ROUNDTABLE ON PATIENT SAFETY
AND HOSPITAL COMPOUNDING

Major Themes of the Delegates' Meeting

October 11th, 2017

Washington, DC

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I. Introduction and Background

In 2012, a fungal meningitis contamination of a compounded steroid medication produced by the New England Compounding Center (NECC) led to 78 deaths and nearly 778 patients suffering an adverse health effect, including 384 cases of meningitis and spinal infection. The scale of this outbreak makes it one of the most fatal or harmful drug safety event in recent history. According to a 2016 State of Pharmacy Compounding report, one-third of health systems acknowledge experiencing a patient health event involving a compounding error over the past five years.

On October 11th – five years after the NECC crisis and on the heels of considerable legislative, regulatory, industry, and public health activity – the Roundtable on Patient Safety and Hospital Compounding was held in Washington, DC. Discussants assessed progress made in hospital compounding safety and to identify opportunities to improve policy and practice in ways that further move the needle toward systemic safety.

The meeting featured presentations and stakeholder discussions on:

- Key Considerations in Hospital Compounding;
- The Role of Technology in Advancing Patient Safety;
- Prescriber Awareness of Compounded Products; and
- Raising the Bar on Drug Quality: Federal, State, and Hospital Policy Activities

Congress enacted the Drug Quality and Security Act (DQSA) in 2013 to provide additional oversight authority to the Food and Drug Administration as it relates to overseeing pharmaceuticals distributed in the United States. The legislation was, in part, in response to the New England Compounding Center crisis and was designed to help protect consumers from exposure to harmful drugs.

The meeting also featured keynote remarks from the father of a child who tragically passed due to a hospital medication error in 2006, compelling him to launch a foundation to make medical facilities in the United States safer for everyone, including children like his daughter. Christopher Jerry, President of the Emily Jerry Foundation, reminded stakeholders that while much has been done to improve hospital patient safety related to compounding, there is a great deal more that clinicians, manufacturers, hospitals and policymakers must do to address continuing system gaps that leave hospital patients unnecessarily vulnerable.

Mr. Jerry spoke to the need to eliminate human error in hospitals though the discussion of technology and better education, and the need to develop and promote leading practices to ensure patient safety, including through increased deployment of technologies, utilization of commercially available pre-mix therapies, and other process improvements.

Following Mr. Jerry's remarks, nearly 40 of the nation's leading patient safety, public health, prescriber, provider, and manufacturer voices discussed in depth the specific challenges that

remain, the policy and clinical improvements that may form an opportunity for cross-stakeholder alignment, and the known, leading practices that can be promoted to ensure the safety of medications given to hospital patients.

II. Discussion Themes

As leaders from around the nation and across key sectors took to addressing the question of whether enough has improved post-NECC to ensure hospital patient safety, and what more should be done, several key themes emerged from the discussion. Some of these included:

- ***Too many compounding errors and most due to human error. More system and policy improvements are urgently needed. Therefore, whenever possible and appropriate, commercially-available pharmaceutical products in ready-to-use format should be used to minimize the need to compound or use an outsourced compounding service.***

In spite of important advances in hospital protocols and technology, preventable human errors that afflict unnecessarily large numbers of patients do not occur intentionally or because we have poor clinicians in the United States, discussants generally agreed. Rather, they continue to occur because there are too many systemic opportunities for human error that can have significant – and sometimes tragic – adverse circumstances.

Panelists and participants expressed that more must be done to ensure that patients are administered safe medications in hospitals, including, for example, through more active regulation, better education and awareness efforts, and through the use of commercially available technological and pre-mix medications.

- ***Additional training is needed for <u>all</u> clinicians – pharmacists, doctors, and nurses.***

The vast majority of participants agreed that clinicians, by and large, are not sufficiently aware about when they are prescribing or administering a compounded product. Some participants believe that prescribers who are compounding sterile drugs may be unaware of the practices that are dictated by the quality standards in USP 797 and many believe that adoption and implementation of 797 varies widely. Subsequent sections of this document, including the overview of the pre-meeting survey, will get more into USP 797.

Providers are facing challenges such as limitations in proper training, the lack of a universally accepted or adequate education curriculum, and poor coordination between and among medical providers in a hospital setting. These deficiencies exist in proper utilization of existing technology, lack of guidance from the FDA, and minimal sterile compounding education and training – both formally in medical or pharmacy school and informally in health systems.

- ***Challenges exist in regulating and enforcing compounding safety guidelines.***

Under the passage of the Drug, Quality and Security Act (DQSA) in 2013, Congress required the FDA to implement guidances related to compounding. Unfortunately, these guidances have yet to be released and providers are also awaiting the release of a new United States Pharmacopeia chapter, 797, to focus on patient safety. Parties are interested as to what USP 797 will look like.

- ***There is need for a standard set of national leading practices to help guide hospitals and clinicians and serve as a checklist to boost the safety of hospital compounding efforts.***

One way to address this challenge, participants noted, would be to develop a uniformly adopted set of best practices for compounding by hospital pharmacies. Many efforts have taken place over the years – including through efforts by USP, ASHP and others. Unfortunately, these guidelines are not widely accepted and implemented throughout health systems in the United States. The need for such a set of guidelines – and one that was uniformly adopted – was a key theme throughout the meeting.

