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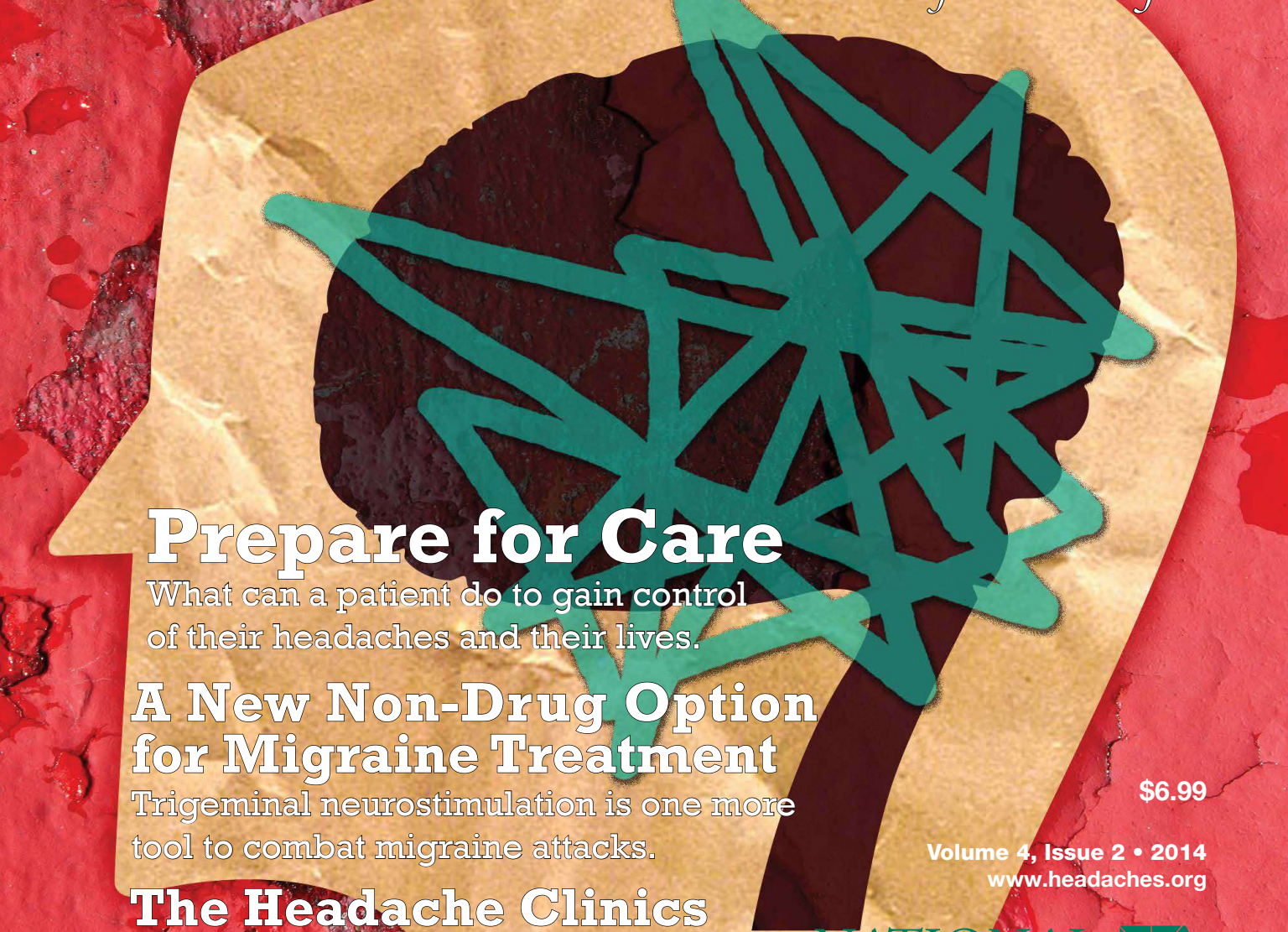
A Voice for People with Migraine and Headache Disorders
From the National Headache Foundation

Difficult to Treat
Refractory Headaches
What can be done to find relief?



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NATIONAL HEADACHE FOUNDATION®

If you think a headache is just a headache, think again. Millions of Americans suffer from migraines, cluster headaches and other serious headache disorders. Chances are, headache disorders affect you or someone you love.

Join the cause by becoming a member of the National Headache Foundation, the world's largest voluntary organization for the support of people with migraine and headache disorders. For more than 40 years, the NHF has assisted millions of individuals seeking education and treatment for their various conditions.

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FROM THE EXECUTIVE CHAIRMAN:

For the next few issues, I thought that I would provide a brief history of the National Headache Foundation, including its origins, composition, activities, and accomplishments. For this issue, I would like to address the beginnings of the NHF.

In 1964, I became an active member and eventually an officer of the professional organization, the American Association for the Study of Headache (AASH). This association, comprised of physicians and other healthcare professionals, is now known as the American Headache Society. As I continued with my practice in headache medicine, I recognized the need for an organization for lay people who were experiencing headache. This type of organization did exist in England – the British Migraine Trust which was founded in 1965.

During a visit to England, my wife, Elaine, and I were able to visit the headquarters of the Trust and observe their operations. We also met with members of the British Migraine Association (now Migraine Action) which was founded by Peter Wilson in 1958. With the help of the AASH, we started the National Migraine Foundation in 1970. I served as its first President, and Elaine was the only employee. The original headquarters were located in a small office in a professional office building which I owned, and was able to donate the space.

The NMF newsletter was started in 1972 through the leadership of my good friend and colleague, Donald J. Dalessio, MD. In 1973, his late wife, Jane, became the editor of the newsletter – a post she served until 1977.

The first National Migraine Foundation lectureship was awarded in 1979 to G.W. Bruyn, MD, from Amsterdam, The Netherlands. And in 1986, the name of the organization was changed to National Headache Foundation. There have been many changes over the years but the focus has remained – to raise awareness about headache and migraine, support research, and promote headache education for patients, their families, health care providers, and to the public.

To be continued…

Seymour Diamond

Seymour Diamond, M.D.
Chicago, Illinois

HeadWise™

The National Headache Foundation • www.headaches.org

NATIONAL HEADACHE FOUNDATION®

Mission
To cure headache, and end its pain and suffering.

Vision
A world without headache.

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This publication discusses a broad range of headache information in an effort to inform and educate readers, but is not intended to substitute for the advice of your health care provider. Statements expressed herein are not necessarily those of NHF.

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FEATURED ARTICLES

IN EVERY ISSUE

Ronald Barnard, Esq.

On April 5, 2014, a great friend and benefactor of the National Headache Foundation passed. Ronald L. Barnard, Esq. was the Executive Director of the Walter S. And Lucienne Driskill Foundation, and an attorney in private practice in Chicago. He was born in Denver on May 30, 1935, and moved to Chicago when he was 8 years old. Ron received his undergraduate education at University of Illinois at Chicago, and attended law school at Northwestern. He was an Army Reservist, and served with the 91st Air Terminal Squadron, a part of the U.S. Air Force. After his active duty service, he returned to Illinois and joined the law firm of Wexman, Mandel, and Kipnis.

It was through his firm that he became acquainted with Mr. Walter Driskill who was the owner of Dribeck Importers which was the importer of Beck's Beer from Germany. In 1968, Ron started his own law firm. The Driskills started their foundation in 1986. Following the deaths of Mr. Driskill in 1998, and Mrs. Driskill in 2009, the Driskill Foundation became more formalized with their own Board of Directors, and Ron assumed the role of Executive Director.

In addition to its generosity to the NHF, the Driskill Foundation has supported many organizations, including the Alzheimer's Association, Memorial Sloan-Kettering, Misericordia, Northwestern's Feinberg School of Medicine, and the University of Colorado and the University of Pittsburgh.

Ron was married to June for almost 20 years. He is also survived by his children–Ellen Barnard, Kenneth Barnard, and Katie Trowbridge, grandchildren–Katelyn Moon, Kyle Barnard, and Nathan Biggs, his sister–Judith Barnard, and brother–David Barnard. June and Katie served as co-chairs of our 2012 and 2013 galas.

At the 2012 gala at the Planetarium in Chicago, Ron received the Seymour Diamond, M.D. Founders Award in recognition of his outstanding support of the National Headache Foundation.

His generosity and support of the Foundation and for all who endure headache will be greatly missed. Personally, I will miss my good friend. HW

10 Rockefeller Center

During July, 2014, the NHF received a most generous donation from EHE International which is the recognized leader for the early detection of preventable diseases and its associated risk factors. EHE International provided their window space at 10 Rockefeller Center, New York, to the NHF for the month of July, thus offering the opportunity for the NHF to raise awareness of the disabling condition of chronic headache, including migraine. "EHE International is proud to support the National Headache Foundation to raise awareness," said Deborah McKeever, President of EHE International. "This donation can help this organization advocate an important cause and can alleviate a worldwide issue."

