Chapter Four

Advance Planning – Health Care Choices and Research Participation

A. Health Care Planning Through Advance Directives

1. *Current law*

Given the characteristically slow progress of the disease, someone diagnosed with probable AD usually will have the opportunity to make plans for a time when he or she no longer is able to make health care decisions personally. This process, often called advance care planning, seeks to have the last portion of a person's life reflect the person's values, ideas, and hopes. As summarized in one of the "principles of palliative care" developed by Last Acts, advance care planning "finds out from you who you want to help plan and give you care, ... helps you figure out what is important, [and] tries to meet your likes and dislikes: where you get health care, where you want to live, and the kinds of services you want."[1]

The process of advance care planning for someone with AD should begin with reflection and conversation, not the signing of legal documents. Nevertheless, the decisions that emerge from kitchen-table discussions are best documented in a legally recognized manner. That is the role of advance directives.

Under Maryland law, advance directives are of two broad types, proxy directives and instructional directives.[2] A proxy directive is used to select a

decision maker. Known previously as a durable power of attorney for health care and now called an advance directive appointing a health care agent, this kind of directive allows an individual to express his or her own preference about who will make health care decisions when, as is inevitable in the later stages of AD, the individual can no longer do so. The individual may describe the health care agent's authority over end-of-life decisions broadly, as in the optional form set out in the Health Care Decisions Act,[3] or as narrowly as the individual wishes.

Advanced AD is an "end-stage condition." Consequently, someone with mild AD is free to use an advance directive to make decisions about end-of-life care for the time when the disease will get far worse.

A instructional advance directive is used to make a decision, rather than select a decision maker. It requires a kind of predictive self-assurance that proves difficult for many people. The typical instructional directive says that, when a person's medical deterioration has reached a certain point, the person no longer wants medical interventions aimed at prolonging life.[4] The Health Care Decisions Act offers *two* optional forms to make decisions of this kind. One, using the familiar title of "living will," address the use of life-sustaining treatments like ventilators in the event of terminal condition[5] or persistent vegetative state.[6] The other, called an advance medical directive giving health care instructions, covers those two conditions and a third, especially pertinent to AD patients: "end-stage condition," which means an irreversible, progressive disease that has reached a state of deterioration so extensive that a patient is no longer able to carry out any activity of daily living independently.[7] Advanced AD is an "end-stage condition."[8] Consequently, someone with mild AD is free to use an advance directive to make decisions about end-of-life care for the time when the disease will get far worse.

Health care facilities are subject to federal and State requirements intended to promote the use of advance directives. The federal Patient Self-Determination Act (PSDA)[9] requires hospitals, nursing

homes, home health agencies, hospice programs, and health maintenance organizations to provide patients with information about advance directives.[10] Likewise, a provision in the Health Care Decisions Act[11] requires health care facilities to inform patients of their "right to make an advance directive ...."

2. *Shifting the focus away from specific treatment instructions*

One problem with advance directives is that too few people use them. "Like other types of preventive medicine, advance directives are underutilized even though they are cheap, low-tech, and potentially highly effective" (Gillick 2004). The generally accepted estimate is that only around 15 percent of the adult population have executed an advance directive (Lynn, Schuster, and Kabcenell 2000, at 75).[12] Even among nursing home residents in Maryland with severe cognitive impairment, who had a strong incentive to have completed advance directives before loss of capacity, data from 2000 show that fewer than one-third did so.[13] Part of the reason for this relatively low prevalence is undoubtedly the difficulty of making prospective decisions about life-sustaining medical treatments. Few people are keen to engage in a detailed medical description of their own demise, especially if, as with AD, the description is of an inexorable loss of the capacities that people value most highly.

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(Gillick 2004).

It is hardly surprising, then, that when the optional advance medical directive form in the Health Care Decisions Act invites, for example, a person to say whether life is to be extended by medical interventions after "severe and permanent deterioration, indicated by incompetency and complete physical dependency,"[14] not many take up the invitation. Most people know that they should, but comparatively few actually do. "[P]rojecting how [a person] will feel in a variety of inherently unknowable

incompetent mental states" is, for most people, hard and distasteful work (Cantor 2001, at 189). In our view, the emphasis on giving instructions about end-of-life care has probably contributed to the limited use of advance directives.[15] We suspect that desk and kitchen drawers all over Maryland are littered with blank living will and instructional advance directive forms.

