

# THE ANNALS: 40-YEAR EVOLUTION

2006 marks the 40th year of publication for *The Annals*. Over that time, *The Annals* has been an important contributor to the development of clinical pharmacy. Throughout 2006, we are publishing articles reflecting on the history of clinical pharmacy through the eyes of practitioners, including those pioneering clinical pharmacy, as well as those who have more recently entered the profession and a well-established specialty. In addition, we are also presenting articles and editorials from the early history of *The Annals* that have given direction and shape to the practice of clinical pharmacy (see page 1174).

## Evolution of Pediatric Clinical Pharmacy

Milap C Nahata

Nearly 42 years ago, Harry Shirkey (a pediatrician from Cincinnati) termed infants and children as “therapeutic orphans.” He was concerned that drugs may be given to these patients without adequate studies on their efficacy and safety. Although progress has been made, many drugs continue to be used in young pediatric patients when they have been approved by the Food and Drug Administration (FDA) only for adults. For the first time, the FDA Modernization Act provides a “carrot” of 6 months of market exclusivity for drugs under patent if the manufacturer conducts studies in children. The Best Pharmaceuticals for Children Act of 2002 directs the Secretary of the Department of Health and Human Services (through the National Institutes of Health Director and the FDA Commissioner) to develop and prioritize a list of drugs that need to be studied. Table 1 provides a list of drugs requiring pediatric studies.

This suggests that the need for pharmacokinetic, pharmacodynamic, pharmacogenetic, efficacy, and safety studies in pediatric patients continues. Since most drugs not la-

beled for this population are not available in appropriate dosage forms, the need for the development of suitable pediatric drug formulations also exists.

### What Has Changed in Terms of Pediatric Pharmacy Practice?

Robert Levin described clinical pharmacy practice in a pediatric clinic in the pages of this journal in 1972 (see page 1175). Pharmacists’ clinical responsibilities at that time included counseling patients and families about medications by obtaining complete family and medication history, identifying adverse drug reactions, and monitoring drug therapy, as well as teaching physicians and pharmacy students about drug therapy.

John Piccoro began an inpatient pediatric clinical pharmacy practice at the University of Kentucky Medical Center in 1969. His recollection of major accomplishments included establishment of a well-defined role in patient care; involvement with making rounds with pediatric teams; provision of unit dose dispensing, dose standardization, parenteral nutrition, resuscitation medications, and clinical pharmacy services through a satellite pharmacy; and training of pharmacy residents as well as pharmacy

---

Author information provided at the end of the text.

Dr. Nahata is Editor-in-Chief of *The Annals*.

students. He also was aware of pediatric pharmacy services offered by Roger Klotz in Chicago.

In 1979, I was the first clinical pharmacist at Columbus Children's Hospital and faced similar challenges. I can remember my first day on the infectious disease ward when all of the physicians seemed to wonder why a pharmacist was on the 6th floor rather than in the basement. I was the interface between the dispensing pharmacist and the physicians and offered clinical pharmacy services and therapeutic drug monitoring. My other responsibilities included developing a research program (writing grants, abstracts, and articles) and teaching physicians, pharmacists, and medical and pharmacy students at the hospital as well as at Ohio State University (OSU). Soon, other specialties, including neonatology, hematology/oncology, and critical care, started requesting clinical pharmacy services. Today, there are 7 clinical pharmacy specialists at Children's—6 funded by the hospital and 1 funded by the college.

Pediatric Pharmacy Advocacy Group (PPAG) developed pediatric pharmacy practice guidelines in 1991. American Society of Health-System Pharmacists [ASHP] Guidelines for Providing Pediatric Pharmaceutical Services in Organized Health Care Systems were published in 1993. These included general principles, orientation and training programs, inpatient services, ambulatory care services, drug information, therapeutic drug monitoring, pharmacokinetic services, patient and caregiver education, medication errors, adverse drug reactions, drug use evaluations, and research. We are able to treat most illnesses more effectively today than before, and yet new challenges among children and adolescents include rising rates of obesity, type 2 diabetes, primary hypertension, and psychiatric/behavioral disorders.

### How Has Pediatric Pharmacy Education and Training Changed Over the Past 40 Years?

The majority of schools of pharmacy during the 1960s through the 1980s offered a BS (Pharmacy) degree; PharmD is now the sole entry-level degree. Both didactic education

and clerkship experiences are now being provided for every pharmacy student. The required number of lecture hours has increased, and many schools, including OSU, offer an elective course in pediatric drug therapy. Clerkship experience in pediatrics is required by the Accreditation Council for Pharmacy Education.

Residencies and fellowships have been instrumental in preparing practitioners and scholars. There are 19 specialty residency programs in pediatric pharmacy practice currently accredited by the ASHP. Additional general pharmacy practice residencies with emphasis in pediatrics may also be offered to PharmD graduates. Seven pediatric fellowship programs are listed in the American College of Clinical Pharmacy (ACCP) database. We have provided fellowship training to 25 fellows over the past 20 years. However, the number of residency and fellowship programs appears to be too low to meet future needs. The funding of 13 pediatric pharmacology research units by the National Institute of Child Health and Human Development has stimulated research in pediatric pharmacotherapy.

### Summary

Pediatric drug therapy has definitely improved over the past 40 years. Activities in practice, research, and education have all expanded. The Pediatric Special Interest Group of ASHP was the main venue for pharmacists; ACCP's Practice and Research Network and PPAG are now additional venues for pediatric practitioners to share their knowledge and skills with colleagues. The future of pediatric pharmacotherapy indeed looks bright.

**Milap C Nahata** MS PharmD, Professor and Division Chair, College of Pharmacy; Professor of Pediatrics and Internal Medicine, College of Medicine, Ohio State University (OSU); Associate Director of Pharmacy, OSU Medical Center, Columbus, OH

I appreciate the input from John Piccoro MS PharmD at the University of Kentucky.

Published Online, 30 May 2006, [www.theannals.com](http://www.theannals.com)  
DOI 10.1345/aph.1G459

**Table 1.** Drugs Listed by Department of Health and Human Services Requiring Studies in Pediatric Patients<sup>a</sup>

Acyclovir	Daunomycin	Heparin	Lithium	Promethazine
Ampicillin	Dexrazoxane	Hydrochlorothiazide	Lorazepam	Rifampin
Ampicillin/sulbactam	Diazoxide	Hydrocortisone valerate ointment and cream	Meropenem	Sevelamer
Azithromycin	Dobutamine	Hydroxychloroquine	Methadone	Sodium nitroprusside
Baclofen	Dopamine	Hydroxyurea	Methotrexate	Spironolactone
Bumetanide	Eletriptan	Isoflurane	Metoclopramide	Vincristine
Bupropion	Ethambutol	Ivermectin	Metolazone	Zonisamide
Clonidine	Flecainide	Ketamine	Morphine	
Cyclosporine	Furosemide	Lindane	Piperacillin/tazobactam	
Dactinomycin	Griseofulvin		Pralidoxime	

<sup>a</sup>April 25, 2006.