An Introduction to Biosimilars • Why I Swim Stories to Inspire

The Motivator
Bringing Information to People with Multiple Sclerosis

MANAGING THE Emotional and Psychological Symptoms OF MULTIPLE SCLEROSIS
INTRODUCING MSAA’S ONLINE

AQUATIC CENTER

at SwimForMS.org

The unique properties of water can create an ideal exercise environment for people with MS. As part of Swim for MS, MSAA has created a comprehensive online Aquatic Center dedicated to increasing awareness, understanding and availability of water-based exercise programs. Special online Aquatic Center features include:

AQUATIC EXERCISE AND MS SECTION: Key information about aquatic exercise, including a guide specifically for people with MS

AQUATIC RESOURCES: Helpful tips & suggestions on how to begin an aquatic exercise program

MULTIMEDIA CENTER: Inspirational stories from people with MS… and a special message from Swim for MS Ambassador and Olympic Gold Medalist Missy Franklin

Visit SwimForMS.org and check out inspirational stories from:

Ginny
ASHEVILLE, NC

Mary
HARLEYSVILLE, PA

Mandy Iris
FLAGSTAFF, AZ

Improving Lives Today!
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WHAT’S THIS?
QR-code enabled smartphone users may scan this image to view this issue of The Motivator on their mobile device.
Information, Advocacy, and Collective Impact

This past winter has been particularly unpredictable and challenging, with record-breaking snowfalls and cold temperatures. These past few months have also proven unpredictable and challenging for our MS population, as individuals experience record-breaking changes in the healthcare system with the introduction of the Affordable Care Act (ACA).

Navigating this uncharted territory has been a challenge for many people with MS. MSAA has played a vital role in educating the MS community about the ACA, helping to bring clarity to these new, changing realities.

Additionally, through the MS Coalition (please see details on left), MSAA has been very involved with advocating for support for individuals with MS. This includes raising questions about decisions from the FDA on the subject of biosimilars and non-biologic complex drugs and their clinical standards, protocols to ensure consistency in the approval process, and opportunities for patient input. Please see our feature story on page 34 for more information.

We were also very active in responding to the FDA’s rejection of the drug Lemtrada® and an MS Coalition-supported appeal was made on behalf of all of our organizations. A major effort to help collect information on early and ongoing access to all disease-modifying therapies is currently in the works. This important work will summarize the current knowledge and evidence about disease modification in MS in the hope that we can ensure appropriate access to care.

MSAA and the MS Coalition are responding to all of these challenges with a renewed emphasis on “Collective Impact,” especially in the area of advocacy. We believe the deepening needs of people with MS will be a driving force to help us all realize a higher level of improving lives together.

Doug Franklin joined MSAA as President & CEO in 1999. He has a distinguished career in nonprofit leadership and is a former national trainer in strategic planning for the Peter Drucker Foundation. A published international expert in social marketing and corporate social investment, he is a graduate of four universities and holds dual certifications in two professional associations. He currently serves on the National Board of the Key Philanthropic Organizations Committee of the American Society of Association Executives and as President of the Multiple Sclerosis Coalition.
Managing the Emotional and Psychological Symptoms of MS

Reviewed by Miriam Franco, MSW, PsyD, MSCS and Jack Burks, MD
Edited by Susan Wells Courtney

INTRODUCTION

This article is the third in a three-part series on the management of MS symptoms. The earlier articles in this series addressed the “hidden” symptoms of MS, such as pain and fatigue, as well as the physical symptoms of MS, which include mobility, spasticity, and several other well-recognized symptoms. These two articles appeared in the Winter/Spring 2013 and the Summer/Fall 2013 issues of The Motivator, respectively.

This latest article addresses the emotional and psychological symptoms of MS, describing depression, anxiety, and pseudobulbar affect (PBA), along with treatment strategies for these symptoms. This writing also examines other important issues affected by emotional factors, such as changing roles and relationships, sexual dysfunction, and self image.

Readers should keep in mind that everyone experiences changes in emotions at one time or another, as well as the typical “ups and downs” of everyday life. A tragic event may cause someone to feel sadness for an extended period of time, and stressful events can cause great anxiety until the problems are resolved. These are normal reactions from which most people recover and eventually return to their usual, healthy outlook on life. However, when someone experiences severe and/or prolonged depression or anxiety, possibly not related to any specific event or issue, professional help may be needed.

According to MSAA’s publication, Understanding and Treating Depression in Multiple Sclerosis, nearly one in 10 American adults suffers from a depressive illness during any given one-year time period. Over the course of a lifetime, estimates increase to one in five for women, and one in eight for men. These rates are for the general population; individuals with MS are at an even greater risk.

Does this mean that everyone with MS will experience emotional issues? Absolutely not! But knowing the symptoms and recognizing a problem if one should arise is vital to maintaining a happy and productive life. The important thing to remember is that effective treatments and support are available, and no one needs to suffer from these debilitating emotions.
With MS, the rate of depression is three-times higher than the general population and it is also higher than with other chronic illnesses. Anxiety, too, is estimated to affect 43 percent of individuals living with MS and is typically undetected and untreated – more so than depression. The combination of heightened levels of depression and anxiety, if untreated, can even pose a risk of suicide in MS. Pseudobulbar affect (PBA) occurs in 10 percent of people with MS, although some research suggests that a much larger number may be affected. It is characterized by sudden, uncontrollable expressions of laughter or crying without an apparent trigger. It occurs in other chronic, neurological conditions and is an extremely distressing symptom.

Depression can result from the physical effects of MS within the nerves of the brain, or as with anxiety, it can be a natural byproduct of living with the disease. PBA is always caused by physical changes in the brain. It is crucial to understand that individuals are not able to control such emotions and they should never feel ashamed or judged for experiencing them. The good news is that these symptoms are treated no differently in MS than in those without MS, and are all highly treatable.

Emotional disturbances can cause significant pain and suffering, and lead to disruptions in family, work, and social life. As noted later in this article, emotional disturbances can also impact roles and relationships, sexual function, and one’s self image. Physicians, nurses, psychologists, and social workers who can identify, diagnose, treat, and manage these disturbances effectively are vitally important. These professionals can help their patients and family members talk about the emotional symptoms of MS – not just the physical ones. They encourage patients and family members to seek psychiatric and psychological treatment, which can have a dramatic, positive impact on the quality of their patients’ lives.

The sections in this article have been written and reviewed by top MS experts, some of whom are members of MSAA’s Healthcare Advisory Council, and reviewed by MSAA’s Chief Medical Officer Jack Burks, MD. Please note that while specific treatment strategies and medications are listed, this information may not be considered as specific medical recommendations or advice. The details provided in this article are for informational purposes only, and readers are strongly urged to see their physician before making any changes to their treatment regimen, exercise routine, or any other aspect of their healthcare or lifestyle.

For more information or to access previous copies of The Motivator or MSAA’s booklet on depression, please visit MSAA’s website at mymsaa.org. While on our website, visitors may view a number of online educational videos and webinars, including those on the symptoms of MS and their treatment options. Readers may also call MSAA at (800) 532-7667 to order copies of publications, learn about MSAA’s programs and services, and speak with a trained Helpline consultant for information, support, and resources.
Depression Versus Sadness and Fatigue

Researchers believe that the high rate of major depressive disorder, dysthymia (a chronic type of depression), and bipolar disorder with MS, is a result of the disease process or the etiology of the disease itself. In other words, the damage to the nerves within certain areas of the brain is believed to increase the chance of greater depressive reactions. Depressive reactions are not to be confused with sadness or fatigue.

Sadness is a feeling in response to disappointments and losses; it is experienced directly in relation to one of these triggers. Experiencing sadness helps us to mourn and move through an experience of pain or loss. It typically does not last long, and once expressed, is relieved.

Fatigue, the most common symptom of MS, occurs in response to having the disease and is greater at certain times of the day. It may not be eliminated, but can be reduced by periods of rest and appropriate planning and pacing of your activities.

A depressive mood typically lasts longer and is not associated with one trigger alone. Moods, by definition, have strong intensity and long duration. Shifting or distracting yourself from your mood is difficult.

Major Depressive Disorder

With this most-common type of depression, you can have one major episode or experience recurring episodes over time.

To be considered to have major depressive disorder, you typically experience a depressed mood most of the day, nearly every day, and you would also have some or all of the following symptoms:

- have a loss of pleasure in most if not all activities that usually give you pleasure
- experience a significant change in weight (loss or gain)
- either have difficulty falling asleep or sleeping too much
- feel a loss of energy and motivation
- likely have feelings of worthlessness, low self-esteem, or major guilt
- have difficulty concentrating or making decisions

Additionally, you may:

- have recurrent thoughts of harming yourself or ending your own life
- lose interest in keeping up your appearance
- have aches and pains that physicians can’t explain
COPAXONE® (glatiramer acetate injection) is indicated for the treatment of patients with relapsing forms of multiple sclerosis.

**Important Safety Information**
Do not take COPAXONE® if you are allergic to glatiramer acetate or mannitol.

Some patients report a short-term reaction right after injecting COPAXONE®. This reaction can involve flushing (feeling of warmth and/or redness), chest tightness or pain with heart palpitations, anxiety, and trouble breathing. These symptoms generally appear within minutes of an injection, last about 15 minutes, and do not require specific treatment. During the postmarketing period, there have been reports of patients with similar symptoms who received emergency medical care. **If symptoms become severe, call the emergency phone number in your area.**

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.
It’s your future.

1-800-887-8100

3-TIMES-A-WEEK COPAXONE® 40 mg

Freedom to...

Treatment on your terms

COPAXONE®
(glatiramer acetate injection)
Important Safety Information (cont’d)

Call your doctor right away if you develop hives, skin rash with irritation, dizziness, sweating, chest pain, trouble breathing, or severe pain at the injection site. If any of the above occurs, do not give yourself any more injections until your doctor tells you to begin again.

Chest pain may occur either as part of the immediate postinjection reaction or on its own. This pain should only last a few minutes. You may experience more than one such episode, usually beginning at least one month after starting treatment. Tell your doctor if you experience chest pain that lasts for a long time or feels very intense.

A permanent indentation under the skin (lipoatrophy or, rarely, necrosis) at the injection site may occur, due to local destruction of fat tissue. Be sure to follow proper injection technique and inform your doctor of any skin changes.

The most common side effects in studies of COPAXONE® (glatiramer acetate injection) are redness, pain, swelling, itching, or a lump at the site of injection, flushing, rash, shortness of breath, and chest pain. These are not all of the possible side effects of COPAXONE®. For a complete list, ask your doctor or pharmacist. Tell your doctor about any side effects you have while taking COPAXONE®.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see brief summary of full Prescribing Information on the following pages.
Patient Information

COPAXONE (co-PAX-own) (glatiramer acetate injection) for subcutaneous use

Read this Patient Information before you start using COPAXONE and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is COPAXONE?
COPAXONE is prescription medicine used for the treatment of people with relapsing forms of multiple sclerosis (MS). It is not known if COPAXONE is safe and effective in children under 18 years of age.

Who should not use COPAXONE?
• Do not use COPAXONE if you are allergic to glatiramer acetate, mannitol or any of the ingredients in COPAXONE. See the end of this leaflet for a complete list of the ingredients in COPAXONE.

What should I tell my doctor before using COPAXONE?
Before you use COPAXONE, tell your doctor if you:
• are pregnant or plan to become pregnant. It is not known if COPAXONE will harm your unborn baby.
• are breastfeeding or plan to breastfeed. It is not known if COPAXONE passes into your breast milk. Talk to your doctor about the best way to feed your baby while using COPAXONE.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. COPAXONE may affect the way other medicines work, and other medicines may affect how COPAXONE works. Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist when you get a new medicine.

How should I use COPAXONE?
For detailed instructions, see the full Prescribing Information for complete information on how to use COPAXONE.
• Your doctor will tell you how much COPAXONE to use and when to use it.
• COPAXONE is given by injection under your skin (subcutaneously).
• Use COPAXONE exactly as your doctor tells you to use it.
• Since every body type is different, talk with your doctor about the injection areas that are best for you.

