Anti-Aging Medicine: Can Consumers be Better Protected?

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The use of interventions claiming to prevent, retard, or reverse aging is proliferating. Some of these interventions can seriously harm older persons and aging baby boomers who consume them. Others that are merely ineffective may divert patients from participating in beneficial regimens and also cause them economic harm. “Free market regulation” does not seem to weed out risky, ineffective, and fraudulent anti-aging treatments and products. Public health messages, apparently, are having little effect. What more can be done to achieve better protection for older consumers? An analysis of the potential for federal and state action reveals many barriers to effective governmental regulation of anti-aging interventions. In view of dim prospects for stronger public regulation, physicians and other professionals—especially geriatricians and gerontologists—will need to be more aggressive in protecting older consumers. In particular, The Gerontological Society of America and the American Geriatrics Society should undertake a sustained program of specific educational efforts, directed at health professionals and the general public, in which they sort out as best they can the helpful, the harmful, the fraudulent, and the harmless anti-aging practices and products.

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The marketing and use of interventions claiming to prevent, retard, or reverse aging seem to have increased substantially in recent years. As the Internet has become a widely used medium of communication, anti-aging Web sites, such as “Youngevity: The Anti-Aging Company,” have proliferated (Youngevity, 2003). According to the American Medical Association, 2,500 physicians have established specialty practices devoted to “longevity medicine” (Shelton, 2000). An American Academy of Anti-Aging Medicine (A4M), created in 1993, has grown to 12,000 members and receives 1.8 million hits per month on its Web site (American Academy on Anti-Aging Medicine, 2003a); its net assets increased from $650,000 in 1997 (Guidestar, 2003a) to $5.3 million in 2000 (Guidestar, 2003b). The goal of the clinical anti-aging community is to extend the time its patients can live without the morbidities of the aging process: “memory loss, muscle loss, visual impairment, slowed gait and speech, wrinkling of the skin, hardening of the arteries, and all the other maladies we call aging” (Shelton, p. 25). Some of its members go even further. The president of A4M has authored books with titles such as Grow Young with HGH:

There are no hard statistics on the size of the overall anti-aging market in the United States, but there are some estimates available. A research report prepared by a “knowledge services company,” FIND/SVP, estimates that the anti-aging market was about $43 billion in 2002 and could increase to $64 billion by 2007 (FIND/SVP, 2003). However, it defines the market very broadly in terms of five categories: cosmetic treatments and surgery; exercise and therapy; food and beverages; vitamins, minerals, and supplements; and cosmetics and cosmeceuticals. The American Academy of Anti-Aging Medicine (2003b) states that the present anti-aging global market is $30 billion.

Current interest in anti-aging interventions is fueled by the appeal of its promises to baby boomers trying to preserve their youthfulness as they approach chronological old age and older persons attempting to rejuvenate themselves (see Haber, 2001–2002, and Puri, 2003). The halo of successes achieved by modern medicine helps to stimulate demand. Yet interest also stems from biomedicine’s conspicuous failures. The inability to win the “war on cancer” and other disappointments have led many consumers to try a variety of so-called alternative medicine approaches that have little or no scientific support for their efficacy and that may be risky to consumers. Not all anti-aging products and therapies fall into this category; but many do.

Anti-aging interventions, like other medical and pseudomedical products and services, raise a number of welfare concerns for patients, practitioners, and the larger society. Foremost is the question of safety for those older adults and aging baby boomers who consume them. The wares being sold and techniques being endorsed include powerful drugs that have the potential to cause serious physical and mental harm. For example, studies have indicated that some short-term anti-aging hormone treatments can have adverse effects, such as diabetes and glucose intolerance (e.g., Blackman et al., 2002; Janssens & Vanderschueren, 2000), and that long-run administration of growth hormone to older adults may potentially elevate the risk of cancer (e.g., Chan et al., 1998). Similarly, hormone replacement therapy consisting of estrogen plus progestin for postmenopausal women has been shown to elevate their risks of dementia (Shumaker et al., 2003) and breast cancer, coronary heart disease, stroke, and pulmonary embolism (Writing Group for the Women’s Health Initiative Investigators, 2002).

