s misgivings insofar as they meant that an ambulatory patient could have disconnected the device himself—and the patient’s evident discomfort with doing so suggested that he viewed deactivation as suicide. *See id.* at 15 (“The fact that the patient does not want to take action on his own, however, does not authorize others to hasten his death for him.”); *id.* (adding that the physician who declines to assist should “perhaps make it clear to [the patient] that he has the means to do so himself”). This aspect of the hypothetical would, of course, fall away if the patient could not act on his own or in the case of a fully implantable device.

90. *Id.* at 14 (“The fact that the LVAD is manufactured and partially external is less important than the fact that it forms an integrated part of an independently functioning organism.”); *see also id.* (“Once the patient leaves the hospital, the LVAD ceases to be a medical treatment and becomes effectively part of the patient himself, much like a transplanted organ or even a native one.”); *id.* (calling the LVAD cases a “harbinger . . . of a much larger group [of patients] we will undoubtedly soon encounter—those who have implanted artificial organs essential to their survival”).

91. *See* Ruth L. Fischbach, Commentary, “*Doctor, Will You Turn off My LVAD?*,” HASTINGS CENTER REP., Jan.–Feb. 2008, at 15, 15 (“After an organ is implanted, it becomes part of the patient and its functioning is relatively independent. However, an LVAD is not itself a vital organ and requires external power, anticoagulation therapy, and consistent maintenance.”). This entirely disregards the necessity for chronic use of antirejection drugs after organ transplantation. *See*

to other forms of external life-sustaining treatments that physicians may withdraw under appropriate circumstances,⁹² and she added that its deactivation simply would allow a patient to die of natural causes.⁹³

D. *Reaching a Consensus of Sorts*

Objections to the prevailing view appear only rarely in the literature.⁹⁴ Recently, a pair of commentators took the position that, unless a patient faces imminent death from an unrelated cause (e.g., massive stroke or multiple organ failure), CIED deactivation qualifies as the cause of the patient's demise and amounts to an unnatural (and, hence, impermissibly physician-aided) death.⁹⁵

Alex Gutierrez-Dalmau & Josep M. Campistol, *Immunosuppressive Therapy and Malignancy in Organ Transplant Recipients: A Systematic Review*, 67 *DRUGS* 1167 (2007).

92. See Fischbach, *supra* note 91, at 15 (“[T]he device is similar to other forms of advanced life support, such as ventilators, which are routinely discontinued in accordance with patients’ wishes in terminal extubation.”); *id.* (“Since the functioning of an LVAD depends on external power sources and pharmaceutical maintenance, removing those externalities is akin to the passive euthanasia that physicians already perform.”).

93. See *id.* (“If the LVAD is disabled, death will occur due to heart failure, not medical intervention—a consolation to one who opposes suicide.”); see also Stein, *Heart Pump*, *supra* note 2, at A1 (quoting Timothy W. Kirk, a bioethicist at Villanova University: “It is not assisted suicide or euthanasia [to deactivate an LVAD], because what’s killing them is the underlying disease.”). But see *id.* (quoting James Kirkpatrick, a cardiologist and ethicist at the University of Pennsylvania: “This is unlike anything else we deactivate. . . . When you turn off an LVAD, it can make the person worse. You can basically worsen the heart function. So you’re not just stopping something and letting nature take its course.”); Katrina A. Bramstedt & Neil S. Wenger, *When Withdrawal of Life-Sustaining Care Does More Than Allow Death to Take Its Course: The Dilemma of Left Ventricular Assist Devices*, 20 *J. HEART & LUNG TRANSPLANTATION* 544, 545–46 (2001) (noting the possibilities of back flow, pooling, and regurgitant flow of blood as well as disruption of the heart’s contractility after deactivation); *id.* at 546 (“[L]eaving an implanted and yet unpowered LVAD in place actually impedes natural heart function.”).

94. As mentioned previously, a distinct minority of commentators view device deactivation in pacemaker-dependent patients as active euthanasia. See *supra* notes 83–84 and accompanying text.

95. See Mohamed Y. Rady & Joseph L. Verheijde, Letter, *When Is Deactivating an Implanted Cardiac Device Physician-Assisted Death? Appraisal of the Lethal Pathophysiology and Mode of Death*, 14 *J. PALLIATIVE MED.* 1086, 1086–87 (2011). Critically, they did not view the underlying cardiovascular disease that necessitated CIED treatment as life-threatening insofar as patients view the “implanted devices as a permanent cure of their preexisting disease.” *Id.* at 1086; see also *id.* (“[D]eactivating [CIEDs] in device-dependent patients sets off a lethal

For example, a pacemaker-dependent patient wishing to end his life asks his physician to assist with premedication and pacemaker deactivation for a rapid death. The lethal pathophysiology is electric asystole and circulatory arrest brought about by pacemaker deactivation. . . . However, deactivating the pacemaker in a similar patient after an acute brainstem infarction sustaining a lethal pathophysiology from apnea and pulselessness is not assisted death but natural death.⁹⁶

Their causation-focused analysis arguably proves too much, however, insofar as it seemingly also would bar withdrawing treatment from ventilator-dependent patients.⁹⁷ Then again, perhaps it just demonstrates that this oft-invoked line of demarcation lacks coherence.⁹⁸

After fifteen years of debate in the medical literature, the views of those defending the ethics of CIED deactivation secured official endorsement in 2010. The Heart Rhythm Society (HRS), along with half a dozen other professional groups (including the American College of Cardiology and the American Heart Association), produced a “consensus statement” covering the subject, with several of the individuals who previously had penned defenses of deactivation listed as co-authors.⁹⁹ The report

pathophysiology of its own causing death even in the absence of life-threatening illness. . . . Having precise control over time, place, and method or mode of death qualifies it as assisting death.”).

96. *Id.* at 1087; *see also id.* (“In the absence of life-threatening illness, deactivating [CIEDs] that replace native cardiac function interrupts normal circulation and constitutes the new lethal pathophysiology (mode of death) in a device-dependent patient.”). For a harsh response, *see* Stuart, *supra* note 41, at 1089–90 (critiquing their position as almost heretical).

97. *See infra* notes 110–23 and accompanying text (discussing judicial analysis of such a case); *see also* Lawrence J. Schneiderman & Roger G. Spragg, *Ethical Decisions in Discontinuing Mechanical Ventilation*, 318 *NEW ENG. J. MED.* 984, 988 (1988). Indeed, this same pair of commentators previously had co-authored with others a paper about LVADs that treated deactivation as largely unremarkable. *See* Aaron G. Rizzieri et al., *Ethical Challenges with the Left Ventricular Assist Device as a Destination Therapy*, 3 *PHIL. ETHICS & HUMAN. MED.* no. 20, at 10–12 (2008).

98. *See* David Orentlicher, *The Legalization of Physician Assisted Suicide: A Very Modest Revolution*, 38 *B.C. L. REV.* 443, 446–62 (1997) (finding no meaningful differences between treatment withdrawals and assisted suicide). For instance, Professor Orentlicher explained that “patients who die when treatment is withdrawn also die an unnatural death,” and he offered the following illustration (without, however, any further elaboration): “[W]hen a person has had an artificial heart valve or a cardiac pacemaker implanted, the patient is now at a new baseline in terms of her physical condition.” *Id.* at 449.

99. *See* Rachel Lampert et al., *HRS Expert Consensus Statement on the*

emphasized the importance of improving dialogue about the question between physicians and their patients.¹⁰⁰ Viewing the matter as no different than requests to withdraw other forms of life-sustaining treatment,¹⁰¹ buttressed by the previously described points about causation and intent,¹⁰² the HRS consensus statement concluded as follows: “Deactivation of a CIED, whether a pacemaker, ICD or other device is not assisted suicide or euthanasia and is ethically and legally permissible.”¹⁰³ In spite of the mildly remarkable confidence expressed in the report,¹⁰⁴ an

Management of Cardiovascular Implantable Electronic Devices (CIEDs) in Patients Nearing End of Life or Requesting Withdrawal of Therapy, 7 HEART RHYTHM 1008 (2010); *id.* at 1009 (“Agreement [among members of the expert panel] was greater than 90% on all recommendations.”); *see also* Luigi Padeletti et al., *EHRA Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices in Patients Nearing End of Life or Requesting Withdrawal of Therapy*, 12 EUROPACE 1480 (2010) (offering similar guidance from the European counterpart of HRS). For a critical assessment of such consensus efforts, *see* Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 420–21 & n.204, 428–29 n.241 (2002).

100. *See* Lampert et al., *supra* note 99, at 1013, 1015–19; *see also* Goldstein, *supra* note 77, at 837 (“[W]e found that clinicians rarely discuss deactivating ICDs with patients, even those patients who are perceived to be near death or those who had previously expressed a desire to limit life-prolonging therapy.”); *id.* (“Conversations about deactivation, as well as the actual turning off of the device, occurred not as decisions planned well in advance of the patient’s death but as reactions to distress in the days, hours, or minutes before the patient died.”). The HRS report also outlined some of the logistics involved in the process of CIED deactivation. *See* Lampert et al., *supra* note 99, at 1019–22.

101. *See* Lampert et al., *supra* note 99, at 1009 (“The right to refuse or request the withdrawal of a treatment is a personal right of the patient and does not depend on the characteristics of the particular treatment involved (i.e., CIEDs). Therefore, no treatment, including CIED therapies, has unique ethical or legal status.”); *id.* at 1011 (“[T]here is no ethical or legal distinction between a treatment that’s integrated within the body, versus one which is outside the body.”).

102. *See id.* at 1009, 1011.

103. *Id.* at 1014. Although framed broadly enough to cover LVADs, the report never once mentioned these devices, except as a possible alternative treatment to pacemakers or ICDs. *See id.* at 1017 (“Patients with worsening congestive heart failure may be candidates for advanced therapies such as left ventricular assist devices or cardiac transplantation.”). Two years earlier, a consensus statement co-sponsored by HRS that focused on the monitoring of CIEDs had included a definition not covering LVADs. *See* Wilkoff et al., *supra* note 8, at 908; *see also id.* at 919–21 (previewing the ethical issues associated with CIED deactivation); Andrew E. Epstein et al., *ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities*, 117 CIRCULATION e350, e388–89 (2008) (same).

104. *See* Lampert et al., *supra* note 99, at 1011 (“[T]he legal precedents and ethical principles are *unambiguous*—a patient has the right to refuse and request the withdrawal of CIED therapies regardless of whether s/he is terminally ill or

ethical consensus in favor of the practice informs but ultimately cannot settle questions about its legality.¹⁰⁵

IV. STRADDLING CONSTITUTIONAL AND STATUTORY LINES

For more than a quarter of a century, judges, legislators, and commentators have given end-of-life legal questions plenty of attention, but they have had essentially nothing to say about the deactivation of implanted cardiac-assist devices. After summarizing the United States Supreme Court's general guidance, which for the most part has left the matter to state legislation, I suggest some ways of addressing this unique problem.

not, and regardless of whether . . . death would follow as a consequence of a decision not to use them." (emphasis added)); *id.* at 1010 ("[E]ven though the Supreme Court has not specifically commented on the question of PM or ICD deactivation, because CIEDs deliver life-sustaining therapies, discontinuation of these therapies is *clearly* addressed by the above Supreme Court precedents upholding the right to discontinue life-sustaining treatment." (emphasis added)); *see also id.* at 1009 ("Because ethics and law are closely aligned, they are considered together in this section."). Subsequent commentators thereupon viewed the matter as settled, treating physicians or patients who expressed qualms about CIED deactivation as misguided. *See* Kramer et al., *supra* note 47, at 1539 ("Deficiencies in physicians' legal knowledge were more pronounced for questions related to cardiac devices."); *id.* at 1540–41 (citing the HRS guidelines for the proposition that "there is no meaningful distinction in the law or among ethicists regarding different life-sustaining therapies, such as mechanical ventilation, feeding tubes, dialysis, and cardiac devices"); Kramer et al., *supra* note 33, at 1073 ("Widespread uncertainty was found [among patients] regarding the legal status of CIED deactivation . . ."); *id.* at 1074 (citing, among other sources, the HRS guidelines for the proposition that "neither PM-dependence nor a patient's prognosis influence the legality of device deactivation").

105. *See* Kapa et al., *supra* note 49, at 987 ("The withdrawal of ICD therapy at the end of life . . . is generally thought to be ethically permissible. However, the legality of this is not as clear, in part due to the lack of court cases focusing specifically on withdrawal of implantable cardiac device therapy." (endnotes omitted)); *see also* Alan Meisel, *The Legal Consensus About Forgoing Life-Sustaining Treatment: Its Status and Its Prospects*, 2 KENNEDY INST. ETHICS J. 309, 314 (1992) ("[T]he law has been substantially influenced by the changing attitudes in clinical practice. Clinical practice exists in an iterative relationship with the law, and vice-versa."). For a scathing critique of legal interpretation undertaken by medical ethicists in a different context, see Lars Noah, *Coerced Participation in Clinical Trials: Conscripting Human Research Subjects*, 62 ADMIN. L. REV. 329, 330, 342–66 (2010); *id.* at 355 ("[A]s an exercise in legal analysis, their defense of the CSP policy comes across as entirely amateurish."). Conversely, future judicial (or legislative) endorsement of CIED deactivation would hardly resolve any lingering ethical uncertainties about the practice. *See* Jansen, *supra* note 59, at 111.

