MATTERS OF THE HEART—KEEPING PACE WITH SCIENCE, ETHICS, AND THE LAW IN DEACTIVATION OF CARDIOVASCULAR IMPLANTABLE ELECTRONIC DEVICES, INCLUDING PACEMAKERS

James H. Pietsch

Pacemakers have been around for over half a century. However, despite the frequent use of pacemakers as a medical device, a decision to turn a pacemaker off can still prompt difficult legal and ethical questions. This Article focuses on a ninety-one-year old retired US Navy veteran who wanted to know if he could have his pacemaker deactivated. Whether deactivating a pacemaker will immediately lead to the death of a patient is dependent on that patient's specific heart condition but, under most circumstances, deactivating a pacemaker can be differentiated from physician-assisted suicide. This Article will explore the various laws and professional guidelines that govern decisions to deactivate cardiovascular implantable electronic devices, including pacemakers, and will also explore the laws and regulations that federal health care facilities, including military medical treatment facilities, must adhere to when deciding whether to deactivate such devices.

James H. Pietsch is a Professor of Law at the William S. Richardson School of Law and an Adjunct Professor at the John A. Burns School of Medicine in Honolulu, Hawaii. Prof. Pietsch has served in both the US Army Medical Service Corps and Judge Advocate General's Corps. Prof. Pietsch teaches various law courses in the fields of Health and Elder Law and is the Director of the University of Hawaii Elder Law Program. Prof. Pietsch has extensive writing experience, having published legal articles as well as having contributed to several books and handbooks. Prof. Pietsch received his J.D. from the Columbus School of Law at the Catholic University of America in 1974. He gives special thanks to Neva Keres, Winter Quinn, Elizabeth Bowman and Brandon Singleton for their contributions to this project.

The author was approached by a ninety-one-year-old retired military member's family with respect to legal/bioethical issues related to the retiree's health care received at an Army Medical Center (not a Department of Veterans Affairs Medical Center, although the retiree is, of course, also a veteran). The issues centered on the patient's desire to have his pacemaker deactivated. He had done some research on the subject and cited the Heart Rhythm Society (HRS) "Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs)" in "Patients Nearing End of Life or Requesting Withdrawal of Therapy" to support his request. He did not see this as assisted suicide (even though he may not survive without the pacemaker), but only as a question of his choice about "whether or not to have artificial support in his body." He does not think of himself as "terminal." While there is no certainty that he would die immediately if the pacemaker is deactivated, it is not unlikely. The Army cardiologist was supportive and, later, an appointment was scheduled to talk

^{1.} Rachel Lampert et al., HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in Patients Nearing End of Life or Requesting Withdrawal of Therapy, 7 HEART RHYTHM. 1008 (2010) [hereinafter Lampert]. This document was developed in collaboration and endorsed by the American College of Cardiology (ACC), the American Geriatrics Society (AGS), the American Academy of Hospice and Palliative Medicine (AAHPM); the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), and the Hospice and Palliative Nurses Association (HPNA). This consensus statement will be discussed in detail in this article. 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) [hereinafter Padeletti].

^{2.} Summary of patient's health care from the perspective of his current cardiologist (on file with the author) states:

The patient is a retired Navy Captain (O-6). The patient has a history of a tachycardia mediated cardiomyopathy diagnosed after his cardiac bypass surgery for coronary artery disease. Based on the doctor's review of the records, there was significant difficulty keeping him in a normal rhythm and he had significant fatigue from heart rate lowering medications, though they appear to have been effective. For this reason he was referred for atrial flutter ablation, but he continued to have symptomatic atrial fibrillation, so AV node ablation and permanent pacemaker were performed. AV node ablation is destruction of the AV node so that it can no longer transmit electrical impulses from the top chambers of the heart to the bottom chambers. This makes the patient dependent on a pacemaker for their heart to beat at an appropriate rate to maintain daily function. The current cardiologist did not have access to the previous cardiologist's notes, so she could not comment on any discussions he and the patient had prior to this procedure. She could report that the patient was advised that he would be pacemaker dependent after this procedure, but she did not see any documentation of discussions regarding deactivation.

more about the deactivation. The hospital ethics committee was convened to address the question and, in the process, a request for legal advice was sought. The Center Judge Advocate sought guidance from the Staff Judge Advocate at their headquarters, the United States Army Medical Command (MEDCOM), which issued an opinion that "such a deactivation would constitute 'physician-assisted suicide' under the Federal Assisted Suicide Funding Restriction Act of 1997," which prohibits using federal funds to support physician-assisted suicide." However, this opinion did not address exceptions in the statute relating to the withholding or withdrawing of medical treatment or medical care, 5 the heart of the story that now begins.

- 3. 42 U.S.C. § 14401 (2012) ("(a) Findings Congress finds the following: (1) The Federal Government provides financial support for the provision of and payment for health care services, as well as for advocacy activities to protect the rights of individuals.
- (2) Assisted suicide, euthanasia, and mercy killing have been criminal offenses throughout the United States and, under current law, it would be unlawful to provide services in support of such illegal activities.
- (3) Because of recent legal developments, it may become lawful in areas of the United States to furnish services in support of such activities.
- (4) Congress is not providing Federal financial assistance in support of assisted suicide, euthanasia, and mercy killing and intends that Federal funds not be used to promote such activities.
- (b) Purpose It is the principal purpose of this chapter to continue current Federal policy by providing explicitly that Federal funds may not be used to pay for items and services (including assistance) the purpose of which is to cause (or assist in causing) the suicide, euthanasia, or mercy killing of any individual.").
- 4. Email from patient to author (May 16, 2016) (on file with author).
- 5. 42 U.S.C. § 14402 (2012) ("(b) Construction and treatment of certain services Nothing in subsection (a) of this section, or in any other provision of this chapter (or in any amendment made by this chapter), shall be construed to apply to or to affect any limitation relating to--
- (1) the withholding or withdrawing of medical treatment or medical care;
- (2) the withholding or withdrawing of nutrition or hydration;
- (3) abortion; or
- (4) the use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.").

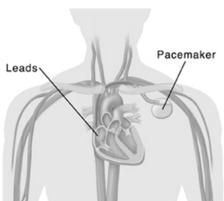
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Pacemakers⁶

Pacemakers (PM₂) have been around for over half a century.⁷ In 1958, the Veterans Administration invented the implantable cardiac pacemaker, "helping many patients prevent potentially lifethreatening complications from irregular heartbeats." The procedure is not complicated although the device is sophisticated. According to the Department of Veterans Affairs?

A pacemaker is a small electronic device that helps your heart's electrical system. It keeps your heart beating at the right pace. Inserting the pacemaker into your body is called IMPLANTATION. You stay awake during the procedure. You may be asked some questions or be asked to take some deep breaths.





^{6.} The author believes that a descriptive summary of pacemakers is helpful to understand the issues presented in this article. The Department of Veterans Affairs pioneered the development of implantable cardiac devices including pacemakers and its description is used in this article.

^{7.} See generally William M. Chardack et al., A Transistorized, Self-contained, Implantable Pacemaker for the Long-term Correction of Complete Heart Block, 48 SURGERY 643 (1960) [hereinafter Chardack].

^{8.} U.S. DEP'T OF VETERANS AFF., TIMELINE OF ACCOMPLISHMENTS (Jan. 12, 2017), http://www.research.va.gov/about/history.cfm; see also Chardack, supra note 7, at 654; William M. Chardack, Andrew A. Gage, & Wilson Greatbatch, A transistorized, self-contained, implantable pacemaker for the long-term correction of complete heart block, 48 SURGERY 643, 654 (1960).

^{9.} U.S. DEP'T OF VETERANS AFF., HEALTH ENCYCLOPEDIA (Dec. 9, 2015), http://www.veteranshealthlibrary.org/Encyclopedia/142,82031_VA (defining pacemakers).

During the Procedure

- A LOCAL ANESTHETIC IS GIVEN by injection to numb the area where the pacemaker will be inserted. This keeps you from feeling pain during the procedure.
- AN INCISION IS MADE where the generator is placed.
- THE LEAD (TRANSMITS TO AND FROM YOUR HEART) IS GUIDED through a vein into your heart's chambers using x-ray monitors
- The pacemaker generator is attached to the lead or leads.
- THE PACEMAKER'S SETTINGS ARE PROGRAMMED to help your heart beat at a rate that's right for you.

After the Procedure

- You will stay in the hospital a day or two.
- Your pacemaker settings will be rechecked.
- Follow the instructions you are given for caring for the implantation site. You will likely be told not to raise the arm on that side for a certain amount of time.
- Take your temperature and check your incision for signs of infection every day for a week.
- Return for a follow-up visit as directed by our staff.

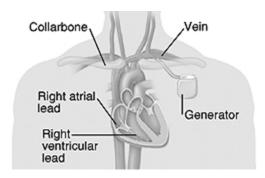
ICDs¹⁰

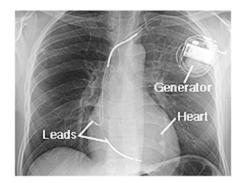
An ICD is a device that is placed permanently inside your body. An ICD monitors your heart rhythm (the speed and pattern of your heartbeat). If this rhythm becomes too fast or too slow, the ICD sends out electrical signals (including either pacing, or sometimes, high-energy shocks) that help bring the rhythm back to normal. The ICD is put inside your body during a minor surgical procedure called IMPLANTATION. In most cases, implantation takes 1 to 3 hours.

^{10.} U.S. DEP'T OF VETERANS AFF., HEALTH ENCYCLOPEDIA (Dec. 9, 2015), http://www.veteranshealthlibrary.org/TestsTreatments/Treatments/142,82025_VA (defining Implantable Cardioverter Defibrillator (ICD)).

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FIGURE 2





How the ICD Is Put into the Body

The ICD is usually implanted on the left side of your chest. Implantation does not require open-heart surgery (your chest will not be opened). During implantation:

- An incision is made in the skin below the collarbone. This creates a "pocket" to hold the ICD.
- A lead (wire) is threaded through the incision into a vein in the upper chest. With the help of x-ray monitors, the lead is then guided into one of the heart's chambers. Depending on how many leads your ICD has, this process may be repeated to guide leads into other chambers.
- The leads are attached to the heart muscle so they will stay in place.
- The generator (battery) is attached to the leads. Then the generator is placed in its pocket under the skin.
- A fast heart rhythm may be induced (started) to test the ICD.
- When everything else is done, the incision is closed with sutures, medical glue, or staples.

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Other Implantation Sites

In some cases, the ICD can be put elsewhere in the body. This could be in the abdomen, on the right side of the chest, or on the left side under the muscle. If one of these is an option for you, your doctor will explain more.

AFTER THE PROCEDURE

You'll stay in the hospital at least overnight. While in the hospital, your heart's signals are monitored to see how the ICD is working. You can go home when your condition is stable. Once you get home:

Follow your discharge instructions to care for your incision. Watch for signs of infection (see box).

Follow any special instructions to care for the side of your body where your ICD was implanted. Your doctor may tell you not to raise that arm above the shoulder for a certain amount of time.

You'll likely have bruising at the incision site for about a month. This is normal and will go away as the incision heals.

You can probably return to your normal routine soon after implantation. Ask your doctor when you can return to work.

You may be instructed not to drive for a certain amount of time.

See your doctor for follow-up visits as recommended.

NOTE: THE ICD BATTERY WILL NEED TO BE REPLACED EVERY FEW YEARS. TALK WITH YOUR DOCTOR TO LEARN MORE.

There are probably several million Americans with cardiovascular implantable electronic devices (CIEDs) such as pacemakers and defibrillators and at least 225,000 pacemakers and 133,000 defibrillators are implanted each year, but few discussions about deactivation seem to occur prior to implantation. These devices can help sustain life, but they can also prolong the dying process or even the suffering of patients who may have debilitating medical conditions. Most patients with CIEDs are not prepared to address the issue. A study of Mayo Clinic patients showed that patients seeking to deactivate their CIEDs share a common profile they are mostly male, old, and very sick.

