

CURRICULUM VITAE

I. PERSONAL

A. Name: Theodore F. Reiss, MD, MBE
treiss@celgene.com

II. EDUCATION

<u>School</u>	<u>Date</u>	<u>Major/Minor/Courses</u>	<u>Degree</u>
University of Pennsylvania Philadelphia, Pennsylvania	1979	Biology & History	B.A.
Vanderbilt University School of Medicine Nashville, Tennessee	1983	Medicine	M.D.
Columbia University New York, New York		Credits towards MS Epidemiology	
University of Pennsylvania School of Medicine Philadelphia, Pennsylvania	2013	Bioethics	MBE

III. EMPLOYMENT HISTORY

<u>Title</u>	<u>From - To</u>
Celgene Corporation Head, Clinical Research and Development, Inflammation and Immunology	Sept 2015 - present
Novartis Pharmaceuticals Corporation Vice President, Clinical Development Head Primary Care	Dec 2012- July 2015
Vanderbilt University School of Medicine Research Professor of Medicine Pulmonary, Allergy, and Critical Care Medicine	July 2011-Nov 2012
Covance, Inc Corporate Vice President Global Clinical Integrated Drug Development	Sept 2009-June 2011

Merck & Co., Inc.

Vice President, Clinical Research Bone, Respiratory, Allergy, Gastroenterology, Musculoskeletal and Endocrine	May 2004 – August 2009
Executive Director, Clinical Research Respiratory & Allergy	August 2000 – April 2004
Senior Director, Clinical Research Pulmonary-Immunology	October 1996 - August 2000
Director Pulmonary/Immunology	April 1993 - September 1996
Associate Director, Clinical Pharmacology	October 1990 - April 1993
Staff, Department of Pulmonary Medicine, Cleveland Clinic Foundation, Cleveland Clinic, Florida (Pulmonary Medicine) Chairman, Department of Medicine Cleveland Clinic Florida (Peer Election) January, 1990 – September, 1990	July, 1989 - October, 1990
Fellow, Cardiovascular Research Institute, University of California, San Francisco, San Francisco, California (Pulmonary and Critical Care Medicine)	July, 1986 - June, 1989
Resident, Columbia-Presbyterian Medical Center, Columbia University, New York, New York (Medicine)	July, 1984 - June, 1986
Intern, Vanderbilt University Affiliated Hospitals, Vanderbilt University, Nashville, Tennessee (Medicine)	July, 1983 - June, 1984

IV. PREVIOUS ACADEMIC EXPERIENCE (ex- Vanderbilt)

December 1991 -2000	Clinical Assistant Professor of Medicine and Adjunct Assistant Professor of Physiology, University of Medicine and Dentistry of New Jersey
September 2009-2016	Member of the Curriculum Committee Master of Science in Translational Research, Institute For Translational Medicine and Therapeutics at the University of Pennsylvania, School of Medicine (Invited Lecturer 2009 –Present)

V. **SOCIETY MEMBERSHIPS**

- 1985 - American Medical Association, Member
- 1987 - American College of Physicians, Associate Member
- 1987 - American Thoracic Society
- 1988 - American College of Chest Physicians, Associate Member
- 1993 - European Respiratory Society

ORGANIZATIONAL MEMBERSHIPS

- 2001 – 2002 Member Board of Directors
Cerebral Palsy of New Jersey, Inc.
- 2004 - 2007 FDA Pulmonary-Allergy Advisory Committee (Industry Member)
- 2003 - 2018 American Thoracic Society: Drug Device Discovery and
Development Committee Chair: 2007-2010, 2012-2018
- 2007 - 2011 American Thoracic Society: Ethics and Conflict of Interest, Membership, Education
Committees
- 2018 - Planning and Evaluation Committee
- 2009 - Trustee of the Foundation of the American Thoracic Society
- 2012- 2016 Vice Chair Foundation of the American Thoracic Society
- 2014- Member FDA Science Board and Sub committee for the evaluation of CERSI and CEBR
programs

VI. **ACADEMIC AND PROFESSIONAL HONORS**

A. Honors

- 1976 - Benjamin Franklin Scholar, University of Pennsylvania
- 1979 - B.A., Summa Cum Laude, University of Pennsylvania
- 1979 - Phi Beta Kappa, University of Pennsylvania
- 1981 - CANCEP Assistantship, Vanderbilt University
- 1998 - Directors' Scientific Award, Board of Directors, Merck & Co., Inc.
- 2009 - Who's Who at American Thoracic Society
- 2018 - ATS Presidential Accommodation – Drug, Device, Discovery and Development Committee

B. Past Reviewer

- American Journal of Respiratory & Critical Care Medicine
- European Respiratory Journal

C. Licensure

<u>Source</u>	<u>Date</u>
New York	1986
California	1987

Florida	1990
New Jersey	1991 - Present
Tennessee	2012

D. Certification

<u>Source</u>	<u>Date</u>
Diplomate, National Board of Medical Examiners	1984
Diplomate, American Board of Internal Medicine	1986
Diplomate, American Board of Internal Medicine, Pulmonary Disease	1988
Diplomate, American Board of Internal Medicine, Critical Care Medicine	1989

VII. PUBLICATIONS

Papers:

