

Connections

"To Improve the Lives ... While We Find the Cure"



IN THIS ISSUE...

Contact Us
page 2

Going Green
page 2

Ask The Experts
page 4

Medication Disposal
page 5

Coins for the Cure
page 6

Awareness
page 7

John Jane, Jr, MD
page 8

Lifeline Alert
page 8

FDA Grants
page 9

ASAP Business Card
page 10

2009 Research Grants Awarded

Thanks to the generous donations of our members and the hard work of volunteers hosting fundraisers across the country, ASAP is proud to announce we have awarded new research grants.

Researchers in Aurora, Colorado will be investigating brain fog in Chiari patients with or without syringomyelia. They will attempt to answer two basic questions: Do cognitive (thinking) problems in patients with Chiari I malformation result directly from the malformation or from another cause? Do cognitive problems improve after surgery? A neuropsychologist will be testing patients before and after surgery and comparing results.

Kerri Thorn, PA-C, of Children's National Medical Center, Washington, DC is our second grant recipient. The title of this research is *Investigation of the Disease Progression of Pediatric Patients with Incidental Chiari I Malformation*. What happens when a patient being evaluated for another reason is found to have a Chiari malformation? Often called incidental Chiari I malformation, not much is known about how care should be managed. What percentage of patients will require surgery? Is there a way to predict which ones will need a surgical procedure? And should these patients have regular MR imaging? This study will investigate those questions.

In addition, the ASAP Board of Directors is pleased to announce that the *Marcy Speer Research Memorial Fund* will be used to fund *Finding Novel Genetic Contribution to Chiari Syndrome with or without Syringomyelia* at Duke University. Dr. Allison Ashley-Koch is continuing the research initiated by Dr. Speer. The goal of research is to identify the genomic expressions that differ in CMI patients, hopefully leading to new diagnostic tools and additional guidance for treating patients.

ASAP Welcomes New Board Members

During the October 14 Board of Directors meeting, Bill Hagelgans and Matt Turmelle were elected to serve as Directors. Michael Scarpone, ASAP CEO, said, "We are so excited to have Bill and Matt be a part of ASAP at this level. As a board member they will have the opportunity to be involved in many decisions regarding the current and future functioning of the organization."

Bill Hagelgans resides in Oreland, Pennsylvania, a suburb of Philadelphia, with his wife, Christine, and two daughters, Paige and Blair. After graduating from high school in Bethlehem, Pennsylvania, Bill enlisted in the United States Coast Guard. He was stationed throughout the lower 48 and did a tour in Ketchikan, Alaska (his most memorable station).

After being discharged, he attended one year at East Stroudsburg University in Pennsylvania, then transferred to Widener University in Chester, where he obtained a Bachelor of Science in Business Administration /Accounting. Bill is presently the Director of Business Development for a logistics company.

Bill's daughter Blair was diagnosed with Chiari and syringomyelia in 2005 at age 8. Unfortunately, it was immediately apparent that the medical community is not well informed or trained when dealing with Chiari and syringomyelia. It was not until his wife, an RN, found the ASAP web site that provided valuable information and support for his family.

After learning about and attending one of the ASAP conferences, he realized there were many people like himself in need of correct information and support. With his wife recently involved in a car accident without any prior symptoms, she too was diagnosed with a Chiari. Being directly affected by the lack of Chiari knowledge involving doctors, insurance companies and the general public, he feels

American
Syringomyelia
& Chiari
Alliance
Project, Inc.

501(c)(3)
tax-exempt
since 1988

continued on page 3

ASAP

Contact Us

ASAP

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Don't Wait for Important Updates!

ASAP sends out monthly eBlasts (emails) to keep members informed about breaking news, upcoming events and much more.

If you are not receiving these announcements, contact info@ASAP.org. Let us know you would like to receive eBlasts. If we have your email address, please be sure to add the domain name ASAP.org to your safe sender list.

Please Note: Articles in this newsletter are not intended as a substitute for medical advice and do not necessarily represent the viewpoints of the editor, Medical Advisory Board or Board of Directors. Please contact your doctor before engaging in any new therapy or medication.

ASAP is Going Green!

What You Need to Know
E-Connections are EASY...

Bi-monthly E-Connections members will receive an email from ASAP notifying them that the newsletter is available for viewing. Simply click on the provided link or log on to www.ASAP.org.

E-Connections are ECONOMICAL...
This FREE service is a great way to support the organization by helping us save time and save money.

E-Connections are ECO-FRIENDLY...
Signing up for E-Connections is also a great way to save paper! You will be able to read your newsletter online or download at your convenience from your own personal computer. E-Connections will be available for viewing online for an extended period of time.

SIGN UP TODAY!
Contact the ASAP office and sign up to receive E Connections online.