The window display alerted passers by, that through education, research, and advocacy, the NHF is striving to create "A World Without Headache." Because the window at 10 Rockefeller Center is located next to the TODAY show, it is estimated that it garners 100,000 monthly onlookers.

We would like to thank EHE International for this great opportunity to raise awareness about headache.

In conjunction with the window presentation, the NHF held a reception on July 9, 2014, at the Cornell Club in New York City. The event was hosted by Board members, Joshua Friedman, Esq. and Mark Green, MD, as well as Honorary Board members, Emily and Paul Kandel. Guests were treated to presentations by the hosts, and watching the video, *A World Without Headache*, which is available for viewing on our website – **www.headaches.org**.

NHF members as well as health care professionals in the tri-state area were invited. We wish to thank all who attended this event, and appreciate those who contributed to the NHF. HW

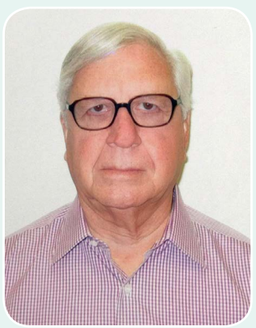
ROCKEFELLER RECEPTION

Josh Friedman, Esq.

Mark Green, MD

10 Rockefeller Reception

TOP RIGHT: Mark Green, MD; Sarah Rahal, MD; Emily Kandel; Josh Friedman, Esq **RIGHT:** Drs. Susan Broner, Dawn Buse, Seymour Solomon **LEFT:** NHF Staff member, Aukosua Stokes



New Board Member Elected

On March 24, 2014, the National Headache Foundation elected Stephen Stern, Esq. to the Board of Directors. Mr. Stern is Of Counsel in the Los Angeles office of O'Melveny and Myers, LLP. He has been engaged in the practice of project and infrastructure financing for the past 40 years, representing airports, air carriers, ports, railroads, transportation companies, developers, operators, investment banks, and other financial institutions. From 1973 through 2006, Mr. Stern was a partner in the Firm, and is a member of the International Practice and the Project Development and Real Estate Practice. He also served as managing partner of the Firm's London office from 2001 through 2004.

He completed his undergraduate work at the University of California at Berkeley, and received his J.D. from the University of San Francisco. He has been admitted to the bar in California and New York, and is a member of the National Association of Bond Lawyers. Mr. Stern has lectured on airport and healthcare financing.

He and his wife, Sheila, reside in Los Angeles.

Tired of searching the internet for answers?

It's time to learn from those in the know. In every issue of *HeadWise™*, our experts respond to reader-submitted questions about migraine and headache disorders.

GOODBYE GLUTEN

As a 31-year-old, I have experienced migraines with auras for 20 years. I have been prescribed medication, injections, vitamins, tests, x-rays, yoga, chiropractors, restrictive diets, Botox, hormonal treatments...the list goes on. With each new recommendation by doctors, neurologists, family and friends, I faced more frustration and failed attempts.

Getting not one, but TWO migraine headaches on my wedding day this summer was my breaking point. On the biggest day of my life (which took 10 months to plan), I hold weighted memories of being curled up in bed in a dark hotel room, only later followed by sitting on the floor of my wedding venue, tears freely falling onto my wedding gown. As my wedding-wrecking, jack-hammering, life-stopping headache continued on to the next morning, all I could think about (other than pain and embarrassment) was that I would make a vow to help others who suffered too.

A few days after the wedding and honeymoon, I was back in my neurologist's office. Out of complete desperation, I barked, "Why is there no cure for migraine headaches?!" While my neurologist could completely understand my frustration, he mentioned how difficult it is to find a cure for migraines because each patient has different triggers, leading to different treatments. Then, my neurologist offered a positive results-driven idea given to him from another patient, similar to myself. He told me that the patient had started a gluten-free diet, and that it may be worth trying.

At this point, I was encouraged. This recommendation didn't include drugs. It didn't include tests. It simply required a change to my eating habits. I started researching as much as I could on gluten-free living and what it entailed. After trying a 75% gluten-free diet, I noticed a tremendous decline in the amount of headaches I was getting. This was the first time I had ever gone 3 months without a migraine. I did fall off the wagon over the holidays and ate several foods containing gluten over the course of a day, which sparked another migraine. Getting this last migraine was a sign that reinforced the fact that gluten, indeed, was my ultimate trigger. Since learning my lesson, I am back on track with a gluten-free diet and am currently migraine-free.

My triggers and treatment may not be yours; however, I am hopeful that education about a gluten-free diet will resonate and treat some of us. There are 36 million Americans who suffer from migraine headaches each year. Help spread the knowledge on treatment, so we can become one less. *Candice H.*

Gluten sensitivity can manifest itself in many forms. Some individuals show signs and symptoms during early childhood. The child usually loses weight, experiences abdominal distress, and may develop a full blown malabsorption (inability to absorb vital nutrients, such as vitamins, calcium, etc) condition in the intestines. That disease is referred to as celiac disease, later in life called sprue.

Other individuals have a sensitivity to gluten and may exhibit some symptoms and signs, but not all. The more serious forms of the sensitivity may have multiple systemic problems including intestinal, neurologic, endocrine, and skin. Migraine may be one of the manifestations. The sensitivity is usually to certain grains, specifically: wheat; barley; rye; or, ethnic variants, such as bulghur and farro, etc. Oats were once thought to be another of the offending grains, but more recently it appears that the sensitivity occurs when oats are contaminated with wheat with the latter being the offender.

Migraine sufferers not responding to usual preventive treatment may try a gluten-free diet. This is not a simple avoidance diet as many processed foods use one of the three offending grains. The consumer must carefully read labels, check with the chef or food preparer in restaurants, etc. Grains such as corn, rice, quinoa, and potato are permissible. At times, very small amounts of the offending grains are sufficient to produce a flood of symptoms in a susceptible individual.

Many gluten-free dietary publications are available and include the preparation of food, what to substitute, and what to avoid in the diet. Currently, many food processing companies have manufactured cereals, pasta, cookies, and even beer which are essentially gluten-free. Recent nutritional science has made eating much more pleasant and satisfying for the gluten-sensitive individual. Purchasing gluten-free foods, which are processed, are usually more expensive.

The individual writing to the National Headache Foundation and reporting improvement with the diet is fortunate to have found relief. However, not all patients refractory to therapy will respond to diet, since chronic migraine may have numerous causes. It is the protein compound called gliadin, which resides in the specific grains mentioned, that is the toxic agent. Celiac disease and sprue are believed to be genetically inherited disorders. Blood tests as well as small intestinal biopsy may be necessary, at times, to establish the exact diagnosis. Readers are recommended to consult with their physicians for further information and the appropriate diet. Gluten-free foods may not contain certain nutrients and vitamins that are necessary to maintain health and therefore, professional nutritional advice is often required.

In summary, migraine sufferers not responsive to treatment may find a gluten-free diet of benefit. The diet is not simple to follow, at times remission may occur unrelated to strict adherence, followed by recurrence. Medical supervision is certainly indicated for the above reasons.

Arthur H. Elkind, MD
President, National Headache Foundation
New Rochelle, NY

SLEEP AND HEADACHE

My son (15) suffers from migraines that usually last for several days. Regular sleep is obviously important (and is a key trigger for him). It is often recommended that when migraines hit, migraneurs retreat to a quiet dark room. I have read that even brief sleep can help end a migraine in children (although it rarely does for my son). That makes sense if it is a short migraine, but the two bits of advice are conflictual for people who suffer LONG migraines. I have never seen this issue discussed and, as a parent, I don't know what to do.

1. You want a regular sleep schedule. Both oversleeping and naps can trigger migraines.
2. When you HAVE a migraine all you want to do is sleep.

If you have a migraine that lasts several days, is it better to try to maintain your sleep schedule - dragging out of bed and trying not to sleep–or is better to just sleep it off? Does it matter if you have suffering from photophobia at the time or just headache pain? What I have been doing is keeping my son's regular waking and bedtime schedule, but letting him nap as much as he wants. However, I am not sure that is the best course of action. I'm sure I'm not the only one with this question. *Darcy H.*

Some migraine sufferers are unable to sleep because of the pain, others are able to sleep off a migraine. If the sleep is not helping, then other strategies are needed, such as almotriptan, which is approved for children over age 12. Many headache specialists will offer sumatriptan to older teenagers with the understanding that the medication is being used off–label. This means that, except for almotriptan, triptans are only indicated for age 18 and above. If headaches are occurring more than a few times per month, it is reasonable to discuss preventative strategies with your son's physician. These strategies include lifestyle management and medications.

Edmund Messina, MD
Michigan Headache Clinic
East Lansing, Mich.

