The Scoop on Heparin

Lisa Crosby Metzger

Over the last few months, there have been several recalls of heparin due to adverse events associated with the product. Several hundred adverse events—from nausea and headaches to rapid heart beat and low blood pressure—have been reported, as well as up to nineteen deaths. Nearly all these adverse events have been associated with larger doses of heparin (5,000 to 50,000 units) given as a bolus, or over a short period of time. A typical heparin flush is in the range of 50 to 1,000 units; as of late March, no adverse events had been reported in association with heparin flushes. Also as of late March, scientists were working to establish if there was a causal connection between the heparin, which was found to be contaminated, and the reactions that were reported.

The recalls started with a limited lot of multi-dose vials but were later expanded to include single-dose vials and heparin flush products. As of late March, the recalls included:

- American Health Packaging—1,421 units (25 vials per unit) of 10,000 USP units/ml heparin sodium injection 1ml vials (vials were manufactured by Baxter and placed by AHP into individually labeled bags for use in pharmacy automation equipment; voluntary recall issued March 20, 2008)
- B. Braun Medical, Inc.—twenty-three lots of heparin sodium injection vials recalled in United States and Canada (voluntary recall issued March 21, 2008)

Experiences are shared in small groups at Oley conferences.
Heparin, from pg. 1

- Covidien Ltd.—thirty-two lots of prefilled lock flush syringes (voluntary recall issued March 28, 2008)
- By late March, recalls had also been issued in Germany, Japan, Canada (see B. Braun, above), Italy, Denmark, France, and Australia.
- Check Oley’s, FDA’s, or the companies’ Web sites, or call the Oley offices for up-to-date information about the recalls.

Reactions
The adverse, allergy-like reactions cited in the Baxter recall notice include stomach pain or discomfort, nausea, vomiting, diarrhea, low blood pressure, chest pain, rapid heart beat, dizziness, fainting, shortness of breath, and headache. The Baxter news release states that “nearly all reported adverse reactions have occurred in three specific areas of product use—renal dialysis, invasive cardiovascular procedures and apheresis procedures” (done to separate blood components from whole blood) and that the “vast majority of the reports...have been associated with the multi-dose products” (February 28, 2008).

As of late March, Baxter had received approximately six hundred heparin-related adverse reaction reports. The FDA also had reports of several deaths possibly associated with the use of contaminated heparin (numbers reported range between four and 19, depending on the source). In a March 19 statement, Baxter noted that it was “continuing its efforts to determine if there is a link between the contaminant and adverse reactions, using additional advanced testing.”

Regarding heparin flushes, in a March 19 media briefing, Dr. Janet Woodcock, director of the FDA Center for Drug Evaluation and Research, said, “To our knowledge we haven’t had any adverse events reported with...these types of devices...that have small volumes of heparin.”

New Testing
In a statement available on the FDA Web site March 7, the FDA said, “After conventional testing did not prove useful in detecting these contaminants, FDA experts developed new test methods that use existing state-of-the-art technologies....FDA scientists determined that the sampled products contained 5 percent to 20 percent of a heparin-like compound—a contaminant that mimicked heparin activity so closely that it was not recognized by routine testing.” As of late March, it was still unclear if this substance was the cause of the adverse events, but many of the manufacturers who supply imported heparin to the United States have agreed to implement the new tests.

The heparin-like substance has been identified by the FDA as oversulfated chondroitin sulfate. Both raw heparin and chondroitin are derived from pigs, but the FDA noted that oversulfated chondroitin sulfate does not occur naturally.

In searching for the source of the contamination, as of late March the FDA was looking at a plant in Changzhou, China, which is owned in part by Wisconsin-based Scientific Protein Laboratories. On March 14, the FDA stated it had obtained 28 active pharmaceutical ingredient (API) samples at the Changzhou plant, and “using our screening tests we found that 20 of these samples had heparin-like contaminant.”

Production
The heparin supply chain can be fairly long and complex. In one scenario, heparin manufacture begins in small workshops in rural China, where pig intestines are scraped, boiled, and cleaned. This process creates raw heparin (interestingly, it also produces sausage casings). Sometimes the raw heparin goes directly from a workshop to an API manufacturer, and sometimes it goes to a consolidator. A consolidator combines the raw heparin from several workshops before supplying it to a factory for the production of heparin API. Finally, different heparin manufacturers or distributors then purchase the API for use in their heparin solution. The Baxter, American Health Packaging, B. Braun, and Covidien recalls are all because the recalled products contain or may contain API from the plant in Changzhou.

On March 19, Baxter’s corporate vice president and chief scientific officer, Norbert Riedel, Ph.D., noted, “The hypersulfated chondroitin sulfate is not only found in the active pharmaceutical ingredient (API) we use to make our heparin, but in the crude material used to make the API. That means that this contaminant was very likely introduced at the workshop or consolidator level, before it reached our API supplier [the plant in Changzhou] and definitely before it reached Baxter.”

While not all heparin is produced with such a diverse supply chain, and not all API originates in China, this production sequence does raise concerns about further recalls. The initial recall of several lots of Baxter heparin

Heparin, cont. pg. 11
Equipment/Supply Exchange

MANY SUPPLIES are available! New items are added regularly and are available free of charge. We have rotating supplies of:

• Formula, such as Isosource 1.5, Replete, Jevity, and Nutren
• Bags, such as Ross Embrace, Ross Companion, and Compat
• Supplies, including tubing, pump sets, ostomy supplies, etc.

For details on what's available currently, how to acquire it, or how to donate, visit www.oley.org or contact our volunteer, Ben Hawkins (benhawkins@fuse.net or toll free 866-454-7351). This number reaches Ben’s home, so please call between 9 a.m. and 9 p.m. EST. ALSO, please let Ben know whether or not you take the items referred to you. If you can’t use them, he can make them available to other members. Oley cannot guarantee the quality of the supplies donated or be responsible for their condition. We ask that those receiving goods offer to pay the shipping costs.

