Teduglutide for Pediatric Short Bowel Syndrome: A Clinical Trial Update

Shreena Patel, MD, Russell J. Merritt, MD, PhD, and Beth A. Carter, MD

Teduglutide is a slightly modified glucagon-like peptide 2 (GLP-2) drug, similar to a hormone we all make in our intestine, that leads to intestinal growth and increases food and nutrient absorption. GLP-2 is one of several growth factors the body produces. After a number of clinical studies, it was approved by the U.S. Food and Drug Administration (FDA) in 2012 for the treatment of adults with short bowel syndrome who are dependent on parenteral nutrition (PN) and/or parenteral hydration. Pediatric studies have been under way since the drug was approved for use in adults.

The initial pediatric safety and efficacy study of teduglutide published in 2017 described its use in short bowel syndrome patients aged 1 to 17 years who are dependent on parenteral nutrition and/or parenteral fluids. The study results, published in the Journal of Pediatrics and entitled “Outcomes from a 12-week, Open Label, Multicenter Clinical Trial of Teduglutide in Pediatric Short Bowel Syndrome,” were summarized by Dr. Beth Carter in a previous LifelineLetter article (“Teduglutide for Pediatric Short Bowel Syndrome: Clinical Trial Highlights,” January/February 2017).

An article about an additional, longer pediatric clinical trial has now been published in the Journal of Parenteral and Enteral Nutrition (September 2019) entitled “Safety and Efficacy of Teduglutide in Pediatric Patients with Intestinal Failure Due to Short Bowel Syndrome: A 24-Week, Phase III Study.” Here we will summarize the most pertinent findings from the new study.

Advocacy Alerts

Step Therapy and IV Selenium

The Issue with Step Therapy (Fail First Policies)

Step therapy is an insurance practice that mandates patients try and fail medications preferred by their insurer before they can utilize treatments prescribed by their doctor. It is also known as a “fail first” protocol. While the practice can sometimes help contain the costs of prescription drugs, it can also have serious negative impact on patients, including delayed access to the most effective treatments, severe side effects, and irreversible disease progression.

What You Can Do

A bill is being considered in the House and Senate called the Safe Step Act (H.R. 2279/S. 2546). This bill establishes important guardrails that protect patients when step therapy is mandated by establishing a transparent appeals process and an expedited review for at-risk patients.

Coping Tips from an HPEN Consumer

Julie M. Andolina

Since I was born nineteen years ago, I have needed home parenteral (IV) and/or enteral nutrition (tube feeding) to survive. Given my first IV line at ten days old, and my first abdominal feeding tube shortly after, it was clear that I would not grow up the way a “normal,” healthy child is supposed to. Chronic illness is a thief: it steals your time, your health, your money, your opportunities, and, sometimes, your happiness and the happiness of your family and friends. With chronic illness, the world doesn’t appear to be this wide-open space for you to achieve your dreams; it becomes a taunt, a reminder that you’re different from everybody else, and that you may never get to do everything you want to do.

I think many people would agree that life without joy isn’t truly life at all, it’s simply existing. The key to thriving, even with a chronic illness, is to not merely exist, but live.
**Oley Corner**

---

**LifelineLetter**

November/December 2019 • Volume XL, No. 6

Publisher:
The Oley Foundation
Albany Medical Center, MC-28
99 Delaware Avenue
Delmar, NY 12054
(518) 262-5079, Fax: (518) 262-5528
www.oley.org

Executive Director:
Joan Bishop • bishopj@amc.edu

Editor, LifelineLetter; Director, Community Engagement:
Lisa Crosby Metzger • metzgel@amc.edu

Communications & Development Director:
Roslyn Dahl • dahlr@amc.edu

Administrative Assistant:
Andrea Guidi • andreaguidi.oley@gmail.com

Executive Assistant:
Vicki Ross, RD, PhD, CNSC, FADA, FASHP

Program Associates:
Philip Kellerman • philkellerman.oley@gmail.com
Mary Wootten • marywootten.oley@gmail.com

Intern: Julie Andolina

Science & Medicine Advisor: Darlene Kelly, MD, PhD

Medical Director/Co-Founder: Lyn Howard, MB, FRCP, FACP

**Oley Board of Trustees:**
Beth Gore, PhD, MBA, President; Joy McVey Hugick, Vice President;
Lillian Harvey Banchik, MD, FAC, CNSC, FASPEN, Secretary; James Senese, BS Pharm, MS, Treasurer; Rhonda Arends; Elizabeth Bond, RN; Jerry Mayer; Manpreet Mundi, MD; Laurie Reyen, RN, MN; Kelly Tappenden, PhD, RD

**Oley Advisory Council:**
Leah Atkinson; Jane Balint, MD; Kevin Baskin, MD; Melissa Bill; Lynda Bosworth; Alan Buchman, MS, MSPH, FACN, FACP, AGAF; Frances Culp, MA; Marcia Deneral; Terry Edwards; Paula Foix-Washesky, RD, LDN, MA; Madalyn George-Steinem, RN, CNS; Kathleen Gura, PharmD, BCNSP, FASPEN, FPPAG, FASPEN; Jocelyn Hill, MN, RN, CVAA(e); OCN, CRNI, VA-BC; Shirley Huang, MD; Kishore Iyer, MBBS, FRCS, FACS; Swapna Kanani; Barbara Kapucinska Kelly, MD; Sue Koprucki; Vanessa Kumpf, PharmD, BCNSP; Jack Leibee; Laura E. Matarese, PhD, RDN, LDN, CNSC, FADA, FASPEN; David F. Mercer, MD, PhD, FRCS; Russell J. Merritt, MD, PhD; Ann Michalek, MD; Jay M. Mirtallo, MS, RPh, BCNSP, FASPEN; Vicki Ross, RD, PhD, CNSC; Trish Skienzbe, RD, LD, CNSC; Michael Smith; Bob and Mary Smithers; and Ezra Steiger, MD, FACS, FASHP

