SCOTT D. BERKOWITZ, MD, FAHA, FACC

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Current Position

Clinician/Scientist, CPC Clinical Research

Research Professor of Medicine, Department of Medicine, Divisions of Cardiology &
 Hematology, University of Colorado School of Medicine

Personal Information

Place of Birth: Wilmington, DE, USA

 Citizenship: United States of America

 Primary language: English

Education

 **Place Date Degree**

 **Professional School** Jefferson Medical College of 1975-1979 Doctor of Medicine (MD)

 Thomas Jefferson University Top 1/3 of class

Philadelphia, Pennsylvania

 **Undergraduate** University of Delaware 1971-1975Bachelor of Arts in Arts

Newark, Delaware With Highest Honors and Science

 Phi Beta Kappa, 1975

**Postgraduate Training and Fellowships**

 **Fellowships**:

 **Postdoctoral Research Fellowship in Experimental Hemostasis**

 1985-1988 Research Institute of Scripps Clinic, Department of

 Molecular and Experimental Medicine, La Jolla, California

(under the late Theodore S. Zimmerman, MD and the late Ernest Beutler, MD)

 **Clinical Hematology/Oncology Fellowship**

 1983-1985 Ohio State University Hospitals, College of Medicine

 Columbus, Ohio

 **Chief Medical Residency** 1982-1983 University of Pittsburgh Medical Center/Mercy

 **Residency (Internal Medicine)** 1980-1982 University of Pittsburgh Medical Center/Mercy

 **Internship (Internal Medicine)** 1979-1980 University of Pittsburgh Medical Center/Mercy

**Professional Qualifications**

**Medical licensure**:

 **1980 Pennsylvania MD-024416-E retired status (Oct 2019)**

**1983 Ohio 35-049086 relinquished**

 **1985 California G54502 retired status (Feb 2011)**

 **1988 New York 174263 relinquished (May 1994)**

 **1993 North Carolina 93-00653 continuous since November 20, 1993**

**DEA Certificate 1982 relinquished July 2019**

**Specialty certification**

 **Diplomate, National Board of Medical Examiners July 1980 (Part III)**

 **American Board of Internal Medicine 09/12/84**

**Professional recognition/honorific titles**

Fellow, American College of Physicians—F.A.C.P. January 1992

Fellow, and founding member, Council on Atherosclerosis, Thrombosis, and November 1998 Vascular Biology, American Heart Association—F.A.H.A.

Fellow, American College of Cardiology—F.A.C.C. February 2008

**Memberships in Professional and Scientific Societies, and select activities**

Member, American Society of Hematology (1984)

Satellite Symposium Speaker 1997, 1999

40th Annual Meeting, Invited Speaker, Educational Session 12/5-6/98

41st Annual Meeting, December 1999 ASH Abstract Reviewer & Session Chair/Moderator

Member, American College of Physicians (1985)

Member, International Society on Thrombosis and Haemostasis (1987)

XVIIth Congress, Washington DC, August 14-21, 1999

-International Advisory Committee member:

-Development of Scientific Program

-Reviewer of abstracts

-Invited Speaker: Meet-the-Expert Session

 -Session Chair/Moderator

Member, American Heart Association, (1991)

72nd Scientific Sessions, Atlanta GA, November 7-10, 1999

-Invited Speaker, Sunday Morning Program

 -Session Chair/Moderator

 Member, American Association of Pharmaceutical Physicians (2002)

 Member, American College of Cardiology (2008)

 Member, Society for Vascular Medicine (2022)

Pharmaceutical Career (March 1, 2000 to April 30, 2021)

 **Bayer U.S. LLC (Whippany, NJ)**

**April 2006 – April 2021**

**Titles: Chief Scientist & Distinguished Bayer Science Fellow,** Thrombosis and Vascular Diseases Therapeutic Area**, and Vice President Clinical Development** at Bayer U.S. LLC (Development, Pharmaceuticals) [April 2020 to April 2021]

**Vice President and Head, Thrombosis Group**, Thrombosis & Hematology Therapeutic Area, Clinical Development [July 2007 – March 2020)

**Global Clinical Leader**, Hematology/Cardiovascular Therapeutic Area, Global Clinical

Development [Apr 2006 - June 2007]

**Roles:** Clinical lead physician for and oversight of the clinical development research activities of all medical indications for Xarelto® (rivaroxaban, an oral direct Factor Xa inhibitor), as well as Xarelto® life-cycle label-enabling clinical trials, and the clinical development of other early antithrombotic (FXI/FXIa) medications in the portfolio. Supervised the work of clinical research physicians (Global Clinical Leaders), having managed a total of 9, and 2 administrative assistants. Assist with management of the research budget to within +/- 2% of year end estimate (since July 2007)

Global Clinical Leader for Rivaroxaban in Stroke Prevention in Atrial Fibrillation, and

the novel fibrinolytic alfimeprase [development stopped June 2007]

