It gives me great pleasure to introduce myself as the incoming Chair of the American Academy of Pediatrics (AAP) Section on Advances in Therapeutics and Technology (SOATT). I want to thank Charlie Thompson for his tireless work to build this section and his innovative ways of bringing children into designing research. My hope is that he will continue to be a part of SOATT leadership and help us increase our “footprint” within the academy.

As a practicing academic neonatologist, my focus has largely been directed towards making sure that my most fragile patients have access to what they need to insure their best chance for survival. In this new role, I intend to extend this access issue to the general pediatric population. While we continue to try to get the best value for our health care dollar through the Accountable Care Act, there is no excuse for lack of acceptable pediatric devices or medications due to inadequate resources for research and development. Innovation in the development of safe technologies and pharmaceuticals for children is something that we can all support. Our academy celebrates increased funding for and research on solutions that have a specific indication for children.

Continued on Page 2
There are multiple examples of AAP funded projects that result in quantum gains in pediatric care. From the private sector, the March of Dimes funded the research that obliterated polio. However, the bottom line is that development for neonatal and pediatric patients has become less profitable, much more expensive, and considerably more risky than development for adult patients.

The Promoting Life Saving New Therapies for Neonates Act of 2015 (S. 2041 and H.R. 5182) is an example of legislation designed to bridge the gap. Persisting threats to newborn health have not been reflected by innovation in the industry, and advancements in neonatal treatments have stalled due to the difficulty of performing clinical trials, the economic challenge of driving investment in treatments for this narrow category of patients, and the cost endemic to our regulatory process for approving new drugs. This legislation would mark a promising step forward in creating appropriate incentives to bring new treatments forward to benefit this vulnerable population. By creating a transferrable “exclusivity voucher” for drug manufacturers who successfully develop products in critical areas of neonatal health, this measure will create an opportunity for vital studies and research that would otherwise be too costly to perform. Further, the legislation is thoughtfully drafted to target only the most critical needs in the neonatal population – fostering cooperation among multiple stakeholders including the National Institutes of Health and the Food and Drug Administration. We need to extend legislation like this to cover the needs of pediatric patients as well.

We need innovative treatments specifically tailored for our patients. Neonates and pediatric patients have their own unique pathology and physiology. While most treatments developed for adults are designed for their physiology, these treatments may prove toxic in our population. Unlike treatments used in other fields of medicine, most medications administered to pediatric patients lack convincing data to support their safety and efficacy, with more than 90 percent not approved by the Food and Drug Administration (FDA) for the prescribed indication. Moreover, performing clinical trials to determine pharmaceutical safety and efficacy in pediatric patients is fraught with challenges – such as low participation numbers in clinical trials, high population variability, and increasingly expensive trial costs.

At this point, I would be remiss if I did not mention the International Children's Advocacy Network (iCAN). Founded by Charles Thompson, our outgoing chairman, the network “is an advisory group of children, adolescents and families focused on understanding, communicating and improving medicine, research, and innovation for children.” As a worldwide collection of children's advisory groups, iCAN works to give a voice to children in designing research, innovating through cooperation, communication, and collaboration. Advocacy in the design process is essential in assuring that the child's viewpoint is included in research and development. This organization will lower the bar for pediatric participation in clinical trials and will increase patient diversity by virtue of its international base.

But, the cost issue remains. Beyond the research and development costs, there are “costs” involved in our patients not receiving indicated medications. In addition to negative short- and long-term health consequences for infants affected by denials for essential goods and services as well as increased financial and emotional stress for families, there is yet another issue.
Even with supporting legislation, if pharmaceutical and medical device manufacturers go through the trouble and expense of producing a product with a known and well established relevant indication only to be denied access to their market by a guideline or policy that severely restricts access, why would these companies continue to develop new products for the pediatric population? The answer is obvious. Restrictive under-dosing or under indication sends a clear message to pharmaceutical and medical device companies, “development for pediatric patients is not worth the risk.” The precedent being set is dangerous. If we are to expect great innovation and research leading to the development of useful biologics, pharmaceuticals, and medical devices for our most fragile patients, we must make every effort to follow FDA indications and to effectuate a process where restrictive guidance on the use of novel products is not tolerated.

I ask you to join me in advocating for improvement in these access issues and in providing all of our children access to advances in therapeutics and technology.

Sincerely,
Mitchell Reid Goldstein, MD, FAAP

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We welcome contributions to the newsletter on any topic of interest to the pediatric community.

Please submit your idea or article to:
Chester J. Koh, MD, FACS, FAAP at cxkoh@texaschildrens.org
Greetings from Washington DC!

As I observe the pitch presentations of the 12 finalists for the National Capitol Consortium for Pediatric Device Innovation’s “Make Your Medical Device Pitch for Kids! Competition” this year, I am amazed at how far pediatric device development in the U.S. has advanced over the past few years. This competition is one of several that take place quarterly or annually across the U.S. with support from the FDA Pediatric Device Consortia Grant Program, and serves as a potential source of seed funding for pediatric device projects as they progress toward clinical implementation in children.