You should receive your first dose of COPAXONE with a doctor or nurse present. This might be at your doctor’s office or with a visiting home health nurse who will teach you how to give your COPAXONE injections.

What are the possible side effects of COPAXONE?
COPAXONE may cause serious side effects, including:
• Post-Injection Reactions. Serious side effects may happen right after you inject COPAXONE at any time during your course of treatment. Call your doctor right away if you have any of these post-injection reaction symptoms including:
  • redness to your cheeks or other parts of the body (flushing)
  • chest pain
  • fast heart beat
  • anxiety
  • breathing problems or tightness in your throat
  • swelling, rash, hives, or itching
  If you have symptoms of a post-injection reaction, do not give yourself more injections until a doctor tells you to.
• Chest Pain. You can have chest pain as part of a post-injection reaction or by itself. This type of chest pain usually lasts a few minutes and can begin around 1 month after you start using COPAXONE. Call your doctor right away if you have chest pain while using COPAXONE.

• Damage to your skin. Damage to the fatty tissue just under your skin’s surface (lipatrophy) and, rarely, death of your skin tissue (necrosis) can happen when you use COPAXONE. Damage to the fatty tissue under your skin can cause a “dent” at the injection site that may not go away. You can reduce your chance of developing these problems by:
  • following your doctor’s instructions for how to use COPAXONE
  • choosing a different injection area each time you use COPAXONE. See Step 4 in the Instructions for Use, “Choose your injection area”.

The most common side effects of COPAXONE include:
• skin problems at your injection site including:
  • redness
  • pain
  • swelling
  • itching
  • lumps
  • rash
• shortness of breath
• flushing (vasodilation)
Tell your doctor if you have any side effect that bothers you or that does not go away.
These are not all the possible side effects of COPAXONE. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store COPAXONE?
• Store COPAXONE in the refrigerator between 36°F to 46°F (2°C to 8°C).
• When you are not able to refrigerate COPAXONE, you may store it for up to 1 month at room temperature between 59°F to 86°F (15°C to 30°C).
• Protect COPAXONE from light or high temperature.
• Do not freeze COPAXONE syringes. If a syringe freezes, throw it away in a sharps disposal container. See Step 13 in the Instructions for Use, “Dispose of needles and syringes”.

General information about the safe and effective use of COPAXONE.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use COPAXONE for a condition for which it was not prescribed. Do not give COPAXONE to other people, even if they have the same symptoms as you have. It may harm them.
This Patient Information Leaflet summarizes the most important information about COPAXONE. If you would like more information, talk with your doctor.
You can ask your pharmacist or doctor for information about COPAXONE that is written for health professionals.
For more information, go to www.copaxone.com or call 1-800-887-8100.

What are the ingredients in COPAXONE?
Active ingredient: glatiramer acetate
Inactive ingredients: mannitol

Marketed by: TEVA Neuroscience, Inc., Overland Park, KS 66211
Distributed by: TEVA Pharmaceuticals USA, Inc., North Wales, PA 19454
Product of Israel

This brief summary is based on COPAXONE FDA-approved patient labeling, revised: January 2014.
• have mood lability, which means you can cry or become angry easily over things that typically would not draw that kind of reaction from you

**Dysthymia**

This type of depression is very similar to major depression except that the symptoms may not be as severe and you may not experience as many of them. The key feature to dysthymia is that it is felt to be a chronic mood, something you have had for at least two years. This form of depression is not episodic, it’s not characterized by a sudden episode or outburst. Rather, it is more like a slow malaise that starts to be associated with your normal mood. Dysthymia is typically experienced with long-standing insomnia, poor appetite or overeating, poor concentration, and poor self-esteem.

**Bipolar Disorder**  
(ormanic depressive disorder)

This type of disorder is highly genetic in that it often runs in families and is sometimes referred to as manic-depressive disorder. You can have a mild or more severe form. If you have a sibling, parent, or close relative who has been diagnosed with this disorder, and you are experiencing any signs of depression, it is a good idea to have this checked by a mental-health professional. With this disorder, episodes of low mood and depression are interspersed with periods of euphoria or heightened activity and agitation. You must have at least a single episode of mania or heightened activity, agitation, and euphoria, to warrant this diagnosis.

**Assessing the Symptoms of Depression**

In all types of depression, activities of daily living can feel overwhelming and there is a tendency to believe you will never change. Several symptoms of depression are common ones of MS, such as fatigue, trouble sleeping, cognitive difficulties – especially being unable to focus and concentrate – and feeling slowed down. These similarities can, however, be distinguished by a mental-health specialist who has experience with chronic disease, such as a social worker, psychologist, or psychiatrist, who is specialized or certified in a related area.

Your MS neurologist or nurse can use many common tools to first assess the presence of symptoms of depression. Having these screening tools on hand can help facilitate a referral to an appropriate mental-health specialist. To follow are common screening tools or questionnaires that can be quickly and easily completed at an MS center, a neurologist’s office, or by a mental-health professional for depression. They each require just a few minutes to complete – the latter two require only one or two minutes – and all can point to the presence of depressive symptoms:

1) The Beck Depression Inventory (BDI)  
2) The Patient Health Questionnaire (PHQ-9)  
3) The Two Question Screen (2QS)  
4) The Quick Screen 20 (QS-20)

**Gender Differences**

Women are not only more likely to have MS, but they are also more likely to
experience depression. It is not known if this is attributable to hormonal factors and fluctuations caused by pregnancy, menopause, and/or menstrual changes. Additionally, women tend to have multiple care-related responsibilities, are under major stress, and are constantly multi-tasking. While women may be more inclined to seek help, men are more likely to self-medicate with drugs and alcohol, as well as take prescribed antidepressants.

Often, depression may present itself first with some men as increased irritability. And those who have been vulnerable to depression prior to having MS will likely have a higher risk for depression during the course of MS. Other risk factors include a lack of or low social support and isolation, substance dependency and abuse, or presence of another medical condition.

Specific Effects of Depression on Quality of Life (QOL)
Depression is Still Highly Untreated in MS

In one study of people with MS who experienced thoughts of suicide, one-third had not received any psychological help, and two-thirds had not received any antidepressant medication. This may be largely due to the fact that such problems are not always communicated to the doctor. Given the wide range of physical symptoms experienced by individuals with MS, physicians tend to spend most of the limited appointment time on the physical course of the disease. Often the patient with MS is the one to bring up the issue of emotional disturbances or mood in order to have them addressed. People with MS, their care partners, and their physicians, all need to be aware of these symptoms that can arise with MS, and be sure to inquire about any emotional issues that could be present.

Patients need to be prepared and proactive; don’t wait for your doctor to ask you about emotional problems. Knowing what is available through your insurance plan in advance is helpful. By calling the mental-health or behavioral-health phone number on the back of your insurance card, you may be able to find out if there are social workers or psychologists in your plan who specialize in MS care or other chronic conditions. Or, ask your nurse or physician to refer you to a mental-health professional with this type of specialty.

![POLAR CoolFit Kit Ad](https://www.polarproducts.com)
If you do not have health insurance or your insurance plan does not cover behavioral-health services, you can still access and receive assistance for emotional challenges. In many communities, behavioral-health centers and other clinicians are available that provide a sliding-scale fee structure or sometimes free care to individuals with a low household income and/or no insurance coverage. To locate a clinic or provider in your area, please call the SAMHSA National Hotline at (800) 662-HELP (4357). Be sure to indicate you are looking for a program that provides payment assistance or operates on a sliding scale. (SAMHSA is the Substance Abuse and Mental Health Services Administration.)

Suicide Risk

Untreated high rates of depression and anxiety increase suicide risk in MS. Also, severe depression, abuse of alcohol, and social isolation (living alone) can increase the risk of suicide as well. Anyone experiencing these types of thoughts, or care partners who might suspect this of their loved one with MS, should immediately contact their physician, therapist, or the National Suicide Prevention Lifeline. Trained counselors are available 24 hours per day, seven days per week, at the following toll-free number: (800) 273-TALK (8255). Information may also be found on their website at www.suicidepreventionlifeline.org.

Strained Family Relationships

For family members, understanding the physical symptoms of MS is often easier than understanding the emotional ones. When depressed, becoming passive, exhibiting a negative mood, and experiencing low motivation are common; some may even withdraw from others. This may irritate family members, causing them to be critical or expecting you to do one thing that will snap you out of your mood. They may feel at a loss encountering your helpless mood.

If you become withdrawn, family members may withdraw too, as they may not fully understand what is needed. A loss of sexual interest or libido is also common and this too can have a negative impact on couples. Depression is not overcome by the power of positive thinking. Family members should avoid giving advice. Instead, a referral to a skilled mental-health professional who can work with both the individual and/or family is needed, as well as an evaluation with a psychiatrist to see if specific antidepressant medication would be helpful.

Social Withdrawal and Job Strain/Loss

Since individuals with depression experience greater fatigue, withdrawing to try to preserve energy is natural. This can result in not taking your medication or forgetting to
do so, not having the energy to exercise, and less energy to put into relationships and work. A good plan is to focus on a few tasks to accomplish each day to conserve energy, instead of trying to cover all of them. Taking the steps needed to engage social supports and resources is far more difficult when depressed, so having these supports and resources in place beforehand is another vital strategy.

If you know you are subject to depression, you may be able to predict times or events when you are more vulnerable to emotional issues, so family members and friends can be more available at these times. For some, this may be during the holidays or during the long winter months with fewer hours of sunlight. Let family and friends know that if they don’t hear from you during these times, that you would like them to contact you. Explain that this is because of your low energy, mood, or motivation, and that you are not trying to be unsocial.

Most people with mild-to-moderate depression can continue to work, but major depression can lead to a loss of employment. If your depression is interfering with your productivity and attitude at work, you may want to consider the pros and cons of alerting your employer if you are being treated for major depression, noting that you are taking medication and seeing a specialist. This is usually preferable to simply becoming absent from work, although you will need to make the decision of whether or not you want to disclose your depression and treatment, and what the ramifications may be. Many can gain relief from severe symptoms in three to four weeks with proper medication and psychotherapy interventions.

Coping with Depression
Depression is treatable and needs the time and attention it deserves, like any other condition. Expecting someone to “just get over it” or “just put up with it” won’t help. Many become depressed following the diagnosis of MS because time is needed to adjust to what the diagnosis means, as well as any potential losses in one’s quality of life that may be anticipated.

Individuals who do not cope well, whose coping skills are highly emotionally centered and involve reacting by escape or avoidance, may well experience a worsening of their depression. It is natural to be upset and struggle with the uncertainty and loss that surrounds the course of living with MS, yet constructive problem-solving and psychological counseling can be extremely beneficial. Getting help with focusing on what you can control, and learning to respond – not just react – to your experience, will help over time.

Treatment Options
Participating in psychological therapy and taking a medication for depression appear to be the most effective means of treating depression. Treating depression with a medication or a drug alone does not address the underlying causes. This is because communicating and sharing your experiences with others and with a mental-health professional has been shown to improve one’s ability to cope and to continue
to find meaning in one’s life.

Many types of psychotherapies may be effective in treating depressive disorders. These include cognitive behavioral therapy (CBT), psychotherapy, problem-focused supportive-group therapy, and telephone-administered CBT for individuals with MS who experience significant levels of depression.

For treatment with medications, consulting a psychiatrist, if possible, may be of greater benefit. Many managed-care and insurance plans have psychiatrists available for medication management. Your therapist can also aid you in this referral process. Consulting a psychiatrist is important because general practitioners (GPs) or family physicians may not be as familiar with the range of antidepressant medications available, versus someone who specializes in this field.

For instance, many GPs will typically prescribe the more common SSRIs (selective serotonin reuptake inhibitors), such as Zoloft® (sertraline), for most people. However, this may not be the best choice for everyone. If you experience more agitated depressions, such as increased anxiety with depression, you may be in need of antidepressants that also work to reduce your agitation – not just your low mood. If you are concerned about lowered sexual libido, certain classes of antidepressants, such as Wellbutrin® (bupropion), tend to not lower libido. If you have bipolar disorder, you may well need two different types of antidepressants to help regulate your low moods and this requires an experienced psychiatrist. This type of specialist is also skilled at optimal dosing over time. Please note that many antidepressants may require several weeks before you experience their full benefit, and some require regular blood work.