1. Wetheral N, Reiss T, Parmenter M, Halter S: Morphological Effects of Natural Retinoids on Human Mammary Carcinoma Cell Lines in Monolayer Culture. *Scan Electron Microsc* 1982; 4:1565-71.
2. Graham B, Reiss T, Gregory D: Pericarditis Associated with Haemophilus Influenza type B Pneumonia and Bacteremia in Two Adults. *Chest* 1983; 84:84-87.
3. Reiss T, Rubinstein I, Emery D, Gold W, Boushey H: Local Mediator Release after Antigen Challenge of a Bronchial Segment in Allergic Dogs. *Am J Physiol* 1989; 1(3):366-372.
4. Rubinstein I, Reiss T, Garner D, Liu J, Bigby B, Boushey H: Effect of Exercise, Hyperpnea, and Bronchoconstriction on Plasma Atrial Natriuretic Peptide in Humans. *J Appl Physiol* 1989; 67(6):2656-2570.
5. Reiss T, Golden J: Abnormal Lung Gallium-067 Uptake Precedes Pulmonary Physiologic Impairment in an Asymptomatic Patient with Pneumocystis Carinii Pneumonia. *Chest* 1990; 97:1261-1263.
6. Rubinstein I, Bigby B, Reiss T, Boushey H: Short-Term Exposure to .3 ppm NO₂ Does Not Potentiate Airway Responsiveness to SO₂ in Asthmatic Subjects. *Am Rev Respir Dis* 1990; 141:381-385.
7. Reiss T, Ahmad M: Asthma: Current strategies for treatment. *Cleveland Clinic J Med* 1991; 58:161-169.
8. Reiss TF, Gruenert DC, Nadel JA, Jacoby DB: Infection of Cultured Human Airway Epithelial Cells by Influenza A Virus. *Life Sci* 1991; 49:1173-1181.
9. Rubinstein I, Reiss TF, Bigby BG, Stites DB, Boushey HA: Effect of 0.60ppm Nitrogen Dioxide on Circulating and Bronchioalveolar Lavage Lymphocyte Phenotypes in Health Subjects. *Environ Res* 1991; 55:18-30.
10. Impens N, Reiss T, Teahan J, DeSmet M, Rossing T, Shingo S, Zhang J, Schandevyl W, Verbesselt R, Dupont A: MK-679, Acute Bronchodilation with an Intravenously Administered Leukotriene D₄ Antagonist, MK-679. *Am Rev Respir Dis*, 1993; 147(6, Part 1):1442-1446.
11. Black D, Reiss T, Cauley J, Karpf D, Cummings S, and the Fracture Intervention Trial Study Group. The Design of the Fracture Intervention Trial. *Osteoporosis Int*. 1993 Suppl. 3:S29-S39.

PUBLICATIONS (cont'd)

Papers:

12. Schoors DF, DeSmet M, Reiss T, Margolskee D, Cheng H, Larson P, Amin R, Somers G: Single Dose Pharmacokinetics, Safety and Tolerability of MK-0476. A New Leukotriene D₄-Receptor Antagonist in Healthy Volunteers. *Brit J Clin Pharmacol* 1995; 40:277-280.
13. Black DM, Cummings SR, Karpf DB, Cauley JA, Thompson DE, Nevitt MC, Genant HK, Haskell WL, Marcus R, Ott SM, Torner JC, Quandt SA, Reiss TF, Ensrud KE for the Fracture Intervention Trial Research Group. Randomized Trial of Effect of Alendronate on Risk of Fracture in Women with Existing Vertebral Fractures: Results of the Fracture Intervention Trial. *Lancet* 1996; 348(9041):1535-1541.
14. Reiss TF, Altman LC, Chervinsky P, Bewtra A, Stricker WE, Noonan GP, Kundu S, Zhang J: Effects of Montelukast MK-0476, a New, Potent, Cysteinyl Leukotriene (LTD₄) Receptor Antagonist, in Patients with Chronic Asthma. *J Allergy Clin Immunol* 1996; 98(3):528-534.
15. Bronsky E, Kemp J, Zhang J, Guerreiro D, Reiss TF: Dose Related Protection of Exercise Bronchoconstriction by Montelukast, a Cysteinyl Leukotriene Receptor Antagonist at the End of a Once Daily Dosing Interval. *Clin Pharmacol Ther* 1997; 62(5):556-561.
16. DeLepeleire I, Reiss TF, Rochette IF, Botto A, Zhang J, Kundu S, Decramer M: Montelukast Causes Prolonged, Potent, Leukotriene D₄-Receptor Antagonism in the Airways of Patients with Asthma. *Clin Pharmacol Ther* 1997; 61(1):83-92.
17. Reiss TF, Hill JB, Harman E, Zhang Ji, Tanaka, WK, Bronsky E, Guerreiro D, Hendeles L: Increased Urinary Excretion of LTE₄ After Exercise and Attenuation of Exercise-Induced Bronchospasm by Montelukast, a Cysteinyl Leukotriene Receptor Antagonist. *Thorax* 1997; 52(12):1030-1035.
18. Reiss TF, Sorkness C, Stricker W, Botto A, Busse WN, Zhang Ji, Kundu S: Effects of Montelukast (MK-0476), a Potent Cysteinyl Leukotriene Receptor Antagonist on Bronchodilation in Asthmatic Subjects Treated With and Without Inhaled Corticosteroids. *Thorax* 1997; 52(1):45-48
19. Santanello NC, Barber BL, Reiss TF, Friedman BS, Juniper EF, Zhang J: Measurement Characteristics of Two Asthma Symptom Diary Scales for Use in Clinical Trials. *Eur Resp J*. 1997; 10(3):646-651.
20. Altman LC, Munk Z, Seltzer J, Noonan N, Shingo S, Zhang J, Reiss TF for the Montelukast Asthma Study Group: A Placebo Controlled, Dose Ranging Study of Montelukast, a Cysteinyl Leukotriene Receptor Antagonist. *J Allergy Clin Immunol* 1998; 102(1):50-56.