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A second problem with instructional advance directives is the disjunction between what people say about life-sustaining treatment in the abstract and what they might want, or what might be best for them, once the actual situation arrives – what one prominent geriatrician calls the concern "that well people will make glib pronouncements about refusing treatment in hypothetical futures" (Finucane 2001). The dilemma of instructional advance directives, he continues, derives from incompatible understandings of what constitutes respect for persons:

> Should we say that if a person has a right to make a living will, he has the responsibility to accept that it will be honored should the circumstances arise? Or should we say that because an ill, incapacitated person is so different from the person who made the advance directive, and so totally vulnerable, that this ill person must be heavily protected, even against bad decisions that he himself made when previously well?

(Finucane 2001.) The first of these alternative views reflects the law, but the second has much force and might be in the back of some people's minds when they put aside the forms uncompleted.

A related problem is that an instruction in an advance directive rejecting a specific treatment lacks nuance. It is difficult to write an instruction, often far in

advance of an actual clinical context, that reflects the sometimes complex relationship between patient goals and the circumstances of treatment. For instance, suppose a patient would value a prolonged life, but not with severe functional impairment. For this patient, CPR probably would be indicated for a witnessed arrest in a coronary care unit but not in a nursing home (Gillick 2003). This distinction, and others like it, is not accommodated in an instructional advance directive form that simply invites refusal of life-sustaining treatments.

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At the same time, family and other proxy decision makers may benefit if they receive at least some guidance about what the individual's preferences and priorities are. Although there remains doubt about reliance on instructional advance directives as an effective means of conforming proxies' decisions to patient preferences (Ditto, Danks, Smucker et al. 2001), proxies who forgo life-sustaining medical treatments experience heightened stress if they bear sole responsibility for the decision, compared with proxies who feel that they have shared responsibility with the patient, based on prior guidance (Tildon, Tolle, Nelson et al. 2001). As the daughter of an AD patient said, two years after her mother's death, "The most important thing that I could tell someone

else, is that this should be discussed way before the person gets sick, so that you have a plan, and you don't have some of the heartaches that my family went through before we finally decided to place my mom into the hospice program" (Markowitz and Rabow 2003). Hence, one of the key goals of advance care planning should be to provide the guidance that will reduce the burden on caregivers.

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This guidance, however, need not be of the legalistic "living will" type, a recitation of "yes/no" decisions about specific treatments. Instead, the guidance to proxy decision makers can be, in essence, a word picture, describing how the individual, in the face of AD and other ailments, wants to live until the end. Thus, for example, the widely praised *Five Wishes* document invites thought and conversation on topics like preferred physical surroundings as the end of life nears and preferences about prayer and similar spiritual matters.[16] The format of the guidance – whether in a formal advance directive, a "family covenant" (Doukas and Hardwig 2003), an informal letter, or simply a conversation – is far less important than the sharing of it. Moreover, a shift to encourage designation of health care agents and provision of informal guidance about personal preferences might be a more comfortable fit with the cultural sensibilities of a wider range of Maryland's minority groups (Eleazar, Hornung, Egbert et al. 1996; Hopp 2000; Hopp and Duffy 2000;Waters 2000).

In sum, the policy of the State should be to encourage, through the materials that it produces and through cooperative efforts with private entities, an advance care planning process that better fits the needs of AD patients and their families. State support of advance care planning also should be attuned to the needs of subgroups with distinct cultural outlooks and those whose primary language is not English. The State Advisory Council on Quality Care at the End of Life, with its mandate to "study the impact of State

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statutes ... and other aspects of public policy on the provision of care at the end of life"[17] and its diverse membership, is best able to pursue this issue.

RECOMMENDATION 4-1: The State Advisory Council on Quality Care at the End of Life should review the current Maryland advance directive forms and consider whether:

(i) a single, optional form should replace the two forms now set out in the Health Care Decisions Act;

(ii) the single form should, through its language and design, encourage the designation of a health care agent; and

(iii) materials accompanying the form should encourage the informal expression of preferences and values, rather than instructions about specific life-sustaining medical treatments.

