EXHIBIT 16

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

CURRICULUM VITAE

01/18/2012

Name:	Timothy Peter Cripe, M.D., Ph.D.
Social Security:	Upon request
Work Address:	Professor and Chief Division of Hematology/Oncology/BMT 700 Children's Drive Columbus, OH 43205 Office location: ED545 Office phone: (614) 722-3521 Office fax: (614) 722-3699 Pager: (614) 690-0204 Podcast: "This Week in Pediatric Oncology" on iTunes Twitter: @TWiPOPodcast Secretary: -----(b)(6)----- (614) 722-3552 ----(b)(6)----@nationwidechildrens.org
Home Address:	Upon request

EDUCATION

1989	University of Iowa Iowa City, IA Ph.D. Genetics: "Regulation of the Human Papillomavirus-16 Oncogene Promoter by the Papillomaviral E2 Proteins and by Cellular Regulatory Factors: Implications for Cervical Carcinogenesis" Research Mentor: ----------(b)(6)----------
1989	University of Iowa Iowa City, IA M.D.
1982	Princeton University Princeton, NJ A.B. Biochemistry, *Magna cum Laude* Research Mentor: ----------(b)(6)----------

POSTGRADUATE EDUCATION

1993 - 1995	Fellow, Hematology/Oncology

	Children's Hospital and University of Colorado Health Sciences Center, Denver, CO Research Mentor: ----------(b)(6)---------
1992 - 1993	Fellow, Hematology/Oncology Children's Hospital and Dana-Farber Cancer Institute Harvard Medical School, Boston, MA
1989 - 1992	University of Iowa College of Medicine Resident, Pediatrics

CERTIFICATION AND LICENSURE

Upon Request

ACADEMIC APPOINTMENTS

1/2012 – present	Professor and Chief Division of Hematology/Oncology/BMT Nationwide Children's Hospital Columbus, OH
1/2012 – present	Adjunct Professor of Pediatrics - Affiliated University of Cincinnati Cincinnati Children's Hospital Medical Center Cincinnati, OH
2008 – 1/2012	Professor of Pediatrics - Affiliated University of Cincinnati Cincinnati Children's Hospital Medical Center Cincinnati, OH
2008 – 1/2012	Medical Co-Director Office for Clinical and Translational Research Children's Hospital Medical Center Cincinnati, OH
2008 – 1/2012	Director of Pilot and Collaborative Studies Center for Clinical and Translational Science and Training University of Cincinnati Cincinnati, OH
2003 – 2008	Director Translational Research Trials Office

2005 – 2010	Medical Director, Little Star Foundation (Andrea Jaeger, Founder) Aspen and Durango, Colorado
2002 – 2010	CCHMC Representative, Annual Golf Charity, teeoffagainstcancer.org Cincinnati, Ohio
2002 – 2003	CCHMC Representative and speaker, annual Smith Family golf charity Morehead, KY

INVITED LECTURES / ORAL PRESENTATIONS

Date	**Event/Venue**	**Location**	**Title**
1/17/97	University of Wisconsin Children's Hospital Grand Rounds	Madison, WI	*Hemophilia: New Approaches to an Old Disease*
4/30/97	University of Wisconsin Children's Hospital and Comprehensive Cancer Center	Madison, WI	*Pediatric Oncology in the 90's*
8/4/97	"Early Bird" Residents Lecture	Madison, WI	*Hematological Emergencies Hemophilia, Bleeding Disorders, and Sickle Cell Crises*
11/6/97	University of Wisconsin Comprehensive Cancer Center Grand Rounds	Madison, WI	*From Ontogeny to Oncology: Harnessing Renegade Developmental Genes for Novel Cancer Gene Therapy*
3/10/98	University of Wisconsin Department of Pediatrics Grand Rounds	Madison, WI	*Sickle Cell Disease: From Gene to Drug*
5/16/98	Hemophilia Treatment Center Family Retreat	Milwaukee, WI	*Hemophilia Therapy for the New Millenium: Promises and Pitfalls of a Gene Therapy Cure*
7/6/98	"Early Bird" Residents Lecture	Madison, WI	*Hematological Emergencies: Hemophilia, Bleeding Disorders, and Sickle Cell Crises*
1/15/99	University of Wisconsin Children's Hospital	Madison, WI	*Understanding Blood Thru Thick and Thin*
3/22/99	University of Wisconsin Children's Hospital and Comprehensive Cancer Center	Madison, WI	*Rhabdomyosarcoma in the Biotech Century*
3/29/00	Surgical Conference	CCHMC	*Oncogenes*
5/11/00	National Cancer Institute Pediatric Oncology Branch (Invited Lecture)	Bethesda, MD	*Chromosomal Translocations and Transcriptional Targeting: Getting in ARMS Way*

