

Anne Zajicek, M.D., Pharm.D., FAAP

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ACADEMIC DEGREES

Doctor of Medicine 1995 University of Pittsburgh, Pittsburgh, PA
Doctor of Pharmacy 1985 State University of New York at Buffalo, Buffalo, NY
Bachelor of Science, Pharmacy 1982 Duquesne University, Pittsburgh, PA

POSITIONS

2017-present **Deputy Director**
Office of Clinical Research, National Institutes of Health

2010-2017 **Branch Chief**
Obstetric and Pediatric Pharmacology and Therapeutics Branch

2009-2010 **Acting Branch Chief**
Obstetric and Pediatric Pharmacology Branch

2007-2009 **Associate Branch Chief**
Obstetric and Pediatric Pharmacology Research Branch

2003-present **Pediatric Medical Officer**
Obstetric and Pediatric Pharmacology Research Branch
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
National Institutes of Health
Bethesda, Maryland

2002-2003 **Medical Officer**
Office of Clinical Pharmacology and Biopharmaceutics
Food and Drug Administration
Rockville, Maryland

2002-present **Assistant Professor**
Department of Pediatrics
Uniformed Services University of the Health Sciences
Bethesda, Maryland

2001-2002 **Research Fellow**
Department of Medicine, Division of Clinical Pharmacology and
Department of Pediatrics, Division of Pediatric Gastroenterology
Stanford University, and
Clinical Instructor
Department of Pediatrics
Stanford University School of Medicine
Stanford, California

1998- 2000 **Pediatrician**
Pediatric and Adolescent Medicine Associates
Pittsburgh, Pennsylvania

1995- 1998 **Resident in Pediatrics**
Children's Hospital of Pittsburgh
Pittsburgh, Pennsylvania

1987-1991 **Assistant Professor**
University of Colorado School of Pharmacy, and
Clinical Pharmacist
Department of Pediatrics
Division of Clinical Pharmacology
National Jewish Center for Immunology and Respiratory Medicine
Denver, Colorado

1985-1987 **Research Fellow**
 St. Jude Children's Research Hospital,
 Pharmacokinetics/Pharmacodynamics Lab
 Memphis, Tennessee

1982-1983 **Pharmacy Resident**
 National Institutes of Health
 Bethesda, Maryland

HONORS AND AWARDS

Eunice Kennedy Shriver National Institute of Child Health and Human Development Collaboration Award 2017

National Institutes of Health Directors Award (Individual) 2015

National Institutes of Health Directors Award (Group) 2015

Food and Drug Administration Group Recognition Award 2014

National Institutes of Health Award of Merit 2012

Food and Drug Administration Group Recognition Award 2009

National Institutes of Health Award of Merit 2006

Medical School: Richard L. Day, M.D., Prize for Pediatrics

Teaching Awards, University of Colorado:
 Syntex "Preceptor of the Year" 1990, Chancellor's Teaching Award 1991

Fellowship: American Society of Hospital Pharmacists Bristol Oncology Pharmacotherapy Fellow, 1985-1986

Graduate School: Rho Chi Pharmacy Honor Society

College: Lambda Sigma Sophomore Honor Society, Schiller Award for Humanities and Social Sciences

PROFESSIONAL SOCIETY MEMBERSHIPS

American Academy of Pediatrics
American Society of Clinical Pharmacology and Therapeutics
Children's Oncology Group
American Association of Pharmaceutical Scientists
American College of Clinical Pharmacology

PROFESSIONAL LICENSURE

Pennsylvania, California (retired)

BOARD CERTIFICATION AND RECERTIFICATION

Pediatrics (1998, 2005, 2012, 2017)

OTHER CERTIFICATIONS AND COURSES

Basic Project Officer (Research and Development) 2004
Advanced Project Officer (Research and Development) 2004
Ethical and Regulatory Aspects of Clinical Research 2004
Introduction to Principles and Practice of Clinical Research 2004-2005
Leadership for Physician Executives (Levinson Institute) 2005
The Science of Small Clinical Trials (FDA-NIH Course) certification 2009
Contracting Officer's Representative (COR) Recertification 2017

COMMITTEES

NIH Liaison: American Academy of Pediatrics Committee on Drugs 2011-2017
Board of Directors: American Society for Clinical Pharmacology and Therapeutics Board of Directors 2012-2016
NIH Representative: Department of Health and Human Services National Advisory Committee on Children and Disasters (NACCD) 2014-present