CLUSTER HEADACHE REOCCURANCE

I began having Cluster Headaches at age 30 and had them on a chronic basis for 30 years and then they vanished. However, recently (now 15 years since the last one) they have returned. Has anyone heard of this bizarre history? *Fredric B.*

It is not particularly unusual for cluster to "disappear" for a number of years and then recur. The main question is whether the new headaches are identical to the previously occurring cluster headaches. If not, these need to be evaluated to be sure they are not due to more ominous causes.

Edmund Messina, MD
Michigan Headache Clinic
East Lansing, Mich.

OPTIONS FOR CHRONIC DAILY HEADACHES

I have had a headache every day for over a year and a half now. The pain is only around a 5 but it's all-day every day. It is located in the center of my head. I have been to three neurologists, one headache specialist, and I am currently going to a pain clinic where I see multiple doctors at once. I have tried changing my diet, acupuncture, nerve blocks, eyes checked, slept with mouth guards, gave up alcohol and tobacco, taken pain killers, stopped pain killers to see if it was rebound headaches, and taken a whole slew of prescription drugs. Nothing seems to help. Do you have any suggestions? *Hayden B.*

If the daily headache began without a prior history of migraine or other headache disorders going back in your past to childhood and was daily in frequency from the onset, it can possibly be due to new daily persistent headache (NDPH). The daily headache pain in NDPH can be described at all points of the pain scale spectrum (from mild to moderate to severe) and can appear like migraine in some cases. The use of acute daily pain medications (opioids such as hydrocodone, oxycodone, morphine, meperidine, etc.) can lead to the development of medication overuse headache (rebounding) within several weeks of daily use. Rebounding can also occur with over-the-counter medications such as Excedrin (aspirin, acetaminophen and caffeine), combination analgesics, and prescription medications for acute migraine (triptans and ergotamine). The overuse of acute medications frequently occurs with NDPH and other daily headache disorders.

Lifestyle modification can sometimes be helpful including diet changes, decreased caffeine and alcohol intake, regular cardiovascular exercise, stress relaxation techniques such as yoga or biofeedback training, psychological counseling, and improved sleep hygiene. Daily migraine preventive medications such as tricylic antidepressants (amitryptyline, nortriptyline, etc), beta blockers (propranolol, metoprolol, etc) and anti-epileptic drugs (topiramate and divalproex sodium) are sometimes effective in the management of NDPH, but are more specific for migraine prevention. In cases in which the daily headache is not responding to conventional preventive medication therapies, it is possible to consult with a headache specialist or neurologist to consider intravenous (IV) non-narcotic medication therapies such as dihydroergotamine (DHE-45) for 3 or more days, which can be administered in either an inpatient or outpatient setting.

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DIFFICULT TO TREAT (REFRACTORY) HEADACHES:

OUTPATIENT TREATMENT OPTIONS

Lawrence Robbins, M.D.
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Northbrook, Illinois

Refractory (difficult to treat headaches), which occur frequently, usually are Chronic Migraine (CM). Chronic Migraine is defined as a headache occurring 15 (or more) days per month, of which at least eight of the headaches are migraine. For those with CM, preventive medications often help. However, approximately one-half of patients with chronic migraine continue to suffer frequent pain, with little relief from medications. This condition is termed Refractory Chronic Migraine (RCM).

RCM is described as frequent migraines that have failed adequate trials of various preventive and/or "as needed" medications. A person must have failed to obtain relief from at least two categories of preventive medications. In addition, the person with RCM usually has not found adequate help from the usual migraine "as needed" medications, such as sumatriptan or naproxen, etc. Those with RCM also find that their functioning and quality of life is impaired by the frequent headaches. RCM affects millions of individuals.

A small minority of those with refractory headaches do not suffer from migraine. Instead, they may experience refractory cluster headaches or another headache syndrome.

There are many questions about RCM, such as:

1. What role does disability play, and should disability help define RCM?
2. How resistant to the myriad of available treatments does the patient need to be to qualify as refractory?

Treatments may differ depending upon the age of the person; medications prescribed for a 16-year-old may not be used at age 80. The resistance demonstrated by some patients may be due to genetics (genetics often plays a huge role), structural changes in the brain (particularly the white matter), and medication overuse.

Various subsets of RCM have been identified. These include post-traumatic headache, headaches exacerbated by medication overuse, headaches in a person with severe psychiatric illness, etc.

OUTSIDE OF MEDICATION

The headache sufferer should not rely solely on medicine for relief. Lifestyle changes are important too. It is crucial to avoid caffeine overuse and to encourage "active coping," through exercise, physical therapy, yoga, psychotherapy, etc. It is important to not rely solely on medications.

Exercise (at least, on average, 20 minutes daily) and weight control may improve headache and quality of life. Yoga or Pilates may be beneficial. Physical therapy is often useful, and is primarily aimed at associated neck pain. Although stress may be a major trigger for the headaches, managing stress is difficult to achieve. For those with anxiety and/or depression, psychotherapy is helpful for improving quality of life. Biofeedback and other relaxation techniques are also underutilized, and should be considered.

Medication overuse headache (MOH) is a critical issue that must be addressed. It is important to try to limit "as needed" medications. If a patient is consuming pain medications or triptans 10 or more days per month, he or she may be suffering from some degree of MOH. However, these analgesics often are the only effective treatment for that person. Withdrawal from the analgesics may be very difficult to accomplish. MOH tends to be over-diagnosed. Many patients overuse the pain or triptan medications. However, overuse of the "as needed" meds does not necessarily mean that the drugs are increasing the headache.

MEDICATION: SELECTED OUTPATIENT OPTIONS

When migraineurs have failed three or more of the "usual" preventive regimens (for example, topiramate, amitriptyline, beta blockers, etc), the physician should consider

other treatment approaches. Most medications used for refractory headaches are considered "off-label:" they were initially developed for another purpose. How is a medication selected that is best suited for the individual? Comorbidities must be identified. These include the psychiatric and medical conditions, other than headaches, that occur in the individual. If someone has anxiety/depression, antidepressants may be prescribed. If weight gain is a major issue, drugs associated with weight gain must be avoided. With hypertension, medications used to lower the blood pressure are prescribed.

Each patient is unique, and our medication choices vary widely between patients. The following is a discussion of various treatment options for RCM.

BOTULINUM TOXIN (BOTOX)

Botulinum toxin type A (specifically Botox), is the only FDA-approved medication for chronic migraine. This treatment may be used once the diagnosis of chronic migraine has been established. Due to insurance or financial restrictions, Botox is usually injected after a number of other standard medications have failed. For chronic migraine, Botox is the most effective migraine preventive with the least side effects. Since 1996, over 3 million patients have received Botox for headache. Botox is effective in 60 to 65% of patients, and the effects usually last for 2.5 to 3 months. Short-term side effects include eye drooping, headache, and neck pain. Long-term side effects have not been reported. The injections are minimally painful because Botox does not sting.

The FDA indication recommends Botox injections every 3 months. This totals 31 injections (155 units). Many patients do well with a lesser dose (60 to 100 units). Some physicians "chase the pain," injecting more Botox at the sites where the pain is located. If the Botox wears off after 2 months, it is generally safe to re-inject before the 3-month interval.

Many insurance policies cover Botox injections, particularly with "prior authorization" obtained by the physician's office. An increasing number of physicians have received training in Botox injections for chronic migraine.

Most physicians, concurrently with Botox, also prescribe other preventive and "as needed" medications. For those patients with severe RCM, a multi-pronged approach is necessary, which includes non-medication treatments, Botox, preventive agents, and "as needed" drugs.

POLYPHARMACY: USING TWO (OR MORE) PREVENTIVES

Most patients with refractory headaches require more than one medication. Comorbidities "drive" the preventive approach. For example, topiramate which is an anti-seizure drug approved for use in migraine prevention, is commonly used with the antihypertensive beta blocking agents (propranolol, timolol), which are also approved for migraine prevention. These drugs may be prescribed with other preventives, including the antidepressant, amitriptyline. It is vital to minimize the drugs and to avoid side effects. For instance, if a person has constipation, we would avoid using the older antidepressants (such as amitriptyline). If weight gain is a problem, we may use topiramate instead of valproate. If a person cannot afford to have any memory problems (such as an accountant), topiramate may not be the best choice. For each migraineur, the "top ten" list of appropriate medications varies.

Concurrently with preventive therapy, almost all patients utilize "as needed" medications. The idea is to minimize the use of these drugs, trying not to "chase the headache" every 4 hours. Most patients with RCM utilize one or two preventive agents, and three or four "as needed" drugs in their medicine cabinet.