III. Key Takeaways and Recommendations

At the conclusion of the panel discussions, Participants at the meeting developed a list of recommended leading practices to distribute to improve patient safety related to compounding of medications, especially because there is widespread concern that existing best practices are still not broadly adopted. In particular, participants discussed leading practices designed to reduce medication errors in hospitals.

The three most often-cited recommendations included:

- ***Increased adoption of technologies in hospitals to prevent human errors***

Participants noted that recent technological advances like IV admixture (or IV workflow) technology, which includes barcoding and gravimetric testing can minimize the potential for human error, including for compounded medicines. Still, these advances are widely underutilized; only 2 in 10 hospitals currently employ these technologies. A majority of the attendees believe that it should be mandatory for hospitals to adopt technologies that support IV drug preparation, recognizing a provider learning curve and costs associated with adopting technology.

- ***Wherever available and appropriate, use commercially manufactured products and medicines***

Discussants noted that, by using commercially premixed medications, sterile compounding conducted in a pharmacy would be reduced and as a result medication errors would also be reduced. Premix solutions would free hospital pharmacists to assist physicians and nurses in

other necessary tasks because premix follows current good manufacturing practices and are technologically friendly.

- ***Increased training and support for uniform curriculum for sterile compounding practices***

Participants noted that schools of pharmacy do not always include sterile compounding as part of their core curriculum. Often, a pharmacy technician, working under the supervision of a pharmacist, prepares intravenous solutions for patients. In addition to mixing IV solutions, the technician is responsible for tasks such as recordkeeping and labeling of solutions. Unfortunately, some participants said lack of clarity from the FDA, lack of knowledge by technicians around proper technique, human error, and inadequate checklists has meant that medication errors are inevitable. To reduce pharmacy technician errors, there should be a standard, accessible pharmacy technician curriculum that teaches core competency.

IV. Survey of Select Participants and Steering Committee Members

In preparation for the October 11th Roundtable discussion, a survey was conducted among Steering Committee members and other select participants designed to help lay the foundation for the meeting's dialogue, and to identify current perceptions about the state of hospital compounding safety from leading stakeholders.

Key findings and themes from this survey are as follows:

1. **Survey respondents (50 percent) cited continued tensions between the cost and availability of medicines and the resulting challenges to the quality and safety of medications administered in a hospital setting.**

2. **Respondents believed (66 percent) that current oversight and regulation of outsourcing facilities is not strong enough, and 92 percent noted that federal enforcement of these guidelines is insufficient.**
    - 92 percent of respondents noted the inadequacy of compounding industry self-regulation efforts, while
    - 75 percent of respondents pointed to the need to improve state enforcement of safety guidelines.

3. **A majority of respondents (75 percent) agreed that prescribers are not sufficiently aware when they are prescribing or administering a compounded medicine and that there is a need to increase the amount and quality of clinical awareness of compounding.**

4. **The most commonly cited best practices to boost patient safety among survey respondents (64 percent) were the use of commercially available pre-mix and the benefit of technological advances that have emerged in recent years.**

Additional survey highlights included:

- Three post-NECC developments were cited by respondents as being the most beneficial changes to compounding policy and practice. These developments included:
    - The enactment of the Drug Quality and Security Act (DQSA);
    - FDA regulations and enforcement of guidelines with regular inspections, and improved implementation of USP <797> by states; and
    - Technological advances including the development of new software to reduce preparation errors, waste, improve pharmacy productivity and boost record-keeping.
- Only 38 percent of survey respondents believed that hospital compounding best practices have been uniformly adopted.
- Respondents were also asked about current challenges to hospital compounding as it relates to sterility and patient safety. A majority of respondents pointed to these three current challenges:
    - Need for better enforcement of standards for compounding outsourcing facilities as well as assurance of hospital compliance with safe practices when performing in-house compounding;
    - Compliance challenges associated with hospital in-house compounding, including varying practices for cleanroom compounding between staff members and differences between systems; and
    - Other related concerns related to outsourcing facilities, including competitive pricing pressures, shortages, and the need for increased FDA oversight.

V. Panel Overviews of the Roundtable and Delegates Discussion

The Roundtable meeting was broken into three sessions, with each yielding active discussion, thoughtful presentations from clinical and policy leaders, and important takeaways from robust delegate dialogue. Each session was structured to highlight leading practices and help generate consensus on next steps to ensuring the safety of medications administered to hospital patients. An overview of those sessions is below.

a. <u>Session 1: The Role of Technology within Health Systems</u>

Delegates noted that prior to the 21st century, the use of barcodes on medications was limited. Immediate drug package labels did not include barcodes and, beginning in 2004, the Food and Drug Administration required drug manufacturers to include barcodes on all immediate packages. Now, over 90 percent of hospitals are scanning patients and most medications at the point of care, which has proven to reduce medication errors.

There was agreement among delegates that commercially premixed IV solutions can also limit the possibility of the human element out of medication errors and – partnered with more scanning – would decrease the amount of errors. Unfortunately, fewer than 20 percent of U.S. hospitals are utilizing available and proven barcode assisted IV preparation technology.

