American College of Clinical Pharmacy
ANNUAL MEETING NEWS
2011 ACCP Annual Meeting • Pittsburgh, Pennsylvania • www.accp.com/am
Issue 1 Sunday, October 16

Annual Meeting Offers Opportunities to Advance and Connect

An ideal 2011 ACCP Annual Meeting will entail more than just a few successful days in Pittsburgh. Rather, it will be an occasion in which participants find inspiration, new ideas, and research initiatives that are relevant to their practice. ACCP President William A. Kehoe, Pharm.D., M.A., FCCP, BCPS, recommends the following not-to-be-missed highlights for first-time attendees and Annual Meeting veterans alike.

Opening General Session/Keynote Address (*8:00 a.m. today, David L. Lawrence Convention Center, Spirit of Pittsburgh Ballroom A*): Start the meeting off right with this event, the "one time when everyone gets together," to paraphrase Dr. Kehoe. Debra Yeskey, Pharm.D., will offer the Keynote Address, speaking on the role of clinical pharmacy in emergency preparedness. Dr. Yeskey is Director, Regulatory and Quality Affairs Division, Biomedical Advanced Research Development and Authority, in the Office of the Assistant Secretary for Preparedness and Response.

The Opening General Session includes the presentation of some of ACCP's national awards, the Therapeutic Frontiers Award Lecture, and the recognition of new ACCP Fellows.

PRN Business Meetings and Networking Forums (*6:00–9:00 p.m. Monday and Tuesday, Westin Convention Center Hotel; see the Meeting Guide for a complete listing*): ACCP's 22 Practice and Research Networks (PRNs) are groups of ACCP members with shared interests in various therapeutic and other professional areas. Their business meetings and networking forums are open to all registrants, providing a great way to learn about PRN activities, Dr. Kehoe explains. "That was my first entry into leadership with the College," he recalls.

ACCP Clinical Pharmacy Challenge (*semifinals, 4:30 p.m. today; finals, 11:00 a.m. Monday, Convention Center, Spirit of Pittsburgh Ballroom A*): In its second year, this competition pits the best and the brightest pharmacy students in a quiz bowl–type format. "This is a good time for our members to attend and cheer the teams and provide support," Dr. Kehoe says.

Platform and Poster Presentations (*Monday, 11:30 a.m.–1:15 p.m.; Tuesday and Wednesday, 8:00 a.m.–10:00 a.m.; see the Meeting Guide for a complete listing*): Dr. Kehoe believes these presentations can be among the most valuable during the Annual Meeting. The platform presentations "represent high-caliber research," he notes.

The poster presentations also are valuable for a clinical pharmacist. "I get ideas constantly that I bring back to my practice or research," Dr. Kehoe said.

All of these events offer an opportunity to better understand the work of the College that occurs between ACCP Annual Meetings, Dr. Kehoe believes "This isn't just a meeting about getting together and learning a few things. It's really a meeting about ways that we can advance clinical pharmacy."

ACCP President William A. Kehoe, Pharm.D., MA, FCCP, BCPS.

Clinical Pharmacy Challenge Underway

ACCP's novel national pharmacy student team competition returns to the Annual Meeting in 2011.

From the initial field of 84 teams, 8 teams have advanced through four preliminary online rounds to represent their institution in the quarterfinal round of competition here in Pittsburgh.

Quarterfinal matches were held Saturday. Winners of the quarterfinal round will compete in the semifinal round of the competition today, Sunday, October 16, at 4:30 p.m. following the ACCP Annual Business Meeting and Town Hall.

The championship round of the Clinical Pharmacy Challenge will be held tomorrow, Monday, October 17, from 11:00 to 11:30 a.m. Both the semifinal and final rounds will be held in the David L. Lawrence Convention Center, Spirit of Pittsburgh Ballroom A.

Be sure to stop by the ACCP registration desk to check the competition bracket and find out the standing of your favorite team.

Schedule

Sunday, October 16

4:30 p.m. –5:00 p.m.
Semifinal A; Winner Quarterfinal A vs. Winner Quarterfinal D

5:15 p.m. – 5:45 p.m.
Semifinal B; Winner Quarterfinal B vs. Winner Quarterfinal C

Monday, October 17

11:00 a.m. – 11:30 a.m.
Final Round; Winner Semifinal A vs. Winner Semifinal B

See page 3 for a complete listing of quarterfinalist teams.

2011 Parker Medalist 'CAB' Bond to Be Honored at Opening General Session

The late C.A. "CAB" Bond, Pharm.D., FCCP, the 2011 recipient of the College's Paul F. Parker Medal for Distinguished Service to the Profession of Pharmacy, will be recognized during this morning's Opening General Session, beginning at 8:00 a.m. in the David L. Lawrence Convention Center. Before his death in June 2009, Dr. Bond served as University Distinguished Professor and Professor of Pharmacy Practice at Texas Tech University Health Sciences Center School of Pharmacy.