A. *Tentative Judicial Guideposts*

In 1990, the Supreme Court decided *Cruzan v. Director, Missouri Department of Health*.¹⁰⁶ The petitioner had sustained permanent brain damage that left her in a persistent vegetative state, and her parents went to court seeking permission to withdraw the gastrostomy tube that supplied life-sustaining nutrition and hydration.¹⁰⁷ The high Court framed the question very narrowly, asking only whether the state could constitutionally require a surrogate decisionmaker to present “clear and convincing evidence” of Ms. Cruzan’s wishes in order to permit the withdrawal of treatment, and it concluded that this standard did not impermissibly infringe on the petitioner’s Fourteenth Amendment liberty interests.¹⁰⁸ The Court had assumed for the sake of argument that patients enjoyed a constitutional right to refuse unwanted medical treatment.¹⁰⁹

Just six months after the decision in *Cruzan*, the Nevada Supreme Court issued its opinion in *McKay v. Bergstedt*.¹¹⁰ A ventilator-dependent quadriplegic had sought a judicial decree to facilitate his desire to remove the respirator.¹¹¹ The trial judge ruled in the petitioner’s favor,¹¹² and, while an appeal to the state’s highest court was pending, Kenneth Bergstedt died after his father disconnected the tracheostomy tube.¹¹³ Even though Kenneth’s demise rendered the case moot,¹¹⁴ the Nevada Supreme Court issued a lengthy opinion affirming the trial judge’s order.

The majority in *McKay* accepted the district court’s findings

106. 497 U.S. 261 (1990).

107. *See id.* at 266–68.

108. *See id.* at 280–87.

109. *See id.* at 279 (“[F]or purposes of this case, we assume that the United States Constitution would grant a competent person a constitutionally protected right to refuse lifesaving hydration and nutrition.”); *id.* at 287–89 (O’Connor, J., concurring).

110. 801 P.2d 617 (Nev. 1990).

111. *See id.* at 620 (Petitioner sought “an order permitting the removal of his respirator by one who could also administer a sedative and thereby relieve the pain that would otherwise precede his demise. [He] also sought an order of immunity from civil or criminal liability for anyone providing the requested assistance.”).

112. *Judge OKs Quadriplegic’s Plea to Die*, L.A. TIMES, June 9, 1990, at A29.

113. *Man in Court Case on Suicide Dies*, N.Y. TIMES, Oct. 6, 1990, at A6. Kenneth’s father died one week later of lung cancer. *Man Dies After Son Fulfilled Wish to End Life Before Him*, L.A. TIMES, Oct. 12, 1990, at A29.

114. *See McKay*, 801 P.2d at 619–20 (adding that the Attorney General had made only a “token” effort on appeal).

that Kenneth was mentally competent and conceded that, while his near total paralysis was irreversible, he did not have any terminal illness—after suffering a childhood swimming accident, Kenneth had already lived more than two decades by virtue of the respirator and could expect to do so for several more decades.¹¹⁵ Given the impending death of his terminally ill father, who had served as sole caretaker during much of this time, Kenneth feared the prospect of long-term institutionalization and asked that medical personnel disconnect his ventilator and administer sedatives to blunt the sensation of resulting suffocation.¹¹⁶ The majority held that Kenneth enjoyed common law and constitutional rights to decline further treatment.¹¹⁷ It then carefully examined the state’s possible countervailing interests—in preserving life, preventing suicide, protecting third parties, preserving the integrity of the medical profession, and encouraging the charitable and humane care of persons with disabilities—before concluding that these did not outweigh Kenneth’s rights.¹¹⁸

After complaining about the majority’s decision to issue what amounted to an advisory opinion in a case that the state had never actively opposed in any event,¹¹⁹ the dissenting judge in *McKay* disagreed with his colleagues’ characterization of the situation:

[A]fter twenty-three years of living and breathing in this machine-aided manner, the whole process becomes something quite more than mere medical *treatment*. The mechanical breather becomes a new way of life for its user, and life cannot go on without it. Mr. Bergstedt lived at home. The “treatment” in any real sense is over; and just as *heart pace-makers*, artificial venous or arterial shunts,

115. See *id.* at 620.

116. See *id.* at 620, 624–25; cf. Peter Applebome, *Judge Rules Quadriplegic Can Be Allowed to End Life*, N.Y. TIMES, Sept. 7, 1989, at A16 (discussing a similar case from Georgia: “In a unique approach, [Larry] McAfee, a former civil engineer, helped a friend design a timing device he can activate with his mouth that would allow him to shut off his ventilator on his own.”); *id.* (“[H]e needed someone to administer a sedative so he could die quietly and not experience the terrifying, suffocating feeling that occurred when he briefly dislodged his ventilator.”).

117. See *McKay*, 801 P.2d at 621–22.

118. See *id.* at 622–28, 631–32; see also *id.* at 629–31 (recommending a more expeditious procedure for considering such petitions). In its discussion of the state’s interest in preserving the integrity of the medical profession, see *id.* at 627–28, the majority failed to consider the possibility that patient requests for medical assistance in discontinuing life-sustaining care might raise more serious problems than initial patient refusals of such care.

119. See *id.* at 632–33 (Springer, J., dissenting).

a variety of prosthetic devices and other such medically sponsored and introduced artifacts may *begin* as a medical treatment modality, the ventilator begins as a form of medical treatment but ends up as an integral part of its dependent user.¹²⁰

In effect, technological advances had turned previously fatal injuries and conditions into manageable medical problems, offering increasingly mundane (neither heroic nor extraordinary) interventions.¹²¹ The dissent also emphasized that disconnection of the ventilator would immediately and proximately cause the petitioner's death, making his request more akin to seeking assistance in committing suicide, rather than that of a terminally ill patient who simply wants to die with dignity, adding that the majority's mischaracterization allowed it to dodge the real and much harder question of whether to ever allow physician-assisted suicide.¹²²

120. *Id.* at 634 (emphasis added); *see also id.* at 634 n.6, 635 (quoting the following statement from an amicus brief submitted by a disability rights organization even though the court had rejected it for filing as tardy: "Life support systems such as ventilators, electric wheelchairs, or other automated devices enhancing one's functions are *real extensions of the person . . .*").

121. *See id.* at 636 ("[T]he technical ability to keep a person with these kinds of injuries alive by means of mechanical respiration has not been available for much more than fifty years."); *see also* WILLIAM H. COLBY, UNPLUGGED: RECLAIMING OUR RIGHT TO DIE IN AMERICA 67–69 (2006) (tracing the history of ventilators); *id.* at 169 ("As medical technology began its advance in the 1970s, . . . pinning down exactly how this ordinary-extraordinary distinction should apply proved as elusive as defining what letting 'nature take its course' involved."). The majority recognized as much, though it held to a baseline that asked what prospects a patient would enjoy in the absence of these advances. *See McKay*, 801 P.2d at 621 (majority opinion) ("Because many individuals find themselves facing a terminal condition susceptible to indefinite suspension by medical intervention, the question arises with increasing frequency and fervor concerning the extent to which persons have the right to refuse an artificial extension of life."); *id.* at 627.

Unlike a person bent on suicide, Kenneth sought no affirmative measures to terminate his life; he desired only to eliminate the artificial barriers standing between him and the natural processes of life and death that would otherwise ensue with someone in his physical condition. . . . [H]e asked no one to shorten the term of his natural life free of the respirator. He sought no fatal potions to end life or hurry death. In other words, Kenneth desired the right to die a natural death unimpeded by scientific contrivances.

Id. at 625–26. The majority repeatedly used terms such as "artificial" and "radical" to describe the interventions that had kept Kenneth alive.

122. *See id.* at 634 (Springer, J., dissenting) ("There was nothing natural about Mr. Bergstedt's death; he killed himself."); *id.* at 636–37 (considering the difficulties with recognition of such a right); *id.* at 637 ("We are not dealing here with 'overtreatment' or unwanted prolongation of the dying process.").

Hypothetical variations of *McKay* might help to situate this decision relative to questions about deactivating implanted cardiac-assist devices, which the next section takes up at greater length. Presumably, even the dissent would have allowed Kenneth Bergstedt—if injured as an adult (without dependents) and deemed competent at the time—to decline ventilator assistance from the outset notwithstanding the inevitability of death as a result. Would it make any difference if, after initially consenting to use of such a device, Kenneth declined to replace it many years later when the original unit or tubing began to fail?¹²³

Conversely, even the majority would have rejected a request by Kenneth for medical assistance designed to halt respiration through the administration of drugs, a question that the United States Supreme Court would take up in due time. So much for the extremes. Now imagine that a technology existed—namely, an implanted pulmonary pacemaker—that allowed quadriplegics to regain lung function by artificially signaling the diaphragm,¹²⁴ thereby freeing them of the need for connection to an external ventilator; would the majority still allow Kenneth to receive medical assistance in shutting off (or explanting) such a device for the express purpose of allowing his original injury to run its course and cause a “natural death”? If not, might a prognosis of impending death from other causes affect the analysis?

Seven years after the decisions in *Cruzan* and *McKay*, the

123. The majority clearly thought not insofar as it regarded a request to disconnect as tantamount to declining (further) treatment. *See id.* at 625 (majority opinion) (“[W]e see no difference between the patient who refuses treatment and the one who accepts treatment and later refuses its continuance because of a resulting loss in the quality of life.”); *id.* at 628 (“Because a competent adult would have enjoyed a qualified constitutional and common law right to refuse a life-sustaining attachment to a respirator in the first instance, there is no reason why such an adult could not assert the same rights to reject a continuation of respirator-dependency that has proven too burdensome to endure.”); *see also* *Cruzan v. Dir., Mo. Dept. of Health*, 497 U.S. 261, 288 (1990) (O’Connor, J., concurring) (asking about the “degree of intrusion and restraint”); *In re Quinlan*, 355 A.2d 647, 664 (N.J. 1976) (focusing on the extent of “bodily invasion,” which in that case included a respirator).

124. Pacemakers do exist for other parts of the body (primarily the brain and spinal cord), but currently these are merely used to help treat conditions such as Parkinson’s tremor, depression, or chronic pain rather than for life-sustaining purposes. *See* Melissa Healy, *Which Patients Benefit Most from Parkinson’s Implant?*, *BALT. SUN*, Oct. 16, 2010, at 6A (reporting that, in the decade since the FDA approved the first deep-brain stimulation device for tremor control, approximately 70,000 patients have received one); Ken Howard Wilan, *Pacemakers Aren’t Just for the Heart Anymore*, *BOS. GLOBE*, Mar. 8, 2005, at E1.

United States Supreme Court confronted physician-assisted suicide in *Washington v. Glucksberg*.¹²⁵ A group of doctors and patients had sought a declaration that one state's prohibition on aiding someone to commit suicide violated the Due Process Clause of the Fourteenth Amendment. Although all nine Justices concurred in the judgment rejecting this challenge,¹²⁶ members of the Court disagreed about—and devoted most of their opinions to delineating—the appropriate methodology for engaging in substantive due process review.

Chief Justice Rehnquist's majority opinion exhaustively surveyed the law's treatment of suicide and those who assist with "self-murder,"¹²⁷ concluding that the claimed right was neither "deeply rooted in this Nation's history and tradition" nor "implicit in the concept of ordered liberty."¹²⁸ As only infringements of fundamental rights would trigger strict scrutiny,¹²⁹ the Court then held that the State of Washington's rationales for the prohibition on assisting suicide satisfied minimum rationality review.¹³⁰ Even

125. 521 U.S. 702 (1997).

126. Justice O'Connor filed a brief concurring opinion (purporting to join Chief Justice Rehnquist's opinion for the Court, but seeming to deviate in important respects), *see id.* at 736 (O'Connor, J., concurring), and four other members of the Court filed opinions concurring in the judgment, *see id.* at 738 (Stevens, J., concurring); *id.* at 752 (Souter, J., concurring); *id.* at 789 (Ginsburg, J., concurring); *id.* (Breyer, J., concurring). Except for Justice Souter's concurrence, these separate opinions applied equally to the Court's contemporaneous decision in the companion case *Vacco v. Quill*, 521 U.S. 793 (1997), discussed more fully below.

127. *See Glucksberg*, 521 U.S. at 710–19; *id.* at 719 ("Attitudes toward suicide itself have changed since [the 13th century], but our laws have consistently condemned, and continue to prohibit, assisting suicide. Despite changes in medical technology and notwithstanding an increased emphasis on the importance of end-of-life decisionmaking, we have not retreated from this prohibition.").

128. *Id.* at 721 (internal quotation marks omitted); *see also id.* at 723 ("[W]e are confronted with a consistent and almost universal tradition that has long rejected the asserted right, and continues explicitly to reject it today, even for terminally ill, mentally competent adults. To hold for respondents, we would have to reverse centuries of legal doctrine and practice, and strike down the considered policy choice of almost every State."); *id.* at 727 ("That many of the rights and liberties protected by the Due Process Clause sound in personal autonomy does not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected . . ."); *id.* at 728 ("conclud[ing] that the asserted 'right' to assistance in committing suicide is not a fundamental liberty interest protected by the Due Process Clause").

129. *See id.* at 721.

130. *See id.* at 728–35 (discussing state interests in the preservation of life, prevention of suicide and treatment of depression, protection of the integrity of

though the Court reiterated *Cruzan*'s presumption that persons enjoyed a fundamental right to refuse life-sustaining treatments,¹³¹ *Glucksberg*'s various opinions offered little guidance on how to distinguish that choice from physician-assisted suicide.¹³²

Even absent any fundamental right, state prohibitions against aiding suicide could not irrationally distinguish between patient refusals of life-sustaining treatment and physician-assisted suicide without violating the Fourteenth Amendment. In a companion case to *Glucksberg* decided on the same day, the Court rejected just such an equal protection challenge.¹³³ A group of physicians and terminally ill patients had argued that New York state laws unconstitutionally differentiated between essentially identical practices: one statute authorized competent patients to reject resuscitation efforts, while another statute broadly criminalized promoting suicide without exempting physicians caring for

the medical profession, protection of vulnerable groups, and prevention of a slide toward euthanasia); *id.* at 735 (“We need not weigh exactly the relative strengths of these various interests. They are unquestionably important and legitimate, and Washington’s ban on assisted suicide is at least reasonably related to their promotion and protection.”). In the end, the Court left the question to the legislative process. *See id.* at 735 (“Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society.”); *id.* at 737 (O’Connor, J., concurring); *id.* at 786–89 (Souter, J., concurring). As it happens, Washington subsequently legalized physician-assisted suicide. *See infra* note 207; *see also* Kathryn L. Tucker, *In the Laboratory of the States: The Progress of Glucksberg’s Invitation to States to Address End-of-Life Choice*, 106 MICH. L. REV. 1593, 1602–11 (2008) (discussing Oregon’s law and unsuccessful legalization efforts in California).