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21. Knorr B, Matz J, Bernstein J, Nguyen H, Seidenberg BC, Reiss TF, Becker A, for the Pediatric Montelukast Study Group: Montelukast, for Chronic Asthma in 6- to 14-Year Old Children: A Randomized, Double-Blind Trial. *JAMA* 1998; 279(15):1181-1186.
22. Kemp JP, Dockhorn RJ, Shapiro GG, Nguyen HH, Reiss TF, Seidenberg BC, Knorr B: Montelukast Once Daily Inhibits Exercise-Induced Bronchoconstriction in 6- to 14-Year Old Children with Asthma. *J Pediatr* 1998; 133(3):424-428.
23. Leff JA, Busse WW, Pearlman D, Bronsky EA, Kemp J, Hendeles L, Dockhorn R, Kundu S, Zhang, J, Seidenberg B, Reiss TF. Montelukast, a Leukotriene-Receptor Antagonist, for the Treatment of Mild Asthma and Exercise-Induced Bronchoconstriction. *N Engl J Med* 1998; 339(3):147-152
24. Lu S, Reiss TF: The Dose Selection of Montelukast Sodium (MK-0476). *Eur Respir Rev* 1998; 8(59):361-365
25. Malmstrom K, Schwartz J, Reiss TF, Sullivan T, Reese J, Jauregui L, Miller K, Scott M, Shingo S, Peszek I, Larson P, Ebel D, Hunt TL, Huhn R, Bachmann K: Effect of Montelukast on Single Dose Theophylline Pharmacokinetics. *Am J Ther* 1998;5(3):189-195.
26. Noonan MJ, Chervinsky P, Brandon M, Zhang J, Kundu S, McBurney J, Reiss TF for the Montelukast Asthma Study Group: Montelukast, a potent leukotriene receptor antagonist, causes dose-related improvements in chronic asthma. *Eur Respir J* 1998;11(6):1232-1239
27. Reiss TF, Chervinsky P, Dockhorn RJ, Shingo S, Seidenberg B, Edwards TB for the Montelukast Clinical Research Study Group: Montelukast a Once Daily Leukotriene Receptor Antagonist in the Treatment of Chronic Asthma; a Multicenter, Randomized, Double-Blind Trial. *Arch Inter Med* 1998; 158(11):1213-1220.
28. Knorr B, Larson P, Nguyen HH, Holland S, Reiss TF, Chervinsky P, Blake K, van Nispen CHM, Noonan G, Freeman A, Haesen R, Michiels N, Rogers JD, Amin RD, Zhao J, Xu X, Seidenberg BC, Gertz BJ, Spielberg S: Montelukast Dose Selection in 6-14 Year Olds: Comparison of Single Dose Pharmacokinetics in Children and Adults. *J Clin Pharmacol* 1999; 39(8):786-793.