**Oley Advisory Council:**
Leah Atkinson; Jane Balint, MD; Kevin Baskin, MD; Melissa Bill; Lynda Bosworth; Alan Buchman, MS, MSPH, FACN, FACP, AGAF; Frances Culp, MA; Marcia Deneral; Terry Edwards; Paula Foix-Washesky, RD, LDN, MA; Madalyn George-Steinem, RN, CNS; Kathleen Gura, PharmD, BCNSP, FASPEN, FPPAG, FASPEN; Jocelyn Hill, MN, RN, CVAA(e); OCN, CRNI, VA-BC; Shirley Huang, MD; Kishore Iyer, MBBS, FRCS, FACS; Swapna Kanani; Barbara Kapucinska Kelly, MD; Sue Koprucki; Vanessa Kumpf, PharmD, BCNSP; Jack Leibee; Laura E. Matarese, PhD, RDN, LDN, CNSC, FADA, FASPEN; David F. Mercer, MD, PhD, FRCS; Russell J. Merritt, MD, PhD; Ann Michalek, MD; Jay M. Mirtallo, MS, RPh, BCNSP, FASPEN; Vicki Ross, RD, PhD, CNSC; Trish Skienzbe, RD, LD, CNSC; Michael Smith; Bob and Mary Smithers; and Ezra Steiger, MD, FACS, FASHP

**Subscriptions:**
The LifelineLetter is a bi-monthly newsletter sent free of charge to those on homeparenteral or enteral nutrition. There is no charge for others as well if they receive the newsletter electronically. Items published are provided as an open forum for the homePEN community and should not imply endorsement by the Oley Foundation. All items/ads/suggestions should be discussed with your health care provider prior to actual use. Correspondence can be sent to the Editor at the address above. Medical/scientific content contained herein has been peer reviewed by an Oley advisor or trustee.

---

**Our Mission**

...is to enrich the lives of those living with home intravenous nutrition and tube feeding through education, advocacy, and networking.

The Oley Foundation provides its 21,000+ members with critical information on topics such as medical advances, research, and health insurance. The Foundation is also a source of support, helping consumers on home IV nutrition and tube feeding overcome challenges, such as their inability to eat and altered body image. All Oley programs are offered FREE of CHARGE to consumers and their families.

**Oley Foundation Programs**

- *LifelineLetter*
- Peer to Peer Support
- Conferences and Webinars
- Resources to Promote Living Well on Tube Feeding and IV Nutrition
- Equipment Supply Exchange
- Advocacy and Awareness

**Resource Spotlight:**
Oley Ambassadors are home parenteral and/or enteral nutrition (HPEN) consumers or caregivers who volunteer to answer questions, share their experiences, or just listen—in person, by phone, or online. They offer peer-to-peer support to other consumers and caregivers; help Oley outreach and support efforts; and heighten awareness of Oley resources in their geographic area, social networking community, clinical circles, etc. Please reach out to them when you want to connect, or when someone you know needs support.

Ambassadors are listed on our website at www.oley.org/ambassadorsmain or call the Oley office for a list.

Several Ambassadors coordinate in-person support group meetings. More information can be found at www.oley.org/SupportGroups.

Clinicians: Oley Ambassadors are a great resource for new (or old) HPEN consumers and their caregivers. Call the Oley office—we are happy to help you make a good connection.

Interested in possibly volunteering as an Oley Ambassador? The “job” responsibilities are flexible based on your skills, available time, and interest. Contact Lisa at (518) 262-5079 or metzgel@amc.edu to learn more.

**How to Support Oley**
Donations are tax deductible and are accepted at www.oley.org/donations or at the street address on left.

---

Mary and Bob, long time ambassadors, attending an Oley training workshop.
A Tail of Two Tubies

Meet Matthew and Oliver. Matthew has mitochondrial disease complex I and III, and chronic intestinal pseudo-obstruction. He is fifteen and has had a G-tube for venting since he was two and a half years old, and a separate J-tube for continuous feeds since he was seven.

Oliver is a Bengal cat, who turned four this year. Oliver was born a day after Matthew had surgery to have his colon removed. He is Matthew’s buddy! When Oliver was eighteen months old, he started vomiting and refused to eat. After a week inpatient, he had no strength. The vet thought he may have an object lodged in his intestine, but exploratory surgery revealed nothing.

Oliver was referred to a specialist, who placed a feeding tube in his neck. Lisa, Matthew’s mom, says, “Once the feeding tube was placed, they [gave] him much needed nutrition. He got stronger every day and we brought him home. We fed him four times a day through the tube, and after six weeks, the tube was removed. He was eating on his own and has been healthy ever since.”

Thanks to Lisa, Matthew, and Oliver C. for sharing this story and photos.
Living Fully on HPEN

Investing Time in Myself and My Health

Katie Marschilok

I am relatively new to the state of needing feeding assistance. My last real meal was August 2018. At that time, I started home enteral nutrition (HEN, or tube feeding) and completely stopped eating anything by mouth. In February 2019, during a routine J-tube change, I had a complication that caused an injury to my small intestine and required total bowel rest for a minimum of eight weeks. That began my home parenteral nutrition (HPN, or IV nutrition) experience. Since then I’ve learned that my digestive problem is dysmotility throughout the small intestine, which makes it very likely that HPN will be a long-term necessity for me.

I had a busy life with many plans prior to this new, not by choice, lifestyle. My booked travel plans included a trip West (Mt. Rushmore, Yellowstone National Park, and Montana) and a twelve-day river cruise in Egypt. When I looked online for advice, for help on how to make these trips possible despite my new challenges, I found out about Oley. Support of my health-care providers at Stratton VA Medical Center in Albany, New York, my infusion provider, and Oley Foundation made these amazing experiences possible. The trip West was made while I was on HEN and the trip to Egypt occurred after I had started HPN.

Requiring HEN or HPN should not limit us.

I feel fortunate to have been able to make a great time and travel investment in myself during the last fifteen months. I made the time to read:

- Current and back issues of the Oley newsletters
- Presentations, Power Points, and outlines from past Oley regional and annual conferences

The variety, quality, and usefulness of the presentations made me decide to attend the 2019 Oley national conference in Chicago, Illinois. What I got out of that conference was so much more than I had expected.

The presentations were of the variety and quality that I had hoped for. And being immersed in a community of people who understand my health challenges without explanation was empowering.

I met a person who has lived a full life on HPN for over thirty-five years. That gave me hope that I can achieve long-term success with this therapy. Meeting families of children of all ages enjoying life on HEN and HPN was inspiring, too.

If you can attend a regional or the annual Oley conference, you should. And I recommend checking the Oley website regularly. I never leave it without learning something and feeling better prepared to handle my new normal.