**Accomplishments:**

* Clinical Lead (head of the Thrombosis clinical research group) for development of Xarelto® (rivaroxaban) since 2007, and FXI/FXIa antithrombotic portfolio
* With my team, we brought this first oral direct Factor Xa inhibitor from Phase I and II trials, through completion of 16 large and mega scale global Phase 3 Xarelto trials, 13 of which met their primary statistical efficacy endpoint(s).
* Successfully completed a full pediatric development program of 6 trials with Xarelto which included a Phase 3 clinical trial of 500 patients
* With academic colleagues, the clinical trials underpinning these achievements were performed and presented at major international cardiovascular and thrombosis & hemostasis scientific meetings (ISTH, ASH, ESC, ACC, AHA, and ESO) and published in high level medical journals, including American Heart Journal, Circulation, CPT Pharmacometrics Syst Pharmacol., J Bone Joint Surg (Am), Journal of Thrombosis & Haemostasis, JACC, JAHA, JAMA, JAMA Neurology, J Bone Joint Surg (Am), Journal of Thrombosis & Haemostasis, Journal of Thrombosis & Thrombolysis, Lancet, Lancet Haematology, N Engl J Med, Stroke, and Thrombosis and Haemostasis, and Thrombosis Journal.
* With my team, we achieved global health regulatory approved labeling (as of this writing) in 7 medical indications:
* Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery
* Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults
* Prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation
* Prevention of cardiovascular death, myocardial infarction and stent thrombosis in patients after an acute coronary syndrome (non-ST elevation or ST elevation myocardial infarction or unstable angina) in combination with acetylsalicylic acid (ASA) alone or with ASA plus thienopyridines clopidogrel or ticlopidine
* Prevention of stroke, myocardial infarction and cardiovascular death, and for the prevention of acute limb ischemia and mortality in patients with coronary artery disease (CAD) or peripheral artery disease (PAD) in combination with ASA
* Prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding Indications
* Pediatric indication
	+ Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing more than 50 kg after at least 5 days of initial parenteral anticoagulation treatment
* Under investigation for the use of rivaroxaban
* Pediatric indication
	+ Thromboprophylaxis in pediatric subjects with single ventricle physiology post-Fontan procedure
* Prevention of major thrombotic vascular events (defined as myocardial infarction, ischemic stroke, cardiovascular death, acute limb ischemia and major amputation of a vascular etiology) in symptomatic peripheral artery disease patients
* Other indications investigated for the use of rivaroxaban
* Prevention of death, myocardial infarction or stroke in patients with heart failure and significant coronary artery disease
* Prevention of stroke and systemic embolism in patients with a recent embolic stroke of undetermined origin
* Prevention of death or thromboembolic events in patients after transcatheter aortic valve replacement
* Prevention of venous thromboembolism in ambulatory cancer patients initiating systemic cancer therapy and at high risk for venous thromboembolism
* Xarelto exposure and market authorization as of 15 SEP 2020
* almost 210,000 subjects have been enrolled in interventional clinical trials (completed and ongoing Phase II, Phase III and Phase IV) including more than 136,000 subjects treated with rivaroxaban
* In the post marketing setting, the estimated interval exposure to Xarelto was approx. 8.3 million patient-years
* Xarelto® is authorized to be marketed in 135 countries worldwide.
* 13 years management of experienced clinical research physicians
* Clinical development representative for Xarelto® labeling and health regulatory interaction
* Oversight of the early clinical development of other novel antithrombotics within Bayer portfolio including FXI/FXIa compounds
* Member of the Bayer Research & Development Team which won the 2009 German Deutscher Zukunftspreis prize for achievements in technology and innovation: Xarelto®
* Member of the Bayer Research & Development Team which won the 2010 Prix Galien in France, Switzerland, and the UK for 2010, as well as the 2010 International Prix Galien for the Best Pharmaceutical Agent: Xarelto®

**AstraZeneca US (Wilmington, DE)**

 **March 2000 - April 2006**

**Titles: Senior Research Physician (Global) / Senior Director, Clinical Research (US)**,

[Cardiovascular Therapeutic Area, Medicine and Science 1) [December 2005 – Apr 2006]

 **Senior Medical Director, Clinical Research**, Cardiovascular

Therapeutic Area, Medicine and Science 1 [Apr 2004 - Nov 2005]

**Medical Director, Clinical Research**, Cardiovascular Therapeutic Area [Mar 2000 – Mar

2004]

**Roles:** **US Medical Lead Physician Cardiovascular Emerging Brands**—provided medical input with US view to 4 Global Product Teams: Antithrombotics, Antiplatelets, Atherosclerosis and Metabolism, and Antiarrhythmics [Nov 2004 – Apr 2006]

## Study Team Physician and Medically Responsible for Orthopedic Venous Thromboprophylaxis and Venous Treatment Indications for oral direct thrombin inhibitor EXANTA™ (ximelagatran) in U.S. [March 2000 – Oct 2004]

**Accomplishments:**

* Member of the Clinical Development team for ximelagatran (Exanta®), the first oral direct thrombin inhibitor and the first novel anticoagulant to receive health regulatory approved labeling and be on the market since the introduction of warfarin almost 50 years earlier. Novel oral antithrombotic programs coming after Exanta® modeled, to various degrees, their Clinical Development Plans on the 4 clinical indications outlined by the Exanta® plan: 1) Venous thromboprophylaxis after total hip and total knee replacement surgery; 2) Treatment of venous thromboembolism (DVT and PE); 3) Prevention of stroke and systemic embolism in subjects with non-valvular atrial fibrillation; and 4) Secondary prevention of cardiovascular events (CV death, MI and stroke) after acute coronary syndrome
* Designed, operationalized, and completed5 large Phase III clinical trials in venous thromboprophylaxis after hip or knee replacement, and venous thromboembolism treatment studying Ximelagatran (Exanta®)
* Member of the submission writing team for the European Marketing Authorization Application (MAA) and for the US NDA submission for Orthopedic Venous Thromboprophylaxis indications (THR, TKR).
* Participant in the FDA Advisory Committee on Exanta® in Sept 2004.
* Exanta® was approved in 22 countries (mostly European, but also including Argentina, Brazil, Hong Kong, and Indonesia, although not the USA) for the prevention of venous thromboembolism following total hip or knee replacement.
* Member of the clinical team assessing the evidence for ximelagatran drug-induced liver injury, the findings of which led to the stoppage of clinical development and withdrawal of Exanta® from the world market.