DAILY (OR NEAR-DAILY) TRIPTANS

Some patients with migraine only respond to the triptans (sumatriptan, naratriptan, rizatriptan, etc). Triptans have been available since 1991, and are relatively safe. Over the past 20+ years, several hundred million individuals have used triptans for their migraine attacks. Short-lasting side effects are often experienced, such as chest or neck pressure, tingling, fatigue, etc. Almost all patients who frequently utilize triptans (4 or more days per week), "self-select" this approach. Their physicians did not recommend daily use of a triptan. The major issue with frequent triptan use is MOH. Although triptans may cause MOH, they are less likely to do so than analgesics containing caffeine, butalbital compounds, or opioids.

In addition to the risk of MOH, the major challenge of triptan use is cardiac effects. However, over the last 20 or more years, very few reports of cardiac problems have emerged. We are not certain of all long-term risks of these drugs, but they may be safer than many alternatives. For example, one triptan per day is less harmful to the body than six aspirin with caffeine (or ibuprofen or naproxen) tablets. Many of the long-term side effects seen in headaches patients are related to daily anti-inflammatory use. Most patients using triptans on a daily basis also have other "as needed" drugs to alternate with the triptan.

The ideal patient for triptan therapy experiences no triptan-related side effects and has minimal cardiac risk factors. Also, it is important to wean a patient from the triptan for a period of time, to ensure that MOH is not occurring due to triptan use. Cost and insurance reimbursement were previously a barrier to this approach. However, inexpensive generic triptans are now available

LONG-ACTING OPIOIDS (LAO)

For a minority of RCM patients, long-acting opioids (LAO) may provide the most effective relief. Short-acting opioids (Vicodin/Norco/Tylenol with codeine) only provide relief for 2 to 4 hours, and have a high risk for MOH. The ideal LAO patient is one who has had excellent pain relief from short-acting opioids, without overuse, and without tolerance to the analgesic effects. Tolerance occurs when a person requires constantly increasing doses in order to achieve the same effect. A person with a personality disorder (borderline, antisocial, narcissistic) is a poor candidate for LAO. Previous abuse of opioids or other addicting drugs, increases the risk of MOH with LAO.

The use of opioids in patients under age 30 should be very restrictive. We rarely use LAO in younger patients. If a person has not used opioids on a daily basis, we are very hesitant to institute these drugs. It is important to avoid creating more headaches through the use of opioids. However, if a RCM sufferer has been using opioids for a prolonged time and fulfills the above criteria, they may respond well to an LAO. The "ideal" RCM patient for LAO would be: middle aged or older; has tried many approaches; no personality disorder; and, has responded well to short-acting opioids (good effectiveness with no overuse and no tolerance).

One key to using LAO is to minimize the dose; if high doses are required, the LAO will not be effective. Patients usually respond quickly to the LAO, enabling the physician to make an assessment after 4 weeks of treatment regarding effectiveness and side effects. If tolerance develops, whereby higher and higher doses are required, the LAO approach will not work for the long-term.

A number of downsides to LAO have been identified, including: the risk for abuse or addiction; side effects such as fatigue or constipation; the stigma of taking daily opioids; difficulty obtaining the prescription; and, dependence on the LAO (withdrawal may be difficult). However, for a small number of RCM patients, LAO greatly enhances their quality of life. LAO may be safer over the long term than the short-acting opioids because acetaminophen contained in the short-acting preparations may cause liver or kidney problems.

A number of LAO are available and usually do not contain acetaminophen, unlike the short-acting opioids. Some patients respond well with buprenorphine (Butrans –a 7-day patch), while others prefer extended release morphine (Kadian–an excellent type of delivery system). Methadone has certain advantages (effective, can split tablets, inexpensive) and disadvantages (difficult withdrawal, more dangerous if overused). Oxycodone controlled-release (Oxycontin) carries a higher risk of abuse, and is much shorter-acting than Butrans or Kadian. Zohydro is an excellent "pure" hydrocodone, without acetaminophen. Whichever type of LAO is used, it is crucial to only prescribe low doses.

NERVE BLOCKS

SPG (sphenopalatine ganglion) nerve blocks have been used for over 100 years. Several new devices are available that facilitate completing an SPG block in the physician's office. The SPG is a nerve center near the top of the nose, between the eyes. The block is accomplished easily, and takes only a minute. No pain has been reported. A type of novocaine is sprayed up the nose via the Tx360 or SphenoCath device. SPG blocks are safe, and most effective if done 2 or 3 times per week for several weeks. If effective, these blocks may provide relief for days or weeks (occasionally longer). Some neurologists and pain specialists perform the SPG blocks in their office.

Occipital nerve blocks involve injecting under the skin in the back of the head. Some type of novocaine is used, sometimes with cortisone. Although somewhat painful, occipital blocks are fairly safe. These injections may help for weeks (usually not more than one month). Some neurologists, and almost all pain specialists, perform occipital nerve blocks.

Trigger point injections are usually undertaken with a type of novocaine, injected into the neck or upper back areas. The effects of these injections may last from days to weeks, and are performed by some neurologists and pain

> "For many chronic headache sufferers, the "usual" approaches are not effective. It is important to utilize non-medication approaches while minimizing medicine."

specialists.

Deeper neck (cervical) injections may help some patients with RCM, particularly when the neck is involved. For those with neck and "back of the head" pain, these injections should be considered. These include steroid epidural injections, and "facet" nerve blocks which are performed by a pain specialist on an outpatient basis. Although generally safe, these injections carry slightly more risk than the superficial injections, and are costly.

MISCELLANEOUS MEDICATION APPROACHES

Monoamine oxidase inhibitors (MAOI) are powerful antidepressants that may be effective for refractory headaches. For those with moderate or severe depression, the MAOIs may be beneficial.

Weight gain and insomnia are common side effects. With traditional MAOI, such as phenelzine (Nardil), the low-tyramine diet must be followed, and certain medications may not be used concurrently. At this time, MAOIs are probably underutilized. There is a milder MAOI patch available, Selegline (Ensam)r, with less side effects.

Stimulants (methylphenidate or mixed amphetamine salts) may help pain as well as some comorbidities (fatigue, weight, attention). For some patients, these agents greatly enhance quality of life. Fatigue is commonly encountered in headache patients, and stimulants may help offset the fatigue. Stimulants are primarily used for ADHD, which is a common condition. Many patients with RCM struggle with their weight, and the stimulants help weight loss (at least for a period of time).

Methylergonovine (Methergine) is a medication used following childbirth and is occasionally helpful for headaches. Methylergonovine is usually dosed 2 to 3 times daily. However, a number of medication interactions have been reported. Cost and availability have been issues.

Memantine (Namenda XR) is a drug used for memory problems (Alzheimer's syndrome). Memantine is fairly safe and well-tolerated. Memantine (used in the XR form, once per day) is effective for some headache patients with very few drug interactions.

Muscle relaxants are occasionally effective for RCM. The non-addicting agents are preferred, such as lioresal (Baclofen), cyclobenzaprine (Flexeril), or tizanidine (Zanaflex). Although generally safe, associated fatigue may limit their use. For those with insomnia, using a muscle relaxant at night may help both sleep and headache.

CONCLUSION

For many chronic headache sufferers, the "usual" approaches are not effective. It is important to utilize non-medication approaches while minimizing medicine. This article presents various treatment approaches for patients who have been unsuccessful with the standard headache therapies. Hopefully, in the near future, more effective therapies for pain will be available. It should be noted that most of the treatments discussed are not FDA-approved for the indication of headache treatment. The therapies presented are this author's approach, and are not intended to represent "mainstream" treatment. This discussion is not prescriptive; the risks and benefits of any treatment should be discussed with your treating physician. HW

RESOURCES:

www.practicalpainmanagement.com
(search: headache)

www.chicagoheadacheclinic.com
(article and blog sections)

Prepare for Care

D. Michael Ready, MD
Director, Headache Clinic
Baylor Scott & White Health
Temple, Texas

Over 36 million Americans suffer from migraine. At last count, only 416 physicians were certified in headache medicine in the U.S. Although headache providers do not need to be certified in the subspecialty of headache medicine, these figures indicate a provider shortage for those experiencing migraine and chronic headaches. It is extremely likely that many of those suffering from headaches will not be seen by a headache specialist. The challenge then becomes what can a patient do to gain control of their headaches and their lives. The French scientist Louis Pasteur once said that "Chance favors only the prepared mind." During the initial history and physical examination (and at all follow-up visits), I ask every migraine patient two questions; "Why do you have migraine?" and "What do you want to do about it?" In other words, how are you going to "prepare your mind" to achieve a different outcome than what you've had before? As a headache specialist, I do have more experience in treating headache, but I possess the same tools as any other health care provider. The difference is only my skill and experience in using them. In this equation, provider + patient = outcome. What will make the biggest difference in the outcome is what the patient contributes. The preparation for migraine treatment success involves understanding three things:

- how you arrived where you are (why you have migraine)
- what is keeping you there (why you are having them as often as you are)
- and, how to reverse the process.

