

Thinking about Complementary and Alternative Medicine?

*An Introduction for People with MS on
How to Find and Evaluate Claims about
Complementary and Alternative Medicine*



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This monograph is dedicated to Jack Burks, MD, by MSAA and the monograph's sponsor, Berlex. Dr. Burks currently holds the position of vice president and chief medical officer for MSAA. Dr. Burks is an internationally recognized expert in the field of MS and has a long-standing commitment to MSAA and its goal to provide individualized patient-focused care.

This is why dedicating this monograph to Dr. Burks is so appropriate; he has spent a lifetime helping those with MS to better understand the disease and obtain information to better manage it. Providing valuable information is the focus of this monograph.



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Thinking about Complementary and Alternative Medicine?

An Introduction for People with MS on How to Find and Evaluate Claims about Complementary and Alternative Medicine

Written by Thomas M. Stewart, JD, MS, PA-C and Allen C. Bowling, MD, PhD

Complementary and alternative medicine (CAM) is a vast topic, so it is impossible to provide a detailed review of the topic in a short booklet. Instead, our main focus is to provide a framework for finding and evaluating claims about CAM. We will also describe some background, such as what CAM means, how many people use CAM, and how to balance the risks of CAM therapies with the evidence of benefit.

DEFINITIONS AND EXAMPLES OF CAM

The National Center for Complementary and Alternative Medicine (NCCAM) defines CAM as “a group of diverse medical and healthcare systems, practices, and products that are not presently considered to be part of conventional medicine – that is, medicine as practiced by holders of MD (medical doctor) or DO (doctor of osteopathy) degrees and their allied health professionals, such as physical therapists, psychologists, and registered nurses.” Another, more flexible definition defines CAM as “all health systems, modalities, and practices... other than those intrinsic to the

politically dominant health system.” Both of these definitions are similar because CAM is essentially defined as that which is other than conventional medicine.

To understand CAM, it is important to begin by understanding conventional medicine. Conventional medicine treatments may be thought of as what is generally recommended by conventional healthcare practitioners; for people with MS, the focus of conventional treatments in medical clinics is on medications, rehabilitation (physical therapy, occupational therapy, and speech therapy), and psychotherapy. Of course, there are exceptions. For example, conventional healthcare

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providers will often recommend calcium for the prevention of osteoporosis or fiber supplements to ameliorate constipation. In general, however, recommendations regarding medications and rehabilitation are the staples of conventional

healthcare practitioners’ recommendations. So, to oversimplify a bit, it may make sense to think of CAM as therapies *other* than medications, rehabilitation, and psychotherapy.

A few other details about the terms

The National Center for Complementary and Alternative Medicine (NCCAM) has done an impressive job organizing the enormous topic of CAM. According to the NCCAM, CAM therapies may generally be grouped into five overlapping categories:

- **Biologically-based practices** use substances found in nature, such as herbs, special diets, or vitamins (in doses outside those used in conventional medicine).
- **Energy medicine** involves the use of energy fields, such as magnetic fields or biofields (energy fields that some believe surround and penetrate the human body).
- **Manipulative and body-based practices** are based on manipulation or movement of one or more body parts. This category includes practices such as chiropractic and osteopathic manipulation, massage therapy, reflexology, and Rolfing. (Also known as “structural integration,” Rolfing uses soft-tissue manipulation to ease pain and stress while improving performance.)
- **Mind-body medicine** uses a variety of techniques designed to enhance the mind’s ability to affect bodily function and symptoms. Examples of CAM therapies within this category include relaxation, hypnosis, visual imagery, meditation, yoga, biofeedback, and spirituality.
- **Alternative (or whole) medical systems** are built upon complete systems of theory and practice. Often, these systems have evolved apart from and earlier than the conventional medical approach used in the United States. One example of a whole medical system is traditional Chinese medicine, which includes acupuncture as well as Ayurvedic medicine, one of India’s traditional systems of medicine.

“complementary” and “alternative” medicine are also useful to know. Alternative medicine refers to unconventional treatments that are used *instead of* conventional medicine. Complementary medicine refers to unconventional treatments used *in addition to* conventional medicine.