**Academic Career Experience**

**Prior Academic Appointments and Clinical Positions**

Adjunct Professor of Medicine 2003 Department of Medicine,

 non-salaried, non-tenured (inactive) Jefferson Medical College
Thomas Jefferson University

 Philadelphia, PA

Adjunct Associate Professor of Medicine 2000-2020 Department of Medicine,

 non-salaried, non-tenured (inactive) Duke University Medical Center

 Durham, North Carolina

Associate Professor of Medicine 1999-2000 Duke University Medical Center

 and Pathology Departments of Medicine and Pathology

 Divisions of Hematology/Coagulation and Cardiology

 Faculty, Duke Clinical Research Institute

Assistant Professor of Medicine 1993-1999 Duke University Medical Center

 and Pathology Departments of Medicine and Pathology

 Divisions of Hematology/Coagulation and Cardiology

 Faculty, Duke Clinical Research Institute

Assistant Professor of Medicine 1988-1989 State University of New York at Stony Brook
 College of Medicine

 Department of Medicine

 Division of Hematology, Stony Brook, NY

 (Division Head: Barry S. Coller, M.D.)

Clinical Instructor in Medicine 1983-1985 Ohio State University Hospitals, College of Medicine,

 Department of Medicine
 Division of Hematology/Oncology, Columbus, Ohio

 (Division Head: Stanley P. Balcerzak, M.D.)

**Additional Clinical Experience**

Consultant in Coagulation 1991-2001 Scripps Reference Laboratory, The Scripps Research Institute

Staff Physician, Clinical Researcher 1991-1993 Scripps Clinic Medical Group

 and Consultant, Section of Coagulation Scripps Clinic and Green Hospital, La Jolla, CA

 Division of Hematology/Oncology

 Departments of Medicine and Pathology

Staff Physician 1989-1991 Southern California Permanente Medical Group

 Division of Hematology/Oncology

 Kaiser Permanente Medical Center, San Diego, CA

 **Selection of Additional Academic Work 1993-2000, prior to joining pharmaceutical industry**

**Participation in academic and administrative activities of Duke University and Medical Center**

Committee Name Dates

Orthopaedic Anticoagulation Standardization Committee 10/23/96

Department of Medicine Committee on Clinical Research

 Activities - Hematology Division Representative 10/24/96 – 2/2000

Deep Venous Thrombosis Clinical Path Committee January 1998, February 1999

Anesthesia/ICU P&T Evaluation Team Focus on Spinal

 Hematomas & Low-Molecular Weight Heparins July-October 1998

Academic Council, Duke University, Clinical Sciences Division April 1999-March 2001

**Manuscript reviewer:**

 *American Heart Journal*  1997 to 2000

 *Arteriosclerosis, Thrombosis, and Vascular Biology* 1998 to 2000

 *Thrombosis and Haemostasis* 1999 to 2000, 2019

 *American Journal of Medicine* 1999 to 2000

 *Thrombosis Research* 1999 to 2000, 2004

 *Blood* 2000

*Circulation* 2002, 2005

*Expert Opinion on Drug Safety* 2002

J*ournal of Thrombosis and Hemostasis* 2004

**Some Positions Held within Academic Clinical Trials (1993- 2000)**

Position Trial

DSMB member ASSENT PLUS-AMI with thrombolytics

DSMB member ORBIT- GPIIb/IIIa antagonist (orbofiban)

Medical Monitor Emisphere Phase 2-venous thromboprophylaxis after THA with oral heparin

Core Lab Director APLAUD-Platelet aggregation studies with GPIIb/IIIa antagonist

Core Lab Director DMP754-010 Parts A, C, & D-Platelet aggregation studies with GPIIb/IIIa antagonist

Site PI On Duke External Support List – available on request

National (US) PI ATBAT 1st Inning (PI)-bivalirudin for HIT in patients needing PCI

National (US) PI ATLAST (Co-PI)-enoxaparin in PCI

National (US) PI ORATOR (Co-PI)-Phase 2 study in PCI patients with GPIIb/IIIa antagonist

International co-PI PROTECT-venous thromboprophylaxis after THA with oral heparin

**Face to face interaction with FDA on behalf of companies related to clinical trials and blood coagulation prior to
joining industry**

 1998 - 3 (1 each for 3 different companies)

 1999 - 1

 2000 - 2 (1 each for 2 different companies)

**Publications**

1. **Refereed (peer-reviewed) journals**
2. Budde U, Dent JA, **Berkowitz SD**, Ruggeri ZM and Zimmerman TS: Subunit composition of plasma von Willebrand factor in patients with the myeloproliferative syndrome. *Blood* 1986; 68:1213-1217. PubMed PMID: 3535924.
3. Tutschka PJ, **Berkowitz SD**, Tuttle S and Klein J: Graft-versus-leukemia in the rat: The antileukemic efficacy of syngeneic and allogeneic graft-versus-host disease. *Transplantation Proceedings* 1987 Feb; 19(1 Pt 3):2668-2673. PubMed PubMed PMID: 3547945.
4. **Berkowitz SD**, Dent JA, Roberts J, Fujimura Y, Plow EF, Titani K, Ruggeri ZM and Zimmerman TS: Epitope mapping of the von Willebrand factor subunit distinguishes fragments present in normal and Type IIA von Willebrand disease from those generated by plasmin.  *J Clin Invest* 1987 Feb;79(2):524-31. doi: 10.1172/JCI112843. PubMed PMID: 2433308; PubMed Central PMCID: PMC424117.