While the doubling of the number of applications for this year’s Washington DC competition mirrors the trajectory of interest and activity in the pediatric device development field, it is also important to remember where this all started. This edition of the SOATT newsletter is dedicated to Linda Ulrich, MD, FAAP, a pediatrician in the FDA’s Office of Orphan Products Development (OOPD) and the Director of the FDA’s Pediatric Device Consortia Grant Program since its inception in 2007. She recently announced that she is stepping down from her position, and we wish to thank her for all of her invaluable contribution, as well as wish her the very best in her future endeavors! During Linda’s tenure, over 775 pediatric device projects have been supported through the consortia since 2009, including 148 currently active projects and 13 collaborations / multi-consortia projects, with a collective investment of about $100 million in research support since 2009. Some of these devices have even reached the bedside via commercialization—a difficult milestone to reach. Some of these accomplishments were noted in her Pediatrics article (Ulrich LC et al, Pediatrics 2013;131:981). Susan K Cummins, MD, MPH, one of our AAP SOATT Executive Committee members, has eloquently described Linda’s contributions in an article in this edition of the newsletter.

We welcome Eric Chen, MS, the director of the FDA Humanitarian Use Device Program, who succeeds Linda as the director of the Pediatric Device Consortia Program, with assistance from Carla Epps, MD, a pediatrician in the FDA Office of Orphan Products Development.

This edition of the SOATT newsletter also welcomes Mitchell Goldstein, MD, FAAP, as he succeeds Charlie Thompson, MD, FAAP as the Chair of the SOATT. It also features a description of the recently released “Pediatric Extrapolation (Final) Guidance: Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices” by Dr. Vasum Peiris, the Chief Medical Officer, Pediatrics and Special Populations, Center for Devices and Radiological Health at the FDA. In addition, Cassie Brugger from the New England Pediatric Device Consortium interviews Johnie Rose, MD, PhD from the University Hospitals Case Medical Center and Case Western Reserve University School of Medicine on the topic of “From Device Concept to Clinical Practice: An Interview with a Clinician Medical Device Developer”. We also highlight a pediatric medical device company in our Spotlight on Pneumokazoo, which is developing a novel pediatric device for collecting uncontaminated lung specimens non-invasively from coughs. This edition also includes an update on the 2016 ICAN
Summit, which was founded in the AAP SOATT, and which has the goal of “educating and empowering our youth to improve pediatric health, medicine, research and innovation by sharing children’s voices in an impactful way.”

We look forward to seeing you at this fall’s NCE meeting in San Francisco and especially at the Section’s program on Pediatric Innovation on Monday, October 24, 2016, 12:00 pm – 2:00 pm.

We hope that you enjoy reading this edition of the newsletter, and please share it with a colleague, patient, or friend. We welcome all suggestions for articles. It is an avenue of communication for our Section, and for those who share the passion of caring for children and improving our care for children.

**Pediatric Medical Device Resource List:**

FDA-funded Pediatric Device Consortia (PDC) – a resource for pediatricians, pediatric caregivers, and pediatric specialists in developing their innovative pediatric medical device projects. Available assistance can include consulting, project management, and seed funding.

Further details can be found in the previous editions of the newsletter at: [https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/soatt/Pages/newsletters.aspx](https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/soatt/Pages/newsletters.aspx)

**Atlantic Pediatric Device Consortium**
(Georgia Institute of Technology / Emory University / Children’s Healthcare of Atlanta / Virginia Commonwealth University Institute for Engineering and Medicine)

**Boston Pediatric Device Consortium**
(Boston Children’s Hospital / Harvard Medical School)
[http://www.childrenshospital.org/](http://www.childrenshospital.org/)

**National Capital Consortium for Pediatric Device Innovation**
(Children’s National Health System / University of Maryland)

**New England Pediatric Device Consortium**
(Simbex / CIMIT / IPI / Mass General Hospital for Children / Dartmouth University)

**Philadelphia Regional Pediatric Medical Device Consortium**
(Children’s Hospital of Philadelphia / University of Pennsylvania / Drexel University)

**Southern California Consortium for Technology and Innovation in Pediatrics**
(Children’s Hospital Los Angeles / University of Southern California)

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Be Informed! Get Involved!

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Farewell to Linda Ulrich, MD, FAAP on her Retirement from the FDA Pediatric Device Consortia Program

Susan K Cummins, MD, MPH
Executive Committee Member, AAP SOATT
susan.cummins@gmail.com

Linda Ulrich, MD, FAAP, the recipient of this year's AAP SOATT Award for Pediatric Innovation, is a native of Rockville, in Montgomery County, MD. Like many of us, she aspired to medicine at an early age, and chose a career in pediatrics at the beginning of her fourth year at Uniformed Services University, upon realizing both the fun of working with kids, and a general pediatrician's focus on wellness, preventative medicine, and primary care. Upon completion of her pediatric internship and residency at Portsmouth Naval Medical Center, she worked as a general pediatrician, caring for the children of active duty service members.

Linda joined the United States Public Health Service in 2004, beginning her FDA career as a medical officer in the Office of Generic Drugs. She subsequently transferred to the Office of Orphan Products Development, working as a medical reviewer of applications from sponsors seeking Federal incentives to advance the development of products for rare diseases.

In March 2007, Linda became the first Director of the Pediatric Device Consortium (PDC) grant program at the FDA. During her tenure, Dr. Ulrich, working with the grantees and her colleagues at the FDA, helped grow the program into a national advisory network for innovators of pediatric medical devices.

Before the PDC program, the concept of a career focused on the development of medical devices for children was non-existent. All too often, pediatric surgical specialists had to create a custom device for their patients from medical devices cleared or approved for conditions vastly different from the need at hand.