SAVE Time...SAVE Trees...with ASAP!

Save Your Canceled Postage Stamps

ASAP members began collecting canceled postage stamps as a fundraiser during the early 90s. They have enlisted the aid of local businesses, churches, social clubs, family and friends. The number of stamps donated has dramatically increased over the years.

This fundraising project is a favorite of many ASAP members. Although commemorative stamps such as the 'State' series bring in more money, the everyday 'flag' stamps are also of value. Since 1999, we have raised over \$6,000 through this project. So the next time you start to toss that envelope, take a few minutes to help ASAP.

Cut stamp from envelope leaving a 1/4 inch border. It must be in good condition. Damaged stamps are not usable.

Please send stamps to:
Maynard Guss
9593 NW 26th Place
Sunrise FL 33322-2738



Mason's Mission

by Melanie Gaffneys

On Sunday, September 20, we held our very first fundraiser to help raise awareness of Chiari malformation and donations for ASAP to help fund research. We named our fundraiser after our son Mason, who was diagnosed at 6 months old. Mason's Mission was an idea of my husband and me after we were frustrated by the lack of knowledge and research of this disorder. We also set up a web site to help raise more awareness www.masons-mission.com.



Our 1st Annual Family Fun Day was a hit. We had over 100 people in a kid friendly environment. An indoor play center served as the venue, along with a DJ, chair massages, art classes and music classes for the kids made for a great event. We also had vendors and lots of goodies in our auction. We had a GREAT time and all the hard work was worth it, we raised over \$6000. We are already excited for next year...so is Mason!

Hi my name is Payton Livingston age 10
Me and my cousin both have A Serious condition.
Mine is called Syringomyelia and my cousin is
called Chiari. Help us find a cure and donate at
www.firstgiving.com/cruisinforchiari.
Please we need your help and if your wondering all the
money you donate will go to American Syringomyelia &
Chiari Alliance project. here a prior thank you for listening
and all the money you donate will make
a big difference and if you have any questions
I will be happy to answer them
Thank you.

Hi

My name is Payton Livingston, age 10.

Me and my cousin both have a serious conditions.
Mine is called syringomyelia and my cousin's is
called Chiari. Help us find a cure and donate at www.firstgiving.com/cruisinforchiari.

Please we need your help and if you are wondering
all the money you donate will go to American
Syringomyelia & Chiari Alliance Project. Thank you for
listening and all the money you donate will make a big
difference.

ASAP Welcomes New Board Members

continued from page 1

strongly the need to support and help raise awareness to increase funding for research and education of Chiari malformation and syringomyelia. Bill believes that this can be accomplished by volunteering and being directly involved as a Board Member with ASAP.

Matt Turmelle is a graduate of the University of New Hampshire with a BS in kinesiology. Upon graduation he was commissioned as an officer in U.S. Army Medical Service Corp. After serving our country for 6 years, Matt exited the Army as a Captain in 2001 and went to work with a medical surgical distribution company, Owens & Minor based out of Richmond, Virginia.

Matt and his wife Tracy reside in Jarrettsville, Maryland (30 miles North of Baltimore) with their two boys Hunter who is 6 and Joseph (Joey) who is 3. The Turmelle's enjoy all outdoor sports and activities; the favorite being horseback riding both for pleasure and local competition. Hunter was diagnosed with Chiari malformation (CM) and syringomyelia (SM) at the age of 3 after finding the development of scoliosis. He had decompression surgery within weeks of his diagnosis to treat CM but still had a significant and stubborn syrinx. Hunter's neurological signs and symptoms were not improving and his curve reached 48% resulting in not one but two additional surgeries whereby the insertion of a shunt was performed. Hunter is currently wearing an aggressive Wilmington brace to correct his scoliosis. Joey, started complaining of the same exact leg pain that Hunter had at the age of two. Having experienced everything they had with Hunter, Matt and Tracy were not going to accept 'it's probably growing pains' so they immediately consulted their neurosurgeon whom ordered an MRI and diagnosed Joey with a mild CM.

Matt and Tracy, as many others, found ASAP and have recently established a Baltimore based support group. Matt passed along an email that was sent to him while they were trying to coordinate the meeting and wanted to share it: "Yes, I will be there with bells on! This is a dream come true for me... I've been the only one around me with these conditions so it will be nice to mingle with those that truly understand everything. Thank you again!"

"This is our personal mission now," Matt said, "to help and support those with CM/SM and to maximize the efforts of raising awareness which will hopefully lead to increase funding for research and education. The last thing a parent wants to hear in regards to the long term effects of CM/SM is, we don't know."

Visit us on the Web
www.ASAP.org

Ask The Experts

Question and Answer

Question: Is there a difference between hydromyelia and syringomyelia?