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29. Laviolette M, Malmstrom K, Lu S, Chervinsky P, Puget JC, Peszek I, Zhang J, Reiss TF for the Montelukast/Beclomethasone Additivity Group. Montelukast added to inhaled beclomethasone in treatment of asthma. *Am J Respir Crit Care Med*. 160(6):1862-1868, 1999.
30. Lofdahl CG, Reiss TF, Leff JA, Israel E, Noonan MJ, Finn AF, Seidenberg BC, Capizzi T, Kundu S, Godard P: Randomized placebo controlled trial of effect of leukotriene receptor antagonist, montelukast, on tapering inhaled corticosteroids in asthmatic patients. *BMJ* 1999; 319(7202):87-90.
31. Malmstrom K, Rodriguez-Gomez G, Guerra J, Villaran C, Piñeiro A, Wei L, Seidenberg BC, Reiss TF for the Montelukast/Beclomethasone Study Group: Oral montelukast, inhaled beclomethasone, and placebo for chronic asthma: a randomized, controlled trial. *Ann Intern Med* 1999; 130(6):487-495.
32. Pizzichini E, Leff JA, Reiss TF, Hendeles L, Boulet LP, Wei LX, Efthimiadis A, Zhang J, Hargreave FE: Montelukast Reduced Airway Eosinophilic Inflammation in Asthma: A Randomized, Controlled Trial. *Eur Respir J* 1999; 14(1):12-18
33. Santanello NC, Zhang J, Seidenberg B, Reiss TF, Barber B: What Are Minimal Important Changes for Asthma Measures in a Clinical Trial? *Eur Respir J* 1999;14(1):23-27.
34. Dockhorn RJ, Baumgartner RA, Leff JA, Noonan M, Vandormael K, Stricker W, Weinland DE, Reiss TF: Comparison of the Effects of Intravenous and Oral Montelukast on Airway Function: A Double-Blind, Placebo-Controlled, 3-Period, Crossover Study in Asthmatic Patients. *Thorax* 2000; 55(4):260-265.
35. Knorr B, Holland S, Rogers D, Nguyen H, Reiss TF, Montelukast Adult (10 mg Film-Coated Tablet) and Pediatric (5 mg chewable tabs) Dose Selections. *J Allergy Clin Immunol* 2000; 106(3):S171-S178.
36. Meltzer EO, Malmstrom K, Lu S, Prenner BM, Wei LX, Weinstein SF, Wolfe JD, Reiss TF: Concomitant Montelukast and Loratadine as Treatment for Seasonal Allergic Rhinitis: A Randomized, Placebo-controlled Clinical Trial. *J Allergy Clin Immunol* 2000; 105(5):917-922
37. Barnes N, Wei LX, Reiss TF, Leff JA, Shingo S, Yu C, Edelman JM: Analysis of Montelukast in Mild Persistent Asthmatic Patients with Near-Normal Lung Function. *Resp Med* 2001; 95(5):379-386
38. Knorr B, Franchi LM, Bisgaard H, Vermeulen JH, LeSouef P, Santanello N, Michele TM, Reiss TF, Nguyen HH, Bratton D: Montelukast, A Leukotriene-Receptor Antagonist, for the Treatment of Persistent Asthma in Children Aged 2 to 5 Years *Pediatrics* 2001; 108(3):E48:754-755.

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Papers:

39. Knorr B, Nguyen HH, Kearns GL, Villaran C, Boza ML, Reiss TF, Rogers JD, Zhang J, Larson P, Spielberg S: Montelukast Dose Selection in Children Aged 2- to 5- Years: Comparison of Population Pharmacokinetics Between Children and Adults. *J Clin Pharmacol* 2001; 41(6):612-619.
40. Noonan GP, Newton-Williams B, Angner R, Lu S, Knorr B, Reiss TF: Use of Oral Montelukast in the Treatment of Asthma. *Compr Ther* 2001; 27(2):148-155.
41. Shingo S, Zhang J, Reiss TF: Correlation of Airway Obstruction (FEV1 and PEF) and Patient-Reported Endpoints in Clinical Studies. *Eur Resp J* 2001; 17:220-224.
42. Storms W, Michele TM, Knorr B, Noonan G, Shapiro G, Zhang J, Shingo S, Reiss TF: Clinical Safety and Tolerability of Montelukast; A Leukotriene Receptor Antagonist, in Controlled Clinical Trials in Patients Aged ≥ 6 Years. *Clin Exp Allergy* 2001; 31:77-87.
43. Williams B, Noonan G, Knorr B, Reiss TF, Guerra J, White R, and Matz J: Long-Term Asthma Control with Oral Montelukast and Inhaled Beclomethasone for Adults and Children 6 Years and Older. *Clin Exp Allergy* 2001; 31:845-854.
44. Dahlen SE, Malmstrom K, Nizankowska E, Dahlen B, Kuna P, Kowalski M, Lumry WR, Picado C, Stevenson DD, Bousquet J, Pauwels R, Holgate ST, Shahane A, Zhang J, Reiss TF, Szczeklik A: Improvement of Aspirin-Intolerant Asthma by Montelukast, a Leukotriene Antagonist. *Am J Respir Crit Care Med* 2002; 165(1):9-14.
45. Holgate ST, Bousquet J, Chung KF, Bisgaard H, Pauwels R, Fabbri L, Rabe K, Doherty M, Snell NJC, Cuss F, Amato MD, and Reginster JY, *Reiss TF (Contributor). Recommendations for the Design of Clinical Trials and the Registration of Drugs Used in the Treatment of Asthma. Group for the Respect of Ethics and Excellence in Science (GREES): Asthma section*, *Int J Pharmaceut Med* 2002; 16:115-127.
46. Malmstrom K, Peszek I, Botto A, Lu S, Enright PL, Reiss TF: Quality Assurance of Asthma Clinical Trials. *Control Clin Trials* 2002; 23:143-156.
47. Michele TM, Knorr B, Vadas EB, Reiss TF. Safety of Chewable Tablets in Children. *J Asthma* 2002; 39(5):391-403.