"CAB" Bond, Pharm.D., FCCP

"The Paul F. Parker Medal recognizes an individual who has made outstanding and sustained contributions to the profession that improve patient or service outcomes, create innovative practices, affect populations of patients, further the professional role of pharmacists, or expand the recognition of pharmacists as health professionals.

In making its selection, the Parker Medal Committee commented on Dr. Bond's contributions to clinical pharmacy:

He stood out because of his seminal research relating pharmacy services to patient outcomes. This sustained work has had major impact on the pharmacy profession as it documented the economic impact of clinical pharmacists in various healthcare settings.

During his career, Dr. Bond received substantial research funding and wrote more than 150 research and professional publications. In 2007, Dr. Bond was appointed as a Scientific Editor for *Pharmacotherapy*.

In 2005, Dr. Bond received the ACCP Russell R. Miller Award for sustained contributions to the literature of clinical pharmacy. In 2001, he was the recipient of Texas Tech University Health Sciences Center President's Distinguished Research Award, and in 2006, the university bestowed on him the title of University Distinguished Professor. In 2007, the University of California–San Francisco School of Pharmacy selected Dr. Bond as its Distinguished Alumnus.

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Curricular Tracks Focus on Topics to Transform and Expand Practices

A diverse array of curricular-based educational offerings highlights the 2011 Annual Meeting. The 2011 Annual Meeting Program Committee, chaired by David Foster, Pharm.D., FCCP, created the curricular tracks over a 2-year process. Dr. Foster is associate professor of pharmacy practice, Purdue University, College of Pharmacy, and adjunct associate professor of medicine, Indiana University. Programming within the Annual Meeting curricular tracks covers three extensive categories.

Track I, *The Role of the Immune System in Disease Pathophysiology: Implications for Pharmacotherapy*, is unique in that it's "somewhat of a departure from the ways we would develop a therapeutics-based track," Dr. Foster said. "Rather than focus on a specific disease state or population, we are exploring inflammation as a mechanism of disease and how it impacts a wide spectrum of diseases. Specific sessions will examine inflammation and neurologic conditions, cardiovascular disease, oncology, organ transplantation, rheumatology, and gastrointestinal disorders.

David Foster, Pharm.D., FCCP

Track II, *Challenges to Expanding the Scope of Clinical Pharmacy*, will help clinicians explore ways in which to expand practices and broaden the scope of care. "This will be very much a practical track," Dr. Foster said. "There will be practical guidance to people who are struggling with this or [who] would like to embark on expanding their scope of practice." The track will also feature several case studies that focus on pharmacy in the setting of an obstetrics clinic, a tuberculosis infection clinic, and family medicine.

Track III, *The Expanding Horizon of Global Health and Clinical Pharmacy in the United States and Abroad,* will acknowledge the changes that have occurred in the world in recent years. "We're a global society with a global economy, and the frequency and ease of global travel has changed the historic geographic boundaries for diseases," Dr. Foster said. "They don't exist anymore as we see shifting populations and migrations. We're dealing with new patterns of disease and disease states."

Specifically, track III will explore global and domestic issues related to immunizations and maternal health challenges.

The three curricular tracks should "inspire people, particularly in the case of tracks II and III, to think about how they can advance their scope of practices and how their institution can have an impact at the global level," Dr. Foster stated.

Student Competition Quarterfinalists

Belmont University School of Pharmacy
Team leader: Lee Rembert
Team members: Rebecca Lucas, Kimberly M. Bentley
Team alternates: John Barnwell, Cortney Manning
Registering faculty member: Cathy H. Ficzere, Pharm.D., BCPS

Butler University College of Pharmacy and Health Sciences
Team leader: Nicole Dores
Team members: Carly D'Agostino, Katherine Cich
Team alternate: Krista Hoose
Registering faculty member: Kena J. Lanham, Pharm.D.

Campbell University College of Pharmacy and Health Sciences
Team leader: Clayton Moore
Team members: Karyn Fabo, Erin Dickert
Team alternates: Dustin Bryan, Stephanie Zyra
Registering faculty member: Melissa A. Holland, Pharm.D., MSCR

Massachusetts College of Pharmacy and Health Sciences Worcester School of Pharmacy
Team leader: Khalid Alburikan
Team members: James Lukose, Catherine Potak
Team alternates: Kerry Mohrien (t*eam leader in Online Rounds 1–4*), Tenley Balla
Registering faculty member: Jennifer L. Donovan, Pharm.D.