In addition to issues of harm, the mere ineffectiveness of some anti-aging interventions can have deleterious consequences for the welfare of patients and consumers. Engaging in an ineffective anti-aging therapy may preclude patients from participating in other regimens that could be beneficial, and these patients may waste money that could be used for helpful medical interventions. For instance, older adults may choose to undergo growth hormone treatments because they are mistakenly led to believe that this will increase their muscle strength and thereby divert themselves from undertaking regimens such as resistance exercise training, which has been shown to increase muscle strength significantly (Blackman et al., 2002; Papadakis et al., 1996; Taaffe et al., 1994). For some treatments the sums involved can be substantial. Growth hormone replacement costs between $7,500 and $10,000 annually according to one report (Vance, 2003), and “longevity clinics” are charging as much as $2,000 per day (Pope, 2002). Granted, the majority of older people and baby boomers are not able to spend such sums. However, even those who can buy comparatively inexpensive mineral waters and ineffective dietary supplements experience some degree of economic harm.

To date, there are no indications that market forces are weeding out risky, ineffective, economically harmful, and fraudulent anti-aging interventions—no sign, that is, of free market regulation. To be sure, it is impossible to document the number of people who consume anti-aging services and products that are risky and harmful, economically damaging, and fraudulently ineffective. But whatever its magnitude, it is likely to grow, and it has already been substantial enough for the National Institute on Aging (2002, 2003), the U.S. Senate Special Committee on Aging (2001), and the U.S. General Accounting Office (GAO; 2001) to disseminate public health messages to warn unwary consumers. Similarly, geriatricians have published articles in which they attempt to sort out those anti-aging interventions that are beneficial from those that are harmful, risky, and ineffective (e.g., Fischer & Morley, 2002). In addition, an international group of 51 biogerontologists managed to reach a wide audience in the spring of 2002 when their message, “No Truth to the Fountain of Youth,” originally published in Scientific American (Olshansky, Hayflick, & Carnes, 2002), was amplified by reaching some 35 million readers in a subsequent newsletter of the AARP Bulletin (Pope, 2002).

Public health messages like these can sometimes reduce consumption of physically and economically harmful, ineffective, and fraudulent anti-aging interventions. Early in the 20th century, for instance, a series of articles in the Journal of the American Medical Association was instrumental in discrediting surgical rejuvenation techniques (Hirschbein, 2000). The ongoing growth of the anti-aging market, however, indicates that contemporary public health messages are not yet having much impact. Many consumers apparently discount warnings about anti-aging interventions. Indeed, when the AARP Bulletin featured the “No Truth to the Fountain of Youth” message on its front page (Pope, 2002), the story provoked a substantial backlash in AARP member online message boards, condemning the biogerontologists’ warning as a scare tactic (AARP Community Message Boards, 2002). In addition, a recent survey

Vol. 44, No. 3, 2004
305
Governmental Regulation and Its Limitations

In principle, one possible approach to achieving greater protection is governmental action. However, there are distinct barriers to effective governmental regulation of anti-aging medicine.

Safety and Efficacy

At the federal level, the FDA bears the responsibility for ensuring the safety and efficacy of medical products. The agency generally relies on evidence from clinical investigations sponsored by the manufacturers of the products, supplemented by reports of adverse events in actual use.

For a variety of reasons, the FDA’s oversight is inadequate when it comes to anti-aging interventions. First, some interventions, such as lifestyle changes that have not been proved to affect aging processes, lie outside of the FDA’s regulatory purview because they constitute the practice of medicine rather than the use of a drug or medical device (Kessler, 1989). The practice of medicine is regulated by state law, through a combination of state medical board oversight and private suits for malpractice. In theory, physicians who practice in a manner that is unsafe or ineffective can face disciplinary action and civil liability. But, in reality, state medical boards infrequently discipline physicians for improper practice (Wolfe, 2003). In its report on the physical and economic harms of anti-aging products, the U.S. General Accounting Office (2001) found that “in general [the states] focused little attention on anti-aging and alternative medicine products” (p. 21). The threat of potential malpractice suits also does not seem to deter the proliferation of questionable anti-aging services.

