Editorials

Alternative Medicine — The Risks of Untested and Unregulated Remedies

WHAT is there about alternative medicine that sets it apart from ordinary medicine? The term refers to a remarkably heterogeneous group of theories and practices — as disparate as homeopathy, therapeutic touch, imagery, and herbal medicine. What unites them? Eisenberg et al. defined alternative medicine (now often called complementary medicine) as "medical interventions not taught widely at U.S. medical schools or generally available at U.S. hospitals."[1] That is not a very satisfactory definition, especially since many alternative remedies have recently found their way into the medical mainstream. Medical schools teach alternative medicine, hospitals and health maintenance organizations offer it,[2] and laws in some states require health plans to cover it.[3] It also constitutes a huge and rapidly growing industry, in which major pharmaceutical companies are now participating.[4]

What most sets alternative medicine apart, in our view, is that it has not been scientifically tested and its advocates largely deny the need for such testing. By testing, we mean the marshaling of rigorous evidence of safety and efficacy, as required by the Food and Drug Administration (FDA) for the approval of drugs and by the best peer-reviewed medical journals for the publication of research reports. Of course, many treatments used in conventional medicine have not been rigorously tested, either, but the scientific community generally acknowledges that this is a failing that needs to be remedied. Many advocates of alternative medicine, in contrast, believe the scientific method is simply not applicable to their remedies. They rely instead on anecdotes and theories.

In 1992, Congress established within the National Institutes of Health an Office of Alternative Medicine to evaluate alternative remedies. So far, the results have been disappointing. For example, of the 30 research grants the office awarded in 1993, 28 have resulted in "final reports" (abstracts) that are listed in the office's public on-line data base.[5] But a Medline search almost six years after the grants were awarded revealed that only 9 of the 28 resulted in published papers. Five were in 2 journals not included among the 3500 journal titles in the Countway Library of Medicine's collection.[6-10] Of the other four studies, none was a controlled clinical trial that would allow any conclusions to be drawn about the efficacy of an alternative treatment.[11-14]

It might be argued that conventional medicine relies on anecdotes, too, some of which are published as case reports in peer-reviewed journals. But these case reports differ from the anecdotes of alternative medicine. They describe a well-documented new finding in a defined setting. If, for example, the *Journal* were to receive a paper describing a patient's recovery from cancer of the pancreas after he had ingested a rhubarb diet, we would require documentation of the disease and its extent, we would ask about other, similar patients who did not recover after eating rhubarb, and we might suggest trying the diet on other patients. If the answers to these and other questions were satisfactory, we might publish a case report — not to announce a remedy, but only to suggest a hypothesis that should be tested in a proper clinical trial. In contrast, anecdotes about alternative remedies (usually published in books and magazines for the public) have no such documentation and are considered sufficient in themselves as support for therapeutic claims.

Alternative medicine also distinguishes itself by an ideology that largely ignores biologic mechanisms, often disparages modern science, and relies on what are purported to be ancient practices and natural remedies (which are seen as somehow being simultaneously more potent and less toxic than conventional medicine). Accordingly, herbs or mixtures of herbs are considered superior to the active compounds isolated in the laboratory. And healing methods such as homeopathy and therapeutic touch are fervently promoted despite not only the lack of good clinical evidence of effectiveness, but the presence of a rationale that violates fundamental scientific laws — surely a circumstance that requires more, rather than less, evidence.

Of all forms of alternative treatment, the most common is herbal medicine.[15] Until the 20th century, most remedies were botanicals, a few of which were found through trial and error to be helpful. For example, purple foxglove was found to be helpful for dropsy, the opium poppy for pain, cough, and diarrhea, and cinchona bark for fever. But therapeutic successes with botanicals came at great human cost. The indications for using a given botanical were ill defined, dosage was arbitrary because the concentrations of the active ingredient were unknown, and all manner of contaminants were often present. More important, many of the remedies simply did not work, and some were harmful or even deadly. The only way to separate the beneficial from the useless or hazardous was through anecdotes relayed mainly by word of mouth.

All that began to change in the 20th century as a result of rapid advances in medical science. The emergence of sophisticated chemical and pharmacologic methods meant that we could identify and purify the active ingredients in botanicals and study

them. Digitalis was extracted from the purple foxglove, morphine from the opium poppy, and quinine from cinchona bark. Furthermore, once the chemistry was understood, it was possible to synthesize related molecules with more desirable properties. For example, penicillin was fortuitously discovered when penicillium mold contaminated some bacterial cultures. Isolating and characterizing it permitted the synthesis of a wide variety of related antibiotics with different spectrums of activity.

