

## Chapter One

# Alzheimer's Disease: Assessing Its Impact and Its Policy Environment



### A. CLINICAL OVERVIEW

Dementia is a disorder characterized by multiple impairments of cognition in an individual who is otherwise fully alert and attentive. The impairments of intellectual functioning include memory, abstraction, judgment, and language (Rabins 2001). Although at least 75 distinct diseases can present as a dementia syndrome, Alzheimer's disease<sup>1</sup> (AD) is the most common type of progressive dementia, accounting for around two-thirds of dementia cases (Cummings and Cole 2002; Mace and Rabins 1999, at 290; Nussbaum and Ellis 2003; Post 1998; Rabins 2001).

The Alzheimer's Association succinctly defines AD as "a progressive, neurodegenerative disease characterized by loss of function and death of nerve cells in several areas of the brain, leading to loss of mental functions such as memory and learning."<sup>2</sup> The American Psychiatric Association's more elaborate definition for "dementia of the Alzheimer's type" speaks of "multiple cognitive deficits," with gradual onset and continuing decline from a person's prior level of functioning (American Psychiatric Association 1994, at 142). As a recent review article summarizes, "The clinical hallmarks are progressive impairment in memory, judgment, decision making, orientation to

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physical surroundings, and language” (Nussbaum and Ellis 2003). Neuropsychiatric symptoms, such as agitation, depression, and delusions are also common in AD patients (Mega, Masterman, O’Connor *et al.* 1999).

AD is often categorized by stages: mild (stage I), moderate (stage II), and advanced or severe (stage III). The first stage, mild AD, is characterized predominantly by memory impairment; the second, by additional impairments in language, the performance of everyday learned activities, recognition of the familiar, and the “executive function” (the ability to initiate, sustain, and stop activities and to be mentally flexible); the third, by severe physical impairments (Rabins 2001; Rabins, Lyketsos, and Steele 1999).<sup>3</sup> A person with severe AD becomes so debilitated as to be especially vulnerable to infectious disease; most commonly, people with severe AD die of bronchitis or pneumonia (Beard, Kokman, Sigler *et al.* 1996; National Institute on Aging 2000, at 6).

The ordinary course from AD onset to death has been estimated as a period of seven to ten years (Mace and Rabins 1999, at 291). A recent analysis of a Canadian population, however, observed that the median survival from the onset of AD “is much shorter than has previously been estimated,” a bit more than three years (Wolfson, Wolfson, Asgherian *et al.* 2001).<sup>4</sup> Nevertheless, “although some patients with [AD], particularly the oldest, may die within three years of receiving the diagnosis, many patients, particularly those in whom the onset occurs at an early age, live for a decade or more with the ravages of severe dementia” (Kawas and Brookmeyer 2001).

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Although researchers have identified many of the components that can lead to AD, a complete picture of its causes and development has not yet emerged (Geller and Reichel 1999). In particular, the onset of the disease is difficult to pinpoint. As one scientist recently put it, "It is commonly assumed that the preclinical stages of [AD] extend over years, maybe even decades.... [L]ate onset [AD] is the result of a life-long accumulation of damage ..." from both internal and external factors (Breteler 2001). Some researchers argue that environmental and lifestyle factors (for example, a high-fat, high-calorie diet) play an important role in the development of AD (Grant, Campbell, Itzhaki *et al.* 2002). Conversely, certain behaviors (for example, regular physical activity) might reduce the risk of AD (Lindsay, Laurin, Verrault *et al.* 2002).

The major pathologic features of the disease, observable directly only by autopsy, are amyloid plaques and neurofibrillary tangles. The plaques, which are most prominent in areas of the brain associated with memory, are deposits primarily of amyloid beta, an abnormal product derived from a protein called amyloid precursor protein. The tangles, which are composed primarily of another protein, tau, are thought by some researchers to play an important role in the later stages of AD (Geller and Reichel 1999). Patients with AD also have deficiencies in several neurotransmitters, primarily acetylcholine; these deficiencies may account for many of the symptoms of AD (Mace and Rabins 1999, at 302).