University of Tennessee Health Science Center College of Pharmacy
Team leader: Jake Smith
Team members: Mark Dunnenberger, Jennifer Rivers
Team alternates: Sloan Regen, Megan Perry
Registering faculty member: Catherine M. Crill, Pharm.D., BCPS, BCNSP

University of the Pacific Thomas J. Long School of Pharmacy & Health Sciences
Team leader: Ryan Conrad
Team members: Ian Ford, Jerline Hsin
Team alternate: Nicole Martinez
Registering faculty member: William A. Kehoe, Pharm.D., FCCP, BCPS

University of Utah College of Pharmacy
Team leader: Jared Koyle
Team members: Scott Nelson, Edward Matterfis
Team alternates: Emily Turley, Taben Main
Registering faculty member: Patricia L. Orlando, Pharm.D., FCCP

Western University of Health Sciences College of Pharmacy
Team leader: Alidz Talatinian
Team members: Sangeeta Salvi, Carrie Bitterlich
Registering faculty member: James D. Scott, Pharm.D., M.Ed., B.S

Boucher, Carter, Ensom to Receive Honors

Bradley Boucher, Pharm.D., FCCP, BCPS; Barry Carter, Pharm.D., FCCP, BCPS; and Mary H.H. Ensom, Pharm. D., FCCP, will receive the association's prestigious 2011 Clinical Practice, Therapeutic Frontiers Lecture, and Education Awards, respectively. In addition, Dr. Carter will receive the 2011 Russell R. Miller Award. The awards will be presented during the Opening General Session to begin at 8:00 a.m. this morning in the David L. Lawrence Convention Center, Spirit of Pittsburgh Ballroom A.

Bradley Boucher, Pharm.D., FCCP, BCPS

Clinical Practice Award

The ACCP Clinical Practice Award recognizes a College member for substantial and outstanding contributions to clinical pharmacy practice. Bradley Boucher is professor of clinical pharmacy and associate professor of neurosurgery at the University of Tennessee Health Science Center. He practices in the area of critical care at the Regional Medical Center at Memphis. In recommending Dr. Boucher, Dr. G. Christopher Wood, a long-time colleague, wrote in his letter of nomination,

Dr. Boucher has practiced as a clinical pharmacist in the level one trauma center at the Medical Center since 1984. He was the first pharmacotherapy clinical pharmacist at the trauma center, which opened in 1983. Thus, he created this practice. The trauma ICU has grown over time to have 23 dedicated trauma ICU beds and 8 step-down beds and is now the third busiest in the country. From 1984 to 2000, Dr. Boucher provided 12 months of clinical coverage per year as a tenure-track faculty member. In addition to creating this clinical service, he developed an independent clinical research program, a critical care/nutrition support residency, and a critical care fellowship; he was promoted to full professor and served ACCP and UT in myriad capacities during this period.

Dr. Boucher has contributed regularly to the medical and pharmacy literature and has delivered many presentations at scientific and professional meetings focusing on critical care pharmacotherapy and other intensive care–related subjects. As a current ACCP fellow and a past president and treasurer of ACCP, he has provided significant leadership within the College and the profession.

Therapeutic Frontiers Award Lecture

The ACCP Therapeutic Frontiers Lecture Award recognizes an ACCP member or nonmember nominee who has made outstanding contributions to pharmacotherapeutics. Barry L. Carter, Pharm.D., FCCP, FAHA, FASH, BCPS, is the Patrick E. Keefe Professor of Pharmacy in the Department of Pharmacy Practice and Science, College of Pharmacy, and a professor and associate head for research, Department of Family Medicine, in the Roy J. and Lucille A. Carver College of Medicine at the University of Iowa. He is known internationally for his sustained work in the pharmacotherapy of hypertension.

Dr. Stuart Haines, professor and pharmacotherapy specialist at the University of Maryland, wrote in his letter of support for Dr. Carter's nomination,

Dr. Carter is examining the systems of care through which medications are used. It is this therapeutic frontier—understanding how best to deliver care and capitalize on the relationships between pharmacists, patients, and prescribers—that Dr. Carter and his colleagues are exploring.

Dr. Carter's lecture, titled "Therapeutic Frontiers in Health Services

Continued on page 7

USAGE

- **To reduce the development of drug-resistant bacteria and maintain the effectiveness of TEFLARO® and other antibacterial drugs, TEFLARO should be used to treat only CABP or ABSSSI that are proven or strongly suspected to be caused by susceptible bacteria.**
- **When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.**

INDICATIONS

- TEFLARO is indicated for the treatment of **community-acquired bacterial pneumonia (CABP)** caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Streptococcus pneumoniae* (including cases with concurrent bacteremia), *Staphylococcus aureus* (methicillin-susceptible isolates only), *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, and *Escherichia coli*.
- TEFLARO is also indicated for the treatment of **acute bacterial skin and skin structure infections (ABSSSI)** caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Klebsiella oxytoca*.

