

CURRICULUM VITAE

Dean Allan Handley

SUMMARY:

Over 20 years experience as an ad hoc editor for many journals in science and medical areas
Published over 80 first author papers in extensive and diverse subject matters: medicine, science, business
Published numerous monographs, book chapters, abstracts, clinical articles, FDA submissions: INDs, NDAs
Extensive format experience according to diverse academic conventions and requirements
Formal understanding of APA, CMS, AMA, CSE and IEEE conventions as required by diverse journals
Excellent skills as editing, increasing authoritative delivery, removing superfluous language
Can determine and augment author's intended meaning and conclusions
Well versed on selective word choice, grammar and sentence structure

EDUCATION

1997-98	MBA	Finance & Marketing; Boston Univ. Graduate School of Business, Boston, MA
1976-78	PhD	Molecular Genetics, College Medicine & Dentistry, Brunswick, NJ
1973-76	MSc	Biochemistry, Waksman Institute, Rutgers University, NJ
1967-71	BSc	Lycoming College, Williamsport, PA

POSTGRADUATE TRAINING

MBA Education- Marketing and Finance

Dept. Physiology, College of Physicians & Surgeons, Columbia University, NY

1978-81 *NHLBI Postdoctoral Fellow/Research Associate*

- Evaluated anti-hypertensive drugs to establish MOA and pathology
- Evaluated anti-coagulants on vascular performance and integrity
- Ad hoc editor, published over 25 peer reviewed first author papers
- Handled writing, formatting, editing, style and content, reference formatting and graphics

Dept. Physiology, College of Physicians & Surgeons, Columbia University, NY

1981-88 *Adjunct Teaching Assistant Professor*

- Teaching courses of pathology, hematology, physiology
- Individual student evaluations, coaching, tutoring, and mentoring

PROFESSIONAL EXPERIENCE

Veridicus Consulting LLC, Shrewsbury, MA 01545

2007- Principal and Founder

- Commercial, licensing, marketing, development
- Intellectual property reviews and patentability status
- Writing of product monographs, publications, review summaries, technical summaries and clinical research findings

Sepracor Inc., Marlborough, MA 01752

2002-2008 Executive Director Medical Communications and Scientific Affairs, Medical Affairs

- Trained physicians for speaker bureau lectures (5000/yr) and Key Opinion Leaders
- Head of Publications Committee and Scientific Review Board for external compound research requests
- Co-chair Strategic Out Licensing Global Task Force (US, Europe and Japan)
- Writing and publishing: product IND, NDA, monograph, medical abstracts and full length publications

1994-2002: Senior Director, Scientific Affairs

- Medical presentations on preclinical and clinical candidates, physician message surveys
- Responsible for company-wide publications, product materials and sales force training

Sandoz Research Institute, Sandoz Inc., East Hanover, NJ 07936 (Novartis Inc.)

1993-94 Senior Fellow & Group Leader, Cardiovascular Dept.

- Developed Established new group to target fibrinogen modulation as a cerebral and CV risk factor
- Extensive exploratory pharmacology with steroids and B blockers as therapeutic targets
- Member, Medical Licensing & Acquisition of candidates aligned with commercial directives
- Published over 30 peer reviewed papers in medical and scientific journals
- Responsible for content fluency and style, journal conventions and all instructions to authors

1990-92 Fellow, Platelet Dept.

1981-89 Associate Fellow, Platelet Dept.

- Developed a new class of anti-neoplastic agents based on cyclic ether analogues of ET-18-OCH₃
- Six direct reports, nine development drugs, two INDs (SRI 64-007 inh. restenosis; SRI-058 asthma)

Book: Platelet-Activating Factor in Endotoxin and Immune diseases. Dean A. Handley, Robert N. Saunders, William J. Houlihan and John C. Tomesch, Marcel Dekker, 1990.