PUBLICATIONS (cont'd)

Papers:

48. Nayak AS, Philip G, Lu S, Malice M-P, Reiss TF and Montelukast Fall Rhinitis Investigator Group: Efficacy and tolerability of montelukast alone or in combination with loratadine in seasonal allergic rhinitis: A multicenter, randomized, double-blind, placebo-controlled trial performed in the fall. *Ann Allergy Asthma Immunol* 2002; 88(6):592-600.
49. Philip G, Malmstrom K, Hampel FC, Weinstein SF, LaForce CF, Ratner PH, Malice MP, Reiss TF for the Montelukast Spring Rhinitis Study Group: Montelukast for Treating Seasonal Allergic Rhinitis: A Randomized Double-Blind, Placebo-Controlled Trial Performed in the Spring. *Clin Exp Allergy* 2002; 32(7):1020-1028.
50. Shingo S, Zhang J, Noonan N, Reiss TF, Leff JA. A Standardized Composite Clinical Score Allows Safe Tapering of Inhaled Corticosteroids in Asthma Clinical Trials. *Drug Info J* 2002; 36:501-508.
51. Zhang J, Yu C, Holgate ST, and Reiss TF. Variability and Lack of Predictive Ability of Asthma End-Points in Clinical Trials. *Eur Resp J* 2002; 20(5):1102-1109
52. Zhang J, Yu C, Noonan G, Reiss TF: Effect of Montelukast, a Once-Daily Leukotriene Receptor Antagonist, on Peak Expiratory Flow Variability. *Clin Ther* 2002; 24:574-582.
53. Baumgartner RA, Martinez G, Edelman JM, Rodriguez Gomez GG, Bernstein M, Bird S, Angner R, Polis A, Dass B, Lu S, Reiss TF: Distribution of Response Between Oral Montelukast and Inhaled Beclomethasone. *Eur Resp J* 2003; 21(1):123-128.
54. Camargo CA, Smithline HA, Malice MP, Green SA, Reiss TF: A Randomized Controlled Trial of Intravenous Montelukast in Acute Asthma. *Am J Respir Crit Care Med* 2003; 167(4):528-533.
55. Endobronchial Biopsy in Clinical Research Task Force: Methods for the Assessment of Endobronchial Biopsies in Clinical Research: Application to Studies of Pathogenesis and the Effects of Treatment: A Consensus Statement. *Am J Respir Crit Care Med* 2003; 168(6part2):S1-S17.
56. van Adelsberg J, Philip G, Pedinoff AJ, Meltzer EO, Ratner PH, Menten J, Reiss TF for the Montelukast Fall Rhinitis Study Group: Montelukast Improves Symptoms of Seasonal Allergic Rhinitis Over a 4-Week Treatment Period. *Allergy* 2003; 58:1268-1276.
57. van Adelsberg J, LaForce CF, Weinstein SF, Menten J, Malice M-P, Philip G, Reiss TF: Randomized Controlled Trial Evaluating Clinical Benefit of Montelukast for Treating Spring Seasonal Allergic Rhinitis. *Ann Allergy Asthma Immunol.* 2003; 90:214-222.

PUBLICATIONS (cont'd)

Papers:

58. Becker A, Swern A, Tozzi C, Yu Q, Reiss T, Knorr B: Montelukast in asthmatic patients 6 years - 14 years old with an FEV1 >75%. *Curr Med Res Opin* 2004; 20:1651-1659.
59. Chervinsky P, Philip G, Malice M-P, Bardelas J, Nayak A, Marchal J-L, van Adelsberg J, Bousquet J, Tozzi C, Reiss TF: Montelukast for Treating Seasonal Allergic Rhinitis: The Effect of Pollen Exposure in a Combined Analysis of Three Fall Studies. *Ann Allergy Asthma Immunol* 2004; 92(3):367-373
60. Green SA, Malice M-P, Tanaka W, Reiss TF: Elevation of Urinary Leukotriene LTE₄ Levels in Acute Asthma: Correlation with Airflow Limitation. *Thorax* 2004; 59:100-104.
61. Holgate ST, Bousquet J, Chung KF, Bisgaard H, Pauwels R, Fabbri L, Rabe K, Doherty M, Snell NJC, Cuss F, Amato MD, and Reginster JY. *Reiss TF (Contributor): Summary of Recommendations for the Design of Clinical Trials and the Registration of Drugs Used in the Treatment of Asthma. Group for the Respect of Ethics and Excellence in Science (GREES): Asthma section*. *Resp Med* 2004; 98:479-487.
62. Perry T, Corren J, Philip G, Kim E, Conover-Walker MK, Malice MP, Massaad R, Daws, SB, Reiss TF, Wood RA: Protective Effect of Monteluast on Lower and Upper Respiratory Responses to Acute Cat Allergen Exposure. *Ann Allergy Asthma Immunol* 2004; 93:431-438.
63. Philip G, Nayak AS, Berger WE, Leynadier F, Vrigens F, Dass SB, Reiss, TF: The effect of montelukast on rhinitis symptoms in patients with asthma and seasonal allergic rhinitis. *Curr Med Res Opin* 2004; 20:1549-1558.
64. Zhang J, Song C, Reiss TF: An Endpoint for Worsening Asthma: Development of a Sensitive Measure and Its Properties. *Drug Info J* 2004; 38:5-13.
65. Patel P, Philip G, Yang W, Call R, Horak F, Laforce C, Gilles L, Garrett GC, Dass SB, Knorr BA, Reiss TF: Randomized, double-blind, placebo-controlled study of montelukast for treating perennial allergic rhinitis. *Ann Allergy Asthma Immunol* 2005; 95:551-557.
66. van Adelsberg J, Moy J, Wei LX, Tozzi CA, Knorr B, Reiss TF: Safety, tolerability, and exploratory efficacy of montelukast in 6- to 24-month-old patients with asthma. *Curr Med Res Opin* 2005; 21:971-979.