Another impediment to effective FDA regulation of anti-aging products is the Dietary Supplement Health and Education Act (DSHEA). Enacted in 1994, it allows certain anti-aging interventions to be marketed as “dietary supplements” without proof of safety or efficacy. The definition of a dietary supplement in this legislation is extremely broad; virtually any anti-aging product would qualify as a dietary supplement as long as it did not make a claim to treat a specific disease, bore a disclaimer on the label that the product is not approved by the FDA, and was taken by mouth; see the Federal Food, Drug, and Cosmetic Act (1994). Prior to the DSHEA, a product that claimed, for example, to “provide you with Increased Energy level, Increased Sex drive, Improved skin texture, Increased muscle mass, Decrease [sic] Body fat, Decreased Cholesterol, Improve [sic] Cognitive Thinking Skills, Improved Immune System, Improved Sleep patterns, and Improved Bone Density” (Hormonal Anti-aging Center, 2003) would have been regulated as a drug because it claims to affect the structure or function of the body (Federal Food, Drug, and Cosmetic Act, 1994). Since the DSHEA, however, products for which such claims are made, and which are sold as dietary supplements, are not subject to FDA regulation as drugs.

Moreover, the DSHEA has reversed the traditional process for proving safety and efficacy. Although the manufacturer of a new drug or medical device is required to establish safety and efficacy prior to marketing, in the case of a dietary supplement the burden shifts to the FDA to show that the product is unsafe before the agency can take action to restrict its sale or remove it from the market.

Finally, unlike the case with drugs and medical devices, manufacturers of dietary supplements are not required to disclose information about adverse events to the FDA, and little voluntary reporting takes place (GAO, 2001). The FDA recently has proposed that dietary supplement manufacturers be required to verify that their products contain the ingredients listed on the label (FDA, 2003), but this is a far cry from making them prove safety and efficacy.

Even in the case of drugs and devices that are subject to full FDA oversight, the agency faces a number of difficulties in ensuring safety and efficacy. In the first place, it is unclear what endpoints the agency should require manufacturers to use in order to prove anti-aging efficacy. Is symptomatic relief sufficient, in which case manufacturers might be allowed to make anti-aging claims for products such as anti-inflammatory drugs? Indeed, what counts as a symptom of aging, and what qualifies as symptomatic relief? If, as the old adage has it, “you’re only as old as you feel,” would an anti-aging claim be appropriate for a stimulant such as amphetamine or a mood-altering drug such as marijuana? How should the FDA deal with the subjective quality of many symptoms? Should the FDA take the position that anti-aging claims are only appropriate for interventions that actually alter the processes of aging themselves, as opposed to those aimed at treating specific diseases and symptoms associated with aging?

Even if the FDA imposed severe restrictions on antiaging claims, this would not prevent practitioners from prescribing drugs that are unproven for anti-aging uses, such as human growth hormone. The Federal Food, Drug, and Cosmetic Act does not restrict physicians from prescribing products for off-label indications. The manufacturer of a drug or device must notify the FDA of adverse event reports stemming from off-label use (U.S. Department of Health and Human Services, 2001), but adverse events in general are
significantly underreported (Ahmad, 2003; Lazarou, Pomeranz, & Corey, 1998). Historically, the agency has attempted to prohibit manufacturers from promoting their products for off-label uses, but since the passage of the Food and Drug Administration Modernization Act of 1997, manufacturers may distribute promotional materials for unapproved uses as long as they are in the process of seeking approval. In addition, the earlier FDA restrictions on promotion of off-label uses have been challenged in court as a violation of the manufacturer’s First Amendment right to freedom of commercial speech (Washington Legal Foundation v. Friedman, 1998).