ONCOLOGY - HEMATOLOGY PUBLICATIONS:

1. Stern DM, Nawroth P, Kisiel W, Handley DA, Drillings M, Bartos J (1984). A coagulation pathway on bovine aortic segments leading to generation of factor Xa and thrombin. *J. Clin. Invest.* 74:1910-1921.
2. Stern DM, Nawroth P, Marcum J, Handley DA, Kisiel W, Rosenberg R, Stern K (1985). Interaction of antithrombin III bovine aortic segments. Role of heparin in binding and enhanced anticoagulant activity. *J. Clin. Invest.* 75:272-279.
3. Stern DM, Nawroth P, Handley DA, Kisiel W (1985). A new endothelial cell-dependent pathway of coagulation. *Proc. Natl. Acad. Sci. USA* 82:2523-2527.
4. Nawroth PP, McCarthy D, Kisiel W, Handley DA, Stern DM (1985). Cellular processing of bovine factors X and Xa by cultured bovine aortic endothelial cells. *J. Exp. Med.* 162:559-572.
5. Nemecek GM, Coughlin SR, Handley DA, Moskowitz MA (1986). Stimulation of aortic smooth muscle cell mitogenesis by serotonin. *Proc. Natl. Acad. Sci. USA* 83:674-678.
6. Nawroth P, Handley DA, Esmon CT, Stern DM (1986). Interleukin-1 induces endothelial cell procoagulant while suppressing cell surface anticoagulant activity. *Proc. Natl. Acad. Sci. USA* 83:3460-3464.
7. Nawroth P, Bank I, Handley DA, Cassimeris J, Chess L, Stern D (1986). Endothelium is a target tissue for tumor necrosis factor/cachectin. *J. Exp. Med.* 163:1363-1375.
8. Houlihan WJ, Lee ML, Nemecek GM, Handley DA, Winslow CM, Jaeggi C (1987). Antitumor activity of SRI 62-834, a cyclic ether analogue of ET-18-OCH₃. *Lipids* 22:884-890.