Dr. Oro: The terminology is a little bit confused and there are advocates one way or the other. In general hydromyelia was more often used for a wide dilatation of the central spinal canal and syringomyelia with disruption of that fluid into the actual tissues themselves. Depending on who you ask either we can call them all the same thing, realizing there may be various different etiologies or continue to use that term. I don't find hydromyelia that useful to myself.

The other term I will mention that is useful is a persistent central canal which gets confused sometimes with syringomyelia and it's very difficult to sort out. These are small thin cavities that are called fusiform. They taper at the top and the bottom. Some of us may have those naturally just because our central spinal canal never closed. It is not a true syrinx and it's not going to grow. I agree there's some debate when it gets to 5mm and 6mm cross section diameter, but if it's a thin fluid cavity in the cord itself some people get really frightened that they've all of a sudden been diagnosed with syringomyelia. That may be what's called a persistent central canal that was there in all of us in fetal life. So I do like that term.

Question: I have cerebral palsy, Chiari and cranial settling. You mentioned one symptom that a lot of children present and you didn't emphasize is drooling. My question over and over again should cerebral palsy be added to that list of associated disorders? I know it is two separate disorders but because of the symptoms and because it affects the motor skills. Can you elaborate on cerebral palsy and cranial settling and Chiari?

Dr. Keating: Sure. It's always hard to figure out which came first, the chicken or the egg. Certainly there are many patients with Chiari malformations without CP and vice versa. I think the difficulty as you point out, with symptoms like drooling, articulation, swallowing difficulties that you can see in either group of patients, it's certainly possible. Then of course there are going to be patients that will have both scenarios. The first thing I would ask as a pediatric neurosurgeon with the CP is there any element of hydrocephalus? And is the hydrocephalus exacerbating or worsening the picture and pushing those tonsils down? That's always a challenge. If you have a child who has a Chiari malformation and visible or easily recognize hydrocephalus; what's causing what? Is it the hydrocephalus pushing the tonsils down? Is it that the patient because the tonsils are lower is obstructing the CSF pathway so the hydrocephalus develops?

Certainly patients with CP are prone to hydrocephalus, not everybody has it, but that's why a lot of these kids end up with shunts. My first question, I would say is there any element to that from above? And is that contributing to the big picture? Or do you just have both situations?

Response: I was born with cerebral palsy and years later I developed the symptoms – dizziness, vertigo – the symptoms of Chiari out of no where. The Chiari developed years later due to maybe scoliosis that I have. I was fine for years. I always knew I was hyper-flexible but never had a reason to believe that there was anything wrong until years later. Do you see that a lot?

Dr. Keating: We have a lot of older kids, 20s, 30s with CP and the issues that they have. I'm trying to figure out what's going on in those patients. Certainly CP should be a static phenomenon; it's a neurological injury early on and you have resultant musculoskeletal imbalances because of that. The difficulty there is as one gets older, age, degeneration, and wear and tear. The long term cost of increased tone in the muscles, the tendons and bones, the scoliosis and so forth, it's hard to be able to figure out what's a natural expected progression versus what is out of the ordinary. If

you're telling me that you were doing fine for a number of years and then all of a sudden have this relatively acute or subacute onset of new issues and symptoms that would be certainly more reflective of a new process or a new problem going on and may represent an entirely different thing. I think what you pointed out, and again for the rest of the audience, this points out is emblematic of the myriad

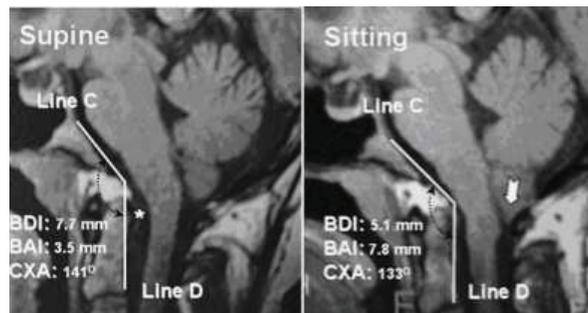
presentations and problems and issues and why it's not a singular disease, it's very unique and every patient is their own textbook.

[The preceding excerpts are from the 2008 ASAP Conference held in Arlington, Virginia;

Dr. John J. Oro is a neurosurgeon experienced in the treatment of Chiari I malformation. In 2005, he founded The Chiari Treatment Center in Aurora, Colorado.

Dr. Robert Keating is Chief of Neurosurgery at Children's National Medical Center in Washington DC and Professor of Neurosurgery and Pediatrics at George Washington University.