Despite the incomplete scientific understanding of AD's etiology, therapies targeting different aspects of the disease process are emerging (DeKosky 2003; Geldmacher 2003). Several drugs aimed at AD symptoms have already been approved, and others are in various stages of testing. The approved medications, all of which act to inhibit the enzyme (cholinesterase) that breaks down acetylcholine, are

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indicated for treatment of mild to moderate AD. Although they do not stop or reverse the progress of AD, they have been shown to improve cognitive and other symptoms in many AD patients (DeKosky 2003; National Institute on Aging 2000, at 13; Straus 2001; Wilcock, Lilienfeld, and Gaens 2000). As a recent commentary notes, the effect of these drugs for patients who respond well to them is “an improvement in cognition roughly equivalent to stemming 6-12 months of natural decline in untreated patients” (O’Brien and Ballard 2001). In addition, psychotropic medications may be indicated for behavioral disturbances, like agitation, that often occur as a consequence of AD (Cummings and Cole 2002; Geldmacher 2003).

Research efforts aimed at the more advanced stages of AD are beginning to show promise. Memantine, an agent intended to avert neuronal damage by inhibiting overproduction of the neurotransmitter glutamate, reduced clinical deterioration in a study population with moderate to severe AD (Reisberg, Doody, Stoffler *et al.* 2003). To be marketed under the trade name Namenda, memantine was approved by the Food and Drug Administration for this indication in October 2003<sup>5</sup>. Research into immunization therapy, while raising serious safety concerns, also gave preliminary hints of possible efficacy (Hock, Konietzles, Streffer *et al.* 2003; Winblad and Blum 2003). Research about AD also includes efforts to better understand the disease’s etiology, improve early diagnosis, and improve support for care givers (National Institute on Aging 2000, at 14). One expert has expressed optimism “that in the next decade we will find treatments ... following the identification of genes that cause the disease ...” (Martin 2000, at 35).<sup>6</sup>

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## **B. PREVALENCE AND ECONOMIC IMPACT**

Four million Americans have AD (Kawas 2003). Primarily as a result of the aging of the “baby boom” cohort, experts project the prevalence of AD to quadruple by 2050, “which means that 1 in every 45 Americans will be afflicted with the disease” (Kawas and Brookmeyer 2001). Nearly 85,000 Marylanders had AD in 2000 (Alzheimer’s Association 2003). This number is expected to increase to nearly 195,000 by 2030 (Alzheimer’s Association 2003).

The true human cost of AD is the suffering it imposes, on its victims and their caregivers. Some dollar amounts, however, suggest the dimensions of the burden. For example, in 2000, total spending for Medicare and Medicaid beneficiaries with AD has been put at approximately \$50 billion (Alzheimer’s Association 2001, at 2). By 2010, this spending is predicted to increase to more than \$82 billion (Alzheimer’s Association 2001, at 4). The cost to U.S. businesses in 2002 was estimated at more than \$61 billion, most of which is attributable to lost productivity from workers who shoulder the burden of caregiving (Koppel 2002).

## **C. IMPACT OF PUBLIC POLICY**

Given AD’s enormous impact on those who have the disease and those who care for them, Maryland officials have, for nearly two decades, recognized AD as presenting important public policy issues. In 1984, Governor Harry Hughes created a Governor’s Task Force on Alzheimer’s Disease and Related Disorders, chaired by Dr. William Reichel, a renowned geriatrician. The following year, in a wide-ranging report issued after a series of surveys and public hearings, the Task Force presented numerous

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recommendations on “service resources” for AD patients and their caregivers, education and training of professionals, and financial relief for those bearing the cost of AD care (Governor’s Task Force on Alzheimer’s Disease and Related Disorders 1985; Reichel, Franch, and Solon 1986; Reichel, Franch and Beacham 1986). The Task Force’s work resulted in several immediate legislative enactments<sup>7</sup> and executive actions and laid the groundwork for ongoing efforts to provide adequate financial support for respite care.

A similarly broad-gauge look at caregiving is emerging from the Maryland Caregivers Support Coordinating Council.<sup>8</sup> Although not focused specifically on AD caregiving, the Council will surely include AD issues as it solicits the concerns of caregivers through public hearings and other means.<sup>9</sup> Among the Council’s responsibilities are the review of successful programs in other states, the development of a “best-practices” model program, and the identification of unmet needs and potential funding sources.<sup>10</sup> In the Council’s initial report, for example, it identified the need to build respite provider capacity to meet “the special needs of the elderly” (Maryland Caregivers Support Coordinating Council 2002).