9. Stern DM, Handley DA, Nawroth PP (1988). Endothelium and the regulation of coagulation. In: Endothelial Cell Biology in Health and Disease (N. Simionescu, M. Simionescu, eds.), Plenum Publishing Corporation, New York. pp. 275-306.
 10. Nawroth P, Handley DA, Matsueda G, De Wall R, Gerlach H, Blohm D, Stern DM (1988). Tumor necrosis factor/cachectin-induced intravascular fibrin formation in meth A fibrosarcomas. *J. Exp. Med.* 168:637-647.
 11. Nemecek GM, St. Denny IH, Van Valen RG, Glinka KG, McCarthy LA, Handley DA, Stutz A (1989). Terbinafine inhibits the mitogenic response to platelet-derived growth factor in vitro and neointimal proliferation in vivo. *J. Pharmacol. Exp. Ther.* 248:1167-1174.
 12. Houlihan WJ, Cheon SH, Handley DA, Larson DA (1991). Synthesis and pharmacology of a novel class of long-lasting PAF receptor antagonists. *J. Lipid Mediators* 3:91-99.
 13. Stern DM, Esposito C, Gerlach H, Ryan J, Handley DA, Nawroth P (1991). Endothelium and regulation of coagulation. *Diabetes Care* 14:160-166.
 14. Tijburg PNM, Ryan J, Stern DM, Wollitzky B, Rimon S, Handley DA, Nawroth P, Sixma JJ, de Groot PG (1991). Activation of the coagulation mechanism on tumor necrosis factor stimulated cultured endothelial cells and their extracellular matrix. *J. Biol. Chem.* 266:12067-12074.
 15. Houlihan W, Cheon S, Handley DA, Larson D (1993). Structural modification of 5-aryl-2, 3 dihydroimidazo [2,1-a] isoquinoline platelet activating factor receptor antagonists. *J. Med. Chem.* 36: 3098-3102.
 16. Houlihan WJ, Lee ML, Munder P, Handley DA, Jaeggi SC, Winslow C (1994). Antitumor activity of a piperidine phospholipid. *Drug Research* 44:1348-1388.
 17. Houlihan WJ, Munder P, Handley DA, Cheon SH, Parillo VA (1995). Antitumor activity of 5-aryl-2, 3 dihydroimidazo [2,1-a] isoquinolines. *J. Med. Chem.* 38:234-240.
 18. Houlihan WJ, Munder P, Handley DA, Nemecek GA (1995). Preclinical pharmacology and possible mechanism of action of the novel antitumor agent 5-(4'-piperidinomethyl phenyl) 2,3-dihydroimidazo [2,1-a] isoquinoline. *Drug Research* 45:1133-1137.
 19. Leff AR, Herrnreiter A, Naclerio R, Baroody FM, Handley DA, Munoz NM. (1997). Effect of enantiomeric forms of albuterol on stimulated secretion of granular protein from human eosinophils. *Pul Pharmacol Ther* 10:97-104.
 20. Lake P, DeLeo J, Cerasoli F, Logdberg L, Weetall M, Handley D. Pharmacodynamic evaluation of the neutralization of endotoxin by PMX622 in mice. *Antimicrob Agent Chemother* 48:2987-92, 2004.
- ## CARDIOVASCULAR PUBLICATIONS
21. Handley DA, Arbeeny CM, Witte LD, Chien S (1981). Colloidal gold-low density lipoprotein conjugates as membrane receptor probes. *Proc. Natl. Acad. Sci.* 78:368-371.
 22. Handley DA, Arbeeny CM, Eder HA, Chien S (1981). Hepatic binding and internalization of low density lipoprotein-gold conjugates in rats treated with 17 α -ethinyl estradiol. *J. Cell Biol.* 90:778-787.
 23. Chien S, Lee ML, Laufer L, Handley DA, Weinbaum S, Colin CG, Usami S (1981). Effects of oscillatory mechanical disturbance on macromolecular uptake by the arterial wall. *Arteriosclerosis* 1:326-336.
 24. Chien S, Laufer L, Handley DA (1982). Vesicle distribution in arterial endothelium determined with ruthenium red as extracellular marker. *J. Ultrastruct. Res.* 79:198-206.
 25. Handley DA, Arbeeny CM, Chien S (1983). Sinusoidal endothelial uptake of low-density lipoprotein-gold conjugates in perfused livers of 17 α -ethinyl estradiol treated rats. *Eur. J. Cell Biol.* 30:266-271.
 26. Handley DA, Chien S, Arbeeny CM (1983). Ultrastructure of hepatic cholesterol crystals in the hyper-cholesterolemic-diabetic rat. *Pathol. Res. Pract.* 177:13-21.
 27. Handley DA, Witte L, Arbeeny CM, Goodman DS, Chien S. (1983). Ultrastructural visualization of low-density lipoproteins during receptor binding and cellular endocytosis. *J. Ultrastruct. Res.* 83:43-47.
 28. Handley DA, Witte LD (1984). Platelet-derived growth factor labeled to colloidal gold for use as a mitogenic receptor probe. *Eur. J. Cell Biol.* 34:281-286.