Medications That Can Trigger Depressive Responses
Steroid use is known to induce depressive reactions or exacerbate bipolar reactions in individuals. Additional medications, such as those used to treat urinary incontinence or spasticity, can also affect mood. If you are taking one or more of these medications, check with your physician to see if they in any way can lower mood.
It could be **PseudoBulbarAffect: PBA**

**PBA** is a neurologic condition that triggers outbursts of crying or laughing in people with brain injuries or neurologic conditions such as Multiple Sclerosis.

**PBA** is a neurologic condition, not psychological. And it’s treatable.

**46% of MS patients** had symptoms of **PBA** in a recent national study of more than 5,000 patients with a variety of underlying neurologic conditions.*

‘**PBA FACTS**’ is a FREE kit that explains the science of **PBA**, how it differs from depression and includes a self assessment to share with your doctor.

Get your FREE ‘**PBA FACTS**’ kit today. Call 1-800-774-4117 or go to **pbafacts.com**

*The PRISM Study was a nationwide study of patients 18+ with Alzheimer’s disease, amyotrophic lateral sclerosis (ALS), Parkinson’s disease, stroke, traumatic brain injury (TBI) or multiple sclerosis (MS) (1215 patients out of total study). Assessed PBA symptoms were measured by the Center for Neurologic Study-Lability Scale (CNS-LS) scores. A CNS-LS score ≥13 may suggest PBA symptoms and merits further diagnostic assessment. Patients or caregivers completed the assessment.
Anxiety in MS: Frequently Overlooked and Undetected

Anxiety is perhaps the most taxing and under-treated psychological effect of living with MS. It does not appear to result from the physical disease process of MS, but rather stems from the realities of living with MS. Individuals living with MS know that it’s the unpredictability, and therefore the difficulty, in planning and preparing for the effects of MS on your life, that drives one’s anxiety. Anxiety disorders are estimated to affect 43 percent of those with MS, and are also more common among women.

The scientific literature suggests that anxiety levels are higher at the onset of the disease and when it co-exists with moderate to severe depression. Tragically, the combination of untreated, sustained depression along with anxiety can produce higher rates of suicide among people with MS. Limited social support and higher rates of alcohol consumption also elevate anxiety disorders in MS.

Anxiety disorders are frequently overlooked and often undetected. As a result, they can worsen one’s quality of life and greatly reduce treatment adherence. One study suggests that only one-third of those with MS who have an anxiety disorder have been given a documented psychiatric diagnosis (Korostil & Feinstein, 2007). Frequently, if anxiety and depression co-exist, only a diagnosis of a depressive disorder is given.

Research suggests that approximately half of those with MS who have a diagnosable anxiety disorder are not receiving an anti-anxiety medication and/or psychotherapy. This is important to consider, because if an anxiety disorder co-exists with a depressive disorder, adequate treatment may require higher doses of an antidepressant medication for a longer period of time. This is something that many healthcare professionals may not be implementing if they are not well-versed in this area of treatment.

Some of the challenges of anxiety disorders are how to detect it, how to reduce it, and how to live with it. Fear is associated with having a real external threat. Stressful situations typically bring on some initial anxiety, like the first day of school, but for most people, this initial anxiety usually disappears with the passage of time and involvement in one’s new situation.

Anxiety represents a symbolic, perceived threat to one’s sense of self, which may be
defined as how someone sees him or her self and the unique qualities that he or she possesses. As MS progresses, different challenges and new uncertainties must be faced. This can result in more adjustments, more losses, and more anxiety.

The Symptoms of Anxiety
The spectrum of anxiety disorders includes panic attacks, phobias, obsessive-compulsive disorder (OCD), and generalized anxiety disorder (GAD). GAD is more prevalent in MS, followed by panic disorder and OCD. Those at higher risk are women, particularly those with a prior history of depression, excess drinking, and the presence of high social stressors. To be considered to have an anxiety disorder, a patient would present physiological and/or psychological symptoms.

Examples of physiological symptoms include:
- Trembling
- Increased heart rate or heart palpitations
- Dry mouth
- Shortness of breath
- Nausea
- Hot or cold sensations
- Tingling in fingers or toes
- Lightheadedness
- Faintness/fatigue
- Muscular tension
- Restlessness
- Insomnia, specifically difficulty falling asleep
- Frequent urination

Examples of psychological symptoms include:
- Chronic unhappiness
- Frequent worry, guilt, or feeling out of control
- Indecisiveness
- Feelings of inadequacy, feeling criticized, or easily embarrassed
- Rigidity, which is to be inflexible and less willing to make changes
- Hostility, feeling anger toward others
- Repeating certain behaviors or ruminative thoughts (pondering over something repeatedly)
- Over-anticipating things
- Excessive concern with physical health
- Negative thinking about the future
- Racing thoughts

Assessing and Treating Anxiety
Several screening tools or questionnaires can be used to assess levels of anxiety in MS. These include:

1) The Hamilton Anxiety Scale (HAS)
2) Hospital Anxiety and Depression Scale (HAD)
3) State Trait Anxiety Inventory (STAI)

The first two tools listed use scales to rate 14 items and take about seven minutes each to complete; the third tool is an inventory of 40 self-reported items (relating to anxiety). Those who are anxious typically know that they are, however, if depression is also present, it is often assumed that depression takes precedence or that its treatment may lower the anxiety. Often, if you suffer from
both depression and anxiety, a different kind of medication is needed, such as one of the SSRIs that treats both disorders.

Lowering anxiety requires many steps that include learning stress-reduction techniques. These techniques include:

- Interrupting and changing both “all or nothing” types of thinking, as well as catastrophic thinking, where an individual dwells on the worst possible outcomes.
- Incorporating exercise into lifestyle where possible.
- Breaking down fearful concerns into manageable, “present-oriented” solutions, aimed at resolving the issues at hand.
- Problem-solving one step at a time.
- Allowing and normalizing feelings of loss of control, while allowing the effect of any losses to be grieved and expressed.

Learning to control your reactions and quiet yourself can allow you to feel anxiety when needed to problem-solve, but not to become so overwhelmed by it. Increasing the areas of where you can have control and prioritizing activities can also help. Developing a more spiritual, entrusting attitude has also been found to be helpful to many.

Psychotherapy, either psychodynamic or cognitive/behavioral, includes stress-reduction techniques such as guided imagery, biofeedback (a technique that teaches individuals how to control their body’s responses), and meditation. These can be very helpful to reduce anxiety. Medication management is also available.

For some, an antidepressant, such as certain SSRIs that work on depressive and anxious symptoms, is indicated. Examples include Clexa® (citalopram) or Lexapro® (escitalopram). Additionally, Effexor® (venlafaxine) or Cymbalta® (duloxetine hydrochloride) may also be considered. Specific anti-anxiety medications like Valium® (diazepam) may work on an as-needed basis, but these tend to have short half-lives. This means that they work only for short periods of time or to aid sleep, but they are not designed for long-term use.

When searching for a therapist to get help with your anxiety, you may want to ask the therapist the following questions:

1) Do you have experience working with anxiety and with MS patients?
2) What types of therapies do you use? (Cognitive therapy, psychodynamic therapy, group therapy, etc.)
3) Do you work closely with physicians?
4) Are your services covered by my insurance?
5) Do you employ specific relaxation techniques such as guided imagery, meditation, biofeedback, hypnotherapy, and eye movement desensitization and reprocessing (EMDR) to lower stress and anxiety reactions? (EMDR is a newer, less-traditional type of psychotherapy that works to reduce emotional problems.)
6) Do you also work with care partners and family members?
7) How do you feel about using medications to help treat anxiety?

These questions will help to identify the best therapist for you.
In two pivotal trials 35% and 43% of patients taking AMPYRA responded to treatment vs. 8% and 9% of patients taking placebo.

Talk to your doctor to see if AMPYRA may be right for you.

AMPYRA® (dalfampridine) is indicated as a treatment to improve walking in patients with MS. This was demonstrated by an increase in walking speed.

IMPORTANT SAFETY INFORMATION
Do not take AMPYRA if you have ever had a seizure, or have certain types of kidney problems, or are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA.

Take AMPYRA exactly as prescribed by your doctor. You could have a seizure even if you never had a seizure before. Your chance of having a seizure is higher if you take too much AMPYRA or if your kidneys have a mild decrease of function, which is common after age 50.

Your doctor may do a blood test to check how well your kidneys are working, if that is not known before you start taking AMPYRA.

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

AMPYRA® may cause serious allergic reactions. Stop taking AMPYRA and call your doctor right away or get emergency medical help if you have shortness of breath or trouble breathing, swelling of your throat or tongue, or hives.

Please see the full Patient Medication Guide on the following page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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MEDICATION GUIDE FOR AMPYRA® (am-PEER-ah) (dal Fangride) Extended Release Tablets

Read this Medication Guide before you start taking AMPYRA and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about AMPYRA?
AMPYRA can cause seizures.
• You could have a seizure even if you never had a seizure before.
• Your chance of having a seizure is higher if you take too much AMPYRA or if your kidneys have a mild decrease of function, which is common after age 50.
• Your doctor may do a blood test to check how well your kidneys are working, if that is not known before you start taking AMPYRA.
• Do not take AMPYRA if you have ever had a seizure.
• Before taking AMPYRA tell your doctor if you have kidney problems.
• Take AMPYRA exactly as prescribed by your doctor. See “How should I take AMPYRA?”

Stop taking AMPYRA and call your doctor right away if you have a seizure while taking AMPYRA.

What is AMPYRA?
AMPYRA is a prescription medicine used to help improve walking in people with multiple sclerosis (MS). This was shown by an increase in walking speed.

It is not known if AMPYRA is safe or effective in children less than 18 years of age.

Who should not take AMPYRA?
Do not take AMPYRA if you:
• have ever had a seizure
• have certain types of kidney problems
• are allergic to dalfampridine (4-amino pyridine), the active ingredient in AMPYRA

What should I tell my doctor before taking AMPYRA?
Before you take AMPYRA, tell your doctor if you:
• have any other medical conditions
• are taking compounds 4-amino pyridine (fampridine, 4-AP)
• are pregnant or plan to become pregnant. It is not known if AMPYRA will harm your unborn baby. You and your doctor will decide if you should take AMPYRA while you are pregnant.
• are breast-feeding or plan to breast-feed. It is not known if AMPYRA passes into your breast milk. You and your doctor should decide if you will take AMPYRA or breast-feed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take AMPYRA?
• Take AMPYRA exactly as your doctor tells you to take it. Do not change your dose of AMPYRA.
• Take one tablet of AMPYRA 2 times each day about 12 hours apart. Do not take more than 2 tablets of AMPYRA in a 24-hour period.
• Take AMPYRA tablets whole. Do not break, crush, chew or dissolve AMPYRA tablets before swallowing. If you cannot swallow AMPYRA tablets whole, tell your doctor.
• AMPYRA is released slowly over time. If the tablet is broken, the medicine may be released too fast. This can raise your chance of having a seizure.
• AMPYRA can be taken with or without food.
• If you miss a dose of AMPYRA, do not make up the missed dose. Do not take 2 doses at the same time. Take your next dose at your regular scheduled time.
• If you take too much AMPYRA, call your doctor or go to the nearest hospital emergency room right away.
• Do not take AMPYRA together with other aminopyridine medications, including compounded 4-AP (sometimes called 4-amino pyridine, fampridine).

What are the possible side effects of AMPYRA?
AMPYRA may cause serious side effects, including:
• serious allergic reactions. Stop taking AMPYRA and call your doctor right away or get emergency medical help if you have:
  – shortness of breath or trouble breathing
  – swelling of your throat or tongue
  – hives
  – kidney or bladder infections

See “What is the most important information I should know about AMPYRA?”

The most common side effects of AMPYRA include:
• urinary tract infection
• trouble sleeping (insomnia)
• dizziness
• headache
• nausea
• weakness
• back pain
• problems with balance
• multiple sclerosis relapse
• burning, tingling or itching of your skin
• irritation in your nose and throat
• constipation
• indigestion
• pain in your throat

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of AMPYRA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store AMPYRA?
• Store AMPYRA at 59°F to 86°F (15°C to 30°C).
• Safely throw away AMPYRA that is out of date or no longer needed.