The PDC program has fundamentally changed the notion that pediatricians and pediatric specialists must make due with one-offs, which established pediatric device development as a career focus for engineers and clinicians. Since its inception, pediatric device development enabled through the PDC grant program has led to clearance or approval of at least eight pediatric medical devices. In addition, the program has expanded from three consortia in 2009 to eight FDA-funded consortia.

Dr. Ulrich recently announced that she was stepping down from her position as director of the PDC grant program. We congratulate Dr. Ulrich for her inspiring career - the creation of an entire new subspecialty that enlists engineers, pediatricians and pediatric specialists, and others to meet the unique needs of children-- and we wish her well in the next phase of her remarkable career.
FDA Supports Medical Device Development for Children

Announcing the “Pediatric Extrapolation (Final) Guidance”:
Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices

Vasum Peiris, MD, MPH, FAAP, FACC, FASE
Chief Medical Officer – Pediatrics and Special Populations
Office of the Center Director
Center for Devices and Radiological Health
U. S. Food and Drug Administration
Vasum.Peiris@fda.hhs.gov

The U.S. Food and Drug Administration (FDA) is dedicated to promoting timely access to safe and effective medical devices for all patients, and recognizes the unique needs of children. We understand the numerous factors specific to pediatric data collection which are associated with relatively few medical devices having pediatric indications and labeling. As part of efforts to support medical device development for children, the FDA Center for Devices and Radiological Health (CDRH) recently published the “Pediatric Extrapolation Guidance,” which took effect September 19th, 2016. The guidance explains the circumstances in which the FDA believes it is appropriate to consider leveraging existing data to support pediatric indications and labeling for medical devices.

Off-label use of devices evaluated and indicated for adults remains a prevalent and necessary practice in pediatrics. The guidance clarifies a process that supports safe and effective device use in children by minimizing risk to pediatric patients while maximizing access to medical devices indicated for pediatric patients.

The guidance provides a framework to consider extrapolating data to evaluate a device’s performance in pediatric patients in pre-market approval applications (PMA’s), humanitarian device exemptions (HDE’s) and de novo requests, which comprise the main pathways by which medical devices are evaluated for potential approval by the FDA’s Center for Devices and Radiological Health. The guidance also outlines the approach FDA uses to determine whether extrapolation is appropriate and to what extent (i.e. full vs. partial extrapolation), and describes statistical methodology (e.g. Bayesian hierarchical modeling) that can be used to leverage data for pediatric indications.

The term extrapolation as used in the guidance refers to the leveraging process where an indication in a new pediatric patient population can be supported by existing data from a studied population. When existing data are relevant to a pediatric indication and determined to be valid scientific evidence, it may be appropriate to extrapolate such data for pediatric use.

Although extrapolation has the potential to benefit pediatric medical device development, CDRH believes it must be used judiciously and only when appropriate. Extrapolation will be considered on a case-by-case basis, with independent evaluation of decisions to extrapolate for safety as well as for efficacy. CDRH will use pediatric expertise in the evaluation of any application in which extrapolation is considered. In addition, CDRH is developing the PEDs (Pediatric Extrapolation for Devices) Team, a centralized group with pediatric expertise available for consultation regarding extrapolation. We believe the PEDs Team will enhance consistency and standardization with respect to extrapolation decisions.

The “Pediatric Extrapolation Guidance” reflects the FDA’s continued commitment to serve the unique needs of pediatric patients. We remain dedicated to work with all stakeholders, including the AAP SOATT, to facilitate efforts to address unmet medical device needs for children.
Editor's note: This section spotlights the development and commercialization of new pediatric medical devices and hopefully serves as a resource and inspiration

**PneumoKazoo™ - A novel pediatric device for collecting uncontaminated lung specimens non-invasively from coughs**

*David N. Ku, MD, PhD*
*President and CEO, MD Innovate, Inc.*
*info@mdinnov8.com, (404) 585-8109*

Pneumonia remains a leading cause of death in the United States and is the leading cause of death in children worldwide. It has always been difficult to diagnose and appropriately treat lower respiratory infections since there is no gold standard for lung sampling, resulting in empiric treatment, overuse of antibiotics, antibiotic side effects, and antibiotic resistance.

New technology developed collaboratively between the US Centers for Disease Control and Prevention (CDC) and Georgia Tech Research Corporation in Atlanta, GA has the potential to drastically change this landscape.

PneumoKazoo™ is a revolutionary device that collects uncontaminated lung specimens non-invasively through coughs from pediatric patients. The device is simple, easy to use, and provides a sample that is free from oral contaminants. The device uses fluid mechanics to separate the upper airway from the lower airway so that only aerosols from the lungs are collected onto a filter. The filter can then be analyzed by a laboratory or rapid diagnostics platforms. The device has an integrated noisemaker, making it fun for kids to use, and also provides a visual and audible indicator for proper use.

Paired with rapid diagnostic technology, PneumoKazoo™ can help provide physicians with a better identification of lower respiratory infections. The pairing of these technologies has broad implications, such as reductions in overall antibiotic use, antibiotic resistance, patient length of stay, and overall

*Continued on Page 10*
healthcare costs. Lower respiratory pathogen identification requires both a good clean specimen and rapid sensitive analysis, not just one or the other. Wouldn't it be nice to not have to collect sputum? And no physician wants to bronch a kid!

PneumoKazoo™ can be a catalyst for improving clinical outcomes and decreasing healthcare costs. This device can be used for a range of issues, including pneumonia, tuberculosis, cystic fibrosis, asthma, lung cancer, surveillance monitoring, etc.