1. Batlle J, Lopez-Fernandez MF, Lopez-Borrasca A, Lopez-Berges C, Dent JA, **Berkowitz SD**, Ruggeri ZM and Zimmerman TS: Proteolytic degradation of von Willebrand factor after DDAVP administration in normal individuals. *Blood* 1987; 70:173-176. PubMed PMID: 3496131.
2. **Berkowitz SD**, Nozaki H, Titani K, Murachi T, Plow EF and Zimmerman TS: Evidence that calpain and elastase do not produce the von Willebrand factor fragments present in normal plasma and IIA von Willebrand disease. *Blood* 1988; 72:721-727. PubMed PMID: 2840990.
3. **Berkowitz SD** and Federici AB: Sialic acid prevents loss of large von Willebrand factor multimers by protecting against amino-terminal proteolytic cleavage. *Blood* 1988; 72:1790-1796. PubMed PMID: 2460162.
4. Dent JA, **Berkowitz SD**, Ware J, Kasper CK and Ruggeri ZM: Identification of a cleavage site directing the immunochemical detection of molecular abnormalities in Type IIA von Willebrand factor. *Proc Natl Acad Sci* 1990; 87:6306-6310. PubMed PMID: 2385594.
5. Federici AB, **Berkowitz SD**, Colibretti ML, Lattuada A, Lotto A, Zimmerman TS and Mannucci PM: Proteolysis of von Willebrand factor after thrombolytic therapy in patients with acute myocardial infarction. *Blood* 1992; 79:38-44. PubMed PMID: 1530813.
6. Federici AB, **Berkowitz SD**, Lattuada A and Mannucci PM: Degradation of von Willebrand factor in patients with acquired clinical conditions in which there is heightened proteolysis. *Blood* 1993; 81:720-725. PubMed PMID: 8427964.
7. **Berkowitz SD**. Treatment of Established DVT: A Review of the Therapeutic Armamentarium. Orthopedics. 1995 Jul;18 Suppl:18-20. DOI:10.3928/0147-7447-19950702-08. PubMed PMID: 24826629.
8. Heit JA , **Berkowitz SD**, Bona R, Cabanas V, Corson JD, Elliot CG, and Lyons R. for the Ardeparin Arthroplasty Study Group. Efficacy and Safety of Low Molecular Weight Heparin (Ardeparin Sodium) Compared to Warfarin for Prevention of Venous Thromboembolism After Total Knee Replacement Surgery: a Double-Blind, Dose-Ranging Study. *Thrombosis and Haemostasis* 1997;1:32-38. PubMed PMID: 9031445.
9. **Berkowitz SD**, Harrington RA, Rund MM, Tcheng JE. Acute Profound Thrombocytopenia After c7E3 Fab (Abciximab) Therapy. *Circulation* 1997;95:809-813. DOI: 10.1161/01.cir.95.4.809; PubMed PMID: 9054735.
10. Oishi CS, D’Lima DD, Morris BA, Hardwick ME, **Berkowitz SD,** and Colwell Jr CW: Hemodilution with Other Blood Reinfusion Techniques in total Hip Arthroplasty. *Clinical Orthopaedics*. 1997;339:132-139. DOI: 10.1097/00003086-199706000-00018; PubMed PMID: 9186211.
11. **Berkowitz SD**, Granger CB, Pieper KS, Lee DK, Gore JM, Simoons M, Armstrong PW, Topol EJ, Califf RM for the Global Utilization of Streptokinase and Tissue plasminogen activator for Occluded coronary arteries (GUSTO) I Investigators: Incidence and Predictors of Bleeding Following Contemporary Thrombolytic Therapy for Myocardial Infarction. *Circulation*. 1997;95:2508-2516. DOI: 10.1161/01.CIR.95.11.2508; PubMed PMID: 9184581.
12. Grocutt HP, Root J, **Berkowitz SD,** deBruijn N, Landolfo K. Coagulation Complicating Cardiopulmonary Bypass in a Patient with Heparin-Induced Thrombocytopenia Receiving the Heparinoid, Danaparoid Sodium. *Jour Cardiothorac Vasc Anesth Vol 11, No 7.* 1997:875-877. DOI: 10.1016/s1053-0770(97)90124-5; PubMed PMID: 9412888
13. Fuster V, Califf RM, Chesebro JH, Cohen M, Comp PC, Gheorghiade M, Hall J, Halperin J, Khan S, Kopecky S, Langer A, Molk B, Moss A, OConnor CM, OGara PT, Raskob E, Sutton J, Braunwald E, Bell WR, Furberg C, Rapaport E, DeMets D, Goldstein S, Richardson D, Hillis D, Bonow R, Kistler JP, Mohr JP, Sherman D, Fisher M, Feyzi J, Cook T, Califf RM, Harrington RA, **Berkowitz SD**, L Jett, L Berdan, M McDougal, E Friedman, J Daniel.et al. Randomised double-blind trial of fixed low-dose warfarin with aspirin after myocardial infarction. Lancet. 1997;350(9075):389-96. PubMed PMID: 9259652.
14. Mark DB, Cowper PA, **Berkowitz SD**, Davidson-Ray L, DeLong ER, Turpie AGG, Califf RM, Weatherly B, Lee KL, Cohen M. Economic Assessment of Low Molecular Weight Heparin (Enoxaparin) Versus Unfractionated Heparin in Acute Coronary Syndrome Patients: Results from the ESSENCE Randomized Trial. *Circulation* 1998;97:1702-1707. DOI: 10.1161/01.cir.97.17.1702; PubMed PMID: 9591764.
15. Mandak JS, Blankenship JC, Gardner LH, **Berkowitz SD**, Aguirre F, Sigmon KN, Timmis GC, Gilchrist IC, McIvor M, Resar J, Weiner BH, George BS, Tally JD, Lincoff AM, Tcheng JE, Califf RM, Topol EJ. Modifiable Risk Factors for Vascular Access Site Complications in the IMPACT II Trial of Angioplasty with Versus without Eptifibatide. *JACC* 1998;31 (7):1518-24. DOI: 10.1016/s0735-1097(98)00130-2; PubMed PMID: 9626829.
16. **Berkowitz SD**, Sane DC, Shavender JH, Sigmon KN, Topol EJ, Califf RM, for the Evaluation of 7E3 for the Prevention of Ischemic Complications (EPIC) Study Group. Occurrence and Clinical Significance of Thrombocytopenia with c7E3 (Abciximab) in the EPIC Trial. *JACC* 1998;32:311-319. DOI: 10.1016/s0735-1097(98)00252-6; PubMed PMID: 9708455.
17. Harrington RA, Kleiman NS, Granger CB, Ohman EM, Scarborough RM, **Berkowitz SD**. Relationship between inhibition of platelet aggregation and clinical outcomes. *American Heart Journal* 1998;136 (4 Part 2 Suppl S):S 43-S 50. DOI: 10.1053/hj.1998.v136.93433; PubMed PMID: 9778087
18. **Berkowitz SD**, Freilinger A, Hillman R. Progress with Point-of-Care Laboratory Testing for Assessing Platelet Function. *American Heart Journal* 1998;136 (4 Part 2 Suppl S):S 51-S 65. DOI: 10.1053/hj.1998.v136.93432; PubMed PMID: 9778088.
19. Madan M, **Berkowitz SD,** Tcheng JE. Glycoprotein IIb/IIIa Integrin Blockade. *Circulation* 1998;98:2629-2635. DOI: 10.1161/01.cir.98.23.2629; PubMed PMID: 9843473
20. Nader HB, Walenga JM, **Berkowitz SD**, Ofosu F, Hoppensteadt DA, Cella G. Preclinical Differentiation of Low Molecular Weight Heparins. *Seminars in Thrombosis and Hemostasis* 1999;25 (Suppl 3): 63-72. PubMed PMID: 10549718.