Keep AMPYRA and all medicines out of the reach of children.

General Information about the safe and effective use of AMPYRA
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AMPYRA for a condition for which it was not prescribed. Do not give AMPYRA to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about AMPYRA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about AMPYRA that is written for health professionals.

For more information, go to www.AMPYRA.com or call 1-800-367-5109.

What are the ingredients in AMPYRA?
Active ingredient: dalfampridine (previously called fampridine)
Inactive ingredients: colloidal silicon dioxide, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol and titanium dioxide.

Distributed by: Acorda Therapeutics, Inc.
Ardley, NY 10502

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This Medication Guide was approved by the U.S. Food and Drug Administration.

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MxDS® is a registered trademark of Alkermes Pharma Ireland Limited (API).
U.S. Patent Nos.: US 5,540,938 and US 8,007,826

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Recognizing the Symptoms of PBA

Pseudobulbar affect (PBA) is a neurologic effect that occurs in 10 percent of people with MS, although some research suggests a much larger percentage. It is characterized by sudden, uncontrollable expressions of laughter or crying without an apparent trigger.

PBA is equally common among men and women and occurs in other chronic, neurological conditions such as Parkinson’s disease and amyotrophic lateral sclerosis (ALS). Once it starts, it cannot be controlled voluntarily. This behavior is extremely distressing as well as embarrassing to those who experience it. PBA is not yet well recognized or understood. With more education, people with MS will know to consult their MS neurologist if they experience any of its symptoms.

PBA is distinguished from depression by its sudden emotional reactivity. Though depression and PBA both appear to result from the disease process of MS itself, PBA is specifically related to a certain set of behaviors, such as sudden laughing or crying. You could have MS and depression and not experience PBA, or you could have PBA but not have depression. Or you could experience both. The etiology of PBA is unclear and it is believed to be a disorder of mood related to the disruption of nerve impulses in the central nervous system.

Treating PBA

In 2010, Nuedexta® (dextromethorphan hydrobromide and quinidine sulfate) was approved by the Food and Drug Administration (FDA) to treat PBA episodes in MS. Nuedexta is the first and only approved treatment for PBA at this time.

Some doctors advocate using certain antidepressant medications, including the SSRIs (selective serotonin reuptake inhibitors), such as Celexa and Zoloft. Although their exact course of action is not clear, they appear to be effective for many. These antidepressants are typically administered at a lower dose than for depression. While these medications may well help to manage the symptoms of PBA, they do not cure its underlying cause.

If you experience PBA, hope is in sight. The Center for Neurologic Study Emotional Lability Scale is a good screening tool available for PBA. You can complete it at your MS neurologist’s office. If you have PBA, you will need to consult an MS neurologist to determine which medication is best for you.
The Emotional and Psychological Symptoms of MS

Changing Needs

The needs of people with MS and their loved ones vary from individual to individual and change over time. What a person requires emotionally and psychologically at the time of diagnosis can be very different as the disease evolves.

For example, the newly diagnosed person must come to grips with having to cope with a long-term illness. He or she may need to choose treatments that vary in risk and complexity, consider living with physical limitations such as overwhelming fatigue or mobility issues, and experience stress and worry for both oneself and his or her family. Periods of relapses may require care and rehabilitation to regain function. Financial insecurity may grow with uncertain employment status, insurance coverage, and growing medical costs. After recovery, and with normal aging, work stamina may be impacted, or job abilities may change. Living with uncertainty is stressful, and over time, can also take its toll.

The Impact of Symptoms on Relationships and Roles

Relationships, even without the unique challenges of living with MS, can be complex. Before thinking about roles, it is important to be aware of stereotypes based on gender. How often we hear terms such as “the man of the house,” and yet many households today are headed by women. When a man is expected to be the breadwinner, protector, and the physically strong one, having MS may seem like a challenge to his masculinity. A partner who needs to take over such responsibilities may also feel she is somehow emasculating her mate. A woman may believe she is less feminine, or try to do it all – and risk burnout and exhaustion.

Another scenario is when a wife, who may be proud of her homemaking skills, may feel devastated that she can no longer do the things she once did well and loved to do. Modern families often cross traditional lines of roles and gender, and this can help to make coping with the role changes with MS easier. At the same time, other factors can make these role changes more challenging. Keeping an open mind and open heart will prove to be vital assets.

Sexual roles may be affected when disability presents symptoms such as sexual dysfunction or bowel and bladder disorders. Intimacy may suffer from any of the above
changes or pressures of daily life, just at a
time when the family is most vulnerable.
Cognitive changes may erode the sense of self
or knowledge of a mate, and demand new
ways of being in a relationship with each
other. Behaviors may also change over time
or because of symptoms. An otherwise
outgoing person with incontinence, for
example, may withdraw from friends and
activities because he or she may feel unable
to be secure or present the image he or she
would prefer.

Parents may feel they are an embarrassment
to their kids because they can’t be the athlete
or classroom aide, or keep up with the rigors
of work, home, and raising children. They
may simply not have the energy or stamina
to keep up with busy youngsters or do what
other parents can. And, independently
minded souls don’t like to ask for help or
rely on others, but options may be limited.
Children may have to assume adult
responsibilities and become caregivers.
Alternatively, the person with MS may feel a
need to compensate and give 110 percent to
make up for what is lost.

Parents of adult children with MS also
may be asked to revert to taking a more
active role in caring for their child with MS.
When returning to live with parents, the
person with MS may feel resentful, rebellious,
or feel as though he or she is destroying the
parents’ “golden years.” Physical care may
include personal care that greatly invades
one’s privacy. And, on a fixed income,
finances may be strained when wages
must be paid from their limited budget
for additional help.

Promoting a Better Quality of Life

We now live in a hopeful time for people
with MS. An array of treatments and
medications are now available. These can
manage symptoms, promote function, hold
disability at bay, and favorably affect the
course of MS by reducing relapse rates.

Adhering to disease-modifying therapies
and symptom-management strategies may
require complex protocols and performing
techniques usually done by healthcare
providers (such as injections or catheter-
ization). Patients and care partners may be
concerned about acquiring these skills and
worry about doing them correctly. They
may even face their own reluctance or
resistance, and catch flack rather than
kudos. This is where the MS team can offer
training, monitoring, moral support, and
encouragement. People with MS and their
loved ones have embraced these challenges
admirably, but they still deserve and need
support.

Fortunately, not every person with MS
faces all of these challenges. Communication
skills, along with the support of caring
professionals, can help families cope with
relationship issues and role changes. Legal
advice can assist with securing financial
benefits or accommodations when issues
arise. A comprehensive medical team can
help weather bouts of worsening symptoms
or growing limitations. Organizations like
MSAA often provide vital links and serve as a
godsend, offering information, education,
and resources to support a chain of care.

Asking for and securing help may be
difficult for some, but it may be necessary to
get things done. That help may need to come from a variety of sources, including family and friends, hired help, community organizations, and/or social supports. Consider engaging in family or couples’ counseling to help ease transitions and make adjustments to promote better understanding.

Ideally, the needs of each family member can be supported in the interest of all. Being able to identify and acknowledge abilities, roles, and expectations, permits a plan to develop – a plan that will meet changing needs and evolving roles, while ultimately promoting a better quality of life.

Sexual Dysfunction:
A Less-Discussed Symptom of MS

Sexuality and intimacy have a significant impact on the quality of life for nearly everyone, including those with a chronic disease such as multiple sclerosis (MS). In MS, sexual dysfunction may be one of the more invisible symptoms of the disease. It is important to recognize and understand the factors that contribute to sexual dysfunction in order to adequately address it.

Both men and women may experience sexual dysfunction. Some studies suggest it affects between 40 to 80 percent of women and 50 to 90 percent of men. Other studies suggest that sexual dysfunction increases over time in people with MS and may be associated with some of the emotional and psychological problems that they may also experience.

People are at times reluctant to discuss sexual dysfunction with their MS-care team, as they may feel awkward discussing things that seem so personal. In order to address these problems as one would address other symptoms, they first must be recognized and discussed.

How Cognitive Problems Affect Sexual Function

Cognitive impairment is common in MS, affecting as many as 50 percent of individuals with MS, and is not necessarily associated with advanced stages of disease. The onset of cognitive impairment in MS is usually not easy to pinpoint. Some people notice distinct changes in their mental functioning that can be attributed to the disease, while others are unaware of how their cognitive limitations may be affecting relationships.

Some of the cognitive functions typically affected in people with MS include: information processing; perceiving; attending/responding...
SPEAK UP TODAY!
Ask your doctor if GILENYA is right for you, and join the thousands of people already speaking out against their relapsing MS.

Only GILENYA® combines proven efficacy to cut MS relapses in half vs a leading injectable in a once-daily* pill.
GILENYA reduced the frequency of relapses by 52% in a 1-year study vs Avonex®, and by 54% in a 2-year study vs placebo.

**Indication**
GILENYA is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS) in adults. GILENYA can decrease the number of MS flare-ups (relapses). GILENYA does not cure MS, but it can help slow down the physical problems that MS causes.

**Important Safety Information**
You should not take GILENYA if in the last 6 months you experienced heart attack, unstable angina, stroke or warning stroke, or certain types of heart failure. Do not take GILENYA if you have certain types of an irregular or abnormal heartbeat (arrhythmia), including a heart finding called prolonged QT, as seen on a test to check the electrical activity of your heart (ECG) before starting GILENYA. You should not take GILENYA if you take certain medicines that change your heart rhythm.

*GILENYA can result in a slow heart rate when first taken. Your first dose will be given in a medical facility where you will be watched for at least 6 hours. If you stop taking GILENYA for more than 14 days after your first month of treatment, you will need to repeat this observation.

Please see additional Important Safety Information on the next page and Brief Summary of Important Product Information on the following pages.
**Important Safety Information**

**GILENYA** may cause serious side effects such as:

- Slow heart rate, especially after your first dose. An ECG will be performed before and 6 hours after your first dose. Your pulse and blood pressure should be checked every hour while you stay in a medical facility during this time. If your heart rate slows down too much, you might feel dizzy or tired, or feel like your heart is beating slowly or skipping beats. Symptoms can happen up to 24 hours after your first dose. After 6 hours, if your ECG shows any heart problems or if your heart rate is still too low or continues to decrease, you will continue to be watched by a health care professional. If you have any serious side effects after your first dose, especially those that require treatment with other medicines, you will stay in a medical facility to be watched overnight and for at least 6 hours after your second dose of GILENYA the next day. If you have certain types of heart problems, or if you are taking certain types of medicines that can affect your heart, you will be watched overnight after you take your first dose. If you experience slow heart rate, it will usually return to normal within 1 month. Call your doctor or go to the nearest emergency room right away if you have any symptoms of a slow heart rate. If you stop taking GILENYA for more than 14 days after your first month of treatment, you will need to repeat this observation.

- Increased risk of serious infections. GILENYA lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 2 months of stopping GILENYA. Your doctor may do a blood test before you start GILENYA. Increased risk of infection was seen with doses higher than the approved dose (0.5 mg). Two patients died who took higher-dose GILENYA (1.25 mg) combined with high-dose steroids. Call your doctor right away if you have fever, tiredness, body aches, chills, nausea, or vomiting.

- Macular edema, a vision problem that can cause some of the same vision symptoms as an MS attack (optic neuritis), or no symptoms. Macular edema usually starts in the first 3 to 4 months after starting GILENYA. Your doctor should test your vision before you start GILENYA; 3 to 4 months after you start GILENYA; and any time you notice vision changes. Vision problems may continue after macular edema has gone away. Your risk of macular edema may be higher if you have diabetes or have had an inflammation of your eye (uveitis). Call your doctor right away if you have blurriness, shadows, or a blind spot in the center of your vision; sensitivity to light; or unusually colored vision.

- Breathing problems. Some patients have shortness of breath. Call your doctor right away if you have trouble breathing.