Where Was Oley This Summer and Fall?

HPN Awareness Week Recap

Thanks to Katie, Jana, and everyone who sent photos or otherwise participated in HPN Awareness Week. If you haven’t done so already, check out and share the video: www.youtube.com/watch?v=gHa-qGiF-HgU. By late November, more than 1,600 people had watched this on YouTube and Facebook.

Many thanks to Baxter for supporting the Oley Foundation’s and members’ efforts to bring awareness of the reality of living with HPN.

Katie M. and Jana D. (next page) are featured in Oley’s 2019 HPN Awareness Week video.
Thankful for HPN

Jana Daigle

I don’t know another street to march down other than gratitude when it comes to my connection to parenteral nutrition. I’m writing this to draw attention to Home Parenteral Nutrition (HPN) Awareness Week. HPN is the intravenous food that has pumped into my body since I was a month old. For thirty-five years, I have been given this every day.

In relation to the illness or disability community, we often praise and spotlight grand feats accomplished despite limitations. There is a surge of optimism (and rightly so) that comes from seeing someone climb a mountain or receive an award or live a prestigious life overcoming physical hurdles. Those things deserve celebration for the remarkable achievements they are. Today I want to speak to a different side of this life of tubes and infusions.

We get the everyday.

Because of HPN, we get the in-between stuff. We get to wake up and brush our teeth. We get to make a recipe we found online, and eat a bowl of Fruity Pebbles when it fails. To throw the ball in the backyard for our golden retriever. We get to register to vote. We get to sit in the grass on a summer day and listen to bird song, and get bitten by ants. We get to finish a library book, realize we forgot milk at the grocery store, pay an electricity bill. We fix beds and hold doors for strangers and smell gardenias in full bloom.

We forget how to spell a certain word, google how to spell it, and somehow end up watching YouTube videos of cats and cucumbers. We get to take naps during rainstorms, check the mail, wonder what is in our Amazon box. We are able to experience forgiveness, loss, grief, and the tension that comes from the three dots that show up in an open text, then disappear without a response. We get the remarkable and mundane miracle of the everyday.

Many of us live with conditions or systems that would be life-limiting, life-threatening were it not for the availability of parenteral nutrition. Something about the daily rhythm of lifting this cold, milky bag of sustenance from the fridge in the morning reminds me and connects me to my dependence, my fragility, my awareness of things that are beyond control. I am still here. I get another day.

I don’t always stay in that place of wide-eyed understanding and gratitude, but that deep knowing is never far removed. I carry it on my back and it flows in my veins. I have been given the gift of everyday, and it is a gift beyond what I could ever say thank you for, so I will try to live thankful instead. Good days, hard days, quiet days, busy days, sick days. Every day.

Adapted from a Facebook post and reused with permission.
Teduglutide, from pg. 1

How was the clinical trial conducted?

Pediatric patients over 1 year of age with short bowel syndrome and dependent on either parenteral nutrition or parenteral fluid were recruited from twenty-four North American and European medical centers between June 2016 and August 2017. No patients had previously received teduglutide. The enrolled patients were assigned to one of three different groups including a self-selected (with parents deciding for their children) “standard of care” group, to whom no teduglutide was given, and two groups in the “treatment arm” treated with teduglutide.

The patients who participated in the treatment arm were randomly assigned to either a 0.025 mg/kg/day dose or a 0.05 mg/kg/day dose, given by injection once daily. The patients, parents, and medical care team were all “blinded” as to which dose of teduglutide research subjects received. All patients followed the same study visit schedule for 24 weeks. An additional follow-up visit was conducted 4 weeks after the 24-week study period. Nine patients chose to participate in the standard of care arm; the investigators were not “blinded” to which patients were in this group. Fifty patients chose to participate in the treatment arm. Twenty-four of these were randomized to receive the 0.025 mg/kg/day dose and 26 to the 0.05 mg/kg/day dose.

Summary of Safety and Efficacy Outcomes

As part of a standard drug safety assessment, investigators reported any “treatment-emergent adverse events” (TEAEs). All patients in the standard of care group and 98% of the patients in the treatment groups experienced ≥1 TEAE. The short-term side effects, such as vomiting and abdominal pain, are consistent with the way the drug-hormone acts to slow intestinal motility. The most commonly reported TEAE among the treatment groups were fever and vomiting. There were no TEAEs that led to discontinuation of teduglutide in either treatment group.

Safety outcomes in this 24-week trial were similar to those in the initial 12-week trial and did not raise any new concerns. Notably, events of special concern related to the use of teduglutide in adults were not observed. These concerns include making abnormal cells grow faster, blockage of the intestine, swelling or inflammation of the gallbladder and pancreas, absorption of too much fluid, and polyp formation in the large intestine. During the adult clinical trials, polyps were found in the large intestine in some patients, but not more than would have been expected without the drug. Though this was not the case in the pediatric studies, it is recommended to test for blood in the stool (if positive, a sign that polyps may be present) before starting treatment and every year while on treatment. Children and adolescents should also have a colonoscopy after one year of therapy and every five years thereafter if continuing therapy.

Given the unexpectedly high number of patients enrolled in the second pediatric study, the investigators were able to conduct “between group” statistical analyses in this study. The “primary endpoint” or result of interest was the percentage of patients in each group that were able to reduce parenteral support (PS) volume by 20% or more. A higher percentage of patients in both teduglutide treatment groups showed a statistically significant reduction in PS volume of ≥20%, as compared to the standard of care group. More specifically, 54%, 69%, and 11% of patients in the 0.025 mg/kg/day, 0.05 mg/kg/day, and standard of care groups respectively, had at least a 20% reduction in PS volume. Though the percentage of patients with ≥20% PS volume reduction in the 0.05 mg/kg/day treatment group was greater than the percentage in the 0.025 mg/kg/day group, this was not a statistically significant difference. (See figure 1, next page.)

Importantly, PS volume correlated with PS calories and reduction in the number of days per week PS was administered. In addition, at the 28-week follow-up visit, these reductions in PS were largely sustained.
The patients who experienced a PS reduction maintained weight and height, indicating that there was no compromise in nutritional status, despite the reduction of PS. This means more nutrients were being absorbed by the intestine.