Discussants said hospitals should support the acquisition of IV admixture technologies that incorporate barcoding and volume-verification technology, which allow pharmacists to confirm correct drugs and volumes without overseeing the technician. There are barriers for students in pharmacy school, such as the cost of teaching sterile compounding and there is also the fear of new technology. Some hospitals resist utilization of this technology because of the challenges of implementation as well as the cost. For those hospitals that have adopted this technology, it is estimated to have prevented over 5 million medication errors.

b. Session 2: Raising the Bar on Drug Quality

There was a belief among many participants that since the passage of the Drug Quality and Security Act (DQSA) in 2013, state Boards of Pharmacy have been more actively involved in efforts to ensure the safety and quality of medicines. This has been evidenced by the higher inspections of compounding facilities to ensure USP compliance. Still, discussants mentioned ongoing compliance challenges: first, while health care providers and health care systems are improving compliance with USP standards for compounding sterile preparations, there is still a 20 percent non-compliance rate. Additionally, since USP 797 was created 13 years ago, only 32 states require compounding pharmacies to comply, and one state does not even require the use of sterile gloves for low-risk compounding.

There was concern among participants that, even with the passage of DQSA, which separated the traditional compounders (pharmacists and physicians) and created a new category for large-scale compounding pharmacies, there is still confusion and too much in flux. For example, delegates mentioned confusion around what the soon-to-be-finalized (December 2019) USP Chapter 800 will look like. The purpose of USP 800 is to describe practice and quality standards for handling hazardous drugs and promote patient safety, worker safety, and environmental protection. FDA's enforcement of the DQSA has also been more limited than it should be, many stakeholders asserted, as it has yet to finalize many DQSA-triggered guidances.

VI. Next Steps

Participants at the Roundtable on Patient Safety and Hospital Compounding agreed on the need to develop a tool to help ensure the safety of medications given to hospital patients. This tool – a checklist – will be developed and disseminated and will encapsulate the common themes and suggestions agreed upon by the participants of the Roundtable.

Appendix A: List of Participants

Terri Albarano, Pharm.D., MS
Group Marketing Manager
Baxter Healthcare
Lake Villa, IL

Monica Brand
Senior Marketing Analyst – Global Nutrition
Baxter International Inc.
Deerfield, IL

Ariella Cohen, JD
Healthcare Products Associate
The Pew Charitable Trusts
Washington, DC

Gabrielle Cosel, MS
Policy Analyst
Food and Drug Administration
Silver Spring, MD

Shannon Curtis, JD
Assistant Director, Federal Affairs
American Medical Association
Washington, DC

Robert Eastin, Pharm.D.
Pharmacy Operations Manager
Scripps Health
San Diego, CA

Todd Ebert, MS
President and CEO
Healthcare Supply Chain Association
Washington, DC

Jonathan Edwards
Group Manager
Marketing – IV Sol, Drug Delivery Marketing
Baxter International Inc.
Deerfield, IL

Beth Ferguson, Pharm.D.
Deputy Director
Minnesota Board of Pharmacy
Minneapolis, MN

Adam Harbison, MS
Director, Congressional Affairs
National Community Pharmacists Association
Alexandria, VA

Katrina Harper, Pharm.D., MBA, BCPS, DPLA
Senior Clinical Manager
Vizient
Irving, TX

Chris Jerry, BBA
President and CEO
The Emily Jerry Foundation
Mentor, OH

Samuel Johnson, Pharm.D., BCPS, FCCP
Associate Executive Director
Board of Pharmacy Specialties
Washington, DC

Christopher Jones, R.Ph.
Director, Pharmacy
Premier, Inc.
Charlotte, NC

Elizabeth Jungman, JD, MPH
Director, Public Health Programs
The Pew Charitable Trusts
Washington, DC

Eric Kastango, MBA, B.S.Pharm, FASHP
President and CEO
Clinical IQ, LLC
Madison, NJ

Jim Lund, Pharm.D., MS
Director of Pharmacy Operations
Massachusetts General Hospital
Boston, MA

Jeannell Mansur, R.Ph, Pharm.D., FASHP, FSMSO, CJCP
Principal Consultant, Medication Management and Safety
Joint Commission Resources
Chicago, IL

Tara Modisett
Executive Director
Alliance for Patient Medication Safety
Chesterfield, VA

Mark Neuenschwander
President
The Neuenschwander Company/Project THRIV
Bellevue, WA

Joy Onuma
Baxter Healthcare
Washington, DC

Anthony Pudlo, Pharm.D., MBA, BCACP
Vice President of Professional Affairs
Iowa Pharmacy Association
Des Moines, IA

Margaret Reagan
Vice President, Advocacy
Premier Healthcare Alliance
Washington, DC

Crystal Riley, Pharm.D., MHA, MBA
Senior Manager, Healthcare Policy and Reimbursement
Baxter Healthcare
Washington, DC

Sara Rothman, JD, MPH
Consumer Safety Officer
Food and Drug Administration
Silver Spring, MD