IMPORTANT SAFETY INFORMATION

Contraindications

- TEFLARO is contraindicated in patients with known serious hypersensitivity to ceftaroline or other members of the cephalosporin class. Anaphylaxis and anaphylactoid reactions have been reported with ceftaroline.

Warnings and Precautions

Hypersensitivity Reactions

- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported with beta-lactam antibacterials. Before therapy with TEFLARO is instituted, careful inquiry about previous hypersensitivity reactions to other cephalosporins, penicillins, or carbapenems should be made. If this product is to be given to a penicillin- or other beta-lactam-allergic patient, caution should be exercised because cross sensitivity among beta-lactam antibacterial agents has been clearly established.
- If an allergic reaction to TEFLARO occurs, the drug should be discontinued. Serious acute hypersensitivity (anaphylactic) reactions require emergency treatment with epinephrine and other emergency measures that may include airway management, oxygen, intravenous fluids, antihistamines, corticosteroids, and vasopressors as clinically indicated.

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IMPORTANT SAFETY INFORMATION (continued)

***Clostridium difficile*-associated Diarrhea**

- *Clostridium difficile*-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial agents, including TEFLARO, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibacterials not directed against *C. difficile* should be discontinued, if possible.

Direct Coombs' Test Seroconversion

- Seroconversion from a negative to a positive direct Coombs' test result occurred in 120/1114 (10.8%) of patients receiving TEFLARO and 49/1116 (4.4%) of patients receiving comparator drugs in the four pooled Phase 3 trials. No adverse reactions representing hemolytic anemia were reported in any treatment group. If anemia develops during or after treatment with TEFLARO, drug-induced hemolytic anemia should be considered. If drug-induced hemolytic anemia is suspected, discontinuation of TEFLARO should be considered and supportive care should be administered to the patient if clinically indicated.

Development of Drug-Resistant Bacteria

- Prescribing TEFLARO in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions

- In the four pooled Phase 3 clinical trials, serious adverse events occurred in 98/1300 (7.5%) of patients receiving TEFLARO and 100/1297 (7.7%) of patients receiving comparator drugs. Treatment discontinuation due to adverse events occurred in 35/1300 (2.7%) of patients receiving TEFLARO and 48/1297 (3.7%) of patients receiving comparator drugs with the most common adverse events leading to discontinuation being hypersensitivity for both treatment groups at a rate of 0.3% in the TEFLARO group and 0.5% in the comparator group.
- No adverse reactions occurred in greater than 5% of patients receiving TEFLARO. The most common adverse reactions occurring in >2% of patients receiving TEFLARO in the pooled Phase 3 clinical trials were diarrhea, nausea, and rash.

Drug Interactions

- No clinical drug-drug interaction studies have been conducted with TEFLARO. There is minimal potential for drug-drug interactions between TEFLARO and CYP450 substrates, inhibitors, or inducers; drugs known to undergo active renal secretion; and drugs that may alter renal blood flow.

Use in Specific Populations

- TEFLARO has not been studied in pregnant women. Therefore, TEFLARO should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
- It is not known whether ceftaroline is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TEFLARO is administered to a nursing woman.
- Safety and effectiveness in pediatric patients have not been established.
- Because elderly patients, those ≥65 years of age, are more likely to have decreased renal function and ceftaroline is excreted primarily by the kidney, care should be taken in dose selection in this age group and it may be useful to monitor renal function. Dosage adjustment for elderly patients should therefore be based on renal function.
- Dosage adjustment is required in patients with moderate (CrCl >30 to ≤50 mL/min) or severe (CrCl ≥15 to ≤30 mL/min) renal impairment and in patients with end-stage renal disease (CrCl <15 mL/min).
- The pharmacokinetics of ceftaroline in patients with hepatic impairment have not been established.

Please see brief summary of Prescribing Information on following page.
Please also see full Prescribing Information at www.TEFLARO.com.

Forest Pharmaceuticals, Inc.
Subsidiary of Forest Laboratories, Inc.
St. Louis, Missouri 63045

Teflaro®
(ceftaroline fosamil) for injection
600 mg • 400 mg

TEFLARO® (ceftaroline fosamil) injection for intravenous (IV) use **Rx Only**
Brief Summary of full Prescribing Information
Initial U.S. Approval: 2010