29. Chien S, Fan FC, Lee ML, Handley DA (1984). Effects of arterial pressure on endothelial transport of macromolecules. *Biorheology* 21:631-641.
30. Stern DM, Nawroth P, Kisiel W, Handley DA, Drillings M, Bartos J (1984). A coagulation pathway on bovine aortic segments leading to generation of factor Xa and thrombin. *J. Clin. Invest.* 74:1910-1921.
31. Stern DM, Nawroth P, Marcum J, Handley DA, Kisiel W, Rosenberg R, Stern K (1985). Interaction of antithrombin III bovine aortic segments. Role of heparin in binding and enhanced anticoagulant activity. *J. Clin. Invest.* 75:272-279.
32. Stern DM, Nawroth P, Handley DA, Kisiel W (1985). A new endothelial cell-dependent pathway of coagulation. *Proc. Natl. Acad. Sci. USA* 82:2523-2527.
33. Liu CY, Handley DA, Chien S (1985). Biochemical characterization of thrombin-gold conjugates and ultrastructural studies of conjugate binding by fibrin. *Analyt. Biochem.* 147: 49-56.
34. Nawroth PP, McCarthy D, Kisiel W, Handley DA, Stern DM (1985). Cellular processing of bovine factors X and Xa by cultured bovine aortic endothelial cells. *J. Exp. Med.* 162:559-572.
35. Handley DA (1985). Current approaches towards inhibition of proliferation in atherosclerosis. *Drug Develop. Res.* 6:167-176.
36. Handley DA, Chien S (1986). Ultrastructural studies of endothelial and platelet receptor binding of thrombin-colloidal gold probes. *Eur. J. Cell Biol.* 39:391-398.
37. Kaperonis AA, Handley DA, Chien S (1986). Fiber, crystals and other forms of HbS polymers in deoxygenated sickle erythrocytes. *Am. J. Hematol.* 21:269-275.
38. Handley DA, Van Valen RG, Melden MK, Saunders RN (1986). Suppression of rat carotid lesion development by the calcium channel blocker, PN 200-110. *Am. J. Pathol.* 124:88-93.
39. Nemecek GM, Coughlin SR, Handley DA, Moskowitz MA (1986). Stimulation of aortic smooth muscle cell mitogenesis by serotonin. *Proc. Natl. Acad. Sci. USA* 83:674-678
40. Nawroth P, Handley DA, Esmon CT, Stern DM (1986). Interleukin-1 induces endothelial cell procoagulant while suppressing cell surface anticoagulant activity. *Proc. Natl. Acad. Sci. USA* 83:3460-3464.
41. Nawroth P, Bank I, Handley DA, Cassimeris J, Chess L, Stern D (1986). Endothelium is a target tissue for tumor necrosis factor/cachectin. *J. Exp. Med.* 163:1363-1375.
42. Arbeeny CM, Rifci VA, Handley DA, Eder HA (1987). Binding and internalization of very low density lipoprotein remnants the perfused liver. *Metabolism* 36:1106-1113.
43. Goldberg IJ, Handley DA, Vanni T, Paterniti JR and Cornicelli J. A (1988). Membrane bound lipoprotein lipase on human monocyte-derived macro-phages: Localization by immuno-colloidal gold technique. *Biochim. Biophys. Acta* 959:220-228.
44. Nawroth P, Handley DA, Matsueda G, De Wall R, Gerlach H, Blohm D, Stern DM (1988). Tumor necrosis factor/cachectin-induced intravascular fibrin formation in meth A fibrosarcomas. *J. Exp. Med.* 168:637-647.
45. Handley DA, Chien S. (1987). Applications of colloidal gold labeling related to vascular and endothelial function, hemostasis and receptor-mediated expression of plasma macromolecules. *Eur. J. Cell Biol.* 43:163-174.
46. Stern DM, Handley DA, Nawroth PP (1988). Endothelium and the regulation of coagulation. In: Endothelial Cell Biology in Health and Disease (N. Simionescu, M. Simionescu, eds.), Plenum Publishing Corporation, New York. pp. 275-306.
47. Stern DM, Esposito C, Gerlach H, Ryan J, Handley DA, Nawroth P (1991). Endothelium and regulation of coagulation. *Diabetes Care* 14:160-166.
48. Tijburg PNM, Ryan J, Stern DM, Wollitzky B, Rimon S, Handley DA, Nawroth P, Sixma JJ, de Groot PG (1991). Activation of the coagulation mechanism on tumor necrosis factor stimulated cultured endothelial cells and their extracellular matrix. *J. Biol. Chem.* 266:12067-12074.
49. Nemecek GM, St. Denny IH, Van Valen RG, Glinka KG, McCarthy LA, Handley DA, Stutz A (1989). Terbinafine inhibits the mitogenic response to platelet-

derived growth factor in vitro and neointimal proliferation in vivo. *J. Pharmacol. Exp. Ther.* 248:1167-1174.