In addition, powerful epidemiologic tools were developed for testing potential remedies. In particular, the evolution of the randomized, controlled clinical trial enabled researchers to study with precision the safety, efficacy, and dose effects of proposed treatments and the indications for them. No longer do we have to rely on trial and error and anecdotes. We have learned to ask for and expect statistically reliable evidence before accepting conclusions about remedies. Without such evidence, the FDA will not permit a drug to be marketed.

The results of these advances have been spectacular. As examples, we now know that treatment with aspirin, heparin, thrombolytic agents, and beta-adrenergic blockers greatly reduces mortality from myocardial infarction; a combination of nucleoside analogues and a protease inhibitor can stave off the onset of AIDS in people with human immunodeficiency virus infection; antibiotics heal peptic ulcers; and a cocktail of cytotoxic drugs can cure most cases of childhood leukemia. Also in this century, we have developed and tested vaccines against a great many infectious scourges, including measles, poliomyelitis, pertussis, diphtheria, hepatitis B, some forms of meningitis, and pneumococcal pneumonia, and we have a vast arsenal of effective antibiotics for many others. In less than a century, life expectancy in the United States has increased by three decades, in part because of better sanitation and living standards, but in large part because of advances in medicine realized through rigorous testing. Other countries lagged behind, but as scientific medicine became universal, all countries affluent enough to afford it saw the same benefits.

Now, with the increased interest in alternative medicine, we see a reversion to irrational approaches to medical practice, even while scientific medicine is making some of its most dramatic advances. Exploring the reasons for this paradox is outside the scope of this editorial, but it is probably in part a matter of disillusionment with the often hurried and impersonal care delivered by conventional physicians, as well as the harsh treatments that may be necessary for life-threatening diseases.

Fortunately, most untested herbal remedies are probably harmless. In addition, they seem to be used primarily by people who are healthy and believe the remedies will help them stay that way, or by people who have common, relatively minor problems, such as backache or fatigue.[1] Most such people would probably seek out conventional doctors if they had indications of serious disease, such as crushing chest pain, a mass in the breast, or blood in the urine. Still, uncertainty about whether symptoms are serious could result in a harmful delay in getting treatment that has been proved effective. And some people may embrace alternative medicine exclusively, putting themselves in great danger. In this issue of the *Journal,* Coppes et al. describe two such instances.[16]

Also in this issue, we see that there are risks of alternative medicine in addition to that of failing to receive effective treatment. Slifman and her colleagues report a case of digitalis toxicity in a young woman who had ingested a contaminated herbal concoction.[17] Ko reports finding widespread inconsistencies and adulterations in his analysis of Asian patent medicines.[18] LoVecchio et al. report on a patient who suffered central nervous system depression after ingesting a substance sold in health-food stores as a growth hormone stimulator,[19] and Beigel and colleagues describe the puzzling clinical course of a patient in whom lead poisoning developed after he took an Indian herbal remedy for his diabetes.[20] These are without doubt simply examples of what will be a rapidly growing problem.

What about the FDA? Shouldn't it be monitoring the safety and efficacy of these remedies? Not any longer, according to the U.S. Congress. In response to the lobbying efforts of the multibillion-dollar "dietary supplement" industry, Congress in 1994 exempted their products from FDA regulation.[21,22] (Homeopathic remedies have been exempted since 1938.[23]) Since then, these products have flooded the market, subject only to the scruples of their manufacturers. They may contain the substances listed on the label in the amounts claimed, but they need not, and there is no one to prevent their sale if they don't. In analyses of ginseng products, for example, the amount of the active ingredient in each pill varied by as much as a factor of 10 among brands that were labeled as containing the same amount.[24] Some brands contained none at all.[25]

Herbal remedies may also be sold without any knowledge of their mechanism of action. In this issue of the *Journal,* DiPaola and his colleagues report that the herbal mixture called PC-SPES (PC for prostate cancer, and *spes* the Latin for "hope") has substantial estrogenic activity.[26] Yet this substance is promoted as bolstering the immune system in patients with prostate cancer that is refractory to treatment with estrogen.[27] Many men taking PC-SPES have thus received varying amounts of hormonal treatment without knowing it, some in addition to the estrogen treatments given to them by their conventional physicians.