- Liver problems. Your doctor should do blood tests to check your liver before you start GILENYA. Call your doctor right away if you have nausea, vomiting, stomach pain, loss of appetite, tiredness, dark urine, or if your skin or the whites of your eyes turn yellow.

- Increases in blood pressure (BP). BP should be monitored during treatment.

GILENYA may harm your unborn baby. Talk to your doctor if you are pregnant or planning to become pregnant. Women who can become pregnant should use effective birth control while on GILENYA, and for at least 2 months after stopping. If you become pregnant while taking GILENYA, or within 2 months after stopping, tell your doctor right away. Women who take GILENYA should not breastfeed, as it is not known if GILENYA passes into breast milk. A pregnancy registry is available for women who become pregnant during GILENYA treatment. Call 1-877-598-7237 or visit www.gilenyapregnancyregistry.com for more information.

Tell your doctor about all your medical conditions, including if you had or now have an irregular or abnormal heartbeat; history of stroke or warning stroke; heart problems; a history of repeated fainting; a fever or infection, or if you are unable to fight infections; eye problems; diabetes; breathing or liver problems; or high blood pressure. Also tell your doctor if you have had chicken pox or have received the vaccine for chicken pox. Your doctor may do a test for the chicken pox virus, and you may need to get the vaccine for chicken pox and wait 1 month before starting GILENYA.

Tell your doctor about all the medicines you take, including medicines for heart problems or high blood pressure or other medicines that may lower your heart rate or change your heart rhythm; medicines that could increase your chance of infections, such as medicines to treat cancer or control your immune system; or ketoconazole (an antifungal) by mouth. If taken with GILENYA, serious side effects may occur. You should not get certain vaccines while taking GILENYA, and for at least 2 months after stopping.

The most common side effects with GILENYA were headache, flu, diarrhea, back pain, abnormal liver tests, and cough.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see additional Important Safety Information on previous page.
MEDICATION GUIDE
GILENYA™ (je-LEN-yah)
(fingolimod)
capsules

Read this Medication Guide before you start using GILENYA and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about GILENYA?
GILENYA may cause serious side effects, including:

1. Slow heart rate (bradycardia or bradyarrhythmia) when you start taking GILENYA. GILENYA can cause your heart rate to slow down, especially after you take your first dose. You will have a test to check the electrical activity of your heart (ECG) before you take your first dose of GILENYA.

You should stay in a medical facility for at least 6 hours after you take your first dose of GILENYA. After you take your first dose of GILENYA:
- Your pulse and blood pressure should be checked every hour.
- You should be watched by a healthcare professional to see if you have any serious side effects. If your heart rate slows down too much, you may have symptoms such as:
  o dizziness
  o tiredness
  o feeling like your heart is beating slowly or skipping beats
- If you have any of the symptoms of slow heart rate, they will usually happen during the first 6 hours after your first dose of GILENYA. Symptoms can happen up to 24 hours after you take your first GILENYA dose.
- 6 hours after you take your first dose of GILENYA you will have another ECG. If your ECG shows any heart problems or if your heart rate is still too low or continues to decrease, you will continue to be watched.
- If you have any serious side effects after your first dose of GILENYA, especially those that require treatment with other medicines, you will stay in the medical facility to be watched overnight. You will also be watched for any serious side effects for at least 6 hours after you take your second dose of GILENYA the next day.
- If you have certain types of heart problems, or if you are taking certain types of medicines that can affect your heart, you will be watched overnight after you take your first dose of GILENYA.

Your slow heart rate will usually return to normal within 1 month after you start taking GILENYA.

Call your doctor or go to the nearest emergency room right away if you have any symptoms of slow heart rate.

2. Infections. GILENYA can increase your risk of serious infections. GILENYA lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 2 months of stopping treatment. Your doctor may do a blood test before you start taking GILENYA. Call your doctor right away if you have any of these symptoms of an infection:
- fever
- tiredness
- body aches
- chills
- nausea
- vomiting

3. A problem with your vision called macular edema. Macular edema can cause some of the same vision symptoms as an MS attack (optic neuritis). You may not notice any symptoms with macular edema. Macular edema usually starts in the first 3 to 4 months after you start taking GILENYA. Your doctor should test your vision before you start taking GILENYA and 3 to 4 months after you start taking GILENYA, or any time you notice vision changes during treatment with GILENYA. Your risk of macular edema may be higher if you have diabetes or have had an inflammation of your eye called uveitis.

Call your doctor right away if you have any of the following:
- blurriness or shadows in the center of your vision
- a blind spot in the center of your vision
- sensitivity to light
- unusually colored (tinted) vision

What is GILENYA?
GILENYA is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS) in adults. GILENYA can decrease the number of MS flare-ups (relapses). GILENYA does not cure MS, but it can help slow down the physical problems that MS causes.

It is not known if GILENYA is safe and effective in children under age 18.

Who should not take GILENYA?
Do not take GILENYA if you:
- have had a heart attack, unstable angina, stroke or warning stroke or certain types of heart failure in the last 6 months
- have certain types of irregular or abnormal heartbeat (arrhythmia), including patients in whom a heart finding called prolonged QT is seen on ECG before starting GILENYA
- are taking certain medicines that change your heart rhythm

If any of the above situations apply to you, tell your doctor.

What should I tell my doctor before taking GILENYA?
Before you take GILENYA, tell your doctor about all your medical conditions, including if you had or now have:
- an irregular or abnormal heartbeat (arrhythmia)
- a history of stroke or warning stroke
- heart problems, including heart attack or angina
- a history of repeated fainting (syncope)
- a fever or infection, or you are unable to fight infections. Tell your doctor if you have had chicken pox or have received the vaccine for chicken pox. Your doctor may do a blood test for chicken pox virus. You may need to get the vaccine for chicken pox and then wait 1 month before you start taking GILENYA.
- eye problems, especially an inflammation of the eye called uveitis.
- diabetes
- breathing problems, including during your sleep
- liver problems
- high blood pressure
- Are pregnant or plan to become pregnant. GILENYA may harm your unborn baby. Talk to your doctor if you are pregnant or are planning to become pregnant.
- Tell your doctor right away if you become pregnant while taking GILENYA or if you become pregnant within 2 months after you stop taking GILENYA.
- If you are a female who can become pregnant, you should use effective birth control during your treatment with GILENYA and for at least 2 months after you stop taking GILENYA.

Pregnancy Registry: There is a registry for women who become pregnant during treatment with GILENYA. If you become pregnant while taking GILENYA, talk to your doctor about registering with the GILENYA Pregnancy Registry. The purpose of this registry is to collect information about your health and your baby’s health.
For more information, you can call the GILENYA Pregnancy Registry at 1-877-598-7237 or visit www.gilenyapregnancyregistry.com.

- Are breastfeeding or plan to breastfeed. It is not known if GILENYA passes into your breast milk. You and your doctor should decide if you will take GILENYA or breastfeed. You should not do both.

**Tell your doctor about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist when you get a new medicine.

Using GILENYA and other medicines together may affect each other causing serious side effects. Especially tell your doctor if you take:

- Medicines for:
  - heart problems or
  - high blood pressure or
  - other medicines that may lower your heart rate or change your heart rhythm
- Vaccines. Tell your doctor if you have been vaccinated within 1 month before you start taking GILENYA. You should not get certain vaccines while you take GILENYA and for at least 2 months after you stop taking GILENYA. If you take certain vaccines, you may get the infection the vaccine should have prevented. Vaccines may not work as well when given during GILENYA treatment.
- Medicines that could raise your chance of getting infections, such as medicines to treat cancer or to control your immune system.
- ketoconazole (an antifungal drug) by mouth

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

**How should I take GILENYA?**

- Your first dose of GILENYA will be given in a medical facility where you will be watched for at least 6 hours after your first dose of GILENYA. See “What is the most important information I should know about GILENYA?”
- Take GILENYA exactly as your doctor tells you to take it.
- Take GILENYA 1 time each day.
- Take GILENYA with or without food.
- Do not stop taking GILENYA without talking with your doctor first.
- If you start GILENYA again after stopping for 2 weeks or more, you will start taking GILENYA again in your doctor’s office or clinic.

**What are possible side effects of GILENYA?**

GILENYA can cause serious side effects.

See “What is the most important information I should know about GILENYA?”

Serious side effects include:

- **Breathing Problems.** Some people who take GILENYA have shortness of breath. Call your doctor right away if you have trouble breathing.
- **Liver problems.** GILENYA may cause liver problems. Your doctor should do blood tests to check your liver before you start taking GILENYA. Call your doctor right away if you have any of the following symptoms of liver problems:
  - nausea
  - vomiting
  - stomach pain
  - loss of appetite

- **tiredness**
- **your skin or the whites of your eyes turn yellow**
- **dark urine**

The most common side effects of GILENYA include:

- **headache**
- **flu**
- **diarrhea**
- **back pain**
- **abnormal liver tests**
- **cough**

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of GILENYA. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How do I store GILENYA?**

- Store GILENYA in the original blister pack in a dry place.
- Store GILENYA at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep GILENYA and all medicines out of the reach of children.

**General information about GILENYA**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use GILENYA for a condition for which it was not prescribed. Do not give GILENYA to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about GILENYA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about GILENYA that is written for healthcare professionals.

For more information, go to www.pharma.US.Novartis.com or call 1-888-669-6682.

**What are the ingredients in GILENYA?**

**Active ingredient:** fingolimod

**Inactive ingredients:** gelatin, magnesium stearate, mannitol, titanium dioxide, yellow iron oxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

GILENYA is a trademark of Novartis AG.

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Novartis Pharma Stein AG
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Distributed by:
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936

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to incoming information; information-processing speed; cognitive flexibility, such as attending to multiple stimuli at the same time (“multi-tasking”); problems with storage, manipulation, and retrieval of information; and executive function, which includes planning, working memory, attention, and problem-solving.

Cognitive impairment may affect sexual function and relationships in many ways. Partners may become frustrated if the person with MS becomes easily distracted during intimacy. Distractions such as children in the home, music, and television may interrupt intimate moments if the person with MS is not able to filter out these distractions and remain focused on his or her partner.

Planning for sexual activity may be complex and overwhelming to the person with MS, and he or she may choose to avoid it all together. Verbal fluency and word finding may also be a problem leading to a partner who feels he or she is not wanted or respected. Fatigue may worsen both cognitive function and the quality of sexual relations as well.

Once cognitive impairment has been identified in a person with MS, what can be done to treat this condition? First, people with relapsing forms of MS should be encouraged to begin or remain on an effective disease-modifying therapy (DMT), if advised by his or her doctor. Based on these agents’ ability to inhibit inflammation and the accumulation of brain lesions, it is likely that they exert some degree of neuroprotection that may limit the progression of cognitive impairment.

Evidence suggests that exercise training in people with MS has the potential to improve many aspects of cognitive performance. Exercise has been proposed to have positive effects in reducing inflammation and neurologic damage in people with MS. Counseling is vital to assist the couple dealing with cognitive challenges affecting sexual function. Patients can be referred to an occupational therapist to assist with adaptation of certain skills or to a psychosocial therapist for assistance with coping and stress reduction.

**How Depression and Anxiety Affect Sexual Function**

Depression is another psychological disorder seen frequently in people with MS that often impacts sexual function. People with MS who are depressed may have a decreased libido, difficulty with certain sexual positions, and fear of developing relationships. Men may also experience erectile dysfunction. The best treatment for depression is usually psychotherapy along with medication and exercise. Seeking strength in spiritual beliefs can also help. Depression can also affect care partners and may increase as disability increases. Care partners need to recognize and treat depression to effectively participate in intimate relations.

Anxiety can affect sexual function as well, and care partners are also at risk. When anxiety impacts sexual function, both of these symptoms can worsen.

**Enhancing Intimacy**

Intimacy may be defined as anything that makes one feel closer to another, particularly in a personal and private way. People with
MS who are experiencing emotional or psychological difficulties may find intimacy particularly challenging. Depression, anxiety, and cognitive dysfunction are all likely to interfere with attempts at intimacy. Recognizing and treating the underlying cause is the best way to enhance intimacy.