131. *Glucksberg*, 521 U.S. at 720 (“We have also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment.”); *id.* at 725 (“Given the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment, our assumption was entirely consistent with this Nation’s history and constitutional traditions.”).

132. *See id.* at 725–26 (“[T]he two acts are widely and reasonably regarded as quite distinct In *Cruzan* itself, we recognized that most States outlawed assisted suicide—and even more do today—and we certainly gave no intimation that the right to refuse unwanted medical treatment could be some-how transmuted into a right to assistance in committing suicide.”). A couple of months before the Supreme Court announced its decisions, Congress hedged its bets by enacting the Assisted Suicide Funding Restriction Act of 1997. Pub. L. No. 105-12, § 3, 111 Stat. 23 (codified at 42 U.S.C. § 14402 (2012)). Without further defining the relevant terms, the statute provides that it does not apply to “the withholding or withdrawing of medical treatment or medical care.” 42 U.S.C. § 14402(b)(1).

133. *See Vacco v. Quill*, 521 U.S. 793, 808–09 (1997).

terminally ill patients.¹³⁴ The Supreme Court declined to find the two situations entirely comparable,¹³⁵ explaining it as “the distinction between letting a patient die and making that patient die.”¹³⁶ Although it conceded that gray areas could arise,¹³⁷ the Court emphasized that causation and intent serve as relevant factors in drawing the distinction.¹³⁸

Given the Supreme Court’s decisions, arguable distinctions among seemingly similar cases continue to matter,¹³⁹ even if such efforts ultimately fail to convincingly differentiate permissible treatment withdrawals from impermissible physician aid in dying.¹⁴⁰

134. See *id.* at 796–98; see also *id.* at 806–07 (elaborating on the evolution of the New York statutes). The Court conceded that the Equal Protection Clause “embodies a general rule that States must treat like cases alike.” *Id.* at 799.

135. See *id.* at 800–01 (“[W]e think the distinction between assisting suicide and withdrawing life-sustaining treatment, a distinction widely recognized and endorsed in the medical profession and in our legal traditions, is both important and logical; it is certainly rational.” (footnote omitted)); cf. *id.* at 800 n.6 (“Of course, as respondents’ lawsuit demonstrates, there are differences of opinion within the medical profession on this question.”).

136. *Id.* at 807.

137. See *id.* at 807–08 (“Granted, in some cases, the line between the two may not be clear”); see also Howard Brody, *Physician-Assisted Suicide in the Courts: Moral Equivalence, Double Effect, and Clinical Practice*, 82 MINN. L. REV. 939, 961 (1998) (“The public policy distinction works precisely because many cases fit nicely within the general categories, but there are also going to be messy cases which sit on the fences.”).

138. See *Vacco*, 521 U.S. at 801 (“The distinction comports with fundamental legal principles of causation and intent. First, when a patient refuses life-sustaining medical treatment, he dies from an underlying fatal disease or pathology; but if a patient ingests lethal medication prescribed by a physician, he is killed by that medication.”); *id.* at 802 (“The law has long used actors’ intent or purpose to distinguish between two acts that may have the same result.”).

139. See Norman L. Cantor & George C. Thomas III, *The Legal Bounds of Physician Conduct Hastening Death*, 48 BUFF. L. REV. 83, 86–87 (2000); Franklin G. Miller et al., *Assisted Suicide Compared with Refusal of Treatment: A Valid Distinction?*, 132 ANNALS INTERNAL MED. 470 (2000); Norton Spritz, *Physician-Assisted Suicide: Three Crucial Distinctions*, 24 FORDHAM URB. L.J. 869, 871–74 (1997); Daniel P. Sulmasy, *Killing and Allowing to Die: Another Look*, 26 J.L. MED. & ETHICS 55, 56–63 (1998) (trying to clarify the distinction based on specific intention and proximate causation).

140. See Tom L. Beauchamp, *The Justification of Physician-Assisted Deaths*, 29 IND. L. REV. 1173, 1200 (1996); *id.* at 1180 (noting that “in many complex cases the elements of these notions are so intertwined as to almost defy neat classification”); Cantor, *supra* note 44, at 1798–808; *id.* at 1816 (“[N]o convincing rationale supports the prevailing distinction between killing and letting die. And the most frequently voiced concern about [physician-assisted death]—the hazards of abuse—does not seem significantly more threatening than in the case of [life-sustaining medical treatment].”); Cantor & Thomas, *supra* note 139, at 153–73 (elaborating); Alan Meisel, *Physician-Assisted Suicide: A Common Law Roadmap for*

As many have noted, the act/omission distinction breaks down quickly in this context.¹⁴¹

Causal judgments about what triggered a patient's death—the underlying disease or the physician's intervention—all too often lie in the eye of the beholder.¹⁴² Although less clear when a patient refuses from the outset (leaving uncertainty about whether a recommended intervention might have prolonged life), the withdrawal of a life-sustaining intervention qualifies as a proximate cause of a patient's death, even if the death certificate lists the underlying disease or condition.¹⁴³ Intention suffers from the same slippery quality. The majority in *Quill* contrasted a physician's assent to a patient's refusal or request for withdrawal of life-sustaining treatment (as an intent to abide by the patient's wishes) with a physician's prescription of lethal medication (as reflecting an intent to cause death),¹⁴⁴ but even the latter situation reflects the physician's intent to abide by the patient's wishes,¹⁴⁵ and substantial

State Courts, 24 *FORDHAM URB. L.J.* 817, 856–57 (1997); *id.* at 823–25 (calling the central distinction a necessary fiction); David Orentlicher, *The Alleged Distinction Between Euthanasia and the Withdrawal of Life-Sustaining Treatment: Conceptually Incoherent and Impossible to Maintain*, 1998 *U. ILL. L. REV.* 837.

141. See, e.g., *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 296–97 (1990) (Scalia, J., concurring); Neil M. Gorsuch, *The Right to Assisted Suicide and Euthanasia*, 23 *HARV. J.L. & PUB. POL'Y* 599, 645–46 (2000); Meisel, *supra* note 140, at 826–32; Note, *Physician-Assisted Suicide and the Right to Die with Assistance*, 105 *HARV. L. REV.* 2021, 2028–29 (1992); see also *id.* at 2040 (“Physician-assisted suicide is not fundamentally different from the withholding or withdrawing of medical treatment.”).

142. See Gorsuch, *supra* note 141, at 643–45; Alexander Morgan Capron, *Death and the Court*, *HASTINGS CENTER REP.*, Sept.–Oct. 1997, at 25, 27 (“[A]s every ethics committee member knows, this view of causation is much too simple, for every event has many causes; a conclusion about causation simply reflects a judgment about the right place to assign responsibility.”). Even so, speed and certainty of demise do seem like relevant factors.

143. See Timothy E. Quill, *Risk Taking by Physicians in Legally Gray Areas*, 57 *ALB. L. REV.* 693, 703 (1994); see also Orentlicher, *supra* note 140, at 840 (“When a physician writes a prescription for a lethal dose of barbiturates, the physician's role in the patient's death is more attenuated than is that of the physician who turns off a ventilator on a patient who cannot breathe without assistance.”). In fact, most deaths of patients in health care institutions spring from treatment withdrawals. See Kathy Faber-Langendoen & Paul N. Lanken, *Dying Patients in the Intensive Care Unit: Foregoing Treatment, Maintaining Care*, 133 *ANNALS INTERNAL MED.* 886, 888 (2000); Charles L. Sprung et al., *Changes in Forgoing Life-Sustaining Treatments in the United States: Concern for the Future*, 71 *MAYO CLINIC PROC.* 512, 513 (1996) (“Up to 79% of deaths in the ICU have been shown to occur after the forgoing of life-prolonging therapies.”).

144. See *Vacco v. Quill*, 521 U.S. 793, 801–02 (1997).

145. See *Washington v. Glucksberg*, 521 U.S. 702, 750–51 (1997) (Stevens, J.,

certainty that death will follow in the former situation would reflect an intent to cause death even if not rising to the level of *mens rea* under the criminal law.¹⁴⁶

B. *Situating Implanted Cardiac-Assist Devices*

Academics have spilled plenty of ink commenting on these legal issues,¹⁴⁷ but, as far as I can tell, not one of them has

concurring).

146. See David Orentlicher, *The Supreme Court and Terminal Sedation: Rejecting Assisted Suicide, Embracing Euthanasia*, 24 HASTINGS CONST. L.Q. 947, 958 (1997); see also Norman L. Cantor, *On Hastening Death Without Violating Legal and Moral Prohibitions*, 37 LOY. U. CHI. L.J. 407, 411 (2006) (“[A] physician, even one motivated by compassion, who enters a suffering pulmonary patient’s room and without consent pulls the plug from the patient’s respirator is guilty of murder if death follows from the physician’s action.”); Cantor & Thomas, *supra* note 139, at 94 n.41, 113–17 (rejecting the focus on specific intent); *id.* at 121–38 (explaining that administration of high-dose analgesics for palliative purposes but with a high likelihood of causing death could lead to prosecution). *But see* Gorsuch, *supra* note 141, at 647–57, 700–02, 706 (defending reliance on intentionality); *id.* at 709–10 (“[A] meaningful moral-legal distinction exists based on intent: the right to refuse need not involve any intention to die or kill, whereas the supposed right to assisted suicide and euthanasia always does.”); cf. Miles J. Edwards & Susan W. Tolle, *Disconnecting a Ventilator at the Request of a Patient Who Knows He Will Then Die: The Doctor’s Anguish*, 117 ANNALS INTERNAL MED. 254, 256 (1992); Timothy E. Quill, *The Ambiguity of Clinical Intentions*, 329 NEW ENG. J. MED. 1039, 1040 (1993) (“[M]ultilayered intentions are present in most, if not all, end-of-life decisions.”). Futility judgments, see *infra* note 170, seem in some tension with these claims. In any event, such questions do not arise solely in criminal law settings, though liability issues normally relate to the opposite problem—namely, when physicians encounter lawsuits for the “wrongful prolongation of life.” See Holly Fernandez Lynch et al., *Compliance with Advance Directives: Wrongful Living and Tort Law Incentives*, 29 J. LEGAL MED. 133, 139–48, 168–78 (2008); S. Elizabeth Wilborn Malloy, *Beyond Misguided Paternalism: Resuscitating the Right to Refuse Medical Treatment*, 33 WAKE FOREST L. REV. 1035, 1060–69, 1075–91 (1998); Philip G. Peters, Jr., *The Illusion of Autonomy at the End of Life: Unconsented Life Support and the Wrongful Life Analogy*, 45 UCLA L. REV. 673 (1998).

147. See, e.g., Norman L. Cantor, *Twenty-Five Years After Quinlan: A Review of the Jurisprudence of Death and Dying*, 29 J.L. MED. & ETHICS 182 (2001); Erwin Chemerinsky, *Washington v. Glucksberg Was Tragically Wrong*, 106 MICH. L. REV. 1501 (2008); Ronald Dworkin, *Lecture, Euthanasia, Morality, and Law*, 31 LOY. L.A. L. REV. 1147 (1998); David J. Garrow, *The Right to Die: Death with Dignity in America*, 68 MISS. L.J. 407 (1998); Neil M. Gorsuch, *The Legalization of Assisted Suicide and the Law of Unintended Consequences: A Review of the Dutch and Oregon Experiments and Leading Utilitarian Arguments for Legal Change*, 2004 WIS. L. REV. 1347; Yale Kamisar, *Physician Assisted Suicide: The Problems Presented by the Compelling, Heartwrenching Case*, 88 J. CRIM. L. & CRIMINOLOGY 1121 (1998); Leon R. Kass & Nelson Lund, *Physician-Assisted Suicide, Medical Ethics and the Future of the Medical Profession*, 35 DUQ. L. REV. 395 (1996); Penney Lewis, *Rights Discourse and Assisted Suicide*, 27 AM. J.L. & MED. 45 (2001); Stephen W. Smith, *Some Realism About End of Life: The Current Prohibition*

considered on what side of the line to place requests to deactivate implanted cardiac-assist devices.¹⁴⁸ A loose-leaf legal treatise devoted to right-to-die issues recently added brief references to the question,¹⁴⁹ but, after citing the HRS consensus statement and a few of the medical journal articles discussed previously, it simply offered the conclusory statement that deactivating CIEDs qualified as the withdrawal of life-sustaining treatment.¹⁵⁰ This strikes me as far from self-evident.

Prescribing fatal doses of barbiturates—the prototypical form of physician-assisted suicide considered in *Glucksberg* and *Quill*—obviously differs from deactivating an implanted cardiac-assist device, but the latter in turn differs from disconnecting tubes or unplugging external life-support machinery, which state courts generally have allowed. Does my original intuition—namely, that “a heart transplant patient who fares poorly and regrets his choice presumably would have no right to ask a surgeon simply to remove the new organ or perhaps try to ‘deactivate’ it by applying a strong electrical current”¹⁵¹—help to situate the problem? If that

and the Euthanasia Underground, 33 AM. J.L. & MED. 55 (2007); Cass R. Sunstein, *The Right to Die*, 106 YALE L.J. 1123 (1997); Melvin I. Urofsky, *Justifying Assisted Suicide: Comments on the Ongoing Debate*, 14 NOTRE DAME J.L. ETHICS & PUB. POL’Y 893 (2000); Symposium, *Euthanasia and Physician-Assisted Suicide*, 25 J. HEALTH POL. POL’Y & L. 377 (2000) (book reviews); Symposium, *Physician-Assisted Suicide: Facing Death After Glucksberg and Quill*, 82 MINN. L. REV. 885 (1998) (including contributions from Robert Burt, Ezekiel Emanuel, and Yale Kamisar).