Both PneumoKazoo™ and its adult version, PneumoniaCheck™, are patented. PneumoKazoo™ is supported by the Atlanta Pediatric Device Consortium.

Administering unnecessary antibiotics is extremely dangerous, particularly for children. But it's hard to know when they're unnecessary if you don't know what is causing the infection, or if there is a chance of co-infection. PneumoKazoo™ can provide the means to justify discontinuing broad-spectrum antibiotics, or changing to narrow-spectrum antibiotics if specific bacteria is identified.

Please visit our website for more information: [www.pneumokazoo.com](http://www.pneumokazoo.com)
From Device Concept to Clinical Practice: An Interview with a Clinician Medical Device Developer

Written by Cassie Brugger, MA, Program Administrator for the New England Pediatric Device Consortium (cbrugger@nepdc.org) in conjunction with Johnie Rose, MD, PhD, Assistant Professor, University Hospitals Case Medical Center

Spending your days thinking about big problems in the world’s poorest places puts you in the ideal position to imagine new devices and technologies to improve pediatric care and outcomes. Dr. Johnie Rose, Preventive Medicine/Public Health physician and Epidemiologist at Case Western Reserve University School of Medicine, applied to New England Pediatric Device Consortium's (NEPDC) grant program in February 2015 with an idea born out of his knowledge of unmet pediatric needs.

In his work on diarrheal diseases, Dr. Rose came to understand that sanitation, rotavirus vaccination, and access to oral rehydration therapy were not a complete answer to preventing the hundreds of thousands of deaths from dehydrating diarrhea that occur worldwide each year. A missing piece was a method to give fluids to the sickest of the sick in areas where personnel skilled at starting IVs are scarce. This enormous need inspired him to create a subcutaneous rehydration device that could be inserted rapidly by individuals with little to no clinical training. This device would provide accessible rehydration therapy to children who might not otherwise receive it due to lack of access to health care facilities. In the interview below, Dr. Rose explains the unique challenges for clinicians developing a medical device, as well as the NEPDC resources he was able to leverage on his pathway towards commercialization.

How did the idea for developing a subcutaneous rehydration device first come to you?

As a PhD student at Case Western Reserve University, my dissertation research focused on predicting the public health and economic outcomes of programs to vaccinate Indian infants against rotavirus. Though rotavirus infects all of us at some point, it tends to kill mainly those in parts of the world with poor access to healthcare. While my work suggested that universal vaccination using a western rotavirus vaccine could save a lot of lives, over 60,000 infants would still die of the disease each year in India alone, despite the availability of World Health Organization (WHO)-recommended oral rehydration solution (ORS). Even with ORS, the sickest of the sick will still need parenteral fluids. The problem is that kids in many parts of the world may be days away from clinical personnel skilled in starting intravenous lines. I wanted to make a user-friendly device that would empower caregivers and community health workers in remote settings to get a head start on parenteral hydration when ORS wasn’t enough and IVs are not a timely option. This could impact mortality from rotavirus as well as from other dehydrating diseases such as cholera. Before IVs were commonplace in the U.S., the subcutaneous route was used frequently in children, and it is still used commonly in the geriatric setting. While fluids cannot be bolused using this route, the fact that a vein does not need to be cannulated is a major advantage for a device intended for use by those with little or no clinical training.

What was the biggest challenge you faced in the development of your device?

My primary area of research lies in using computer simulation to examine population health interventions—nothing at all to do with device development. Nor do I come from an engineering or entrepreneurship background. So, the biggest challenge for me was just figuring out where square...
One was and who could help get me there. It has been like learning a new language, but I’ve been fortunate to get a lot of great help along the way!

**What types of resources does your institution provide for faculty, clinicians, or staff who have an idea for a medical device or technology?**

As a first-year faculty member, I was fortunate to benefit from some institutional assistance when I won the University Hospital Case Medical Center's (UHCMC) “Pediatric Innovation Day” contest with nothing more than the idea for my device. The technology transfer experts at UHCMC’s Center for Clinical Research and Technology connected me with individuals who helped me start to find my way, including colleagues in the Case Western Reserve University School of Engineering and industry contacts. They have also supported the costs associated with prototyping and intellectual property protection.

**What was the most helpful assistance that New England Pediatric Device Consortium was able to provide to you?**

The single biggest boost to the whole effort was the assistance I’ve received from NEPDC. Even more valuable than the grant money was the expertise that NEPDC’s network of engineers and commercialization professionals provided. They really helped me put together a strategy for finding a market for my idea and refining the design based on feedback from end users. I am still learning as I go, but I would be nowhere without the help I’ve gotten along the way. NEPDC has been, and continues to be, one of my best advocates.

**Why do you think programs, such as NEPDC and the FDA’s Pediatric Device Consortia program, are important for improving pediatric medicine and care?**

Ideas for solving problems often come from the people most familiar with those problems; and very often, those people don’t have expertise in device development and commercialization. It’s an intimidating arena to enter, and having these consortia programs available to nurture ideas and help move them toward something that is actually helping patients is a vital function. Without an advocate to help an inventor turn an idea into something that will attract investment, ideas like mine would wither on the vine.