Emotional and psychological impairment affects quality of life, which includes intimate and sexual relationships. Recognizing these impairments in people with MS and their care partners is the first step to a healthy sexual relationship. Quality of life can be impacted and treatment for many of the underlying emotional and psychological causes of sexual dysfunction should be investigated. With early recognition and treatment, a healthy and satisfying sexual relationship is certainly possible.

References

SELF IMAGE AND SELF ESTEEM

By Pat Kennedy, RN, CNP, MSCN
Nurse Educator, Can Do Multiple Sclerosis

The Impact of an MS Diagnosis

When we consider the impact that the diagnosis of multiple sclerosis has on an individual, one only needs to ask, “When were you diagnosed?” Most people remember the date, the time, the doctor, and what was happening in their life at that moment. The experience was life-changing not only for the individual, but also for his or her family, friends, and the future.

The day before the diagnosis was most likely a “normal” day. The day of the diagnosis was probably a shocker. On the day after, everything changed. For the person with the new diagnosis, there is a shift in how the world, the future, and his or her self are viewed. There clearly is a difference in perception of self esteem and self image, although others may not perceive this.

Living life is something like balancing on a teeter totter. There are ups and downs. The person on the other end may alter how high you go or how fast you come down, but typically you are able to keep it balanced in the middle. Being diagnosed with MS suddenly puts a huge weight on one end, and lifts the person on the other end up in the air – feeling out of control and helpless. Things
can be done to lighten the heavy end and restore balance. Part of lightening the load is to work on self image and self esteem.

**The Importance of Positive Thinking**

People with chronic diseases such as MS may view themselves as changing negatively, and may find it difficult to engage in positive thinking. Pulling on previous experiences to repair their self image can be challenging. Without that positive framework, self esteem and self image become defined by the illness, and as a result, one's overall self concept is altered.

Richard M. Cohen is an accomplished correspondent, author, speaker, father, and husband, who was diagnosed with MS more than 30 years ago. In an article in *The Magazine* published by AARP in October of 2011, he speaks of his need to tend to his positive self image. He explains his need to hang on to all he has accomplished and not to let his worst fears define him. Mr. Cohen admits that his friends and acquaintances reassure him that when they look at him, they see his strengths, but when he looks in the mirror, he sees a man with MS. He goes on to say that perhaps he should lift his eyes and see what a good life he has.

People living with MS struggle with the following issues:

- Increased self concern in thinking about what was in the past and what abilities have been lost
- Increased sense of dependence, which can lead to strained relationships
- Increased personal attention to illness, which tends to decrease social interactions

- Increased belief that society emphasizes what we do and discounts us if we don't or can't accomplish certain goals. We then respond by not participating more fully and losing some of the skills that may promote a more meaningful life.

**Resilience and Bouncing Back**

Reducing the impact of MS on how a person feels, and then moving forward in a positive way, is possible. One strategy is to become more resilient. Resiliency is the ability to take life’s punches in stride. Bad things still happen, but function can continue. Prior to dealing with the diagnosis of MS, most have had to deal with other significant issues in their lives. As a result, coping skills were developed. These same coping skills, as well as new ones yet to be developed, will assist in being resilient.

Some basic ideas to improve resiliency include the following:

- **Work on improving relationships.** Changes may occur in your circle of people, but work on keeping a support system going. Surround yourself with positive people who care about you. This is a key way to improve self esteem.

- **Consider past successes.** Remembering your accomplishments and the personal satisfaction they brought may help develop new directions, which may enable you to accomplish similar goals and replicate those good feelings.

- **Look ahead, even if the future looks different.** Change can be positive and a legitimate sign of resiliency.

- **Begin to make healthy choices.** If not
feeling positive about oneself, individuals may also easily ignore the efforts they need to make in order to stay healthy. This is the time to make healthy dietary choices, practice good sleeping habits, manage weight in a healthy range, and exercise. Books are written about all the values of exercise; it's hard to be resilient without it.

**Remain hopeful.** Huge changes have been made in the treatment and management of MS. Individuals with MS may look ahead and feel positive! This positive attitude will help maintain self-esteem and image as well as add to the resiliency bank.

If resiliency is a way to “bounce back,” learning how to be proactive is important as well. Developing and nurturing a healthy sense of self-esteem and a positive self-image are possible. Most people, with or without MS, are a work-in-progress. When changes in the disease or changes in function occur, these may threaten the sense of safety that you hold within yourself. Revisiting some of the following ideas may be helpful to balance those feelings of loss of control, as well as those persistent and irritating negative thoughts about self-image:

- **Begin to express gratitude.** Many good things occur in life, and by showing gratitude for them, it tends to attract more good events. Expressing this gratitude to others or journaling the things you are grateful for adds positives to your quality of life. Practice it daily and it will soon be a part of routine.
- **Find things that bring joy.** “Stop and smell the roses” is not just an overused expression. Take time to seek out pleasurable activities, learn new skills, or spend more time on existing activities that make life happier. It's hard to not feel good while smiling.
- **Explore spirituality.** Spirituality evokes strength in dealing with the negatives that MS might present, as well as bringing those in support closer to you. People experience spirituality in many ways, so examine what you personally find to be inspirational and see if it provides strength.
- **Changes can be small.** If changes occur in small amounts on a regular basis, they have a positive cumulative effect. Starting to train for a marathon usually begins with a mile or two. Training for MS and its effect on self-esteem will start the same way. Tiny steps are cumulative, progressive, and eventually yield major strides.

Hopefully, over time, the load on the teeter totter will diminish. Enjoyment and quality of life with MS will improve. It's all about learning to balance and bounce back.

**IN CONCLUSION**

Individuals with MS are at higher risk for emotional disorders, which can significantly disrupt family, work, and social life. These mood disorders are highly treatable through a combination of psychiatric and psychological therapy and medication treatment.

The resources exist, but the delivery of these treatments is not always well-implemented. Learning to address your concerns about your emotional reactions with your MS neurologist and other members of your healthcare team is essential. People with MS must not only focus on the physical symptoms of MS, but
also on the emotional and psychological symptoms. When needed, ask your physician and/or nurse to refer you to mental-health professionals who are skilled in this area and who ideally have experience with MS or other chronic conditions.

Please note, however, that mental-health professionals who specialize in MS are extremely limited. According to MSAA’s client services department, “When people call for a referral, we refer them first to their MS center or neurologist, who may have someone to recommend. As a second option, we advise people with insurance to check with their provider for mental-health professionals who have a specialty in chronic illness, pain management, or neurological disorders. We explain that not every therapist may be a good match for every person, and that individuals may need to schedule a few introductory sessions with different providers before finding someone they are comfortable with.”

We hope that this article will help individuals with MS who are experiencing emotional or psychological issues to know that they are not alone – and that they should not feel embarrassed over these symptoms that they cannot control. Seeking help by discussing these issues with your doctor is the first step toward returning to a happier and more satisfying quality of life.

Readers may visit MSAA’s website at mymsaa.org, or call MSAA at (800) 532-7667, for more information. ◆
Very likely, the FDA will soon decide on the status of the first alternative “biologic” drugs to challenge the branded disease-modifying therapies (DMTs) presently in use by individuals with multiple sclerosis (MS). Several of the current DMTs approved by the United States Food and Drug Administration (FDA) are “biologics,” which means that the active ingredient for each of these drugs is derived from living cells.

The biologic DMTs for MS include Avonex®, Betaseron®, and Rebif® – three beta interferons that were among the earliest long-term treatments approved for MS, plus Extavia®, a later-approved beta interferon that is the same drug as Betaseron. Tysabri® (natalizumab) and Novantrone® (mitoxantrone) are also biologics.

Copaxone® (glatiramer acetate) and the three oral DMTs, Gilenya® (fingolimod), Aubagio® (oral teriflunomide), and Tecfidera™ (dimethyl fumarate), are not biologics. However, the FDA is currently reviewing alternative drugs similar to Copaxone. Even though it is not a biologic, it has a very complex molecular structure that is difficult to replicate.

In the near future, some of these biologic medications that play a primary role in many treatment regimens for people with MS, will no longer be protected by their original 12-year exclusivity period, thus opening the market to competitors. When ready, these competitors will be able to submit a biologics license application (BLA) to the FDA, possibly bringing less-expensive drug alternatives to the MS community.

The process of exclusivity and subsequent competition was put into place by the Drug Price Competition and Patent Term Restoration Act -- or Hatch-Waxman Act -- in the 1980s. These acts were passed in hopes of accomplishing two important objectives: (1) to encourage research by large pharmaceutical companies, by allowing them that period of exclusivity to see a return on their investment required for the initial development of complex drugs; and (2) to lower overall healthcare costs through competition among newly introduced drugs.

Today, the Patient Protection and Affordable Care Act includes similar provisions under the Biologics Price Competition and Innovation Act (BPCI Act), opening the market to the types of medications that MS patients often use: biologics.

Many individuals are familiar with this idea when discussing generic versions of traditional medications, such as Tylenol® versus acetaminophen. However, biologics and their new counterparts, biosimilars, pose unique challenges due to their complex nature.
The Science behind a Biosimilar

In order to bring a biosimilar to market, manufacturers will need to follow specific guidelines set by the FDA before submitting an application. It must include clinical data showing that the product is of the same efficacy (effectiveness), along with the same safety and purity, as the original biologic, making it “highly similar” to the original, with “no clinically meaningful difference.” This is why the term “biosimilar” is used.

The manufacturer must demonstrate through analysis of the drug and clinical studies that the biosimilar uses the same mechanism of action for the same condition as the original biologic drug. In other words, the biosimilar drug must work the same way within the body, to fight the same disease, as the originally approved medication.

“Currently, at a minimum, as a scientific matter, we expect that there will be a comparative clinical study that is done at least to evaluate pharmacokinetics and possibly pharmacodynamics, if there is a relevant marker,” Leah Christl, MD, the FDA expert on biosimilars, said in an interview with MSAA.

For anyone not familiar with these terms, pharmacokinetics is “the process by which a drug is absorbed, distributed, metabolized, and eliminated by the body,” and pharmacodynamics is “the study of the action or effects of drugs on living organisms.”

Roughly translated, although the biosimilar drug and the original biologic drug cannot be identical in make-up, due to their creation in a living cell, they must have the same effect in the end. Readers should note that inactive ingredients can differ between the original biologic drug and the biosimilar as well.

The manufacturer is also responsible for showing how its drug delivery is comparable to the original. Drug delivery refers to how the drug is administered, i.e., if it is given orally, via injection, via intravenous (IV) infusion, or via other methods. Manufacturers may be allowed to make some changes in the delivery device, but they must not interfere with its efficacy.

“Ultimately, a biosimilar sponsor would not only need to provide support for biosimilarity, but they would also have to provide data to support presentation in terms of functionality and patient usability,” Dr. Christl said. This means that the drug must be equal in terms of effectiveness and safety, as well as offer a similar degree of ease of administration. The sponsor needs to ensure that their delivery device is compatible with the proposed product. This ensures that a patient may be able to take the medication with a similar amount of comfort and convenience as the original biologic drug, and be equally inclined to adhere to the treatment schedule.

Bringing Biosimilars to Market

The idea of approving biosimilars is relatively new, especially to the American market. In 2005, the European Union implemented its pathway (approval process) for biosimilars and has since approved more than 10 of these drugs. The United States did not pass its act until 2010 and has yet to approve a biosimilar for public use.
Dr. Christl said the FDA has observed the process in Europe and there is a cooperative working group in which the FDA works with the European Medical Agency (EMA) and Health Canada.

“The purpose of that group is to promote global development of biosimilars and identify emerging issues,” Dr. Christl said. She explained that this group has regular and as-needed meetings to best address concerns among their experts and prepare educational communications to prescribing physicians and patients.

This new field of drug development is not only extremely complex, but is also quickly growing. Dr. Christl explained that the FDA has already seen the demand for biosimilar regulation steadily increase. The FDA expects further increases as the exclusivity period expires for more and more biologics, for which competing companies will want to develop biosimilars, each requiring stringent regulation.