148. The closest that I could find was an old column authored by a group of medical ethicists in a state bar journal. See Frederick Paola et al., *Automatic Implantable Cardioverter Defibrillators (AICDS): Management Under New York State’s DNR Law*, N.Y. ST. B.J., Mar.–Apr. 1997, at 36, 37 (concluding that ICDs represent a form of cardiopulmonary resuscitation (CPR) so a “do not resuscitate” (DNR) order would allow for their deactivation, but noting that, in the case study presented, the family members disagreed because they thought that the device “had, by then, become a part of the patient”); see also Aine McGeary & Anselm Eldergill, *Medicolegal Issues Arising When Pacemaker and Implantable Cardioverter Defibrillator Devices Are Deactivated in Terminally Ill Patients*, 50 MED. SCI. & L. 40, 41, 43 (2010) (offering a brief and somewhat confused perspective from the U.K.); Orentlicher, *supra* note 98, at 449 (making a passing reference to pacemakers); Thomas D. Manganello, *Disabling the Pacemaker: The Heart-Rending Decision Every Competent Patient Has a Right to Make*, HEALTH CARE L. MONTHLY, Jan. 2000, at 3.

149. See ALAN MEISEL & KATHY L. CERMINARA, *THE RIGHT TO DIE: THE LAW OF END-OF-LIFE DECISIONMAKING* §§ 1A.13[C], 6.03[A1] (3d ed. 2004 & Supp. 2012) (indicating that this material was added in 2011).

150. See *id.* at § 6-62 (“[D]isabling that device results in the patient’s death from the underlying illness or condition that necessitated use of the device in the first place, just as the withdrawal of any other life-sustaining treatment would.”).

151. See NOAH, *supra* note 1, at 1148; see also Simon, *supra* note 88, at 14–15 (suggesting the same parallel); Sulmasy, *supra* note 56, at 71 (“Certainly, this

hypothetical describes an even more extreme and unpalatable version of physician aid in dying, then does CIED deactivation more closely resemble it or, as most ethicists have argued, remain firmly in the same domain as the withdrawal of ventilators and gastrostomy tubes (or advance directives rejecting any use of external defibrillators for resuscitation)?¹⁵²

Deactivation differs from manually removing tubes or unplugging equipment—physicians typically would not surgically explant the life-saving device; instead, they would induce a retained device to malfunction.¹⁵³ Surely, convincing an electrophysiologist to reprogram a pulse generator so that it triggers a potentially fatal arrhythmia would qualify as active euthanasia.¹⁵⁴ Perhaps the

intuition seems correct if one is talking about a heart transplant. Stopping the function of a transplanted heart with an injection of KCl [potassium chloride] seems morally no different from stopping a native heart with an injection of KCl.); Stein, *Heart Pump*, *supra* note 2, at A1 (quoting Robert Veatch, a prominent bioethicist at Georgetown University: “If you think about stopping the left ventricular assist device as something like stopping the heart, then you have to deal with the possibility that this is an active killing.”); *cf.* Veatch, *supra* note 87, at 309 (“Throwing a switch that stops a TAH is more like injecting a drug that paralyzes the heart muscle [This] would be considered direct, active killing. How can it be that turning off the heart is any different?”). Dr. Mueller and his associates distinguished such a case, though without anticipating these alternative methods of “deactivating” a transplanted heart. *See* Mueller et al., *supra* note 86, at 795 (“Removing a [heart] valve or an organ is invasive and painful and therefore introduces a new pathology (e.g., a surgical wound), whereas turning off a VAD is noninvasive and painless and does not introduce a new pathology.”).

152. *See* England et al., *supra* note 63, at 539 (“ICDs are unique. Though not organic, a patient may consider the implant as a part of his physical being [A]n ICD is neither perfectly analogous with [an external] medical device nor a biological transplant; these two models of thought represent extremes between which we believe ICDs fall.”).

153. Imagine that, instead of disconnecting the endotracheal tube for a ventilator (perhaps something about the patient’s condition would have made that unduly cumbersome or extremely painful), a physician created a closed circuit so that exhaled carbon dioxide or nitrogen rather than oxygen returned through the intake tube—I trust that no one would call that simply withdrawing life-sustaining treatment. *Cf.* Russel D. Ogden, *Non-Physician Assisted Suicide: The Technological Imperative of the Deathing Counterculture*, 25 DEATH STUD. 387, 391–93 (2001) (discussing a “closed circuit breathing system” called the Debreather); *id.* at 394 (describing “devices using cylinders of compressed [inert] gas”); Russel D. Ogden et al., *Assisted Suicide by Oxygen Deprivation with Helium at a Swiss Right-to-Die Organisation*, 36 J. MED. ETHICS 174, 175–76 (2010).

154. Actually, so would CIED deactivation, just as administering—as opposed to merely prescribing for self-administration—a fatal drug dose goes beyond physician-assisted suicide. *See* *Washington v. Glucksberg*, 521 U.S. 702, 785 (1997) (Souter, J., concurring) (noting that “a physician who would provide a drug for a patient to administer might well go the further step of administering the drug himself; so, the barrier between assisted suicide and euthanasia could become

principle of “double effect” (which basically overlooks the risk of causing an adverse outcome that arises as a foreseeable but unintended and unavoidable consequence of pursuing a laudable purpose) would shield a physician who deactivates an implanted cardiac-assist device in a terminally ill patient from criminal charges. Normally this question arises when the administration of controlled substances for palliative purposes may itself hasten death.¹⁵⁵ Although shutting off an LVAD generally will pose an immediate risk of death,¹⁵⁶ deactivating an ICD or pacemaker rarely would do so. If ICD withdrawal qualifies as a palliative measure, then the physician’s knowledge that the procedure exposed the patient to a heightened risk of death would not suffice to turn this into active euthanasia.¹⁵⁷ The same reasoning would not, however, apply to pacemaker deactivation.¹⁵⁸

porous”); *see also* Am. Med. Ass’n, Council on Ethical & Judicial Affairs, *Decisions Near the End of Life*, 267 JAMA 2229, 2233 (1992) (explaining that physician-assisted suicide “is contrary to the prohibition against using the tools of medicine to cause a patient’s death” (emphasis added)). In the CIED context, assisted suicide would arise where a physician instructs a patient about how to use a programmer or magnets to shut off the device. Ultimately, however, this distinction would make no difference, even in the few states (including Washington) that have legalized physician-assisted suicide only by the prescription of certain drugs. *See infra* note 207 and accompanying text.

155. *See* J. Andrew Billings & Larry R. Churchill, *Monolithic Moral Frameworks: How Are the Ethics of Palliative Sedation Discussed in the Clinical Literature?*, 15 J. PALLIATIVE MED. 709, 710–11 (2012); Charles Foster et al., *The Double Effect Effect*, 20 CAMBRIDGE Q. HEALTHCARE ETHICS 56, 66–69 (2011); Jeffrey T. Berger, *Rethinking Guidelines for the Use of Palliative Sedation*, HASTINGS CENTER REP., May–June 2010, at 32, 33–34.

156. *See* Larry A. Allen et al., *Decision Making in Advanced Heart Failure: A Scientific Statement from the American Heart Association*, 125 CIRCULATION 1928, 1938 (2012) (explaining that LVAD deactivation would, on average, lead to death in approximately 20 minutes); *see also* Bramstedt & Wenger, *supra* note 93, at 548 (“LVAD therapy is a relatively new medical technology that makes us aware of wrinkles in end-of-life decisions that we may not have considered before.”).

157. *See* Ballentine, *supra* note 32, at 16; Lewis et al., *supra* note 77, at 896 (“Withdrawal of shock therapy when a patient has made the decision for comfort care prevents painful shocks at the end of life.”); *cf.* Brody, *supra* note 137, at 946 (discussing application of the double effect principle to the removal of a ventilator).

158. *See* Braun et al., *supra* note 80, at 128 (“[I]t is rare that disabling the pacemaker will result in a swift and painless death. It is more likely it would result in symptomatic bradycardia with slow and relentless failure of major organs and, perhaps, an even poorer quality of death.”); Robert E. Enck, Editorial, *Management of Cardiac Devices as the End Nears*, 22 AM. J. HOSPICE & PALLIATIVE MED. 7, 7 (2005) (“[T]he issue of pacemaker deactivation is less clear-cut. Is this the double effect in reverse? . . . This ultimately hastens death but then produces a slow, agonizing end punctuated by heart failure.”); Lewis et al., *supra* note 77, at 896

1. *Questions of Ownership and Control*

Perhaps a property law framework might facilitate analysis.¹⁵⁹ Ownership issues can get tricky upon device removal or recipient death,¹⁶⁰ but deactivation requests involve a device still inside a living patient.¹⁶¹ When you get an implant, it belongs to you;¹⁶² patients literally may take these to the grave with them.¹⁶³ No

(“[D]iscontinuation of pacing therapy may worsen heart failure because of complete atrioventricular block or lead to syncope. This study demonstrates that continuing pacing therapies in pacemaker-dependent individuals did not artificially prolong life”); Rhymes et al., *supra* note 78, at 1062 (“Because there is no significant ongoing burden incurred by the pacemaker, double-effect reasoning cannot be used to justify deactivating the pacemaker.”).

159. See England et al., *supra* note 63, at 539 (“Arguably, some other sort of property law model (though not one concerned with fixtures) would be unavoidable in cases where the patient has paid for the device. . . . [I]t is worth briefly mentioning some of the relevant considerations that a property model raises.”). These commentators made some inapt references to the duties of car owners in the U.K. and ultimately sought only to make a far more limited claim—namely, that physicians could not unilaterally deactivate an ICD on grounds of futility (as they could in the case of an external device that remained under their continued control). See *id.* at 539–40 (concluding that only patients or their surrogates could demand deactivation); see also *id.* at 539 (“[H]e may be able to claim a physical ownership that would prevent interference by a third party.”); *infra* note 167 (elaborating). A consensus statement co-sponsored by HRS (and which focused on monitoring rather than deactivation of CIEDs) cited this article for the proposition that “[t]he decision to inactivate an ICD cannot be made unilaterally by the patient’s medical provider.” Wilkoff et al., *supra* note 8, at 920.

160. Cf. *Brotherton v. Cleveland*, 923 F.2d 477, 480–82 (6th Cir. 1991) (holding that the plaintiff had a sufficient interest in her dead spouse’s corneas to claim a deprivation of due process); *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 487–97 (Cal. 1990) (rejecting conversion claims after researchers created a valuable cell line from a spleen removed from a patient). See generally Radhika Rao, *Property, Privacy, and the Human Body*, 80 B.U. L. REV. 359 (2000). I encountered these issues in 2000 while serving as a member of the expert advisory panel for the National Institutes of Health’s technology assessment conference on retrieving implanted medical devices for failure analysis.

161. See *supra* notes 60–73 and accompanying text (discussing the relevance of an internal/external distinction).

162. See John H. Fielder & Jonathan Black, *But Doctor, It’s My Hip!: The Fate of Failed Medical Devices*, 5 KENNEDY INST. ETHICS J. 113, 124 (1995) (“Most implants are purchased for patients by a third party. . . . [I]t seems clear that the patient owns the device”); *id.* at 125 (“We advocate a strong presumption in favor of the patient owning any medical device whether implanted or explanted. . . . Implanted medical devices are (new) parts of one’s body and should be treated as such, regardless of who has paid for them.”).

163. See Bharat K. Kantharia et al., *Reuse of Explanted Permanent Pacemakers Donated by Funeral Homes*, 109 AM. J. CARDIOLOGY 238, 239 (2012) (“Surveys of morticians in [two cities] have indicated that nearly 19% of deceased patients possess a cardiac device, and 85% of these are buried with these patients”); see also William J. Groh, Editorial, *You Shouldn’t Take It with You: Postmortem Device*

physician, hospital, curious manufacturer, jilted creditor, or regulatory agency may demand its return.¹⁶⁴ Contrast this with equipment used in hospitals (including external pacemakers, defibrillators, and heart pumps),¹⁶⁵ which patients (and their insurers) pay handsomely to use but have no right to retain. Similarly, external life-sustaining devices used in the home typically get leased.¹⁶⁶

If implanted cardiac-assist devices really do not differ from other life-sustaining interventions, then physicians could deactivate them on grounds of futility (in theory even without patient or proxy consent, though in practice that seems highly unlikely).¹⁶⁷

Reuse, 9 HEART RHYTHM 215 (2012). In cases of cremation, however, pulse generators first must get excised to guard against a possible explosion, and loved ones sometimes find wire fragments from the leads among the ashes. See Braun et al., *supra* note 80, at 130; Christopher P. Gale & Graham P. Mulley, *Pacemaker Explosions in Crematoria: Problems and Possible Solutions*, 95 J. ROYAL SOC'Y MED. 353, 354 (2002); Butler, *supra* note 76, at 38.

164. See James N. Kirkpatrick et al., Letter, *Postmortem Analysis and Retrieval of Implantable Pacemakers and Defibrillators*, 354 NEW ENG. J. MED. 1649, 1650 (2006) (finding that ninety-three percent of funeral directors and embalmers in the Chicago area responding to a survey “said that without the consent of the family, it would not be appropriate to . . . remove the devices”); James N. Kirkpatrick et al., *Reuse of Pacemakers and Defibrillators in Developing Countries: Logistical, Legal, and Ethical Barriers and Solutions*, 7 HEART RHYTHM 1623, 1626 (2010) (“Presuming that in most circumstances patients own their devices and may control their disposition after removal, the aforementioned pacemaker/defibrillator living will would allow patients officially to authorize embalmers to remove pulse generators for donation or return to the manufacturers”); cf. Gowri Ramachandran, *Assault and Battery on Property*, 44 LOY. L.A. L. REV. 253, 263–64 (2010) (“The intuition that once something is internal to a physically continuous body it is properly thought of as part of that body also seems to give force to fictitious horror scenarios in which artificial organs are repossessed, in bloody scenarios, by heartless corporations.”).