Soothing Skin Irritation

Our son, Matthew, was diagnosed with pseudo-obstruction syndrome of the small bowel and had a G-tube placed a few months before his second birthday. The nurses told me about a concoction that they called “butt paste.” They said it was the best ever for any skin irritation. They made it with equal parts of Desitin, Mycostatin powder (or you can substitute any anti-yeast cream), Neosporin ointment (or generic), and hydrocortisone cream (over the counter).

When Matthew started having problems with persistent granulomas, the doctors wanted to use silver nitrate to clean up the site. They told me it would burn and so I told them not to use it. I tried the butt paste instead and it worked beautifully.

Matthew is twenty-one years old now and we have had several comments from medical professionals and special education school personnel about how healthy and clean his stoma looks. I have tweaked the concoction over the years. I’ve deleted the Desitin and added Prep H (or generic) ointment. I use just a small amount on the stoma after every bath. It works. The site is healthy and not painful at all.

—Teresa Madden
lbmaddenmom@aol.com

Editor’s note: There are some concerns amongst our medical advisors about chronic use of topical steroids and antibiotics (Neosporin and Mycostatin). Also, one of our medical advisors adds, “Butt paste is aquaphor jelly cholestyramine in my lexicon.”

Welcome to the Forum

You asked for it! The Oley Foundation’s online discussion forum is now up and running. The forum is a great way to meet other HPEN consumers, friends, and family members with similar concerns. Share your stories, support, and information. We’ve suggested some topics, like travel and parenting, but you can start your own discussion threads as well. To learn more about the discussions and join in, go to www.oley.org, “Meet Patients.”
My First Conference
Lisa Crosby Metzger

I went to the Oley conference in Cape Cod last year as a new staff member, but also with a little personal experience of parenteral nutrition (PN). And while Cape Cod was familiar turf for me, in the last several years conference experiences had become foreign. From the time my oldest child was born until starting at Oley, I'd worked as a free-lance editor; for twenty years it was largely just me, a manuscript, and a red pencil. Going back to working in an office was an adjustment, and with the conference looming before me, I felt overwhelmed by the unknown.

Oley members who consider going to the conference for the first time may feel some similar apprehension. What can you expect at an Oley conference? In my limited experience, it's busy, but it's not unmanageable. There's lots of help, and people everywhere to answer questions. The people I met at the conference were warm, welcoming, and open. This is an exceptional group of people who give so much despite the challenges they face.

And while a full schedule is offered at conference, there is down time. You also always have the option of passing something by if you are just too tired. I was grateful for the opportunity to sit with Oley members at the meals provided and to visit at other events. The opportunities to talk to other members and professionals were abundant. All in all, I was impressed by what a small staff, with the help of incredible volunteers, could accomplish.

Being amongst so many homePEN consumers as someone who was briefly on parenteral nutrition evoked some other, unexpected, deeper reactions from me. I was on PN for about five months during each of two pregnancies. My kids are now young adults (nineteen and twenty-one), and very healthy. I don't think we would have made it through without PN, but there were times when I didn't think we'd make it through with PN, either.

A lot happened in the ten months I was on PN. I had a pneumothorax, blood transfusions (twice), chest tubes (twice), a line infection, and...
Darla: Oley’s Newest RC

Darla Edwards of Fairfield, California, has recently volunteered to join the ranks of Oley Regional Coordinators. We are so pleased to welcome her. Darla is a full-time college student, majoring in child psychology, and she brings with her a lot of experience, energy, and enthusiasm.

When Darla was just two years old, she was diagnosed with congenital intestinal lymphangiectasia. Since then she has received additional diagnoses of secondary protein-losing enteropathy, secondary hypogammaglobulinemia, asthma, and spinal osteopenia. Darla was parenteral-nutrition (PN) dependent for eight years and also received enteral (EN) nutrition through a G-tube. She has experienced beginning-stage liver failure and pitting edema, and suffers from compromised immunity.

Now in her early twenties, Darla is currently off PN. She still receives intravenous immunoglobulin (IVIG) and protein infusions. She is employed as a part-time child daycare provider and spends her free time drawing, singing, dancing, and doing jigsaw puzzles. She believes it is important to set and achieve goals in spite of the challenges put forth by her diseases. Darla hopes that by sharing her medical experiences and personal knowledge, she will be able to help other Oley members. She is very interested in developing local fundraisers and searching for new outreach avenues.

Darla can be reached at 2764 Shearwater Way, Fairfield, CA 94533; (707) 437-0241; or Cookie0241@aol.com.

Recognize Someone Special

Oley Award Nominations

The Oley awards give us each a chance to acknowledge someone in our life who has inspired us by their courage, perseverance, or willingness to help others. Nominate someone who has earned your respect because of what they have overcome or inspired you by how they live.

The significance of being nominated is great by itself, as each nominee will be recognized at the Oley conference in San Diego, CA. Combine this with the potential of a travel grant, and this is awesome!

Ring your own bell!

Don’t resist nominating yourself. Tell your story, or share examples of how you have helped others. At the very least, it will motivate other consumers.

It’s FREE and easy!

A simple form with three, quick questions is all you need to complete. Find it on our Web site, www.oley.org, or request a form from Cathy Harrington at harrinc@mail.amc.edu. Just type in your answers — fax it, mail it or click “submit” — and you’re done. Send as many forms as you’d like.

Questions?

Call (800) 776-OLEY or visit www.oley.org. Award nominations must be submitted by April 25, 2008.
Meet Tim Weaver: A Teenager on the Go

Todd Friedman

Tim’s diagnosis of Hirschsprung’s disease has necessitated that he receive parenteral or enteral feedings since he was three days old. But you would never know by looking at him that he has any kind of health condition whatsoever.

I had never met Tim until the Oley regional conference in Chicago, Illinois, earlier this year, though I had agreed to write this article about him and I had met his mother, Ann, once or twice. When I first sought Tim out once the conference had started, I couldn’t find him. I did notice a young man about five foot five with a healthy-looking build standing at a table next to mine during one of the presentations, but it didn’t even occur to me that he could be thirteen-year-old Tim. I initially thought this young man was perhaps a student in high school who was at the conference lending support to a relative on parenteral (PN) or enteral (EN) nutrition.