^{11.} See Harry G. Mond & Alessandro Proclemer, M.D., The 11th World Survey of Cardiac Pacing and Implantable Cardioverter-Defibrillators: Calendar Year 2009–A World Society of Arrhythmia's Project, 34 PACE 1013 (2011); see also Paula Span, A Decision Deferred: Turning Off the Pacemaker (Jan. 29, 2014), http://newoldage.blogs.nytimes.com/2014/01/29/a-decision-deferred-turning-off-the-pacemaker/; Lillian C. Buchalter et al., Features and Outcomes of Patients Who Underwent Cardiac Device Deactivation, 174 JAMA INTERNAL MEDICINE 80, 81 (Jan. 2014), http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1783304?resultClick

^{12.} Buchalter, *supra* note 11, at 82. In a survey of 150 patients at the Mayo Clinic, more than half had signed advance directives, but of those, only one specifically mentioned a CIED.

^{13.} See generally id.

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More than half of the patients with CIEDs surveyed had advance directives. ¹⁵ However, almost none of those advance directives addressed the patient's implanted device. ¹⁶

Unwanted CIEDs may seriously impair quality of life for patients.¹⁷ In a survey of patients with implantable cardioverter-defibrillators (ICDs), during the last few weeks of their lives, twenty percent of the patients received shocks which were painful and the experience greatly increased the stress of patients and their families.¹⁸ By contrast, deactivation of a pacemaker is a painless process.¹⁹ A pacemaker may be remotely programmed to lower its output rendering it non-functional, while the functions of an ICD can be suspended by simply placing a magnet over it.²⁰

While implanting CIEDs has become a standard practice, the prospect of deactivating them is still often uncertain. What is certain is that all patients with implanted CIEDs will eventually die, either because of their heart conditions or the development of another terminal illness. Physicians, nurses, and other health care providers are increasingly dealing with the prospect of CIED deactivation. In a study of health care providers who primarily interacted with patients with CIEDs, most had participated in device deactivations. However, many physicians, patients, and families report uneasiness in discussing the topic of managing the devices, especially in the context of end-of-life decision-making.

Implantation of CIEDs is a standard service provided to authorized military healthcare beneficiaries such as the patient who is the subject of this article. ²⁵ TRICARE, the health care program that provides health benefits to military members and veterans, covers the

^{14.} Id.

^{15.} Id.

^{16.} Id.

^{17.} See generally Lampert, supra note 1.

^{18.} Id. at 1008.

^{19.} *Id*.

^{20.} *Id.* at 1021.

^{21.} *Id*.

^{22.} *Id.* at 1015.

^{23.} Paul S. Mueller et al., *Deactivating Implanted Cardiac Devices in Terminally Ill Patients*, 31 PACE 560 (May 2008) [hereinafter Mueller].

^{24.} Lampert, supra note 1, at 1008.

^{25.} See TRICARE REIMBURSEMENT MANUAL: PERSPECTIVE PAYMENT METHODOLOGY 6010.58-M, at 33 (Feb. 1, 2008), http://manuals.tricare.osd.mil/DisplayManualPdfFile/TO08/1/AsOf/TR08/C13S3.PDF.

cost of implantation and replacement of CIEDs, such as pacemakers.²⁶ While CIEDs are readily available, the existing military healthcare program should address not only implantation, but also continued maintenance of and potential deactivation of CIEDs, to improve patient autonomy and to enhance informed consent.

The Heart of the Matter: Whether cardiac devices may be withdrawn or deactivated if therapy is ineffective, no longer needed, or not desired.

Deactivation of pacemakers has been the subject of much discussion over the years.²⁷ Stopping a cardiac pacemaker may lead to death within minutes, or may not be a factor in the final cause of

27. See, e.g. Mueller, supra note 23. This article describes the practices and attitudes of physicians, nurses, and other health-care workers regarding deactivation of pacemakers and ICDs in terminally ill patients; see also Eric Widera, Is Deactivating a Cardiac Pacemaker Euthanasia? GERIPAL: A GERIATRICS AND PALLIATIVE CARE BLOG (September 4, 2014), http://www.geripal.org/2014/09/deactivating-cardiac-pacemaker.html. The focus of the blog is to separate deactivation of pacing devices from euthanasia (or physician-assisted suicide). The blog explains that the main difference between deactivation and euthanasia is intent. The intent behind both euthanasia and physician-assisted suicide is "relief of suffering through death." However, the main intent in pacemaker deactivation is to respect the patients' or surrogates' choice to discontinue an unwanted medical treatment. The blogger emphasizes that even though death might result, "death is not the means to meeting the intent of deactivation." See also Dario Pasalic et al., "The Prevalence and Contents of Advance Directives in Patients with Pacemakers," NAT'L INST. OF HEALTH, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3981886/pdf/nihms 531503.pdf (last visited Mar. 30, 2017). This article is about a retrospective review of the medical records of residents of Olmstead County, MN, who underwent implantation of cardiac pacemaker, at Mayo Clinic during 2006 and 2007 and determined the prevalence and contents of advance directives in these patients.

Results/conclusions: more than half of the patients with pacemakers had executed an advance directive but only one had specifically mentioned her pacemaker in her advance directive. Therefore, patients with pacemakers should be encouraged to execute advance directives and specifically mention their end-of-life device management in their advance directive (doing so may help prevent end-of-life eth-ical dilemmas).

The article also states that it *is* ethically and legally permissible to deactivate a cardiac pacemaker, so long as the patient or the surrogate has given informed consent. Sufficient informed consent must include the consequences of, and alternatives to, deactivation. Furthermore, the article recommends adding pacemaker deactivation into a patient's advanced directive to minimize ethical dilemmas at the end of life; AMA, *Heart Devices Can Be Turned Off Near End of Life;* AMEDNEWS (May 31, 2010), http://www.amednews.com/article/20100531/profession/305319943/4/. This article discusses the ethical and legal justification for cardiac pacemaker deactivation set out by the Heart Rhythm Society's Consensus Statement.

^{26.} Id.

death.²⁸ Even prior to the Heart Rhythm Society consensus statement, healthcare providers had discussions whether cardiac devices may be withdrawn or deactivated if therapy is ineffective, no longer needed, or not desired.²⁹ Some argue that disabling ICD shocks is analogous to a do-not-resuscitate order and is ethically permissible whereas withdrawing pacing from a pacemaker-dependent patient is an act of intentionally hastening death and not morally licit.³⁰ Some suggest that the right to refuse treatment applies to treatments involving ongoing physician agency and that this right cannot underwrite patient demands that physicians reverse the effects of treatments previously administered in which ongoing physician agency is no longer implicated, such as the permanently indwelling pacemaker.³¹ Deactivating ICDs as opposed to pacemakers does not seem to be controversial under most circumstances.³²

Some suggest that physicians ought to initiate a deactivation conversation, whether for ICDs or PMs, ideally at the time of implantation.³³ Some also suggest that the institutions that serve patients with such devices should promulgate guidelines for deactivation.³⁴ The subject has been discussed for decades,³⁵ and there are continuing sto-

^{28.} RJ Reitemeier et al., *Retiring the Pacemaker*, HASTINGS CENT. REP. 24, 24-26 (Jan. 1997), https://www.jstor.org/stable/pdf/3528022.pdf [hereinafter Reitemeier].

^{29.} Debra Lynn-McHale Wiegard & Peggy G. Kalowes, Withdrawal of Cardiac Medications and Devices, 18 AACN ADVANCED CRITICAL CARE 415, 415-425 (Dec. 2007), http://www.nursingcenter.com/journalarticle/Article_ID=751941#P120.

^{30.} See, e.g., G. Neal Kaye & Frank Pelosi, An Ethical Analysis of Withdrawal of Therapy in Patients with Implantable Cardiac Electronic Devices: Application of a Novel Decision Algorithm, 80 THE LINACRE QUARTERLY 308, 308-16 (Oct. 2013).

^{31.} See, e.g., Thomas Stewart Huddle & F. Amos Bailey, *Pacemaker Deactivation: Withdrawal of Support or Active Ending of Life*, 33 THEORETICAL MED. AND BIOETHICS 421, 421-33 (Feb. 2012) (outlining some of the theoretical objections to deactivating a pacemaker).

^{32.} See, e.g., Daniel B. Kramer et al., Time for a Change—A New Approach to ICD Replacement, 366 N. ENGL. J. MED. 291, 291-93 (Jan. 26, 2012). In discussing ICDs the authors indicate "[f]or many patients, changes in values and preferences since initial implantation may shift the balance of risks and benefits of device therapy. For example, progressive heart failure or end-stage renal disease with multiple hospitalizations may change a patient's perspective on sudden death in relation to other possible outcomes...."

^{33.} See, e.g., Cynthiane Morgenweck, Ethical Considerations for Discontinuing Pacemakers and Automatic Implantable Cardiac Defibrillators at the End-of-Life, 26 CURRENT OP. IN ANAESTHESIOLOGY 171, 171-75 (Mar. 2013).

^{34.} Id.

^{35.} See, e.g., Reitemeier, supra note 28. The particular case studies Mr. S, a seventy-four year old male resident in a skilled nursing facility. Mr. S became ill with a cardiac condition, which required bypass eighteen years prior to the study and then a pacemaker five years before. Mr. S's mental health deteriorated to an extent

ries of families struggling with this issue, but doctors and patients do not seem to be prepared.³⁶

Clinical Practice Guidelines (CPGs)

Increasingly, clinical practice guidelines are being incorporated into the practice of medicine to provide healthcare providers (and ultimately, patients) guidelines covering a variety of medical practices.³⁷

that his wife (Mrs. S) of fifty years could no longer care for him at home. Dementia and Alzheimer's made recognition of his wife, his son, and the medical staff nearly impossible. These ailments have progressed enough so that Mr. S does not express any willful desires, is confined to bed, neither initiates nor refuses movement, and does not communicate at all. Mr. S has a DNR order that also prohibits any artificial nutrition or hydration. Everyone involved agrees that Mr. S would not wish to continue living in this state and would request termination of medication and deactivation of his pacemaker. A problem arises when Mr. S's internist agrees to discontinue the cardiac medication but does not agree to deactivate the pacemaker without a cardiologist's approval. The cardiologist refused to even discuss pacemaker deactivation and the manufacturer technicians said they could not turn it off without a physician's order. In their commentary, Paul Reitemeier and Arthur Derse conclude that patients have the right to request withdrawal or termination of any medical treatment, regardless of whether stopping the therapy will hasten death. They further concede that the cardiologist should have discussed this with the patient and his family before implanting the pacemakers. Thorough informed consent should include alternatives, risks, and the option of refusing treatment altogether. Furthermore, the cardiologist should have made known any moral struggle he had with discontinuing pacemaker treatment prior to implantation. "Is an implanted pacemaker a medical treatment that, once begun, can be withis the main issue at hand, according to another commentator, Jeffrey Spike. Spike compares a pacemaker to both an implanted heart valve and a portable ventilator. It is similar to a heart valve because it is surgically implanted into the body and both devices are used until they can no longer function. According to Spike, the better analogy is the ventilator because deactivating it does not require surgery or an invasive procedure. Furthermore, like ventilators, deactivation can cause death within minutes or could not even be a factor in the final cause of death. The commentator disagrees with the most common reason given to refuse deactivation, that the pacemaker is not burdensome to the patient. He reasons that it is unconvincing because a feeding tube is not burdensome, yet feeding tubes are regularly "stopped if the life it prolongs is burdensome to the person living it." Finally, a pacemaker is most similar to an ICD. Spike argues that an ICD deactivation and DNRs should be equally accepted because they are functionally and ethically the same. Spike concludes that they should find a cardiologist who will deactivate Mr. S's pacemaker.

36. Katy Butler, What Broke My Father's Heart, N.Y. TIMES (June 18, 2010), http://www.nytimes.com/2010/06/20/magazine/20pacemaker-t.html?page wanted=all&_r=1. This story is about the life and death of her father, a retired college professor who had a pacemaker installed shortly after he was diagnosed with dementia. Although the patient had signed an advanced directive expressing his desire not to have his life prolonged artificially and did not wish to be a burden to his wife or children, the family was devastated by its experience in trying to deactivate his pacemaker.

Integrating evidence-based medicine (EBM) into the U.S. healthcare system is essential to recent healthcare reform strategies and one of the main ways to implement EMB is by utilizing clinical practice guidelines (CPGs).³⁸

The U.S. Congress, through the *Medicare Improvements for Patients and Providers Act of 2008*, asked the Institute of Medicine (IOM) to undertake a study on the best methods used in developing clinical practice guidelines, and the IOM developed eight standards for developing rigorous, trustworthy clinical practice guidelines.³⁹

37. See Arnold J. Rosoff, The Role of Clinical Practice Guidelines in Healthcare Reform: An Update, 21 ANNALS OF HEALTH A. 21, 21-33 (2012), http://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1013&context=annals.