An important goal of intestinal rehabilitation is to eliminate PN dependence. It is important to note that 2 patients (8%) of the 0.025 mg/kg/day group and 3 patients (12%) of the 0.05 mg/kg/day group achieved this goal, compared with no patients from the standard of care group. Lastly, blood citrulline (a marker for the amount of intestinal surface area available for nutrient absorption) increased in both treatment groups during the trial compared to pre-treatment citrulline measurements.

**Impact of Pediatric Teduglutide Studies**

Both the 12-week and 24-week clinical trials showed the safety and benefits of teduglutide treatment in pediatric patients with short bowel syndrome. As a result, teduglutide was approved by the U.S. FDA for pediatric use in patients 1 year of age and older in May 2019. It has not been approved for use in children less than 1 year of age.

The possible benefits of teduglutide in children with short bowel syndrome include a reduction in daily PS volume, reduction of hours of infusion per day, reduction in days of infusion per week or, in a small percentage of patients, discontinuation of PS. It appears likely that in most patients ongoing teduglutide therapy will be necessary to sustain the beneficial effects. That is, these effects are likely to be lost or diminished if the medication is stopped. Ongoing studies are evaluating the safety and benefits of longer term teduglutide use in children and adults.

Teduglutide is an expensive medication. Its annual cost is in the range of the cost of providing home PN for a year. For most patients, insurance coverage will be required to make its use affordable. At this time, there is limited experience obtaining such coverage for children. The manufacturer (Takeda Pharmaceuticals) provides assistance to physicians in applying for such coverage for their eligible patients.

There remain unknowns about the best use of teduglutide. It will be important for health-care providers to determine the ideal timing of therapy initiation following the surgery that leads to short bowel syndrome and to determine which patients (based on the anatomy of the remaining bowel) are best suited for therapy. Longer term data related to side effects are needed. Answers to these present unknowns will help clinicians target teduglutide therapy to those most likely to benefit.

In the future, we may see longer acting forms of GLP-2 drugs. It is also possible that multiple growth factors will prove more beneficial than a single one.

The advent of parenteral nutrition has been lifesaving, but it does not treat the underlying problem of short bowel syndrome. The quality of life of pediatric short bowel syndrome patients and their caretakers can be improved. The availability of teduglutide and the clinical trials evaluating it are leading to a new era in intestinal rehabilitation, where the underlying condition is becoming more treatable. This progress has provided much needed hope for further treatment breakthroughs for this challenging condition.

References for this article are available upon request to Oley offices or online at www.oley.org/Teduglutide_Pediatric.
Nominate Someone Who Inspires You!

The five awards Oley will present in 2020 recognize those in our community who have earned our respect, inspired us, and taught us. Nominate someone today at www.oley.org/nominations. Alternatively, you can use the form below as a guide and submit nomination(s) by email or US mail. Nominations must be received by **March 20, 2020.** Please notify the person that you are nominating them for the award.

**Awards will be presented at the conference, to be held this summer in southern California. Winners will receive a $750 grant to attend the meeting, and will be spotlighted in the LifelineLetter. Recognition is given to all nominees.**

### The Awards and Criteria

**Innovator/Advocator Award**
Sponsored by Avanos, Bronze Star Partner

- Current home enteral nutrition (HEN) consumer or caregiver for one year or longer, **OR** Current home parenteral nutrition (HPN) consumer or caregiver for one year or longer
- Any age
- Sets an example by promoting innovation in nutrition therapy, or by advocating for themselves or someone in their care

**LifelineLetter Award, HPN**
Sponsored by Nutrishare, Inc., Silver Circle Partner

- Current home parenteral nutrition (HPN) consumer or caregiver for one year or longer
- 19 years of age or older
- Demonstrates courage, perseverance, a positive attitude in dealing with illness or caregiving, and exceptional generosity in helping others in their struggle with HPN

**LifelineLetter Award, HEN**
Sponsored by Nestlé Health Science, Benefactor Level Partner

- Current home enteral nutrition (HEN) consumer or caregiver for one year or longer
- 19 years of age or older
- Demonstrates courage, perseverance, a positive attitude in dealing with illness or caregiving, and exceptional generosity in helping others in their struggle with HEN

**Child of the Year Award**

- Current home enteral nutrition (HEN) consumer for one year or longer, **OR** Current home parenteral nutrition (HPN) consumer for one year or longer
- 18 years of age or younger
- Shows a positive attitude in dealing with illness and therapy which encourages and inspires others

**Celebration of Life Award**
Sponsored by ThriveRx, Silver Circle Partner

- Current home enteral nutrition (HEN) consumer for three years or longer, **OR** Current home parenteral nutrition (HPN) consumer for three years or longer
- Any age
- Lives life to the fullest: traveling, fishing, gardening, volunteering, attending school, spending time with family, etc.

---

**2020 Oley Award Nomination**

1. **Provide the following information:**
   I am pleased to nominate the following individual for the:
   - [ ] Innovator/Advocator Award
   - [ ] LifelineLetter Award, HPN
   - [ ] LifelineLetter Award, HEN
   - [ ] Child of the Year Award
   - [ ] Celebration of Life Award

   Nominee’s name: ________________________________

   Age: ______ Daytime Phone: (______) _______ - ______

   E-mail: ___________________ @ ______________________

   Primary diagnosis: ____________________________________________

   Number of years on HEN (enteral, tube feeding) ______ **and/or**

   Number of years on HPN (parenteral, IV nutrition) ______

   [ ] I’ve notified this person that I am nominating them for an award.

   Your name: ____________________________

   Daytime Phone: (______) _______ - ______

   E-mail: ___________________ @ ______________________

2. **Tell us why you are nominating this person.**
   Cite specific examples of how the nominee meets the award criteria. Please limit length to one page (attach).

3. **Submit nomination by March 20 to:**
   The Oley Foundation
   Albany Medical Center, MC-28
   99 Delaware Avenue
   Delmar, NY 12054
   Fax (518) 262-5528
   E-mail andreaguidi.oley@gmail.com

   **Questions? Call (518) 262-5079**

---

HEN = home enteral nutrition = tube feeding
HPN = home parenteral nutrition = IV nutrition, TPN
Noble Memorial Scholarship

In 2007, the Noble family established the Kyle R. Noble Scholarship to further the educational goals of individuals relying on home parenteral and/or enteral nutrition for their primary nutritional needs. Each academic year, a $2,000 scholarship will be awarded to an applicant who embodies the qualities for which Kyle will be remembered.