PUBLICATIONS (cont'd)

Papers:

67. Weinstein SF, Philip G, Hampel FC Jr, Malice MP, Swern AS, Dass SB, Reiss TF: Onset of efficacy of montelukast in seasonal allergic rhinitis. *Allergy Asthma Proc* 2005; 26:41-46
68. Meltzer EO, Philip G, Weinstein SF, LaForce CF, Malice MP, Dass SB, Santanello NC, Reiss TF. Montelukast effectively treats the nighttime impact of seasonal allergic rhinitis. *Am J Rhinol.* 2005;19:591-8.
69. Green S, Alon, A, Tozzi CA, Ianus J, TF Reiss: Efficacy and safety of an NK-1 receptor antagonist in postmenopausal women with urge urinary incontinence. *J Urol* 2006; 176:2535-2540.
70. Pedersen S, Agertoft L, Williams-Herman D, Kuznetsova O, Reiss TF, Knorr B, Dass SB, Wolthers OD. A randomized, double-blind, placebo-controlled study of montelukast and budesonide in short-term growth in prepubertal asthmatic children. *Pediatric Pulmonology*; 2007;42: 838-843.
71. Becker AB, Kuznetsova O, Vermeulen J, Soto-Quiros ME, Young B,. Reiss TF, Dass SB, Knorr BA for the Pediatric Montelukast Linear Growth Study Group. Linear growth in prepubertal asthmatic children treated with montelukast, beclomethasone or placebo: a 56-week, randomized, double-blind study. *Ann Allergy Asthma Immunol* 2006;96:800-807.
72. Pearlman DS, van Adelsberg J, Philip G, Tilles SA, Busse W, Hendeles L, Loeys T, Dass SB, Reiss TF. Onset and duration of protection against exercise-induced bronchoconstriction by a single oral dose of Montelukast. *Ann Allergy Asthma Immunol* 2006; 97: 98-104.
73. Diemunsch P, Gan TJ, Philip B, Girao M, Eberhart L, Irwin M, Pueyo J, Chelly J, Carides AD, Taylor A, Reiss TF, Hinz M, Evans JK, Lawson FC, and the Aprepitant-PONV International Study Group. Single-dose aprepitant versus ondansetron for the prevention of postoperative nausea and vomiting: a randomized, double-blind phase III trial in patients undergoing open abdominal surgery. *Br J Anaesthes, British Journal of Anasthesia* 2007; 99 (2): 202-11
74. S.Lu, D.D. Parekh, O.Kuznetsova, S.A. Green, C.A. Tozzi, T.F. Reiss. An oral selective M3 cholinergic receptor antagonist in COPD. *Eur Respir J* 2006; 28: 772-780.
75. Diemunsch P, Apfel C, Gan TJ, Candiotti K, Philip BK, Chelly J, Carides AD, Evans JK, Ho TW, T.F.Reiss: Preventing postoperative nausea and vomiting: 2 randomized active-controlled trials of aprepitant. *Current Medical Research and Opinion* 2007; 23 (10) 2559-2565

PUBLICATIONS (cont'd)

Papers

76. Philip G, Villaran C, Pearlman D.S., Loeys T, Balachandra D.S., T.F. Reiss: Protection against exercise-induced bronchoconstriction two hours after a single, oral dose of Montelukast. *Journal of Asthma*. 2007; 44 (3): 213 – 217
77. Philip G, Pearlman DS, Villarán C, Legrand D, Loeys T, Langdon RB, Reiss T.F. Single-dose montelukast or salmeterol as protection against exercise-induced bronchoconstriction. *Chest*. 2007 132(3):875-883.
78. Philip G, van Adelsberg J, Loeys T, Liu N, Wong P, Lai E, Dass SB, Reiss T.F. Clinical studies of the DPI receptor antagonism laropiprant in asthma and allergic rhinitis. . *Journal of Allergy Clin Immun* 2009;124:942-8
79. Pedersen S, Agertoft L, Williams-Herman D, Kuznetsova O, Reiss TF, Knorr B, Dass SB, Wolthers OD. Placebo-controlled study of montelukast and budesonide on short-term growth in prepubertal asthmatic children. *Pediatr Pulmonol*. 2007; 42:838-843.
80. Kearns GL, Lu S, Maganti L, Li X, Migoya E, Ahmed T, Knorr B, Reiss TF. Pharmacokinetics and Safety of Montelukast Oral Granules in Children 1 to 3 Months of Age with Bronchiolitis. *J Clin Pharmacol* 2008; 48: 502-511.
81. Bisgaard H, Flores-Nunez A, Goh A, Azimi P, Halkas A, Malice MP, Marchal JL, Dass SB, Reiss T.F., Knorr B. Study of montelukast for the treatment of respiratory symptoms of post-RSV-bronchiolitis in children. *Am J Resp Crit Care Med* 2008; 178: 854-860.
82. Ramsay C, Sullivan P, Gizycki M, Wang D, Swern AS, Barnes NC, Reiss TF, Jeffrey PK. Montelukast and bronchial inflammation in asthma: a randomised, double-blind place-controlled trial. *Respiratory Medicine* 2009; 103: 995-1003.
83. Lu S, Liu N, Dass SB, Reiss TF, Knorr B. Randomized, Placebo-Controlled Study Of A Selection PDE-4 Inhibitor In The Treatment Of Asthma. *Respiratory Medicine* 2009; 103:342-347.
84. Bisgaard H, Skoner D, Boza ML, Tozzi CA, Newcomb K, Reiss TF, Knorr B, Noonan G. Safety and tolerability of montelukast in placebo-controlled pediatric studies and their open-label extensions. *Pediatr Pulmonol* 2009; 44: 568-579.
85. Lu S, Liu N, Dass SB, Reiss TF. A Randomized Study comparing the Effect of Loratadine Added to Montelukast with Montelukast, Loratadine and Beclomethasone in Patients with Chronic Asthma. *Journal of Asthma* 2009; 46: 465-469.