The Attorney General’s Office has neither the expertise to address global issues of AD care, as the Task Force did, nor the desire to undertake work that has wisely been assigned to others, like the Caregivers Council. Therefore, this report will be more modest in scope than the Task Force report, and it will not address caregiving as such.

We believe that we can be helpful, however, in identifying key features of the Maryland legal and policy environment in which care is delivered.<sup>11</sup> State law and policy in areas as diverse as personal health

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care planning, health facility regulation, Medicaid services, and driver licensing can make an important difference in the lives of people with AD and their professional and family caregivers. The goals of public policy, in our view, should be these:

- ▶ to further the right of individuals to plan for health care and other decisions in accordance with their personal values;
- ▶ to safeguard individuals against abuse, neglect, and financial exploitation;
- ▶ to promote systematic improvement in care, especially in state-regulated facilities;
- ▶ to support both family and professional care givers as they respond to the changing needs of people with AD;
- ▶ to balance support for research with protection of vulnerable research participants;
- ▶ to promote mobility while protecting public safety.

Furthermore, in pursuing policies that accord with these goals, State and private sector leaders should carefully attend to the means by which positive change is most likely to occur and the need for evidence that it actually is occurring. Because announcements of good intentions or edicts from elites rarely have practical effect on their own, an inclusive process is itself a key to change. As business consultant Michael Porter has observed, “What separates success from failure is not the ability to grasp the ideas but to mobilize action” (Gurwitt 2000).

Moreover, because well-intentioned and apparently logical policy recommendations can turn out to do more harm than good, policy decisions should be grounded in empirical evidence whenever possible, even if, as will usually be the case, the evidence is more suggestive than unequivocal (Macintyre et al. 2001).

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## Endnotes

1. In current medical style, a disease or syndrome named after an individual – here, Alois Alzheimer, the German neurologist who, in 1907, first published a description of this type of dementia – is designated without the possessive: for example, Alzheimer disease, Bell palsy, or Down syndrome. In this report, however, we use the more traditional and familiar term “Alzheimer’s disease,” which we abbreviate to AD.
2. This and other definitions related to AD may be found on the “glossary” page of the Alzheimer’s Association web site, <http://www.alz.org/ResourceCenter/ByType/Glossary.htm> (accessed June 28, 2003). We note that the formal name of the organization is the Alzheimer’s Disease and Related Disorders Association, Inc. For brevity’s sake, however, and reflecting the organization’s own usage, we refer in this report to the Alzheimer’s Association.
3. A fourth stage, “profound/terminal,” has also been designated for the very end of the disease process (Hughes et al. 1982).
4. The specific estimated median survival found by these investigators was 3.1 years for subjects with probable AD and 3.5 years for subjects with possible AD. It is difficult, however, to establish an accurate date of onset, given that “the majority of people with [AD] have symptoms for several years before receiving a diagnosis” (Kawas and Brookmeyer 2001).
5. <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00961.htm> (accessed January 5, 2004).
6. A listing of potential treatments and their current status may be found at <http://www.alzheimers.org/potreat.html> (accessed June 28, 2003). A listing of current clinical trials related to AD may be found at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) (accessed June 28, 2003).
7. Chapters 632, 633, and 634 of the Laws of Maryland 1986.
8. The Council was created by Chapters 400/401 of the Laws of Maryland 2001.
9. Article 88A, § 129A(c)(1) of the Code.
10. Article 88A, § 129A(c)(3), (4), (6), and (7).
11. Many of these issues were identified and discussed on a broader scale at a Joint Conference on Legal/Ethical Issues in the Progression of Dementia, held at the University of Georgia



on November 29 to December 2, 2000. The Joint Conference was co-sponsored by the Borchard Foundation Center on Law and Aging, the Alzheimer's Association, the American Bar Association's Commission on Legal Problems of the Elderly, the National Academy of Elder Law Attorneys, and the University of Georgia School of Law. The Joint Conference's recommendations appear in a symposium issue of the Georgia Law Review (Spurgeon et al. 2001).