38. *Id.* at 21. This article highlights some of the main developments in the CPG movement over the last two decades and emphasizes "formulating CPGs and making them available to practicing physicians is a vital step towards achieving and maintaining universal health care (UHC) in the US." According to the article, UHC is "a national regime where all have adequate access to quality health care. The following bulleted points are from the article:

The following bulleted points are from the article: As defined by the IOM in its seminal 1990 report, *Clinical Practice Guidelines: Directions for a New Program*, 2 CPGs are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." The IOM's definition has been widely disseminated and adopted. CPGs are, then, one of the principal mechanisms through which the results of outcomes research are put into practice, in pursuit of the important goal of advancing EBM. Potential (legal) problem in implementing: To put the matter more starkly, if one of the principal purposes of promoting EBM is to move physicians away from customary approaches and toward demonstrably more efficient and effective approaches, but the law continues to use customary practice to define what is legally required, physicians who practice EBM might find themselves caught between Scylla and Charybdis. The committees concluded their work in early 2011, submitted their reports to Congress, and released them to the public in March 2011. The two reports are titled *Finding What Works in Health Care: Standards for Systematic Reviews and Clinical Practice Guidelines We Can Trust.*

39. Robin Graham et al., Clinical Practice Guidelines We Can Trust, NAT'L ACAD. PRESS (2011), https://www.nap.edu/read/13058/chapter/1#ii. This report stated physicians are increasingly unable to keep abreast of the ever-expanding knowledge bases related to health. There are massive amounts of new literature from clinical trials each year. Furthermore, the studies may be biased or inapplicable to key sub-groups of target populations, resulting in quality concerns. With this, obtaining and applying CPGs is important because CPGs "embody and support the interrelationships among critical contributors to clinical decision making". CPGs can avoid a "one-size-fits-all" approach by enhancing clinician and patient decision-making, scientific evidence and reasoning behind clinical recommendations easily accessible and relevant to a specific patient-encounter. CPGs can potentially enhance the quality of healthcare by effectively translating complex scientific research findings into recommendations for clinical practice.

Updated Definition of CPG: "Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." The report goes on, describing a number of recommendations, mostly regarding how to develop trustworthy guidelines.

The American College of Cardiology and the American Heart Association Clinical Practice Guidelines

The American College of Cardiology and the American Heart Association have formally agreed with the Institute of Medicine in its recommendations in developing clinical practice guidelines. In 2008, these two groups, in association with the Heart Rhythm Society, developed "Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities," which include considerations for addressing terminal care. In the American College of Cardiac Rhythm Abnormalities, which include considerations for addressing terminal care.

40. Amy Murphy, American College of Cardiology/American Heart Association Media Comment: Institute of Medicine Makes Recommendations on Producing Trustworthy Guidelines, Am. C. OF CARDIOLOGY (Mar. 29, 2011), http://www.acc.org/about-acc/press-releases/2011/03/29/10/04/institute-of-medicine-makes-recommen dations-on-producing-trustworthy-guidelines.

dations-on-producing-trustworthy-guidelines.

41. Andrew E. Epstein et al., *ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities*, 51 J. OF THE AM. C. OF CARDIOLOGY 2085, 2085-2105 (May 2008). This is a revision of the "ACC/AHA/NASPE Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices which updates the previous versions written in 1984, 1991, 1998, and 2002. "3.4.4 Terminal Care: In the United States, the withholding and withdrawal of life-sustaining treatments (e.g., cardiopulmonary resuscitation, mechanical ventilation, or hemodialysis) from terminally ill patients who do not want the treatments is ethical and legal. Honoring these requests is an integral aspect of patient-centered care and should not be regarded as physician-assisted suicide or euthanasia. When terminally ill patients (or their surrogates) request pacemaker, ICD, or CRT

When terminally ill patients (or their surrogates) request pacemaker, ICD, or CRT deactivation, questions related to the ethics of device deactivation may arise. Questions commonly asked include: Are implantable devices life-sustaining treatments? Is deactivation the same as physician-assisted suicide or euthanasia? Is deactivation ethical? Is it legal? Under what conditions (e.g., code status) should deactivation be performed? Who should carry out deactivation? What documentation should exist? The prevalence of implantable devices in patients dying of noncardiac diseases makes this an increasingly encountered clinical issue. Patients and families fear that devices will prolong the dying process, and some dying patients with ICDs fear uncomfortable defibrillations. In fact, investigators have found that some patients with ICDs experience uncomfortable defibrillations throughout the dying process, including moments before death.

Physicians do not usually talk about it: Cardiologists who implant devices do not commonly have discussions with patients about end-of-life issues and device deactivation. Furthermore, published experience with deactivation of devices is limited. Distinction between deactivating ICD and PM: There is general consensus regarding the ethical and legal permissibility of deactivating ICDs in dying patients who request deactivation. However, caregivers involved in device management generally make a distinction between deactivating a pacemaker and deactivating an ICD or CRT device. All are "medical treatments": Given the clinical context, all three can be considered life-sustaining treatments. (ICD, PM, CRTs="all three") Patients may "refuse" all three: Notably, patients may refuse all of these devices, and to impose them on patients who do not want them is unethical and illegal (battery).

No ethical/legal distinction between withhold/withdraw: Furthermore, ethics and law make no distinction between withholding and withdrawing treatments.

There is a 2012 update, but the update does not change section 3.4.4. Terminal Care. The patient about whom this article is written does not consider himself as terminal, and whether or not a patient is considered "terminal" may or may not be an issue. The Heart Rhythm Society Expert Consensus Statement does directly address the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy, developed in collaboration and endorsed by the American College of Cardiology (ACC), the American Geriatrics Society (AGS), the American Academy of Hospice and Palliative Medicine (AAHPM), the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), and the Hospice and Palliative Nurses Association (HPNA).

The patient about whom this article is written cited the HRS Expert Consensus Statement in his request to the Army to provide him an answer to his question about deactivation of his pacemaker. The Army never directly addressed this document, which appears to support this patient's autonomy, self-determination and his constitutional right to accept or to refuse unwanted medical treatment.

Highlights of the Heart Rhythm Society Expert Consensus Statement

The expert consensus statement needs no translation. Below are highlights taken from the statement and arranged and concentrated in bullet points.

Recommendation of approach to take with dying patients who request deactivation:

Informing BEFORE implantation: Clinicians involved in device education at the time of implantation may need to provide more comprehensive information with regard to end-of-life issues. For example, clinicians should encourage patients undergoing device implantation to complete advanced directives and specifically address the matter of device management and deactivation if the patient is terminally ill.

42. Cynthia M. Tracy, 2012 ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities, 60 J. OF THE AM. COL. OF CARDIOLOGY e7, e7-e85 (Oct. 2012). These focused updates do not seem to alter any of the areas relating to medical/ethical/legal issues surrounding deactivation.

43. See Lampert, supra note 1. Cardiac Implantable Electronic Devices (CIEDs) include all pacemakers, ICDs, and CRT devices and have grown in popularity over the years. Every patient with a CIED will eventually reach the end of their life, whether it is due to the underlying cardiac condition or from developing another disease.

- Basic principles: a patient with decision-making capacity always has the legal right to refuse or request the withdrawal of any medical treatment or intervention. When a patient lacks capacity, the patient's legal guardian has the right to refuse or request the withdrawal of treatment, based on what the patient would have chosen, if they had capacity.⁴⁴
- The definition of a life-sustaining treatment is an intervention provided and managed by a clinician that prolongs life but does not necessarily reverse the underlying disease. Ethically and legally, there is no difference between refusing CIED therapy and requesting withdrawal of CIED therapy. The right to refuse or discontinue treatment is a personal right of the patient and does not depend on the characteristics of the particular treatment involved. Common examples include hemodialysis, ventilation, and artificial nutrition and hydration but most clinicians who work with CIEDs consider pacemakers and ICDs life-sustaining treatments as well. 45
- There are four *prima facia* principles regarding most medicalethics concerns: respect for patient autonomy (duty to respect patients and their rights to self-determination), beneficence (duty to promote patient interests), non-maleficence (the duty to prevent harm to patients), and justice (the duty to treat patients and distribute health care resources fairly). Carrying out a request to withdraw medical treatment, specifically CIED therapy, is neither physicians-assisted suicide nor euthanasia. The panel also suggests that advance directives should be encouraged for all patients with CIEDs. 46
- A physician cannot be forced to carry out an ethically- and legally-permitted procedure if it goes against the physician's personal values. However, nor can the clinician abandon the patient. Instead, the clinician must make a reasonable effort to help the patient find a physician who will comply with their wishes. 47
- Informed consent is a crucial aspect of the patient-doctor relationship and derives from the ethical principle of respecting persons. Personal autonomy is furthered when patients un-

^{44.} Id. at 1009.

^{45.} Id.

^{46.} Id.

^{47.} Id.

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derstand the nature of their diagnosis and procedures and participate in the decision-making process of their health care. The elements of informed consent include information, patient voluntariness, and patient decision-making capacity. Clinicians are legally and ethically required to provide sufficient informed consent to allow their patients to participate in decision-making regarding treatment options. One of these options must be no treatment at all or refusal of treatment. The corollary to informed consent is informed refusal. Patients have the right to refuse any medical treatment, including those that prolong life. Furthermore, a patient has the right to refuse a previously consented treatment if the treatment no longer meets the patient's health care goals.

- A patient has the right to refuse or request the withdrawal of CIED therapies regardless of whether he or she is terminally ill or not, and regardless of whether the therapies prolong life, and hence, death would follow as a consequence of a decision not to use them. Two main factors differentiate discontinuing an unwanted treatment and physician-assisted suicide or euthanasia: the intent of the clinician and the cause of death. The intent of the physician in withdrawing or withholding any medical treatment, including CIED therapy, is to discontinue an unwanted treatment that the patient considers a burden and allow the underlying condition to run its course. The physician's intent is not to cause the patient's death. With assisted suicide, however, the patient intentionally terminates his or her life using medication a physician prescribed for that purpose. However, when an unwanted life-sustaining treatment is deactivated, an underlying medical-condition ultimately causes death.
- Advance directives promote personal autonomy and lessen the possible ethical dilemma suffered by clinicians and surrogates should they decide to deactivate a patient's pacemaker.⁵¹
- Any facility that implants CIEDs should have a clearly defined process to withdraw therapies when necessary. Deactivation

^{48.} See Jessica DeBord, Informed Consent (Mar. 7, 2014), http://depts.washington.edu/bioethx/topics/consent.html.

^{49.} Lampert, supra note 1, at 1010.

^{50.} *Id.* at 1011.

^{51.} *Id.* at 1013.

of CIED therapies requires an order from the attending physician, along with proper documentation. The documentation must include a physician-determination of capacity or recognition of an appropriate surrogate, record of a discussion regarding potential consequences of deactivation, and of possible alternatives. The orders must include exactly what proceprocedure will be done.⁵²

• Deactivation should be performed by physicians, device-clinic nurses, or technologists with electrophysiology expertise. Pacing therapies may be "withdrawn" by programming them to specific modes. If those modes are unavailable, it is possible to set the device to pace slow enough to render it essentially non-functional. Deactivating ICDs is more common and can be accomplished by placing a magnet over the device for a certain amount of time. Deactivation can occur in different settings, most typically in an acute-care hospital, patient facility, or in a patient's home.

End of Life Decision-Making and Deactivation of Pacemakers

Bolstered by the ACC/AHA Clinical Practice Guidelines and strengthened by the HRS Expert Consensus Statement, the authority for making the decision to deactivate a pacemaker still revolves around the concepts of informed consent and a person's constitutional right to accept or refuse unwanted treatment, including life-sustaining treatment.⁵⁴

In general and with few exceptions, an individual with decision-making capacity has the right to consent to or refuse any suggested medical treatment, even if refusal may result in death.⁵⁵

It has been forty years since the landmark case *In re Quinlan*, in which the New Jersey courts faced the issue of removing life-

^{52.} Id. at 1019.