But that’s the beauty of being on PN and/or EN feedings! They keep many of us so healthy that it is sometimes very difficult to tell who the patients are at Oley conferences and other gatherings for homePEN consumers.

Trouble at Birth

Tim has been on PN and/or EN feedings essentially since birth. Doctors actually knew that something was amiss when Ann was thirty-one weeks pregnant with him. Her ultrasound showed that ‘Tim had a dilated (enlarged) bowel, which is sometimes indicative of an obstruction. When Tim was born, he was diagnosed with Hirschsprung’s disease. Hirschsprung’s is a condition where nerve cells that are responsible for peristalsis don’t descend into the lower intestinal tract. The absence of these nerve cells make passing stool difficult or sometimes not possible at all, thus causing an obstruction.

Hirschsprung’s is often detected at birth as infants don’t pass meconium, which also contributes to difficulty having a bowel movement. Hirschsprung’s is frequently diagnosed with a rectal biopsy; in Tim’s case, it was discovered when he underwent exploratory surgery at three days old. During this surgery, the doctors discovered that Hirschsprung’s had affected Tim’s entire colon, all of his ileum, and half of his jejunum. All of this portion of Tim’s intestinal tract had to be surgically removed. This surgery left Tim with only 51 centimeters of bowel, and dependent on PN.

When Tim was only two weeks old, his parents were asked, “Do you want to do anything more?” Several physicians felt that Tim’s condition was incompatible with life. These physicians told Tim’s parents, Ann and Mike, that Tim would need PN to survive, and that the PN would lead to liver failure and, ultimately, to Tim’s death. The physicians felt that it might be better for Ann and Mike to let go—before they became too attached. Fortunately, Tim’s parents obtained a second opinion.

Tim was PN dependent for several years, but his PN was gradually reduced as his bowel grew and as he tolerated increases in his EN. By the time Tim was three-and-a-half years old, he was completely off of PN and was growing from a combination of EN and oral intake. He kept his central line for an additional four years for hydration. Tim currently receives 1400 ccs of formula through his gastrostomy tube (G-tube) nightly, eats multiple meals throughout the day, and takes an additional liter of electrolyte solution.

Teamwork

While many kids Tim’s age are dependent upon their parents to help them hook up to and disconnect from their PN and/or EN feedings, Tim manages his own EN feeding care. He changes his button, hooks himself up to his pump each night, and disconnects himself from his pump in the morning. Tim has been mixing his own formula and taking charge of his own care since age six or seven. Now thirteen, he feels he really mastered the entire process about five years ago.

A good part of Tim’s success health-wise can be attributed to his having a very supportive family and an outstanding doctor managing his care. Tim is treated for his illness at Children’s Memorial Hospital in Chicago, and he had wonderful things to say about the phenomenal care he has received there over the years. Tim’s doctor has followed him since he was a month old and both he and Ann are comforted in knowing that they can call her any time day or night.

School Days

Tim’s doctor is very proud of all that Tim has accomplished thus far in spite of his having a challenging health condition—as she should be! Not only does Tim have an admirable positive mental attitude with regards to his care, but he also earns all As and Bs in school! In addition to maintaining an impressive grade point average, Tim also enjoys playing the tuba in the school band.

Tim does a conscientious job of managing his enteral feeding regimen, and he has managed to avoid being hospitalized for more than a week at a time. This permits him to keep up with his schoolwork. Other than the occasional button leak or challenge in tolerating his formula if his gut is having a bad day, Tim has enjoyed good health with few serious complications over the years.

Tim prides himself on blending in with his classmates and not calling a lot of attention to his health condition. In fact, when he wears the backpack that carries his EN formula to school, many of
the other students and teachers have mistaken it for a Camelback®, which holds regular water. While Tim does keep a low profile about his health condition, the teachers and faculty at school are aware of it, and they are very accommodating when necessary. Tim has received an extra set of books for home just in case he is too sick to make it to school and needs to take a day or two off. Tim also takes the books with him on the rare occasion that he needs to be hospitalized.

In order to keep well hydrated during the day, Tim keeps plenty of water bottles in his “learning team’s” office. He is also permitted to use a private bathroom at school if and when he needs to change his ostomy bag. While some kids in junior high school can be cruel to those who are different, Tim’s friends at school are very accepting of his illness and they don’t treat him any differently than they treat everybody else.

Go White Sox!

Tim’s hobbies and interests are very diverse. In addition to playing the tuba, he also plays the bass guitar. Like most thirteen year olds, Tim also loves playing Golden Tee, video games, and chatting with friends online. Tim has also recently joined an online fantasy baseball league.

Speaking of baseball, Tim is a fervent fan of the Chicago White Sox. He tries to go to one or two White Sox games per year at U.S. Cellular Field, and he especially enjoys attending Elvis Night, an annual event where many fans go to the game dressed like Elvis Presley. Being one of the White Sox’s biggest fans, Tim was thrilled when they won the World Series in October 2005. Lastly, Tim loves to play golf and go bowling. In fact, Tim’s high game in bowling is an impressive 186!

Tim also has a philanthropic side. To raise money for kids to attend ostomy camp, he sells raffle tickets at the local ostomy association meetings. He also volunteers at Friends of Ostomates Worldwide (FOW), which provides ostomy supplies to ostomates in Third World countries.

Because Tim studies hard and applies himself during the school year, he welcomes the summer months to engage in some well-earned recreation and relaxation. Tim has enjoyed attending Double “H” Hole in the Woods camp, which is located just north of Saratoga Springs in upstate New York. This camp, along with the other Hole in the Wall Gang camps, is supported by the Newman Foundation. These camps provide children and teenagers who have long-term chronic illnesses the opportunity to take part in the overnight camp experience. During Double “H” Camp, Tim’s favorite activities included going horseback riding, attending a carnival, arts and crafts, and an excursion to a local

Meet Tim Weaver, cont. pg. 15

Tim with Jana, a counselor at Double "H" Hole in the Woods camp.
For Twenty Years, Group Has Gathered for Support

“Our Oley support group has been a tremendous help to me in coping all these years,” says June Bodden, who has been totally dependent on parenteral nutrition (PN) for twenty-three years. “The support of all my Oley friends has made all the difference in my life.”