INDICATIONS AND USAGE: Teflaro® (ceftaroline fosamil) is indicated for the treatment of patients with the following infections caused by susceptible isolates of the designated microorganisms. **Acute Bacterial Skin and Skin Structure Infections -** Teflaro is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes, Streptococcus agalactiae, Escherichia coli, Klebsiella pneumoniae, and Klebsiella oxytoca.* **Community-Acquired Bacterial Pneumonia -** Teflaro is indicated for the treatment of community-acquired bacterial pneumonia (CABP) caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Streptococcus pneumoniae* (including cases with concurrent bacteremia), *Staphylococcus aureus* (methicillin-susceptible isolates only), *Haemophilus influenzae, Klebsiella pneumoniae, Klebsiella oxytoca,* and *Escherichia coli.* **Usage -** To reduce the development of drug-resistant bacteria and maintain the effectiveness of Teflaro and other antibacterial drugs, Teflaro should be used to treat only ABSSSI or CABP that are proven or strongly suspected to be caused by susceptible bacteria. Appropriate specimens for microbiological examination should be obtained in order to isolate and identify the causative pathogens and to determine their susceptibility to ceftaroline. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS: Teflaro is contraindicated in patients with known serious hypersensitivity to ceftaroline or other members of the cephalosporin class. Anaphylaxis and anaphylactoid reactions have been reported with ceftaroline.

WARNINGS AND PRECAUTIONS: Hypersensitivity Reactions - Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterials. Before therapy with Teflaro is instituted, careful inquiry about previous hypersensitivity reactions to other cephalosporins, penicillins, or carbapenems should be made. If this product is to be given to a penicillin- or other beta-lactam-allergic patient, caution should be exercised because cross sensitivity among beta-lactam antibacterial agents has been clearly established. If an allergic reaction to Teflaro occurs, the drug should be discontinued. Serious acute hypersensitivity (anaphylactic) reactions require emergency treatment with epinephrine and other emergency measures, that may include airway management, oxygen, intravenous fluids, antihistamines, corticosteroids, and vasopressors as clinically indicated. ***Clostridium difficile*-associated Diarrhea -** *Clostridium difficile*-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial agents, including Teflaro, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of *C. difficile. C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibacterials not directed against *C. difficile* should be discontinued, if possible. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated *[see Adverse Reactions].* **Direct Coombs' Test Seroconversion -** Seroconversion from a negative to a positive direct Coombs' test result occurred in 120/1114 (10.8%) of patients receiving Teflaro and 49/1116 (4.4%) of patients receiving comparator drugs in the four pooled Phase 3 trials. In the pooled Phase 3 CABP trials, 51/520 (9.8%) of Teflaro-treated patients compared to 24/534 (4.5%) of ceftriaxone-treated patients seroconverted from a negative to a positive direct Coombs' test result. No adverse reactions representing hemolytic anemia were reported in any treatment group. If anemia develops during or after treatment with Teflaro, drug-induced hemolytic anemia should be considered. Diagnostic studies including a direct Coombs' test, should be performed. If drug-induced hemolytic anemia is suspected, discontinuation of Teflaro should be considered and supportive care should be administered to the patient (i.e. transfusion) if clinically indicated. **Development of Drug-Resistant Bacteria -** Prescribing Teflaro in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS: The following serious events are described in greater detail in the Warnings and Precautions section: Hypersensitivity reactions; *Clostridium difficile*-associated diarrhea; Direct Coombs' test seroconversion. **Adverse Reactions from Clinical Trials -** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be compared directly to rates from clinical trials of another drug and may not reflect rates observed in practice. Teflaro was evaluated in four controlled comparative Phase 3 clinical trials (two in ABSSSI and two in CABP) which included 1300 adult patients treated with Teflaro (600 mg administered by IV over 1 hour every 12h) and 1297 patients treated with comparator (vancomycin plus aztreonam or ceftriaxone) for a treatment period up to 21 days. The median age of patients treated with Teflaro was 54 years, ranging between 18 and 99 years old. Patients treated with Teflaro were predominantly male (63%) and Caucasian (82%). **Serious Adverse Events and Adverse Events Leading to Discontinuation -** In the four pooled Phase 3 clinical trials, serious adverse events occurred in 98/1300 (7.5%) of patients receiving Teflaro and 100/1297 (7.7%) of patients receiving comparator drugs. The most common SAEs in both the Teflaro and comparator treatment groups were in the respiratory and infection system organ classes (SOC). Treatment discontinuation due to adverse events occurred in 35/1300 (2.7%) of patients receiving Teflaro and 48/1297 (3.7%) of patients receiving comparator drugs with the most common adverse events leading to discontinuation being hypersensitivity for both treatment groups at a rate of 0.3% in the Teflaro group and 0.5% in comparator group. **Most Common Adverse Reactions -** No adverse reactions occurred in greater than 5% of patients receiving Teflaro. The most common adverse reactions occurring in > 2% of patients receiving Teflaro in the pooled phase 3 clinical trials were diarrhea, nausea, and rash. Table 4 in the full prescribing information lists adverse reactions occurring in ≥ 2% of patients receiving Teflaro in the pooled Phase 3 clinical trials (two in ABSSSI and two in CABP). The first value displays the percentage of patients in the pooled Teflaro trials (N=1300) and the second shows the percentage in the Pooled Comparators[a] trials (N=1297). **Gastrointestinal disorders:** Diarrhea (5%, 3%), Nausea (4%, 4%), Constipation (2%, 2%), Vomiting (2%, 2%); **Investigations:** Increased transaminases (2%, 3%); **Metabolism and nutrition disorders:** Hypokalemia (2%, 3%); **Skin and subcutaneous tissue disorders:** Rash (3%, 2%); **Vascular disorders:** Phlebitis (2%, 1%) [a] Comparators included vancomycin 1 gram IV every 12h plus aztreonam 1 gram IV every 12h in the Phase 3 ABSSSI trials, and ceftriaxone 1 gram IV every 24h in the Phase 3 CABP trials. **Other Adverse Reactions Observed During Clinical Trials of Teflaro -** Following is a list of additional adverse reactions reported by the 1740 patients who received Teflaro in any clinical trial with incidences less than 2%. Events are categorized by System Organ Class. **Blood and lymphatic system disorders -** Anemia, Eosinophilia, Neutropenia, Thrombocytopenia; **Cardiac disorders -** Bradycardia, Palpitations; **Gastrointestinal disorders -** Abdominal pain; **General disorders and administration site conditions -** Pyrexia; **Hepatobiliary disorders -** Hepatitis; **Immune system disorders -** Hypersensitivity, Anaphylaxis; **Infections and infestations -** *Clostridium difficile* colitis; **Metabolism and nutrition disorders -** Hyperglycemia, Hyperkalemia; **Nervous system disorders -** Dizziness, Convulsion; **Renal and urinary disorders -** Renal failure; **Skin and subcutaneous tissue disorders** - Urticaria.