^{53.} Id. at 1020-21.

^{54.} See generally H. Hosmer-Cernava, Ethics: Deactivating a Cardiac Pacemaker: Is it Ethical?, ONLINE J. OF ISSUES IN NURSING (Sept. 4, 2013), http://www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol-18-2013/No3-Sept-2013/Deactivating-Pacemaker. html.

^{55.} See, e.g., U.S. CONST. amend XIV; Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990) (assuming, and strongly suggesting, that the Fourteenth Amendment Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment).

^{56.} In re Quinlan, 355 A. 2d 647, 651 (N.J. 1976).

sustaining treatment, namely a respirator, from a comatose patient. Since then, courts have been faced with other heart-breaking cases involving decisions at the end of life and often the cases involve technological advances which can keep a body alive artificially. Some cases have been highly publicized and often the courts have relied on basic informed consent principles to make their decisions. For this article, the question arises—"Why is the deactivation of a pacemaker different than removal of a respirator?"

In 1976, the New Jersey Supreme Court concluded that, pursuant to her guardian's (her father) request, life-sustaining treatment could be removed from Karen Ann Quinlan, a comatose patient who was in a persistent vegetative state. The court based its decision primarily on Karen Ann Quinlan's constitutional right to privacy as well as to her right to self-determination. In its decision, the court also addressed several issues relating to informed consent, including the concept of informed refusal of treatment and stated, "...it is the constitutional right of privacy that has given us the most concern." The court concluded that if Karen were "miraculously lucid for an interval . . . and perceptive of her irreversible condition, she could effectively decide upon discontinuance of the life-support apparatus, even if it meant the prospect of natural death."

Ten years later, in *Bouvia v. Superior Court*, the California Supreme Court held that Elizabeth Bouvia was a mentally competent patient who understood the risks of refusal of life sustaining treatment by means of artificial nutrition and hydration and, using basic informed consent principles, found that Ms. Bouvia had the right to refuse treatment and that the State's interest in preserving her life did not outweigh her right to refuse.⁶³

A few years later, a Hawaii Circuit Court found that individuals have an independent, constitutional right to privacy under Article 1, Section 6 of the Hawaii Constitution and that this right would allow a person, or a guardian acting on behalf of an incompetent person (us-

^{57.} See generally Cruzan, 497 U.S. 261; In re Guardianship of Schiavo, 916 So. 2d 814 (Fla. Dist. Ct. App. 2005).

^{58.} *Id.*

^{59.} In re Quinlan, 355 A. 2d at 651.

^{60.} *Id.* at 662. As a result, "removal of a respirator is [now] routinely performed without judicial intervention." Note, *The Current State of Termination of Medical Treatment Case Law*, 9 NOVA L. J. 159, 159 (1984).

^{61.} In re Quinlan, 355 A. 2d at 662.

^{62.} Id. at 663.

^{63.} Bouvia v. Superior Court, 225 Cal. Ct. App. 297 (1986).

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ing "substituted judgment"), the right to refuse unwanted medical treatment, including artificially provided nutrition and hydration, if done consistent with accepted medical practice.⁶⁴

The seminal case regarding withdrawal of unwanted medical treatment was decided by the U.S. Supreme Court in Cruzan v. Director, Missouri Department of Health. ⁶⁵ In this case, the guardians of a patient in a vegetative state sought to terminate the artificial nutrition and hydration that was keeping her alive, but the hospital employees refused to do so without a court order. 66 The District Court granted the request to terminate treatment, and the Missouri Supreme Court reversed. On appeal, the U.S. Supreme Court affirmed the Missouri Supreme Court decision, ruling that the evidence produced at trial was not clear and convincing proof of Nancy Cruzan's wish to have hydration and nutrition withdrawn. ⁶⁸ However, the Court also recognized that there exists a protected liberty interest in refusing medical treatment based on prior decisions regarding invasions into the body and that the forced administration of life-sustaining medical treatment, and even of artificially-delivered food and water essential to life, might implicate a competent person's liberty interest. The Court went on to state, "for 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." In her concurrence, Justice O'Connor noted that receiving nutrition and hydration via gastronomy or jejunostomy tubes is just as invasive as other types of medical treatment and "[r]equiring a competent adult to endure such procedures against her will burdens the patient's liberty, dignity, and freedom to determine the course of her own treatment."

The Court held that there are situations where the State may decline to make decisions about the "quality of life" but instead asserting an "unqualified interest in the preservation of human life, to be weighed against the constitutionally protected interests of the individual."⁷² However, the facts in that case are different from the facts

 $^{64.\;}$ In re Guardianship of Crabtree, No. 86-0031 (Hawaii Fam. Ct. 1st Cir. Apr. 26, 1990) (Heeley, J.).

^{65.} Cruzan, 497 U.S. at 261.

^{66.} Id. at 268.

^{67.} Id.

^{68.} Id. at 263.

^{69.} Id. at 278.

^{70.} Id.

^{71.} Id. at 289.

^{72.} Id. at 280.

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presented by the patient who is the subject of this article. He is a mentally capacitated adult who is seeking deactivation of his CIED. In *Cruzan*, the court was presented with issues surrounding a patient who was incapacitated.⁷³

Except, as will be discussed later in this article, with respect to a desire to commit suicide or for a health care provider to cause a person to become dead, the patient's particular reasons or intent do not seem to be factors in these articulated protections. It also seems clear that the patient, while capacitated, could also project instructions and express desires for further treatment or refusal of treatment.

The Patient Self-Determination Act

Passage of the Patient Self-Determination Act⁷⁴ (PSDA) in 1990, established the right of all patients with decision-making capacity to state their treatment preferences in advance, and the related responsibilities of health care organizations. The PSDA requires organizations to do five things:

- 1. Provide written information to patients at the time of admission or initial provision of services concerning patients' rights under state law to make decisions about what medical care they want or do not want including a patient's right to accept or refuse life-sustaining or life-prolonging medical treatment.
- 2. Maintain written policies and procedures regarding advance directives and provide written information to patients about what those policies are.
- Document in the patient's medical records whether he or she has executed advance directives.
- 4. Ensure compliance with state law at each health care organization which is subject to the federal law.
- 5. Provide information for the education of the staff and community on issues concerning advance directives.

This federal law has been used as a basic foundation for state legislatures, health care regulating agencies, health care providers, consumer advocates and federal entities to promote patient rights.⁷⁶ While the PSDA applies only to those health care organizations that participate in

^{73.} Id. at 266.

^{74.} Omnibus Budget Reconciliation Act of 1990, Pub.Law 101-508, §§ 4206, 4751 (codified as amended at 42 U.S.C. §§ 1395cc, 1396a (2012)).

^{75.} *Id.*

^{76.} Law for Older Americans, AM. BAR ASS'N, http://www.americanbar.org/groups/public_education/resources/law_issues_for_consumers/patient_self_det ermination_act.html (last visited Mar. 30, 2017).

Medicare and Medicaid, it provides the model and context for federal policy on advance care planning. The intent of this law is to help individuals understand that they have strong rights regarding their medical treatment and to help them exercise those rights if they wish. The intent of this law also is to help avoid problems and litigation over the initiation or continuation of unwanted life-prolonging medical treatment. An advance directive can be used to document a person's wishes in advance of incapacity and can be used to provide clear and convincing evidence of how treatment should proceed.

The federal law also prohibits the health care organization from conditioning the provision of care or otherwise discriminating against patients based on whether or not advance directives have been executed. "The PSDA strengthened the effect of codified legal options of individuals wanting to avoid the dilemma confronted by Nancy Cruzan and her family. These options are called advance directives. . . . [Thus,] each state establishe[d] its own criteria for making advance directives orally or through documents such as the living will" ⁸²

^{77.} See, e.g., DEP'T OF VETERANS AFF., Advance Care Planning and Management of Advance Directives, (Dec. 24, 2013), https://www.va.gov/vhapublications/View/Publications.asp?pub_ID=2967. The military health system (MHS) has followed the provisions of the Patient Self Determination Act for many years. This was not because the MHS was required to comply by statute; it was not. Until the institution of TRICARE for Life, the MRS was prohibited from accepting either Medicare or Medicaid funds, the trigger for requiring compliance. Compliance with the provisions of the Patient Self Determination Act is the result of the Defense Department's requirement for medical treatment facilities to be accredited by the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), hereafter referred to as the Joint Commission. The Department of Defense (DoD) requires "all fixed hospitals and free-standing ambulatory clinics, including those providing care to DoD beneficiaries under various managed care support contracts" to be accredited by the Joint Commission.

^{78.} What is Patient Self-Determination Act?, LEGAL HELPMATE, http://www.legalhelpmate.com/health-care-directive-patient-act.aspx (last visited Mar. 30, 2017).

^{79.} Id.

^{80.} KATHRYN BRAUN ET AL., CULTURAL ISSUES IN END-OF-LIFE DECISION MAKING 40 (Kathryn L. Braun et al. eds., 2000) [hereinafter BRAUN].

^{81.} Omnibus Budget Reconciliation Act of 1990 § 4206 (2)(c).

^{82.} BRAUN, *supra* note 80, at 42. Although a written advance directive is desirable, some states do not mandate written declarations. For example, in Hawaii a verbal statement made by the patient to a physician or even perhaps to a friend or relative of the patient may be considered in deciding whether the patient would want life-sustaining procedures to be withdrawn or withheld. Unambiguous verbal statement by the patient or reliable reports thereof, are to be documented in the patient's medical record. As in many states, Hawaii's law provides that, in the absence of any declaration at all (written or verbal) ordinary standards of current medical practice will be followed.

Overview of Health Care Decision Making In Hawaii

The patient who is the subject of this article lives in Hawaii, and the Army health care facility, which provides his cardiac care, is in Hawaii.

Hawaii's Constitution incorporates an explicit privacy provision, which states, "[t]he right of the people to privacy is recognized and shall not be infringed without the showing of a compelling state interest."83 This section guarantees a right to privacy that protects an individual's interest in avoiding disclosure of personal matters and in freely making certain important personal decisions. 4 In the context of health care decision-making, this provision has been cited as a basis for upholding the right of a person (or a guardian for an incompetent person) to refuse unwanted medical treatment.

Over two decades ago, Hawaii adopted a strong public policy in favor of a person's right to accept or refuse medical treatment." This seminal law provided that "all competent persons have the fundamental right to control the decisions relating to their own medical care, including the decision to have medical or surgical means or procedures calculated to prolong their lives provided, continued, withheld or withdrawn. The artificial prolongation of life for persons with a terminal condition or a permanent loss of ability to communicate concerning medical treatment decisions, may secure only a precarious and burdensome existence, while providing nothing medically necessary or beneficial to the person."87

Hawaii has a number of laws that help to assure health care providers will carry out a patient's wishes, including an intention to withdraw or withhold treatment and alleviate undue suffering." Health care is defined broadly under Hawaii law and can be read to

^{83.} HAW. CONST. art. I, § 6.

See, e.g., Doe v. City and County of Honolulu, 816 P.2d 306 (Haw. Ct. App. 1991).

^{85.} In re Guardianship of Crabtree, No.86-0031 (Haw. Fam. Ct., 1st Cir. April 26, 1990).

^{86.} Medical Treatment Decisions (repealed 1999), HAW. REV. STAT. CH. 327D (First enacted in 1986, amended periodically and subsequently repealed, effective July 1, 1999). 87. *Id*.

^{88.} See id.

^{89.} HAW. REV. STAT. § 327E-3 (1999) ("Health-care" means any care, treatment, service, or procedure to maintain, diagnose, or otherwise affect an individual's physical or mental condition, including:

⁽¹⁾ Selection and discharge of health-care providers and institutions;

include providers of medicine, surgery, psychiatry, dentistry and other health care practices affecting an individual's physical or mental condition. 90

Informed Consent

As in other jurisdictions, health care decisions are made every day in Hawaii by patients or their authorized representatives, along with their physicians or other health care providers. Over the years, it has become increasingly important to address not only what health care an individual wants, but also how decisions are made and enforced when the patient is unable personally to make informed decisions. As in other states, a combination of laws impact health care decision-making in Hawaii.

Across the country, the process for making medical treatment decisions revolves around the concepts of informed consent and a person's constitutional right to accept or to refuse unwanted medical treatment. In general, and with few exceptions, the United States Constitution and the common law provide that an individual with decision-making capacity has the right to consent to or refuse any suggested medical treatment, even if refusal may result in death. Hawaii, like the other states, has treated this issue with relative consistency.