**Are Anti-Aging Interventions Therapies or Enhancements?**

Still another factor complicating government regulation of anti-aging interventions is fundamental disagreement within the scientific community over whether aging is inherently pathological or simply a series of biological processes that increase vulnerability to disease. Leonard Hayflick (2001–2002) expressed the view that “aging is not a disease, so the concept of seeking a cure for it is tantamount to seeking a cure for embryogenesis or adult development” (p.21). On one hand, many gerontologists agree with him. On the other hand, others argue that a dichotomous view of aging and disease is untenable (see Blumenthal, 2003).

If aging is not regarded as pathological, then interventions that claim to slow, halt, or reverse aging would not be therapies but enhancements, similar to cosmetic medicine. From a regulatory standpoint, this would reinforce their ability to be marketed as dietary supplements because they would not be making claims to treat specific diseases. If they did not qualify as dietary supplements—for example, because they were not orally ingested—the FDA could classify them as drugs or medical devices, and regardless of whether they were regarded as enhancements or therapies, their manufacturers would have to prove the safety and efficacy of their products before they could be marketed. But the FDA’s experience with cosmetic medicine, including nonprescription contact lenses, breast implants, liposuction, and Botox, demonstrates the difficulties of measuring efficacy and of comparing risks and benefits outside of the therapeutic context (Mehlman, 1999).

Another consequence of regarding anti-aging interventions as enhancements rather than therapies is that an important motivation for manufacturers to establish the safety and efficacy of off-label uses of their products—the need to have the product use covered by health insurance—is removed. Health insurers generally refuse to cover treatments that are “experimental,” which typically includes off-label uses that are not generally recognized within the scientific community as safe and effective or that are not backed up by adequate and well-controlled clinical investigations. This gives manufacturers an incentive to conduct clinical trials on off-label uses of their products so that these uses can be added to the FDA-approved—hence, nonexperimental—labeling indications. But, health insurance does not cover enhancement interventions regardless of whether they are safe and effective at achieving their enhancement objectives; witness the universal lack of coverage for cosmetic surgery. Therefore, there is no insurance-based incentive for manufacturers to clinically test anti-aging products regarded as enhancements.

Ironically, there is one respect in which regarding anti-aging products as enhancements rather than therapies could create a legal roadblock for manufacturers and distributors. It is a federal felony to distribute one product that is frequently touted for its anti-aging effects, human growth hormone, “for any use in humans other than the treatment of a disease or other recognized medical condition” (Federal Food, Drug, and Cosmetic Act, 1994, §333). This prohibition, which is enforced by the Drug Enforcement Administration, was added to the Federal Food, Drug, and Cosmetic Act in the early 1990s following reports of abuse by athletes. If other anti-aging products presented similar risks to health or to other societal goals, Congress could bring them within this prohibition.

**Truth in Advertising**

Even as the FDA is responsible for ensuring the safety and efficacy of health products at the federal level, the Federal Trade Commission (FTC) has the primary responsibility for protecting consumers from economic injury stemming from false claims for ineffective or unproven products sold in interstate commerce. The states have the power to regulate marketing within their borders, but, as noted earlier, they have made little effort to control anti-aging interventions.

Under the Federal Trade Commission Act (1914), the FTC reviews advertising to determine whether it is truthful and nondeceptive and whether advertisers have evidence to back up their claims (FTC, 2003). Although this gives the agency ample legal authority to regulate marketing and advertising, it has only a limited amount of resources for carrying out its responsibilities. Anti-aging interventions comprise only one of the many types of products that the agency must police, and its budget also must cover its substantial role in enforcing antitrust and other procompetitive laws.

The FTC’s job in ensuring truthful marketing is complicated by the ease with which manufacturers and distributors of anti-aging products can reach potential customers. In addition to ubiquitous print ads and television commercials and infomercials, there are numerous Web sites hawking anti-aging products (Drazen, 2003). The FTC targets such practices. Its most notable effort to police questionable claims on the Internet is “Operation Cure.All,” which consisted of two Internet surfs in 1997–1998 that netted over 1,600 sites worldwide and 800 sites in the United States alone.
But the agency itself admits that this was only “the tip of the iceberg” (Beales, 2001).