165. Cf. Gorsuch, *supra* note 141, at 701–02 (“Patient[s] often reject treatment because they . . . are tired of invasive tubes, or simply wish to leave the hospital and go home.”); Simon, *supra* note 88, at 15 (focusing on portability: “If ventilators become backpack devices attached to a tracheostomy in otherwise independent patients, we may have to reassess our permissive attitude towards extubation.”); *id.* at 14 (contrasting LVADs from “other life-support technologies [that] can be used only in a professional health care setting with ongoing medical support”).

166. AEDs may represent an exception. See Barnaby J. Feder, *Do It Yourself: The Home Heart Defibrillator*, N.Y. TIMES, May 3, 2005, at C1 (reporting that consumers can purchase these nonprescription devices for less than \$2000). In such a case, a person no longer wanting to get resuscitated could simply instruct their caregivers not to use the AED.

167. See England et al., *supra* note 63, at 539 (“Considering an ICD as a continuing medical intervention permits a unilateral decision by a doctor to deactivate the device, even if this is contrary to a patient’s wish.”); see also Berger, *supra* note 39, at 633 (“Physicians of patients with limited physical or cognitive function may assess continued use of ICDs as ‘futile.’ . . . This statement prompts

Ownership normally means the freedom to make a range of choices about disposition and use,¹⁶⁸ but here it means that hospitals and their employees have transferred control of an item over to a patient,¹⁶⁹ which would prevent health care professionals from unilaterally withdrawing the treatment on grounds of futility.¹⁷⁰ If the patient wanted to stop using such an item, then it

a question the medical community has not yet answered: How ought already implanted defibrillators be used in patients with limited life expectancies?"); Katrina A. Bramstedt, *Contemplating Total Artificial Heart Inactivation in Cases of Futility*, 27 DEATH STUD. 295, 301–03 (2003); Katrina A. Bramstedt, Editorial, *Destination Nowhere: A Potential Dilemma with Ventricular Assist Devices*, 54 ASAIO J. 1, 2 (2008) (“[N]o therapy should be considered permanent. Often, there comes a time when implanted therapies such as pacemakers, cardioverter defibrillators, and VADs should be terminated before a patient is actually declared dead.”); Padeletti et al., *supra* note 99, at 1482 (“[I]f the device has an ON/OFF button [as ICDs do], then the physician has the power to withhold such treatment on the grounds of futility, even if the patient demands otherwise.”); cf. Tia P. Powell & Mehmet C. Oz, Editorial, *Discontinuing the LVAD: Ethical Considerations*, 63 ANNALS THORACIC SURGERY 1223, 1223 (1997) (“[W]e have not encountered a case where we found it necessary or appropriate to discontinue the LVAD in the face of objections from a patient’s family.”). *But see* Veatch, *supra* note 87, at 311 (calling Bramstedt’s conclusion “offensive”); *id.* at 311–14 (elaborating on his broader objections to futility judgments); Wilkoff et al., *supra* note 8, at 920 (“The decision to inactivate an ICD cannot be made unilaterally by the patient’s medical provider.”).

168. See Roger F. Friedman, Comment, *It’s My Body and I’ll Die If I Want To: A Property-Based Argument in Support of Assisted Suicide*, 12 J. CONTEMP. HEALTH L. & POL’Y 183, 204 (1995). For instance, patients may indicate a desire to donate their CIEDs after death (or the decedents’ family members may do so). See Timir S. Baman et al., *Feasibility of Postmortem Device Acquisition for Potential Reuse in Underserved Nations*, 9 HEART RHYTHM 211, 213 (2012) (“The goal of our proposed initiative is to create a reproducible model where funeral directors are given a framework to consent families of loved ones for device removal prior to burial or cremation.”); Timir S. Baman et al., *Pacemaker Reuse: An Initiative to Alleviate the Burden of Symptomatic Bradyarrhythmia in Impoverished Nations Around the World*, 122 CIRCULATION 1649, 1650 (2010) (“[A] great majority of the patient population with devices and the general public [are] willing to consent to cardiac device removal for philanthropic reuse in underserved nations.”).

169. These questions arise when courts ask whether hospitals or surgeons fall within the chain of distribution for purposes of applying strict products liability after an implanted device causes injury. See Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 918 & n.343, 923–25 (2009).

170. See generally John M. Luce, *A History of Resolving Conflicts over End-of-Life Care in Intensive Care Units in the United States*, 38 CRITICAL CARE MED. 1623 (2010); Thaddeus Mason Pope, *Medical Futility Statutes: No Safe Harbor to Unilaterally Refuse Life-Sustaining Treatment*, 75 TENN. L. REV. 1 (2007); Robert D. Truog, *Medical Futility*, 25 GA. ST. U. L. REV. 985 (2009); Patrick Moore, Note, *An End-of-Life Quandary in Need of a Statutory Response: When Patients Demand Life-Sustaining Treatment That Physicians Are Unwilling to Provide*, 48 B.C. L. REV. 433 (2007); Symposium, *Medical Futility Issues*, 18 HEALTH MATRIX 229 (2008); Pam Belluck,

would require a new round of intervention by medical personnel rather than their continued involvement with respect to something that they retain ownership and control over. If the patient did not want to stop using the device, then physician deactivation would constitute homicide.¹⁷¹

Along similar lines, a pair of physicians once suggested that ICDs resemble “fixtures” added to real property.¹⁷² The law of fixtures attempts to define when personal property (e.g., a kitchen appliance or a fence) becomes sufficiently integrated with the structure or land so that, in the event of ambiguity, it normally would get conveyed as part of the package.¹⁷³ The authors of this article emphasized as follows:

[T]he ICD is an indwelling device and arguably has *become a part of* the patient. In this way, it is distinguishable from an external defibrillator [or] a ventilator The idea that something can have such an ontologic metamorphosis, becoming a part of something theretofore disjoint, is intriguing and not without precedent.¹⁷⁴

Even as Doctors Say Enough, Families Fight to Prolong Life, N.Y. TIMES, Mar. 27, 2005, § 1, at 1.

171. See Veatch, *supra* note 87, at 311 (calling unilateral action by physicians to deactivate TAHs “murder”). Similarly, I have no doubt that, if a CIED malfunctions or is programmed incorrectly, *cf.* Mary Jane Rasmussen et al., *Unintentional Deactivation of Implantable Cardioverter-Defibrillators in Health Care Settings*, 77 MAYO CLINIC PROC. 855, 856 (2002) (discussing errors that may occur after implantation), courts resolving wrongful death claims against the manufacturer or physician would treat the device’s failure as the proximate cause of death even if a preexisting disease process had made the patient vulnerable in the event of such a failure, *see* Lars Noah, *An Inventory of Mathematical Blunders in Applying the Loss-of-a-Chance Doctrine*, 24 REV. LITIG. 369, 390 & nn.69–70 (2005); *see also* Wendland v. Sparks, 574 N.W.2d 327, 330 (Iowa 1998) (allowing loss-of-a-chance claim against a physician who unilaterally decided not to resuscitate a patient suffering from numerous maladies); Beauchamp, *supra* note 140, at 1184.

172. See Frederick A. Paola & Robert M. Walker, *Deactivating the Implantable Cardioverter-Defibrillator: A Biofixture Analysis*, 93 S. MED. J. 20, 21–22 (2000). Both authors were affiliated with the University of South Florida’s College of Medicine, and Dr. Paola also held a law degree.

173. See generally Ronald W. Polston, *The Fixtures Doctrine: Was It Ever Really the Law?*, 16 WHITTIER L. REV. 455 (1995); Marc L. Roark, *Groping Along Between Things Real and Things Personal: Defining Fixtures in Law and Policy in the UCC*, 78 U. CIN. L. REV. 1437 (2010).

174. Paola & Walker, *supra* note 172, at 21; *see also id.* at 22 (“We believe that the ICD falls into that gray zone, between unequivocal biofixtures (such as transplanted allogenic organs) at one extreme and unequivocally extrinsic medical treatments . . . at the other, where reasonable arguments can be made characterizing it as one or the other.”); *id.* (“As indwelling devices like ICDs and

They had, however, a fairly limited question in mind when drawing this parallel—namely, what happens when a surrogate decisionmaker consents to a “do not resuscitate” (DNR) order for an incompetent patient who the physician later discovers to have an ICD? The authors concluded that, under such circumstances, the DNR should not authorize deactivation of the device.¹⁷⁵ They clearly assumed that, absent an ambiguity, the physician could turn off the ICD,¹⁷⁶ evidently not appreciating the fact that their invocation of the law of fixtures and focus on the peculiarities associated with a fully implanted device might cast serious doubt on the legality of deactivation even upon a direct request from a competent patient.¹⁷⁷

A focus on device ownership raises subsidiary questions about the nature and scope of the treatment relationships between the patient and different physicians.¹⁷⁸ When a patient gets hooked up

pacemakers become more prevalent, physicians will increasingly confront this complex set of issues.”).

175. See *id.* at 21 (“This distinction may provide an alternative basis for treating the use of the ICD differently than conventional CPR and for not interpreting the family’s consent to a DNR order as implicitly authorizing its deactivation.”); *id.* at 22 (“In our ICD case, we seek an answer to the question: What resuscitative measures that were not explicitly forgone by the patient’s family may properly be forgone in reliance on its consent to the DNR order?”).

176. See *id.* at 22 (“[T]he family might regard the ICD as an intrinsic part of the patient . . . and conclude that deactivating the ICD is fundamentally different from forgoing extrinsic treatments. In these circumstances, serious limitations are placed on a physician’s liberty to interfere with the functioning of the device.”); *cf.* Berger, *supra* note 39, at 631–33 (concluding on other grounds that a DNR order does not invariably call for ICD deactivation).

177. Shortly afterwards, the authors alluded to this possibility. See Frederick Paola & Robert M. Walker, Letter, *Is It Ethical to Withdraw Low-Burden Interventions in Chronically Ill Patients?*, 284 JAMA 1380 (2000) (“[A]cts interfering with pacemaker function would be more akin to killing than to letting die.”). Their letter prompted a pair of generally dismissive responses. See Edmund D. Pellegrino, Letter, *Is It Ethical to Withdraw Low-Burden Interventions in Chronically Ill Patients?—Reply*, 284 JAMA 1381 (2000) (“This is a specious argument because . . . [t]he pacemaker has not undergone any change in its nature and is still a mechanical device.”); Jill A. Rhymes et al., Letter, *Is It Ethical to Withdraw Low-Burden Interventions in Chronically Ill Patients?—Reply*, 284 JAMA 1381 (2000) (“While Paola and Walker have proposed a very interesting line of ethical inquiry, it is not yet sufficiently developed”); see also England et al., *supra* note 63, at 539 (“Allowing a duality whose resolution is purely determined by the patient’s understanding may lead to a plurality of bad outcomes.”); Sulmasy, *supra* note 56, at 69 (“This interesting foray into ontology and ethics raises many more questions than it answers”).

178. See generally BARRY R. FURROW ET AL., HEALTH LAW § 6-1 (2d ed. 2000); *id.* at 261 (“After surgery, where follow-up care is needed, a surgeon must continue to care for the patient until the threat of post-operative complications is past.”);

to hospital machinery, he or she remains under the care of various doctors and nurses,¹⁷⁹ and a request for the withdrawal of life-supporting treatment effectuates the patient's right to terminate or limit the scope of a treatment relationship.¹⁸⁰ When a patient departs the hospital but remains hooked up to machinery, health care professionals presumably remain responsible for supervising use of the equipment.¹⁸¹ When, however, a patient walks out the door with a pacemaker, ICD, or LVAD, generally they are "good to go,"¹⁸² subject, of course, to periodic return visits including eventual

James L. Rigelhaupt, Jr., Annotation, *What Constitutes Physician-Patient Relationship for Malpractice Purposes*, 17 A.L.R. 4TH 132 (1982 & Supp. 2012).

179. Thus, one court offered the following explanation of the equivalence between withholding and withdrawing a life-sustaining intervention:

Even though these life support devices are, to a degree, "self-propelled," each pulsation of the respirator or each drop of fluid introduced into the patient's body by intravenous feeding devices is comparable to a manually administered injection or item of medication. Hence "disconnecting" of the mechanical devices is comparable to withholding the manually administered injection or medication.

Barber v. Superior Court, 195 Cal. Rptr. 484, 490 (Ct. App. 1983) (ordering the dismissal of murder charges against physicians who removed life-sustaining treatments at the request of the patient's family). Would it also be accurate to regard each pulse from an implanted pacemaker (or jolt from an ICD) as akin to letting physicians utilize external versions of these same devices on a hospitalized patient?

180. See Gorsuch, *supra* note 141, at 653 (explaining that physicians who comply with such requests "may intend only to discontinue treatment to permit the patient to go home, to live without intrusive assistance"); *id.* at 706 (willing to "leave ample room for patients to refuse the often hyper-technological burdensome end-of-life care found in modern hospital environments"); Jed Rubenfeld, *The Right of Privacy*, 102 HARV. L. REV. 737, 795 (1989) (envisioning "the life of one confined to a hospital bed, attached to medical machinery, and tended to by medical professionals[;] . . . the most elemental acts of existence—such as breathing, digesting, and circulating blood—are forced upon him by an external agency").

181. See, e.g., *McKay v. Bergstedt*, 801 P.2d 617, 620 (Nev. 1990) (involving quadriplegic using respirator at home); *In re Farrell*, 529 A.2d 404, 415 (N.J. 1987) (involving an outpatient patient with amyotrophic lateral sclerosis (ALS) who "died shackled to the respirator" during the pendency of her appeal); *id.* at 408 ("Mrs. Farrell was paralyzed and confined to bed in need of around-the-clock nursing care."); *id.* at 414–15 (addressing the fact that she was at home). See generally BRINGING THE HOSPITAL HOME: ETHICAL AND SOCIAL IMPLICATIONS OF HIGH-TECH HOME CARE (John D. Arras ed., 1995).