To date, four draft guidances, one procedural and three scientific, have gone through the public-comment process and are in the process of being finalized. Guidances are documents that are provided by the FDA to answer common questions regarding the approval process for a new drug, medical device, or procedure. When in draft form, the document is distributed for comment before it is finalized.

According to the FDA’s website, “FDA guidances contain science-based recommendations that help eliminate uncertainty about what FDA will accept as valid evidence of product safety, product efficacy, and manufacturing quality.” For more information on FDA guidances or any topic mentioned in this article, readers may visit www.fda.gov and enter the topic in the site-search area.

FDA officials said that another five guidances are targeted to be drafted in 2014, including one on considerations in demonstrating interchangeability. Interchangeability creates a unique situation in which the FDA deems a biosimilar to be eligible to be substituted for an existing biologic, with the intention that it “can be expected to produce the same clinical result as the reference product in any given patient,” according to the FDA’s website.

Patient Awareness

One of the items the FDA has gleaned from Europe’s experience is the need for prospective patient and prescriber education, according to Dr. Christl. She explained that individuals should actively engage with their doctors and discuss all options available to them, but they can also access webinars produced by the FDA for consumers to better understand biologics and biosimilars as a whole. To access these webinars, readers may go to www.fda.gov/aboutfda/transparency/basics/ucm355978.htm for part 1 and www.fda.gov/aboutfda/transparency/basics/ucm364686.htm for part 2. After learning about biosimilars, members of the MS community can integrate themselves into the overall process via patient networks, clinical trials, and the public-comment time period. The public-comment time period enables people to take part in the ongoing process of creating pathways for drug approval.
“We rely on the FDA, their judgment, and their analysis of the situation to assure us that the drugs are as effective and safe as the original drugs. We also rely on the FDA to ensure that the biosimilars are as pure as the original drugs,” Jack S. Burks, MD, chief medical officer for MSAA, said.

But were he to discuss biosimilars with his patients, Dr. Burks said he would want to know and want his patients to know that the studies met the endpoints for safety, purity, and efficacy. A major concern for Dr. Burks and other physicians is the reality of a biosimilar being approved as interchangeable with the original biologic. He asks if a drug derived from different living cells can truly be interchangeable.

“The material they’re made from cannot be the same,” Dr. Burks explained. So knowing it will work in exactly the same manner is a difficult concept to pinpoint.

Still, the FDA has those definitions and requirements in place because, Dr. Christl said, “The FDA fully expects interchangeables to be licensed in the future.”

She explained that the FDA has laid a foundation in comparative analytics and comprehensive comparison. These comparisons will identify where differences, if any, may be found in the structure and function of the biosimilar drug. They will then go through a risk-based assessment to look at any impact that these differences might have on safety and efficacy.

As these competitive biosimilar drugs make their way through the approval process, members of the MS community should be aware of when an interchangeable biosimilar is approved and becomes available in the marketplace. As Dr. Burks suggested, patients need to weigh personal risks and comfort level before accepting a substitution for a medication that for many years, has been providing successful treatment for them.

Future Considerations

Eventually, the other factor that physicians and individuals with MS will need to weigh will be cost. The FDA does not consider cost in their evaluation or approval of biosimilars, Dr. Christl said, but with the act named Biologics Price Competition and Innovation Act, price seems an inherent part of the plan.

In the act, it states that the goal is “balancing innovation and consumer
interests” by pursuing this pathway of approvals and introducing competition to the biologics market. With the costs of branded medications continually increasing, the hope is that biosimilars will be less expensive to develop and less costly to produce, eventually passing those savings on to consumers.

Cost savings may not be an easy goal to reach. In a 2011 study looking at the European biosimilar market, a researcher suggested that despite the agency’s attempt to create a more cost-effective treatment environment, a long-term impact on price remained to be seen.

“Given that there may be uncertainty surrounding the long-term safety and effectiveness of a biosimilar, the cost-effectiveness of a biosimilar needs to be calculated at multiple time points throughout the life cycle of the product,” the author concluded.²

And like that researcher, patients in the MS community will need to maintain vigilance over the biosimilars market as it applies to them individually and as a community. People will need to know the options as these biosimilars are approved and have their own cost-benefit conversations with their physician. If an interchangeable is approved, people must realize that it could potentially be substituted by a pharmacist without approval from their physician.

As with many processes leading to drug approval, the development of biosimilars will have its hurdles that will affect government decisions. The development of biosimilars will also impact patients, who will need to keep aware of these competitive biosimilar medications as they monitor their own treatment options. ◆


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**A Special Thank You to the Employees of Biogen Idec**

Through their voluntary efforts, the employees of Biogen Idec generously donated nearly $50,000 to help MSAA fulfill its mission of improving lives today! This money will help to fund vital programs and services for the MS community.

On behalf of our entire organization and the MS community that we serve, we want to express our deepest appreciation for this generous gift made collectively by these individuals. This donation will go a long way toward improving lives today.

**THANK YOU!**
THE BIOSIMILARS GUIDE: A Quick Reference for Readers

BIOLOGIC: Biologics are drugs that are derived from a biological source (blood products, proteins, antibodies, etc.) and mimic pathways within our own bodies. These are different from many of the common drugs people use each day that are created in a lab from chemicals. In the MS community, biologics include: Avonex, Betaseron, Extavia, Rebif, Novantrone, and Tysabri.

BIOSIMILAR: Once a biologic drug’s exclusivity period has expired, other drug companies may compete with the original drug by developing a “biosimilar” drug. This term refers to a biological product that is highly similar to the original (reference) biological product, despite minor differences in clinically inactive components, AND, no clinically meaningful differences can exist between the biological product that is highly similar and the original (reference) product in terms of safety, purity, and potency of the product. The standards of both “highly similar” and “no clinically meaningful differences” must both be met for a drug to be a biosimilar of another drug.

Since the active ingredient for biologic drugs is derived from living cells, biosimilar versions of these drugs will not contain the identical molecules. For this reason, biosimilar drugs must meet the two standards mentioned above before they may be considered for approval. Generic versions of the traditional, nonbiologics drugs can be identical in terms of chemical combinations, because they are not derived from living cells, which contain their own unique molecules.

EXCLUSIVITY PERIOD: When a biologic is approved by the FDA, it holds market exclusivity for 12 years (plus an extra six months for any pediatric medications), meaning that competitors cannot enter the market during that time period. In theory, this allows the original developers to recoup their investment and gives incentive for research and development of new biologics. After 12 years, the exclusivity period expires and biosimilars to the original drug can be approved.

GUIDANCE: Just as it sounds, these documents put forth by the FDA will guide manufacturers in their submission of biosimilars for approval. They explain the procedure and the data required and, before finalization, go through a period of public comment in which manufacturers, physicians, patients, and other key stakeholders can give input and request clarification.

INTERCHANGEABLE: This designation, if given to a biosimilar, would be similar to a generic drug in that this biosimilar could be substituted exactly for its biologic (original) reference drug. This would also mean it could be substituted without direction from the healthcare provider who prescribed the original medication.
Q: I started having MS-like symptoms in 1997 at the age of 36; I'm now 52. I had an MRI of my brain in 2009 (funded by MSAA). Unfortunately, my local doctor did not include the dye for the enhanced MRI. The MRI did show some lesions according to the radiologist's report, but the neurologist didn't think the MRI of my brain indicated MS. I also had a lumbar puncture, which according to the neurologist, did not have any evidence of the markers for MS in the spinal fluid.

My medical history includes: two mini-strokes (one showing on the MRI; another a few months after the lumbar puncture); toxoplasmosis (an infection caused by a parasite) discovered at age 20 when I went blind in one eye (which was later corrected by surgery); and I take medications for Type 2 diabetes (diagnosed in 2009), high blood pressure, and high cholesterol. My MS symptoms include weakness in my arms, heat sensitivity, fatigue, bowel problems, frequent urine leaking, and sporadic pain in my wrists and ankles (causing me to limp).

Questions: Is it possible that I have MS, but it is not showing up in the spinal fluid after 12 years, and since the MRI was not enhanced with the dye, more (older) lesions are not showing up? Is it possible that my congenital toxoplasmosis (likely culprit - my mother came in contact with cat feces in the garden when pregnant with me) could have caused lesions in my brain and/or spine causing neurological symptoms similar to MS? Note: A study at the Toxoplasmosis Center in Chicago indicated that toxoplasmosis can cause lesions in the spine. Is it possible that I have another disease that is mimicking MS and what are the other possibilities?

A: Sixteen years of confusion about your diagnosis is a long time. I can understand your frustration. Congenital toxoplasmosis (a parasite disease) complicates your medical history. There are many conditions that may “mimic” MS and neurologists are trained to look for these in “possible MS” patients.

I do not want to speculate about your potential for having MS. However, I would recommend getting another opinion from an MS expert who can go over your medical history in detail, perform a neurological examination, look at past and current MRI results, and possibly order another MRI with a more powerful magnet (3-T). Additional testing could possibly include repeating your lumbar puncture, getting “evoked-potential tests,” or getting an OCT (optical coherence tomography) test on your eyes. Other tests for “MS mimickers” may also be needed to rule out other possibilities.

Have you ever been treated with an MS drug? If so, did it help? In summary, I...
recommend another opinion from an MS specialist. You may have a condition that mimics MS in some ways. I wish you luck in your search for your diagnosis and possible treatment.

**Q:** My question is about foot swelling. My right side is affected by MS and I experience ankle drop. I had to get a new ankle-foot orthosis (AFO), due to swelling of my foot. The swelling became so severe that the AFO was cutting into my foot. My doctor had a venous Doppler ultrasound done, but the results turned up no problems and I have excellent circulation. What causes this type of swelling and is there a name to this condition?

**A:** It is not uncommon for MS patients to have swollen feet and hands, or to have red, blue, or white feet and hands. Some of these symptoms are painful and others are just annoying.

One explanation is that in addition to the central nervous system (CNS), MS may also damage the autonomic nervous system (ANS). The ANS helps control blood flow to and from the extremities. The ANS also controls the heart rate, blood pressure, and other functions. The underlying cause of feet swelling may be from ANS damage in the brain or spinal cord. However, I am pleased that your evaluation showed “excellent circulation.”

One last thought, have your tried the electrical-stimulation technologies to help reduce foot drop? These may be of help, and if interested, please ask your doctor and physical therapist (PT) if something like this may be appropriate for you.

**Q:** Is it possible for a medical event to trigger MS, which may otherwise be suppressed? Twenty years ago, I was overcome by carbon monoxide and lost consciousness. About a year later, I exhibited symptoms, and after a lumbar puncture, it was confirmed that I had MS. Although my condition continues to degrade, I have maintained a very healthy and positive attitude.

**A:** Since we do not fully understand the underlying cause of MS, attributing it to any one factor is difficult. Obviously, carbon monoxide can be deadly or very toxic to the brain. However, patients who recover usually remain stable. You had a year lapse before developing MS, which makes it more unlikely that it triggered your MS. And please keep up your healthy and positive attitude. Remember that happiness is a state of mind more than a state of health.

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Dr. Jack Burks is an international MS neurologist, writer, lecturer, and researcher. Dr. Burks is a clinical professor of neurology at the Florida International University in Miami and has authored textbooks, chapters, and articles on MS.

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Please submit questions via mail to:
MSAA, Questions for Ask the Doctor
706 Haddonfield Rd, Cherry Hill, NJ 08002
or via email to: askdr@mymsaa.org
Aquatic Exercise and MS Showcased in New Online Resource Center

MSAA is proud to announce the launch of its new Swim for MS online Aquatic Center as part of our national campaign promoting water-based exercise for people with multiple sclerosis, developed through a collaborative partnership with Genzyme, a Sanofi company. Accessed at SwimForMS.org, the comprehensive web center showcases MSAA’s national program initiative supporting the awareness, understanding, and availability of swimming and aquatic exercise as a positive wellness opportunity for the MS community.

Swimming and other forms of water-based exercise have well-established health benefits for many fitness levels. The unique properties of water along with its cool temperature can create an inviting exercise environment for individuals with MS, especially for people who may have difficulty managing traditional land-based activities. In fact, recent research on individuals with MS suggest that aquatic exercise is effective for improving flexibility and range of motion, cardiovascular endurance, fatigue level, muscle strength, mobility function (including gait and balance), quality of life, and psychological well-being. In addition, none of the studies identified an increase in relapse or reported any other adverse change in neurologic status.