The Need for a More Aggressive Professional Response

Given these many difficulties of governmental regulation, what can be done to improve protection of the public, and particularly older adults and aging baby boomers, from threats to their health and economic harm that may be caused by unsafe and ineffective anti-aging interventions?

One solution would be to strengthen governmental regulatory oversight through a series of measures. The FDA could be given broader authority to regulate off-label uses of drugs and devices and the practice of medicine generally. The DSHEA could be repealed or the license that it gives to the marketing of dietary supplements could be curtailed. The European Union, for example, has announced its intent to increase oversight of “herbal remedies” (Commission of the European Communities, 2002). Both the FDA and the FTC could be given greater resources, and the states could direct more of their enforcement efforts at the anti-aging market.

However, none of these steps are likely to be taken, at least in the near term. Organized medicine is staunchly opposed to granting the FDA authority over the practice of medicine. The size, financial strength, and political power of the dietary supplement industry have been manifest in its ability to have DSHEA enacted and preserved. In the absence of a safety disaster involving its products, it may be able to block any Congressional effort to make major changes to DSHEA that would enable stronger regulation of the industry. In an era of substantial federal deficits, the government is unlikely to substantially increase the budgets of the FDA and the FTC. State governments are in even worse financial shape. In the context of existing budgets for the regulatory agencies, the anti-aging industry is but one of many that must be regulated. If underregulated anti-aging interventions can be shown clearly to pose a dire health hazard, this might give them a higher regulatory priority. But the consequences of economic harm and fraud, alone, even involving especially vulnerable older adults, are unlikely to be viewed as a top regulatory priority.

In view of these dim prospects for enhanced governmental regulation, physicians and other health care professionals—especially gerontologists and geriatricians—will need to bear a major responsibility for protecting consumers from harm. This responsibility must be carried out on several fronts.

The first line of defense occurs in the direct relationship with the patient. In accordance with the maxim “first, do no harm,” health care professionals must refrain from actively promoting unsafe or ineffective products and should describe the risks of using unproven interventions that patients bring up on their own.

Second, medical organizations can play a more active role. They should more actively apply their existing codes of ethics to harmful and ineffective anti-aging practices. Opinion 8.06 of the American Medical Association’s Council on Ethical and Judicial Affairs (2002), for example, states that “[p]hysicians who choose to sell health-related products from their offices should not sell any health-related products whose claims of benefit lack scientific validity.” Opinion 8.20 states that “[t]reatments which have no medical indication and offer no possible benefit to patients should not be used.” These rules must be better enforced against professionals who purvey harmful and ineffective anti-aging interventions.

Such tasks of professional self-regulation will not always be easy to carry out. In cases of outright fraud—selling products and treatments that the purveyors know to be ineffective—the challenge for professional regulation (as well as government regulation) is relatively straightforward. Identify and sanction the perpetrators. However, when products and services are marketed in the true belief that they may work, even though scientific evidence is contradictory or lacking, protecting consumers is more difficult. It may be hard to distinguish between a biological and a placebo effect, yet patients may derive considerable benefit from both. Moreover, the practice of medicine must remain open to new approaches. Physicians must be able to deviate from the mainstream without necessarily violating the law or being liable for malpractice, and patients must be permitted to try interventions that lack scientifically rigorous proof of safety and efficacy (Kapp, 2003). The challenge is to accommodate new approaches and afford patients a range of choice without subjecting them to an unreasonable risk of harm and to distinguish between legitimate trial-and-error and quackery. One telltale sign would be if physicians earn substantial sums of money by selling unproven products or services and do not participate in clinical trials.

Third, editors of journals that circulate to health care professionals can more frequently call attention to anti-aging advertising that improperly relies on previously published studies. The editor-in-chief of the New England Journal of Medicine did this recently in an editorial on “Inappropriate Advertising of Dietary Supplements” (Drazen, 2003).

Most important, organized groups of gerontologists and geriatricians should undertake much more vigorous leadership than they have so far in the arena of anti-aging medicine. Presumably, it is professionals in these specific fields who are and should be most concerned about the impact of anti-aging interventions on older adults and aging baby boomers.