**Applicant Should Submit:**

1. Cover letter with name, address, daytime phone, email address, age, diagnosis, HPN and/or HEN, and years on therapy.
2. A one- to three-page essay wherein the applicant describes how he or she has overcome obstacles/challenges posed by HPEN and inspired others to live life to the fullest.
3. A letter from an advisor or teacher supporting applicant’s educational pursuits.
4. A letter from a clinician or homecare company reflecting the applicant’s need for HPEN.
5. Applicants must submit their transcripts at the end of the semester of study in order to receive the second half of the scholarship amount.

**Deadline is March 20, 2020.** Details and application online at www.oley.org or call the Oley Foundation at (518) 262-5079.

Apply for HPN Research Prize: $7,500 in Awards!

The Oley Foundation encourages researchers to apply for an HPN Research Prize. Oley will award $2,500 prizes to each of the top three clinical research papers best aligned with the foundation’s mission to enhance the lives of HPN patients, and that generate interest among HPN patients and improve their well-being.

A portion of each prize ($1,000) will be used to cover travel expenses to bring the winning prize recipients to the Annual Oley Consumer/Clinician Conference to present their research. We are grateful to Nutrishare, Inc., for sponsoring the prizes.

To apply, researchers must submit their abstracts to the Oley Foundation by **March 20, 2020.** The abstract must have been accepted for poster or oral presentation, or publication by a respected, relevant professional association such as ASPEN, ESPEN, INS, AGA, etc. between July 2019 and March 2020.

For additional details and application go to www.oley.org/HPN_ResearchPrize. Questions? Email the prize coordinator at andreaguidi.oley@gmail.com, or call Andrea at (508) 460-1707 or the Oley office at (518) 262-5079.
Advocacy, from pg. 1

You can urge your members of Congress to improve patient access to appropriate care by co-sponsoring the Safe Step Act. Action is especially needed from members in Pennsylvania, North Carolina, Tennessee, Connecticut, Michigan, and Washington.

Urge members of Congress to improve patient access to appropriate care by co-sponsoring the Safe Step Act.

- Identify your two U.S. Senators and your member of Congress (available at www.govtrack.us).
- Contact their D.C. offices by phone or email and ask for the staffer who handles health-care issues. You can use the template below to guide your conversation and/or correspondence. Or, if they are already co-sponsors, you can thank them and state why the bill is important to you. If you call and they are not available to talk to you, ask to leave a message for them with the staffer you’re speaking with, or get their email address.
- Visit the websites for each Senator and House member to find their social media pages (often at the bottom of the website homepage) and tag them in your posts. Here are some suggested social media posts (Twitter, Facebook, Instagram, LinkedIn, etc.):
  - “@_____, please co-sponsor the #SafeStepAct [use S. 2546 for Senate, H.R. 2279 for House]. Protect patient access and #ReformStepTherapy.”
  - “Step therapy impedes the doctor-patient relationship and makes it harder for patients to access essential treatment. Congress must #ReformStepTherapy and pass #SafeStepAct.”

IV Selenium
The Issue
As discussed in the September/October issue of this newsletter, the FDA has approved a new IV selenium product from American Regent, in a new concentration (see www.oley.org/Update-on-IV-Selenium). It is currently the only IV selenium available and it is significantly more expensive than the previously available product (a lower concentration, also from American Regent).

In addition to the high price, the company has not done extended stability studies and the product insert states that once the product is added to parenteral nutrition (PN), the bag should be used within twenty-four hours. This is impractical for PN consumers who get several bags of PN delivered to their home weekly. We have been told that American

Template to Urge Co-sponsorship of the Safe Step Act
Hi [Staffer’s Name],

My name is [Your Name] and I am a constituent from [Your City, State]. I am contacting you today to ask that your office please co-sponsor the Safe Step Act [use S. 2546 for Senate, H.R. 2279 for House]. This important legislation works to improve patient access by reforming insurance-mandated step therapy.

Step therapy is a tool used by health insurers that requires patients to fail first on the insurance company’s preferred treatment before they can access treatments prescribed by their doctors. If left unchecked, the practice can impede the doctor-patient relationship and cause serious harm to patients. The Safe Step Act establishes important guardrails that protect patients when step therapy is mandated by establishing a transparent appeals process and an expedited review for at-risk patients. [Include your personal experience with step therapy briefly, if applicable.]

Thank you for your consideration. Please let me know if your office will co-sponsor this important legislation.

Sincerely,

[Your Name]
[Your Address]
Regent is working on the necessary studies. In the meantime, some infusion companies have adequate supply of the older IV selenium product that they can continue using; or you may be getting selenium as part of MTE-5 (a multi-trace element product); or (for adults) you may be asked if you can absorb an oral form of selenium to supplement your PN. If none of these pertain to you, you may not be getting selenium.

As noted in the IV selenium article by Penny Allen, RD, LDN, CNSC, mentioned above, “Pediatric patients DO need individual selenium added to their PN bags since the neonatal and pediatric trace element combinations do not have selenium in them. Please check with your doctor and your company to make sure they are continuing to prescribe and provide the IV selenium in your child’s PN bag.”

What You Can Do

- You should be made aware of any changes to your prescription. If you have any questions or notice a change on your label, call your physician and/or your home infusion company to ask questions.
- Oley has joined the American Society for Parenteral and Enteral Nutrition (ASPEN) and the National Home Infusion Association (NHIA) in asking American Regent to reconsider the price and to conduct extended stability studies.
- We encourage you to share your story with American Regent and urge them to consider how the pricing and extended stability studies impact you. Email Lisa for contact information (metzgel@amc.edu). Please let Lisa know what you are doing. It helps us as we advocate for you as an organization, and it helps us understand what is important to you.

Making a Difference with a Monthly Donation and Matching Gift

After our son Jameson required emergency surgery to alleviate an intestinal volvulus, his life, and ours, changed dramatically. Thankfully, through support of family and his very loyal friends, Jameson began to adjust to his new normal, but there was still a void present in his life...he had no one he could relate to concerning his medical issues.

Then we learned about a wonderful organization called the Oley Foundation. Although Oley sounded like what our family needed, it took us another four years before we made plans to attend one of their conferences. What an amazing experience!