To ensure that the patient's consent to treatment is informed, the State of Hawaii legislature has provided the Board of Medical Examiners the option, within certain boundaries, to establish standards for health care providers to follow in giving information to a patient, or to a patient's guardian or "surrogate" if the patient is not competent.⁹³ These

⁽²⁾ Approval or disapproval of diagnostic tests, surgical procedures, programs of medication, and orders not to resuscitate; and

⁽³⁾ Direction to provide, withhold, or withdraw artificial nutrition and hydration; provided that withholding or withdrawing artificial nutrition or hydration is in accord with generally accepted health-care standards applicable to health-care providers or institutions.

[&]quot;Health-care decision" means a decision made by an individual or the individual's agent, guardian, or surrogate, regarding the individual's health care.").

^{90.} *Id.* "Health-care provider" means an individual licensed, certified, or otherwise authorized or permitted by law to provide health care in the ordinary course of business or practice of a profession.

^{91.} See, e.g., U.S. CONST. amend. XIV; Cruzan, 497 U.S. at 270.

^{92.} See HAW. REV. STAT. ANN. § 671-3 (1983).

^{93.} See id. (On January 1, 2004, Hawaii Laws Act 114 (H.B. 651) (2003) became effective. The Act amends section 671-3 substantially by recognizing "legal surrogates" for the purposes of making health-care decisions. For the purposes of the Act, a

standards may include the substantive content of the information to be given, the manner in which the information is to be given by the health care provider, and the manner in which consent is to be given by the patient or guardian. The concept of informed consent continues to evolve, but essentially, it revolves around a patient's right to have the opportunity to be an informed participant in his or her healthcare decisions. Discussions regarding the treatment or procedures normally include information regarding the patient's diagnosis, the nature and purpose of a proposed treatment or procedure, their attendant risks and benefits, alternative treatments or procedures and their attendant risks and benefits and the risks and benefits of not receiving or undergoing a treatment or procedure.

The doctrine of informed consent to treatment includes the right to informed refusal of treatment. A competent adult patient has the right to refuse all forms of health care intervention, including life-saving or life-prolonging treatment.⁹⁷

Hawaii has adopted a patient-oriented standard applicable to the duty to disclose risk information prior to treatment. The patient-oriented standard of informed consent focuses on what reasonable patients objectively need to hear from the health care provider to allow them to make informed and intelligent decisions regarding proposed medical treatment. Questions about failure to provide informed consent, e.g., by an Army Medical Center, that once a pacemaker is implanted may implicate a failure to provide adequate informed consent and thus make the Army susceptible to claims of medical malprac-

[&]quot;legal surrogate" is "an agent designated in a power of attorney for health care or a surrogate designated or selected in accordance with Chapter 327E.").

^{94.} See id.

^{95.} See id.

^{96.} H.B. 651, 2003 Leg., 23rd Sess. (Haw. 2003); S.B. 624, 2003 Leg., 23rd Sess. (Haw. 2003). These statutes were introduced in the 2003 legislative session to update Hawaii's informed consent laws. A compromise bill was passed and signed into law as Act 114. In brief, the changes to the law, effective January 2004, included changes to update Hawaii law to make it more consistent with other laws and extending the right to consent to or refuse medical treatment to legal guardians or surrogates.

97. See Cruzan, 497 U.S. at 278-79 (assuming, and strongly suggesting, that

^{97.} See Cruzan, 497 U.S. at 278-79 (assuming, and strongly suggesting, that the Fourteenth Amendment Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment).

^{98.} Carr v. Strode, 904 P.2d 489, 498 (Haw. 1995).

^{99.} Id . at 499. This case overruled the prior standard as expressed in $\mathit{Nishi}\ v$. $\mathit{Hartwell}$, 473 P.2d 116 (Haw. 1970).

tice 100 under the Federal Tort Claims Act, 101 which will be discussed at the end of this article.

Hawaii's Uniform Health Care Decisions Act (Modified)

For the most part, Hawaii's Uniform Health Care Decisions Act (Modified) or UHCDA follows a model act developed by the National Conference of Commissioners on Uniform State Laws (NCCUSL), but has a few provisions that are unique to Hawaii. 102 The UHCDA takes a comprehensive approach by placing the so-called "living will," the durable power of attorney for health care, a "family consent" or surrogate law, and general provisions regarding health care and health care decisions together in one statute. The new "individual instruction," which takes the place of what is commonly called the "living will," applies to a wide range of health care decisions, not just end-oflife decisions. 104 The residual decision-making portion of the Act is somewhat like family consent statutes that have been adopted in a majority of states. 105 This section of the Act applies only if there is no applicable individual instruction, guardian, or appointed agent. 106 Hawaii has established a unique framework for appointing or selecting surrogates. In Hawaii, there is no established hierarchy for surrogates.10

Under Hawaii's version of the UHCDA, an adult or emancipated minor may make advance health care directives by giving an "individual instruction" orally or in writing and/or by executing a power of attorney for health care, which may authorize the agent to make any health care decision the principal could have made while

^{100.} HAW. REV. STAT. ANN. § 671-3 (1983) is included in Chapter 671 Medical Torts. HAW. REV. STAT. § 671-1 (a) ("'Medical tort' means professional negligence, the rendering of professional service without informed consent, or an error or omission in professional practice, by a health care provider, which proximately causes death, injury or other damage to a patient.").

^{101. 28} USC § 2674 (2016).

^{102.} See generally JAMES H. PIETSCH & LENORA H. LEE, THE ELDER LAW HAWAI'I HANDBOOK (1998) [hereinafter PIETSCH].

^{103.} Nowhere in the statute is the term "living will" used.

^{104.} See generally PIETSCH, supra note 102.

^{105.} Id.

^{106.} *Id.*

^{107.} Id.

^{108.} Id.

^{109.} HAW. REV. STAT. ANN. § 327E-3 (1999).

^{110.} *Id.* (defining an "Individual Instruction" as an individual's direction concerning a health care decision for the individual).

having capacity. An individual may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider, ¹¹¹ but an individual may revoke all or part of an advance health care directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke. ¹¹² The law even provides an optional sample form (and explanation), which may be duplicated or modified to suit the needs of the person. ¹¹³ Alternately, one may use a completely different form that contains the substance of the sample form found in the statute. ¹¹⁴

For purposes of this article, if a patient requests that a pace-maker (or other internally placed cardiac device such as an implantable cardioverter-defibrillator (ICD)) be deactivated, the patient should include such directions in an advance directive (as well as in Comfort Care Only-Do-Not-Resuscitate and Provider Orders for Life-Sustaining Treatment-POLST), as will be discussed. 115

Under the UHCDA, a surrogate may make a health care decision for a patient if the patient lacks capacity and no agent or guardian has been appointed or neither the agent nor guardian is available. A patient may designate or disqualify any individual to act as a surrogate by personally informing the supervising health care provider. In the absence of such a designation, or if the designee is not reasonably available, a surrogate may be appointed to make a health care decision for the patient. Unlike the Uniform Act approved by the NCCUSL, Hawaii's modified version of the UHCDA does not provide for the more common approach of a hierarchy of decision-makers for a decisionally incapacitated patient, but instead provides for decision-making by surrogates selected from a group of "interested persons."

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111. Id. § 327E-4(a).
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^{112.} Id. § 327E-4(b).

^{113.} Id. § 327E-16.

^{114.} Id

^{115.} For example, "I want my Pacemaker turned off or deactivated if:

[•] I have a Do-Not-Resuscitate or Comfort Care Only Order; or

[·] I have an incurable illness or injury and am dying; or

[•] I am admitted to Hospice (e.g., inpatient or home)

unless my physician believes deactivation would cause further burden or suffering."

^{116.} Id. § 327E-2 (defines "capacity" as an individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health-care decision).

^{117.} Id. § 327E-5(a).

^{118.} *Id.* § 327E-5(b).

^{119.} Id.

Under the Hawaii statute, "interested persons" means the patient's spouse (unless legally separated or estranged), a reciprocal beneficiary, any adult child, either parent of the patient, an adult sibling or adult grandchild of the patient, or any adult who has exhibited special care and concern for the patient and who is familiar with the patient's personal values. As explained above, the patient can designate or disqualify a surrogate. Accordingly, interested persons can be "trumped" by an orally designated surrogate. In the same manner, a patient may orally disqualify someone who otherwise might be entitled to make decisions on behalf of the patient.

Hawaii's version of the UHCDA places restrictions on decisions by "non-designated surrogates." For example, the statute provides that "artificial nutrition and hydration may be withheld or withdrawn upon a decision by the surrogate only when the primary physician and a second independent physician certify in the patient's medical records that the provision of artificial nutrition or hydration is merely prolonging the act of dying and that the patient is highly unlikely to have any neurological response in the future." Neither physician-assisted suicide nor physician-assisted death is addressed in the surrogate section of the statute.

Hawaii's statute follows the UHCDA, for the most part, in dealing with decisions by guardians, obligations of health-care providers, health care information, immunities, statutory damages, judicial relief, uniformity of application, and other administrative matters. The provisions relating to obligations of health-care providers are especially important to the issues addressed in this article in that there is a general obligation to "[c]omply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health-care decisions

^{120.} Id. § 327E-2.

^{121.} *Id.*

^{122.} Id.

^{123.} *Id.* § 327E-5 (e) (mentions a "surrogate who has not been designated").

^{124.} *Id.* This particular provision has been the source of some confusion. There are several unanswered questions. Does "any neurological response" equate to something less than brain death and if so, what? Must tube feeding be applied or continued for every patient who has a "non-designated" surrogate selected to make health-care decisions if no definition of "any neurological response" can be agreed on by the medical community? Would seeking guardianship rather than selecting a "non-designated" surrogate be an effective means of circumventing the limitations?

^{125.} Id. § 327E-5.

^{126.} Id. § 327E-1.

for the patient."¹²⁷ In Hawaii, a health-care provider may decline to comply with an individual instruction or health-care decision for reasons of conscience.¹²⁸ A health-care institution may decline to comply with an individual instruction or health-care decision if the instruction or decision is contrary to a policy of the institution, which is expressly based on reasons of conscience and if the policy was timely communicated to the patient or to a person then authorized to make health-care decisions for the patient.¹²⁹ The institution involved in this article's case does not appear to have discussed any pacemaker deactivation policy with the patient.

Advance health-care directives under the UHCDA can be useful in providing instructions for deactivation, but these directives may not be very useful when a patient suffers cardiac or respiratory arrest. In a hospital or other health-care facility setting, a patient who suffers an arrest is routinely resuscitated unless there is a written donot-resuscitate order in the medical record. The DNR order is only

127. Id. § 327E-7. Obligations of health-care provider.

(d) Except as provided in subsections (e) and (f), a health-care provider or institution providing care to a patient shall:

(1) Comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health-care decisions for the patient; and

(2) Comply with a health-care decision for the patient made by a person then authorized to make health-care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(e) A health-care provider may decline to comply with an individual instruction or health-care decision for reasons of conscience. A health-care institution may decline to comply with an individual instruction or health-care decision if the instruction or decision is contrary to a policy of the institution which is expressly based on reasons of conscience and if the policy was timely communicated to the patient or to a person then authorized to make health-care decisions for the patient.

(f) A health-care provider or institution may decline to comply with an individual instruction or health-care decision that requires medically ineffective health care or health care contrary to generally accepted health-care standards applicable to the health-care provider or institution.

(g) A health-care provider or institution that declines to comply with an individual instruction or health-care decision shall:

(1) Promptly so inform the patient, if possible, and any person then authorized to make health-care decisions for the patient;

(2) Provide continuing care to the patient until a transfer can be effected; and

(3) Unless the patient or person then authorized to make health-care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health-care provider or institution that is willing to comply with the instruction or decision.

128. *Id.* § 327E-7(e).

129. Id.

130. Id. § 321-23.6(a)(1).

131. See id.

an instruction to withhold the otherwise automatic initiation of cardiopulmonary resuscitation, and it should not affect other forms of treatment. Outside of a health-care facility, emergency response personnel normally attempt to resuscitate an individual who suffers a cardiac or respiratory arrest. This may or may not be the course of action that the individual would request if he or she still could make and express a choice. Since 1995, Hawaii law has provided for so-called out-of-hospital do-not-resuscitate protocols.