50. Handley DA (1995). Developmental preclinical therapies and clinical strategies in the treatment of vascular restenosis. *Drugs Future* 20:265-290.
51. Handley DA (1995). Experimental therapeutics and clinical studies in (re) stenosis. *Micron* 26:51-68.
52. Handley DA (1995). Developmental preclinical therapies and clinical strategies in the treatment of vascular restenosis. *Drugs Future* 20:265-290.
53. Handley DA, Hughes TE (1997). Pharmacological approaches and strategies for therapeutic modulation of fibrinogen. *Thromb Res* 87:1-36.

INFLAMMATION - PULMONARY - ALLERGY PUBLICATIONS

54. Handley DA, Van Valen R, Melden M, Saunders RN (1984). Evaluation of dose and route effects of platelet activating factor-induced extravasation in the guinea pig. *Thromb. Haemost.* 52:34-36.
55. Handley DA, Arbeeney C, Lee M, Van Valen RG, Saunders RN (1984). Effect of platelet-activating factor on endothelial permeability of plasma albumin and lipoproteins. *Immunopharmacology* 8:137-142.
56. Handley DA, Lee ML, Saunders RN (1985). Evidence for a direct effect on vascular permeability of platelet-activating factor-induced hemo-concentration in the guinea pig. *Thromb. Haemost.* 54:756-759.
57. Handley DA, Van Valen RG, Melden MK, Flury S, Saunders RN (1986). Inhibition and reversal of endotoxin- aggregated IgG- and PAF-induced hypotension in the rat by SRI 63-072, a PAF receptor antagonist. *Immuno-pharmacology* 12:11-17.
58. Handley DA, Farley C, Saunders RN (1986). Evidence for distinct systemic extravasation effects of platelet activating factor, leukotrienes B₄, C₄, D₄ and histamine in guinea pigs. *Prostaglandins, Leukotrienes Med.* 21:269-277.
59. Handley DA, Van Valen RG, Saunders RN (1986). Vascular responses of platelet-activating factor in the *Cebus apella* primate and inhibitory profiles of PAF antagonists SRI 63-072 and SRI 63-119. *Immunopharmacology* 11:175-182.
60. Handley DA, Tomesch J, Saunders R (1986). Inhibition of PAF-induced systemic responses in the rat, guinea pig, dog and primate by the receptor antagonist SRI 63-441. *Thromb. Haemost.* 56:40-45.
61. Handley DA, Van Valen RG, Tomesch JC, Melden MK, Jaffe JA, Ballard F, Saunders RN (1987). Biological properties of the receptor antagonist SRI 63-441 in the PAF and endotoxin models of hypotension in the rat and dog. *Immunopharmacology* 13:125-132.
62. Handley DA, Van Valen R, Tomesch JC, Saunders RN (1987). Pharmacological profiles of the PAF antagonist, SRI 63-675. *Thromb. Haemost.* 57:187-190.
63. Patterson R, Harris KE, Handley DA, Saunders RN (1987). Evaluation of the effect of a platelet activating factor (PAF) receptor antagonist on platelet activating factor and ascaris antigen-induced airway responses in rhesus monkeys. *J. Lab. Clin. Med.* 110:606-611.
64. Handley DA, Anderson R, Saunders R (1987). Inhibition by SRI 63-072 and SRI 63-119 of PAF-acether and immune complexes in the guinea pig. *Eur. J. Pharmacol.* 141:409-416.
65. Handley DA (1987). New developments for clinical applications for PAF antagonists. *J. Clin. Exp. Med.* 143:415-417.
66. Handley DA, Van Valen R, Melden M, Houlihan W, Saunders RN (1988). Biological effects of the orally-active PAF receptor antagonist SDZ 64-412. *J. Pharmacol. Exp. Ther.* 247:617-623.
67. Patterson R, Smith LJ, Harris KE, Handley DA (1988). Studies of platelet activating factor in rhesus monkeys and man. *J. Clin. Exp. Med.* 148:44-49.
68. Patterson R, Harris KE, Bernstein PR, Krell RD, Handley DA, Saunders RN (1989). Effects of combined receptor antagonists of leukotriene D₄ (LTD₄) and platelet activating factor (PAF) on rhesus airway responses to LTD₄, PAF and antigen. *Int. Arch. Allergy Appl. Immunol.* 88:462-470.
69. Handley DA (1990). Preclinical and clinical pharmacology of platelet activating factor receptor antagonists. *Med. Res. Rev.* 10:351-370.