Everyone was so friendly and welcoming to us as newcomers into the group. Jameson seemed to meld right into a group of teens similar in age to him. Being a part of this wonderful group of people ensures that you no longer feel as though you’re traveling alone on your medical journey.

We have remained regular attendees since that first conference, and have formed many lasting friendships. Because we were so impressed with the work that Oley does to assist and educate those dependent on enteral and/or parenteral nutrition, we committed in 2007 to provide financial support to this very worthwhile organization. As an Oley donor, we have a percentage of each paycheck automatically donated to their foundation.

Also, since my husband is an employee of Johnson & Johnson, it is J&J’s commitment to match each dollar that we donate.

In honor of those who have helped and supported us throughout the years, we view our donations as a “Pay it Forward” opportunity.

—Steve and Leah Atkinson

Steve, Ross, Leah, Jameson, and Ivy Atkinson

Visit coramhc.com.

©2019 Coram LLC. All rights reserved.
75-50312A 102419

(518) 262-5079 • LifelineLetter — 11
Coping, from pg. 1

difficult. How can you possibly be happy with all these tubes coming out of you? How can you possibly be happy when you spend your life in and out of hospitals or doctors' offices? How can you possibly be happy when you're in pain, on medication, unable to eat or move the way you want to or participate in “normal” activities, maybe ones you used to be able to enjoy? As an HPEN consumer, I understand all of these frustrations, and in my nineteen short years, I've learned a lot about myself and my health, and have found a balance in my life. So here, I want to share with you those oh-so important lessons I have learned.

1. **Have a good support system.**

   This may seem obvious; it may even be taken for granted. *Don't take your support system for granted.* Whether that system consists of family, close friends, trusted teachers, your doctors, or even your pet that you snuggle with when you don't feel well, it is so, so important to think about that system and all it does for you. Think about all of the things you can do because of them. Write down a list. It may not be easy to come up with, it may take some time, and that is perfectly okay, it's just important to try.

   Feel the gratitude in you as you pencil in each name; let it fill you until it can no longer be contained and then let it burst through you, surrounding you in warmth. When you're sick, gratitude feels impossible to reach—believe me, I know—but the more you think on it, the more you focus on that feeling and those people, the more you will feel it and the better you will feel. When life can't seem to get any worse, use the people in your life, and be thankful for them.

2. **Know your limits.**

   I, personally, struggle with this often. When you suffer from an illness—be it physical or mental (or both)—it's important to know yourself and your limits, and to accept them. Being chronically ill is draining, and everyone is different. Maybe you can work forty hours a week without losing energy, and maybe you can't. Maybe you get tired after a day at school, and maybe you don't; maybe you start to feel pain three hours into your shift, and maybe you don't.

   Whatever your schedule looks like, it's vital to listen to your body and your mind in the moment. Maybe yesterday you went for a walk with a friend and then went home and studied for a few hours, but today you can barely get out of bed because of pain or exhaustion. That's okay. Every day, every moment, stands alone. Don't try to compare yourself to yesterday-you. Chronic illness can mean chronic change; the best way to stay mentally healthy is to go with the flow, feel the change, and adjust accordingly. Be gentle with yourself, and don't push yourself too hard.

3. **Be a self-advocate.**

   Chronic illness and HPEN are different for everybody, and while doctors often have answers and diagnoses, the only expert on your condition is you. Only you know what your energy is like on a daily basis; only you know how much HPEN or oral consumption you can tolerate while remaining comfortable; only you know what activities cause and alleviate your pain. Take note of those things, and talk to your doctors about them. Advocate for yourself—if you know something isn't working, bring it up with your doctor or caregiver, and make an adjustment.

   Stay informed on the HPEN community. Research different equipment and supplies (formulas, pumps, dressings, tubes, etc.) and treatment options (diets, medications, surgical procedures, etc.). *Ask questions.* There is no better way to learn than to ask questions. Go to a variety of sources: your doctors, other consumers and caregivers, your homecare company, the Oley Foundation. Get your answers and compare them. Find the best solution to your problem, and if it doesn't work, keep trying. Don't give up, and don't give in. No one knows your body better than you.

4. **Have an outlet.**

   When life seems to be nothing but tubes, hospitals, antiseptics, and discomfort, it can be overwhelming. Find something outside of the medical world to give yourself a break. Maybe that means reading a book, doing a craft, listening to music, meditating, playing a sport, seeing some friends, or any number of other things. Try new things, too.

   There is a world of possibility out there, even for the less-than-energetic, even for the less-than-mobile, even for the less-than-healthy. Whatever you choose to do, focus all of your energy on it. *Be mindful.* I can't stress that enough—be mindful of your days. When you take this break, focus solely on it. Devote all of your brainpower to whatever it is you're doing. Don't leave any room for stress or anxiety. Just allow yourself to be.

5. **Pay attention to your mental and emotional health.**

   When your physical health is deteriorating, your mental health can go just as fast. Don't let it. *Mental health is real and it is important.* Investigate your mental health—don't assume that because your body is sick, your mind can't be. HPEN can lead to depression and anxiety, among other things, but that doesn't mean you have to suffer through it. Talk to someone. Find a therapist, or a psychiatrist. Being in therapy is not bad; being on mood stabilizers is not bad; allowing your mental health to go down the drain along with your physical health is bad.
6. Don’t compare yourself to others.
Whether you’re looking at someone who appears to be perfectly healthy, or someone who may be much worse off, comparing yourself to others just ends badly. You are unique. You have your own set of needs different from anybody else’s (different even from the needs of your former self). Focus your energy on yourself (and no, it’s not selfish to think about your needs).

It’s hard not to compare yourself to others. How often do we walk down the street and think, “She looks so much better than I do” or “Why can’t I just eat like he does?” or “Why can’t I have that kind of energy?” Those kinds of thoughts take a toll on your self-image, which may already be damaged by chronic illness.

Conversely, you don’t have to build yourself up by looking at other people’s misfortunes. If you’re having an off day, feeling poorly or sluggish, you don’t have to think about “how much worse it could be for someone else.” If that helps, you can, but if it doesn’t, then don’t! Think thoughts about yourself that make you feel good. It’s such a simple idea, and yet it can be nearly impossible. It takes practice.