In March, June and twenty-six others celebrated the twentieth anniversary of the Oley–Tampa Bay support group. Friends, family, and members of the home health community gathered at the H. Lee Moffitt Cancer Center to share their personal histories and their friendships. Several nurses present told about caring for people in the early days of homePN.

Personal Histories

June was diagnosed with, as she says, “what now is known as Crohn’s disease” when she was fifteen. She experienced several years of flare-ups and surgeries. In 1984, “adhesions and gangrene required emergency surgery. The doctor tried me on enteral feedings, but I continued becoming dehydrated. Then, after six months, six hospitalizations, and five surgeries, a Hickman catheter was placed and TPN therapy began.”

“A note arrived with my therapy supplies in November 1986,” says June. “It was from Madalyn Goldfarb, a TPN patient. For the first time, I knew someone was out there doing TPN like me! I phoned her immediately. She told me she had been doing infusions for nine years. Then she told me about the Oley Foundation. I had been on hydration and TPN without knowing a soul for two long, lonely years! Madalyn also had an ileostomy and Crohn’s disease. We met in October 1987, when my mother and I went to see her.”

For Nancy Backinger, “Crohn’s disease began in 1968. I was thirty-eight years old.” She continues, “I had seven resections due to Crohn’s [in the 1970s and 1980s], and in May 1988, I had surgery for a major flare-up and was given a jejunostomy. In June 1988, a Broviac catheter was placed and TPN was started. I joined the Oley group in 1990.” Nancy has had a series of infections, with the most recent hospitalization as recent as this February. But Nancy ends this chapter of the story with a smile and a determined, “This story will be continued!”

Diane Wagner was also diagnosed with Crohn’s disease, and later with pseudo-obstruction. But, she says, “the Lord is good. Although I have had lots of physical challenges, the Lord has truly been good to me and carried me through all the way.” She has been on and off parenteral and enteral nutrition since the spring of 1992, and currently is on neither therapy. “But I have lost my appetite (resulting in a big weight loss) over the last few months,” she told the group. “The doctor is concerned about my nutritional status and I may need to go back on some sort of nutritional therapy.”

“My name is Linda Stokes. I am sixty-one years old,” says Linda, introducing herself to the group. “I have been battling Crohn’s disease since my middle twenties. I was misdiagnosed for about five years before they decided it was Crohn’s: nervous stomach, spasitic colon, all in my head, etc. etc.” When Linda was thirty-one, her doctor discovered a cyst on her ovary and she went to have it removed by laparoscopic surgery. “Unfortunately, I woke up in recovery eight hours later with a complete hysterectomy and a section of my bowel removed. The Crohn’s had destroyed my female organs during those years that I was in tremendous pain. That was the beginning of many hospitalizations for resection surgeries and to receive TPN to build myself back up.” In 1986 Linda went on homePN.

“I am so fortunate,” Linda says, “because I have only had three Hickman catheters (in only two sites) since 1986. I have never had a line infection and I am so grateful for that.” “I don’t let PN control my life,” she concludes, “but I know I have to get those thirteen hours every night so I just schedule my activities around this and do anything I want—no problem. I am just so thankful that the PN process can be done at home instead of in the hospital as it was years ago.”

Portia Hutton attended the support group meeting with her husband, Wally. Portia is very succinct with her story: “I had a blood clot in March of 1999, so they removed all but about six inches of my small intestine and about half of my large intestine. I am on my third pump and for over two and a half years have been battling an infection of Mycobacterium fortuitum, which they have decided is systemic. I feed for fourteen hours, seven days a week.”

Encouragement, Friendship

Over the years, attendance at the support group meetings has ebbed and flowed. “Linda and I are the only remaining HPNers from our original meeting in 1988,” says June. “Since then, others have come to our meetings and the encouragement and friendships have grown. Meg Cass-Garcia has been our dedicated medical advisor since day one. She also is our historian—she has every meeting notice and LifelineLetter for the entire twenty years!”

A special event at the meeting was the reunion of Nancy Davenport, now the branch manager of Coram in Tampa, and Nina, an exuberant nine year old. Nancy was one of the nurses who worked with Lesley Marino when Nina was an infant.

The group celebrated the twentieth anniversary with photo albums, display boards, banners, and balloons, and was pleased to receive Coram’s Celebration of Life award from Coram representative Linda Gravenstein. June notes, “We were all disappointed that Joan Bishop [Oley’s executive director] got the flu and was unable to join us. Joan, you were greatly missed! Everyone here recognizes the tremendous strength and support we have received from the Oley Foundation and its members. And we hope and pray it will continue for many more years.”

“It has been a privilege and a pleasure to work with June and her group,” Joan responded recently, “whether we are coordinating a response to someone in need, planning an event, or brainstorming ideas. It is courage and determination that serves as the backbone for all that June does and this translates into sheer energy and inspiration to everyone in her path. I cannot think of anything more rewarding than an opportunity to spend another twenty years standing behind June and her efforts!”

Thanks to the following for their generous support of this event: Meg and Margaret Carter from Moffitt; Coram; InfuScience; and Option Care.
Book Explores Diet and Inflammatory Bowel Disease
Michael Medwar

When I was diagnosed with Crohn’s disease, almost thirty years ago, patients were instructed to follow a low-roughage diet. This basically meant that almost any fruit or vegetable you could think of—and a few other items you wouldn’t expect, like ketchup—should be avoided. More recently, knowledge about diet and its effect on the health of inflammatory bowel disease patients has expanded far beyond the relatively simple doctor’s orders of the past.

To help give IBD sufferers direction in this philosophy, registered dietitian Tracie Dalessandro has penned *What to Eat with IBD: A Comprehensive Nutrition and Recipe Guide for Crohn’s Disease and Ulcerative Colitis.* Tracie was diagnosed with ulcerative proctitis at nineteen; this progressed to ulcerative colitis and then to Crohn’s by the time Tracie was thirty-one. Tracie’s book is split into two parts. The first part looks at nutrition, food choices and healing, and the second contains more than fifty nutritional IBD-friendly recipes.