When an individual seeks care for their headaches, the diagnosis will almost always be migraine. In its simplest terms, migraine is an inherited hypersensitive nervous system that is poorly tolerant of change (stress). The genetic predisposition to migraine is what determines whether or not you are susceptible for an attack. The attack frequency is a product of an individual's past experiences and their current environment. Migraine pain is not intuitive. Patients frequently obsess about "why" they hurt, and do not accept migraine as a sufficient explanation for their pain. For these individuals, it can be challenging to believe that one can be in that much pain without having anything "broken."The failure to recongnize migraine as a legitimate explanation for their pain demonsrates a lack of knowledge and understanding of migraine.

The World Health Organization ranks the acute disability of a severe migraine attack at its highest level, equivalent to the disability associated with dementia, quadriplegia, and an acute psychotic attack. Migraine is the fourth leading cause of disability in women and the seventh leading cause overall. It is responsible for half of all disability associated with neurological conditions. If migraine is not accepted as a sufficient explanation for a patient's pain, it is unlikely that any significant improvement will occur as the patient will likely search for some undiscoverable pathological pain generator.

Chronic migraine – the most disabling form – does not develop *de novo*. Rather, the attacks evolve from episodic to chronic. This progression has been divided into stages (Cady, Lipton et al):

- Stage I is infrequent episodic migraine (1 to 2 headache days a month). In this stage, an emphasis is placed on resolving the attack as soon as possible.
- Stage II is frequent episodic migraine (3 to 8 headache days a month). At this stage, we still utilize effective acute migraine treatment but behavioral and preventive interventions are started.
- Stage III is "Transforming Migraine" (9 to 14 headache days a month). The role of the acute treatment of the attack starts to be minimized and emphasis is placed on aggressive prevention in order to arrest progression.
- Stage IV is Chronic migraine – the point at which the headaches are occurring on more days than not. At this point, almost all resources are devoted toward prevention and to improve function. Abortive measures are limited and frequently ineffective. Now, a multidisciplinary approach is often required if not unavoidable.

This progression from infrequent episodic to chronic migraine is attributed to the effect of stress (change) on the sensitive nervous system. Too often, individuals view stress too narrowly, believing that stress is the current crisis about which they are worrying. In reality, stress is much more. Stress is any change, good or bad, that acts on us to provoke a response – and it encompasses most of our world. Often, when asked specifically, the majority of patients will say that what is primarily "provoking" them is the headache pain. As migraine progresses, so does the need for greater care. What worked in the past may now be of little benefit.

The migraine progression risk factors increase the stress an individual faces and the comorbidities diminish an individual's ability to manage the stress. Migraine progression risk factors which can be modified include attack frequency, obesity, snoring (in the presence of, or in the absence of, obstructive sleep apnea), stressful life events, medication overuse, and caffeine overuse. When migraine progresses, it becomes important to identify migraine comorbidities, such as depression, anxiety, and insomnia, and to develop an appropriate treatment plan. As the migraine disability increases, so does the need for different and greater therapy.

Often, the biggest mistake that patients make is believing that they can avoid stress. A more effective approach is to identify real and potential stressors and address them. If the stress factors cannot be preemptively managed, then it should be accepted that stress will occur. The goal becomes strengthening oneself so that the stress factors can be tolerated without provoking a migraine attack. Remember – in order to get the answers you are seeking, you need to ask the right questions. So ask yourself – what am I doing so I can better tolerate my headache stress?

Migraine management is delivered throughout our health care system. Primary headache care is often the first level of therapy, with treatment provided by Family and Internal Medicine physicians, and advanced care practitioners. Secondary headache care is usually performed by community neurologists. Tertiary headache care is most often delivered at headache clinics by specialty–trained headache physicians. Quaternary headache treatment is reserved for those patients in need of the greatest care, and utilizes multidisciplinary approaches involving inpatient, procedural, behavioral, and physical interventions.

If the successful management of your headache has not been achieved in a primary or secondary care setting and if quaternary care is inaccessible, then it is essential to optimize your tertiary care experience. It will be important to understand why you have failed previous management attempts and learn from these failures. An individual does not have migraine because they are missing a molecule (a specific drug). When greater and increasingly more comprehensive headache care is required, greater patient involvement is the answer. The question should no longer be what the doctor is going to do for you but what you are going to do in collaboration with your physician, and how will you prepare your mind for success?

The diagnosis of migraine must be accepted as a sufficient explanation for your disabling pain. Although migraine will not protect you from other types of headache, secondary headaches (due to another cause) are rare. In spite of their rarity, attention should still be paid to the pattern of your headache. It is likely that changes in pattern will not only warn of the development of any secondary headaches, but also provide clues as how to best manage your current headaches. Keeping a regular headache diary can help demonstrate your headache pattern.

The need for a higher level of care requires that we consider several theories. First, Sir William Osler, the father of American medicine, reminded us that "it is much more important to know what sort of patient has the disease than what sort of disease a patient has." The second, from the American philosopher and physician, William James, noted that the "as if" principle which states that if you want a characteristic, act "as if" you already have it, and you will acquire it. It is important to consider these words. Apply Osler's principle to the risk factors for progression. We must learn what type of person we are so that we may influence the way we respond to our experiences and our environment. We will never be able to change the fact that

"Often, the biggest mistake that patients make is believing that they can avoid stress."

*** Based on Doctor Ready's *2014 National Headache Foundation Lectureship*, "Tertiary Care for Primary Headaches," presented at the 27th Annual Practicing Physician's Approach to the Difficult Headache Patient, on February 16, 2014, at the Island Hotel, Newport Beach, CA.

"Patient-centered tertiary care involves the patient becoming their own headache expert. It is accomplished by establishing an understanding of their condition, the how and why of its progression, and what can be done to alter the progression."

we were born with a migraine brain. What we may hope to influence is the frequency and intensity of the attacks.

Several characteristics have been found in individuals who gain better control of their headaches – principally they become knowledgeable about their conditions and they are active participants in their care. Applying the "as if" principle leads us to ask and then answer the question "what are people like me doing to get better?" And then we go out and start to do those things so we can get better. The most effective medical care for migraine management is the collaborative model of care, which presupposes the presence of two headache experts in any clinical environment: the patient who is living the experience and the provider who is guiding the patient toward healing. Both partners must be, or become, headache experts as a chain is only as strong as its weakest link. Both experts' perspectives are legitimate, but they may have different goals. The patient likely has a priority of what to do for the next attack while the provider is often focused on reducing attack frequency. Success depends upon these two "experts" developing a shared vision for the pathway to healing.

This knowledge of how we got here (frequent migraines, sensitive brain that does not like change) and what is keeping them going (migraine progression risk factors and comorbidities) allow us to build a foundation for successful care. Providing headache care is done by dividing treatment plans into three parts: preventive, restorative, and rescue. The goal of prevention is to reduce migraine frequency and intensity while improving the response to acute medications. Restorative migraine care aims to return the individual to function and hopefully, a pain-free state. Migraine rescue treatment is initiated when the attack has continued beyond 24 hours or is not resolved by sleep. The prevention plan is usually considered when the headache frequency is greater than 3 days a month. It should be understood that this is an arbitrary point. The defining time to offer prevention should be the stage at which an individual is willing to take a medication on a daily basis to reduce their headache burden. However, as the headaches progress from stage 2 to stage 3, the clinician should strongly encourage preventive therapies to inhibit the inevitable progression.

Restorative care is achieved when evidence-based, migraine-specific therapies are used. The effectiveness of restorative care is enhanced when we treat at the area of mild pain. Previously, the most common restorative treatments used the "step-care" approach when a patient takes one medication and waits to see if that single dose resolves the headache. If it does not, after a period of time, the next medication is used, and so on. Now we know the best restorative care is the "stratified care" model, in which the migraine treatment is tailored to the characteristics of the specific attack. It requires a more engaged patient who is able to distinguish which headaches require what treatment. These different levels of care are stratified according to the level of disability that is likely to be caused by the attacks. Although the principle diagnosis is migraine, not all migraine attacks will be identical. A migraine headache that awakens someone from sleep may require more aggressive treatment than an attack, which a patient recognizes early and is able to intervene while still at a mild threshold of pain.

Migraine rescue is reserved for those attacks that fail to respond to earlier interventions. These attacks can also be some of the more challenging headaches to treat. The migraine that requires rescue frequently does not respond well to oral medications. As an individual migraine attack progresses, other accompanying symptoms may occur, including migraine-induced gastroparesis, which impairs the gastrointestinal absorption of medication. For this reason, migraine rescue involves alternate routes of medication administration – nasal, rectal, subcutaneous, or intramuscular. Whenever possible, patients should be educated and offered their own version of self-administered rescue treatments.

Patient-centered tertiary care involves the patient becoming their own headache expert. It is accomplished by establishing an understanding of their condition, the how and why of its progression, and what can be done to alter the progression. Tertiary care also involves individualized preventive, restorative, and rescue treatments. We should all be aware that effective migraine management is not a spectator sport. It requires the active engaged participation of all involved.