National gerontological and geriatrics organizations, such as The Gerontological Society of America
(GSA) and the American Geriatrics Society (AGS), can play a number of important roles through a series of activities that educate professionals and the public. One arrangement for carrying out these activities would be to establish task forces on anti-aging medicine within GSA and AGS that could work both separately and jointly, depending on the nature of the activity.

One important step would be to develop educational programs that embrace health care professionals who are practicing anti-aging medicine. The task forces can plan symposia and workshops at GSA and AGS annual meetings and ad hoc conferences at other times of the year that are aimed at anti-aging practitioners, emphasizing those anti-aging interventions that work, and contrasting them with those that do not and those that are harmful or risky. This would reinforce the efforts of those physicians and others (many of whom are GSA and AGS members) who are in fact offering safe and effective interventions (such as nutritional and exercise regimens and vitamins) that maintain and improve health and functioning at older ages. It would also undermine charges by the American Academy of Anti-Aging Medicine that “the gerontological establishment” and “the death cult of gerontology” are against coping with the declines, infirmities, and diseases associated with old age (see Binstock, 2003).

A second task force activity would be to target specific anti-aging treatments and products that may be harmful and ineffective and arrange for knowledgeable experts to write and submit reviews of the relevant evidence to journals that circulate to health care professionals. A good example of this genre is a recent article in the New England Journal of Medicine that addressed the issue of “Can Growth Hormone Prevent Aging?” (Vance, 2003). Even occasional special issues of the Journal of the American Geriatrics Society and the Journal of Gerontology: Medical Sciences would be helpful in this regard, just as a recent special issue of The Gerontologist usefully delineated issues and challenges in the arena of nursing home care (Quadagno & Stahl, 2003).

Another effort can be to disseminate information to the general public about the good, the bad, and the fraudulent in anti-aging medicine so that consumers can be better informed in making their choices. For instance, the task force(s) could develop occasional white papers on critical issues in the anti-aging arena and release them in highly visible public venues that are likely to maximize coverage in the popular media. One such vehicle for achieving wide coverage might be a news conference to release a white paper at the National Press Club in Washington, with GSA and AGS orchestrating participation by AARP, the Leadership Council of Aging Organizations, various consumer protection groups, the American Medical Association and specialty medical societies, the American Public Health Association, and other organizations that would lend visibility and credibility to such a coalition of sponsors. Another approach might be to develop and disseminate, with government or foundation funding, a series of public service messages on television.

The geriatrics and gerontological communities have been successful in much more difficult undertakings in the past. The very notion of geriatrics as a specialty was staunchly opposed for many years by the U.S. medical establishment (see U.S. Senate Special Committee on Aging, 1977). But, persistent efforts by leaders in geriatric medicine finally achieved in 1988 the recognition of a Certificate of Added Qualifications in Geriatric Medicine by the American Boards of Internal Medicine and Family Practice (Warshaw, Bragg, & Shaull, 2003). Similarly, as chronicled by Lockett (1983), the effort of GSA to establish a National Institute on Aging (NIA) throughout the early 1970s was fought strongly by the National Institutes of Health, the Office of the Secretary of the Department of Health, Education, and Welfare, and by the Office of Management and Budget. Indeed, when Congress enacted legislation for NIA in 1972, President Nixon vetoed it. Nevertheless, GSA lobbyists persevered, and the NIA legislation ultimately succeeded in 1974.

Conclusion

A primary raison d’être of both the GSA and the AGS organizations, as well as a goal of their individual members, is to promote the well-being of older people. From all signs the anti-aging market is growing. Some of its interventions are beneficial, benign, and not greatly harmful in terms of economic loss. Yet, others are harmful, risky, and economically damaging. As baby boomers continue to age, the demand for anti-aging products and services will increase. Activities to help professionals and the public sort out the good from the bad and deceptive aspects of the market would be in excellent harmony with the goal of promoting the well-being of older people. Whether GSA and AGS take on these responsibilities and do so with substantial commitment and vigor to be effective will be one indication of just how central that goal is to the organizations and their members.

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Vol. 44, No. 3, 2004 309