Comfort Care Only-Do-Not-Resuscitate

Under a 2006 statute that modified the 1995 law, ¹³⁵ the Department of Health was to adopt new rules for emergency medical services, which include uniform methods of rapidly identifying an adult person who has certified, or for whom has been certified, in a written "comfort care only" document that the person (or, consistent with the UHCDA, the person's guardian, agent, or surrogate) directs emergency medical services personnel, first responder personnel, and healthcare providers not to administer chest compressions, rescue breathing, electric shocks, or medication, or all of these, given to restart the heart if the person's breathing or heart stops, and directs that the person is to receive care for comfort only, including oxygen, airway suctioning, splinting of fractures, pain medicine, and other measures required for comfort. ¹³⁶ As of the date this chapter was written, no rules have been adopted but practical information has been provided by the Hawaii Department of Health. ¹³⁷

^{132.} See id.

^{133.} See id.

^{134.} See HAW. REV. STAT. ANN. § 321-23.6 (2006) (Rapid identification documents).

^{135.} Act 46 was signed into law amending HAW. REV. STAT. § 321-23.6 on Apr. 27, 2006; see H.B. 3126, 23rd Leg., Reg. Sess. (2006) (enacted).

^{136.} For specific requirements for the written document containing the certification, see HAW. REV. STAT. § 321-23.6 (2006). Several other states have addressed the issue of out-of-hospital DNRs and, while Hawaii has taken a unique approach to its statute, several states have similar documents to identify patients who do not want CPR. The documents have varying names but several are called "Physician Orders for Life-Sustaining Treatment" or POLST. See also Robert C. Anderson, Physician Orders for Life Sustaining Treatment (POLST): Breathing New Life Into Endof-Life Care Planning, 259 ELDER L. ADVISORY 1 (2012).

^{137.} See Comfort Care Only: Do Not Resuscitate Information, STATE OF HAWAII, DEP'T OF HEALTH EM. MED. SERVS. (2017), http://health.hawaii.gov/ems/home/comfort-care-only-do-not-resuscitate-information/ (last visited Mar. 30, 2017) [hereinafter Comfort Care Only].

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Provider Orders for Life-Sustaining Treatment

In 2009, the Hawaii Legislature passed a law providing for a health care protocol called Physician Orders for Life-Sustaining Treatment ("POLST"). This law was modified in 2014 to include advance practice registered nurses. The POLST form contains information and directions about an individual's end-of-life decisions, such as cardiopulmonary resuscitation ("CPR") and tube feeding, that emergency medical personnel and other health care professionals are required to follow. By law, the POLST form is not an advance directive but a physician or advanced practice registered nurse's order and, accordingly, is immediately actionable.

Even though it is not an advance directive, the most frequent use of the POLST form is as a summary of an individual's advance directive decisions and information about life-sustaining treatment.¹⁴² The form turns the information and expressed desires into a physician's order that is signed by the physician or advanced practice registered nurse and the individual, or his or her health care agent or surrogate. The individual, or his or her health care agent or surrogate, is encouraged to discuss health care treatment decisions with the primary care doctor and document these decisions on a brightly colored POLST form, which is then signed by both the individual, his or her health care agent or surrogate, and the doctor. The form is lime green in color, so it easily can be found when needed and because it copies clearly on white paper. ¹⁴⁵ A plain white copy, completed correctly and signed by a doctor, is equally legal and valid. 46 Briefly, a POLST contains orders in a standardized form and addresses a range of life-sustaining interventions with the patient's preferences for intensity of each intervention. ¹⁴⁷ The POLST gives an individual an op-

^{138.} HAW. REV. STAT. ANN. § 327k (2016).

^{139.} *Id.* § 327k-3.

^{140.} Id. § 327k-2(C).

^{141.} *Id.* § 327k-1 ("A provider orders for life-sustaining treatment form is not an advance health-care directive.").

^{142.} Health Care Decision Making, U. OF HAWAI'I ELDER L. PROGRAM, https://www.hawaii.edu/uhelp/healthcare.htm (last visited Mar. 30, 2017).

^{143.} Id.

^{144.} Id.

^{145.} *POLST Information for Providers*, HAWAII HOSPICE AND PALLIATIVE CARE ORG., http://www.kokuamau.org/professionals/polst (last visited Mar. 30, 2017) [hereinafter *POLST*].

^{146.} See id.

^{147.} See id.

portunity to direct how life-sustaining health care treatment wishes, including a desire to have a pacemaker deactivated, are to be addressed. The form is recognized by the Hawaii Emergency Medical Services System, and although it does not replace the Comfort Care Only/Do Not Resuscitate Bracelet/Necklace, it provides immediately actionable directions pertaining to life-sustaining treatment and follows the patient between settings of care, including acute care hospitals, nursing facilities, and community settings. ¹⁵⁰

Since the POLST form is not an advance directive and does not name an agent or surrogate, an individual should still consider providing individual instructions and appointing a health care agent through an advance directive. The combination of POLST and advance directive gives an individual the best opportunity to have health care treatment wishes followed, including a desire to have a pacemaker deactivated under certain circumstances. Individuals can ask their doctors about both types of forms.

(But this is not) Suicide and Hawaii's Blue Ribbon Panel on Living and Dying with Dignity

In 1997, the United States Supreme Court unanimously held that terminally ill people do not have a constitutional right to physician-assisted suicide. The court upheld laws in New York State and Washington State that make it a crime for physicians to give life-ending drugs to mentally competent but terminally ill patients who no longer want to live. The state of the

The Court set forth the nation's "history, legal traditions, and practices" to establish the "longstanding expressions of the States' commitment to the protection and preservation of all human life." The Court indicated that "for over 700 years, the Anglo-American common-law tradition has punished or otherwise disapproved of both suicide and assisting suicide."

^{148.} See id.

^{149.} Comfort Care Only, supra note 137.

^{150.} POLST, supra note 145.

^{151.} Washington v. Glucksberg, 521 U.S. 701, 02 (1997); Vacco v. Quill, 521 U.S. 793, 793 (1997).

^{152.} Washington, 521 U.S. at 702; Vacco. 521 U.S. at 793.

^{153.} Washington, 521 U.S. at 710.

^{154.} Id.

^{155.} Id. at 711.

Then, the Court implicated a number of state interests: preservation of life; protecting the integrity and ethics of the medical profession; protecting vulnerable groups, including poor and elderly, from abuse, neglect, and mistakes; and preventing a slippery slope toward voluntary, or even involuntary, euthanasia. 156 Ultimately, the Court held that the ban against physician-assisted suicide was reasonable due to the overwhelming state interests. ¹⁵⁷ Although the Court held that Washington's assisted-suicide ban did not violate the Due Process Clause, the Court reiterated, "[t]he Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment." 158

Justice Stevens, in his concurring opinion, stated that there is a "possibility that an individual plaintiff seeking to hasten her death, or a doctor whose assistance was sought, could prevail in a more particularized challenge." ¹⁵⁹ Justice Stevens also states that there are times where hastening death is legitimate and "entitled to constitutional protection."160

In Vacco v. Quill, the United States Supreme Court held that New York's prohibition on assisting suicide did not violate the Equal Protection Clause of the Fourteenth Amendment. 162 "Everyone, regardless of physical condition, is entitled, if competent, to refuse unwanted lifesaving medical treatment; no one is permitted to assist in suicide. Generally speaking, laws that apply evenhandedly to all 'unquestionably comply' with the Equal Protection Clause." The Court held that New York's ban was rationally related to several of the state interests: "prohibiting intentional killing and preserving life; preventing suicide; maintaining physicians' role as their patients' healers; protecting vulnerable people from indifference, prejudice, and psychological and financial pressure to end their lives; and avoiding a possible slide towards euthanasia[.]"164

In distinguishing the difference between assisting suicide and withdrawing life-sustaining medical treatment, the Court points to a weak explanation of causation and intent. 465 "A doctor who assists a

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156. Id. at 728-32.
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^{157.} Id. at 742.

^{158.} Id. at 720.

^{159.} Id. at 750.

^{160.} Id. at 742.

^{161.} See Vacco, 521 U.S. at 793.

^{162.} *Id.* at 796-97.

^{163.} Id. at 800.

^{164.} Id. at 808-9.

^{165.} See generally U.S. v. Bailey, 444 U.S. 394 (1980).

suicide ... 'must, necessarily and indubitably, intend primarily that the patient be made dead."166 Withdrawing life-sustaining medical treatment, like assisting suicide, would ultimately lead to a patient's death; life-sustaining treatment sustains a patient's life, and without it, the patient will die. The Court held that, as a matter of causation and intent, "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." Moreover, the right to refuse treatment is not limited to terminally ill patients. 168 In Vacco, the Court held that, "[e]veryone, regardless of physical condition, is entitled, if competent, to refuse unwanted lifesaving medical treatment; no one is permitted to assist a suicide." As a life-sustaining treatment, a CIED should be considered a treatment that can be withheld or withdrawn and such withholding or withdrawal of this medical treatment should not be considered assisted suicide.

In 1997, Governor Benjamin Cayetano established a Blue Ribbon Panel on Living and Dying with Dignity to explore the issues of living and dying with dignity in Hawaii. On June 8, 1998, the Blue Ribbon Panel presented its final report. The panel reached unanimous agreement on six major areas affecting most of the deaths that occur in Hawaii every year. Panel members differed only on Physician-Assisted Death and Physician-Assisted Suicide (PAD and PAS).

The Blue Ribbon Panel was unanimous on the following points:

Spiritual counseling should be made more available to individuals
who are afflicted with life threatening illnesses by integrating
those services more fully into the healthcare system;

^{166.} Vacco, 521 U.S. at 802.

^{167.} Id. at 801.

^{168.} Id. at 800.

^{169.} Id.

^{170.} FINAL REPORT OF THE GOVERNOR'S BLUE RIBBON PANEL ON LIVING AND DYING WITH DIGNITY, 27 (May 1998) [hereinafter Blue RIBBON REPORT].

^{171.} Id.

^{171.} Id.

^{173.} *Id.* at 10. Physician Assisted Death: Deliberate action taken with the intent to hasten the death of another individual at the request and consent of the individual. Voluntary Active Euthanasia is another term that may be used to describe this action.

Physician Assisted Suicide: A physician provides an individual with the means by which the individual may take their own life. The primary intent of the physician is to cause the death of the individual. The means may include the provision of medication or a prescription, or taking other measures. The person who dies directly takes their own life.

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- Public and healthcare professional education programs should be designed and implemented to increase awareness of the choices available to the dying;
- The content of advance directives for healthcare, including "living wills," should be made more specific, their use more widespread, and their provisions more binding;
- Hospice care should be made more available and offered more expediently to the dying;
- Effective pain management programs should be required in all healthcare institutions;
- Involuntary euthanasia should continue to be a crime. 174

The overall premise of the governor's charge to the committee was that "[d]ying has not been managed as it could be." Healthcare decisions, including end-of-life decisions, are made every day by patients or their authorized representatives, along with their physicians or other healthcare providers. Family members, friends, judges, guardians, agents, surrogates, and even attorneys are now commonly involved in what is usually thought of as a private concern of the patient and healthcare provider. ¹⁷⁶

Even if the risk of death is increased, the American Psychological Association recognizes that "the reasoning on which a terminally ill person (whose judgments are not impaired by mental disorders) bases a decision to end his or her life is fundamentally different from the reasoning a clinically depressed person uses to justify suicide." Although there is no law against suicide in Hawaii, the Hawaii Penal Code has been interpreted to prohibit physicians from assisting in suicides or otherwise helping to cause a death. As in other jurisdictions,

^{174.} Id. at 5.

^{175.} *Id.* at 4-5 ("Technologic advances have made the prolongation of life an expectation. Healthcare providers rarely recommend an acceptance of death even when it is clearly the most rational decision. Hospice care, a reasonable alternative to futile medical care, is not considered often or early enough. Pain control so critical to the dying is often poorly administered.").

^{176.} Health Care Decision Making, U. OF HAW. ELDER. L. PROGRAM, https://www.hawaii.edu/uhelp/healthcare.htm (last visited Mar. 30, 2017).