182. See Simon, *supra* note 88, at 14 ("LVADs are implanted into patients and, once implanted, can perform their functions independently of hospital-based equipment or even medical intervention. They are meant for patients to live with at home."). Although they do not raise end-of-life issues, prosthetic limbs (and joints) may provide another useful context for thinking about whether a mechanical device has become an integral part of a person. See Ramachandran,

replacement when the battery dies.¹⁸³

A request to deactivate an implanted cardiac-assist device may require seeking out medical personnel and entering into a new relationship for the sole purpose of discontinuing treatment.¹⁸⁴ Herein lies one of the practical problems that have arisen in these situations, especially when patients are dying from some other condition: upon entering hospice, they sometimes forget to

supra note 164, at 273–74 (“[I]n the case of a pacemaker or a robotic arm, humans have merged with inorganic property [A]s these mergers between what we have called ‘the body’ and ‘property’ become more common, sustaining different formal legal statuses for the inorganic and the organic, for the ‘human’ and the ‘non-human,’ or for the internal and the external, may appear more and more arbitrary.”); Rao, *supra* note 160, at 454 n.483 (“[A] pacemaker or an artificial limb may be governed by the law of property only so long as it is separate from a living human body. Once integrated with the body, however, such objects become part of the person and should be afforded protection under the individual’s right of privacy.”); Collin R. Bockman, Note, *Cybernetic-Enhancement Technology and the Future of Disability Law*, 95 IOWA L. REV. 1315, 1323–31 (2010); *id.* at 1317 (“In the near future, advances in neuroscience and robotics will change the way our society views the human body by further reinforcing the concept of the body as a machine with interchangeable, replaceable, and upgradeable parts.”); Brian Vastag, *Paralyzed Woman Moves Robotic Arm with Her Mind*, WASH. POST, May 17, 2012, at A1.

183. See Wilkoff et al., *supra* note 8, at 911–13 (HRS consensus statement offering guidelines for the nature and frequency of follow-up monitoring of patients with different CIEDs); *id.* at 922 (emphasizing the importance of regular monitoring after implantation); see also Mark H. Schoenfeld, Editorial, *Deciding Against Defibrillator Replacement: Second-Guessing the Past?*, 23 PACING & CLINICAL ELECTROPHYSIOLOGY 2019, 2020 (2000) (“[T]he most common reason for generator replacement, namely battery depletion, can be simply addressed with an outpatient procedure.”).

184. See Nathan Goldstein et al., *Management of Implantable Cardioverter-Defibrillators in Hospice: A Nationwide Survey*, 152 ANNALS INTERNAL MED. 296, 298 (2010) (“Hospices must create relationships with local electrophysiologists and representatives from device manufacturing companies to ensure that patients—especially those who cannot leave their place of residence—can have their [ICD] devices reprogrammed [i.e., deactivated].”); Lewis et al., *supra* note 77, at 895 (noting that it has become “increasingly difficult for an electrophysiologist to closely follow each patient, shifting follow-up to primary care physicians or cardiologists,” adding that “device manufacturer representatives are frequently relied on to perform device reprogramming”); Kolata, *supra* note 2, at A1 (reporting that, according to one expert, “medical care had become so fragmented that doctors implanting the devices in patients still functioning well could have a very different impression from doctors who care for people in the end stages of heart disease”); see also Strachan et al., *supra* note 33, at 10 (“It has been suggested that the onus for considering ICDs in relation to [end-of-life] planning and issues surrounding resuscitation must also be shared by those involved in implanting the devices.”); Wilkoff et al., *supra* note 8, at 916 (recognizing the “important interdependent relationship between the referring or primary care physician, the implanting center, the implanting physician and the CIED follow-up clinic”).

mention their CIED, or their oncologists may defer to the judgment of the patient's (former) cardiologist.¹⁸⁵ In fact, electrophysiologists who order CIED deactivation typically would have to utilize a separate device (i.e., the programmer) not sold to the patient but retained by the hospital and often delegate the task to employees of the device manufacturer.¹⁸⁶

2. *Invoking Informed Consent Doctrine*

The doctrine of informed consent also may help to define the point where one crosses the line. After all, the right to refuse life-sustaining medical care originates in principles of patient self-determination.¹⁸⁷ The right to seek withdrawal of such care closely tracks the right to refuse it initially. The parallel seems closest

185. See Meier, *supra* note 2, at B1; Stein, *Devices Can Interfere*, *supra* note 2, at A1; see also Amy S. Kelley et al., *Management of Patients with ICDs at the End of Life (EOL): A Qualitative Study*, 25 AM. J. HOSPICE & PALLIATIVE MED. 440, 445 (2009) (“[I]n the context of advancing medical technology, which may be inadequately understood by patients and their primary care providers, subspecialists have an increasingly important role in discussions surrounding care at EOL.”); Jane MacIver & Heather J. Ross, *Withdrawal of Ventricular Assist Device Support*, 21 J. PALLIATIVE CARE 151, 155 (2005) (“Turning the [LVAD] off requires knowledge of how to silence alarms, cease pump operation, disconnect the equipment, and turn the power unit off. . . . The physicians in the ICU felt that, since the transplant team had implanted the pump, the implanting surgeon should accept responsibility for withdrawing support.”); Mueller, *supra* note 51, at 1543 (“[O]ne would expect that fewer generalists have participated in and carried out CIED deactivations than electrophysiologists and others who manage patients with CIEDs. In addition, carrying out CIED deactivations requires technical expertise and programming equipment that generalists do not have.”).

186. See Mueller et al., *supra* note 35, at 254 (“Evidence suggests that most CIEDs are deactivated by [industry employees], not by physicians or nurses.”); *id.* at 257, 260 (confirming this impression). In the case of pacemakers, however, several companies do not allow their personnel to perform the deactivation. See *id.* at 258; *id.* at 260 (“Even so, these [employees] reported participating in pacemaker deactivations by entering settings for deactivation into the CIED reprogramming instrument and having clinicians ‘push the button’ to execute the deactivation commands.”).

187. See *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 270 (1990) (“The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment.”); Meisel, *supra* note 140, at 845–49; *id.* at 821 (“Consent is the mechanism for implementing the fundamental principle of self-determination on which the entire edifice of the law of medical decision-making at the end of life . . . is built.”); Danuta Mendelson, *Historical Evolution and Modern Implications of Concepts of Consent to, and Refusal of, Medical Treatment in the Law of Trespass*, 17 J. LEGAL MED. 1, 6, 36–41 (1996). For more on this doctrine, see Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 363–70 (2002).

when the patient did not consent initially—perhaps because the physician had acted in an emergency—and belatedly rejects the intervention.¹⁸⁸ Alternatively, intermittent courses of treatment (e.g., dialysis) would offer recurring opportunities for a patient to withdraw simply by refusing to undergo another round.¹⁸⁹ Courts and commentators generally have rejected suggestions that any meaningful distinction exists between initially withholding and later withdrawing life-sustaining treatment.¹⁹⁰ Nonetheless, many clinicians remain uncomfortable with this equivalence.¹⁹¹

A patient may, of course, revoke a previously granted permission, even once a procedure has commenced, at least up until the point of no return.¹⁹² After a procedure has concluded, however, a patient wishing it undone would have to enter into a

188. See, e.g., *Bartling v. Superior Court*, 209 Cal. Rptr. 220, 221, 224 (Ct. App. 1984) (holding that a patient, who suffered a collapsed lung during a routine biopsy, later had the right to demand the withdrawal of ventilator); see also M.G. Tweeddale, *Grasping the Nettle—What to Do When Patients Withdraw Their Consent for Treatment*, 28 J. MED. ETHICS 236, 237 (2002) (explaining that some patients may “wish to revoke the implied consent that was assumed when emergency treatment was initiated”). Federal rules governing human subjects research also specify a right to withdraw. See Noah, *supra* note 105, at 357 & n.122.

189. See, e.g., *Stouffer v. Reid*, 993 A.2d 104, 106 (Md. 2010); *In re Spring*, 405 N.E.2d 115, 118, 120 (Mass. 1980); see also Lewis M. Cohen et al., *Practical Considerations in Dialysis Withdrawal: “To Have That Option Is a Blessing,”* 289 JAMA 2113, 2114 (2003) (equating withdrawal with “discontinuation” of treatment).

190. See *In re Conroy*, 486 A.2d 1209, 1234 (N.J. 1985); Cantor & Thomas, *supra* note 139, at 92 (“Courts have uniformly rejected such a distinction, preferring to recognize a patient’s prerogative to forgo medical intervention (whether by withholding or withdrawing care) based on interests in self-determination and bodily integrity.”); see also Lipman, *supra* note 32, at 109 (“Often, deciding to withdraw treatment after a therapeutic trial is less problematic than deciding to withhold the treatment in the first place. It is then clearer that the treatment did not result in clinical improvement and the risks of continuing treatment outweigh the benefits.”); Orentlicher, *supra* note 140, at 856 n.104 (“[E]thicists have long argued that withholding life-sustaining treatment is worse than treatment withdrawal because treatment withdrawal at least comes after a trial of the therapy, while withholding denies the chance for an unexpected recovery.”).

191. See Neil J. Farber et al., *Physicians’ Decisions to Withhold and Withdraw Life-Sustaining Treatment*, 166 ARCHIVES INTERNAL MED. 560, 563 (2006); Whitlock et al., *supra* note 84, at 1186 (noting “the discomfort some clinicians and family members may feel when withdrawing, rather than withholding life-sustaining therapies”).

192. See *Schreiber v. Physicians Ins. Co.*, 588 N.W.2d 26, 31–33 (Wis. 1999) (holding, in an obstetrics case, that a patient may withdraw consent in the middle of a procedure, which then would require a new round of disclosure); *id.* at 31 (“We reject the notion that the onset of a procedure categorically forecloses a patient’s withdrawal of consent. To be sure, at some point in virtually every medical procedure a patient reaches a point from which there is no return.”).

new relationship, and, even if the patient is eager to permit it, a physician has no obligation to comply.¹⁹³ For instance, a patient frightened by news of problems with an implanted device may demand its explantation,¹⁹⁴ but a surgeon (even if he or she handled the original implantation) may refuse to participate if such a procedure lacks medical justification.¹⁹⁵

One would think this even more obvious in the case of life-saving devices implanted into a patient. For the sake of argument,

193. See Simon, *supra* note 88, at 15 (“Becoming involved in ending an independent patient’s life [by deactivating an LVAD]—even one whose life is being prolonged by our previous actions (to which he consented)—would be impermissible. Medicine has no role in such cases.”); Wu, *supra* note 3, at 532 (“By consenting to having an implantable device placed, . . . the patient forfeits the right to request removal of the device without due cause. A doctor should not entertain requests for removal of a pacemaker which is functioning perfectly, just because the patient changes his mind after informed consent.”).

194. See Katie Thomas, *Unpredictable Danger Looms Close to the Heart*, N.Y. TIMES, Sept. 8, 2012, at A1 (reporting that, even though the FDA recently “recommended that all patients with the [St. Jude] Riata undergo imaging to see if their [ICD] lead was failing” but “advised against removing the leads pre-emptively,” a number of patients have opted to undergo the risky explantation procedure prophylactically). If a medical device manufacturer recalls an implant, courts generally have allowed recipients to recover the costs associated with explant surgery and accompanying emotional distress. See, e.g., *Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273, 1285–87 (Haw. 1992). If, however, explant surgery is not medically indicated but undertaken at the patient’s insistence, courts have rejected such claims. See, e.g., *O’Brien v. Medtronic, Inc.*, 439 N.W.2d 151, 152–54 (Wis. Ct. App. 1989). Where defects may require explantation in limited circumstances, plaintiffs instead may request “medical monitoring” costs. See, e.g., *In re Telectronics Pacing Sys., Inc.*, 172 F.R.D. 271, 276–78, 284–87 (S.D. Ohio 1997), *rev’d on other grounds*, 221 F.3d 870 (6th Cir. 2000); see also *Dillon v. Evanston Hosp.*, 771 N.E.2d 357, 366–70 (Ill. 2002) (allowing a claim for increased risk of future injuries where a catheter fragment became embedded in the wall of a patient’s heart and she had abided by medical advice against attempted removal).

195. See Thomas L. Hafemeister & Richard M. Gulbrandsen, Jr., *The Fiduciary Obligation of Physicians to “Just Say No” if an “Informed” Patient Demands Services That Are Not Medically Indicated*, 39 SETON HALL L. REV. 335, 373–74 (2009); see also Mitesh S. Amin et al., *Management of Recalled Pacemakers and Implantable Cardioverter-Defibrillators: A Decision Analysis Model*, 296 JAMA 412, 419 (2006); Paul A. Gould & Andrew D. Krahn, *Complications Associated with Implantable Cardioverter-Defibrillator Replacement in Response to Device Advisories*, 295 JAMA 1907, 1910 (2006) (“ICD generator replacement is not a benign procedure and carries a substantial risk of complications, which include death.”); David Brown, *Implantable Defibrillators Can Be Erratic, Studies Find*, WASH. POST, Apr. 26, 2006, at A8 (“[P]eople who learn that the device implanted in their chest may have a defect should think hard before having it replaced. Switching it out may be more risky than leaving it in.”); Barry Meier, *A Life or Death Decision*, N.Y. TIMES, Apr. 7, 2009, at B1 (describing some of the difficulties involved in removing defective ICD leads).

take wireless programmers out of the picture, so that the only way to deactivate a cardiac-assist device would require explantation. If a physician agreed to remove such a device at the patient's request, then death could result directly from a procedure that did not promise any therapeutic benefit. The HRS consensus statement included the following concession:

Patients might request removal of generator and/or leads rather than reprogramming. Since the same effect can be obtained by reprogramming and as surgical intervention carries with it significant chance of introduction of a new life-threatening pathology (e.g., infection, and/or mechanical complications of lead extraction), surgical intervention is not recommended. Legally, patients have a right to refuse any treatment, but do not have the right to demand mistreatment.¹⁹⁶

But, again, what if we assume away the ability to deactivate wirelessly—does the patient's right to withdraw consent then mean an ability to insist on explantation surgery?¹⁹⁷ Although the ease of noninvasive deactivation offered an easy out in this context,¹⁹⁸ the

196. Lampert et al., *supra* note 99, at 1012 (“A physician may judge the removal reasonable under the particular circumstances and do so with informed consent, but there is no ethical or legal obligation to meet this request.”). Occasionally, explantation may have medical justification. See Michael Geist et al., *Permanent Explantation of Implantable Cardioverter Defibrillators*, 23 PACING & CLINICAL ELECTROPHYSIOLOGY 2024, 2026, 2028 (2000).