1. McClure MW, **Berkowitz SD,** Sparapani R, Tuttle R, Kleiman NS, Berdan LG, Topol EJ, Lincoff AM, Deckers J, Diaz R, Simoons M, Califf RM, Gretler D, Kitt M, Karsch KR, Harrington RA, for the PURSUIT Investigators. The Clinical Significance of Thrombocytopenia During a non-ST Elevation Acute Coronary Syndrome: The PURSUIT Experience. *Circulation* 1999;99:2892-2900. DOI: 10.1161/01.cir.99.22.2892; PubMed PMID: 10359733.
2. Madan M, Blankenship JC, **Berkowitz SD**. Bleeding with Platelet GPIIb/IIIa Receptor Antagonists. *Current Opinion in Hematology* 1999;6:334-341. DOI: 10.1097/00062752-199909000-00011; PubMed PMID: 10468150.
3. Madan M , **Berkowitz SD.** Understanding Thrombocytopenia and Antigenicity with Glycoprotein IIb/IIIa Inhibitors. *American Heart Journal* 1999 Oct;138(4 Pt 2):317-326. DOI: 10.1053/hj.1999.v138.a100465; PubMed PMID: 10502237.

1. **Berkowitz SD**. Current Knowledge of the Platelet Glycoprotein IIb/IIIa Receptor Antagonists for the Treatment of Coronary Artery Disease. *Haemostasis*. 2000;30 Suppl 3:27-43. doi: 10.1159/000054195. DOI: 10.1159/000054195; PubMed PMID: 11182626.
2. Madan M, Kereiakes DJ, Hermiller JB, Rund MM, Tudor G, Anderson L, McDonald MB, **Berkowitz SD**, Sketch MH, Phillips HR, and Tcheng JE. Abciximab Readministration in Coronary Intervention. *American Journal of Cardiology*, 2000;85:435-440. DOI: 10.1016/s0002-9149(99)00768-7; PubMed PMID: 10728946.
3. Kereiakes DJ, **Berkowitz SD**, Lincoff AM, Tcheng JE, Wolski K, Achenbach R, Melsheimer R, Anderson K, Califf RM, Topol EJ. Clinical correlates and course of thrombocytopenia during percutaneous coronary intervention in the era of abciximab platelet glycoprotein IIb/IIIa blockade. *Am Heart J*. 2000;140:74-80. DOI: 10.1067/mhj.2000.106615; PubMed PMID: 10874266.
4. Hull RD, Pineo GF, Francis C, Bergqvist D, Fellenius C, Soderberg K, Holmqvist A, Mant M, Dear R, Baylis B, Mah A, Brant R.\* Low-Molecular-Weight Heparin Prophylaxis Using Dalteparin in Close Proximity to Surgery vs Warfarin in Hip Arthroplasty Patients: A Double-blind, Randomized Comparison. Arch Intern Med. 2000 Jul 24;160(14):2199-2207. **\***While an author search in PubMed does not recognize this, **Scott D. Berkowitz** is a co-author on this paper in accordance with Criteria for Authorship formulated by the International Committee of Medical Journal Editors, which is documented in the manuscript after the Comment section and just ahead of the References, where it is stated: “The following is list of the additional coauthors: ... Scott D. Berkowitz, MD, Duke University Medical Center, Durham, NC...” DOI: 10.1001/archinte.160.14.2199; PubMed PMID: 10904464.
5. Hull RD, Pineo GF, Francis C, Bergqvist D, Fellenius C, Soderberg K, Holmqvist A, Mant M, Dear R, Baylis B, Mah A, Brant R\*. Low-Molecular-Weight Heparin Prophylaxis Using Dalteparin Extended Out-of-Hospital vs In-Hospital Warfarin/Out-of-Hospital Placebo in Hip Arthroplasty Patients: A Double-blind, Randomized Comparison. *Arch Intern Med*. 2000 Jul 24;160(14):2208-2215. **\***While an author search in PubMed does not recognize this, **Scott D. Berkowitz** is a co-author on this paper in accordance with Criteria for Authorship formulated by the International Committee of Medical Journal Editors, which is documented in the manuscript after the Comment section and just ahead of the References, where it is stated: “The following is list of the additional coauthors: ... Scott D. Berkowitz, MD, Duke University Medical Center, Durham, NC...” DOI: 10.1001/archinte.160.14.2208; PubMed PMID: 10904465.
6. Campbell KR, Mahaffey KW, Lewis BE, Weitz JI, **Berkowitz SD,**  Ohman EM, Califf RM. Bivalirudin in Patients with Heparin-Induced Thrombocytopenia Undergoing Percutaneous Coronary Intervention. *Journal of Invasive Cardiology* 2000 Dec; 12 Suppl F: 14F-19F. PubMed PMID: 11156729.
7. Madan M, **Berkowitz SD**, Christie DJ, Jennings LK, Smit AC, Sigmon KN, Glazer SN, Tcheng JE. Rapid assessment of glycoprotein IIb/IIIa blockade using the Platelet Function Analyzer (PFA-100) during percutaneous coronary interventions. *American Heat Journal* 2001 Feb;141:226-233. DOI: 10.1067/mhj.2001.112489; PubMed PMID: 11174336.
8. Lewis BE, Wallis DE, **Berkowitz SD**, Matthai WH, Fareed J, Walenga JM, Bartholomew J, Sham R, Lerner RG, Zeigler ZR, Rustagi PK, Jang IK, Rifkin SD, Moran J, Hursting MJ, Kelton JG for the ARG-911 Study Investigators. Argatroban anticoagulant therapy in patients with heparin-induced thrombocytopenia. Circulation. 2001 Apr 10;103(14):1838-43. DOI: 10.1161/01.cir.103.14.1838; PubMed PMID: 11294800.
9. **Berkowitz SD**. Antithrombotic therapy after prosthetic cardiac valve implantation: improving postoperative, long-term patient management. Introduction. Am Heart J. 2001 May;141(5):847-8. DOI: 10.1067/mhj.2001.114977; PubMed PMID: 11320376.
10. Menon V, **Berkowitz** **SD**, Antman EM, Fuchs RM, Hochman JS. New heparin dosing recommendations for patients with acute coronary syndromes. *American Journal of Medicine* 2001 June 1;110:641-650. DOI: 10.1016/s0002-9343(01)00715-x; PubMed PMID: 11382373.
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**d. Articles Selected for Summary and Review in American College of Physicians Journal Club**