A complete transcript of the 2008 ASAP Conference is available for sale from ASAP.]



example of cranial settling

New FDA Web Page Lists Disposal Instructions for Select Medicines

The U.S. Food and Drug Administration launched a web page for consumers with information on how to dispose of certain drugs, including several high-potency opioids and other selected controlled substances. These medicines have the potential to be harmful, even deadly, in a single dose if taken by someone other than the intended person.

The FDA recommends that these medicines be disposed of by flushing down the sink or toilet. The goal is to keep them away from children and others who could be harmed by taking them accidentally.

Medicines not listed should be thrown away in the household trash after mixing them with some unpalatable substance, such as coffee grounds, and sealing them in a bag or other container. Another option is to dispose of them through drug take back programs, if federal and state law permit.

“The safe disposal of medicines from the home after they are no longer needed is an important concern for the FDA,” said Douglas Throckmorton, M.D., deputy center director of FDA’s Center for Drug Evaluation and Research.

All medicines listed have disposal instructions in their professional prescribing information; however, this information is targeted to health care professionals. The web page provides clear instructions for consumers on whether a medicine should be flushed or disposed of in the trash.

Throckmorton also said, “The FDA is working with other groups to improve the use of several drug disposal methods, including drug take back programs. However, for some potent medicines that can cause harm or death if inadvertently taken by family members, the FDA currently recommends flushing them down the sink or toilet to immediately and permanently remove them from the home. Simple precautions like these can reduce the likelihood of accidental and potentially dangerous exposure to unused medicines.”

The FDA worked with the White House Office of National Drug Control Policy (ONDCP) to develop the first consumer guidance for proper disposal of prescription drugs. The ONDCP federal guidelines were first issued in February 2007.

For more information visit <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>

If you do not have internet access you may contact the ASAP office for a printed copy.

Miracle Wish for Chiari Weekend

by Michael Scarpone

It is hard to know where to begin when describing Victory Junction. Even though we have referred to it as a camp, it is more like a resort for children. Complete with riding stables, 4-lane bowling alley, water park, auditorium, indoor kickball/wiffle ball park (including night lights and score board), Victory Junction is an opportunity for children and families to escape the day to day struggle of health challenges.



L-R: M Scarpone, A Koch, Dr Fuchs, P Schaublin and Dr Sim

The medical facility (called the body shop) is a miniature hospital. Dr. Sim, the resident physician, told me that they bring in specialists for transfusions and chemotherapy if needed as well as pharmacists. They have a pharmacy on site. A total feeling of safety and security prevails throughout Victory Junction.

Several highlights of the weekend:

- On Saturday, parents met with Drs. Alison Koch and Herb Fuchs in the auditorium. Dr. Fuchs spoke about CM/SM and neurosurgery and Dr. Koch spoke of the genetic research study at Duke. There was a three-hour window allotted for the session and we were worried that the talks would not use up the entire time. We were wrong. There was a great discussion and we went over the three hours.
- There was a communal dance after every meal.
- In true camp fashion, there was a skit night on Saturday with 23 families participating. Each “act” ended with a thunderous applause from the audience. Everyone on stage was a star.
- Victory Junction provided a full video crew and filmed activities throughout the weekend. Each family and volunteer received a group photograph (above) and a DVD of the weekend.
- Lifelong friendships were made. It is impossible to describe the number of smiles and the glow in people’s eyes. One child said it best, “I don’t want to go home.”
- After the families left, volunteers gathered for a debrief. I thanked everyone for all their work and told them that they may never fully understand the positive impact on they had.



Out of all the activities I have been involved in, Victory Junction stands out as a highlight in my career. ASAP

ASAP's National Coins for the Cure Day

Volunteers, across the nation, came together to spread awareness and raise funds for Chiari and syringomyelia on October 10. Weather ranged from bright and sunny, to cold, rainy and even snowy, but volunteers didn't let that get in the way of their goal making CM and SM a household name.

Participants came up with lots of creative ideas to get the word out. Locations varied from festivals, malls, schools, grocery and shopping stores even a plane—yes, that's right, a plane flight from Raleigh to Philadelphia served as a *Coins for the Cure* site!

Sharing their adventures, members wrote:

Seth, Jupiter, FL: Hi, I'm 10 years old and have syringomyelia. My mom told me I could wait around for someone to find a cure for syringomyelia, or I could take action and help the American Syringomyelia & Chiari Alliance (ASAP for short). So I decided to collect money for the *Coins for the Cure* day and even held a bake sale at my school. We collected \$500 from the Bake Sale. However... we collected over \$1,600 Total.



Lisa, Vicksburg, MI: I set up a booth at the Vicksburg Harvest Festival. I talked to a couple hundred folks that came by about Chiari. The folks that did come by were very nice. I didn't make much cash but had a blast talking everyone's ear off about Chiari and raising awareness. My mom sat with me the entire day and told me that she was very proud of me and all the work that I have been doing. That was all that I needed to hear.