PUBLICATIONS (cont'd)

Papers

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88. Philip G, Hustad C., Malice MP, Noonan G., Ezekowitz A, Reiss TF, Knorr B. Analysis of behavior related adverse experiences in clinical trials of montelukast. *Journal Allergy Clin Immunol.* 2009;124:699-706
89. Camargo CA, Guerner DM, Smithline HA, Chapell R, Fabbri LM, Green Sa, Malice MP, Legrand C, Dass SB, Knorr B, Reiss TF. A randomized placebo controlled study of intravenous montelukast for the treatment of acute asthma. *Journal of Allergy Clin Immunol* 2010;125:374-80
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94. Greenberg S, Liu N, Kaur A, Lakshminarayanan M, Zhou Y, Nelsen L, Noonan G, Reiss TF, Knorr B Airway obstruction lability helps distinguish levels of disease activity in asthma. *Respiratory Medicine* 2012; 106(4): 500-507.
95. Philip G, Pedinoff A, Vandormael K, Tymofyeyev Y, Smugar S, Reiss TF, Korenblat PE A phase –I randomized placebo controlled, dose adaptive study of inhaled montelukast in patients with chronic asthma *J Asthma* 2010;47;1078-84.

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97. Reiss TF, Moss J, Osborn M, Curtis JR, Hill, NS. Collaborative Science and the ATS: Cooperation in harmony with conflict of interest. *Am J Resp Crit Care Med* 2012; 185:347-349.
98. Greenberg S, Liu N, Kaur A, Lakshminarayanan M, Zhou Y, Nelsen L, Gates DF, Kuo LW, Smugar SS, Reiss TF, Barnes N, Fuhlbrigge A, Milgrom H, Schatz M, Knorr B. The Asthma Disease Activity Score: A Discriminating, Responsive Measure Predicts Future Asthma Attacks. *J Allergy Clin Immunol.* 2012;130:1071-1077.
99. Reiss TF, Taylor KA, Connor EM. Public-Private Collaboration in Biomedical Research and Development: Can We Achieve a Balanced Approach that Serves the Public Interest? (submitted)
100. Holgate S, Agusti A, Strieter R, Anderson G, Fogel R, Bel E, Martin T, Reiss TF. Drug Development in Airway Disease: Looking Forward. *Nature Reviews: Drug Discovery* 2015;14: 367-368
101. Reiss TF, Moss J, Watkins, T, Malhora A. The Bear Cage: Mentorship by Engagement (editorial) *American Journal of Respiratory and Critical Care Medicine* 2016;193(7):714-6.
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104. Lu S, Hartert TV, Everard ML, Giezek H, Nelsen L, Mehta A, Patel H, Knorr B, Reiss TF. Predictors of asthma following severe respiratory syncytial virus (RSV) bronchiolitis in early childhood. *Pediatr Pulmonol.* 2016;51(12):1382-1392.

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Reiss T, Katzung B, Boushey H: Drugs in Respiratory System Disease., In: *A Manual of Clinical Pharmacology*, Katzung, BG, editor. Appleton and Lange, Chapter 9, pp 87-104, 1988.

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Seidenberg B, Reiss TF: Montelukast: An Anti-Leukotriene Treatment for Asthma. In: *Five-Lipoxygenase Products in Asthma*, Drazen/Dahlen/Lee, editors. Marcel Dekker, pp 327-346, 1998.

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Letters to the Editor:

Reiss TF: Exercise-Induced Asthma. [Response to Letter] *N Engl J Med* 1998; 339(24):1785.

Knorr B, Reiss TF: Montelukast for children with asthma [Response to Letter]. *JAMA* 1998;280(11):967.

Reiss TF: Inhaled Corticosteroids or Antileukotrienes for Asthma? [Response to Letter] *Ann Intern Med* 1999; 131(11):865.

Malmstrom K, Laviolette M, Reiss TF: Montelukast Added to Inhaled Beclomethasone in Treatment of Asthma. *Am J Respir Crit Care Med* 2000; 162(1):331-332

Reiss TF. Flawed Report. Drug Combination for Asthma Treatment: [Response to Letter] *Arch Intern Med* 2001; 161(15):1920-1920

Zhang J, Yu C, Holgate ST, Reiss TF: Asthma Variability. [Response to Stempel Letter] *Eur Resp J* 2003;21:909-910.