**ABOUT NEPDC GRANT OPPORTUNITIES**

Through NEPDC grant awards, clients receive both seed funding and access to NEPDC Core Services, providing short-term, concentrated assistance to accelerate the commercialization process. Depending on each client’s unique background and commercialization requirements, our consortium of engineers, researchers, clinicians, and entrepreneurs provide expert guidance in the form of:

- Engineering design and transfer to manufacturing
- Development of intellectual property and regulatory strategy
- Pre-clinical and clinical trial design and execution

*Continued on Page 13*
• Strategic market planning and business development
• Identifying co-funding opportunities

We encourage individuals and organizations seeking either pediatric device solutions or pediatric device commercialization assistance to share your idea with us today. At NEPDC, we believe that no hurdle is too high for a product that can positively impact the life of a child.

NEPDC awards funding and in-kind service hours on a quarterly basis. We do this through a multi-phase review process. You can apply through our web-based submission system.

Learn more about the application process at http://nepdc.org/application.html.
(The next round takes place in January, 2017)
The 2016 iCAN Research and Advocacy Summit was an engaging five-day conference held in Barcelona, Spain that brought together over 160 youth advisors, team leaders, parents and scientific partners representing 15 iCAN chapters from 6 countries on 2 continents. iCAN partnered with Sant Joan de Déu Hospital to host this event, which held a myriad of interactive sessions, workshops and expert panels. The objective of iCAN and the Summit is to educate and empower our youth to improve pediatric health, medicine, research and innovation by sharing children's voices in an impactful way.

Among those in attendance were speakers and representatives from leading organizations such as the US Food and Drug Administration, Health Canada, European Medicines Agency, Pfizer, Premier Research, European Organization for Rare Diseases, Dravet Syndrome Foundation, Pharmaceutical Product Development, Nuffield Council on Bioethics, European Patients’ Academy on Therapeutic Innovation, The Royal College of Paediatrics and Child Health, and various Children’s Hospitals from around the world. Children and families had the opportunity to engage with world leaders in science, while learning about different innovative treatments, personal health, regulation, the clinical research design and process, and patient advocacy. A poster session gave children and young people the opportunity to present the many projects each team has worked on since iCAN’s launch. The Summit also included other educational and cultural activities such as tours of the Sagrada Familia de Gaudi, FC Barcelona's Camp Nou, CosmoCaixa Museum of Science, and Fundació Alícia, a research center focused on healthy lifestyles.

Please

SAVE THE DATE

The

2017 iCAN Research and Advocacy Summit

will take place on

Monday, July 10 – Friday, July 14, 2017
Loews Sapphire Falls Resort at Universal Orlando
Orlando, Florida

Sponsorship opportunities are available and are needed - please contact Meghan at mgwara@icanresearch.org

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This event provided our youth with an invaluable opportunity to learn from one another and network with professionals from across the globe, while allowing the scientific community to engage with children and learn about the value and the significant importance of the influence of children on research, medicine, and innovation. iCAN aims to continue to expand the network and opportunities for our youth, as well as increase the success of the Summit each year. More information and pictures from the 2016 Summit can be found at www.icanresearch.org/summit.

Recipient: Linda Ulrich MD, FAAP

Award Description:
The AAP Section on Advances in Therapeutics and Technology Award for Pediatric Innovation recognizes an individual who has greatly contributed to the field of pediatrics, pediatric therapeutics or pediatric technology through hard work and innovation. The 2016 recipient is Linda Ulrich, MD, FAAP.

This Award is support by Pfizer, Inc.
### 2016 NCE Abstracts

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<td>The Role of Intravenous Access during Oral Food Challenges in Food Protein-Induced Enterocolitis Syndrome</td>
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<td>Effect of KRN23, a Fully Human Anti-FGF23 Monoclonal Antibody, on Rickets in Children with X-linked Hypophosphatemia (XLH): 40-week Interim Results from a Randomized, Open-label Phase 2 Study</td>
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<td>Quantification of the Distribution of Azelastine HCl/Fluticasone Propionate Nasal Spray in an Anatomical Model of the Human Nasal Cavity</td>
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<td>A Multifaceted Waveform High Frequency Ventilator System</td>
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<td>Extracorporeal membrane oxygenation bridge to pediatric lung transplantation: trends in the United States</td>
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<td>Long-Term Safety of Crisaborole, a Novel, Nonsteroidal, Topical, Anti-inflammatory, Phosphodiesterase 4 Inhibitor in Children and Adults With Mild to Moderate Atopic Dermatitis</td>
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<td>Harmonics of High Frequency Ventilation at 3Hz</td>
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<tr>
<td>A Novel Nonsteroidal, Topical Anti-inflammatory, Phosphodiesterase 4 Inhibitor, Crisaborole Ointment, Reduced Pruritus and Signs of Atopic Dermatitis in 2 Phase 3 Studies in Children and Adults</td>
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<tr>
<td>Phase 3 Studies Treating Children and Adult Patients With Mild to Moderate Atopic Dermatitis With Crisaborole Ointment, a Novel, Nonsteroidal, Topical Anti-inflammatory, Phosphodiesterase 4 Inhibitor</td>
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**AAP experience**

National Conference & Exhibition

October 22 – 25, 2016 | San Francisco

**We’re New and Need You!**

**How to Join . . .**

It’s easy! There are NO DUES to join the SOATT if you are an AAP member.

Send an e-mail to Jackie Burke at jburke@aap.org to request to be added to the Section.
A Message from the Membership Committee

Chris Rizzo, MD, FAAP
SOATT Membership Committee Chair
crizzo624@gmail.com

It is an exciting time to be involved in generating new information on pediatric technology, devices and medications.