7. Don’t isolate yourself.
It’s so easy to isolate yourself when you’re sick. To lay in bed all day, ignore your texts, close your doors and shut your blinds. This is, without a doubt, one of the worst things you can do for yourself. Isolation breeds depression and anxiety. So, even if you don’t want to, send that text to a friend. Even if you’d rather roll over and go back to sleep, try to sit up, try to stand up, try to walk. Open those blinds, go outside and get some sunshine. Call your mom, a coworker, a friend from school. Reach out to another human being! I know it’s hard, and I know it may be the last thing you want to do, but it will help you. It will make you feel so much better than sitting in isolation.

8. Be as honest as you want with others.
Here’s the thing about chronic illness: You don’t owe anyone any explanation. You don’t have to tell people why you carry a backpack around, why you don’t eat at meals, why you use the bathroom so frequently. People don’t have a natural right to know. On the other hand, if you’re comfortable with yourself and your condition, it can be liberating to explain your health to someone else. It’s all up to you.

9. Stay positive.
This is absolutely the best and worst piece of advice I have ever been given. When you aren’t feeling good, mentally or physically, you want to mope and be negative. “Just be positive!” sounds so easy right? It’s not! It’s hard to be positive when you’re chronically ill! But it works. It really, truly does work.

Focusing on the positives in life makes each day a little brighter. Start slow. Take a few minutes a day to think about the good things in life. It won’t happen immediately—give it some time—but eventually you’ll notice that you’re feeling a little better.

10. You are more than a patient.
Even though your body may be sick, you are not just a body. You are a soul, too, and your soul deserves to live just as much as your body does. You aren’t a file-folder of diagnoses and surgeries; you are memories, you are talent, you are relationships, and so much more. You are a whole human being, just like anybody else, and you deserve to live life to the fullest, just like everybody else. It is important to remember that HPEN should not be a hindrance on life, it should allow you to live it.

Consider the Ring Theory
Lisa Metzger

The drawing on right illustrates a simple, yet brilliant concept called the “ring theory.” It was first outlined by clinical psychologist Susan Silk and mediator, arbitrator and author Barry Goldman in an article in the LA Times (April 7, 2013).

To see how it works, try this: Draw a circle and put your name or the name of your loved one (the person currently in need of comfort) in it. Draw a larger circle around that; put the name of the person or people next closest to you or your loved one in it. Draw as many circles as you need to, with the names of the next closest people in them. Parents and children; close friends; distant relatives, neighbors, coworkers; and so on.

Silk and Goldman write, “The person in the center ring can say anything she wants to anyone, anywhere. She can kvetch and complain and whine and moan and curse the heavens and say, ‘Life is unfair’ and ‘Why me?’... Everyone else can say these things too, but only to people in larger rings.”

They continue, “When you are talking to a person in a ring smaller than yours, someone closer to the center of the crisis, the goal is to help. Listening is often more helpful than talking. But if you’re going to open your mouth, ask yourself if what you are about to say is likely to provide comfort and support. If it isn’t, don’t say it. Don’t, for example, give advice. People who are suffering from trauma don’t need advice. They need comfort and support.”

It’s a simple, elegant way to illustrate what we all know: One should provide support and comfort to someone in need, not ask them to support and comfort us. “Comfort IN, dump OUT.”
Oley News

Feeding Tube Awareness Week, February 10–14, 2020

Help others understand what life with feeding tubes and enteral nutrition is all about. Increase tolerance and knowledge, and create bridges to people who are feeling isolated by or struggling with tube feeding.

Submit your photos for the Oley awareness video now! Looking for photos of you or your loved one “living life” on home tube feeding, with a short explanation we can use as a caption. Watch last year’s video on the Oley YouTube channel for inspiration, then send to Lisa (email below).

Be sure to watch the new video on YouTube in February, and to join the conversations on the Oley Facebook page and Oley-Inspire forum February 10–14.

We are here to support you if you want to plan an event, contact the media, etc. Contact metzgel@amc.edu, (518) 262-5079, or The Oley Foundation, Albany Medical Center MC-28, 99 Delaware Ave., Delmar, NY 12054.

FEEDING TUBE AWARENESS WEEK® is a registered trademark of Feeding Tube Awareness Foundation, Inc. and is used here under license.

Celebrating Rare Disease Day

In 2020, Rare Disease Day falls on the rarest day of the year—February 29. There are over 7,000 rare diseases. Celebrate and bring awareness to your rare disease and Rare Disease Day by posting your pictures at #rarediseaseday (you can find a social media post template at rarediseases.org/rare-disease-day/get-involved) or by submitting your pictures online (www.rarediseaseday.org). Visit the National Organization for Rare Disorders (NORD) website (www.rarediseases.org) to look for a Rare Disease Day event planned near you.

Thank You Corporate Partners!

Please join Oley in thanking the companies that support us year round. Learn more about our most recent corporate contributors below. For a complete list of corporate partners go to www.oley.org/PartnerShowcase.

Coram / CVS Specialty Infusion Services

CVS Specialty and Coram provide personalized, compassionate, high-quality infusion care to patients where they live, work, or travel. With more than thirty years of experience and nearly 1,200 skilled clinicians, Coram / Specialty Infusion Services leads with commitment from the heart. The company maintains a 96 percent patient satisfaction rating.

Soleo Health

NutriSole®, Soleo Health’s Nutrition Support Program, provides personalized care and service to consumers requiring TPN at home. The company knows you have a choice in healthcare providers. Soleo Health has a 98% consumer satisfaction rate and 99% of its consumers would refer the company to a friend or family member.

And We Have Two Winners!

Thanks to everyone who updated their Oley profile in response to our email and newsletter requests. Knowing more about you helps us better meet your needs and advocate for you!

Congratulations to the winners of the gift card drawing: Karla H. and Jung L.

Don’t Forget Your Annual Donation

If you have sent your annual gift to the Oley Foundation already, thank you! If not, you can use the envelope enclosed in this issue of the newsletter; or donate through Oley’s secure online web portal at www.oley.org/donations/donate.asp?id=13882 (scan the QR code on right for a direct link).

Scan for easy online giving

Join Pam and Ally in supporting Oley programs.
Oley Corporate Partners

The following companies provide over one-half of the funds needed to support Oley programs. Corporate relationships also strengthen our educational and outreach efforts. We are grateful for their strong commitment.

