Should Home Screening Tests for Alzheimer's Disease Be Regulated?

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Guest Editorial

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Many older individuals live in dread of one day becoming a victim of Alzheimer’s disease (AD) or some other form of dementia. Especially for those who believe they are experiencing what they understand to be early symptoms of this devastating condition, the psychological appeal of products that may offer even a scintilla of useful information about the person’s actual medical status is strong. In their article on page 295 of this issue, Kier and Molinari (2003) describe a “Do-It-Yourself” gross screening tool that is being marketed directly to potential consumers for home use. They articulately discuss a number of significant scientific and ethical misgivings regarding the public availability and use of this product at the present time.

The advent of the Early Alert Alzheimer’s Home Screening Test (AHST) also implicates a panoply of potential legal issues, some of which are alluded to at least indirectly by Kier and Molinari (2003). For instance, what are the legal responsibilities (and the possible liability exposures for a breach of those responsibilities), in terms of appropriate diagnostic and therapeutic follow-up, of the physician who is presented with the results of an AHST that a patient has self-administered (Kapp, 2002)? What are the confidentiality obligations of health care providers whose patients give them their self-administered AHST results, especially in light of the new medical privacy regime ushered in by regulations implementing the Health Insurance Portability and Accountability Act (HIPAA; 1996)? What are the legal ramifications of misuse of AHST results by insurers, employers, or others for discriminatory purposes (Americans With Disabilities Act, 1990)? What are the legal parameters shaping the health care provider’s permissible response to a patient’s request for advice regarding, or help in performing, an AHST (Kapp, 2000)?

These issues about the consequences of AHST results deserve fuller exploration. In this brief essay, however, I concentrate on the question of whether (and, if so, how) the federal government ought to be regulating the marketing and availability of the AHST to a consumer public that, because of apprehension about the ravages of dementia, may be described as vulnerable bordering on desperate.

Falling Between the Legal Cracks

Most aspects of the modern American health care industry are extensively regulated. To understand why the AHST’s entry into the consumer marketplace is essentially unconstrained by the current regulatory structure, it is useful to distinguish AHST from other kinds of products and activities.

First, the federal Food and Drug Administration (FDA) imposes detailed premarketing approval requirements, in terms of demonstrated safety and efficacy, on drugs and medical devices. The Food, Drug, and Cosmetic Act (FDCA; 1938a) defines a drug as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” (§[g][1]); a device “means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease” (§[h][2]). The FDA does not have authority to regulate the AHST as a drug or device, nor as a biological product used for “the prevention, treatment or cure of a disease or condition of human beings” (FDCA, 1938b). Unlike, for example, home-testing kits used for identifying genetic mutations or defects and thereby predicting (with more or less certainty) the particular consumer’s medical future (Stevenson, 1999), AHST is designed and sold only as a gross screening instrument rather than as a diagnostic device. Kier and Molinari (2003) point out the screening versus...
diagnosis test distinction. Although they are correct that many patients fail to appreciate the difference (and, I would argue, this confusion extends to numerous professionals who misuse the results of mental status screening tools in making categorical judgments about patients’ decisional capacity [Kapp & Mossman, 1996]), the fact that AHST falls in the screening test classification is crucial in its effect of putting it outside of the FDA’s jurisdiction.

Second, because the AHST is a screening test intended exclusively for home use, it falls outside of the provisions of the FDCA and the Clinical Laboratories Improvement Act (CLIA; 1988) pertaining to test kits manufactured for use in laboratories. A laboratory is defined in CLIA as “a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings” (§263 a[a]). For the same reason, AHST cannot be regulated under the various state law counterparts to CLIA.

Third, even though at this time its use is still very much a matter of clinical innovation rather than scientifically proven or accepted professional practice, the advertised intended purpose of the AHST is to provide some benefit to the specific consumer who is taking the test. The AHST is not undertaken by any consumer as part of a scientifically designed research protocol being conducted to gather data from which generalized conclusions may be drawn to benefit unknown other persons in the future. Thus, the substantial body of federal regulation that protects the rights and safety of human beings who are asked to enroll as participants in research studies (Protection for Human Research Subjects, 2003) is inapplicable to the AHST context.

Possible Regulatory Actions

In regards to the availability of an AHST marketed directly to, and used in the home by, members of the general public, should health professionals’ reaction be, “There ought to be a law against, or at least setting certain limitations regarding, such a thing”? The answer, I think, is both yes and no.

At the least, consumers need more and better information to assist them in deciding whether to purchase, use, and rely on the results of this product. On packaging or other materials that are readily readable without first buying and opening the kit, the manufacturer should be required to clearly state for lay persons that (a) the product is a gross screening tool rather than a diagnostic test, (b) it has certain limitations (which should be listed), and (c) the consumer should consult with a physician regardless of the test results. This information also ought to be mandated for inclusion in any advertising done for this product. Because the manufacture, marketing, and sale of the AHST is a matter of interstate commerce, the Federal Trade Commission could impose such informational admonitions on manufacturers under its authority to study and regulate “unfair or deceptive” acts or practices (Nature, Authority, and Use of Trade Regulation Rules, 2003). State FTC counterparts have matching authority exercisable within their own respective borders. Government regulation of commercial speech, including compelling business entities to provide specified information to the public, is an important and legitimate strategy to safeguard consumer health and safety (Gostin, 2000, pp. 154–167).

Beyond strategies aimed at empowering consumers to make informed, voluntary choices, however, health professionals should be cautious about advocating any broad new regulatory initiatives, such as expanding the reach of the FDCA or CLIA to encompass home screening tests like AHST. Decisions about the use of even well-validated screening tools for early detection of disease in older adults must be made on a very individualized basis, “reflecting the primacy of individual choice” (American Geriatrics Society Ethics Committee, 2003, p. 270), “Let the buyer beware” is no longer a completely adequate response to an increasingly complex health care marketplace, but to deprive or unduly restrict the opportunity for consumers to choose to avail themselves of a product that they may feel, even in light of full and honest disclosure regarding the product’s limitations, offers them the possibility of sufficient benefit (defined according to their own set and prioritization of values) to justify its use would be an exercise of governmental paternalism that disrespects the autonomy interests of competent adults. Although the ethical propriety of selling a product that preys on the (often overblown and misinformed) anxieties of a vulnerable population may be questioned, health professionals should be wary about enlarging the role of government qua protective nanny when that means excessively imposing on the prerogative of older adults to make informed, albeit perhaps ill-advised, decisions about the most personal aspects of their lives.

References


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