Those of you reading this newsletter are likely SOATT members. We rely on your help to recruit others to the Section. Members of the Section do not need to be eligible for AAP membership. See below for membership categories and eligibility.

Our Section continues to grow and now has 629 members!

Who Can Join?
1. AAP Members

Membership in the section is open to AAP Fellows, Specialty Fellows, Candidate Members, Post Residency Training Members, Honorary Fellows, Residents, Medical Students, Emeritus Fellows, and Corresponding Fellows with an interest in advances in therapeutics and technology. There is no fee for AAP members.

2. SOATT Affiliate Members

Affiliates are those who are not eligible for membership in the AAP and hold a Masters degree or Doctorate (or equivalent) in pharmacy or other health science concentration. Affiliates must submit an application (see “How to Join” below) and have a signed letter of support from an AAP fellow in good standing. There is a $40 annual fee for section affiliate members.

How To Join?
If you are already a member of the AAP and would like to become a SOATT member, join online by:

1. Going to Member Center of the AAP website and use your AAP login and password.
2. Click on “Join a Section or Council” under Member Community
3. Choose “Advances in Therapeutics and Technology”, answer a few questions, and click “Submit”.

Membership applications can be found at:
Members: http://membership.aap.org/Application/AddSectionChapterCouncil
Affiliates: http://membership.aap.org/Application/SectionAffiliate

If you have any questions about membership, please contact Chris Rizzo MD FAAP at crizzo624@gmail.com or the section staff at jburke@aap.org.
Welcome New Members
(April 2016 to September 2016)

Richa Varshney, MD
Sarah Cheema, MD
Saif Ullah, MD
Shashirekha K. Shetty, MD, FAAP
Andrew O. Hopper, MD, FAAP
Himat G. Tank, MD, FAAP
Linda P. Slater-Myer, MD, FAAP
Daniel Anthony Deane, MD, FAAP
Manaf G. Ahmad, MD, FAAP
Wafaa G. Hanna, MD, FAAP
Cindy Burch Daugherty, MD, FAAP
Gloria Cecilia Valiente, MD, FAAP
Neepa Jay Ved, MD, FAAP
Deborah Maria Fernandes, MD, FAAP
Kimberley Jo Dilley, MD, MPH, FAAP
Clemente Diaz, MD, FAAP
Rekha Prakash Manghnani, MD, FAAP
Stacey A. Walker, MD, FAAP
Mariam W. Fahim, DO, FAAP
Ziad Solh, MD, MSc, FRCPC, FAAP
Nimisha Gupta, MD, FAAP
Mohamad Charif Hassan, MD, FAAP
Ingrid Yolanda Camelo, MD, FAAP
Parvathy Thaikkendiyil, MD, MBBS, FAAP
Ganesh K Namachivayam, MD, MPH, FAAP
Shalini Reddy Beesam, MD, FAAP
Hector Eduardo de Leon, MD, FAAP
Sunanda Kotagiri Chelikani, MD, FAAP
Kathleen Asas, MD, FAAP
Cigal Tzivia Shaham, MD, FAAP
Kalyan Ray Parashette, MD, MPH, FAAP
Tonia Nateria Barton, MD, FAAP
Shahrouz Daniel Ganjian, MD, FAAP
Katherine A. Wu, MD, FAAP
Matthew P. Malone, MD, FAAP
Krishnawari Pant, MD, FAAP
Justin Waco Goodnight, MD, FAAP
Fahimot Oyinlola Faduile, MBBS, FAAP
Ophelia Adipa, MD, FAAP
Jeffrey Brian Smith, MD, FAAP
Nicole Aleida Gavallas, DO, FAAP
Tetsuya Hirano, MD
Melanie Widjaja, MD
Reham Ismail Ali, MD
Nawaf Saeed Alkhayat, MD
Rodrigo Ferreira Basilio, MD
Antonio Carlos Martins, MD
Shruthi Kumar Bharadwaj, MD, DM
Subrat Singh, DCh, DNB
Rita Goncalves, MD
Heba Morsi, MD
SchMiyah Smith
Brian Wu
Madeleine O’Keefe
Minella Capili
Jatinderpal Kaur Gosal
Joshua Maxwell
Jonathan James Uhl
Brittani M. Corbisiero
Nicole Anderson
Sumeet Gill
Ancy Mohan
Zachary Burch
Doel Dhar
Tahnee Ludwig
Kristin Mitchell
Matthew O’Brien
Julie A. Klensch
Eureka Llowanna Phillip
Aida Francis
Sarah Morse
Catherine Ezzio
Tai Pham
Lindsay Schleifer
Tim Jaeger
Mythili Rao
Rachel Segal
Mehrin Islam
Hannah Hoerner