PUBLICATIONS**Original Articles**

1. Glynn AM, Slaughter RL, Brass C, D'Ambrosio R, Jusko WJ. Effects of ketoconazole on methylprednisolone pharmacokinetics and cortisol secretion. *Clin Pharmacol Ther* 1986; 39:654-659.
2. Crom WR, Glynn AM, Abromowitch M, Pui C, Dodge R, Evans WE. Use of the automatic interaction detector method to identify patient characteristics related to methotrexate clearance. *Clin Pharmacol Ther* 1986; 39:592-597.
3. Strother DR, Glynn-Barnhart AM, Kovnar E, Gregory RE, Murphy SB. Variability in the disposition of intraventricular methotrexate: A proposal for rational dosing. *J Clin Oncol* 1989; 7(11): 1741- 47.
4. Corren J, Glynn-Barnhart AM. Poor bioavailability of sustained-release theophylline: a case for liquid theophylline. *J Asthma* 1991; 28(1):57-60.
5. Glynn-Barnhart AM, Erzurum SC, Leff JA, Martin RJ, Cochran JE, Cott GR, Szeffler SJ. Effect of low-dose methotrexate on the disposition of glucocorticoids and theophylline. *J Allergy Clin Immunol* 1991; 88(2): 180-186.
6. Glynn-Barnhart AM, Erzurum SC, Leff JA, Martin RJ, Evans-Cochran JE, Cott GR, Szeffler SJ. Pharmacokinetics of low-dose methotrexate in adult asthmatics. *Pharmacotherapy* 1992; 12 (5):383-390.
7. Malone RA, Hollie MC, Glynn-Barnhart AM, Nelson HS. Optimal duration of nebulized albuterol therapy. *Chest* 1993; 104:1114-18.
8. Zajicek A, Esquivel C, Millan M, Cox K, Berquist R, Berquist W. Thirteen Years' Experience in Pediatric Liver Transplantation: Differences between tacrolimus and cyclosporine. *Transplant Proc* 2002 Aug; 34(5):1976-78.
9. Johnson JR, Bross P, Cohen M, Rothmann M, Chen G, Zajicek A, Gobburu J, Rahman A, Staten A, Pazdur R. Approval Summary: Imatinib mesylate capsules for treatment of adult patients with newly diagnoses Philadelphia chromosome-positive chronic myelogenous leukemia in chronic phase. *Clinical Cancer Research* 2003; 9:1972-79.
10. McGrath PJ, Walco GA, Turk DC, Dworkin RH, Brown MT, Davidson K, Eccleston C, Finley GA, Goldschneider K, Haverkos L, Hertz SH, Ljungman G, Palermo T, Rappaport BA, Rhodes T, Schechter N, Scott J, Sethna N, Svensson OK, Stinson J, von Baeyer CL, Walker L, Weisman S, White RE, Zajicek A, Zeltzer L; PedIMMPACT. Core outcome domains and measures for pediatric acute and chronic/recurrent pain clinical trials: PedIMMPACT recommendations. *J Pain* 2008; 9(9):771-83.
11. Zajicek A. The National Institutes of Health and the Best Pharmaceuticals for Children Act. *Paediatric Drugs* 2009; 11(1): 45-47.
12. Haas DM, Renbarger JL, Denne S, Ahmed MS, Easterling T, Feibus K, Meslin EM, Koren G, Zajicek A, Snodgrass WR, Flockhart DA. Pharmacotherapy and pregnancy: Highlights from the first International Conference for Individualized Pharmacotherapy in Pregnancy. *Clin Transl Sci.* 2009; 2(1):11-14.
13. Beigi RH, Han K, Venkataramanan R, Hankins GD, Clark S, Hebert MF, Easterling T, Zajicek A, Ren Z, Mattison DR, Caritis SN. Obstetric-Fetal Pharmacology Research Units Network. Pharmacokinetics of oseltamivir among pregnant and non-pregnant women. *Am J Obstet Gynecol.* 2011 Jun; 204 (6 Suppl 1): S84-88.