RECOMMENDATION 4-2: The State Advisory Council on Quality Care at the End of Life should review Maryland health care facilities' implementation of the federal Patient Self-Determination Act and its Maryland counterpart, § 5-615 of the Health-General Article. The goal of this review would be to identify best practices and to develop more effective strategies for public and patient education and engagement, not to determine any particular facility's regulatory compliance.

RECOMMENDATION 4-3: The State Advisory Council on Quality Care at the End of Life should consider how advance directives and other tools of advance care planning can most effectively be made available to cultural and linguistic minority groups. As a first step, consideration should be given to translating advance directive forms and related materials into Spanish.

B. Planning for Future Research Participation

1. *Current law*

The Health Care Decisions Act, as its name implies, is a law about health care, not medical research. As we discussed in Chapter 2 of this report, however, sometimes research participation can rightly be considered, from the patient's perspective, a "health care" alternative. Under the Act, a competent individual "may, at any time, make a written advance directive regarding the provision of health care to that individual, or the withholding or withdrawal of health care from that individual."[18] Therefore, so long as research can fairly be characterized as holding out the prospect of direct medical benefit to participants, participation in it after loss of capacity may be addressed by an advance directive.

If an individual with mild AD wishes to authorize future participation in a wider range of potentially beneficial research, he or she should execute a proxy advance directive, with as specific an account as possible of the individual's intention.

As a practical matter, however, an advance directive's authorization for research participation would rarely suffice by itself as legally effective informed consent.[19] In the words of the National Bioethics Advisory Commission, prospective authorization for research participation "cannot be a 'blank check ...'" but instead must be limited to research about which "the potential subject, while capable, understood the 'risks, potential direct and indirect benefits, and other pertinent conditions ...'" (National Bioethics Advisory Commission 1998, at 61). If an individual with mild AD wishes to authorize future participation in a wider range of potentially beneficial research, he or she should execute a proxy advance directive, with as specific an account as possible of the individual's intention. "This does not mean that all possibilities should be covered through detail, but rather that the warranting of certain practices must be established so that the specific intentions of the subjects can be honored to the highest degree possible" (Moorhouse and Weisstub 1996). As discussed in Chapter 2, the named health care agent

could then decide whether a concrete instance of research fits within the individual's expressed intentions.

When research does not hold out any potential for direct medical benefit to participants, research participation cannot be "health care" for purposes of the advance directive provisions of the Health Care Decisions Act. Nor does any other statute authorize a research advance directive.

Under the common law of agency and the Maryland durable power of attorney statute,[20] an individual likely could empower an agent to give consent on the principal's behalf to participation in research that does not hold out the prospect of direct medical benefit. A risk-related limiting principle, however, is that the agent has a fiduciary duty to act primarily for the benefit of the principal.[21] Enrolling someone in high-risk, no-expected-benefit research would not meet that standard.

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2. *Data collection about research advance directives*

Beyond general endorsement of the concept, there exists no consensus about implementing a policy recognizing research advance directives, either nationally or in Maryland (Dresser 2001a, at 686-688; Dresser 2001b; Hoffmann, Schwartz, and DeRenzo 2000; National Bioethics Advisory Commission 1998, at 33). Indeed, a 1999 bill endorsed by the Attorney General's Office that, in part, would have specifically authorized research advance directives under some circumstances drew strong opposition and was killed in committee (Hoffmann, Schwartz, and DeRenzo 2000). We have no plans to offer similar legislation in the near future.

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fortunate to have in Maryland the nation's preeminent facility for clinical research, the Clinical Center at the National Institutes of Health. The NIH Clinical Center uses an advance directive document that encompasses both health care and research participation. With regard to the latter, the advance directive requests designation of a "substitute decision maker" and solicits the research subject's decision about research participation in the event of incapacity. The stated choices are as follows:

> If I lose the ability to make my own decisions, I do <u>not</u> want to participate in any medical research.
>
> If I lose the ability to make my own decisions, I am willing to participate in medical research that might help me
>
> If I lose the ability to make my own decisions, I am willing to participate in medical research that won't help me medically, but might help others as long as it involves no more than minimal risk of harm to me.
>
> If I lose the ability to make my own decisions, I am willing to participate in medical research that will not help me medically, but might help others, even if it involves greater than minimal risk of harm to me

The advance directive also encourages the individual to "indicate any specific values, goals, or limitations that you would like to guide your participation in medical research."