(Continued on Page 21)
<table>
<thead>
<tr>
<th>Welcome New Members Continued from Page 20</th>
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<tr>
<td>Kimberly A. Samonte</td>
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<td>Lakshmi Menon</td>
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<td>Priyamvada Pillai</td>
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<td>Jun Yu</td>
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<td>Matthew Charles Wilkinson</td>
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<td>Sana Virani</td>
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<td>Irfan Helmy</td>
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<td>Ioni Kokodis</td>
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<td>Keira Kilmartin</td>
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<td>Prisca Takundwa</td>
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<td>Kamaris Loor</td>
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<td>Cassandra Busler</td>
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<td>Gabrielle Butts</td>
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<td>Alexander Tuttle</td>
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<td>Daniel Liu</td>
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<td>Shruti Sakhuja</td>
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<td>Robert Garner</td>
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<td>Sarah Bronwyn Lowry</td>
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<td>Jennifer Flores Kaswick</td>
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<td>Subodh Arora</td>
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<td>Ashley Young</td>
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<td>Syed M. Rizvi</td>
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<td>Antonia Kopp</td>
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<td>Leigh Joan Boghossian</td>
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<td>Alexa Goldfarb</td>
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<td>Julia White</td>
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<td>Beau Bigelow</td>
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<td>Benjamin Philipson</td>
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<td>Mona Farahi</td>
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<td>Rina Desai</td>
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<td>Shannon Daly</td>
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<td>Saima Sarmin Mukta</td>
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<td>Michael Sean Bowie</td>
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<td>Kristin Michelle Bird</td>
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<td>Rifat Zaman</td>
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<td>Radhika Mehdinratta</td>
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<td>Rebecca Webb</td>
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<td>Andrew Monson</td>
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<td>Samuel Pabon</td>
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<tr>
<td>Arthur Fu</td>
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<td>Cassandra Koid Jia Shin</td>
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<td>Laura Kirkpatrick</td>
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<td>Allan Joseph Medwick</td>
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<td>Aparna Alavalapadu</td>
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<td>Brock Phillips</td>
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<td>Bushra Rizwan</td>
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<td>Lauren Thai</td>
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<td>Jacqueline Bolt</td>
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<td>Emma Arlene Moradogli Haftevani</td>
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<td>Alaa Ramadan</td>
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<td>Amber Marie Alberts</td>
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<td>Danielle Daniels</td>
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<td>Roya Edalatpour</td>
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<td>Ekta Shah</td>
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<td>Rabjot Kaur Rai</td>
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<td>Scott Treece</td>
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<td>Desiree Jones</td>
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<td>Kanneganti Divya</td>
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<td>Kevin Francioni</td>
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<td>Annais Antoinette Santiago</td>
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<td>Amanda Rae Holloway</td>
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<td>Alexi Jordan Shean</td>
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<td>Emily Moody</td>
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<td>Katina Summerford</td>
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<tr>
<td>Basavaraj Mallappa Kerur, MD, FAAP</td>
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<td>Tavleen Bhatia, MBBS, FAAP</td>
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<td>Divij Pasrija Sr., MD</td>
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<td>Louise Malburg, MD</td>
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<td>Mai-Anh Tran-Ngoc, DO</td>
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<td>Geoanna Marie S. Bautista, MD</td>
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<td>Pavan Bang, MBBS</td>
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<td>Alaa Ahmed Ebrahim, MD</td>
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<td>Alexandre Guilherme Troullioud Lucas, MD</td>
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<td>Suzet Wasfy Francis Moawad, MD</td>
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<tr>
<td>Juhi Uddin, DO</td>
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<td>Tatiana Lara Ospina, MD</td>
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<td>Harold Delasalas, MD, PharmD, FAAP</td>
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Section on Advances in Therapeutics and Technology - Fall 2016  Page 21
Announcements from the AAP

Section Produces Patient Education Brochure on Clinical Trials

Should My Child Join a Clinical Trial? Patient education brochure was finalized and published in February 2014. The brochure covers:

- Why are clinical trials for children needed?
- How are clinical trials done?
- What are the benefits and risks of a clinical trial?
- What do I need to know before I sign up my child for a clinical trial?
- What questions should I ask about a clinical trial?
- Words to Know
- For more information

For a free sample copy of the brochure, please contact AAP Customer Services at 866/843 -2271.


Letter to the Editor of Pediatrics on Unpublished Children's Research

In August, 2016 the Pediatrics journal published an article about “Children's Research Often Goes Unpublished.” See the original article at http://pediatrics.aappublications.org/content/early/2016/08/02/peds.2016-0223?sso=1&sso_redirect_count=1&nfstatus=401&nftoken=0000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token

Members of the SOATT submitted a letter to the Editor on that article:

Children's Research Often Goes Unpublished LETTER TO THE EDITOR

Drs. Florence Bourgeois and Natalia Pica – pediatricians at Harvard Medical School and Boston Children's Hospital – recently published a manuscript in Pediatrics (Pediatrics 2016; 138: 1-9) investigating interventional clinical trials in children conducted between 2008 and 2010. Their paper revealed two “troubling” findings. First, that 104 of the 559 trials started (19%) were discontinued