**The Book**

Tracie does a good job breaking down nutrition and the diseases into practical terms. She says having IBD (inflammatory bowel disease) is like having an open wound in your intestine and asks you to think about what makes sense to rub on those wounds. Choosing foods that soothe or heal the bowel, not irritate it, are the way to go.

She points out that the healthiest foods are not always suitable for IBD patients. Whole grain wheat bread may be great for the rest of the population, but for IBD (and irritable bowel syndrome, she adds) she doesn’t recommend it. Tracie explains that whole wheat bread contains insoluble fiber, which draws water into the GI tract, as opposed to soluble fiber (oats for example), which is beneficial because it absorbs water.

Tracie talks about choosing peeled fruits and well-cooked vegetables that won’t cause pain and also add a high nutrition element. Cooked apples, bananas, cantaloupe, watermelon, butternut squash, carrots, and very-soft broccoli are among the items on her list of foods that heal.

But a good diet doesn’t stop there. Tracie talks about all the major vitamins and minerals and other necessary supplements, the importance of each and the best sources to get them. She also explains why you should avoid high-fat meals that can be malabsorbed and the importance of high-quality proteins, food safety, and planning your meals.

I haven’t tried any of the recipes yet, but they look tasty and easy to prepare. The recipes cover snacks, to entrees to desserts.

**Another Chapter?**

The only topic in this book that Tracie could have focused on just a bit more is fluids. She does say that when diarrhea is present, at least ten glasses of fluid should be consumed per day. She says water is best, but when a person has severe electrolyte losses, “sports drinks diluted with water are acceptable.” This could have been explained further, because, as I’ve heard at many Oley conferences, for people with short bowel, drinking water is counterproductive and rehydration fluids should be sipped throughout the day.

But overall, Tracie has written an informative, interesting book with useful recipes. It does a service to IBD sufferers and further reminds us how important diet and nutrition are in living with these diseases.
Chicago, from pg. 1

In the morning, Darlene Kelly, MD, PhD, FACP, calmed the chatter in the room and introduced the speakers: Doug Seidner, MD, FACG, CNSP; Laura Matarese, PhD, RD, LDN, FADA, CNSD; and Lyn Howard, MB, FRCP, FACP. Dr. Seidner gave a comprehensive overview of different parenteral (PN) and enteral (EN) devices, while Dr. Matarese offered suggestions on how consumers could customize tube feeding to fit their lifestyles. As Dr. Matarese concluded, “It is important to be responsible, but you can also be flexible.” Dr. Matarese’s presentation is available online at www.oley.org (under “Tools for Better Living,” “Tube Feeding Tips”).

The final address of the morning session was “Hot Topics in HPEN.” Dr. Howard, Oley’s Medical and Research Director, focused on new studies that show liver failure is rare in well-managed adults and children, as well as how fish oils may be safer than plant oils in pediatric PN solutions. Dr. Howard also explored the potential for standard trace element solutions in PN to be toxic, and talked a little about the 2009 Clinical Nutrition Week Research Workshop, which will address the PN requirements for micronutrients (trace elements, vitamins, and small additives such as choline and carnitine).

Traffic at the exhibits was brisk through lunch, and then we broke into three roundtable sessions, where conference-goers had the opportunity for more personalized discussion on a variety of topics. Alan Buchman, MD, MSPH, FACN, FACP, FACG, AGAF, addressed the issues involved in reducing homePN dependency; those at the table of Jon Fryer, MD, discussed the issues involved in being evaluated for intestinal transplant; Dr. Matarese and those at her table shared some practical solutions for tube-feeding problems; and Timothy Sentongo, MD, gave considerable thought to questions posed on a number of pediatric issues.

This one-day conference was supported in part by the Daniel E. and Ada L. Rice Foundation. You can borrow a DVD of the conference free of charge from the Oley video/DVD library. (You can find information about this and other videos and DVDs available from the Oley video/DVD library. You can find information about this and other videos and DVDs available from the Oley video/DVD library at www.oley.org (under “Tools for Better Living,” “Tube Feeding Tips”).)

Clinical Nutrition Week

For several in the Oley community, the one-day conference was a brisk kickoff to a very busy week in Chicago: Clinical Nutrition Week (CNW), presented by the American Society for Parenteral and Enteral Nutrition (A.S.P.EN.).

Clinical Nutrition Week brings together researchers and clinicians in the field of homePEN from around the world, and offers exciting learning opportunities. Oley staff attended lectures and visited exhibits to gather information about the latest research pertaining to homePEN. Our goal was to seek the information that would be most useful to you, our Oley members.

Oley was also at CNW to share information with clinicians who provide care to people on IV and tube feeding. At A.S.P.EN.’s invitation, Oley put together a panel that included Oley trustee and HPN consumer Sheila Messina, MA, RN; Oley Regional Coordinator Ann Weaver, an HPEN caregiver; Tim Weaver, an HPEN consumer; and Oley Executive Director Joan Bishop. Sheila, Ann, and Tim spoke from the heart about what it means to live with HPEN, and Joan gave an overview of Oley’s programs. A DVD of this session is also available from the Oley video/DVD library.

The Oley booth in the exhibit hall, sparkling with silver balloons and stars in honor of Oley’s twenty-fifth anniversary, was seldom quiet. Oley staff and volunteers, including Oley President Rick Davis, answered questions and passed out hundreds of informational brochures, posters, and Keep Me Safe bracelets. We couldn’t have done it without the help of the volunteers, and offer many thanks to Terry Edwards, Kathleen and Larry McInnes, Patricia Tabron, and Ann Weaver.

The Oley staff came back tired, but brimming with ideas from CNW, and, as always, inspired by the Oley members whom we met.

First Conference, from pg. 4

the cap come off my line once while I was sleeping. During the first several months of my second pregnancy, we had no health insurance. Before the placement of my first line, my obstetrician really seemed to think that I could stop vomiting if I tried (his idea only planted counterproductive feelings of guilt and self-doubt).

It was a tough time for us. But it wasn’t clear to me until last summer that it has been hard for me to let go of some of the difficulties from that time. I’ve had a lot of questions, but I never sought the answers. In fact, I think it’s safe to say I avoided any answers. I was busy raising those kids, and I tried to never look back too deeply.