6/14/00	Biocrystal, Ltd.	Wester-ville, OH	*Chromosomal Translocations and Transcriptional Targeting: Getting in ARMS Way*
8/1/00	Divisional Research Conference	CCHMC	*Chromosomal Translocations and Transcriptional Targeting: Getting in ARMS Way*
9/22/00	CCHMC Board of Trustees Scientific and Education Committee: Trustee Grant Presentation	CCHMC	*Adenovirus Oncolysis for Pediatric Alveolar Rhabdomyosarcoma*
1/13/01	Divisional Phase I Conference	CCHMC	----------*(b)(4)*----------
1/15/01	Division of Infectious Diseases (Invited Lecture)	CCHMC	----------*(b)(4)*----------
4/8/01	Divisional Research Conference	CCHMC	----------*(b)(4)*----------
1/30/02	Surgical Conference	CCHMC	*Overview of Cancer Biology*
(b)(4)	----------(b)(4)----------	(b)(4)	----------*(b)(4)*----------
4/30/02	Gene Therapy Working Group	CCHMC	----------*(b)(4)*----------
5/2/02	Memorial Sloan Kettering Cancer Center, Pediatric Grand Rounds	New York, NY	*Targeting Viruses to Pediatric Sarcomas*
5/31/02	Fellow Research Conference	CCHMC	*Rhabdomyosaracoma Xenografts*
9/3/02	Kishwaukee Community Hospital	DeKalb, IL	*Pediatric Oncology*
9/9/02	Children's Oncology Group, Soft Tissue Sarcoma Committee Meeting	Chicago, IL	----------*(b)(4)*----------
12/16/02	CCHMC Gene Therapy Retreat	Coving-ton, KY	----------*(b)(4)*----------
2/20/03	Molecular Developmental Biology Graduate Program Orientation	CCHMC	*Oncolytic Viruses as Cancer Therapeutics*
7/11/03	Tumor Biology Nidus Group	CCHMC	----------*(b)(4)*----------
12/12/03	Divisional Resaerch Conference (Floor Meeting)	CCHMC	----------*(b)(4)*----------

12/12/03	Divisional Phase I Conference	CCHMC	----------(b)(4)----------
1/16/04	Tumor Board	CCHMC	*Extremity Rhabdomyosacoma in Children: Prognostic Factors*
2/24/04	St. Jude Children's Research Hospital (Invited Lecture)	Memphis, TN	*Oncolytic Virus Therapy for Cancer: Fad or Foothold?*
3/17/04	Fellows Didactic Lecture	CCHMC	*Soft Tissue Sarcomas in Children*
3/26/04	International Symposium on Rare Lung Diseases	Cincinnati, OH	*Creating a Global PAP Registry*
3/30/04	Translational Research Trials Office Symposium	CCHMC	*Translational Research Trials Office*
4/18/04	MD Anderson Cancer Center Grand Rounds	Houson, TX	*Oncolytic Virus Therapy for Cancer: Fad or Foothold?*
4/26/04	High School Student Research Symposium	CCHMC	*Introduction to Translational Research: The Petri-Patient Cycle*
5/7/04	Department Faculty Meeting	CCHMC	*Translational Research Initiative Grants Program Update 2004*
6/18/04	Children's Oncology Group, Soft Tissue Sarcoma Committee Meeting	Chicago, IL	----------(b)(4)----------
6/25/04	Physician Scientist Training Program (Invited Lecture)	U of Cincinnati	*Introduction to Translational Research: Opening the Valves of the Pharmaceutical Pipeline*
7/8/04	Parent Project Muscular Dystrophy Annual Meeting	Cincinnati, OH	*Introduction to Clinical Trials*
7/9/04	Tumor Board	CCHMC	*BEACOPP in Advanced Stage Hodgkin's Disease*
7/19/04	External Advisory Committee	CCHMC	*UC Cancer Center/Tumor Biology/Tumor Models Subgroup*
7/21/04	External Advisory Committee	CCHMC	*Translational Research Trials Office*
9/8/04	Residents Research Conference	CCHMC	*Oncolytic Virus Therapy for Cancer: Fad or Foothold*
9/12/04	Divisional Research Conference (Floor Meeting)	CCHMC	*Utility of Oncolytic Viruses (Ovs) for Cancer*
9/14/04	Ohio State University Comprehensive Cancer Center Pediatric Oncology Program Retreat	Columbus, OH	----------(b)(4)----------
10/4/04	Fellows Didactic Lecture	CCHMC	*Cancer Immunotherapy and Biologic Response Modifiers*
10/27/04	Fellows Didactic Lecture	CCHMC	*Gene & Viral Therapy of Cancer*