FREQUENCY AND PATTERNS OF CAM USE AMONG PEOPLE WITH MS

Surveys have been done to identify the number of people with MS who use CAM therapies. To measure this, most surveys have asked participants to indicate whether they have used one or more items from a specific list of CAM interventions, but these lists have

varied considerably among the surveys.

Because the lists vary, it is difficult to compare the results from different surveys. With that in mind, studies done in North America suggest that, excluding prayer and exercise, the lifetime use of CAM among people with MS ranges from 50 to 60 percent. This is similar to CAM use in the general population. As in the general population, people with MS who use CAM tend to be disproportionately female, better educated, and have a higher income. In the general population as well as among people with MS in particular, CAM is used in a complementary rather than an alternative fashion.

However, although there are superficial

similarities between CAM use in the general population and in the MS population, there may be significant differences as well. For example, people with MS may visit practitioners of CAM (such as acupuncturists, massage therapists, or chiropractors) more often than people in the general population; people with MS may also use dietary supplements more frequently, and are more likely to use different kinds of dietary supplements.

The precise number of people with MS using CAM, the number using specific kinds of CAM, and the precise characteristics of CAM users are less important to understand than the fact that CAM is widely used in the MS community. Accordingly, it is reasonable for people with MS to expect that they can comfortably discuss this topic with their conventional healthcare providers and that education and research related to CAM is supported by MS organizations.

EVALUATING THE EVIDENCE

Obviously, not all CAM therapies are effective merely because they are claimed to be effective. One of the most important steps in evaluating CAM claims – or any other health claim – is to look for the basis of the recommendation. In other words, one of the first questions to ask is, “How persuasive is the evidence in support of the claim?” There are many different levels of evidence and it is important to be able to understand the relative strengths and weaknesses of each.

Minimally Persuasive

Anecdotal Evidence: Anecdotes are basically stories. An anecdote by someone you do not know well, who is selling a product, may be considered the weakest evidence of all.

Anecdotes may be somewhat more persuasive when told by credible sources, such as close friends, family members, or healthcare providers, but in the end, anecdotes are mere stories and should generally be considered as weak evidence.

Laboratory Evidence: Laboratory evidence is usually done under very controlled conditions, such as

in a test tube or in a Petri dish. For example, a particular treatment studied in the laboratory may be found to suppress certain immune cells. While such experiments may be highly valuable for certain purposes, it would be unacceptable to simply assume that such a treatment would be good for people with MS. With actual testing of the compound in people with MS, it might be found that it has no effect whatsoever. For this reason, laboratory evidence is not very persuasive evidence of efficacy in MS.

Moderately Persuasive

Animal Evidence: This type of information may be more reliable than anecdotal evidence, but nevertheless cannot be considered highly persuasive. Often, before money is invested in clinical trials involving people, investigators study the effects of a therapy in animals with an MS-like disease known as

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Herbal medicine has been used for thousands of years and has experienced a renewed popularity among Americans since the mid-1990s. Unlike conventional drugs, herbs consist of many chemical compounds, which can be beneficial, harmful, or have unknown effects. Individuals with MS need to be cautious as clinical trials with herbs, especially with MS specifically, have been very limited. Certain herbs can interact with medications, worsen one's MS by over-stimulating the immune system, or may damage organs including the heart and liver. While some herbs may potentially help certain MS symptoms, such as St. John's wort for depression or cranberry for the prevention of urinary tract infections, individuals with MS should always consult their physician before taking an herb (or participating in any CAM therapy).



“EAE” (experimental allergic encephalomyelitis). Effectiveness in the animal model of MS, while encouraging, is still not a guarantee for efficacy in people with MS. In fact, there is a long list of potential MS therapies that looked very promising in animal studies, but ultimately proved to be ineffective for treating the disease. Importantly, a few therapies that were effective in the animal model of MS actually worsened MS in people. For this reason, animal evidence should not be considered highly persuasive. Rather, animal evidence may be considered “hypothesis generating,” useful for generating ideas for more systematic study.

Observational Evidence: As the name implies, observational studies involve an investigator whose role is limited to observing without intervening. For example, a researcher might note the frequency of MS in regions of the world varies in relation to a particular kind of diet. While interesting, this is not highly persuasive. The variation may have nothing to do with diet but may instead be related to other factors, such as genetics. For this reason, observational evidence is also best considered to be hypothesis generating.