^{177.} Rhea K. Farberman, Terminal Illness and Hastened Death Requests: The Important Role of the Mental Health Professional, 28 PROF. PSYCHOL.: RES. & PRAC. 544, 544 (1997).

^{178.} See HAW. REV. STAT. ANN. § 707-702 (2003). This section states in part: "A person commits the offense of manslaughter if...[h]e intentionally causes another person to commit suicide." BLUE RIBBON REPORT, supra note 170, at 24, 49 (referring to the provision as the basis for concluding that PAS and PAD are illegal. However, in the author's conversation with the City and County of Honolulu Prosecutor's Office, it was apparent that the issue is not clear as seen in the author's personal communica-

Hawaii law often treats the subject of suicide in the context of mental illness. For example, Hawaii provides, in part, that if a person is believed to be mentally ill or suffering from substance abuse and is imminently dangerous to self or others, that person may be subjected to involuntary emergency examination and hospitalization. There also are provisions that justify the use of physical force to prevent another from attempting suicide under specific circumstances. Finally, the penal code addresses suicide by requiring coroners to report the death of an individual if it appears that suicide is the cause. The penalty for failing to report such a death is a fine of \$100.

A law enacted in 1976 in Hawaii declared that the state did not condone, authorize, or approve of mercy killing or euthanasia. In 1999, this law was replaced by the UHCDA, and the provision regarding withholding or withdrawing medical treatment, which is more neutral and which tracks very closely the Federal Assisted Suicide Funding Restriction Act of 1997 as previously indicated in this article. The question becomes: if deactivation of a pacemaker is not for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, and/or it is considered withdrawal of medical treatment, would this be considered assisted suicide?

tions with Peter Carlisle, City and County of Honolulu Prosecutor's Office, Jan., 2003 and Feb. 26, 2004).

- 179. HAW. REV. STAT. ANN. § 334-59 (1997).
- 180. Id. § 703-308.
- 181. *Id.* § 841-3.
- 182. Id.
- 183. See id. § 327D-131 (repealed 1999) (Mercy killing or euthanasia prohibited).
- 184. *Id.* § 327E-13. Effect of this chapter, provides: . . . (b) Death resulting from the withholding or withdrawal of healthcare in accordance with this chapter shall not for any purpose constitute a suicide or homicide or legally impair or invalidate a policy of insurance or an annuity providing a death benefit, notwithstanding any term of the policy or annuity to the contrary. (c) This chapter shall not authorize mercy killing, assisted suicide, euthanasia, or the provision, withholding, or withdrawal of healthcare, to the extent prohibited by other statutes of this State.
- 185. *Id.* § 327D-131 (repealed 1999) ("(b) Construction and treatment of certain services. Nothing in subsection (a) of this section, or in any other provision of this chapter (or in any amendment made by this chapter), shall be construed to apply to or to affect any limitation relating to—
- (1) the withholding or withdrawing of medical treatment or medical care;
- (2) the withholding or withdrawing of nutrition or hydration;
- (3) abortion; or
- (4) the use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.").

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While the Army's apparent position 186 is that deactivation is never permitted in Army hospitals, even in Hawaii since it is a federal facility. 187 The Navy and the Air Force seem to have different opinions. 188 The Department of Veterans Affairs has addressed the issue in

186. As of December 2016, the author had not received any confirmation or clarification of its position as communicated to the patient and the patient's cardiologist despite repeated requests. These are the questions the author has been asking the Army to answer, starting in May 2016 and ending in December of 2016. Questions:

(1) If deactivation of a pacemaker is not for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, and/or it is considered withdrawal of medical treatment, would this be considered assisted suicide in a military health system?

(2) In addressing cardiology issues, does the Army follow clinical practice guidelines such as those developed by the ACC/AHA/HRS? (3) As military hospital systems become more integrated (e.g., Walter Reed National Military Medical Center) how are clinical policies developed, if there are no published VA/DoD CPGs—Army, Navy or Air Force lead?

187. 42 U.S.C. § 14401 (1997) ("(c) Limitation on Federal facilities and employees Subject to subsection (b) of this section, with respect to health care items and services furnished-

(1) by or in a health care facility owned or operated by the Federal government, or (2) by any physician or other individual employed by the Federal government to provide health care services within the scope of the physician's or individual's employment, no such item or service may be furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

(d) List of programs to which restrictions apply

(1) Federal health care funding programs Subsection (a) of this section applies to funds appropriated under or to carry out the following:

(A) Medicare program Title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

(B) Medicaid program Title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]

(C) Title XX social services block grant Title XX of the Social Security Act [42 U.S.C.

(D) Maternal and child health block grant program Title V of the Social Security Act [42 U.S.C. 701 et seq.].

(E) The Public Health Service Act [42 *U.S.C.* 201 et seq.]. (F) The Indian Health Care Improvement Act [25 *U.S.C.* 1601 et seq.]. (G) Federal employees health benefits program Chapter 89 of title 5.

(H) Military health care system (including Tricare and CHAMPUS programs) Chapter 55 of title 10.

(I) Veterans medical care Chapter 17 of title 38.

(J) Health services for Peace Corps volunteers Section 2504(e) of title 22. (K) Medical services for Federal prisoners Section 4005(a) of title 18.

(2) Federal facilities and personnel: The provisions of subsection (c) of this section apply to facilities and personnel of the following:

(Å) Military health care system: The Department of Defense operating under *chapter 55 of title 10.*

(B) Veterans medical care: The Veterans Health Administration of the Department of Veterans Affairs.

(C) Public Health Service").

188. E-mail from Air Force Cardiologist and Air Force Electrophysiologist, to James H. Pietsch (July 8, 2016; Nov. 29, 2016) (on file with author) (An Air Force

the past and concluded that it may not only be ethically and legally appropriate to deactivate a pacemaker under certain conditions but that "(a) patient with decision-making capacity has the legal right to refuse or request the withdrawal of any medical treatment or intervention, regardless of whether s/he is terminally ill, and regardless of whether the treatment prolongs life and its withdrawal results in death."¹⁸⁹

Cardiologist and an Air Force Electrophysiologist indicated that the Air Force does not have a formal policy for deactivating pacemakers. They said, "[d]eactivation of pacemakers is handled on a case-by-case basis involving close coordination between patient and provider."); see also End of Life Heart Rhythm Devices, HEART & RHYTHM

Soc. (2014),

http://www.hrsonline.org/content/download/21396/940307/file/End%20of%20 Life%20and%20Heart%20Rhythm%20Devices.pdf; e-mail from a Navy Cardiologist to James H. Pietsch (Nov. 2, 2016) (on file with author) (A Navy Cardiologist indicated, "The Navy follows the clinical guidelines and consensus statements of the ACC/AHA/HRS and other clinical societies. There is no Department of the

Navy (DON) or Bureau of Medicine (BUMED) written policies.").

- 189. E-mail from Dept. of Vet. Aff. Med. Dr. to James H. Pietsch (Dec. 13, 2016) (on file with author) (stating, "I have reviewed your request with my Chief Dr. Berkowitz, copied on this e-mail. The 2006 National Center for Ethics in Health Care teleconference you have already seen remains the best statement of our position and we would refer you to that document for the questions you posed."); Dr. Ken Berkowitz, Ethical Considerations of Cardiac Pacemakers and Implantable Defibrillators for End-of-Life Care, www.ethics.va.gov/.../NET_Topic_2006045_Cardiac_ Pacemakers_and_Implantable_Defibrillators.doc. Dr. Ken Berkowitz is the Chief of the Ethics Consultation Service at the VHA National Center for Ethics in Health Care and a physician at the VA NY Harbor Healthcare System. On April 25, 2006, Dr. Berkowitz, Susan Own, PhD., and Joel Roselin, MTS conducted a National Ethics Teleconference. The VHA Center sponsors teleconferences such as this one to provide an opportunity for regular education and open discussion of ethical concerns relevant to the VHA. This teleconference focuses on identifying and discussing ethical considerations of cardiac pacemakers and implantable defibrillators for end-of-life care and relevant VHA policies regarding withholding and withdrawal of life-sustaining medical treatment. Three main issues are discussed during the teleconference:
 - (1) Is it ethically permissible to disable the implanted cardiac devices for a patient who is actively dying?
 - (2) Are such implanted devices different from any other kinds of supportive measures that patients and their surrogates can request to have withdrawn?
 - (3) Are there limits to how far clinicians must go to accommodate the requests of patients or surrogates to have treatments discontinued?

Mr. Roselin begins by briefly describing the difference between the two main types of cardiac support devices: pacemakers and defibrillators. According to Roselin, pacemakers help the heart maintain a regular rhythm by sensing the rhythm and, if necessary, sending a pulse to the heart's conduction system to trigger the heart to contract. Most pacemakers only pace the heart intermittently, while others work constantly, allowing a slow heart to beat at a more appropriate rate. Usually, pacemakers cannot be turned off from outside the body, but can be turned down low enough to essentially render them useless. However, since pacemakers support the heart's natural yet inadequate rhythm, deactivating them rarely hastens death. Rather, deactivation of a pacemaker may simply diminish a

patient's quality of life and result in "a poorer quality of death." However, according to Dr. Berkowitz, proper palliative care can readily avoid this problem.

Defibrillators are most commonly used to treat patients who are at risk of sudden death from ventricular tachycardia and ventricular fibrillation. A defibrillator can sense these conditions and discharge a sudden electrical impulse so the heart can regain an organized rhythm. Unlike pacemakers, defibrillators can be completely turned off from outside the body and deactivation is much more likely to lead to death because the defibrillator-shock effectively resuscitates the patient. Without the electrical impulse, the heart will not regain the ability to beat correctly.

The devices are similar in that they are both implantable, charged by batteries, and can be reprogrammed from outside the body.

According to the panel, the fundamental ethical question is whether it is ethically permissible to disable an implantable defibrillator in a patient who is actively dying and who has either through themselves or their surrogate requested that the device be disabled. Dr. Owen explains that deactivation is not only ethically permissible but ethically required. This requirement is supported by established medical-ethical principles and VHA policy.

VHA policy promotes shared decision-making, supports the right of a capable patient to refuse life-sustaining treatment, and authorizes the surrogate to make decisions on behalf of the patient when appropriate. Dr. Owen emphasizes that such treatment refusals should be honored. A patient's right to refuse treatment is codified in Handbook 1004.1, VHA Informed Consent for Clinical Treatments and Procedures which allows a patient to refuse or request withdrawal of any treatment, even life-sustaining treatments. Furthermore, withdrawal or withholding treatment must follow VHA informed consent policy.

The bioethical principle of respect for individual autonomy supports the patient's right to refuse treatment and the physician's duty to comply with informed consent policy. Patients have the right to accept or reject treatment based on their own values, context, and treatment goals.

The conversation continues to clear up some common misconceptions regarding the issue. Dr. Owen concedes correcting certain misconceptions may aid in consistent application of VHA policy. First, the panel maintains that the governing ethical tenants are no different for cardiac devices than they are for other life-sustaining treatments, such as mechanical ventilation. With all treatments, the patient has the right to decide whether to discontinue. Furthermore, the surrogate is free to decide on the patient's behalf, based first on the patient's wishes, and if these are not known, on the patient's best interest. Second, the process of disabling these devices is non-invasive and painless. Third, disabling such devices is not euthanasia or assisted suicide because the underlying disease process causes the patient's death, rather than the patient or surrogate who authorizes the treatment refusal or the physician who implements it. Finally, intent matters for the ethical question as well, but here, the intent behind the treatment withdrawal is to honor and respect the patient's or authorized surrogate's decision. The intent is not to cause the patient's death.

Problems still arise because:

- Protocols about implementation have not kept pace with the technology itself but, there is a general consensus among ethicists, clinicians, and legal scholars that there is no difference between withholding and withdrawing treatments, the reasons that would justify the withholding treatment in the first place, might also justify the withdrawal
- "A patient with decision-making capacity has the legal right to refuse or request the withdrawal of any medical treatment or intervention, regardless of whether s/he is terminally ill, and regardless of whether the treatment prolongs life and its withdrawal results in death." Under "Informed Consent and

Even the Catholic Health Association, appears to have a more nuanced approach than the Army. 190

- the Right to Refuse Treatment" namely in the paragraph beginning with "The corollary to informed consent is...."
- "When a patient lacks capacity, his/her legally-defined surrogate decisionmaker has the same right to refuse or request the withdrawal of treatment as the patient would have if the patient had decision-making capacity." under "Surrogate decision making"
- "Legally, carrying out a request to withdraw life-sustaining treatment is neither physician-assisted suicide nor euthanasia." further under "Common concerns related to withdrawing CIED therapies" subsection: "Concern: Is withdrawing a CIED therapy akin to assisted suicide or euthanasia?"
- "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." Under subsection "Concern: are there unique factors about CIED therapy that differentiate it from other life-sustaining therapies?"