The only legal requirement in the sale of such prod-

ucts is that they not be promoted as preventing or treating disease.[28] To comply with that stipulation, their labeling has risen to an art form of doublespeak (witness the name PC-SPES). Not only are they sold under the euphemistic rubric "dietary supplements," but also the medical uses for which they are sold are merely insinuated. Nevertheless, it is clear what is meant. Shark cartilage (priced in a local drugstore at more than $3 for a day's dose) is promoted on its label "to maintain proper bone and joint function," saw palmetto to "promote prostate health," and horse-chestnut seed extract to "promote . . . leg vein health." Anyone can walk into a health-food store and unwittingly buy PC-SPES with unknown amounts of estrogenic activity, plantain laced with digitalis, or Indian herbs contaminated with heavy metals. Caveat emptor. The FDA can intervene only after the fact, when it is shown that a product is harmful.[28]

It is time for the scientific community to stop giving alternative medicine a free ride. There cannot be two kinds of medicine — conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted. But assertions, speculation, and testimonials do not substitute for evidence. Alternative treatments should be subjected to scientific testing no less rigorous than that required for conventional treatments.

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CHRONIC RENAL FAILURE — A VASCULOPATHIC STATE

CHRONIC renal insufficiency (defined by a serum creatinine concentration of 1.5 to 3.0 mg per deciliter [133 to 265 μmol per liter]), chronic renal failure (serum creatinine concentration, >3.0 mg per deciliter), and end-stage renal disease should be regarded as parts of a continuum. Of the 300,000 patients who are currently receiving renal-replacement therapy in the United States,[1] 220,000 receive dialysis therapy and the remainder depend on a successful kidney graft. The current annual increase in the number of patients receiving renal-replacement therapy is 6 to 7 percent; by extrapolation,[2] at least 600,000 patients will be receiving such therapy by 2010 unless we can more effectively prevent or postpone end-stage renal disease. The average age at which renal-replacement therapy is required by patients with renal failure is now 60 years.

Mortality among patients on dialysis, although it has been falling slowly over the past few years, remains high, at 20 percent per year.[1] Depending on age, life expectancy ranges from 17 percent to 39 percent of that of members of the general population of the same age and sex. Survival among patients on dialysis is better in many other industrialized nations, but coexisting illness and the higher rates of acceptance of patients for dialysis in the United States contribute to this discrepancy.[1,3] Continuing efforts in this country focus on delivering an adequate "dose" of dialysis[4] and, perhaps, on earlier initiation of renal-replacement therapy, before the onset of any uremic manifestations and especially of malnutrition.[5]

At all stages of progressive renal disease, cardiovascular problems are the most important cause of death[1,6]; they account for approximately 50 percent of mortality among both patients on dialysis and recipients of renal allografts.[7] Overall mortality after renal transplantation is lower than among patients receiving dialysis. Because almost all patients receiving renal-replacement therapy are insured by Medicare, we have many more data about the incidence and prevalence of end-stage renal disease than we have for chronic renal failure; however, patients with chronic renal failure in the United States number approximately 2 million. In patients with end-stage renal disease cardiac arrest, acute myocardial infarction, and cardiac arrhythmia account for about one third of all deaths.[1] In this issue of the *Journal,* Herzog et al.[8] highlight the greatly increased mortality from myocardial infarction in this group, as compared with that in the general population or even among patients with diabetes without renal disease. A similarly high mortality rate has been seen in Europe, and despite considerable differences in background prevalence and mortality in different countries, mortality after myocardial infarction is 16 to 19 times as high among patients with renal failure as in the general population.[9]

About two thirds of cases of end-stage renal disease are caused by diabetes mellitus or primary hypertensive renal disease. These two diseases cause diffuse atherosclerosis and arteriolosclerosis, but the rates of both cardiovascular disease and mortality are also elevated among patients with primary renal diseases such as chronic glomerulonephritis. Many of the causes of vasculopathy in patients with chronic renal failure are the same as those in the general population, but some appear to be specific to progressive renal disease.[10] Primary hypertension is an important risk factor for stroke and heart disease, and although successful treatment substantially reduces damage to the heart and the brain, such amelioration has not been proved for the kidney. Secondary hypertension occurs early in many progressive renal diseases and is present in virtually all patients by the time renal-replacement therapy is initiated. Smoking,[11] hyperlipidemia (including elevated Lp(a) lipoprotein levels), the insulin resistance syndrome, and hyperhomocystinemia[10] are all factors contributing to both vasculopathy induced by renal disease and coronary artery disease in the normal population. In patients with renal disease, the risk is compounded because of the high prevalence of multiple risk factors.