Most Persuasive

Experimental Clinical Evidence:

Experimental clinical evidence refers to evidence in people and, when designed correctly, is often the most persuasive kind of evidence. The best type of clinical evidence is obtained through studies known as *multi-center, randomized, double-blind, placebo-controlled clinical trials (RCCT)*. What this means is that a large number of people are randomly assigned to receive either a placebo or an active treatment (*randomized, placebo-controlled*); neither the patients nor the evaluators know who received the placebo or the active treatment (*double-blind*); and the study is carried out at multiple institutions (*multi-center*). If people who receive the active treatment do better than those who receive the placebo, in a way that would not be expected to occur by chance alone, then the treatment should probably be accepted as effective. All of the FDA-approved MS medications have been found effective for some measures in at least some groups of people in multi-center RCCTs.

CONSIDER RISK, COST, AND OTHER FACTORS

It is reasonable to demand that some therapies be proven effective in RCCTs before being used. The currently approved MS therapies are good examples. They are all expensive and can have serious side effects. Moreover, they are all patented agents so the manufacturers have a financial incentive to pay the enormous cost of conducting a RCCT.

What about CAM therapies? Should people demand RCCTs before using these therapies? It depends. For some CAM therapies, there is limited financial incentive to conduct

RCCTs, and many have low risk to the user and little cost involved for the treatment. For example, consider different types of mind-body medicine, such as yoga. Properly done, yoga is safe, inexpensive, and enjoyed by many regardless of disease. If one person with MS finds yoga helpful for MS-related fatigue and recommends it to another person with MS, it may be perfectly reasonable for the second person to try yoga on this basis alone – even though the recommendation was nothing more than a minimally persuasive anecdote.

Experimental clinical evidence refers to evidence in people and, when designed correctly, is often the most persuasive kind of evidence.

On the other hand, consider the following example. An alternative medicine clinic advertises an expensive, multi-day treatment involving the administration of IV fluids, claiming to alter the immune system and produce dramatic results in slowing the progression of MS. In this situation, highly persuasive evidence should be demanded because the treatment is expensive, invasive, and depending on what fluids are introduced, possibly even dangerous.

Furthermore, in this example the therapy was touted as a treatment to slow the disease process. While it might be easy for an individual to perceive the effect of a treatment on a symptom, such as fatigue, it would be very difficult for an individual to measure a change in the rate of disease progression over time. Finally, a therapy that is claimed to alter the immune system through a biological process warrants additional

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FINDING INFORMATION ABOUT CAM

There are a number of ways for people with MS to learn about CAM, including books on the topic, individual experts, and the internet. But be warned: finding high-quality information about CAM for people with MS can be difficult. A survey conducted through the Rocky Mountain MS Center demonstrates this. The sections on MS were reviewed in 50 different CAM books found in two large book stores in Denver, Colorado. In these books, MS was sometimes defined incorrectly as a form of muscular dystrophy; five to six different therapies were generally recommended; and no two books had the same recommendations. In addition, it was rare for the use of any CAM therapy to be discouraged, while dangerous therapies were sometimes recommended! Clearly, consumers need to exercise healthy skepticism when reading about CAM therapies.

A few general suggestions may be helpful:

- **To begin, a healthcare provider should be consulted.** This is a good idea for a number of reasons. For instance, a healthcare provider may be knowledgeable about the specific topic of interest to you; he or she may also know of the risks involved, and can possibly discuss any interactions that might occur with other medications.
- **Consider using databases of peer-reviewed scientific literature that are accessible on the internet.** Two helpful databases in this regard are: (1) CAM on PubMed (www.nlm.nih.gov/nccam/camonpubmed.html) maintained jointly by the NCCAM and the National Library of Medicine, and (2) the International Bibliographic Information on Dietary Supplements (IBIDS) Database (ods.od.nih.gov/databases/ibids.html) maintained by the National Institute of Health Office of Dietary Supplements (ODS). Although searching such databases will sometimes yield highly technical and difficult-to-read results, the information will usually be of high quality.
- **Of course, it can be helpful to go to your local library,** especially a medical library if one is available, and talk with a librarian. This is usually an excellent way to identify reliable sources of information on CAM topics that interest you.
- **Finally, general internet search engines** such as Google (www.google.com), Yahoo (www.yahoo.com), and MSN Search (search.msn.com) can be powerful tools for finding information. Such search engines generate results through technical means that may include keyword density (the number of times a keyword appears on a site) and traffic (the number of visitors to a website). It is important to keep in mind that search results are also affected by sponsorship. In other words, some websites, often commercial in nature, pay to be ranked near the top of certain searches, which may lead searchers to biased, commercial information.