DRUG INTERACTIONS: No clinical drug-drug interaction studies have been conducted with Teflaro. There is minimal potential for drug-drug interactions between Teflaro and CYP450 substrates, inhibitors, or inducers; drugs known to undergo active renal secretion; and drugs that may alter renal blood flow *[see Clinical Pharmacology].*

USE IN SPECIFIC POPULATIONS: Pregnancy Category B - Developmental toxicity studies performed with ceftaroline fosamil in rats at IV doses up to 300 mg/kg demonstrated no maternal toxicity and no effects on the fetus. A separate toxicokinetic study showed that ceftaroline exposure in rats (based on AUC) at this dose level was approximately 8 times the exposure in humans given 600 mg every 12 hours. There were no drug-induced malformations in the offspring of rabbits given IV doses of 25, 50, and 100 mg/kg, despite maternal toxicity. Signs of maternal toxicity appeared secondary to the sensitivity of the rabbit gastrointestinal system to broad-spectrum antibacterials and included changes in fecal output in all groups and dose-related reductions in body weight gain and food consumption at ≥ 50 mg/kg; these were associated with an increase in spontaneous abortion at 50 and 100 mg/kg. The highest dose was also associated with maternal moribundity and mortality. An increased incidence of a common rabbit skeletal variation, angulated hyoid alae, was also observed at the maternally toxic doses of 50 and 100 mg/kg. A separate toxicokinetic study showed that ceftaroline exposure in rabbits (based on AUC) was approximately 0.8 times the exposure in humans given 600 mg every 12 hours at 25 mg/kg and 1.5 times the human exposure at 50 mg/kg. Ceftaroline fosamil did not affect the postnatal development or reproductive performance of the offspring of rats given IV doses up to 450 mg/kg/day. Results from a toxicokinetic study conducted in pregnant rats with doses up to 300 mg/kg suggest that exposure was ≥ 8 times the exposure in humans given 600 mg every 12 hours. There are no adequate and well-controlled trials in pregnant women. Teflaro should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nursing Mothers -** It is not known whether ceftaroline is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Teflaro is administered to a nursing woman. **Pediatric Use -** Safety and effectiveness in pediatric patients have not been established. **Geriatric Use -** Of the 1300 patients treated with Teflaro in the Phase 3 ABSSSI and CABP trials, 397 (30.5%) were ≥ 65 years of age. The clinical cure rates in the Teflaro group (Clinically Evaluable [CE] Population) were similar in patients ≥ 65 years of age compared with patients < 65 years of age in both the ABSSSI and CABP trials. The adverse event profiles in patients ≥ 65 years of age and in patients < 65 years of age were similar. The percentage of patients in the Teflaro group who had at least one adverse event was 52.4% in patients ≥ 65 years of age and 42.8% in patients < 65 years of age for the two indications combined. Ceftaroline is excreted primarily by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group and it may be useful to monitor renal function. Elderly subjects had greater ceftaroline exposure relative to non-elderly subjects when administered the same single dose of Teflaro. However, higher exposure in elderly subjects was mainly attributed to age-related changes in renal function. Dosage adjustment for elderly patients should be based on renal function *[see Dosage and Administration and Clinical Pharmacology].* **Patients with Renal Impairment -** Dosage adjustment is required in patients with moderate (CrCl > 30 to ≤ 50 mL/min) or severe (CrCl ≥ 15 to ≤ 30 mL/min) renal impairment and in patients with end-stage renal disease (ESRD – defined as CrCl < 15 mL/min), including patients on hemodialysis (HD) *[see Dosage and Administration and Clinical Pharmacology].*