Carolyn, Fairhope, AL: I was a sole volunteer and was at the WalMart from 10:00 am - 12:00 noon. I collected \$84.27 there and another \$100 from a company I solicited. The remaining bookmarks that I have are going to be placed with MRI centers.



Carol, Dyersville, IA: We raised \$229. However, I was really proud of my team (my kids and best friend) volunteering and getting the word out and proud of all the people who took the time to look at our display and videos and open their hearts and pocketbooks.



Karen, Kimberly, Stephanie and friends, Richmond VA: We had a great time doing *Coins for the Cure* today. We were at our grocery store, it was alternating between raining and windy but it didn't matter to us. Stephanie and Kimberly texted their friends who came by for support. We raised over 200 dollars in 3 hours. We also had some



people donate directly through the web site.

Sara and Holly, Madison, WI: An unexpected medical trip had us participating in *Coins for the Cure* far away from our home state of Florida. We joined Jeanne and her team of volunteers inside of a mall where we stayed warm and talked about CM and SM to whoever would lend us their ear. Our friends were amazed that our organization had coordinated this geographical feat and we could travel so far from home and still participate in the event. That's the beauty of ASAP, our members are everywhere and they know how to come together to accomplish the important stuff!

Awareness and Fundraising: Working Together

Arizona Miracle Race Draws A Crowd

by Sara Eaton

On Sunday, September 20, 2009, the Arizona Chiari/Syringo Support Group, friends and family joined Mylee Grace at Kiwanis Park in Tempe, Arizona. The day brought awareness to our community, joy to our friends and family and lots of sunshine!

Our event kicked off bright and early with the help of the JB Martial Arts program who worked hard to set up the event, help vendors and cheer on participants along the walk route.

Ronald McDonald jazzed up the crowd with a few stretches while DJ KAZ provided music to get the crowd energized. The 2-mile charity walk kicked off at 7:30 with Ronald McDonald leading the way. All participants crossed the finish line and received goody bags filled with items donated by multiple sponsors.

Our first raffle item was chosen by another fun guest appearance. Our very own NBA Phoenix Suns gorilla ran around with kids at the event and even caused some mischief with some of the vendors on site. We raffled off fun prizes, including Phoenix Zoo tickets, Wildlife World Zoo tickets, tickets to Brad Paisley, Arizona Diamondback tickets and gift certificates from Costco, Fry's Grocery Store and Target.

Our vendors on site included massage therapist offering free massages and reiki, Arizona Kettle Korn, Jamba juice, jewelry, children's wear and informational booths.

We closed the event with an announcement that we raised over \$17,000 for research. A check was presented to Mike Scarpone, CEO of ASAP. It was an awesome experience and we are looking forward to getting started on the event in 2010.

Walk for Chiari Awareness and Research

by Patricia Maxwell

Jaxon Eilers may someday be a doctor but today he just wants to be like his friends.

As 7-year-old Jaxon watched neighborhood kids going door-to-door selling magazines and delivering Cub Scout popcorn, he wanted to do a fundraiser, too.

His parents helped turn his dream into reality. Jaxon's Quest for a Cure, an awareness walk for Chiari malformation, was held October 10 at Noelridge Park in Cedar Rapids, Iowa.

Besides raising awareness, the event generated \$3,975 for research.

Cruisin' For Chiari

by April Barillari

It was nothing but smooth sailing for the *First Annual Cruisin' for Chiari*, held on August 30 in Brielle, New Jersey.

Over 75 guests boarded the River Queen, a traditional paddle boat that sails the Manasquan River, Point Pleasant Canal, Barnegat Bay and Metedeconk River. Guests enjoyed a 3 hour cruise that included a buffet lunch, silent auction, music and raffle.

Joining us for the event were ASAP members traveling from 5 different states, CEO Mike Scarpone, Board member Patrice Schaublin, the Livingston family, their friends, family and the guest of honor, 3 yr old Gabriel Livingston.

The event was a tremendous success and we were able to raise over \$10,000 to be donated towards research.

We thank all that attended and supported the event, as well as JR Warnet of Nevermore Photography, DJ Johnny's Magic Moments, Payton Livingston and the many businesses that made generous donations.

Planning for the *Second Annual Cruisin' for Chiari* has already begun, so we hope to see more of you out there next year!

Member Fundraising

by Patricia Maxwell

ASAP is a publicly supported non-profit. That means we depend upon the public to fund programs and research. Much of that support comes from our member fundraisers.