Taking the job with Oley and consequently attending the conference, learning about parenteral and enteral nutrition, and meeting others who have overcome similar—but so much more difficult—circumstances has given me a lot of answers, as well as a welcome perspective on my own experience. I’ve learned that the events that marked my pregnancies were exceptional, and that they weren’t. And I’ve learned to better understand gratitude, true gratitude for all the things that were done right that allowed my two wonderful children entry into this world.
solution, which became a broader recall (once Baxter and the FDA determined that a more general recall would not result in shortages), has expanded to a recall by several manufacturers in several countries. On March 26, the Wall Street Journal reported that heparin linked to adverse events in Italy appears to have originated at a different API production plant in China. This producer supplies APP Pharmaceuticals, Inc., another large distributor of heparin in the United States. If API produced at another plant is found to be contaminated, it is possible that more heparin will be recalled.

It is significant to note, however, that the recalls issued thus far seem to have served the desired purpose. In a press conference on March 14, Dr. Woodcock stated that since the recall, “we [the FDA] have not received a report of a death from this.” She went on to say that, since the recall, “We are not seeing a cluster of events like we saw earlier.” Dr. Woodcock urged that any adverse events be reported to the FDA’s MedWatch, with as much information and detail as possible (www.fda.gov/medwatch/report/hcp.htm or 800-FDA-1088).

FDA Protections

In its media briefing March 19, FDA representatives spoke of greater cooperation with Chinese authorities than existed a year ago, when the FDA sought to investigate the source of contaminated pet food. In December 2007, the United States and China signed a Memorandum of Agreement (MOA) designed to enhance the safety of drugs, excipients (inert substances used in drugs), and medical devices imported to the United States from China.

Provisions of the MOA include: a requirement that many Chinese drug producers register with the Chinese government; development of a joint U.S.-Chinese certification program for certain drugs exported to the United States; greater access for U.S. authorities to Chinese production facilities; establishment of a tracking system to protect against counterfeiting; and establishment of a system to ensure information sharing between the two governments.

In late March, the FDA took steps to ensure that imported heparin and heparin API will be tested using the newly developed tests, either by manufacturers themselves or by the FDA.

Summary

How does this affect you? It’s important to note that as of late March, no adverse events were reported in association with heparin flush syringes, and most of the adverse events reported were linked to procedures that require larger doses of heparin. The recall of the prefilled syringes was issued as a precaution, since the products recalled might contain the contaminated API. The FDA advises that you do not use any of the recalled products; please consult your home care company to arrange for their return or disposal.

By the time you read this, the heparin recall might be old news. Or it might be front-page news. It’s hard to say. But what does seem certain is that these recalls will generate further discussion about how we can best ensure the safety of products—including the medicines—we import. And that will have an impact on all of us.

Heparin, from pg. 2

As of late March, no adverse events were reported in association with heparin flush syringes.
Seeking Auction Items

In the past, Oley’s silent auction—held at the annual conference—has raised thousands of dollars! Please consider donating something others will enjoy bidding on, even if you can’t attend the conference. Your support means so much!

Need ideas? Items donated in recent years include items created by Oley members, such as quilts, photos, paintings, scarves, and afghans; electronics, such as MP3 players, radios, and televisions; gift certificates and baskets; certificates for travel opportunities, such as time-share units, vacation packages, and airfare; tickets to sporting events, concerts, and tourist attractions; DVDs and CDs, games, and toys. The possibilities are endless! We have an excellent letter available that describes Oley and the auction if you need help appealing to local vendors, businesses, friends, or family for donations. Call us and we’ll send you copies.

Items can be brought to the Oley registration desk at the Marriott on Friday morning or mailed to the Marriott (San Diego Marriott Mission Valley, 8757 Rio San Diego Dr., San Diego, CA 92108) c/o Guest, Joan Bishop, to arrive on June 24 or 25. Please consider that many conference attendees will be traveling by plane, and may have limited space in their luggage. Small items and certificates are welcome!

Orphan Drug Act at 25

In celebration of the twenty-fifth anniversary of the Orphan Drug Act, on May 19, FDA, industry, and patient advocacy groups are coming together to discuss accomplishments, perspectives, globalization, and future challenges in the development of therapeutic drugs and devices for the treatment of rare diseases. This all-day meeting, sponsored by the Drug Information Association (DIA) in conjunction with FDA, will be held at the Capitol Hilton in Washington, D.C.

Current updates on the processes, procedures, and resources to enable the successful movement of products for rare diseases from research to approval will be discussed. This will include information on Orphan Drug Designation applications, Humanitarian Use Device designation applications, and Orphan Products Grant applications as well as other regulatory components. For more information, contact Jessica Kusma at 215-442-6182 or Jessica.kusma@diahome.org.

Oley 25 Years Ago

As the Oley Foundation celebrates its twenty-fifth anniversary, we hope to speak to some of our early members and trustees. In this issue we share a couple of thoughts from John Balint, MD, Oley Trustee from 1982–1994, with responses from Oley staff in brackets.

Believe it or not, “in the early years, Dr. Howard and one of her patients traveled around the Northeast showing patients how to use the pumps, etc.” Patients were very instrumental in the development of smaller pumps.

Dr. Balint tells of a patient who did not want to start on parenteral nutrition (PN). At that time, Dr. Balint had a kitchen available at the hospital and he made a deal with his patient: He would give the man two weeks to develop a diet he could tolerate, and if nothing worked, the man would try PN. When the two weeks were up, the man reluctantly agreed that PN was the best option.

On the Oley Foundation, Dr. Balint recalls, “we had some times when we wondered if this was a viable enterprise.” [Indeed, in the mid-1990s, Oley underwent a financial crisis, which, with donor support, was able to weather.] But “I’ve been very impressed by how Oley has seemed to establish a donor base that has generated a sustaining income.” [And Oley hopes to continue this trend as we develop an endowment.]