70. Havill AM, Van Valen RG, Handley DA (1990). Prevention of non-specific airway hyperreactivity after allergen challenge in guinea pigs by the PAF antagonist SDZ 64-412. *Br. J. Pharmacol.* 99:396-400.
71. Handley DA (1995). Experimental therapeutics and clinical studies in (re) stenosis. *Micron* 26:51-68.
72. Jafarian A, Handley DA, Biggs DF (1996). Effects of RS-albuterol on the development of antigen-mediated airway hyperreactivity in guinea pigs. *Clin Rev Allergy Immunol* 14: 91-100.
73. Handley DA (1996). R-albuterol. Preclinical and clinical pharmacology. *Clin Rev Allergy Immun* 14: 1-2.
74. Handley DA, Rubin PD (1996). Beta agonists: one product, two drug. *J Respir Care Pract.* Oct 101-108.
75. Leff AR, Herrnreiter A, Naclerio R, Baroody FM, Handley DA, Munoz NM. (1997). Effect of enantiomeric forms of albuterol on stimulated secretion of granular protein from human eosinophils. *Pul Pharmacol Ther* 10:97-104.
76. Jerussi TP, Caubet JF, McCray JE, Handley DA. (1998). Clinical endo-scopic evaluation of the gastroduodenal tolerance to (R)- ketoprofen, (R)-flurbiprofen, racemic ketoprofen and paracetamol: A randomized, single-blind, placebo-controlled trial. *J Clin Pharmacol*, 38:S19-S24.
77. Handley DA, Cervoni PS, McCray JE, McCullough J. (1998). Preclinical enantioselective pharmacology of R- and S- Ketorolac. *J Clin Pharmacol*, 38:S25-25.
78. Templeton AGB, Chapman ID, Morley J, Handley DA. (1998). Effects of S-salbutamol on isolated human bronchus. *Pulmon Pharmacol*, 108:111-117.
79. Handley DA, Graff F. (1998). Allergy drug research: Third generation antihistamines. *Adv. Managers Respir. Ther.* 7:33-36.
80. Handley, DA, Cervoni, P, McCray, JE, McCullough, JR. (1998). Preclinical enantioselective pharmacology of (R)- and (S) ketorolac. *J Clin Pharmacol* 38:25S-35S.
81. Handley, DA, Morley, J, Vaickus, L. (1998). Levalbuterol. *Exp. Opin. Invest. Drugs* 7(12):2027-2041.
82. Handley, DA. (1999). The asthma-like pharmacology and toxicology of (S)-isomers of β agonists. *J Allergy Clin Immunol* 104: S69-S76.
83. Handley, DA. (1999). Advancement of the third generation of antihistamines. *Ped Asthma, Allergy Immunol* 13: 163-168.
84. Handley, DA, Tinkelman, D, Noonan, M, Rollins, TE, Snider, ME, Caron, J. (2000). Dose-response evaluation of levalbuterol versus racemic albuterol in patients with asthma. *J Asthma* 37L 319-328.
85. Handley, DA, Senanayake, CH, Dutczak, W, Benovic, JL, Walle, T, Penn, RB, Wilkinson, HS, Tanoury, GJ, Andersson, RGG, Johansson, F, Morley, J. (2002). Biological actions of formoterol isomers. *Pul Pharmacol Ther* 15:135-145.
86. Lake P, DeLeo J, Cerasoli F, Logdberg L, Weetall M, Handley D. Pharmacodynamic evaluation of the neutralization of endotoxin by PMX622 in mice. *Antimicrob Agent Chemother* 48:2987-92, 2004.