197. Cf. Bramstedt & Wenger, *supra* note 93, at 545 (“Some devices, such as ventriculoperitoneal shunts, lack on/off settings and, after they have served their intended purpose and are no longer clinically needed, they are nonetheless not explanted due to surgical risks.”); Jansen, *supra* note 59, at 107 (“Not unreasonably, clinicians would balk at actively dismantling a patient's mechanical heart valve as a means to hastening his death. At least in most cases, such an intervention would plausibly be described as a killing rather than as a withdrawal of aid.”); Lampert et al., *supra* note 99, at 1012 (“Most would regard carrying out a request to deactivate a pacemaker in a terminally-ill patient as far less morally problematic than carrying out a request to remove an implanted porcine heart valve in the same patient. Deactivating a pacemaker is non-invasive and does not introduce a new pathology.”); Veatch, *supra* note 87, at 308 (imagining a scenario where removal would pose little separate risk: a lung cancer patient undergoing exploratory chest surgery); Wu, *supra* note 3, at 532 (“In devices that do not have an off button or require sustaining [e.g., drug] therapy, neither the doctor nor the patient has the right to remove it for futility or autonomy reasons, just as the practice has been for renal transplants for the past few decades.”).

198. See, e.g., Spike, *supra* note 84, at 26 (“[A] pacemaker is [more] like a portable ventilator [than an implanted heart valve], in that it is a life-sustaining mechanical device whose source of control is external to the patient's body.”). Ventricular assist devices may, however, pose additional complexities if not also explanted. See *supra* note 93 (discussing consequences of LVAD deactivation

doctrine of informed consent can at best only partially explain a patient's right to demand withdrawal of an implanted life-sustaining treatment.¹⁹⁹

Moreover, the prior decision to allow implantation of a cardiac-assist device seems to represent the polar opposite of an advance directive declining resuscitation—for instance, elderly patients might want an ICD as insurance against the fear that, in the event of a cardiac arrhythmia, health care professionals otherwise might not undertake resuscitation on grounds of futility²⁰⁰ (or, in the event of later incapacity, a surrogate

without explantation); *see also* Bramstedt & Wenger, *supra* note 93, at 546 (“In some ways, deactivating an LVAD is similar to turning off a ventilator, while leaving the endotracheal tube in place. This action would make spontaneous respiration even more difficult for the patient due to the increased dead space of the tube.”). Nonetheless, these commentators defended the ethical propriety of deactivation: “[A]lthough an implanted and yet unpowered LVAD may pose some clinical harm to the patient, it is not equivalent to active killing of the patient, as would be evident, for example, by infusion of a massive dose of potassium chloride.” *Id.* at 547. (“The distinction between removing the LVAD and other life-sustaining treatment is subtle but significant, and yet both are quite different than the active promotion of death by external intervention.”).

199. Consider this foundational premise in the HRS consensus statement: “If a clinician initiates or continues a treatment that a patient (or his/her surrogate) has refused, then ethically and legally the clinician is committing battery, regardless of the clinician’s intent.” Lampert et al., *supra* note 99, at 1010. In what sense does an electrophysiologist unlawfully “continue” treatment with a previously implanted CIED after a patient experiences a change of heart (pun intended)?! *Cf.* Sulmasy, *supra* note 56, at 69 (“Patients and cardiologists alike seem to view implanting an ICD as a ‘bridge’ that one crosses with no possibility of return.”); Veatch, *supra* note 87, at 307 (“We do not have a well-developed analysis of whether physicians faced with a refusal of continuing consent for the use of these implanted technologies must remove them—as they would a trach tube or ventilator—or must merely cease supporting their function. If they must merely back off from support, the[se] . . . would, of course, continue to function for some time.”).

200. *See* Richard A. Knox, *Study Finds ICU Doctors Withholding Treatment*, BOS. GLOBE, Feb. 18, 1995, at A1 (reporting that “doctors often act unilaterally to terminate life-sustaining treatment”); *see also supra* note 170. In one interesting article, a couple of physicians explained what they saw as the benefits of ICD deactivation at the end of life: “[I]n cases of terminal illness a sudden arrhythmic cardiac death may be desirable to potentially reduce the period of suffering.” Richard Kobza & Paul Erne, *End-of-Life Decisions in ICD Patients with Malignant Tumors*, 30 PACING & CLINICAL ELECTROPHYSIOLOGY 845, 845 (2007). Their survey of a small group of fully informed ICD patients with advanced cancer surprised them. *See id.* at 848 (“[A]lthough all six patients had previously suffered from an appropriate or inappropriate ICD shock, none approved deactivation of their ICD.”); *id.* (“[W]e [mistakenly] expected that some of our patients with an ICD and terminal cancer would have wished for a deactivation of their ICD.”); *see also* Anders Ågård et al., *Views of Patients with Heart Failure About Their Role in the Decision*

decisionmaker declines it²⁰¹). No doubt recipients may come to regret such choices, based perhaps on their experience with the devices²⁰² (or, as discussed herein, the development of an unrelated terminal illness not contemplated at the time of implantation²⁰³), but the informed consent doctrine fails to establish any subsequent right to insist on removal (or, by extension, the far less complicated step of wireless deactivation).²⁰⁴

to Start Implantable Cardioverter Defibrillator Treatment: Prescription Rather Than Participation, 33 J. MED. ETHICS 514, 517 (2007) (finding that some recipients view ICDs as “life insurance”); Garrick C. Stewart et al., *Patient Expectations from Implantable Defibrillators to Prevent Death in Heart Failure*, 16 J. CARDIAC FAILURE 106, 110 (2010) (“[M]ost [ICD patients surveyed] indicated that they would not consider inactivating defibrillation even in the presence of end-stage heart failure or other disease.”).

201. See Paola & Walker, *supra* note 172, at 20–21 (offering such an illustration, but making no mention of the original implantation decision as a relevant factor when the surrogate later consents to a DNR order). This could become important if a proxy requests CIED deactivation for an incompetent patient. Although individuals can always change their minds, and modify or rescind an advance directive, the implanted device, especially an ICD implanted in a situation where the patient has not (yet) experienced an arrhythmia, see Pasquale Santangeli et al., *Meta-Analysis: Age and Effectiveness of Prophylactic Implantable Cardioverter-Defibrillators*, 153 ANNALS INTERNAL MED. 592, 597–98 (2010), seems to speak loudly about the recipient’s preferences, see Rady & Verheijde, *supra* note 95, at 1087 (noting that, “if the device is deactivated without the onset of [an unrelated] life-threatening illness, then the mode of death is what patients have objected to when consenting to device implantation”); see also John A. Robertson, *Precommitment Issues in Bioethics*, 81 TEX. L. REV. 1849, 1854 (2003) (“[I]t strikes me as helpful to view the use of implantable defibrillators as a type of precommitment.”). Perhaps that means a default rule of deactivating CIEDs only at the insistence of patients at the end-of-life or by explicit mention in an advance directive.

202. See Arash Arya et al., *Prevalence and Predictors of Electrical Storm in Patients with Implantable Cardioverter-Defibrillator*, 97 AM. J. CARDIOLOGY 389 (2006); Margret Leosdottir et al., *Health-Related Quality of Life of Patients with Implantable Cardioverter Defibrillators Compared with That of Pacemaker Recipients*, 8 EUROPACE 168 (2006); Huagui Li et al., *Causes and Consequences of Discontinuation of the Implantable Cardioverter-Defibrillator Therapy in Non-Terminally Ill Patients*, 81 AM. J. CARDIOLOGY 1203, 1204 (1998).

203. See Jeffrey T. Berger et al., *Advance Health Planning and Treatment Preferences Among Recipients of Implantable Cardioverter Defibrillators: An Exploratory Study*, 17 J. CLINICAL ETHICS 72, 74, 76 (2006) (finding some “evolution of preferences” in this regard); Goldstein et al., *supra* note 33, at 11 (predicting the same); see also Stacey Burling, *Mechanical-Heart Patient Comes to Regret His Life-Saving Choice*, PHILA. INQUIRER, July 14, 2002, at A1; cf. Strachan et al., *supra* note 33, at 7 (“Interestingly, when asked to anticipate their preferences should they become terminally ill, the majority of patients with heart failure who received an ICD for primary prevention said they would not deactivate it, even if they were receiving daily shocks.”).

204. Separately, some commentators fear that denying a right of later withdrawal will make physicians and patients more apt to refuse potentially

C. *Navigating Imprecise Legislative Boundaries*

The characterization problem does not arise solely in constitutional and common-law litigation. Indeed, because ultimately the question boils down to whether physicians might risk prosecution, one must pay attention to ambiguities and variations among different state statutes as they might apply to the deactivation of implanted cardiac-assist devices.²⁰⁵ Most states have laws that allow individuals to execute advance directives to decline life-sustaining treatments and exempt physician involvement in such cases from prohibitions on assisting suicide.²⁰⁶ A few state laws go further and authorize physician-assisted suicide, though only in limited circumstances,²⁰⁷ while leaving withdrawal requests largely

beneficial interventions from the outset. See Cantor, *supra* note 44, at 1804–05 & n.65; Philip G. Peters, Jr. et al., *Physician Willingness to Withhold Tube Feeding After Cruzan: An Empirical Study*, 57 MO. L. REV. 831, 834–35 & n.17, 838–40 (1992). Whether or not this suffices to make the two types of choices equivalent, the available research on patient views of cardiac-assist devices suggests that it is highly unlikely to occur in this setting. As for physicians, perhaps they should think more carefully before implanting such devices in very elderly or frail patients. Lastly, of course, this concern presumably would not suffice to allow “deactivation” of transplanted hearts or other critical organs.

205. See Katherine Ann Wingfield & Carl S. Hacker, *Physician-Assisted Suicide: An Assessment and Comparison of Statutory Approaches Among the States*, 32 SETON HALL LEGIS. J. 13, 64 (2007) (finding a “wide degree of variation among the states with respect to physician-assisted suicide”).

206. See *Vacco v. Quill*, 521 U.S. 793, 796–97 & n.2, 805 n.9 (1997); Meisel, *supra* note 140, at 822 (“Passively hastening death includes refusal of treatment, termination of life support, forgoing treatment, or withholding and withdrawing treatment, and variants on these terms.”); Marni J. Lerner, Note, *State Natural Death Acts: Illusory Protection of Individuals’ Life-Sustaining Treatment Decisions*, 29 HARV. J. ON LEGIS. 175, 184–85 & n.45, 187–208, 212–21 (1992). Several states also create a limited safe harbor for “terminal sedation.” See *Washington v. Glucksberg*, 521 U.S. 702, 780 & n.15 (1997) (Souter, J., concurring); see also George P. Smith, II, *Terminal Sedation as Palliative Care: Revalidating a Right to a Good Death*, 7 CAMBRIDGE Q. HEALTHCARE ETHICS 382, 382 (1998). At least one state’s statute provides a non-exhaustive list of covered treatments. See Illinois Living Will Act, 755 ILL. COMP. STAT. § 35/2(d) (2012). Legislators also have amended these statutes to address ambiguities about whether they reach artificial nutrition and hydration. See MEISEL & CERMINARA, *supra* note 149, § 7.07[B].

207. See Oregon Death with Dignity Act, OR. REV. STAT. §§ 127.800–.897 (2012); Washington Death with Dignity Act, WASH. REV. CODE § 70.245 (2012); *Baxter v. State*, 224 P.3d 1211, 1222 (Mont. 2009); see also Katie Hafner, *In Ill Doctor, a Surprise Reflection of Who Picks Assisted Suicide*, N.Y. TIMES, Aug. 12, 2012, at A1 (noting limited use of the two statutes); Kim Severson, *Georgia Court Rejects Law Aimed at Assisted Suicide*, N.Y. TIMES, Feb. 7, 2012, at A19 (reporting that Vermont and Massachusetts are considering legislation to authorize physician-assisted suicide, while 37 states criminalize it).

unencumbered by any restrictions.²⁰⁸ Conversely, rather than rely on existing and generally applicable prohibitions on assisting suicide, a couple of states have enacted legislation specifically designed to ban physician aid in dying.²⁰⁹ Putting aside the relatively low likelihood of detection or prosecution, consensus statements from professional groups approving an end-of-life practice such as CIED deactivation provide no meaningful assurance against legal jeopardy in such cases.²¹⁰

D. “Kill” Switches to the Rescue?

Congress did not impose licensure requirements for medical devices until 1976, a move prompted in part by widely publicized pacemaker recalls.²¹¹ Over the last decade, the Food and Drug Administration (FDA) has confronted tricky regulatory difficulties with CIEDs, but these have revolved around the threat of malfunctions involving life-sustaining products,²¹² especially

208. Cf. Susan M. Wolf, *Holding the Line on Euthanasia*, HASTINGS CENTER REP., Jan.–Feb. 1989 (Special Supp.), at 13 (warning that recognition of a right to physician assistance might encroach on the heretofore broad right to decline or withdraw). In other words, even in places like Oregon, patients seeking physician assistance in deactivating cardiac-assist devices would prefer that it get characterized as a request for the withdrawal of life-sustaining treatment rather than PAS.