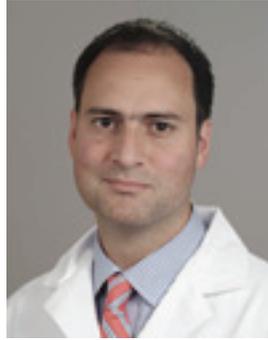
In addition to the Arizona Support Group, the Eilers, Livingston and Barillari families and friends our appreciation goes to Christine Marchesano for the *Spaghetti Dinner*, the Chiari People of Pennsylvania walkathon, Peg Curtacci, the Patterson family yard sale and craft fair, Melanie Gaffney's *Mason's Mission Fun Day*, Stefani Kurutz's *Music with a Backbone* concert, the AZ group's *Winter Holiday* event and all who participated in the *Coins for the Cure Day*.

When you hold a fundraiser for ASAP, please submit your story so we can include it on our web site and in *Connections*.

If you are interested in organizing an event to support ASAP programs, spread awareness of Chiari and syringomyelia or fund research, contact Michael Scarpone at Michael_Scarpone@ASAP.org or 207-439-2538.

Meet the Medical Advisory Board John Jane, Jr, MD

Dr. Jane, Jr. attended college at the University of Chicago where he graduated with honors. He then returned to Virginia and attended medical school at the University of Virginia where he also completed his general surgery internship and began neurosurgical residency in 1997. After spending a year as a Fellow in Neurosurgery at Auckland Hospital in Auckland, New Zealand, he returned to UVA to finish his chief year in Neurosurgery. He then completed a pediatric neurosurgery fellowship acting as the Chief Fellow of Pediatric Neurosurgery at the renowned Hospital for Sick Children in Toronto.



Dr. Jane, Jr. became the Director of the Division of Pediatric Neurosurgery at the University of Virginia in 2004. He also specializes in surgical care for patients with neuroendocrine tumors including craniopharyngiomas and pituitary adenomas. He is a specialist in the neuro-endoscopic treatment of hydrocephalus, intraventricular brain tumors, pituitary adenomas, and parasellar skull base tumors.

He has written over 60 peer-reviewed articles and 20 chapters, and been an invited speaker over 40 times.

What is Neuropathy?

Peripheral neuropathy, also known as peripheral nerve disease, is one of the most common diseases most people have nerve heard of (15-20 million Americans have peripheral nerve disease). Caused by deterioration of the peripheral nerves, neuropathy disrupts the body's ability to communicate with its muscles, organs and tissues. Neuropathy is like the body's wiring system going haywire, causing unusual or unpleasant irritations including tingling, burning, itchiness, crawling sensation, dizziness, clumsiness and more. If ignored, as they too often are, these neuropathy symptoms can lead to numbness at one extreme to unremitting pain at the other. However, if diagnosed and treated early, peripheral neuropathy can often be controlled.¹

Nerve conduction studies/electromyography has generally been considered the gold standard for diagnostic testing in peripheral neuropathy. However, these studies evaluate only large-fiber function.

¹ The Neuropathy Association

Philips Lifeline Issues Safety Alert for Lifeline Pendant Personal Help Buttons

The U.S. Food and Drug Administration on September 22, 2009 cautioned users of personal emergency response buttons worn around the neck of a potential choking hazard associated with this product.

The FDA is aware of at least six reports between 1998 and 2009 of serious injury or death, including three deaths in the United States and one in Canada, from choking after the cord on the Philips Lifeline Personal Help Button became entangled on other objects worn around the neck. There are more than 750,000 users of these devices in the United States and Canada. By pushing the "help" button on the device when in distress, users can call for emergency assistance to their home. According to Philips Lifeline, the device is used primarily by seniors living independently, who feel they are at risk for falls or other medical emergencies.

The Lifeline pendant button is intentionally designed to not break away when tugged, which prevents the button from accidentally falling off. However, because it does not break away, there is a risk of choking, including the possibility of serious injury or death. Risks are greater for those with mobility limitations or for those who use wheelchairs, walkers, beds with guard rails, or other objects that could entangle with a neck cord.

Philips Lifeline is currently sending letters to its 750,000 customers and has changed the labeling of this product to include a warning against the potential choking hazard. The FDA recommends that users consult their health care providers to determine which style of emergency button, including those that are worn on the wrist, is most beneficial for them.

These widely used devices provide critical and immediate access to emergency care for those at risk of falls or who may be more likely to need outside assistance. While the number of adverse events reported is small compared to the number of people who use this device, the severity of these events is of concern. It remains important that users, along with their health care providers, assess the options provided by each style of button, and choose the option that best fits their condition.

FDA News Release, September 22, 2009

Save the Date!