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**g. Patents**

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**4. Scientific Abstracts**

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	126. **Berkowitz SD**, Bauersachs RM, Szarek M, Nehler MR, Debus ES, Patel MR, Anand SS, Hess CN, Muehlhofer E, Haskell LP, Bonaca MP. Prevention Of Arterial And Venous Vascular Events In Symptomatic Peripheral Arterial Disease Patients After Lower Extremity Revascularization in the VOYAGER PAD trial: Dual Anticoagulant/Antiplatelet Regimen Vs Antiplatelet Therapy Alone [abstract]. *Res Pract Thromb Haemost*. 2021; 5 (Suppl 1). https://abstracts.isth.org/abstract/prevention-of-arterial-and-venous-vascular-events-in-symptomatic-peripheral-arterial-disease-patients-after-lower-extremity-revascularization-in-the-voyager-pad-trial-dual-anticoagulant-antiplatelet/. Accessed July 21, 2021.
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	128. Morrison, J., W. Hiatt, M. Patel, S. Anand, E. S. Debus, M. Nehler, C. Hess, W. H. Capell, T. Bracken, **S. Berkowitz**, E. Muehlhofer, L. Haskell, R. Bauersachs, and M. Bonaca. "Efficacy and Safety of Low-Dose Rivaroxaban in Symptomatic Pad Patients Undergoing Revascularization Currently Smoking: Insights from Voyager Pad." Journal of the American College of Cardiology 77, no. 18 (May 2021): 1808-08
	129. Krantz, M., W. Hiatt, S. Anand, E. S. Debus, M. Patel, M. Nehler, C. Hess, W. H. Capell, T. Bracken**, S. Berkowitz**, E. Muehlhofer, L. P. Haskell, R. Bauersachs, and M. Bonaca. "Efficacy and Safety of Rivaroxaban in Elderly Patients with Symptomatic Pad Undergoing Revascularization: Insights from Voyager Pad." Journal of the American College of Cardiology 77, no. 18 (May 2021): 1783-83.
	130. Govsyeyev, N., M. R. Nehler, S. Debus, R. Bauersachs, M. Patel, S. Anand, W. Capell, M. Szarek, E. Muehlhofer, L. Haskell, **S. Berkowitz**, and M. Bonaca. "Efficacy of Rivaroxaban and Aspirin in Patients with Peripheral Artery Disease with Venous and Prosthetic Surgical Bypass Conduits: Insights from the Voyager Pad Trial." Journal of Vascular Surgery 74, no. 3 (Sep 2021): E24-E25
	131. Bonaca, M. P., M. R. Patel, E. S. Debus, M. R. Nehler, S. S. Anand, C. N. Hess, W. H. Capell, R. K. Rogers, S. Hogan, J. Hsia, E. Muehlhofer, L. P. Haskell, **S. D. Berkowitz**, and R. M. Bauersachs. "Risk Profile and Efficacy and Safety of Rivaroxaban in Patients Undergoing Revascularization for Claudication: Insights from Voyager Pad." Circulation 144, no. 25 (Dec 2021): E588-E88.
	132. Hogan, S. E., M. Nehler, S. Anand, M. R. Patel, E. S. Debus, M. T. Jackson, C. Buchanan, R. W. King, E. Muehlhofer, L. Haskell, R. Bauersachs, **S. D. Berkowitz**, J. A. Hsia, and M. P. Bonaca. "Walking Impairment in Patients with Symptomatic Peripheral Artery Disease after Lower Extremity Revascularization." Journal of the American College of Cardiology 79, no. 9 (Mar 2022): 1774-74. <Go to ISI>://WOS:000781026601873.
	133. Svet, M., J. A. Hsia, M. R. Patel, S. Anand, E. S. Debus, M. Nehler, C. N. Hess, W. Capell, E. Muehlhofer, L. Haskell, **S. D. Berkowitz**, R. Bauersachs, and M. P. Bonaca. "Rivaroxaban Reduces Hospitalizations for Thromboembolic Events in Patients with Peripheral Artery Disease after Revascularization in Those with and without Chronic Kidney Disease." Journal of the American College of Cardiology 79, no. 9 (Mar 2022): 1739-39. <Go to ISI>://WOS:000781026601838.
	134. Heilman, A., R. Bauersachs, S. Anand, M. R. Patel, E. S. Debus, M. Nehler, C. N. Hess, W. H. Capell, B. Osiemo, J. A. Hsia, E. Muehlhofer, L. Haskell, **S. D. Berkowitz**, and M. P. Bonaca. "Benefits of Rivaroxaban after Lower Extremity Revascularization for Symptomatic Peripheral Artery Disease Are Consistent with and without Background Statin Therapy." Journal of the American College of Cardiology 79, no. 9 (Mar 2022): 1747-47. <Go to ISI>://WOS:000781026601846.
	135. Wang, C. C. L., M. R. Nehler, L. Haskell, **S. D. Berkowitz**, R. M. Bauersachs, and M. P. Bonaca. "Risk Profile of Comorbid Diabetes and Benefit of Rivaroxaban in Patients with Critical Limb Ischemia: Insights from Voyager Pad." Diabetes 70 (Jun 2021). https://dx.doi.org/10.2337/db21-8-LB