Acupuncture is a component of traditional Chinese medicine and more than one million Americans are estimated to use acupuncture each year. Chinese medicine proposes that energy flows through 14 main pathways and disease is thought to result from a disruption in this energy. Acupuncture involves inserting thin, metallic needles into patients along these pathways. For individuals who are uncomfortable using needles, other therapies, such as acupressure (which uses finger pressure on these pathway points) are available. In small and preliminary studies, individuals with MS may experience improvements in anxiety, depression, dizziness, pain, bladder difficulties, and weakness, although drowsiness may occur as a side effect. While adverse events are rare, serious complications can result if the acupuncturist is poorly trained or negligent. Individuals with MS should consult their physician before seeing an acupuncturist.

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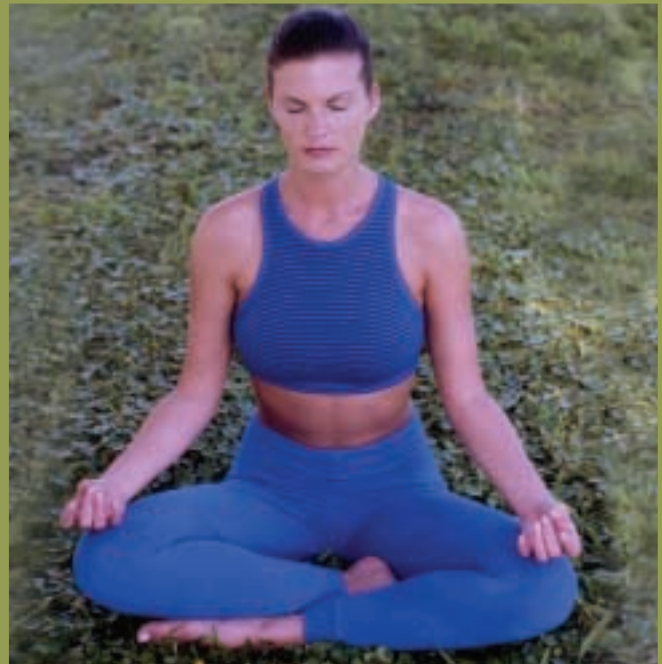
caution, because it is possible that some immune system changes may worsen MS or antagonize the effects of conventional disease-modifying medications. At the time of this writing, approved disease-modifying medications include interferons (Avonex[®], Betaseron[®], and Rebif[®]), glatiramer acetate (Copaxone[®]), mitoxantrone (Novantrone[®]), and natalizumab (Tysabri[®]).

Thus, the level of evidence that should be demanded before trying a CAM therapy depends on the risks, cost, and effort involved, as well as the inherent appeal of the activity and the way that the treatment works, i.e., whether the treatment uses substances to alter the immune system. In the appropriate situation, it may be reasonable to consider the use of CAM when the risks and costs are low even in the absence of highly persuasive evidence of efficacy. On the other hand, it is unreasonable to use a form of CAM that has high risks or costs and a difficult-to-measure outcome unless there is highly persuasive evidence of benefit.

EVALUATING THE CREDIBILITY OF INFORMATION ABOUT CAM

The internet has become a major source of information for consumers of healthcare. Of those with internet access, about 80 percent have searched broadly for health-related infor-

Yoga was developed thousands of years ago in India to unite mind, body, and spirit through a series of body postures, movements, and breathing exercises. The different postures may be adapted to fit the capabilities of individuals with physical limitations, even those with severe arm and leg weakness. Studies with yoga are very limited, but some individuals with MS have reported improvements in anxiety, stress, and muscle stiffness; some may potentially experience beneficial effects in emotional and physical functioning. A recent study found that yoga improved fatigue for individuals with MS. Yoga is associated with few adverse effects, although difficult positions or vigorous exercise should be done with caution, particularly if pregnant or if other conditions exist, such as heat sensitivity,



impaired balance, heart or lung disorders, or bone conditions. Individuals with MS should consult their physician before participating in any new physical activity.

mation on the web, 66 percent have looked for information about specific diseases, and 28 percent have looked for information about CAM. Impressively, about a quarter of those with internet access report that the web has influenced their decision about how to treat their illness. People with MS may be especially likely to use the internet to obtain health-related information; MS has been found to be among the twenty most commonly searched diseases on the internet.