See Ron Hamel, Implantable Cardiac Devices at Life's End: Is Deactivation Morally Licit? ETHICS CATH. HEALTH ASS'N (2010), https://www.chausa.org/ docs/default-source/hceusa/bibliography-implantable-cardiac-devices-at-life'send.pdf?sfvrsn=0. "Deactivation ought not be a means for bringing death about ... " Rather, deactivation should be about allowing the underlying disease process to run its course unfettered, and to provide comfort to the patient in the process. This article discusses the nature of the devices, major conclusions and recommendations of the Heart Rhythm Society consensus statement, and how deactivation of the devices might fit into the Catholic moral tradition. The article discusses the key recommendations of the Heart Rhythm Society's consensus statement, which draws upon legal precedence of autonomy, beneficence, nonmaleficence, and justice. These well-established principles give a patient the legal right to withdraw/withhold any medical treatment whether the treatment prolongs life and withdrawal will result in death and have a surrogate make decisions in the event of incapacitation. The Consensus Statement concludes that withdrawal of life-sustaining treatment is neither physician-assisted suicide nor euthanasia because the intent of withdrawing/withholding is to remove unwanted medical treatment, and ultimate cause of death is an underlying medical disease/condition. Finally, if deactivation is against the physician's personal moral values, they are not required to carry it out (p.4). However, the physician should not abandon the patient but help find a colleague who is willing to follow the patient's wishes.

This article then discusses how CIED-deactivation fits into the Catholic moral tradition. First of all, the device should be assessed just like any other type of life-sustaining medical treatment, even though they are implanted into the body (p.4). According to Dr. Hamel, the key moral consideration is not where the device is situated but what the benefits and burdens the device places on the patient. Second, contrary to the Heart Rhythm Society's statement, personal autonomy is not the principal factor in considering the morality of deactivation. The Catholic moral tradition begins with an obligation to preserve life. Assessing whether deactivation could be morally licit requires weighing the benefits and the burdens of the device for a particular person, taking into consideration the patient's condition as a whole. Simply desiring deactivation does not make it morally sound. Therefore, contrary to the HRS Consensus Statement, personal autonomy is important

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A Familiar Tune?

Tune v. Walter Reed Army Medical Center 191 is considered to be the military's leading case on removal of life-sustaining treatment, the court relied heavily on a famous informed consent case, Canterbury v. Spence 192 in stating that "it is the patient, not the physician, who ultimately decides if treatment-any treatment-is to be given at all." 193 Mrs. Tune was a terminally ill cancer patient at Walter Reed Army Medical Center, which was then located in the District of Columbia. 194 She was being kept alive by a respirator, which she wanted disconnected so that she could die naturally. 195 Although the doctors were sympathetic to her wishes, Army policy at that time precluded withdrawal of any life-support system once it was placed in operation and, as a federal institution, Walter Reed Army Medical Center was not (at that time) subject to the District of Columbia Natural Death Act. 196 A guardian ad litem was appointed to ascertain Mrs. Tune's state of health, her desires, and her competence. 197 All members of the family were in accord with the patient's wishes. 198 The Army concurred in all but the prayer for relief and even waived appellate review prior to the court's decision. 199 The court granted the patient's petition and ordered that she be

but not a decisive factor in the decision to deactivate. According to Dr. Hamel, "when the benefits of a device offer little or no hope of benefit or when the burdens of the device outweigh any benefits, there is a moral warrant for deactiva-

However, according to Dr. Hamel, deactivation is not morally licit solely because the patient no longer wants to live. If there are other circumstances in the patient's life that create a desire not to live, deactivation is not permissible.

Deactivation of ICDs is more frequently allowable because they can cause physical pain and mental anguish, diminishing the overall wellbeing of the patient at the end of their life. Pacemakers are different because they do not impose the same physical and mental burdens, do not necessarily prolong the dying process, and deactivation itself may be painful.

191. Tune v. Walter Reed Army Med. Hosp., 602 F. Supp. 1452, 1456 (D.D.C. 1985).

Canterbury v. Spence, 464 F. 2nd 772 (D.C. Cir. 1972), cert. denied, 409 U.S. 1064 (1972). Canterbury generally "discarded the professional standard of disclosure, replacing it with a 'lay' standard which effectively withdrew from the medical profession the right to determine what information must be disclosed to patients. See Alan Meisel, The Expansion of Liability for Medical Accidents: From Negligence to Liability by Way of Informed Consent, 56 NEB. L. REV. 51, 96 (1977).

193. Tune, 602 F. Supp. at 1455. 194. *Id.* at 1452.

^{195.} Id.

^{196.} Id. at 1453 n.2.

^{197.} Id. at 1453.

^{198.} Id. at 1454.

^{199.} Id.

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removed from life-support systems.²⁰⁰ The court concluded "a competent, mature patient has a right to be fully informed of the possible consequences of a course of treatment before he permits the medical ministrations to begin." The informed consent doctrine as enunciated in Canterbury was an integral part of the court's decision to remove life-support equipment. The *Tune* court found that, "[t]he rule has never been qualified in its application by either the nature or purpose of the treatment, or the gravity of the consequences of acceding to or foregoing it."²⁰³

Later, the Army incorporated procedures for do-not-resuscitate and removal of life-support equipment into its regulations and now includes a provision that "(a) patient with decision making capacity has the legal and moral right to participate in medical care decisions, including the right to refuse medical treatment at any time even if the treatment is lifesaving."204

As a retiree, the patient who is the subject of this article is not under military authority for purposes of health care treatment, but the courts have generally upheld that, like civilians, even members of the armed services are entitled to informed consent. 205 Even in the context of military health care, the court acknowledges that there must be a balance between preservation of life, and the potential negative effects of continuing medical treatment. 206 The court in Tune held, in the context of an Army hospital terminating life support, that, "while preservation of life in the abstract is no doubt a transcendant [sic] goal for any society which values human life, the state's interest in maintaining life must defer to the right to refuse treatment of a competent, emotionally stable, but terminally ill adult whose death is imminent and who is, therefore, the best, indeed, the only, true judge of how such life as remains to him may best be spent."207

In a United States District Court, Doe v. Rumsfeld, the court held that the right to bodily integrity and importance of complying with legal requirements were among the highest public policy concerns.²⁰⁸

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200. Id. at 1456.
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^{201.} Id. at 1455.

^{202.} Id.

^{203.} Id.

^{204.} Medical, Dental, and Veterinary Care, Army Regulation 40-3, 2-3 a (Sept. 12, 2003), http://www.apd.army.mil/pdffiles/r40_3.pdf. 205. *See generally* Doe v. Rumsfeld, 297 F. Supp. 2d 119, 134 (D.D.C. 2003).

^{207.} Tune, 602 F. Supp. at 1455-56.

^{208.} Doe, 297 F. Supp. 2d at 134.

In that case, the court ruled in favor of members of the armed services who asserted that their rights had been violated when the government did not obtain informed consent from the members before administering anthrax vaccinations. While the medical procedure here (deactivation of a CIED) differs, that court ruling stands for the proposition that, even for military members, informed consent invokes matters of bodily integrity, and the requirement must be upheld "even if obtaining informed consent were to significantly interfere with military function."

What information should an Army doctor or any doctor provide the patient about deactivation of CIEDs prior to implantation and during the course of the doctor-patient relationship? A series of articles in *The Journal of the American Medical Association* provides some insight into how to talk to patients, including "What Clinicians Can Say about Device Deactivation." The Honolulu cardiologist the author questioned for this article follows such guidelines and suggests that such discussions should be included in the doctor-patient relationship.

The Federal Tort Claims Act makes a thorough knowledge of state law crucial to resolving tort issues, including issues relating to the negligent provision of informed consent. Section 2674 of the Federal Tort Claims Act provides that the United States shall be liable . . . in the same manner and to the same extent as a private indi-

^{209.} Id.

^{210.} Id.

^{211.} See e.g., Daniel D. Matlock & John M. Mandrola, *The Antidote for Unprepared Patients: A Caring Clinician*, 174 JAMA INTERNAL MED. 86, 86-87 (Jan. 1, 2014). What Clinicians Can Say about Device Deactivation At implantation:

While the purpose of this device is to help you live a longer and better life, whether we like it or not, we all eventually die, and there will come a time when this device could be doing more harm than good. I want you to know that this device can be turned off at any time.

I encourage you to think about this ahead of time. Talk with your family, and write down your wishes in a living will or an advance directive. I'm committed to taking care of you for however long you have this device, and I'm happy to answer any questions you may have.

During routine follow-up:

It looks like things are going well for you right now. As we've talked about before, there may come a time when this device is no longer helping you, or it might even become burdensome.

I don't want to be morbid, but I just want to remind you that you have control here. We can turn the device off at any time. I'm committed to helping you, and I'm happy to answer any questions you may have.

^{212. 28} U.S.C. §§ 1346(b), 2674 (2012).

vidual under like circumstances."²¹³ Section 1346(b) further provides that the federal district courts have exclusive jurisdiction over claims against the United States arising "under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred."²¹⁴

The Federal Tort Claims Act waives the sovereign immunity of the United States.²¹⁵ But like any other waiver of sovereignty, the Act is subject to the restrictions and exceptions imposed by Congress.²¹⁶ This is where we started the inquiry of whether deactivation of a pacemaker violates the Federal Assisted Suicide Funding Restriction Act of 1997.²¹⁷

The University of Hawaii Elder Law Program sponsored a Spring 2017 seminar in conjunction with the law school's Elder Law-Veterans Focus Clinic. Approximately 200 persons attended. One of the topics was "Medical, Legal and Ethical Considerations in Deactivation of Pacemakers." The patient who is the subject of this article was a panelist as was his Army doctor (not in uniform), a civilian cardiologist, a Department of Veterans Affairs Geriatric Psychiatrist and the Deputy Prosecuting Attorney for the Elder Justice Unit of the City and County of Honolulu Office of the Prosecutor. Legal representatives from the Army Medical Center and Army Regional Health Command had also been invited to be on the panel but none participated. The consensus of the panel, each speaking on his or her own behalf and not on behalf of any organization, was that a mentally capacitated individual who is not under any undue influence has the right to request that his or her pacemaker be deactivated and that, under most circumstances, deactivation would not constitute suicide or assisted suicide.

Two months after the seminar, and nearly a year after he first contacted the author, the patient who is the subject of this article sent an email to let the author know that, as a service-connected disabled

^{213. 28} U.S.C. § 2674 (2012).

^{214. 28} U.S.C. § 1346(b) (2012).

^{215.} Rayonier, Inc. v. United States, 352 U.S. 315, 319 (1957). The Court goes so far as to say "the very purpose of the Tort Claims Act was to waive the Government's traditional all-encompassing immunity from tort actions and to establish novel and unprecedented governmental liability."

^{216.} See Dalehite v. United States, 346 U.S. 15, 24-26 (1953).

^{217. 42} U.S.C. § 14401 (2012).

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veteran, he is entitled to receive healthcare services at the VA Medical Center (which is co-located on the same campus as the Army Medical Center) and he has asked the VA "...if I request that my pacemaker be turned off is there a procedure where I can have it done at or by the V.A.?" He also said he would be interested in having the author and Elder Law —Veterans Focus Clinic help him submit a request for assistance to the Army Regional Health Command Inspector General (IG) to provide clarification on Army policies and procedures with respect to deactivation of pacemakers in Army healthcare facilities. 218

Stay tuned.

^{218.} See Army Regulation 20-1, Inspector General Activities and Procedures, November 29, 2010, Chapter 6–1. a. Assistance as an inspector general function. Assistance is the IG function that provides Soldiers, Family members, DA civilians, retirees, and contract employees the ability to seek help from the IG on matters affecting their health, welfare, and personal readiness.