The Clinical Center's overall experience with this or similar advance directives and, in particular, its experience in dementia research might help provide an empirical basis for future policy decisions. Indeed,

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one study already provides important evidence on the question whether individuals with mild to moderate AD have capacity to execute a durable power of attorney related to research (Dukoff and Sunderland 1997). If NIH has other data on, for example, the rate of completion of the decisional component of the research advance directive, the decisions made, and the types of research in which the advance directive is ultimately applied, these data should be collected and analyzed. In addition, it may be that other centers conducting such research might have useful data.

RECOMMENDATION 4-4: The Health Policy Division of the Attorney General's Office should explore the feasibility of an empirical study of research advance directives, with the goal of basing future policy recommendations on the data analysis.

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Endnotes

1. Last Acts, supported by The Robert Wood Johnson Foundation, is a national coalition of member organizations seeking to improve care and caring at the end of life. Last Acts’ “five Principles of Palliative Care” may be found at the following URL: http://www.lastacts.org:80/scripts/InfoWare.exe?FNC=preceptsForUsers1__Ala_info_Precepts_Start_html___ (accessed August 1, 2003).

2. Health-General Article, §§ 5-602 and 5-603.

3. The optional form’s printed language grants to the health care agent “full power and authority to make health care decisions for me, including the power to ... consent to the provision, withholding, or withdrawal of health care, including, in appropriate circumstances, life-sustaining procedures.” Health-General Article, § 5-603 (Form II, Part A, paragraph (2)d).

4. It can also say that, no matter the person’s condition, he or she wants “all available medical treatment in accordance with accepted health care standards.” Health-General Article, § 5-603 (Form II, Part B, paragraph (5)). This use of a decisional advance directive is just as valid legally as a decision to limit treatment but is, we believe, comparatively rare.

5. “Terminal condition” means the point in an irreversible disease process at which death has become “imminent.” Health-General Article, § 5-601(q).

6. “Persistent vegetative state” means a permanent loss of consciousness. Health-General Article, § 5-601(o).

7. Health-General Article, § 5-601(i). The definition is explained in 78 *Opinions of the Attorney General* 208, 211-214 (1993).

8. The application of the definition to advanced dementia is explained in 85 *Opinions of the Attorney General* ___ (2000) [Opinion No. 00-029, at 9-11 (November 16, 2000)].

9. Although usually called by this name, the PSDA was not a separate piece of legislation. Rather, it was contained within a huge omnibus bill, the Omnibus Budget Reconciliation Act of 1990. The PSDA is codified at 42 U.S.C. §§ 1395cc(f)(1) and 1396a(a).

10. The PSDA's requirements are linked to eligibility for Medicare or Medicaid reimbursement.

11. Health-General Article, § 5-615.

12. A ten-state survey of nursing homes three years after enactment of the PSDA showed a tripling of documented living wills, but only to an average rate of 13.3 percent across all study sites (Teno et al. 1997). Perhaps the main effect of laws like the PSDA is to improve documentation of existing advance directives rather than to motivate people who have not done so (Bradley et al. 1998).

13. These data are compiled by the Center for Gerontology and Health Care Research at Brown University and are available at: http://as800.chcr.brown.edu/dying/mdprofile.htm (accessed October 31, 2003).

14. This language is the form's paraphrase of the definition of "end-stage condition." Health-General Article, § 5-601(i).

15. The Health Care Decisions Act has a slight bias toward instructional advance directives. This is so because, of the two optional forms set out in the statute, one (the living will) is entirely instructional in content. The other (the advance medical directive) has two parts, one of which permits designation of a health care agent and the other of which again sets out instructions about end-of-life medical care.

16. *Five Wishes*, which is legally valid in Maryland, is a copyrighted brochure distributed by Aging with Dignity, www.agingwithdignity.org (accessed August 1, 2003).

17. Health-General Article, § 13-1604(2).

18. Health-General Article, § 5-602(a).

19. 45 C.F.R. § 46.116.

20. Estates and Trusts Article, § 13-601.

21. *United Capitol Insurance Co. v. Kapiloff*, 155 F.3d 488 (4th Cir. 2000 (applying Maryland law); *Faith v. Keefer*, 127 Md. App. 706, 736 A.2d 422, *cert. denied*, 357 Md. 191 (1999).