**Lectures at the University of Colorado Anschutz School of Medicine**

* September 16, 2021: “Thrombosis”
* September 24, 2021: "Drug Discovery & Development of Novel Antithrombotic Medications From Conception to Market Approval: Perspective of a Clinical Research Physician". Cardiology Grand Rounds, University of Colorado Anschutz Medical Campus
* November 30, 2021:” Anticoagulant Medications - A History and A Story of Discovery and Development”. Hematology Cardiology Grand Rounds, University of Colorado Anschutz Medical Campus

**Lectures by Invitation to External Institutions/Groups**

**Local**

* February 23, 1989: "When to Use Platelet Inhibitors or Anticoagulants in Cardiac Disease." Medical Grand Rounds, Huntington Hospital, Huntington, New York,.
* January 27, 1995: “Use of the INR in Anticoagulation with Coumadin”. First Annual Symposium in Cardiovascular Medicine, Central Carolina Hospital.
* May 31, 1997: “Venous Thromboembolism: Update 1997” for the Symposium “Joint Replacement 1997: Engineering and Biology.

**Regional**

* September, 1987: "Studies on the Structure and Function of von Willebrand Factor. Proteolysis in vivo in Normals and Disease." Research Conference, Oregon Health Sciences Center, University of Oregon, Portland, Oregon.
* May 21, 1997: “Thrombocytopenia with Glycoprotein IIb IIIa Inhibitors” Presented at Rhone Poulenc Rorer, Collegeville, PA.
* December 7, 1997: Results of Platelet Aggregation Study with Roxifiban in a Phase II Randomized, Double-Blind, Multicenter, Acetylsalicyclic Acid-Controlled, Multi-Dose Study of DMP 754 in Patients with Coronary Artery Disease (DMP 754-010; DuPont Merck Pharmaceutical Company), San Diego, CA.
* March 24, 1998: “Low Molecular Weight Heparin; Uses in Cardiovascular Disease”. Department of Medicine Grand Rounds, Sisters of Charity Hospital.
* October 23, 1998: “Novel Antithrombotic Therapies.” Tenth Annual Western North Carolina Cancer Conference, Asheville, NC
* May 13, 2000: “Thromboembolism Update: New Strategies, New Drugs”. Joint Replacement 2000, Pinehurst, North Carolina
* November 1, 2002: Stroke Belt Consortium, “Direct Thrombin Inhibitors”