Gordon Sacks, Pharm.D., BCNSP, FCCP
Professor and Department Head, Pharmacy Practice
Auburn University Harrison School of Pharmacy
Auburn, AL

Roslyne Schulman, MBA, MHA
Director, Policy Development
American Hospital Association
Washington, DC

Jillanne Schulte Wall, JD
Director, Federal Regulatory Affairs
American Society of Health-System Pharmacists
Bethesda, MD

Nadine Shehab, Pharm.D.
Senior Service Fellow, Division of Healthcare Quality Control
Centers for Disease Control and Prevention
Atlanta, GA

Liz Shlom, Pharm.D., BCPS
Senior Vice President and Director, Clinical Pharmacy Program
Acurity, Inc.
New York, NY

Stephanie Silverman, MBA
Chief Executive Officer
Venn Strategies
Washington, DC

Kathryn Spates, JD, ACNP-BC
Director, Federal Relations
The Joint Commission
Washington, DC

Connie Sullivan, R.Ph.
Vice President of Research and Innovation
National Home Infusion Association
Alexandria, VA

Jeanne Sun, Pharm.D.
Scientific Liaison for the Compounding Expert Committee
United States Pharmacopeial Convention
Rockville, MD

Iris Tiongco, MPH
Senior Associate, Healthcare Products
The Pew Charitable Trusts
Washington, DC

Krystalyn Weaver, Pharm.D.
Vice President, Policy and Operations
National Alliance of State Pharmacy Associations
Washington, DC

Gregory Westby, BA, B.S.Pharm, MSCR, R.Ph.
Clinical Compounding/Quality Assurance
Duke Compounding Facility
Duke University Health System
Durham, NC

Angela Yaniv, Pharm.D.
Assistant Director of Pharmacy -Sterile Products
Cleveland Clinic
Cleveland, OH

Appendix B: Speaker Biographies

Chris Jerry
President and CEO
Emily Jerry Foundation
Mentor, Ohio

Since Emily Jerry's tragic death 10 years ago from a preventable medication error, Chris began this unintentional quest, chosen for him, to work diligently to affect positive change in medicine. Consulting with the brightest minds in healthcare, he has helped transform the culture of medicine, how it is practiced in the U.S., and more importantly how we respond and learn from these preventable errors which have now been identified as being the third leading cause of death in the United States.

Chris founded the Emily Jerry Foundation, in honor of his daughter's name, to focus attention on the underlying systems, processes, and protocols in medicine, and to find comprehensive solutions that minimize this inherent "human error component of medicine." Following Emily's tragic medication error, he identified where and how the human error occurred and, subsequently, found solutions to prevent this from ever happening again.

The foundation began in August of 2009 in the state of Ohio shortly after the passage of "Emily's Law". Chris has become a respected speaker and sought-after advocate, not only for patient safety, but for clinicians as well. There has been a significant increase in public awareness of the foundation's key patient safety-related issues. Chris passionately seeks solutions which not only would have saved Emily's life, but countless others who have died senselessly ever since.

Crystal A. Riley, Pharm.D., MHA, MBA
Senior Manager of Healthcare Policy and Reimbursement
Baxter Healthcare Corporation
Washington, DC

In her role, she is responsible for all policy stakeholder engagement activities for Baxter's US acute care biosurgery and medical product franchises in addition to managing the company's health information technology and quality and performance measurement policy issues.

Prior to joining Baxter, Dr. Riley was the associate director of federal relations for the Joint Commission where her portfolio included drug information, healthcare quality measurement, and hospital issues including emergency preparedness. Dr. Riley also practiced as a clinical pharmacist in large community hospitals, focusing on quality research, drug information, and training staff on various quality initiatives and clinical protocols. Her prior experience additionally includes providing drug information and clinical reviews for state-sponsored public assistance pharmacy claims for a large payer and acting as a policy and practice liaison to outside organizations and federal agencies in her role as Director of Professional Affairs at a national pharmacists association.

Along with her work at Baxter, Dr. Riley teaches courses part-time in the Health Sciences department at Grand Canyon University. Dr. Riley earned her doctorate of pharmacy from Howard University in Washington, DC, and dual master's degrees in Healthcare Administration and Business through the University of Maryland. In addition to her academic degrees, Crystal is also a Certified Professional in Health Information Management Systems (CPHIMS), a Certified Professional in Healthcare Quality (CHPQ), is a registered and certified immunization pharmacist, and holds a Yellow Belt in Lean Six Sigma processes.

Dr. Riley was also published in 2013, providing a case study on leadership in healthcare and "lessons learned" in a healthcare administration textbook and has conducted reviews of national clinical practice guidelines and academic texts. She has given presentations at national conferences on healthcare topics ranging from needlestick safety to barriers to implementation of telehealth policies at the Federal level.

Most recently, Dr. Riley collaborated with the Agency for Healthcare Quality and Research to construct two statistical briefs examining the prevalence of malnutrition in US acute care hospitals and its impact on hospital readmissions and is currently looking in racial disparities in access to home dialysis therapy in patients with end-stage renal disease.