**ASAP's Chiari & Syringomyelia
Conference
July 21 - 24, 2010**

**check-in Wednesday, July 21
check-out Sunday, July 25**

FDA Awards Grants Designed to Stimulate Development of Pediatric Medical Devices

Awardees will work with industry and the FDA to address unmet pediatric device needs

The U.S. Food and Drug Administration announced the awarding of three grants to stimulate the development and availability of medical devices for children.

A panel of six experts with experience in medicine, business, and device development reviewed 16 applications for the grants, which will be administered by the FDA's Office of Orphan Products Development.

The recipients and grant amounts include:

- James Geiger, M.D., and the Michigan Pediatric Device Consortium, \$1 million
- Pedro DelNido, M.D., and the Pediatric Cardiovascular Device Consortium, \$500,000
- Michael Harrison, M.D., and the University of California at San Francisco Pediatric Device Consortium, \$500,000.

Development of medical devices for children lags up to a decade behind similar devices intended for use in adults. Children differ in terms of size, growth and body chemistry and present unique challenges to device designers. In addition, the activity level and ability to manage some implantable or long-term devices may vary greatly among children.

“Congress provided the FDA with this funding so that we could help connect innovators and their ideas with experienced professionals who assist them through

development” said Timothy Cote, director of the FDA's Office of Orphan Product Development. “These grants will strengthen public health by spurring the development of medical devices that safely and effectively meet the special and unique needs of our children.”

Medical device legislation passed by Congress in 2007 established funding to be distributed as grants for nonprofit groups to help stimulate projects to promote the development and availability of pediatric devices. Those receiving these grants will:

- Encourage innovation and connect qualified individuals with good pediatric device ideas to potential manufacturers
- Mentor and manage pediatric device projects through their development, including prototype design and marketing
- Connect innovators and physicians to existing federal and non-federal resources
- Assess the scientific and medical merit of proposed pediatric projects and provide assistance and advice on business development, training, prototype development and post-marketing needs.

As part of the legislation, each of the grant recipients will coordinate among the FDA, device companies, and the National Institutes of Health's Eunice Kennedy Shriver National Institute of Child Health and Human Development to facilitate research and any necessary applications for device approval or clearance.

FDA News Release, September 21, 2009



Thank You, United Way Donors

Over the years ASAP has received thousands of dollars through the United Way program. When asked to fill out their United Way pledge form, individuals designate their donation to the American Syringomyelia and Chiari Alliance Project.

Most United Way organizations allow pledges to be designated to non-affiliated non profits. Located on the back of the pledge form is an area to assign your donation to a specific nonprofit organization.

Our appreciation to everyone who gives to ASAP through their local United Way.

Happy 2010

*We take this opportunity to thank all
our ASAP family and friends for their
generosity and dedication over the years.*

Remember ASAP...

When It's Time to Remember Loved Ones

Our appreciation to everyone who made a recent donation to ASAP on behalf of their friends / loved ones.

In Honor of

Donor
Holly & Hope Patterson
Daniel Murphy
Stuart & Sara Patterson
Udo & Marilyn Guddat
Amanda Stanley
Judy Hunt
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Margot Oppenheimer
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Barbara White
Leo Nelson
Adelle Grindall
Guy & Marlene Petersen
Shelly Mackowsky
James & Elizabeth Wurzer
Roxanne Kreyling
Paul & Carol Kreyling
Preston "Pug" Moore
Terry Kirkland
Wilbur Dubois III
Robert DuBois

To honor a loved one or a friend through a gift to ASAP. Send a check or money order to the ASAP office with the name and address of the person or family member you would like to honor.

An acknowledgement card will be sent in your name to the person honored or the family of a dearly departed friend or loved one for a donation of \$5 or more. Please include the name of the individual you wish to honor or remember.

Spread Awareness with an ASAP Business Card

Don't Just Tell People About CM/SM... Show Them!

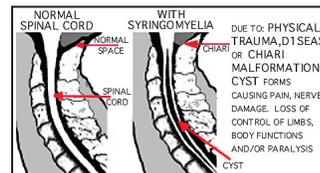
Jerry Lindner, an ASAP member, designed the cards. He prints them on his home computer and makes them available to others for a small fee to cover the cost of stock and ink.

To place an order, include the information you would like on the front of the card; it may also be left blank. Enclose a self-addressed stamped (one stamp) envelope with \$3.00 for 20 cards. Enclose a self-addressed stamped (two stamps) envelope with \$6.00 for 40 cards.