**TITANIUM LEVEL PARTNER**
($150,000+)
Takeda Pharmaceutical

**GOLD MEDALLION PARTNER**
($50,000–$69,999)
Option Care

**SILVER CIRCLE PARTNERS**
($30,000–$49,999)
Coram / CVS Specialty Infusion Services
Nutrishare, Inc.
ThriveRx

**BRONZE STAR PARTNERS**
($20,000–$29,999)
Avanos
Baxter International Inc.
Cardinal Health, Inc.
Fresenius Kabi USA
Kate Farms

**BENEFACTOR LEVEL PARTNERS**
($10,000–$19,999)
BioScrip Infusion Services
Nestlé Health Science
Optum Infusion Pharmacy
Real Food Blends
Zeeland Pharma

**PATRON LEVEL PARTNERS**
($5,000–$9,999)
Applied Medical Technology, Inc.
Cook Medical
MOOG Medical
Soleo Health

**Notable Individual Gifts**

Among the contributions we receive, there are always several dedicated to those who have inspired the donor. We share this list of honorees below. We are grateful for the following gifts received from August 22, 2019, through November 8, 2019.

**Tributes:** In honor of Michael Aklufi’s family, Frances, Mia, and Michelle; Julie Andolina; Hadar Birger-Bray; Rosemary Gutenberg’s seventieth birthday; Aidan Koncious; Dashiell Lyon; Al Mackay; Bobbiejo Winfrey’s fourteen-year multivisceral transplant anniversary

**Memorials:** In memory of Michael Aklufi; Ann DeBarbieri; Darrell Gardner; Linda Gulden; Ken Lighthall; Peter Michalski; Caroline Mitter; Deborah Myers; Sophie Prunty; Josh Shapiro

**Fund-raisers:** Al Mackay’s Long Trail hike; Facebook birthday campaigns by Chelsea Edwards, Melissa Hughey, Candace J. Jackson, KateThunberg O’Connor, and Delores Salvinski; Phil Kellerman’s ongoing political memorabilia fund-raiser on Ebay

Thank you for all gifts and the kind comments we receive throughout the year. Your support overwhelms us and continues to be a source of inspiration.

**Oley Horizon Society**

Many thanks to those who have arranged a planned gift to ensure continuing support for HPEN consumers and their families. Learn how you can make a difference by calling (518) 262-5079 or visiting www.oley.org/plannedgifts.

Felice Austin
Jane Balint, MD
John Balint, MD
Joan Bishop
Ginger Bolinger
Pat Brown, RN, CNSN
Faye Clements, RN, BS
Katherine Cotter
Jim Cowan
Rick Davis
Ann & Paul DeBarbieri
David & Sheila DeKold
Dale & Martha Delano
Tom Diamantidis, PharmD
Gail Egan, MS, ANP
Selma Ehrenpreis
Herb & Jay Emich
Jerry Fickle
Don Freeman
Linda Gold
Linda Gravenstein
Deborah Groeber
The Groeber Family
Valerie Gyurko, RN
Alfred Haas
Shirley Heller
Alicia Hoelle
Lyn Howard, MD
William Hoyt
Portia & Wallace Hutton
Kisbore Iyer, MD
Doris R. Johnson
Darlene Kelly, MD, PhD
Family of Shirley Klein
Jim Lacy, RN, BSN, CRNI
Robin Lang
Joyce Madden
Hubert Maiden
Laura Matavec, PhD, RD
LDN, CNSC, FADA, FASPEN
Kathleen Mclnnes
Michael Medowar
Meredith Nelson
Nancy Nicholson
Rodney Okamoto, RPh, & Paula Okamoto
Kay Oldenburg
Harold & Rose Orland
Judy Peterson, MS, RN
Clemens Pietzner
Beverly Promisel
Abraham Rich
Wendy B. Rinner
Roslyn & Eric Scheib Dahl
Susan & Jeffrey Schesnol
Doug Seidner, MD, FACC, CNSP
Judith Smith
Steve Swensen
Cheryl Thompson, PhD, RD, CNSG, & Gregory A. Thompson, MD, MS;
Cathy Tokarz
Eleanor & Walter Wilson
Marion & Larry Winkler
James Wittmann
Patty & Darrell Woods
Roaline Ann & William Wu

(518) 262-5079 • LifelineLetter — 15
2020 Oley Calendar

**Ongoing:** Applications being accepted for Oley Tim Weaver Camp Scholarship

**January 9 (and then the first Thursday every month, February through December):** Philadelphia Suburbs Tube Feeding/HPN Support Group, Blue Bell, PA, more info @ www.oley.org/SupportGroups

**February 10–14:** Feeding Tube Awareness Week

**February 13:** Capital District Tube Feeding/HPN Support Group, Delmar, NY, more info @ www.oley.org/SupportGroups

**March 1–2:** Oley participating in Digestive Disease National Coalition (DDNC), Washington, DC

**March 20:** Nominations for Oley awards, applications for Kyle Noble Scholarship, and submissions for HPN Research Prize due

**March 28–31:** Oley exhibiting at and attending the ASPEN Nutrition Science and Practice Conference, Tampa, FL

**April 5–9:** Oley attending National Home Infusion Association (NHIA), Aurora, CO

**May 2–5:** Oley attending and participating in Digestive Disease Week, Chicago, IL

**August 18 (and then the third Tuesday every month, September through December):** South Florida Ostomy and Tube Feeding/HPN Support Group, Weston, FL, more info @ www.oley.org/SupportGroups

For updates or if you are able to help at one of the Oley exhibits listed above, please email harrinc@amc.edu or call (518) 262-5079.

**Additional Meetings of Interest**

**January 24–25:** Feeding Matters International Pediatric Feeding Disorder Conference, Virtual Meeting

**March 13–15:** American College of Gastroenterology (ACG/FGS) Spring Symposium, Naples, FL

**May 16–19:** Infusion Nurses Society (INS), Las Vegas, NV

**May 30–June 2:** American Society of Nutrition (ASN), Seattle, WA

**June 26–28:** International Pediatric Intestinal Failure Rehabilitation Symposium, Ontario, Canada

Give a Gift to Oley
Mail a check in the envelope inside this issue, or scan the QR code below to make a credit card donation.