209. See Wingfield & Hacker, *supra* note 205, at 49–50 (Arkansas and Rhode Island). Perhaps feeling hemmed in by three of its neighboring states that allow the practice, Idaho passed such a law in 2011. See IDAHO CODE ANN. § 18-4017(3)–(6) (2012); see also *id.* § 18-4017(5)(b) (exempting a “health care professional who withholds or withdraws treatment or procedures” upon request from the patient or a proxy).

210. Cf. Lampert et al., *supra* note 99, at 1023 (“[T]here are European countries where deactivation of antibradycardia pacing in pacemaker dependent patient[s] is prohibited by law. It is therefore crucial that clinicians are aware of the legal situation in the country and jurisdiction in which they are practicing.”).

211. See Susan Bartlett Foote, *Loops and Loopholes: Hazardous Device Regulation Under the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act*, 7 ECOLOGY L.Q. 101, 102 & n.4 (1978); see also Robin Miller, Annotation, *Products Liability: Cardiac Pacemakers*, 23 A.L.R. 6TH 223 (2007 & Supp. 2012) (canvassing some of the case law that has emerged from tort litigation over pacemakers and ICDs).

212. See Kim A. Eagle, Editorial, *Safety Alerts Involving Device Therapy for Arrhythmias*, 286 JAMA 843, 844 (2001); William H. Maisel et al., *Pacemaker and ICD Generator Malfunctions: Analysis of Food and Drug Administration Annual Reports*, 295 JAMA 1901, 1904–05 (2006); Marc Kaufman, *More Heart Devices Malfunction; As Sophistication Has Grown, So Have Failures*, FDA Reports, WASH. POST, Sept. 17, 2005, at A7; see also Barry Meier, *F.D.A. Seeks Better Data from Tests of Devices*, N.Y. TIMES, Dec. 30, 2009, at B1 (summarizing reviews that found problems with the quality of information submitted to the agency in support of high-risk cardiovascular

questions about when to order recalls or recommend explantation.²¹³ Now, instead of potential failures or other safety problems, the agency also might have to worry that the devices work too well or last too long. Rarely, however, does “overefficacy” counsel against product approval,²¹⁴ and the FDA typically does not consider ethical questions when reviewing licensing applications.²¹⁵

To the extent that health care professionals refuse to assist, whether on ethical grounds or from fears of prosecution (well-founded or not),²¹⁶ a few commentators have called on

devices).

213. See Edward M. Basile & Beverly H. Lorell, *The Food and Drug Administration's Regulation of Risk Disclosure for Implantable Cardioverter Defibrillators: Has Technology Outpaced the Agency's Regulatory Framework?*, 61 FOOD & DRUG L.J. 251, 261, 265–69 (2006).

214. See Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 654–59, 663, 664–65 (2003) (concluding that the FDA should revisit previously granted licenses for ovulation-inducing agents because of their tendency to result in dangerous multifetal pregnancies); *id.* at 628 (“Normally, efficacy and safety operate independently of one another In the case of fertility drugs, however, the primary risk inheres in their very effectiveness.”).

215. See Dov Fox, *Safety, Efficacy, and Authenticity: The Gap Between Ethics and Law in FDA Decisionmaking*, 2005 MICH. ST. L. REV. 1135, 1197 (focusing on enhancement technologies, especially the approval of human growth hormone for otherwise healthy children of short stature, and concluding that “the FDA’s one-size-fits-all system of approval is unsuited to evaluate the ethical concerns accompanying the emerging class of medical products that act not to prevent disease or restore health, but instead to reduce wrinkles or enlarge breasts or sharpen memory”). The agency’s review of TAHs provided a stark illustration of this gap. See David Brown, *Artificial Heart Gets Limited FDA Approval: Device, Which Can Provide Extra Months of Life, Meets Humanitarian Provision*, WASH. POST, Sept. 6, 2006, at A8 (discussing the fully implanted AbioCor, which extended patients’ lives by approximately four months at a cost of \$350,000); Rob Stein, *FDA Approves Artificial Heart for Those Awaiting Transplant; Doctors Hail the \$100,000 Device, but Critics Question Whether Cost Is Justified*, WASH. POST, Oct. 19, 2004, at A3 (reporting that SynCardia’s update of the Jarvik-7 as a bridge to transplant represented a milestone as “the first [FDA-approved device] to supplant most of the functions of the heart or any other major organ,” but adding that “critics questioned the value of the \$100,000 device, saying it will only add expense to the nation’s already bloated health care bill without increasing the number of heart patients who survive” because it does nothing about the underlying shortage of organs available for transplant).

216. See Farr A. Curlin et al., *Religion, Conscience, and Controversial Clinical Practices*, 356 NEW ENG. J. MED. 593, 596 tbl.1 (2007) (finding, for instance, that 17% of surveyed physicians objected to terminal sedation); *id.* at 597 (adding that “29% of patients—or nearly 100 million Americans—may be cared for by physicians who do not believe they have an obligation to refer the patient to another provider for such [controversial] treatments”); Lampert et al., *supra* note 99, at 1013 (recognizing that conscientious objectors could decline to deactivate

manufacturers to supply recipients with clear directions or a simple mechanism for disabling implanted cardiac-assist devices.²¹⁷ Insofar as physicians often fail to broach the subject at the time of implantation, the FDA could require better patient labeling that included such information.²¹⁸ Less plausibly, the agency could demand the inclusion of patient-controlled remote deactivation switches in the design of these devices, but, even if one could overcome serious practical difficulties, any technological fix empowering patients to act on their own undoubtedly would trigger a variety of objections.

V. CONCLUSION

This hardly represents the first time that technological advances have affected previously settled legal lines.²¹⁹ In the

CIEDs); Alan Meisel et al., *Seven Legal Barriers to End-of-Life Care: Myths, Realities, and Grains of Truth*, 284 JAMA 2495, 2495–96 (2000).

217. See Deborah Grassman, Letter, *EOL Considerations in Defibrillator Deactivation*, 22 AM. J. HOSPICE & PALLIATIVE MED. 179, 179 (2005) (wondering whether ICD manufacturers should take responsibility for supplying printed patient education materials and perhaps also magnets allowing for self-deactivation); Raphael et al., *supra* note 33, at 1632 (“We looked at the possibility of a variable switch-off mode for future device development. . . . Theoretically, toward the end of life, the [ICD] could be programed so it was inactive while the patient was asleep, allowing a peaceful death from natural causes if a life-threatening arrhythmia were to occur during this time.”); cf. Lampert et al., *supra* note 99, at 1021 (“suggest[ing] that clinicians consider providing a doughnut magnet (along with specific instructions on its use) to [ICD] patients who are diagnosed with a terminal illness”). Researchers gave the first recipient of an artificial heart just such a mechanism. See James Rachels, *Barney Clark’s Key*, HASTINGS CENTER REP., Apr. 1983, at 17.

218. Recently, the agency has mandated that physicians secure written informed consent from patients—coupled with other restrictions on prescribing and dispensing certain drugs—though in order to ensure against inappropriate use that carries serious risks of injury. See Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 188–91 (2004) (discussing a variety of distribution restrictions on prescription drugs considered by regulatory officials); Lars Noah, *Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice*, 44 SAN DIEGO L. REV. 231, 234–36 (2007) (focusing on teratogens such as Accutane and Thalomid); see also Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85, § 901(b), 121 Stat. 823, 930 (codified at 21 U.S.C. § 355–1(f)(3)(A) (2012)) (granting the FDA express authority to impose such restrictions).

219. See Michael H. Shapiro, *Constitutional Adjudication and Standards of Review Under Pressure from Biological Technologies*, 11 HEALTH MATRIX 351, 385–86, 417–18, 422–27, 484–86 (2001); *id.* at 462 (“[A]lterations in the technological terrain have pushed us beyond simple conceptualizations of life and death.”); *id.* at 468 (referring to “category straddling induced by technological changes”); see also *id.*

context of abortion, for example, improvements in neonatology have dramatically lowered the threshold of fetal viability,²²⁰ thereby undermining the trimester framework suggested in *Roe v. Wade*.²²¹ Some critics might respond that CIEDs offer further evidence of incoherence in the distinctions originally drawn by the Supreme Court in the right-to-die cases,²²² though proponents of those lines likely would not relent, instead taking comfort in the views of most medical ethicists that equate deactivation with the permissible withdrawals of other forms of life-sustaining treatment. Perhaps categorical judgments (one way or another) ultimately must remain elusive—homogeneity does not exist among implanted cardiac-assist devices, much less among the various patients who might request their deactivation—so that one cannot escape paying greater attention to nuance, especially the extent to which a patient is device dependent (both in the sense that the implant has turned a terminal illness into a successfully managed chronic condition, and in the sense that withdrawal likely spells doom for the patient).

Implanted cardiac-assist devices pose serious challenges to the well-accepted equivalence between refusing and requesting the withdrawal of life-sustaining treatments. No doubt many judges would find deactivation lawful because—perhaps taking a cue from the near consensus among medical ethicists—it shares enough superficial similarities with the withdrawal of other interventions.

at 442 (cautioning against “exaggerat[ing] the degree of conceptual innovation that constitutional jurisprudence will have to bear as biomedical technology develops”).

220. See Kathy L. Kyser et al., *Improving Survival of Extremely Preterm Infants Born Between 22 and 25 Weeks of Gestation*, 119 *OBSTETRICS & GYNECOLOGY* 795, 800 (2012); Noah, *supra* note 214, at 619–20 & nn.70–71; Christine Hauser, *For the Tiniest Babies, the Closest Thing to a Cocoon*, *N.Y. TIMES*, May 29, 2007, at F1 (reporting that the record for viability had dropped below 22 weeks of gestation).

221. 410 U.S. 113, 163–65 (1973); *see also id.* at 160 (conceding that viability may occur earlier); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 860, 870 (1992) (recognizing this development); *id.* at 872–73 (rejecting as unduly “rigid” the trimester framework); Nancy K. Rhoden, *Trimesters and Technology: Revamping Roe v. Wade*, 95 *YALE L.J.* 639, 641, 655–62 (1986) (same); Jessica H. Schultz, Note, *Development of Ectogenesis: How Will Artificial Wombs Affect the Legal Status of a Fetus or Embryo?*, 84 *CHI.-KENT. L. REV.* 877, 886–88 (2010) (anticipating the consequences of possible future advances); *cf.* John Leland, *Abortion Might Outgrow Its Need for Roe v. Wade*, *N.Y. TIMES*, Oct. 2, 2005, § 4, at 14 (explaining that, “while combatants focus on the law, technology is already changing the future of abortion,” particularly with the off-label use of misoprostol to induce a miscarriage).

222. *Cf.* Orentlicher, *supra* note 146, at 963–64 (making such a point about the Court’s willingness to countenance terminal sedation).

Even if patients should enjoy the freedom to cease using implanted cardiac-assist devices, I have little use for such charades.²²³ Deactivation represents a distinctive form of physician aid in dying, one that we should allow candidly rather than by pretending that it fits comfortably within the existing category of permissible withdrawals of life-sustaining treatment.²²⁴ Thus, states should consider amending their statutes to clearly authorize physician deactivation of some or all cardiac-assist devices,²²⁵ subject to whatever collateral restrictions seem appropriate. In addition to confirming the legality of deactivation, revisions to these advance directive statutes should prompt specific questions about patients' wishes about the continued use of their implanted cardiac-assist devices.

223. See Cantor, *supra* note 44, at 1841 (objecting to “the hypocrisy of pretending that contemporary American society truly bars PAD [physician-assisted death]”); cf. Lars Noah, *A Postmodernist Take on the Human Embryo Research Debate*, 36 CONN. L. REV. 1133, 1152–61 (2004) (lambasting an effort to sidestep controversy over research using embryonic stem cells simply by redefining certain terms); Lars Noah, *Civil Jury Nullification*, 86 IOWA L. REV. 1601, 1638–52 (2001) (decrying judicial tolerance of jurors' tendencies to disregard their instructions in tort litigation); Lars Noah, *Pigeonholing Illness: Medical Diagnosis as a Legal Construct*, 50 HASTINGS L.J. 241, 296–306 (1999) (criticizing physician dishonesty).

224. Twenty years ago, one prominent bioethicist drew the following conclusion pertinent to this set of problems:

There is no denying that a substantial moral and legal consensus exists about how to handle most cases involving forgoing of life-sustaining treatment. The core elements seem firmly established. Yet as we apply that consensus to more and more cases we discover novel situations to which the consensus cannot be applied directly. Unlike the controversy over active mercy killing, it is not necessarily that there is enormous moral or legal disagreement about these cases. Rather we are discovering new twists on the old problems for which our old principles . . . do not provide clear conclusions. We are ready for a new generation of moral debates in the ethics of terminal care from which newer, more subtle guidelines will have to emerge.

Robert M. Veatch, *Forgoing Life-Sustaining Treatment: Limits to the Consensus*, 3 KENNEDY INST. ETHICS J. 1, 17–18 (1993).

225. See Paola et al., *supra* note 148, at 37 (concluding that a DNR order would allow for ICD deactivation, but adding that “clarification via an amendment to the [applicable New York] statute or the regulations would be welcome”); cf. Timothy E. Quill et al., *Palliative Options of Last Resort: A Comparison of Voluntarily Stopping Eating and Drinking, Terminal Sedation, Physician-Assisted Suicide, and Voluntary Active Euthanasia*, 278 JAMA 2099, 2104 (1997) (“Explicit public policies about which of these 4 practices are permissible and under what circumstances could have important benefits.”). But cf. Brody, *supra* note 137, at 962 n.68 (“[T]here is relatively little established law, either statutory or case law, regarding these ‘fence-sitting’ cases. . . . Many physicians probably prefer that the law remain silent on these cases and that they be handled in the future by medical discretion . . .”).