OVERDOSAGE: In the event of overdose, Teflaro should be discontinued and general supportive treatment given. Ceftaroline can be removed by hemodialysis. In subjects with ESRD administered 400 mg of Teflaro, the mean total recovery of ceftaroline in the dialysate following a 4-hour hemodialysis session started 4 hours after dosing was 76.5 mg (21.6% of the dose). However, no information is available on the use of hemodialysis to treat overdosage *[see Clinical Pharmacology].*

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IF95USCFR04
Revised: April 2011
 69-1020503-BS-A-APR11

Please also see full Prescribing Information at www.teflaro.com.

BPS Nears Completion of Practice Analysis for Several Pharmacy Specialties

The Board of Pharmacy Specialties (BPS) is nearing completion of role delineation studies in Critical Care, Pain and Palliative Care, and Pediatric Pharmacy. Conducting a role delineation study is a critical step in evaluating a proposed specialty.

The purpose of the role delineation study is to determine whether these three practice areas are based upon specialized knowledge of the pharmaceutical sciences, as well as specialized functions routinely performed by practitioners in these proposed specialties.

This past summer, the Practice Analysis Taskforce for each proposed specialty convened to draft an outline of the functions that a specialist in each practice area would routinely engage in. Following the completion of this work, independent review panels were established to make edits and provide feedback to the Practice Analysis Taskforce. The role delineation, including specialized tasks and knowledge areas, has been translated into web-based surveys for each proposed specialty. These surveys will be fielded to pharmacists in each proposed specialty before the end of 2011.

It is anticipated that the final report for each role delineation study will be completed during the first quarter of 2012. If the role delineation studies in these three areas yield information suggestive that Critical Care, Pain and Palliative Care, and/or Pediatrics should be recognized as a specialty practice in pharmacy, the BPS Board of Directors will issue a call to the profession for a petition to recognize the proposed specialty or specialties. The criteria outlined in the BPS Petitioner's Guide for Recognition of a Pharmacy Practice Specialty will be followed in the petition for new specialty recognition. The petition criteria can be viewed on the BPS website at http://www.bpsweb.org/pdfs/petitionersguide.pdf

The complete process leading to the administration of a certification exam in a new specialty takes approximately three years to complete.

BPS Executive Director, William M. Ellis commented; "The interest in these proposed specialties has been very high. BPS received almost 300 nominations to serve on the Pediatric Pharmacy and Critical Care Pharmacy Practice Analysis Taskforces. The conduct of this and other role delineation studies demonstrates the active commitment of BPS to recognize pharmacy specialties and certify pharmacists' knowledge and skill at the advanced practice level. The exploration of new specialties is consistent with the increased interest and recognition of BPS specialty certification over the past five years where the number of board certified pharmacists has doubled."

Ellis also commented that BPS will be looking to conduct one or two new role delineation studies in 2012, however the proposed pharmacy specialty areas have not been confirmed at this time.

Honors

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Research: Methods and Intervention Models," will be delivered at 10:30 a.m. during today's Opening General Session.

Russell R. Miller Award

Dr. Carter will also receive the 2011 Russell R. Miller Award during the Opening General Session. The Russell R. Miller Award is presented in recognition of substantial contributions to the literature of clinical pharmacy. Dr. Carter will receive this award for his many significant contributions to the literature focusing on the treatment of hypertension.