Eric S. Kastango, M.B.A., B.S.Pharm., FASHP
President and CEO
Clinical IQ, LLC and CriticalPoint, LLC
Madison, New Jersey

Eric S. Kastango, M.B.A., B.S.Pharm., FASHP, is president of Clinical IQ LLC, a health care consulting firm and CriticalPoint, LLC, a web-based education company. Mr. Kastango received his Bachelor of Science degree in pharmacy from the Massachusetts College of Pharmacy and Allied Health Sciences and his Master of Business Administration degree from the University of Phoenix. He completed 65 hours of training in nuclear pharmacy at Purdue University and 80 hours of didactic training for the Six Sigma-Green Belt certification that he started with BD Medical Systems. Eric was admitted to the Johns Hopkins Bloomberg School of Public Health, Masters of Public Health Program, starting January 2018.

Eric received a coveted ISMP Cheers Award in 2015 for his work related to sterile compounding safety. He is one of four recipients of the 2013 Outstanding Service Award from the Massachusetts Society of Health-System Pharmacists and the 2014 recipient of the NABP Henry Cade Memorial Award that recognized his efforts and assistance to the states and NABP to address the compounding tragedy that occurred in 2012.

Since 1980, he has practiced pharmacy in a number of practice settings, including hospitals, community, and home care, in a number of different of roles, including the Corporate Vice President of Pharmacy Services for Coram Healthcare Corporation. He has also managed a FDA-registered cGMP manufacturing operation for Baxter Healthcare Corporation.

He is an active member and Fellow of the American Society of Healthcare Pharmacists and served on the USP Sterile Compounding Committee from 2005-2010 and 2010-2015 USP Council of Experts, Compounding Expert Committee until April 2013. In May 2013, USP recognized Eric and the members of Compounding Expert Committee with an Award for Outstanding Contribution to the USP Standards-Setting Process. He has served on the USP Hazardous Drug Expert Panel since 2010.

He is actively working with NABP and state boards of pharmacy to provide training to their sterile compounding inspectors. Eric served on the Expert Panel for ASHP Research & Education Foundation in the development of the 2015 Outsourcing Sterile Products Preparation Vendor Assessment Tool and ASHP's Insourcing Readiness Assessment Tool.

Robert Eastin, Pharm.D.
Director of Central Pharmacy and Shared Services
Scripps Health
San Diego, CA

Dr. Eastin was previously the manager of pharmacy operations for the Scripps Mercy, San Diego campus, the largest teaching hospital of the Scripps Health system.

Dr. Eastin received his Bachelor of Science degree in biology from Duke University. Prior to earning his doctor of pharmacy degree from the University of the Pacific, he served four years as a surface warfare officer in the United States Navy and worked as a pharmaceutical sales representative for Eli Lilly and Company. He completed his PGY-1 Pharmacy Practice Residency at Scripps Mercy Hospital and worked as a clinical pharmacist at two of the Scripps Health hospital locations. As the pharmacy operations manager at Scripps Mercy, Robert was primarily responsible for the training and quality assurance associated with sterile compounding. He also co-chaired the health system's "Beyond-Use-Dating" Committee which formalized the process for reviewing, establishing and maintaining the beyond-use-dates for compounded sterile preparations.

Robert is currently the pharmacist-in-charge of Scripps Central Pharmacy Production Center (CPPC), a centralized hospital packaging pharmacy. CPPC provides sterile injectable preparations, produces repackaged oral solids and solutions, and administers the environmental sampling program for the five hospital system. He also oversees Scripps telepharmacy service and the System Resource Services for pharmacy which provides workforce staffing support to the hospital and clinics in the system.

Mark Neuenschwander
President and CEO
The Neuenschwander Company/ Project THRIV
Bellevue, Washington

Mark Neuenschwander is considered by many to be the world's leading expert on bar-code-enabled medication-use technology. He was a key catalyst in moving America's hospitals to adopt bar-coding at the point of care.

Today, he is a nationally renowned thought leader and champion for bar-code medication-preparation technology in hospital pharmacy clean rooms. Neuenschwander, an engaging communicator and insightful consultant, has clients across the United States and throughout the world in Canada, Australia, Europe, and Asia. Neil Davis, Editor of Hospital Pharmacy, says, "I don't know of anyone more knowledgeable about medication use automation than Mark Neuenschwander. Before you commit in this area, it makes sense to consult with the expert."

Neuenschwander is the tenth recipient of the Institute for Safe Medication Practices Lifetime Achievement Award.

Gordon S. Sacks, Pharm.D., BCNSP, FCCP
Professor and Department Head
Pharmacy Practice
Auburn University Harrison School of Pharmacy
Auburn, Alabama

Dr. Sacks earned a Doctorate of Pharmacy degree from the University of Texas (1994) after receiving his BS degree in Pharmacy from Auburn University (1989). He has completed a Pharmacy Practice Residency at Huntsville Hospital and a 2-year Nutrition Support Fellowship at the University of Tennessee, Memphis.

During his tenure at the University of Mississippi (1995-2001), he achieved the rank of Associate Professor of Pharmacy Practice and was Coordinator of the Nutrition Support Team at University of Mississippi Medical Center, Jackson. Between 2001-2008, he was a Clinical Professor at the University of Wisconsin – Madison and Chair of the Pharmacy Practice Division in the School of Pharmacy. He was also Coordinator of the Surgical Nutrition Support Team at the University of Wisconsin Hospital and Clinics in Madison, WI.