14. Langholz B, Skolnik JM, Barrett JS, Renbarger J, Seibel NL, Zajicek A, Arndt CA. Dactinomycin and vincristine toxicity in the treatment of childhood cancer: a retrospective study from the Children's Oncology Group. *Pediatric Blood Cancer* 2011 Aug; 57(2) 252-57.
15. Giacoia GP, Taylor-Zapata P, Zajicek A. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatrics Formulation Initiative: proceedings from the Second Workshop on Pediatric Formulations. *Clin Ther.* 2012 Nov;34(11):S1-10. doi: 10.1016/j.clinthera.2012.09.013
16. Caritis SN, Sharma S, Venkataramanan R, Hankins GD, Miodovnik M, Hebert MF, Umans JG, Benedetti T, Mattison D, Zajicek A, Fischer D, Jackson A; Eunice Kennedy Shriver National Institute of Child Health and Human Development Obstetrical-Fetal Pharmacology Research Units Network. Pharmacology and placental transport of 17-hydroxyprogesterone caproate in singleton gestation. *Am J Obstet Gynecol.* 2012 Nov;207(5):398.e1-8. doi: 10.1016/j.ajog.2012.08.015. Epub 2012 Aug 16.
17. Swezey R, Shinn W, Green C, Drover DR, Hammer GB, Schulman SR, Zajicek A, Jett DA, Boss GR. Comparison of a new cobinamide-based method to a standard laboratory method for measuring cyanide in human blood. *J Anal Toxicol.* 2013 Jul-Aug;37(6):382-5. doi: 10.1093/jat/bkt037. Epub 2013 May 6.
18. Pillai VC, Han K, Beigi RH, Hankins GD, Clark S, Hebert MF, Easterling TR, Zajicek A, Ren Z, Caritis SN, Venkataramanan R. Population pharmacokinetics of oseltamivir in non-pregnant and pregnant women. *Br J Clin Pharmacol.* 2015 Jun 3. doi: 10.1111/bcp.12691.
19. Drover DR, Hammer GB, Barrett JS, Cohane CA, Reece T, Zajicek A, Schulman SR. Evaluation of sodium nitroprusside for controlled hypotension in children during surgery. *Front Pharmacol.* 2015 Jul 6;6:136. doi: 10.3389/fphar.2015.00136.
20. Barrett JS, Hirankarn S, Holford N, Hammer GB, Drover DR, Cohane CA, Anderson B, Dombrowski E, Reece T, Zajicek A, Schulman SR. A hemodynamic model to guide blood pressure control during deliberate hypotension with sodium nitroprusside in children. *Front Pharmacol.* 2015 Jul 28; 6:151. doi: 10.3389/fphar.2015.00151.
21. Acute Responses to Diuretic Therapy in Extremely Low Gestational Age Newborns: Results from the Prematurity and Respiratory Outcomes Program Cohort Study. Blaisdell CJ, Troendle J, Zajicek A; Prematurity and Respiratory Outcomes Program. *J Pediatr.* 2018 Jun;197:42-47.e1. doi: 10.1016/j.jpeds.2018.01.066. Epub 2018 Mar 26.

Chapters

Glynn-Barnhart AM, Teresi M, Crom W. "Solid Tumors and Childhood Leukemias." In: Pharmacotherapy: A Pathophysiologic Approach. Eds. JT DiPiro, RL Talbert, PE Hayes, GC Yee, LM Posey. Elsevier Press, 1989.

Karan L, Zajicek A, Pating D. "Pharmacokinetic and Pharmacodynamic Principles." In: Principles of Addiction Medicine 3rd, 4th, 5th editions. ASAM Publications, 2003, 2009, 2014.

Zajicek A, Karan L. "Pharmacokinetic and Pharmacodynamic Principles." In: The ASAM Essentials of Addiction Medicine Second Edition. ASAM Publications, 2015.

Reviews

Inclusion of pregnant and breastfeeding women in research - efforts and initiatives.

Illamola SM, Bucci-Rechtweg C, Costantine MM, Tsilou E, Sherwin CM, **Zajicek A**.

Br J Clin Pharmacol. 2018 Feb;84(2):215-222. doi: 10.1111/bcp.13438. Epub 2017 Oct 22

Enrollment of Neonates in More Than One Clinical Trial.

Davis JM, Baer GR, Portman R, Nelson R, Storari L, Aranda JV, Bax R, **Zajicek A**, Klein A, Turner M, Baygani S, Thomson M, Allegaert K; International Neonatal Consortium.

Clin Ther. 2017 Oct;39(10):1959-1969. doi: 10.1016/j.clinthera.2017.09.006. Epub 2017 Oct 4.