In patients with renal disease, specific cardiovascular risk factors include secondary hyperparathyroidism, increased sympathetic-nerve activity caused by afferent renal reflexes, elevated levels of oxidized low-density lipoprotein, and endothelial dysfunction characterized by excess endothelin levels and diminished vascular nitric oxide production.[10,12] The chronic anemia of renal disease and the hypervolemia that is often present in patients with chronic renal failure and those on dialysis contribute to left ventricular hypertrophy, an independent risk factor for death from cardiovascular disease.[12] There is diminished coronary-artery reserve and impairment of the myocardial microcirculation.[9,10] Treatment of anemia in patients with chronic renal failure or end-stage renal disease with recombinant erythropoietin appears to reduce left ventricular hypertrophy and the incidence of cardiac failure.[9,12] Chronic renal failure also causes increased arterial stiffness,[13] with decreased elasticity that is independent of and occurs in addition to atherosclerotic lesions and that could contribute to cardiac afterload. The nephrotic syndrome especially heightens the risk of cardiovascular events in patients with renal disease because of the associated hyperlipidemia and hypercoagulable state.

At the time renal-replacement therapy is initiated, cardiovascular disease is usually well established. The prevalence of left ventricular hypertrophy, coronary artery disease, and congestive heart failure in patients with end-stage renal disease is far in excess of that in control populations.[10,12] Herzog et al.[8] point out the increased risk of acute myocardial infarction, especially in the first year after the initiation of dialysis. Removal of excess fluid in this group of functionally anephric patients is achieved by ultrafiltration during three dialysis treatments, lasting a total of 10 to 12 hours, per week. Although the process of dialysis is now much improved by better control of ultrafiltration,[3] episodes of hypotension are still frequent and may precipitate cardiac or cerebral ischemia. Less often, dialysis-induced hypotension may be precipitated by inadequate increases in cardiac output — due to myocardial ischemia or diastolic dysfunction — in response to vascular volume depletion. Candidates for renal transplantation, especially patients with diabetes, are evaluated carefully for coronary and cerebrovascular disease, and they may require angioplasty or vascular surgery before undergoing transplantation. Herzog et al.[8] argue persuasively that nephrologists should also assess the

cardiovascular system at the time dialysis is initiated and, in particular, ascertain the presence and severity of coronary artery disease. This approach needs to be tested prospectively to determine its cost effectiveness.

In the future it may be possible to screen for renal injury–susceptibility genes.[14] At present, we can identify microalbuminuria, which is an important harbinger of diabetic glomerulosclerosis and probably of hypertensive nephrosclerosis. Identification of patients at risk for progressive renal disease may facilitate focused therapeutic efforts, such as euglycemic control of diabetes and meticulous control of hypertension. Injury to the heart, the kidneys, and the vascular tree in patients with diabetes, hypertension, or chronic renal failure appears to be ameliorated by the reduction of blood pressure to normal or near-normal levels, by the use of angiotensin-converting–enzyme inhibitors (which have effects other than the reduction of blood pressure[15]), antihyperlipidemic therapy, smoking cessation, and possibly measures to reduce hyperhomocystinemia. Only early recognition and aggressive targeted treatment of all patients with renal disease are likely to decrease the high mortality from cardiovascular causes among patients with "renal vasculopathy." Such measures, if used early enough, may also reduce the prevalence of end-stage renal disease itself. For at least some patients on dialysis, more prolonged and frequent nocturnal dialysis[3,16] may improve quality of life and overall survival, especially by ensuring better blood-pressure control.

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REGULATION OF FIREARMS

IN the United States, the rates of injury and death due to firearms and the rate of crimes committed with firearms are far higher than those in any other industrialized nation. Every hour, guns are used to kill four people and to commit 120 crimes in our country.

Perhaps the most appropriate international comparisons are among the United States and other developed "frontier" countries where English is spoken: Canada, Australia, and New Zealand. These four nations have similar cultures, and all have histories that include the violent displacement of indigenous populations. They also have similar rates of property crime and violence.[1,2] What distinguishes the United States is its high rate of lethal violence, most of which involves guns.

Gun-related deaths among children and adolescents are a particular problem in the United States. Among developed nations, three quarters of all murders of children under the age of 14 years occur in this country. More than half of children younger than 14 who commit suicide are Americans, even though the rate of suicide by methods other than firearms among children here is similar to that in other countries.[3]

Canada, Australia, and New Zealand all have many guns (though not nearly as many handguns as does the United States). The key difference is that these countries do a much better job than we do of keeping guns out of the wrong hands. Their experience shows that when there are reasonable restrictions, relatively few outlaws can possess or use guns.

Success in the United States in reducing motor vehicle injuries — we now have one of the lowest rates of death per vehicle-mile in the world — provides insight into methods that could reduce firearm injuries. In the 1950s, efforts to reduce motor vehicle injuries focused on the driver. Commonly presented

statistical data seemed to show that almost all automobile crashes were caused by error on the driver's part. The greatest attention was thus paid to education and enforcement: training motorists to drive better and punishing them for committing safety violations. Despite these well-intentioned efforts, further success in reducing motor vehicle injuries had to await a more comprehensive approach.