Starting in November 2008, Dr. Sacks became Department Head of Pharmacy Practice at the Harrison School of Pharmacy at Auburn University, Auburn, Alabama. He has been a board-certified Nutrition Support Pharmacist since 1995. Dr. Sacks is active in numerous scientific and professional societies. He was recently the President of the American Society for Parenteral and Enteral Nutrition (ASPEN) from July 2015 – June 2016.

Terri Albarano, Pharm.D., MS
Group Marketing Manager
Baxter International, Inc.
Deerfield, Illinois

Terri Albarano received her Bachelor of Science degree in Biology/Biological Sciences from the University of Pittsburgh-Greenburg. She earned both her Doctor of Pharmacy and Master of Science in Pharmacy Administration and Pharmacy Policy and Regulatory Affairs from the University of Pittsburgh.

Before joining Baxter, Dr. Albarano spent several years working as a pharmacist in Jeffreys Drugstore and Ranier's Pharmacy, and as clinical coordinator and pharmacist of North Shore Medical Center in Miami, Florida. As the clinical pharmacist at North Shore Medical Center, Dr. Albarano developed an IV to oral dose conversion protocol, a renal dosing protocol, and led an initiative to standardize drip concentrations in the neonatal intensive care unit. She then went on to work at Allegheny General Hospital as the Pharmacy Practice Coordinator, serving as a member of the Medication Error Reduction and Improvement Team.

Remaining at Allegheny General Hospital, Dr. Albarano then became the Manager of Operations for Inpatient Pharmacy where she was accountable for managing the provision of pharmaceutical care, staff, and work flow processes for the pharmacy department.

Joining Baxter International Inc. in 2013, Dr. Albarano serves as the Group Marketing Manager focusing on Parenteral Nutrition Therapy and Pharmacy Operation.

Todd Ebert, R.Ph., MS
President and CEO
Healthcare Supply Chain Association (HSCA)
Washington, DC

Healthcare Supply Chain Association (HSCA) President and CEO Todd Ebert is a nationally recognized supply chain leader, a group purchasing industry expert, and a registered pharmacist with more than 30 years of healthcare experience.

Ebert joined HSCA in 2015 from Amerinet, Inc., a national healthcare solutions organization and HSCA member, where he had served as President and CEO since 2007. After joining Amerinet from Intermountain Healthcare in 1991, Ebert served in a series of leadership roles including Vice President of Amerinet's pharmacy program; President of Amerinet's private-label company, Amerinet Choice, LLC; Executive Vice President for Contracting Operations and Purchasing Program Development Units; President of Operations; and as President and Chief Operating Officer. Prior to Amerinet, Ebert gained extensive experience in several other sectors of the healthcare industry.

He is a former vice president and general manager of a specialty healthcare product logistics company; a director of hospital and retail pharmacy; and has owned and operated a nursing home clinical pharmaceutical consulting company.

Internationally, Ebert has provided pharmaceutical consulting to foreign government officials and healthcare providers.

Ebert is a former Chair of HSCA and is the immediate past Chair of the Healthcare Industry Supply Chain Institute (HISCI). He is often requested as a guest speaker for industry events on subjects ranging from pharmacy to group purchasing trends.

Ebert holds bachelor's degrees in pharmacy and business management from the University of Utah and a Master of Science degree in pharmacy administration. He is a registered pharmacist.

Elizabeth Jungman, JD, MPH
Director, Public Health Programs
The Pew Charitable Trusts
Washington, DC

Elizabeth Jungman directs Pew's work on public health, overseeing initiatives related to antibiotics and innovation and the safety of prescription drugs, over-the-counter medicines, and other consumer health care products.

Before joining Pew, she served as a senior health policy adviser with the U.S. Senate Committee on Health, Education, Labor, and Pensions, where she played a key role in drafting and negotiating the Food and Drug Administration Safety and Innovation Act of 2012, the FDA provisions in the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, and the Drug Quality and Security Act of 2013, which included drug compounding and supply chain security measures.

Before moving to the Hill, Jungman was in private legal practice, counseling clients on a broad range of FDA regulatory matters and other health care issues related to the human pharmaceutical industry.

She serves on FDA's Pharmacy Compounding Advisory Committee and represents Pew as a member of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria.

She has an undergraduate biology degree from Harvard College, a Juris Doctor from Georgetown University, and a master's degree in public health from Johns Hopkins University.

Anthony Pudlo, Pharm.D., MBA, BCACP
Vice President of Professional Affairs
Iowa Pharmacy Association
Des Moines, Iowa

Following his 2007 graduation from Drake University College of Pharmacy & Health Sciences, Dr. Pudlo completed the University of North Carolina at Chapel Hill Community Pharmacy Practice Residency with Kerr Drug in Chapel Hill, NC.

After completion of his residency training, Dr. Pudlo has served as a Clinical Coordinator and then as Regional Clinical Manager with Kerr Health in Asheville, NC. While at Kerr Health, he worked directly with patients, employers and physicians to help prevent and treat chronic diseases within communities across western North Carolina, which includes working with patients enrolled in the Asheville Project®. In addition, he has served as preceptor for over 50 student pharmacists from schools/colleges of pharmacy across the country.