This pathway for healing has at least two parts – the needs of the sensitive nervous system (based upon headache frequency) and the requisite plans for satisfying those needs. Many available resources can help you in acquiring the necessary knowledge of the sensitive nervous system and what you can do about it. **HW**

Recommended reading:

Clarke DD. *They Can't Find Anything Wrong! 7 Keys to Understanding, Treating, and Healing Stress Illness.* Boulder, CO: First Sentinent Publishing, 2007.

Cady R, Lipton R, Farmer K, Bigal M. *Managing Migraine–A Patient's Guide to Successful Migraine Care.* Hamilton, Ont: Baxter Publishing, 2008.

Marcus DA, Bain PA. *The Woman's Migraine Toolkit–Managing Your Headaches from Puberty to Menopause.* New York: DiaMedica Publishing, 2011..

Ruoff, G. *Knock Out Headaches.* Ann Arbor, MI: Spry Publishing, 2013.

Schubiner H, Betzold M. *Unlearn Your Pain.* Pleasant Ridge, MI: Mind Body Publishing, 2010.

Outstanding stress management resources:

Davis M, Eskelman ER, McKay M. *The Relaxation and Stress Reduction Workbook*, 5th edition. Oakland, CA: New Harbringer Publications, 2006.

Kenefick K. *Migraine Be Gone–7 Simple Steps to Taking Control of Your Migraines…And Your Life.* Boulder, CO: Roots and Wings Publishing, 2006.

www.dawnbuse.com–online information

A NEW NON-DRUG OPTION FOR MIGRAINE TREATMENT

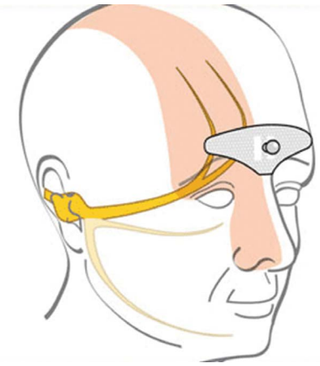
In March, 2014, for the first time, the Food and Drug Administration (FDA) granted approval to a transcutaneous neurostimulation device for the preventative treatment of episodic migraine headaches. However, the technology has been used for decades, for pain control as well as rehabilitation. This device provides "supraorbital" transcutaneous stimulation. Supraorbital refers to the area right above the eye sockets, at the eyebrows. Electrical impulses are used to send a signal through the skin to the trigeminal nerve. At this point, it works to desensitize the trigeminal center in the brain which has been identified as playing a major role in migraine headaches. The superior branch of the trigeminal nerve ends at the exit of the eye socket, underneath the skin of the forehead. The device stimulates this nerve by sending precise micro-impulses during 20-minute sessions. This helps to desensitize the nerve and reduce the number of migraine attacks.

The published study on this method of treatment was undertaken in Belgium, at five tertiary headache centers. The study involved 67 subjects who were required to have at least two migraine attacks per month and were randomized to 1 of 2 groups – actual stimulator or sham stimulator. However, the patients who participated in the study experienced just slightly less than seven attack days per month. The majority of these patients may be considered as having low frequency migraine which is defined as less than 9 headache days per month. The treatment period was 3 months. The patients were to apply the device for 20 minutes daily. At the end of the 3 months, monthly migraine days were measured and compared to the baseline frequency of their migraine attacks. There was no significant difference between the sham group and the treatment group. However, a significant difference was noted in monthly attack frequency and the use of acute/abortive medications in those subjects using the actual device. Between the groups, there was no significant difference in headache severity or associated symptoms, including light and sound sensitivity. No side effects were reported for either group. It should be noted by nature of the study, it did not have a true placebo arm which is an important part of research. Despite the study size, the device received approval from the FDA for the prevention of migraine.

In a much larger study, in Belgium, the device was shown to be a safe treatment with few side effects. However, nearly one-half of the study subjects stopped treatment after 60 days for several reasons. In this study, the most common side effects after stimulation were local pain/intolerance to numbness and tingling, arousal changes (mostly fatigue/sleepiness), occasional insomnia, and headache.

The stimulator is battery-operated and resembles a headband or a tiara, and is manufactured by CEFALY Technology in Belgium. Once it received approval, the device began to ship to the U.S. in April. "The FDA approval of the Cefaly® medical device is significant," said Doctor Pierre Rigaux, the chief executive officer of CEFALY Technology and one of its inventors. "Migraine patients now have a neurostimulation device of their very own."

The drug-free, prescription-only treatment, is used for 20 minutes per day. According to reports, the device has been providing relief for many patients who are unable or unwilling to take medication. It has also been utilized by patients who are currently on pharmacologic therapy, but are seeking to improve their results.



Denise Chou, MD, Assistant Professor of Neurology and Director of the Columbia University Headache and Facial Pain Center in New York City, noted about her patients: "I may often use Cefaly concurrently with medication with the goal either of expediting their progress or weaning them off of their medication. Although Dr. Chou has treated some patients with high doses of preventive medications, she reports some patients using the device on a routine basis managed to stop their medications. However, she stresses that each patient is different as is each migraine attack.

"It's definitely not a blanket solution," she said. "I'll recommend the Cefaly device to patients if they have side effects to medications or they're concerned with potential side effects to medications, or if they've tried some medications and have some partial improvement. I'll often use this as opposed to adding another medication."

Across the U.S., headache physicians rely on the standard therapies: prophylactic medications to prevent the occurrence of migraine attacks; abortive medications to resolve a migraine attack once it has started; and, rescue medications to provide relief of the acute pain and the associated symptoms. Some headache specialists will recommend alternative therapies, such as acupuncture, biofeedback, and herbal therapies. A device providing trigeminal neurostimulation is one more tool to combat migraine attacks.

Some headache patients may be familiar with transcutaneous electrical nerve stimulators (TENS devices) that have been available in the U.S. since the mid-1970s. Until now, the non-invasive nerve stimulation treatment was most familiar to patients with chronic neck and lower back pain. The FDA has categorized the Cefaly device as a TENS unit but more specifically, it is an external trigeminal nerve stimulation (eTNS).

Cefaly is indicated for patients 18 years of age and older and should only be used once per day for 20 minutes. It is only available by prescription and must be ordered online. The NHF reported on this device a year ago, when it was still being evaluated. At the time, Arthur Elkind, MD, the president of the NHF's board of directors, urged migraineurs to be cautious about buying this new tool and suggested they wait for regulatory approval in the United States. Now that approval has been granted, Doctor Elkind said he believes migraineurs with aura may find it beneficial.

Seymour Diamond, MD, reviewed the published study and noted the need for a controlled study, involving more patients, and for longer than the 3-month treatment period. He feels that it is essential that further investigation is required to determine the long-term safety and benefits of the device.

Finally, Larry Charleston, IV, MD, of the University of Michigan, stated that this device may be helpful for a certain population of migraine sufferers as part of their treatment plan. Dr. Charleston strongly recommended that you discuss the device with your headache specialist or other healthcare provider before investing in the device.

HW

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THE HEADACHE CLINICS

featuring:

The Headache and Facial Pain Program
University of Cincinnati College of Medicine
Cincinnati, Ohio

Vincent Martin MD; Reena Shah, MD; David O'Hare, Medical Assistant

The Headache and Facial Pain Program, at the University of Cincinnati College of Medicine, in Cincinnati, Ohio, was established in October, 2013. It is part of the UC Neuroscience Center. Although this program is fairly new, the university has a long tradition of headache clinics. Robert Smith, MD started one of the first headache clinics in the U.S. at the University of Cincinnati and it was staffed by primary care physicians. This Clinic was started during the late 1970s and continued through 1990.

The following is based on an interview with the Program's Co-Director, Vincent Martin, MD. Doctor Martin is also Professor of Clinical Medicine in the Division of General Internal Medicine, at the University of Cincinnati College of Medicine.

Doctor Martin attended medical school and completed his residency and fellowship in General Internal Medicine at the University of Cincinnati. He was able to study under Doctor Smith and was exposed to the practice of headache medicine. Doctor Martin is board certified by the American Board of Internal Medicine, board certified in Headache Medicine by the United Council for Neurologic Subspecialties, and is a Diplomat of the National Board for the Certification of Headache Experts. He is a Fellow of the American College of Physicians and a Fellow of the American Headache Society. He was elected to the Board of Directors of the National Headache Foundation in 2009, and has served as its Vice President since 2011. Doctor Martin is also President of the Ohio Headache Association.

The Program at the University of Cincinnati is a multidisciplinary group of headache physicians and other specialists (ENT, dentists, pain medicine, neurosurgeons). Their goal to treat the wide array of headache and facial pain disorders with a multidisciplinary approach. This Program is one of the only centers in the Midwest to treat both headache and facial pain.