Continued on Page 23
before they were completed. Second, of the 455 completed trials, 136 (30%) were not published. As Bourgeois and Pita note, there is an ethical imperative to ensure that the results of clinical trials are reported and that the risks taken by the children who participated in the research benefits all children. Determinants of study discontinuation and publication are complex. Discontinuation was less common among industry funded than among investigator-initiated studies and failure to publish was more common among industry-funded studies. Many unpublished studies were funded by classical academic sources and conducted in leading academic centers. Clearly other factors are at play. A recent commentary on NPR Health News reviewing this study suggested that this occurs because investigators “don't take the effort to publish and share their results.” Having published many clinical trials, we found this assessment is unfair to the researchers and fails to identify likely causes. Several practical issues make publication of pediatric clinical trials difficult. Pediatric trials are often small, especially when compared to many adult studies, which detracts from their perceived scientific and societal impact and negatively affects publication decisions. Trials involving children are more likely to be published in pediatric journals as opposed to more widely read mainstream biomedical journals. This is especially true for studies reporting negative results, a factor known to be associated with editorial bias. Pediatric trials are often conducted long after adult approval when “off-label” pediatric treatment is frequent which reduces parent, practitioner and investigator enthusiasm contributing to small studies. Pediatric studies may be conducted to satisfy a regulatory requirement rather than to generate new knowledge to improve pediatric therapy reducing both investigator and publisher enthusiasm, again contributing to small and hard to publish studies. Finally, clinical trials initiated after September 27, 2007 that meet the FDAAA 801 definition of an “applicable clinical trial, conducted at one or more sites in the U.S. or those supported by funding from the U.S. National Institutes of Health must register at ClinicalTrials.gov. While this mechanism does make information from specific trials generally accessible, it is not a substitute for the proven, time-honored peer review publication process. In conclusion, child health researchers are by and large hard working, ethical and highly motivated professionals who are committed to improving the health and welfare of children through the process of discovery, which includes conducting and publishing research to the highest standard. The implication that the publication gap is due to lack of effort is, in our view, neither accurate nor fair.

Gregory L. Kearns, PharmD, PhD, FAAP  
Sr. Vice President / Chief Research Officer, Arkansas Children’s  
President, Arkansas Children’s Research Institute  
Professor of Pediatrics, University of Arkansas for Medical Sciences

Michael Rieder MD Ph.D FRCP FAAP  
CIHR-GSK Chair in Paediatric Clinical Pharmacology  
Schulich School of Medicine & Dentistry  
Distinguished University Professor  
Western University

Robert Ward, MD, FAAP, FCP  
Emeritus Professor, Pediatrics  
University of Utah
MILESTONES 2010-2016

➢ July, 2010 - Provisional Section approved by the AAP Board of Directors
➢ Section begins with 40 charter members and has 596 members today
➢ Section develops communication tools for members: list serv, Web page, newsletter
➢ October, 2011 - Section launches first educational program at NCE
➢ October, 2011 - Andy Schuman showcases new gadgets at NCE's Office of the Future
➢ SOATT writes about non-traditional pediatric careers for the young physician newsletter
➢ October, 2012 - Section showcases a parent (Lindsey Elsaesser) at NCE program to talk about pediatric clinical trials from the parent's perspective
➢ February, 2013 - Section creates a forum for scientific research abstracts, which are showcased @ the NCE. To date, 135 papers have been submitted, reviewed, scored and many showcased at NCE both in oral and poster formats. Posters have been showcased in several different areas of the NCE space including the exhibit hall and convention centers so that attendees (other than those attending the SOATT H program) can view.
➢ May, 2013 - Section changes its bylaws to accept affiliate members who are PHARMD's and other health care providers
➢ May, 2013 - Section offers its first webinar on Gadgets & Gizmo's for the Pediatric Office with Andy Schuman; over 100 register. Can view on-demand
➢ May, 2013 - Section approved to be full Section of the AAP
➢ October, 2013 - SOATT expands its reach at the NCE by offering a plenary with Stephen Spielberg on the Importance of Pediatric Research and a Gadgets & Gizmo’s session.... sold out!
➢ October 2013 - Section participates in Resident Career Day at NCE (Toback, Schuman)
➢ February, 2014 - Section publishes a brochure for parents on “what is a pediatric clinical trial?”
➢ March 2014 - Section holds its first section election

Continued on Page 25
➢ 2014 - Section is now regularly collaborating with other AAP Sections and Committees, including Clinical Pharm, Drugs, Pediatric Research, and the NCE Planning Group

➢ October 2014 - Section gives its first annual award for pediatric innovation

➢ November 2014 - Section convenes the Stakeholder Forum, an international effort to explore the development of a pediatric clinical trials network. The Forum is an overwhelming success. Groups writes consensus statement to: Establish a Global Pediatric Clinical Trials Network and are committed to engage in the work to create and sustain it.

➢ 2014 Kids Impacting Disease through Science (KIDS) program piloted


➢ Fall 2015 Section abstracts published in Pediatrics

➢ December, 2015 - Section publishes a paper in Pediatric Research on the Stakeholder Forum to study the formation of a Global Pediatric Clinical Trials Network. Kathleen Neville appointed by AAP to serve on Critical Path's team to create Network.

➢ October 2015 - Dianne Murphy gives session at NCE on the Role of the FDA in Issues Facing Practicing Pediatricians

➢ January, 2016 - Parent joined SOATT executive committee as advisor

➢ March, 2016 - Section receives Section Innovation Award from the AAP during the 2016 Annual Leadership Forum
Thank You Charlie Thompson and Seth Toback

Charlie Thompson, MD, FAAP rotates off as SOATT Chairperson on November 1, 2016. Charlie is the inspiration behind most of the accomplishments of the Section noted in the MILESTONES article in this newsletter. If you don’t know Charlie, he is a real idea guy constantly thinking of new ways to inspire and highlight innovations in pediatrics. He will be greatly missed by the leadership team. The good news is that Charlie will stay on as immediate past chairperson to help keep our great momentum rolling. Charlie, we can’t thank you enough for all that you have done! THANK YOU!

Seth Toback, MD, FAAP rotates off as SOATT Executive Committee Member on November 1, 2016. Seth served in many roles for the Section over the last six years including Communications Subcommittee Chairperson, Membership Chairperson and Newsletter Editor. Good luck to Seth and THANK YOU!