Development of Drug Therapies for Newborns and Children: The Scientific and Regulatory Imperatives.

Mulugeta YL, **Zajicek A**, Barrett J, Sachs HC, McCune S, Sinha V, Yao L.

Pediatr Clin North Am. 2017 Dec;64(6):1185-1196. doi: 10.1016/j.pcl.2017.08.015.

Wang J, Johnson T, Sahin L, Tassinari MS, Anderson PO, Baker TE, Bucci-Rechtweg C, Burckart GJ, Chambers CD, Hale TW, Johnson-Lyles D, Nelson RM, Nguyen C, Pica-Branco D, Ren Z, Sachs H, Sauberan J, Zajicek A, Ito S, Yao LP. Evaluation of the Safety of Drugs and Biological Products Used During Lactation: Workshop Summary. Clin Pharmacol Ther. 2017 Jun;101(6):736-744. doi: 10.1002/cpt.676.

Doctor A, Zimmerman J, Agus M, Rajasekaran S, Bubeck Wardenburg J, Fortenberry J, Zajicek A, Mairson E, Typpo K. Pediatric Multiple Organ Dysfunction Syndrome: Promising Therapies. Pediatr Crit Care Med. 2017 Mar;18(3_suppl Suppl 1): S67-S82. doi:

10.1097/PCC.0000000000001053.PMID: 28248836

Ren Z, Zajicek A. Review of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act: What can the obstetric community learn from the pediatric experience? Semin Perinatol. 2015 Nov;39(7):530-1. doi: 10.1053/j.semperi.2015.08.006. Epub 2015 Oct 9. PMID: 26455383

Zajicek A, Fossler MJ, Barrett JS, Worthington JH, Ternik R, Charkoftaki G, Lum S, Breikreutz J, Baltezor M, Macheras P, Khan M, Agharkar S, MacLaren DD. A report from the pediatric formulations task force: perspectives on the state of child-friendly oral dosage forms. AAPS J. 2013 Oct;15(4):1072-81. doi: 10.1208/s12248-013-9511-5. Epub 2013 Aug 2.

Crom WR, Glynn-Barnhart AM, Rodman JH, Teresi ME, Kavanagh RE, Christensen ML, Relling MV, Evans WE. Pharmacokinetics of anticancer drugs in children. Clinical Pharmacokinetics 1987; 12:168-213.

Glynn-Barnhart AM, Hill M, Szeffler SJ. Sustained-release Theophylline Preparations: Practical recommendations for prescribing and therapeutic drug monitoring. Drugs 1988; 35(6):597-729.

Mattison DM and Zajicek A. Gaps in knowledge in treating pregnant women. Gender Medicine 2006; 3(3): 169-182.

Commentaries

Zajicek A and Giacoia GP. Obstetric Clinical Pharmacology: Coming of age. Clinical Pharmacol Ther 2007; 81(4): 481-1.

Simpson LA, Peterson L, Lannon CM, Murphy SB, Goodman C, Ren Z, Zajicek A. Special challenges

in comparative effectiveness research on children's and adolescents' health. *Health Aff (Millwood)* 2010 Oct; 29(10): 1849-56.

Parisi MA, Spong CY, Zajicek A, Gutmacher AE. We don't know what we don't study: the case for research on medication effects in pregnancy. *Am J Med Genet C Seminar Med Genet* 2011 Aug 15; 157(3):247-50.

Giacoaia GP, Taylor-Zapata P, Zajicek A. Drug studies in newborns: a therapeutic imperative. *Clin Perinatol* 2012 March; 39(1): 11-23.

Connor EM, Smoyer WE, Davis JM, Zajicek A, Ulrich L, Purucker M, Hirschfeld S. Meeting the demand for pediatric clinical trials. *Sci Transl Med.* 2014 Mar 12;6(227):227fs11. doi: 10.1126/scitranslmed.3008043

Zajicek A, Barrett JS. The grand challenges in obstetric and pediatric pharmacology. *Front Pharmacol.* 2013 Dec 30;4:170. doi: 10.3389/fphar.2013.00170

Abstracts

Crom WR, Glynn AM, Evans WE. Factors affecting intermediate-dose methotrexate (MTX) clearances (CL) in the treatment of acute lymphocytic leukemia (ALL). American Society of Clinical Pharmacology and Therapeutics, 86th Annual Meeting, March 28-30, San Antonio, Texas, 1985.