In addition to Doctor Martin, the members of the staff include: Joe Nicolas, MD; Reena Shah, MD; Walter McFarland, MD (see staff graph).

Internal Medicine
Vincent Martin, MD

Neurology (Headache)
Joe Nicolas, MD
Reena Shah, MD
Walter McFarland, MD

Neurosurgery
George Manybur, MD (Co-Director)
John Tew, MD
Mario Zuccarello, MD
Ronard Warnick, MD

ENT
Allen Seiden, MD
Lee Zimmer, MD
Ryan Collar, MD
Alfred Sassler, MD

Anesthesia and Pain Management
James Bruns, MD
James Fortman, MD
Phillip Pham, MD

Neuropsychology
Mei Wang, MD, PhD

Integrative Medicine
Stephanie Stevenson, MD

Dentistry
Gary Robin, DDM
John McDonald, DDS

To be seen at the Center, patients do need a referral from another physician. Generally, the wait for an initial evaluation is 2 to 3 months, but there is a waiting list. Adolescents (14 years and older) and adults are seen at the headache center. A pediatric headache clinic is located elsewhere at the University of Cincinnati. Prior to the initial visit, patients will need to complete some questionnaires regarding their past medical history. While at the Clinic, the patient will undergo a comprehensive history and physical examination. During the visit, the patient will only be seen by a physician, and the visit will take approximately 2 hours. If needed, laboratory testing and MRIs can be performed in the same building. Any other tests would be completed at the adjacent hospital.

At the Clinic, the treatment philosophy is a holistic therapeutic approach to the headache patient, assisting them in identifying trigger factors that could be increasing the frequency of their headaches. Because of the multidisciplinary staff, an integrative approach is provided to each patient. The Integrative Medicine department offers acupuncture, relaxation techniques, dietary therapies, aroma therapy, yoga, etc. For the refractory headache patient, inpatient therapy is available. A Clinic physician would follow the patient if hospitalization is required. Currently, there is not a dedicated unit at the hospital for headache patients, but Dr. Martin advised that they are trying to develop a headache inpatient facility.

At the Clinic, the staff have particular expertise in hormonally-triggered migraine in women and in headaches that occur in patients with connective disease disorders (eg Ehlers Danlos Syndrome, Marfan Syndrome, Joint Hypermobility Syndrome). In addition, the Clinic has published studies regarding the relationship between migraine and sinus disease/rhinitis (hay fever).

In regards to growth or changes to the Clinic during the next few years, Doctor Martin expects an increase in the number of physicians on the staff in the near future. At the Clinic, research continues into the relationship between migraine and female hormones. In a recent presentation at the annual meeting of the American Headache Society, they noted that perimenopause was associated with a 50 to 60% increased risk for headache as compared to premenopausal women with migraine. They are continuing research on the role of allergies and sinus disease and migraine. Also, they are undertaking a study to determine the relationship between migraine and joint hypermobility or Ehlers Danlos syndrome.

When asked what he enjoyed most about working in headache medicine, Doctor Martin noted that his most satisfying experience is in helping headache patients -- "There is no better feeling than a headache patient telling you that you have changed their life." His advice to headache patients: *"Don't give up!!! Successful treatment can be obtained by the vast majority of patients, but it takes a team approach. I often tell patients that there will be things that I need to do and things that they will need to do. Working together, we have the greatest chance of successfully treating the headache disorder."* HW

FOR MORE INFORMATION ON THE CLINIC, PLEASE VISIT:

www.uchealth.com/headache-facial-pain

Center for Headache and Pain Medicine
University of Cincinnati College of Medicine
222 Piedmont Avenue Cincinnati, Ohio 45219
(513)-475-8730

During the month of June, as part of Migraine and Headache Awareness month, three webinars were presented:

June 3	Complimentary & Alternative Medicine in the Treatment of Migraine Susan W. Broner, MD Manhattan Headache Center, New York, New York
June 10	Medication Overuse Headaches Larry Charleston, IV, MD, FAHS Headache & Neuropathic Pain Clinic University of Michigan Medical Center, Ann Arbor, Michigan
June 17	Debbie Zajac, R.N. Cleveland Clinic, Cleveland, Ohio

These, and other webinars are available for viewing on our website

www.headaches.org

MEDICATION GUIDE

BOTOX® and BOTOX® Cosmetic (Boe-tox) (onabotulinumtoxinA) for Injection

Read the Medication Guide that comes with **BOTOX** or **BOTOX Cosmetic** before you start using it and each time it is given to you. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. You should share this information with your family members and caregivers.

What is the most important information I should know about BOTOX and BOTOX Cosmetic?

BOTOX and BOTOX Cosmetic may cause serious side effects that can be life threatening, including:

- **Problems breathing or swallowing**
- **Spread of toxin effects**

These problems can happen hours, days, to weeks after an injection of BOTOX or BOTOX Cosmetic. Call your doctor or get medical help right away if you have any of these problems after treatment with BOTOX or BOTOX Cosmetic:

1. Problems swallowing, speaking, or breathing. These problems can happen hours, days, to weeks after an injection of BOTOX or BOTOX Cosmetic usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with **BOTOX** or **BOTOX Cosmetic**.

- People with certain breathing problems may need to use muscles in their neck to help them breathe. These people may be at greater risk for serious breathing problems with **BOTOX** or **BOTOX Cosmetic**.
- Swallowing problems may last for several months. People who cannot swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving **BOTOX** or **BOTOX Cosmetic** have the highest risk of getting these problems.

2. Spread of toxin effects. In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include:

- loss of strength and muscle weakness all over the body
- double vision
- blurred vision and drooping eyelids
- hoarseness or change or loss of voice (dysphonia)
- trouble saying words clearly (dysarthria)
- loss of bladder control
- trouble breathing
- trouble swallowing

These symptoms can happen hours, days, to weeks after you receive an injection of **BOTOX** or **BOTOX Cosmetic**.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving **BOTOX** or **BOTOX Cosmetic**?"

There has not been a confirmed serious case of spread of toxin effect away from the injection site when **BOTOX** has been used at the recommended dose to treat chronic migraine, severe underarm sweating, blepharospasm, or strabismus, or when **BOTOX Cosmetic** has been used at the recommended dose to treat frown lines and/or crow's feet lines.

What are BOTOX and BOTOX Cosmetic?

BOTOX is a prescription medicine that is injected into muscles and used:

- to treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents (urge urinary incontinence), a strong need to urinate right away (urgency), and urinating often (frequency) in adults when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- to treat leakage of urine (incontinence) in adults with overactive bladder due to neurologic disease when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day.
- to treat increased muscle stiffness in elbow, wrist, and finger muscles in adults with upper limb spasticity.
- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.
- to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older.

BOTOX is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough.

BOTOX Cosmetic is a prescription medicine that is injected into muscles and used to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults for a short period of time (temporary).

BOTOX Cosmetic is a prescription medicine that is injected into the area around the side of the eyes to improve the look of crow's feet lines in adults for a short period of time (temporary).

You may receive treatment for frown lines and crow's feet lines at the same time.

It is not known whether **BOTOX** is safe or effective in people younger than:

- 18 years of age for treatment of urinary incontinence
- 18 years of age for treatment of chronic migraine
- 18 years of age for treatment of spasticity
- 16 years of age for treatment of cervical dystonia
- 18 years of age for treatment of hyperhidrosis
- 12 years of age for treatment of strabismus or blepharospasm

BOTOX Cosmetic is not recommended for use in children younger than 18 years of age.

It is not known whether **BOTOX** and **BOTOX Cosmetic** are safe or effective to prevent headaches in people with migraine who have 14 or fewer headache days each month (episodic migraine).

It is not known whether **BOTOX** and **BOTOX Cosmetic** are safe or effective for other types of muscle spasms or for severe sweating anywhere other than your armpits.

Who should not take BOTOX or BOTOX Cosmetic?

Do not take **BOTOX** or **BOTOX Cosmetic** if you:

- are allergic to any of the ingredients in **BOTOX** or **BOTOX Cosmetic**. See the end of this Medication Guide for a list of ingredients in **BOTOX** and **BOTOX Cosmetic**.
- had an allergic reaction to any other botulinum toxin product such as *Myobloc*®, *Dysport*®, or *Xeomin*®
- have a skin infection at the planned injection site
- are being treated for urinary incontinence and have a urinary tract infection (UTI)
- are being treated for urinary incontinence and find that you cannot empty your bladder on your own (only applies to people who are not routinely catheterizing)

What should I tell my doctor before taking BOTOX or BOTOX Cosmetic?