**National**

* May 20, 1994: “Pathophysiology of DVT”, National Association of Orthopaedic Nurses Program, Nashville, TN,.
* April 18, 1994: “Immunoglobulin Therapy and Plasmapheresis.” Department of Pathology Weekly Seminar Series, Loyola University, Chicago, Illinois.
* February 16, 1995: “Treatment of Established Deep Vein Thrombosis: A Review of the Therapeutic Armamentarium”. Symposium, Surgical Challenges: Surveillance, Prevention, and Treatment of DVT, American Association of Orthopaedic Surgeons.
* June 7, 1996: “Novel Antithrombotic Drugs and their Potential Clinical Usefulness“. Medical Grand Rounds, Scott & White Clinic and the Texas A&M University Health Science Center and College of Medicine, Temple, Texa.
* April 25, 1997: “Low Molecular Weight Heparins: Uses in Venous and Arterial Disease” Mercy Heart Institute, Mercy Hospital, Pittsburgh, PA.
* December 11, 1997: “Low Molecular Weight Heparins”. Loyola University Medical Center, Chicago (invited by Dr. Jawed Fareed).
* December 5, 1997: “Low Molecular Weight Heparins in Cardiology”. Satellite Symposium on Low Molecular Weight Heparins: Current Use and Future Indications. American Society of Hematology. San Diego.
* March 31, 1998: “Understanding Thrombocytopenia and Antigenicity with Platelet Glycoprotein IIb/IIIa Receptor Antagonists.” Safety issues concerning the use of GPIIb/IIIa inhibitors in the management of acute ischemic coronary syndromes. Atlanta, GA
* July 20 1998: “Laboratory Monitoring of Antithrombins.” Boeringer Ingelheim Advisory Panel, New York City
* September 13, 1998: “Thrombocytopenia and Antigenicity Associated with Platelet Glycoprotein IIb/IIIa Receptor Antagonists.” Recent Advances in Antiplatelet Therapies. Cambridge, MA
* October 2, 1998: Thrombocytopenia Associated with Platelet Glycoprotein IIb/IIIa Receptor Antagonists.” Seventh Midwest Platelet Conference, Memphis, TN
* December 5 & 6, 1998: “Understanding Thrombocytopenia Associated with Platelet Glycoprotein IIb/IIIa Receptor Antagonists.” American Society of Hematology Educational Sessions, Miami Beach, FL
* January 8-9, 1999: Antithrombotic therapy after prosthetic cardiac valve implantation: Improving postoperative, long-term patient management –“ Potential novel antithrombotic therapies”. Pinehurst, North Carolina - January 8-9, 1999
* January 29-30, 1999 “Pharmacokinetic Differences: Anti-Xa:Anti-IIa Ratios and Their Impact on Biological Actions.” International Summit: Differentiation of Low Molecular Weight Heparins- Applied and Clinical Considerations. St. Petersburg, FL
* February 3, 1999: “Laboratory Monitoring of Novel Antithrombins and Anti-Factor Xa Agents.” Parke-Davis Consultants Meeting, Ypsilanti, Michigan
* May 12, 1999. “Diagnosis and Management of Heparin-induced Thrombocytopenia.” Memorial West Hospital. Miami, FL
* August 19, 1999 “Anticoagulation and Thrombolysis in Acute Myocardial Infarction”- Meet the Expert Session. XVII Congress of the International Society on Thrombosis and Hemostasis, Washington DC
* August 19, 1999 “Heparin Administered Orally via a Novel Carrier System (SNAC) is Comparable to SQ Heparin When Used to Prevent Venous Thromboembolic Events Following Elective Total Hip Arthroplasty.” Heparins-Clinical, Oral Session, XVII Congress of the International Society on Thrombosis and Hemostasis, Washington DC
* August 21, 1999 “Heparin Administered Orally via a Novel Carrier System (SNAC) is Comparable to SQ Heparin When Used to Prevent Venous Thromboembolic Events Following Elective Total Hip Arthroplasty.” Symposium: Heparins in the New Millenium: Will Unfractionated Heparin Survive? Washington DC
* September 22, 1999: “Oral Heparin and Vascular Disease.” Molecular Cardiology and Local Cardiovascular Therapeutics, Transcatheter Cardiovascular Therapeutics, Washington DC
* October 4, 1999: “Heparin by Oral Delivery: Studies to Phase II.” Advances in Anticoagulant, Antithrombotic and Thrombolytic Drugs, Boston, MA
* October 5, 1999: “Management of Bleeding Related to Newer Antithrombotic and Thrombolytic Agents.” Advances in Anticoagulant, Antithrombotic and Thrombolytic Drugs, Boston, MA
* October 7, 1999: “Bleeding Complications with Platelet GPIIb/IIIa Receptor Antagonists.” Advances in Antiplatelet Therapies, Boston, MA
* November 23, 1999: “Understanding Heparin-induced Thrombocytopenia and Thrombosis, and Management Strategies.” Jersey Shore Medical Center, Neptune, New Jersey
* July 19, 2000: “Venography in Orthopaedic Clinical Trials-Overview for Radiologists”, Chicago, Illinois
* October 2-3, 2000: “Oral Direct Thrombin Inhibitors.” Advances in Anticoagulants, Antithrombotics, and Thrombolytic Drugs. Boston
* January 30, 2002: Hematology Advisory Board, “Orthopaedic Surgery & Venous Thromboembolism Trials with Exanta”
* May 21 & 22, 2002: Scripps Clinic, Green Hospital, Medical Grand Rounds (“Novel Antithrombotics”), & Research Nurses (“Orthopaedic Clinical Trials”), La Jolla, CA.

**International**

* October 29, 1999.: “Platelet GPIIb/IIIa Receptor Antagonists: Results of Clinical Trials, and Potential Complications and Their Management.” Tokai University, Kanagawa, Japan
* October 30, 1999: “New Frontiers of Antiplatelet Therapy in the Treatment of Coronary Artery Disease-Current Progress on GPIIb/IIIa Inhibitor Therapy.” The 20th Platelet Lake Ashi Conference, Hakone-machi, Japan
* November 1, 1999: “New Frontiers of Antiplatelet Therapy in the Treatment of Coronary Artery Disease-Clinical Trials with Platelet GPIIb/IIIa Inhibitors,” Keidanren-Kaikan, Tokyo, Japan
* October 24, 2002: International Orthopaedic Surgery Advisory Board, “EXANTA in OS-US program”
* July 19, 2021: Prevention Of Arterial And Venous Vascular Events In Symptomatic Peripheral Arterial Disease Patients After Lower Extremity Revascularization in the VOYAGER PAD trial: Dual Anticoagulant/Antiplatelet Regimen Vs Antiplatelet Therapy Alone. LB 01.1. ISTH 2021 Virtual Congress, Philadelphia, PA.

**Visiting Professor**

* March 8, 2001: “Direct Thrombin Inhibitors and the H 376/95 (Ximelagatran) Development Program”, Dartmouth Hitchcock Medical Center (invited by Dr. Ted Bovill), Burlington Vermont
* April 26-28, 2001: “Newer Antithrombotics: The Landscape and the Horizon”. 18th Annual Temple University Hemostasis and Thrombosis Update 2001, Philadelphia, PA
* May 10-11, 2001: “Antithrombotics: The Landscape and the Horizon”. 3rd Annual Midwest Symposium on Hemostasis and Thrombosis, Indianapolis
* November 17, 2001: New Antithrombotics. 9th Conference on Thromboembolic Conditions. Advocate Illinois Masonic Medical Center
* April 22, 2003: “Antithrombotics: The Landscape and the Horizon”. Special Research Seminar, Cardeza Foundation, Division of Hematology, Thomas Jefferson University (invited by Profs. Jamie Siege and Steve McKenzie, Division of Hematology)
* May 16, 2003: “Antithrombotics: The Landscape and the Horizon”. Division of Hematology, University of Pennsylvania (invited by Dr. Barbara Konkle)
* October 16, 2003: “Ximelagatran: Oral Antithrombotic on the Horizon” at Harvard Medical School Thrombosis and Thromboembolism: New Strategies for Improved Patient Care Course, Boston, MA (invited by Prof. Sam Goldhaber)
* May 5, 2004: “Phase III Clinical Development of Ximelagatran, an Oral Direct Thrombin Inhibitor”, UNC Heart Center Grand Rounds: Chapel Hill, North Carolina. (invited Prof. E. Magnus Ohman, Chief of Cardiology Division)
* October 11, 2012: “Antithrombotic Medications: A History and A Story of Development”, UNC Division of Hematology Seminar (invited by Dr. Nigel Key, Chief of Hematology Division)