For his efforts in student pharmacist education, Dr. Pudlo was awarded the 2011 NACDS Community Pharmacy Preceptor of the Year. For his efforts to Drake, Dr. Pudlo was awarded the 2011 Drake College of Pharmacy & Health Sciences Young Alumni Achievement Award, and then the 2015 Drake University Young Alumni Loyalty Award.

Currently Dr. Pudlo serves as the Iowa Pharmacy Association's Vice President of Professional Affairs in Des Moines, Iowa and acts as a liaison between pharmacists, student pharmacists, and pharmacy technicians to the various state agencies in state of Iowa to promote safe and effective medication use to improve the health of patients. He became a Board Certified Ambulatory Care Pharmacist in 2012.

Jim Lund, Pharm.D., MS
Director of Pharmacy Operations
Massachusetts General Hospital
Boston, MA

Jim Lund is the Director of Pharmacy Operations, at the Massachusetts General Hospital in Boston, MA, where he is responsible for the operations of the hospital's central pharmacy distribution systems, hazardous and non-hazardous compounding areas and perioperative pharmacy services.

Dr. Lund received his Doctor of Pharmacy degree from the University of Wisconsin and completed a PGY-1 and PGY-2 Health-System Pharmacy Administration Residency at the University of Wisconsin Hospital and Clinics. Jim also holds a Masters of Sciences degree in Health System Pharmacy Administration at the University of Wisconsin.

Dr. Lund previously was the Manager of Inpatient Pharmacy Operations at the University of Wisconsin Hospital and Clinics, as well as the system Medication Safety Officer. In this role, Jim was responsible for the inpatient pharmacy distribution system and staff, including pharmacy automation, dispensing technology and narcotic control systems.

Additionally, Jim chaired the UW Health Medication Safety Committee and coordinated safety initiatives throughout the UW Health enterprise. Prior to his time with the leadership team at the University of Wisconsin, Jim was the Assistant Director of Pharmacy Operations at the University of Chicago Medical Center where he was responsible for sterile and non-sterile compounding, central pharmacy distribution services, pharmacy automation and pharmacy facility design.

Dr. Lund is an active member of the American Society of Health-System Pharmacists (ASHP) and the University HealthSystem Consortium (UHC) Pharmacy Council. Jim has served on the ASHP Section of Pharmacy Practice Managers Educational Steering Committee, the ASHP Section of Pharmacy Informatics and Technology Advisory Group on Pharmacy Operations Automation, the UHC Performance Improvement and Compliance Committee and the UHC Pharmacy Practice Advancement Committee.

Jeannell M. Mansur, R.Ph, Pharm.D, FASHP, FSMSO, CJCP
Principal Consultant, Medication Management and Safety
Joint Commission Resources
Joint Commission International
Chicago, Illinois

Jeannell Mansur is Principal Consultant for Medication Management and Safety for Joint Commission Resources and Joint Commission International. In this role, she provides direction to hospital leaders on medication safety design, medication system optimization and technology implementation to support patient safety and effectiveness.

Her expertise in lean six sigma and change acceleration performance improvement methods and tools is of immense value to organizations that are seeking to implement effective and sustainable improvement to challenging issues. Also in her role as Principal Consultant, Dr. Mansur provides expertise to the Joint Commission enterprise on medication system themes. Dr. Mansur has been recognized for her distinguished work by the designation of Fellow with the American Society of Health-System Pharmacists and the American Society for Medication Safety Officers. She is a voting member of the United States Pharmacopeial (USP) Convention.

Dr. Mansur completed training with the Institute for Healthcare Improvement in medication safety under the direction of Drs. Donald Berwick and Lucian Leape. The learning from these leaders and the experiences from this Institute resulted in the crafting of a systems-based approach to medication safety that has molded Dr. Mansur's philosophies.

Dr. Mansur has extensive experience in all aspects of medication system design and implementation as well as hospital pharmacy which includes clinical, operational and management responsibilities. She was Director of Pharmaceutical Services for 12 years at the University of Chicago Medical Center before she became Executive Director for Pharmacy Informatics, where she was involved in the planning, building and implementation of the organization's electronic medical record.

Dr. Mansur received her B.S. Pharmacy from the University of Michigan and her Doctor of Pharmacy degree from Wayne State University. Dr. Mansur has consulted throughout the US and internationally in Europe, Asia, Africa, Central and South America, the Far East and the Middle East.

Dr. Mansur has published and presented extensively in the areas of medication safety and pharmacy operations improvement. Among these publications is the chapter she authored on Medication Safety in "*Pediatric Safety in the Emergency Department*", a textbook published jointly by Joint Commission Resources and the American Academy of Pediatrics, an article "Medication Systems and the Important Role of Pharmacists", published in 2016 in Journal of Drugs and Aging, and the chapter she authored "Immediate-Use Compounding" in the recently published "*Compounding Sterile Preparations, Fourth Edition*", published by the American Society of Health-system Pharmacists.