Although increased access to health information is certainly a good thing for consumers, it also creates new responsibilities. One of these responsibilities is to be able to critically evaluate web-based information because not all information on the internet is

accurate. This is true of health information in general, but may be especially true for those looking for information about CAM.

Distinguishing good and bad information on the internet is difficult and no precise formula for this exists. Making such distinctions will always require judgment.

Credibility of Sources: Important aspects of this judgment will include an evaluation of the credibility of the source of the information as well as the content itself. There is no easy way to evaluate the credibility of a source, but, as an example: (1) a panel of MS experts working together on statements within their expertise will usually be very credible; (2) similarly, well-regarded MS organizations will usually be considered authoritative when

speaking about aspects of MS care within their expertise; considerations of sponsorship and bias are also important; (3) a university or government-run website designed for educational purposes may be more reliable than a commercial website designed to sell products; and (4) a number of third-party quality endorsements for health-related websites exist and these may sometimes assist in determining whether information is credible.

One such health-related website is HONcode (The Health on the Net Foundation Code of Conduct, at www.hon.ch/HONcode), which specifies eight principles intended to improve information standards and disclosures. Although participation is voluntary and the number of participating sites small, sites displaying the foundation's symbol are probably of relatively high quality. Other third-party quality endorsements include the Internet Health Care Coalition (www.ihealthcoalition.org) and Hi Ethics (www.billingsclinic.com/body.cfm?id=433).

Credibility of Content: When evaluating content, perhaps the most important consideration is whether the authors describe the facts upon which conclusions are based. References should usually be made available and should generally be to original sources. If the website describes treatments, priority should be given to certain kinds of evidence, as described earlier. Ideally, the content should be dated because information can quickly become outdated.

There are other considerations too, of course. For example, be highly suspicious of fanciful claims such as a “miracle cure,” “quick cure,” or “new discovery.” The idea

that someone has found a cure for MS with secret products and without publicity in the mainstream media (newspapers, television news) is quite unlikely.

For more information on evaluating web content, please see the Medical Library Associations (MLA) User's Guide to Finding Health Information on the Web (www.mlanet.org/resources/userguide.html), as well as Criteria for Assessing the Quality of Health Information on the Internet (<http://hitiweb.mitrettek.org/docs/criteria.html#credibility>); the latter is an approach that has also been endorsed by the MLA.

Although this section has focused on internet claims, many of the same principles apply to evaluating CAM claims obtained from books or from individuals. Pay careful attention to the nature of the content and credibility of the source and stay away from “miracle cures.”

SPECIAL CONSIDERATIONS RELATING TO BIOLOGICALLY BASED FORMS OF CAM

The 1994 Dietary Supplement Health and Education Act, or DSHEA (often pronounced “de-shay”) set up a framework for FDA regulation of dietary supplements. Under this framework, the FDA's role in the regulation of dietary supplements, such as herbs and vitamins, is much more limited than it is for other products it regulates, such as prescription and over-the-counter medications. This means that consumers and manufacturers have an increased responsibility for evaluating the safety of dietary supplements and for determining the truthfulness of label claims.

Individuals should realize that the term ‘natural’ appearing on a label does not guarantee that a product is safe. In fact, some supplements are inherently unsafe, such as comfrey or chaparral, and should be avoided.

Safety will depend, in part, on the quality of the ingredients in a particular supplement as well as the particular manufacturing processes used. For this reason, you should pay attention to the reputation of the manufacturer or distributor. Supplements made by a nationally known food and drug manufacturer, for example, may be more likely to have been made under tight controls because these companies already have high manufacturing standards in place.