Jusko WJ, Glynn AM, Slaughter RL, Brass C, D'Ambrosio R. Effects of ketoconazole on methylprednisolone pharmacokinetics and cortisol secretion. American Society for Clinical Pharmacology and Therapeutics, 87th Annual Meeting, March 20-22, Washington, D.C., 1986.

Crom WR, Kalwinsky D, Glynn AM, Evans WE. Clearance of etoposide during continuous 72-hour intravenous infusion in children. 7th Annual Meeting, American College of Clinical Pharmacy, July 28-30, Chicago, Illinois, 1986.

Glynn-Barnhart A, Christensen M, Melton E, Crom W, Rivera G, Evans W. Pharmacokinetics of vincristine in children: relationship to neurotoxicity. American Society of Hospital Pharmacy, 21st Annual Midyear Meeting, December 7-11, Las Vegas, Nevada, 1986.

Strother D, Glynn-Barnhart AM, Kovnar E, Murphy SB. Variability in cerebrospinal fluid methotrexate disposition following intra-Ommaya therapy. American Association of Cancer Research, 79th Annual Meeting, New Orleans, Louisiana, May 1988.

Glynn-Barnhart AM, Chan MA, Gelfand EW. Effect of methotrexate on *in vitro* lymphocyte proliferation. American College of Clinical Pharmacy, 10th Annual Meeting, August 6-9, Kansas City, Missouri, 1989. *Pharmacotherapy* 9(3): 194, 1989.

Glynn-Barnhart AM, Szeffler SJ, Erzurum SC, Leff J, Martin R, Evans-Cochran J, Cott G. Methotrexate disposition in adult asthmatics. American College of Clinical Pharmacy, 10th Annual Meeting, August 6-9, Kansas City, Missouri, 1989. *Pharmacotherapy* 9(3): 194, 1989.

Glynn-Barnhart AM, Szeffler SJ, Cott GR. Effect of methotrexate on prednisolone and theophylline pharmacokinetics. American Society for Clinical Pharmacology and Therapeutics 90th Annual Meeting, March 21-23, San Francisco, CA 1990. *Clin Pharmacol Ther* 47: 130, 1990.

Milgrom HM, Barnhart AM, Gaddy J, Bush R, Busse W. The effect of a 24 hour sustained theophylline

(Uniphyll) on diurnal variations in airway responsiveness, The American Academy of Allergy Annual Meeting, Baltimore, MD, March 1990. J Allergy Clin Immunol 85 (1 Part 2):144, 1990.

Glynn-Barnhart AM, Szeffler SJ, Cott G. Effect of methotrexate on prednisone and theophylline disposition. American College of Clinical Pharmacy Annual Meeting August 5-8, San Francisco, CA 1990. Pharmacotherapy 10(3): 255, 1990.

Zajicek A, Esquivel C, Millan M, Cox K, Berquist R, Berquist W. Twelve years' experience in pediatric liver transplantation: differences between tacrolimus and cyclosporine. Second International Congress on Immunosuppression, San Diego, CA, December 2001.

Desai DM, Millan MT, O'Hali WA, Zajicek A, Monge HL, Cox KL, Castillo R, Berquist WE, Esquivel CO. Influence of race on outcomes in pediatric liver transplantation. American Transplant Conference, Washington, D.C., April 2002.

Booth B, Zajicek A, Gobburu J, Rahman N, Pazdur R. A population pharmacokinetic (PPK) approach to oncologic agents in renal impairment: zoledronic acid (ZA). American Society of Clinical Oncology Annual Meeting, Chicago, IL May 2003.

TEACHING

Faculty Facilitator, USUHS Ethics Course, 2009-present

Preceptor, Pediatric Clinic, National Naval Medical Center, Bethesda, Maryland, 2003-2007

Lecturer in Clinical Pharmacology course at Uniformed Services University of the Health Sciences, 2003-2007

Preceptor, Resident Pediatric Clinic, Stanford University, Stanford, California 2001-2002

Coordinator and principle lecturer for "Clinical Pharmacokinetics" course 1987-90.

Preceptor of "Clinical Pharmacokinetics" rotation 1988-91.

Lecturer in "Pharmacotherapeutics" course 1988-90.

Lecturer in "Non-Prescription Drugs" course 1990.