Eventually, injury-control experts recognized that to increase the safety of driving, it would be more cost effective to try to change the vehicle and the highway environment than to try to change human behavior. People will always make mistakes, and sometimes they will behave recklessly. But when they do, should they die? Should others?

Thus, numerous alterations were made both in cars and in roads to make collisions less likely (better brakes, a third brake light, and divided highways, for example) and to make serious injuries more avoidable if there was a collision (collapsible steering columns, nonrupturable gas tanks, breakaway road signs, more advanced emergency medical systems, and so on). No one believes that today's drivers are more careful than those of the 1950s, yet the number of motor vehicle fatalities per mile has been reduced by more than 75 percent.

Firearms, like motor vehicles, lawn mowers, and chain saws, are consumer products that cause injury. The safety of virtually every consumer product is regulated by federal or state government. The conspicuous exception is the gun, which, per minute of exposure, is probably the most dangerous of all such products. Unfortunately, because firearms have been deliberately exempted from the oversight of the Consumer Product Safety Commission, we are in the indefensible position of having stronger consumer-protection standards for toy guns — and teddy bears — than for real guns.

Stronger safety standards can help make firearms less dangerous. At a restaurant during a recent American Public Health Association convention in Indianapolis, a patron bent over and a derringer fell from his pocket. The gun hit the ground, discharged, and wounded two convention delegates. This person had a permit to carry the gun, and the firearm met all relevant safety standards — of which there are none.[4] Anecdotes such as this demonstrate why such standards are needed.

Survey results reported in this issue of the *Journal* by Teret et al.[5] provide evidence that the majority of Americans want to see guns treated and regulated as consumer products. In nationally representative polls, at least two thirds of all respondents were in favor of six policies that would enhance the safety of new guns. Examples of these policies are childproofing, personalization (which prevents firing by an unauthorized person), and indicators that show whether the gun is loaded. These measures may not substantially reduce gun-related crime, but they are inexpensive and could decrease the number of deaths and injuries that occur each day as a result of unintentional gunshots.

In one state, Massachusetts, the attorney general, who is the state officer responsible for protecting consumers' rights, recently issued regulations implementing several of these moderate safety standards for firearms sold in the state. Domestic gun manufacturers and firearm-sports organizations are challenging his authority to ensure, among other things, that firearms are childproof and meet the safety standards required of imported guns.[6] Both these measures are favored by more than 80 percent of gun owners and non–gun owners alike in the national sample polled by Teret et al.[5] We can expect that similar conflicts will develop in other states as new regulatory policies are invoked.

These recent polls also show very high public support, among both gun owners and non–gun owners, for innovative policies designed to keep guns out of the wrong hands.[5] One proposed type of law would prohibit the purchase of guns by persons who have been convicted of any one of various felonies, such as assault and battery. Another set of requirements would reduce illegal gun sales by, for example, state adoption of one-gun-per-month laws to decrease gun running across state lines.[7] Such moderate measures would limit the easy access to guns by those most likely to misuse them, while imposing only a slight inconvenience on "decent, law-abiding citizens." Previous surveys have shown that most Americans, most gun owners, and even most self-reported members of the National Rifle Association are in favor of many moderate measures that could reduce gun injuries.[8-10] Unfortunately, most of these measures have not been enacted.

The United States has more cars per capita than any other developed nation. Because of reasonable policies to regulate automobiles and roadways, we now have one of the lowest motor vehicle fatality rates. We are also a society with more guns per capita than any other developed nation. We can remain a nation with many guns yet control our gun-injury problem if we take reasonable steps to make firearms safer and to keep them out of the wrong hands. Few individual gun policies, if enacted alone, would substantially reduce the firearm-injury problem. Similarly, few individual highway-safety initiatives of the past 40 years, by themselves, made a great difference in reducing highway deaths. Together, however, many small policies can have a large effect. It is now quite clear that the implementation of policies focused exclusively on education and enforcement (training in the handling of guns and punishment for criminal violations) is not the most effective way to reduce our firearm-injury problem substantially.

Much can be done to decrease the gun problem in

the United States without changing the fundamental availability of firearms for most citizens. In the past decade, the public health community has been studying this issue and has suggested many reasonable, feasible policies. Through such policies we can begin to change social norms, as we have with cigarette smoking and motor vehicle injuries. In the case of firearms, the norm to be changed is the one that accepts lethal violence as a part of everyday American life.

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