The Swim for MS online Aquatic Center features four main sections:

- **About Aquatic Exercise and MS** – Extensive information about the benefits of aquatic exercise and how water-based activities can be adapted to fit all levels of ability and types of MS

- **Aquatic Resources** – Helpful tips and suggestions on how to begin an aquatic exercise program and where to find a pool in your area

- **Multimedia Center** – Inspirational videos of people living with MS who incorporate swimming and aquatic classes into their healthy lifestyle plan

- **For Healthcare Professionals** – Research findings and supportive information on aquatic exercise and MS for neurologists, physical therapists, rehab specialists, and aquatic fitness instructors
Included among the new print, video, and web-based content featured on MSAA’s online Aquatic Center are the recently published booklet, *Aquatic Exercise & Multiple Sclerosis: A Guide for Patients*, and the latest MSAA archived webinar, *Discovering Aquatic Exercise and MS*. Developed with the help from experts in the field of aquatic exercise, rehabilitation therapy, and MS, resources on the Aquatic Center are designed to help the MS community better understand swimming and community-based water exercises.

“At MSAA, our mission is improving lives today,” said MSAA President and CEO Doug Franklin. “Through our partnership with Genzyme, we are very excited to bring these important resources to the MS community and provide them with an opportunity to enhance their physical and emotional quality of life through aquatic exercise.”

The topic of aquatic exercise is as broad and varied as the individuals with MS who might want to participate. Whether participant interest lies in performing high-level aerobic workouts, moderate cardio and strength training, or gentle slow-moving forms, aquatic exercise can be adapted for all levels of physical abilities. Individuals are urged to consult their physician and physical therapist prior to the start or change of any exercise program or routine. MSAA also encourages participants to contact the aquatic fitness instructor prior to joining a class and discuss their overall health needs as well as any factors related to multiple sclerosis.

Having an open dialogue between the participant and the professional can help ensure a safe and enjoyable experience for everyone.

Based on your discussions with your healthcare team, you should be able to develop an individualized aquatic exercise plan with specific goals to meet your needs. To locate an appropriate pool facility in your community, ideal resources to search include the national network of YMCAs, recreational centers, college/university campuses, and national and local gyms and fitness centers. When selecting a pool facility, you should consider safety (hand rails, non-slip surfaces, etc.), accessibility, location, activity/class, schedule, pool temperature, and appropriate instructor. It is also important to note that at this time there is no definitive research supporting water-temperature guidelines for an MS exercise program. The general recommendation is for water temperature to be between 80 and 86 degrees Fahrenheit.

MSAA invites you to learn more about aquatic exercise and MS by visiting our exciting new online center at SwimForMS.org. You may also contact our Client Services Department by phone at (800) 532-7667, extension 154 or by email at MSQuestions@mymsaa.org.

Please read our “Stories to Inspire” column on page 46 to learn more about the campaign from MSAA and Genzyme featuring people with MS who have all discovered numerous benefits from swimming and aquatic exercise.
As the debate continues around ratings, ratios, and watchdogs, nonprofits around the country are focused on how to emphatically and accurately communicate their value. If the purpose of charities is to right social wrongs, alleviate distress, or improve lives, how do we know when we are doing our job? What do overhead and stars have to do with the effect an organization is having on the fulfillment of its mission? If ratings do not suitably portray the efficiency of an organization's operations – then how do we know our dollars are being well spent? What is our impact?

Impact, in the nonprofit world, refers to the change in behavior (outcome) that is a result (output) of the activities and resources provided (inputs). For example, an organization provides a class and information on the health risks associated with smoking cigarettes (input), and finds that 42 percent of attendees stop smoking (outcome), resulting in higher scores on overall health measures at their next checkup (output). If their mission was to improve health scores by decreasing the number of smokers, then this organization can clearly state this as their impact.

MSAA’s mission is to be a leading resource for the MS community and improve lives today. A quick look at the Merriam-Webster online dictionary tells us that “improve” means “to make (something) better; to enhance in value or quality; to advance or make progress in what is desirable.” But how do we measure this improvement? And how much improvement is enough? In the previous example, if the smoking-cessation classes improved health scores by 50 percent, this sounds great, but what if they only improved by 5 percent...is that enough? If 5 percent kept that person from having a heart attack, would it then be enough?

The improvement of a life is not easily shown on a graph or a financial statement. Sometimes we need to hear the stories that accompany the percentages and the ratios, the revenues, and the expenses. The stories that remind us why we do what we do.

“From the bottom of my heart, I thank you – all of you, for helping me to live independently [through MSAA’s free equipment distribution program]. I put my shoes on by myself!! It has been years since I have done that! Thank you for the leg lifter. It lifted my spirits too!”

— F.H. from South Carolina

This is not to say that numbers do not matter. Knowing that more than 400,000 people have been diagnosed with MS in the United States, we at MSAA are determined to increase the numbers of people who benefit
from our vital programs and services. Last year, 1,040,554 people accessed our website for information – 814,776 of them for the first time. That’s a significant number of people, who, like F.H. from South Carolina, can have their spirits lifted and their lives improved.

In an effort to evolve and grow, MSAA is working to evaluate our effectiveness in fulfilling our mission. We ask everyone who engages with us to help us by completing our surveys and program evaluations, which we continually review to ensure we are asking the right questions. Currently, more than 50 percent of those who receive adaptive equipment from MSAA respond that the item “greatly impacted their independence and quality of life;” 76 percent said the item “allowed them to do things they previously could not do;” 90 percent would not have been able to acquire this item without MSAA’s assistance. The collection of this information helps us show improvement in that person’s life, and this helps us to show our impact.

MSAA has been able to improve the lives of people like M.A. from New Hampshire because of an increase in the number of generous donors who support us in this mission. We are incredibly thankful for this growing number of people who, through their vital contributions, experience the joy of creating an impact – and improving lives today!

“I would like to thank everyone at MSAA for providing assistance to me [through MSAA’s MRI Institute]. I can’t explain how grateful I am for this opportunity. I remember some time ago when my neurologist scheduled an MRI, the price of the MRI was equivalent to the cost of a car, so I had to skip the MRI. Additionally, with that expense and the expense of MS medications, it made me feel that I wouldn’t have a fair chance at combating MS. Words can’t express my gratitude. Thank you!

— M.A. from New Hampshire
During December 2013, MSAA held a nationwide call for entries for the Swim for MS – Why I Swim campaign through a collaborative sponsorship with Genzyme. Individuals with MS who swim or participate in water-based exercise as part of their wellness plan were asked to share their personal story about how these water activities made a positive impact on their lives.

We received amazing stories from all over the country from people who had just started to get into the pool, and from people who had been swimming for years. Today, MSAA is excited to share three of these inspirational stories featuring individuals in various stages of the MS journey, all of whom have discovered the numerous benefits from being in the water.

Mary from Harleysville, Pennsylvania was diagnosed with relapsing-remitting MS 20 years ago. Frightened and mad, Mary wasn’t sure she was ready for the challenges she would have to face. When it became necessary for her to stop working due to her MS symptoms, Mary decided this was the opportunity for her to focus on herself and her well-being. She slept more, rested when she needed to, ate better, and continued to see her doctors regularly. She also began to exercise. At her local YMCA, she first began with a water-walking program, and as she became more confident and stronger in the water, she graduated to a water-aerobics class.

Mary is actively involved in the MS and swimming communities. She even championed to have her pool hold an MS-specific water class and install a chairlift for individuals with MS who may be just starting out in the water.

Mary is thrilled to feel and see the physical benefits she derives from her water-aerobics classes. She never felt like a muscular person before, but being in the pool several times a week has increased her strength. She marvels at what her body can
do in the water. Mary performs things that she wouldn’t even dream of trying on land, like standing on one foot or even dancing!

Beyond the physical benefits, Mary treasures the friendships that she has gained through her time at the pool. “Sometimes I forget that I’m doing something that’s good for me. I’m just having fun with friends.”

Mandy Iris from Flagstaff, Arizona was diagnosed with MS two years ago, at just 24 years of age. As a registered nurse, she understood her early symptoms could be the sign of a serious neurological condition. At such a young age, she was crushed by the news, but was determined to “keep looking forward.”

Within months of her diagnosis, Mandy Iris had to deal with another crushing blow – the devastating and sudden loss of her mother to cancer. Grieving the loss of her mother and the loss of the life she had dreamt for herself prior to her diagnosis, she found herself looking for an appropriate outlet for her emotions. So she started swimming.

When she first began swimming, she found getting in the pool and just swimming laps to be difficult and boring, but she stuck with it and now knows that she can’t live without it. For Mandy Iris, the pool is a place for meditation and self-reflection; a place where she can feel free to be herself and work out anything that is bothering her.

“I can swim as angry as I want. I can be as sad as I want. It all just seems to melt away every time I jump in the pool.”

Mandy Iris currently swims one mile every other day as part of her wellness plan. Swimming has helped increase her strength so she can enjoy other activities, such as biking and running. She has also felt an improvement in other symptoms, including depression.

Mandy Iris is also an active supporter and fundraiser for the MS community. She has participated in MSAA’s Swim for MS fundraiser and other activities.

Ginny of Asheville, North Carolina has secondary-progressive MS. When she was first diagnosed 26 years ago, she was advised by her doctors to not push herself and go easy with exercise. But not exerting herself wasn’t an option for Ginny. An avid long-distance runner, mountain climber, backpacker, and kayaker, Ginny knew there was no way she was going to let her disease dictate how she was going to live her life.

Today, Ginny is aided by the use of a walker, and she is fully committed to her wellness plan. This includes daily exercise, a nutritious diet, and a positive attitude. When
she first got into her exercise program, she was hoping only to be able to increase her strength for better mobility and stamina, but she found it far surpassed that. She is now fully energized to be able to work at the job of her dreams and has more energy and stamina than most of her able-bodied friends.

“When I walk from the locker room to the pool deck, I actually say these words to myself – that swimming has brought me… joy, clarity, oxygen, endorphins, freedom.”

Ginny’s current exercise routine includes swimming laps for an hour, lifting weights and stretching. But she didn’t start at this level. When she first began swimming, she could only swim five minutes and was unable to really kick her legs properly, but she was determined to keep trying. Over time, Ginny developed her own strokes and style of kicking that work for her – while also working to increase her strength. Ginny is now a nationally certified personal-fitness trainer and is proud to share her skills and inspiration with others.

The Swim for MS – Why I Swim campaign is part of a larger effort from MSAA and Genzyme, a Sanofi company to raise awareness and understanding of aquatic exercise as a positive wellness opportunity for the MS community.

“At Genzyme, we are driven by our unwavering commitment to the patient communities that we serve,” said Carole Huntsman, VP and MS Business Unit Head, North America, Genzyme. “We hope that by sharing these success stories and the important information on the Swim for MS online Aquatic Center that we’re proud to sponsor, we will inspire more people to be active and get in the pool.”

In addition to these inspirational stories, MSAA has developed a variety of resources on aquatic exercise and MS available on our new Swim for MS online Aquatic Center, accessed at SwimForMS.org. For more information on the Swim for MS online Aquatic Center, please read the Program Notes column of this publication on page 42. 

To learn more about programs and services from Genzyme, sign up at www.MSOnetoOne.com.
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The following thoughtful corporations, foundations and individuals have contributed generously to MSAA to improve lives today for the entire MS community. Those providing gifts of $10,000 or more are shown in this listing.
Spring is finally here and summer is fast approaching!

A perfect time to remind everyone about MSAA’S COOLING PROGRAM.

Offered year-round, the MSAA Cooling Program provides a variety of lightweight ice-pack vests and accessories to help you stay cool this summer while at work, play or participating in your favorite exercise. As the heat starts to build, so do requests for this free MSAA service, so please place your order now before the summer rush. To receive an application, please visit mymsaa.org or call (800) 532-7667, ext. 130.

MSAA’s Cooling Program includes:

- Standard vests
- The Fit Kit
- Children’s cooling vests