Barry Carter, Pharm.D., FCCP, BCPS

Education Award

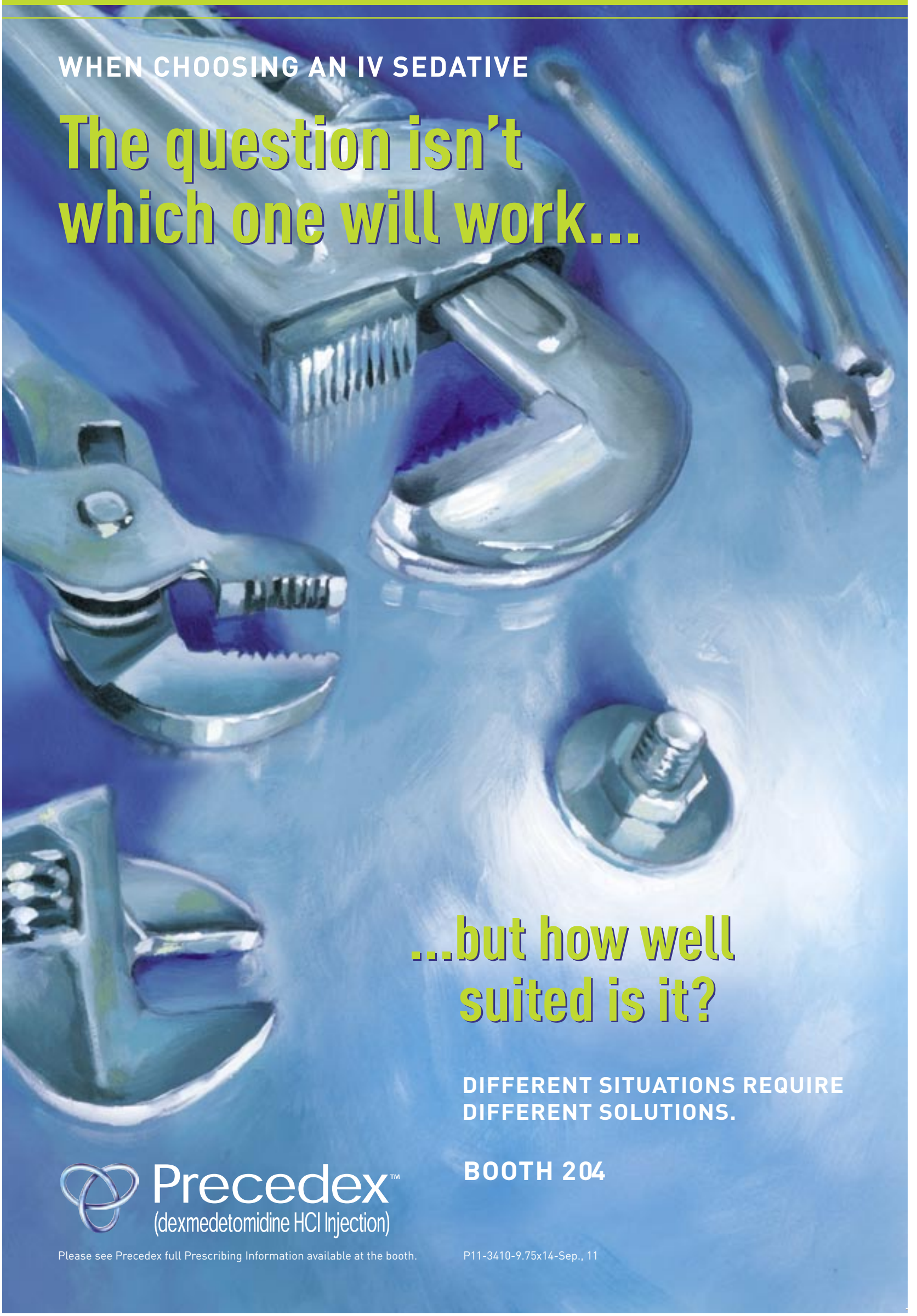
The Education Award recognizes an ACCP member who has made substantial and outstanding contributions to clinical pharmacy education. Mary H.H. Ensom (formerly *Chandler*) is professor and director of the Doctor of Pharmacy Program, Faculty of Pharmaceutical Sciences, and Distinguished University Scholar, University of British Columbia, and clinical pharmacy specialist, Children's & Women's Health Centre of British Columbia. Dr. Ensom's main areas of expertise are clinical pharmacokinetics and pharmacodynamics.

Letters written by colleagues in support of Dr. Ensom's nomination speak to her passion for teaching pharmacokinetics. Dr. Samuel Poloyac, associate professor of pharmaceutical sciences at the University of Pittsburgh School of Pharmacy, wrote in his letter of support,

Mary H.H. Ensom, Pharm. D., FCCP

"Mary's teaching style is very effective. She uses a strong theoretical understanding of pharmacokinetic concepts to teach the clinical application in patients…. More importantly, since Mary teaches from the theoretical foundation, students are able to retain the material well beyond the classroom and throughout their professional careers."

Dr. Ensom has more than 420 publications to her credit, and she received the ACCP Russell R. Miller Award in 2006. She is a fellow of ACCP and one of only eight pharmacists who are fellows of the Canadian Academy of Health Sciences, Canada's equivalent to the Institute of Medicine.


WHEN CHOOSING AN IV SEDATIVE
The question isn't which one will work...
...but how well suited is it?
DIFFERENT SITUATIONS REQUIRE DIFFERENT SOLUTIONS.
BOOTH 204
Precedex™
(dexmedetomidine HCl Injection)
Please see Precedex full Prescribing Information available at the booth.
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