Individuals should realize that the term “natural” appearing on a label does not guarantee that a product is safe. In fact, some supplements are inherently unsafe, such as comfrey or chaparral, and should be avoided. The FDA maintains a list of some dangerous supplements on its website (www.fda.gov/fdac/features/1998/dietchrt.html).

Another difficulty with dietary supplements or other forms of CAM that involve ingesting substances is that medication interactions are possible. However, often there will be no information about whether a particular substance interferes with the medications used in MS. There is no easy way around this problem. You should factor in this uncertainty and, to minimize the risk as much as possible, consult your healthcare provider.

CONCLUSION

Exploring the world of CAM can be rewarding for many reasons. At its best, CAM can open doors to a new kind of wellness; it can be a way to take charge of your own health; and it may even be a way to manage some symptoms. But there are also risks. Many CAM therapies, like medical therapies, can cause harm.

What is different is that the responsibility for identifying risks and rewards and for making decisions falls squarely on you, the consumer of healthcare. Take that responsibility for education and decision-making seriously and carefully. To follow are some good resources for educating yourself about CAM in general and for MS in particular.

RESOURCES

Websites

www.msaa.com – This is the official website of the Multiple Sclerosis Association of America, providing general information about MS, its symptoms, and its treatments. The website also includes a host of other useful information, such as: MSAA’s publications; MSAA’s regional events and activities; MSAA programs and services; news updates; and links to additional MS-related websites. MSAA’s Helpline consultants may be contacted by calling **(800) 532-7667**.

www.ms-cam.org – This site is maintained by the Rocky Mountain MS Center and contains MS-specific information about CAM therapies. Registration allows for participation in surveys to further research into CAM and MS.

Massage has been used as a healing method for thousands of years in ancient China and Egypt, although many forms of massage used in the United States today come from Swedish massage. Massage is usually performed in a warm and quiet room with soft lighting and relaxing music. Oil or lotion is typically added to keep movements smooth, and different techniques include pressing, rubbing, and tapping. While studies with MS are very limited, beneficial effects may include improvements in anxiety, depression, muscle stiffness, pain, and possibly self-esteem and overall quality of life. Care must be taken to avoid massage to areas affected by injury, infection, or other conditions. As with all CAM therapies, consulting one's physician will help avoid any adverse effects.



nccam.nih.gov – This is an excellent starting point to learn about CAM in general as well as particular CAM treatments.

www.fda.gov, **www.cfsan.fda.gov**, and **www.fda.gov/opacom/7alerts.html** – The FDA is a good source of information about dietary supplements in particular.

www.nationalmssociety.org/spotlight-cam.asp – The National Multiple Sclerosis Society (NMSS) offers information on CAM therapies and related issues that may be of interest to members of the MS community.

www.ftc.gov and **www.ftc.gov/bcp/menu-health.htm** – The Federal Trade Commission is a good site to access to see if there are any fraudulent claims or consumer alerts regarding any therapy.

www.nlm.nih.gov/nccam/camonpubmed.html – CAM on PubMed, maintained jointly by the NCCAM and the National Library of Medicine provides access to peer-reviewed scientific articles on CAM therapies.

ods.od.nih.gov/databases/ibids.html –

The International Bibliographic Information on Dietary Supplements (IBIDS) Database, maintained by the National Institute of Health Office of Dietary Supplements (ODS) provides access to peer-reviewed scientific articles on CAM therapies.

Books:

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The mission of the Multiple Sclerosis Association of America (MSAA) is to enrich the quality of life for everyone affected by multiple sclerosis. MSAA accomplishes its mission by offering many vital programs and services to members of the MS community.

MSAA's free programs and services include: toll-free telephone Helpline with trained consultants (English and Spanish); MSAA publications; Equipment Distribution Program; Cooling Equipment Distribution Program; MRI Institute and MRI Diagnostic Fund; Barrier-Free Housing Program; regional events and activities; Networking Program; Lending Library; and other programs. Please call the Helpline at (800) 532-7667 or visit MSAA's website at www.msaa.com for information and assistance.

Help or support to MSAA in any way is truly appreciated. To inquire about volunteering, fundraising, or making donations, please contact MSAA at (800) 532-7667 or visit MSAA's website at www.msaa.com for information and assistance.



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