Dr. Balint referred to the foundation’s early goals: research, patient education, and advocacy. [Although it may not be what was originally envisioned, Oley is actively developing a quality of life study and is very interested in current research; the Foundation does, however, presently lack dedicated funds to sponsor extensive research.] “Clearly,” says Dr. Balint, “Oley has become established as an advocacy group. It does a great job at that. The conference is an interesting mix of fun and science.”

Tysabri Linked to Liver Injury

In mid-January, the FDA issued regulatory approval for the use of the multiple sclerosis drug Tysabri (natalizumab) for the treatment of moderate to severe Crohn’s disease on a limited basis. The drug was approved for use in patients with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional Crohn’s disease therapies.

On February 27, however, the FDA notified healthcare professionals of reports of clinically significant liver injury, including markedly elevated serum hepatic enzymes and elevated total bilirubin, which occurred as early as six days after the first dose of Tysabri in some patients. According to the FDA, the combination of transaminase elevations and elevated bilirubin without evidence of obstruction is recognized as an important predictor of severe liver injury that may lead to death or the need for a liver transplant in some patients. Tysabri should be discontinued in patients with jaundice or other evidence of significant liver injury.

For more information on the FDA alert, check the links at http://www.fda.gov/medwatch/safety/2008/safety08.htm#tysabri

For questions or concerns regarding Tysabri, contact your physician.
We’d Be Lost without You

Where would Oley be without you, our members? You are our reason for being! Please take a minute to renew your membership—to update your address or contact information if necessary, and to donate to help support Oley’s programs if you can. The suggested donation for professionals is $40 and for consumers and family members, $20. An envelope is enclosed for your convenience.

And don’t forget to take advantage of the many benefits your membership confers, whether it’s requesting information from Oley’s extensive information clearinghouse, accessing Oley’s large network of volunteers, exchanging thoughts on Oley’s new forum site, attending Oley’s annual conference (where a wealth of information and networking opportunities galore are all available free to consumers and family members!), or something else. Visit www.oley.org to see what resources we have available. And don’t forget, Oley staff and volunteers are only a phone call or e-mail away.

Manual Is Valuable Resource

The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) has done a great service in gathering materials from dozens of organizations and individuals recognized as leaders in their fields and publishing them in The A.S.P.E.N. Nutrition Support Patient Education Manual. The manual contains hundreds of documents (including Oley’s complication charts) focused on homePEN and makes them available as handouts. To quote the preface, “The purpose of this manual is to provide clinicians with a compilation of some of the best patient education tools, all conveniently located in one place.”

The book is divided into eight parts, a listing of which will give you an idea of its scope: parenteral nutrition; enteral nutrition; surgical procedures; medical conditions; pediatrics; Spanish-language materials; patient education resources; and clinical resources. This manual will be a welcome addition to many libraries.

Conference, from pg. 1

to Maximize Absorption, Intestinal Transplantation Update, Coping, Diarrhea as the Elephant in the Living Room, and Staying Hydrated.

These and other topics will be covered in lectures and breakout sessions, with many opportunities for audience participation. Of special interest to many will be the 2.5-hour workshop on Day 1 addressing the ins and outs of tube feedings, while a highlight for parents will be a session on Day 2 devoted exclusively to pediatric issues.

We are also planning many fun and relaxing social events for adults and kids. Don’t miss this opportunity to share stories with people who truly understand your challenges and successes.

Have questions regarding rooms, sessions, traveling? Check out the registration packet in this newsletter. We also encourage you to visit www.oley.org for updates or contact Oley staff at 800-776-6539 or harrinc@mail.amc.edu. We look forward to seeing you there! ¶


A.S.P.E.N. has just published The A.S.P.E.N. Nutrition Support Patient Education Manual for healthcare professionals to assist their patients/consumers and caregivers. The Patient Education Manual is a compilation of over 200 materials from many prestigious organizations and institutions. The book and CD allow the clinician to easily copy or printout patient education brochures to give to their patients. This book contains information on the following:

- Parenteral Nutrition
- Enteral Nutrition
- Diets for Medical Conditions
- Diets for Surgical Procedures
- Pediatrics
- Selected Procedures in Spanish
- Reading Levels for These Materials

For more information and to see the Table of Contents and Patient Education Samples, go to www.nutritioncare.org or call A.S.P.E.N. at 1-800-727-4567

THE AMERICAN SOCIETY FOR PARENTERAL & ENTERAL NUTRITION
Individual Donors—Thank You!

The following list represents everyone who contributed between January 16 and March 19, 2008. We also want to thank all of those who are not listed below, yet have supported the Foundation by volunteering their time and talents.

Ambassadors ($2,000+)
Abbott/Pediasure, Kyle R. Noble Scholarship Fund
Joyce Madden, in honor of friends who have passed
National Grid, Matching Gift of Nancy Goodick
Beverly Promisel
Susan Schensol

President’s Circle ($1,000–$1,999)
Leah & Steven Atkinson
George Blackburn, MD, via United Way
Rice Foundation, to support the Chicago Regional Conference

Benefactors ($500–$999)

Sponsors ($250–$499)
Robin Eldridge, in honor of Olivia DeKold
Mann Wireless Ltd.
Anna Nowobilski-Vasilios, in honor of Ann Weaver** and her presentation to NW Univ. students
Mary & Doug Seidner,* MD

Patrons ($100–$249)
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Diane Bendenagel, in memory of John Chamberlain
Mr. & Mrs. William Fitzpatrick, Sr.
Charles & JoAnn MacMullan

Supporters ($50–$99)
Victor Chaney, in memory of Melissa Chaney
Richard & Faith Dillon
Guadalupe & Virginia Garcia, in honor of Sean May’s 9th birthday
Brenda Hansen
Barbara** & Lee Klingler, in honor of Joanna Lang
Thomas & Alison Siragusa, in honor of Don Young

Contributors ($30–$49)
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Doug Scartelli, RD, CNSD, LDN
Edith Schuler
Darlene Vargo
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Friends (Up to $30)
Elizabeth Dieckhoff
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Glen & Karen Hillen, in honor of Allison’s 26th birthday and 1 yr anniversary of liver & bowel transplant
Tina Kerrigan
Hubert Maiden
Ron & Lisa Metzger,*** in honor of Dr. Lyn Howard***
Lois Moran
Network for Good
Mary Probus
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Kathleen Vadin

In Memory of Bruce Greffar
The Women’s Committee of Prince George’s Chapter of the National Symphony Orchestra
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In Memory of Tracy Phalen
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Barbara** & Lee Klingler
Martha & Larrie Mackie
Richard & Harriet Real
Bev & Bruce Swanson

*Oley Trustee
**Oley Regional Coordinator
***Oley Staff

Thanks Abbott Nutrition!