Appendix C: Meeting Agenda

8:00AM **Registration and Buffet Breakfast**

8:30AM **Welcome, Overview and Introductions/Review of Survey Results**

9:00AM **KEYNOTE ADDRESS**
Speaker: **Chris Jerry, President and Chief Executive Officer, The Emily Jerry Foundation**

9:45AM **Session ONE:**
Key Considerations in Hospital Compounding
Moderated by: Crystal Riley, Pharm.D., MHA, MBA, Baxter Healthcare Corporation

Panelists: **Eric Kastango, MBA, R.Ph., FASHP, President and CEO, ClinicalIQ**
Robert Eastin, Pharm.D., Director of Pharmacy, Scripps Health Central Pharmacy Production Center

10:30AM **Session TWO:**
Avoiding Errors: The Role of Technology in Advancing Patient Safety
Moderated by: Mark Neuenschwander, President, The Neuenschwander Company

Panelists: **Gordon Sacks, Pharm.D., FCCP, BCNSP, Head of Pharmacy Practice, Harrison School of Pharmacy, Auburn University**
Terri Albarano, Pharm.D., MS, Group Marketing Manager, Baxter International Inc.

11:15am - DELEGATE ROUNDTABLE DISCUSSION

11:45AM **BREAK**

NOON **Moderated Luncheon Discussion: Prescriber Awareness of Compounded Products**
Moderated by: Todd Ebert, R.Ph., President, Healthcare Supply Chain Association

12:45PM **Session THREE:**
Raising the Bar on Drug Quality: Federal, State, and Hospital Policy
Moderated by: Elizabeth Jungman, JD, MPH, Director, Public Health, The Pew Charitable Trusts

Panelists: **Anthony Pudlo, Pharm.D., MBA, Vice President, Professional Affairs, Iowa Pharmacy Association**
Jim Lund, Pharm.D., MS, Director of Pharmacy Operations, Massachusetts General Hospital

1:45pm – DELEGATE ROUNDTABLE DISCUSSION

2:15PM **BREAK**

2:30PM **Session FOUR:**
Delegates' Plenary: Best Practices and Recommendations
Moderated by: Jeannell Mansur, R.Ph., Pharm.D., FASHP, FSMSO, CJCP, Joint Commission Resources

3:15PM **Next Steps/Adjourn**

Appendix D: Pre-Meeting Questionnaire

1. How are you or your organization involved with the issue of hospital sterile compounding?
    a. Patient safety/expert organization
    b. Hospital policy or advocacy organization
    c. Pharmacist
    d. Prescriber/caregiver or prescriber organization
    e. Manufacturer of pharmaceutical products and/or compounding devices
    f. Other (Please specify)
2. What changes do you believe have been effective in boosting the safety of sterile compounding in the last 5 years? Answer all that apply.
    a. Federal legislative and/or regulatory changes (please describe)
    b. State regulatory or other policy changes (please describe)
    c. Technology (please describe)
    d. Other or None (please describe)
3. Please indicate your views on the current strength (weak/moderate/strong) of:
    a. Federal enforcement of compounding sterility guidelines/policy
    b. State enforcement of compounding sterility guidelines/policy
    c. Self-regulation among compounding pharmacy facilities
    d. Implementation of technologies and procedures in hospital environments to improve patient safety related to the use of compounded therapies
4. List up to three changes in policy or practice that you believe have had the most beneficial impact on patient safety in the aftermath of the NECC incident (within last 5 years).
5. If you are in the healthcare setting, please describe any changes your organization has adopted in the last 5 years to improve the safety of sterile compounding.
6. Do you believe that there are best practices among hospitals for compounding of patient therapies that are…
    a. Standardized? If no, please explain
    b. Broadly recognized? If no, please explain
    c. Adopted uniformly? If no, please explain
7. Please select the statement that best reflects your views:
    a. Prescribers are not aware enough about whether the medications they prescribe are compounded; more prescriber awareness is needed
    b. Prescribers don't know enough about which of the medications they prescribe are compounded, but they needn't know more
    c. Prescribers are generally aware about which of the medications they prescribe are compounded
8. What would you say are currently considered best practices for patient safety related to sterile compounding (check the top three):

a. Existing state accreditation/certification procedures
b. Use of pre-mix where available instead of compounded preparations
c. Deployment and use of new technologies to assist in compounding products
d. Improved care team communications
e. Improved prescriber awareness
f. Centralization of outsourced compounding suppliers for hospital systems
g. Hospital efforts to bring more sterile compounding in-house
h. Other

9. Broadly speaking, what do you consider the greatest current challenges to sterile compounding for hospital patients? Please list up to three.

Appendix E: Steering Committee List

Jillanne Schulte Wall, JD
American Society of Health-System Pharmacists

Crystal Riley, Pharm.D., MHA, MBA
Baxter Healthcare Corporation

Todd Ebert, R.Ph
Healthcare Supply Chain Association

Jeannell Mansur, R.Ph, PharmD, FASHP, FSMSO, CJCP
Joint Commission Resources

Krystalyn Weaver, Pharm.D.
National Alliance of State Pharmacy Associations

Elizabeth Jungman, JD, MPH
The Pew Charitable Trusts