Camargo CA, Green SA, Reiss TF: Intravenous Montelukast in Acute Asthma (letter). [Response to Drs. Rodrigo and Rodrigo] *Am J Respir Crit Care Med* 2004;169:131.

Reiss TF, Edelman JM, Heyse JF: Distribution of Therapeutic Response in Asthma Control (Letter). *Eur Respir J* 2003; 22:568-569.

Green S, Malice M-P, Reiss TF: Urinary Leukotriene LTE4 Levels in Non-responders to Antileukotriene Therapy. In reply: *Thorax* 2004; 59:727.

VIII. INVITED PRESENTATIONS

1988 - 1989	Winter	Isolated Airway Challenge, Northwestern University
1990	Spring	Asthma: Diagnosis and Treatment, Medical College of Ohio
1992	Summer	Asthma: Current Concepts in Pathogenesis and Treatment, University of Medicine and Dentistry of New Jersey, Pulmonary Grand Rounds
1995	Autumn	Leukotrienes in Asthma: Department of Physiology, University of Medicine and Dentistry of New Jersey
1996	Winter	Asthma: What's New: New Jersey Thoracic Society
1997	Spring	5-Lipoxygenase Products in Asthma, Cerromar Beach, Puerto Rico
1997	Summer	Assessing the Health-Related Quality of Life Impact of Asthma. Pharmaceutical Education & Research Institute, Inc., (PERI), Annapolis, MD
1998	Winter	Asthma: Current Concepts in Pathogenesis and Treatment, University of Medicine and Dentistry of New Jersey, Pulmonary Grand Rounds
1998	Spring	Columbia, Department of Pulmonary Medicine
1998	Summer	Assessing the Health-Related Quality of Life Impact of Asthma. PERI Respiratory Clinical Care Training Course
1999	Spring	NIH/FDA Conference on Surrogate Markers
2000	Winter	Airway Clinical Trial Methodology London, UK
2001	Winter	Clinical Development of New Chemical Entities. Vanderbilt University, TN
2001	Spring	American Thoracic Society: Poster Session Facilitator

INVITED PRESENTATIONS (cont'd)

2002	Spring	Focusing Resources on Relevant Therapeutic Areas Smi – Asthma Therapeutics Third Annual Event London, UK
2002	Spring	PG2-Bronchial Biopsies in Clinical Research: Application to Studies of Pathogenesis and the Effects on Treatment – Hypothesis Generation vs. Hypothesis Testing American Thoracic Society Atlanta, GA
2002	Autumn	“Montelukast: from Bench to Bedside” 30 th Drug Activity Symposium Seminar Fukuoka, Japan
2005	Spring	“Bench to Bedside” The Debate Over The Evolution of Translational Science: Who Will Contribute? American Thoracic Society 2005 International Conference San Diego, CA
2007	Spring	Inflammatory Biomarkers In Asthma & COPD SMi's Asthma & COPD Conference London, UK
2007	Spring	Translational Science: The Need For Collaboration American Thoracic Society 2007 International Conference San Francisco, CA
2008	Winter	COPD and Asthma Summit Drug Discovery & Development, A Complex Process Leuven, Brussels
2008	Spring	The Focus of the Drug Device Discovery and Development Committee of the ATS The Art and Science of "Bench to Bedside" American Thoracic Society 2008 International Conference Toronto, Canada

INVITED PRESENTATIONS (cont'd)

2009	Spring	Heterogeneity And Discovery & Development: Can A Complex Process Get Any More Complex? American Academy of Allergy, Asthma and Immunology Washington, DC
2009	Spring	Conflict of Interest (COI) Achieving the Broad, Balanced View American Thoracic Society 2009 International Conference, San Diego, California
2010	Spring	Overview of the Art and Science of the Integrated Drug Discovery and Development Process Development Program Strategy and Design from First Administration to a Human Through Regulatory and Pricing and Reimbursement Agencies Approval Post Graduate Course: The Art and Science of Translational Research (Co-chairing) American Thoracic Society 2010 International Conference, New Orleans, Louisiana
2011	Winter	Discovery and Development: What is Everyones Roll? Vanderbilt University Pulmonary Grand Rounds Nashville, Tennessee
2011	Fall	Models and Funding for Regulatory Science Institute of Medicine Workshop on Regulatory Science Washington, DC (20-21 Sept)
2012	Winter	Drug Discovery and Development: From a Productive Past Towards an Uncertain Future University of Pennsylvania, Vagelos Scholars Program Philadelphia, Pennsylvania
2012	Spring	Therapeutic Discovery and Development: From a Productive Past to an Uncertain Future American Thoracic Society 2012 International Conference, San Francisco, California
2012	Summer	4 th Summer School on Medicines Art and Science of Development –The Continuum Between Early and Late Development

		Case Study of Montelukast Montreal (Quebec) Canada
2014	Spring	University, Pharma, Government – Motives, Perspectives and Goals: Different or Similar? American Thoracic Society 2014 International Conference, San Diego, California
2016	Spring	Medical College of Georgia – How Do Pharma Scientists Think? And Seminar to Medical/ Graduate Students – The art and Science of Drug Development
2018	Spring	American Throacic Society 2018 International Conference Wednesday Key Note Address – On Pharma: the Increasing Complexity of Innovation San Diego, California