Richard and Donna Noble established the Kyle R. Noble Scholarship Fund in 2007 in memory of their beloved son Kyle. This lasting memorial supports an educational scholarship each year.

What no one envisioned was that upon receiving notification that Kyle’s $10,000 life insurance policy was “kicking off” this endeavor, someone at Abbott (a.k.a. Julie Fisk) went quietly to work on an initiative to match it! This generous gift of $10,000 arrived recently, warming the hearts of the many who hold Kyle’s memory close. Thank you Abbott Nutrition.
Thank You for Supporting Oley Programs!

Please join Oley in thanking our corporate donors. This issue we highlight:

**Abbott Nutrition**

Abbott Nutrition is a longtime leader in the U.S. nutritional marketplace, and strives “to be the worldwide leader in providing superior nutritional products that advance the quality of life for people of all ages.” Abbott Nutrition manufactures and distributes medical nutritional products such as: PediaSure® Enteral Formulas, designed to provide a source of Complete, Balanced Nutrition® for children ages 1-13; Vital jr®, a semi-elemental formula for the nutritional needs of children ages 1-13 years; Jevity® 1.2 Cal, an isotonic, fiber-fortified tube-feeding product with the prebiotic NutraFlora® scFOS®, and the Embrace® ambulatory feeding pump.

**Critical Care Systems**

Critical Care Systems is a leading national specialty infusion company that provides comprehensive clinical services to pediatric and adult populations through a national footprint of Joint Commission accredited community-based branches. The company’s Specialty Nutrition Support Program is supported by a team of dietitians, nurses, pharmacists, and reimbursement specialists who excel in parenteral nutrition, clinical support, and customer service. Whether their customers require short- or long-term therapy, Critical Care Systems provides flexible, individualized care adapted to the consumer’s lifestyle.

**Kimberly-Clark**

Kimberly-Clark develops, manufactures, and markets the comprehensive line of MIC* feeding tubes, including the Kimberly-Clark* MIC-KEY* low-profile gastrostomy feeding tube (now available in 12 Fr size for pediatrics) and the Kimberly-Clark* MIC-KEY* low-profile transgastric jejunal feeding tube. The company is the maker of the first balloon gastrostomy feeding tube and is a leader in ongoing research, development, and customer support.

*Registered trademark or trademark of Kimberly-Clark Worldwide, Inc., or its affiliates.

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**Meet Tim Weaver**, from pg. 7

amusement park. Tim was very impressed with how supportive and encouraging both his counselors and fellow campers were.

While Tim does not permit his illness to deter him from participating in the activities he enjoys, his movement can sometimes be restricted trying to bowl or play golf while being hooked up to his feeding pump and wearing a backpack. To get around this, Tim often opts to partake in these activities during the hours he isn’t hooked up to his pump or he adjusts his feeding schedule.

When asked how the Oley Foundation has helped him over the years, Tim said that he has met some good friends at the Oley conferences, and he appreciates the opportunity to talk to other teens close to his own age who face similar health challenges. In between conferences, Tim keeps in touch with them by phone, e-mail, and chatting online.

Lastly, when asked what advice he would give other kids and teenagers who are new to PN and/or EN feedings, Tim replied, “Being on PN or enteral feedings isn’t the end of the world.” ¶
Bruce & On's son Matthew (now 19) has been on HPN since the age of nine. He has SBS due to malrotation of the gut and uses a CADD pump. They have traveled abroad with HPN and look forward to sharing their experiences with you.

Rick knows about tube feeding (HEN). He wants you to call. He is 63, cannot swallow, has been 100% dependent on HEN for 6 years, and is very active. He hikes and skis extensively. He and his wife also travel frequently and enjoy being retired. He looks forward to hearing from you.

Mary has been on HPN for 15 years due to short bowel syndrome and Crohn's disease (37 years); she has attended six Oley conferences. Mary is active in community groups, travels with her HPN, and keeps busy with family and friends. Please call evenings 7–10 pm EST as Mary works during the day.

When Sue’s daughter Emily was diagnosed with a form of pseudo-obstruction at birth and started on HPEN, Sue felt frightened, isolated, and frustrated. Connecting with families in similar situations helped her find what she needed to make life work for her family. Emily now has short bowel and an ostomy. Sue has experience with lines, ports, g-tubes, and ostomies, as well as working with schools.

Chuck is a hospital pharmacist and the father of Mason, who suffered an accident that left him HPEN dependent and with an ileostomy. Mason passed away in 2005, but his legacy continues through the Mason Lindley Miracle Foundation, which supports children and families facing medical challenges through music.

A lifetime of abdominal problems and nearly twenty years of HPN have led Rose and her husband, Bill, to take each new day as a gift. Rose and Bill benefit from a strong family of lifeliners in their area and try to keep them connected. They have attended several Oley conferences and have traveled with HPN. Rose was the first recipient of the Lenore Heaphey Grassroots Education Award in 1994.

### Toll-Free Numbers

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<th>May '08</th>
<th>Bruce &amp; On Braly</th>
<th>Davis, CA</th>
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<td>Rick Davis</td>
<td>Salt Lake City, UT</td>
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<td>Chuck Lindley</td>
<td>Burlington, NC</td>
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<td>Roseline Wu</td>
<td>Livonia, MI</td>
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### LifelineLetter

**The Oley Foundation**

214 Hun Memorial

Albany Medical Center, MC-28

Albany, NY 12208

### Join Us in San Diego!

“After struggling for months with tube feeding and being depressed...I went to an Oley Conference where I learned things and met people that changed my life.”

— Rick Davis, on tube feeding since 2000.