Mail to: Jerry Lindner
5855 Muir St.
Simi Valley, CA 93063

If you have questions: call 805-581-1344, or Email jlindner99@sbcglobal.net

	Your Name Street Address City, State, Zip Code Telephone No. Email Address
ASAP American Syringomyelia & Chiari Alliance Project Inc P.O. Box 1586 Longview, Texas 75606-1586 903-236-7079 Website: www.ASAP.org	



Free Ways to Help ASAP Raise Funds

Every time you shop at any of 700+ online stores in the iGive network, a portion of the money you spend benefits American Syringomyelia & Chiari Alliance Project, Inc. It's a free service, and you'll never pay more when you reach a store through iGive. In fact, smart shoppers will enjoy iGive's repository of coupons, free shipping deals, and sales. To get started, just create your free iGive account. And when you search the web, do it through iSearchiGive.com where each search means a penny (or more!) for our cause!



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FDA Orders Postmarket Surveillance Studies on Certain Spinal Systems

FDA to request premarket clinical data for new versions of these devices

The U.S. Food and Drug Administration ordered manufacturers of certain types of pedicle screw systems, called dynamic stabilization systems, to conduct postmarket surveillance studies to collect clinical data on a number of potential safety issues, including fusion rates and frequency of additional surgeries.



Dynamic stabilization systems are used in spinal surgery and some are intended to provide stabilizing support to the spinal column during bone fusion. Currently, there is not enough clinical data to determine whether these dynamic stabilization systems provide enough spinal stability to allow for complete spinal fusion, as the system components may loosen, bend, or break over time. If fusion does not occur, a patient's condition could worsen and possibly require additional surgical procedures.

The FDA is requiring postmarket studies to address these potential risks for systems already on the market. In addition, the FDA is requesting manufacturers with new dynamic stabilization systems or components to submit clinical information for agency review prior to marketing.

The FDA is not recommending any changes regarding the use of dynamic stabilization systems until it collects and reviews clinical data to better understand how these devices are being used. Patients who have or are considering the implantation of a dynamic stabilization system should consult with their health care practitioner.

Dynamic stabilization systems have different design features that allow bending or rotation while still facilitating fusion. Components used to achieve this flexibility include polymer cords, moveable screw heads, and springs.

Traditional, rigid stabilization systems have been on the market for decades, and provide stability via screws inserted into segments of the spine. The screws act as anchors that are then connected by uniform metallic rods, which immobilize the spinal segments and facilitate fusion. These systems are not intended to allow motion.

When intended as stabilizers during bone fusion, this type of device is class II and is subject to FDA's premarket notification requirement (also known as 510(k)). Devices subject to this requirement are cleared for marketing in the United States if FDA finds them to be substantially equivalent to legally marketed predicate devices.

The FDA cleared the first dynamic stabilization system component in 1997. The FDA has cleared numerous dynamic stabilization systems or components since then.

FDA has only ordered postmarket surveillance studies for the class II dynamic stabilization systems and components, which are intended for bone fusion.

The FDA has required the manufacturers of 16 dynamic stabilization systems or components on the market for spinal fusion to conduct postmarket surveillance studies, which must address the following:

- the fusion rate for dynamic stabilization systems compared to traditional stabilization systems;
- the incidence rate, severity, and time course of adverse events for dynamic stabilization systems compared to traditional stabilization systems;
- the type, incidence rate, and time course of subsequent surgical procedures for dynamic stabilization systems compared to traditional stabilization systems; and
- the cause of failure for dynamic stabilization systems based on analysis of all reasonable available systems that have been removed from patients, along with any association between the patient's demographic and clinical data and the device failure.

In reviewing the clinical data gathered from the postmarket surveillance studies, the FDA will consider whether labeling changes or additional preclinical and clinical testing requirements are necessary for these devices.

FDA News Release October 5, 2009
Consumer Inquiries: 1-888-INFO-FDA

Miracle Wish for Chiari

continued from page

was well represented in Karen Spiroff, Patrice Schaublin and myself. We had the opportunity to publicly thank Leann Vercher of Miracle Wish for Chiari for partnering with us and to speak about our work. In addition, ASAP was thanked over and over again by the participants for our involvement.



The biggest impact on me was seeing children be children. The laughter and smiles spoke volumes.

I spoke with Dr. Sim about ASAP coming back next year. We did not get a firm commitment although he did say that he would do everything he could to make this happen.

The American Syringomyelia & Chiari Alliance Project (ASAP) is a tax-exempt 501(c)(3) organization. Our goals include providing a clearinghouse for information on syringomyelia (SM), Chiari malformation (CM), and related conditions. We offer a supportive network of programs and services and fund research to find better therapies and cures. ASAP is supported by tax deductible donations.

ASAP Connections is published bimonthly for ASAP members. Your articles, letters to the editor, etc. are encouraged. The deadlines for these submissions are the 1st of February, April, June, August, October and December. The editor reserves the right to edit any article in order to accommodate space. Please send newsletter suggestions to: Patricia_Maxwell@ASAP.org or ASAP, PO Box 1586, Longview TX 75606

Patricia Maxwell Editor, *ASAP Connections*

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