Tell your doctor about all your medical conditions, including if you:

- have a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome). See "What is the most important information I should know about **BOTOX** and **BOTOX Cosmetic**?"
- have allergies to any botulinum toxin product
- had any side effect from any botulinum toxin product in the past
- have or have had a breathing problem, such as asthma or emphysema
- have or have had swallowing problems
- have or have had bleeding problems
- have plans to have surgery
- had surgery on your face
- have weakness of your forehead muscles, such as trouble raising your eyebrows
- have drooping eyelids
- have any other change in the way your face normally looks
- have symptoms of a urinary tract infection (UTI) and are being treated for urinary incontinence. Symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever.
- have problems emptying your bladder on your own and are being treated for urinary incontinence
- are pregnant or plan to become pregnant. It is not known if **BOTOX** or **BOTOX Cosmetic** can harm your unborn baby.
- are breast-feeding or plan to breastfeed. It is not known if **BOTOX** or **BOTOX Cosmetic** passes into breast milk.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal products. Using **BOTOX** or **BOTOX Cosmetic** with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX or BOTOX Cosmetic in the past.**

Especially tell your doctor if you:

- have received any other botulinum toxin product in the last four months
- have received injections of botulinum toxin, such as *Myobloc*® (rimabotulinumtoxinB), *Dysport*® (abobotulinumtoxinA), or *Xeomin*® (incobotulinumtoxinA) in the past. Be sure your doctor knows exactly which product you received.
- have recently received an antibiotic by injection
- take muscle relaxants
- take an allergy or cold medicine
- take a sleep medicine
- take anti-platelets (aspirin-like products) and/or anti-coagulants (blood thinners)

Ask your doctor if you are not sure if your medicine is one that is listed above.

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

How should I take BOTOX or BOTOX Cosmetic?

- **BOTOX** or **BOTOX Cosmetic** is an injection that your doctor will give you.
- **BOTOX** is injected into your affected muscles, skin, or bladder.
- **BOTOX Cosmetic** is injected into your affected muscles.
- Your doctor may change your dose of **BOTOX** or **BOTOX Cosmetic**, until you and your doctor find the best dose for you.
- **Your doctor will tell you how often you will receive your dose of BOTOX or BOTOX Cosmetic injections.**

What should I avoid while taking BOTOX or BOTOX Cosmetic?

BOTOX and **BOTOX Cosmetic** may cause loss of strength or general muscle weakness, or vision problems within hours to weeks of taking **BOTOX** or **BOTOX Cosmetic. If this happens, do not drive a car, operate machinery, or do other dangerous activities.** See "What is the most important information I should know about **BOTOX** and **BOTOX Cosmetic**?"

What are the possible side effects of BOTOX and BOTOX Cosmetic?

BOTOX and BOTOX Cosmetic can cause serious side effects. See "What is the most important information I should know about **BOTOX** and **BOTOX Cosmetic**?"

Other side effects of BOTOX and BOTOX Cosmetic include:

- dry mouth
- discomfort or pain at the injection site
- tiredness
- headache
- neck pain
- eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes.
- urinary tract infection in people being treated for urinary incontinence
- painful urination in people being treated for urinary incontinence
- inability to empty your bladder on your own and are being treated for urinary incontinence. If you have difficulty fully emptying your bladder after getting **BOTOX**, you may need to use disposable self-catheters to empty your bladder up to a few times each day until your bladder is able to start emptying again.
- allergic reactions. Symptoms of an allergic reaction to **BOTOX** or **BOTOX Cosmetic** may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

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 **BOTOX** and **BOTOX Cosmetic**. 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.

General information about BOTOX and BOTOX Cosmetic:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

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

What are the ingredients in BOTOX and BOTOX Cosmetic?

Active ingredient: botulinum toxin type A

Inactive ingredients: human albumin and sodium chloride

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

Manufactured by: Allergan Pharmaceuticals Ireland a subsidiary of: Allergan, Inc.
2525 Dupont Dr.
Irvine, CA 92612

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ALLERGAN

Based on 72284US16
APC13NF13

NATIONAL HEADACHE FOUNDATION®

Keeping a headache diary can help your doctor help you

NHF suggests answering the following questions to compile your headache history:

- When did you start having headaches?
- How often do they occur? At what time of day? During the week or on weekends? How long do they last?
- Where is the pain?
- Which word best describes it: throbbing, pounding, splitting, stabbing, and blinding?
- Are your headaches associated with your menstrual cycle?
- What triggers your headache: certain foods, certain physical activities, bright light, strong odors, change in temperature or altitude, noise, smoke, stress, and oversleeping?
- What symptoms do you experience prior to the headache?
- Does anyone else in your family suffer from headaches?
- Do you notice visual disturbances before or after your headaches?
- Do you suffer from more than one type of headache?

It is important to make an appointment with your doctor for the specific purpose of addressing your headache history rather than discussing headaches as part of a physician visit for other reasons. The National Headache Foundation also recommends keeping a diary to track the characteristics of your headaches. Patterns identified from your diary may help your doctor determine which type of headache you have and the most beneficial treatments.

For more information about headache causes and treatments, visit the NHF web site at: www.headaches.org or call 888-NHF-5552

820 N. Orleans, Suite 411, Chicago, IL 60610-3132
Toll Free (888) NHF-5552 Fax (312) 640-9049

NATIONAL HEADACHE FOUNDATION®

Date	**Time**	**Intensity** rate 1-10 (most severe being 10)	**Preceding Symptoms**	**Triggers**	**Medication** (and dosage)	**Relief** (complete/ moderate/ none)

NATIONAL HEADACHE FOUNDATION®

Date	Time	Intensity rate 1-10 (most severe being 10)	Preceding Symptoms	Triggers	Medication (and dosage)	Relief (complete/ moderate/ none)

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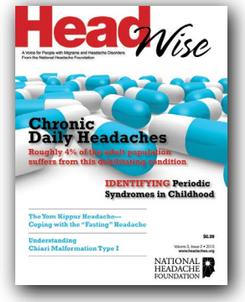

PREVIOUS EDITION

E-NEWSLETTER VIA EMAIL

Gift Membership:

☐ $20.00 to send ***HeadWise***™ plus the monthly e-newsletter, ***NHF News to Know***.

In addition, I'd like to make a tax-deductible contribution to the NHF in the amount of: ☐ $5 ☐ $10 ☐ $20 ☐ Other: $_____

Receipient's Name (Please Print)

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City/State/Zip

Preferred Phone # E-mail Address (to get the e-newsletter)

Payment:

☐ Payment enclosed (Make check payable to National Headache Foundation)

Charge to my credit card:
☐ Amex ☐ Discover ☐ Mastercard ☐ Visa

Credit Card Number Expiration Date

Cardholder's Name Cardholder's Signature

Billing Address City/State/Zip

Preferred Phone # E-mail Address

Please mail this form with your payment to: National Headache Foundation, 820 N. Orleans, Ste. 411, Chicago, IL 60610

Your Contributions to the National Headache Foundation Help Fund Projects

What's being done to help your headache problem? There is an unprecedented amount of research being undertaken regarding migraine and other headache pain. The National Headache Foundation is involved in this effort with the help of funding from you. Contributions are a key part of the financial support of important headache research. Your gift provides funds for (a) NHF-financed research projects, (b) advocacy with health policy decision makers, and (c) patient-education initiatives. You can help! The National Headache Foundation, the #1 source for headache help, provides these services and many others through the generosity of people like you.

Please select one of the following giving categories:

❒ $250 ❒ $125 ❒ $100 ❒ $75 ❒ Other_____

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New Membership | Toll-Free (888) NHF-5552 | www.headaches.org

Individual Membership:

☐ $20.00 to receive ***HeadWise™*** plus the monthly e-newsletter, ***NHF News to Know***, when you join the National Headache Foundation

In addition, I'd like to make a tax-deductible contribution in support of **NHF's educational programs** in the amount of: ☐ $10 ☐ $25 ☐ $50 ☐ Other: $_____

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Name (Please Print)

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City/State/Zip/Country

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Preferred Phone # E-mail Address

Payment:

☐ Payment enclosed (check payable to National Headache Foundation)

Charge to my credit card: ☐ Amex ☐ Discover ☐ Mastercard ☐ Visa

_____
Credit Card Number Expiration Date

_____
Cardholder's Signature

_____
Billing Address (If different from mailing address)

_____
City/State/Zip/Country

Please mail this form with your payment to: National Headache Foundation, 820 N. Orleans, Ste. 411, Chicago, IL 60610 or renew online by visting www.headaches.org

Thank you for participating in Migraine and Headache Awareness Month

National Headache Foundation
820 N. Orleans Street–Suite 411
Chicago, Illinois 60610

In recent years, the Afghan and Iraq Wars have increased the prevalence of migraines and headaches in veterans returning to the U.S.

NHF feels it is vital to reach out to those who have served our country.

Active duty military members and veterans can visit *www.headaches.org* for more information on a complimentary one-year membership to the National Headache Foundation.

NATIONAL HEADACHE FOUNDATION