10/28/04	American Society of Pediatric Hematology/Oncology Board Review Course	Chicago, IL	*Oncology Images*
11/15/04	Fellows Didactic Lecture	CCHMC	*Pediatric Malignant Bone Tumors: Osteosarcoma*
1/8/05	Divisional Research Conference	CCHMC	*Pegylated Liposomal Doxorubicin*
1/21/05	Fellow Lecture: DataBlitz	CCHMC	*Oncolytic Virus Therapy for Cancer: Basic & Translational Research*
2/23/05	BioCEO & Investor Conference	New York, NY	----------*(b)(4)*----------
3/2/05	Divisional Translational Research Conference: Clinical Development Plan	CCHMC	*Safety Studies of -(b)(4)-*
4/4/05	Divisional Research Conference (Floor Meeting)	CCHMC	----------*(b)(4)*----------
5/16/05	WRHR Scholars and Directors Meeting	CCHMC	*Translational Research at Academic Health Centers: Promises and Perils*
5/23/05	Fellow Lecture: DataBlitz	CCHMC	*Oncolytic Virus Therapy for Cancer*
5/23/05	Immunohematology Seminar Series	CCHMC	*Oncolytic Virus Therapy for Cancer: Can One Scourge Cure Another?*
6/21/05	Division of Pediatric Hematology/Oncology (Invited Lecture)	CCHMC	*Chromosomal Translocations and Transcriptional Targeting: Getting in ARMS Way*
6/25/05	Divisional Research Conference	CCHMC	*Translational Research Initiative: Summary*
6/26/05	American Society of Pediatric Hematology/Oncology and Pediatric Academic Societies Annual Meeting	San Francisco, CA	*Exploiting Genetic Defects for Targeting Oncolytic Viruses to Pediatric Cancers*
6/26/05	American Society of Pediatric Hematology/Oncology and Pediatric Academic Societies Annual Meeting	San Francisco, CA	*Introduction to Translational Research: Opening the Valves of the Pharmaceutical Pipeline*
6/30/05	Columbus Children's Hospital (Invited Lecture)	Columbus, OH	*Oncolytic Virus Therapy for Cancer: Can One Scourge Cure Another?*
7/1/05	Columbus Children's Hospital (Invited Lecture)	Columbus, OH	*Translational Research at Academic Health Centers: Promises and Perils*
9/6/05	Fellows Didactic Lecture	CCHMC	*Ewing's Sarcoma Family of Tumors (ESFTs)*
10/10/05	Fellow Research Conference	CCHMC	*Oncolytic Virus Therapy for Cancer: Can One Scourge Cure Another?*

10/10/05	Fellow Research Conference	CCHMC	*Gene Therapy of Cancer*
1/18/06	Fellow Lecture: DataBlitz	CCHMC	*Targeted Experimental Therapeutics for Pediatric Solid Tumors: Basic & Translational Research*
3/31/06	Tumor Biology Nidus Group	CCHMC	*Targeted Experimental Therapeutics for Pediatric Solid Tumors: Basic and Translational Research*
5/4/06	Ohio State University Comprehensive Cancer Center Pediatric Oncology Program Retreat	Wilmington, OH	*Targeted Experimental Therapeutics for Pediatric Solid Tumors: Basic, Translational, and Clinical Research*
5/16/06	Interlab Orientation	CCHMC	*Targeted Experimental Therapeutics for Pediatric Solid Tumors: Basic, Translational, and Clinical Research*
10/5/06	Faculty Crosstalk	CCHMC	*Promises and Perils of Translational Research at Academic Health Centers: The CCHMC Model*
10/16/06	Fellows Didactic Lecture	CCHMC	*Soft Tissue Sarcomas in Children*
11/18/06	CCHMC Board of Trustees Scientific and Education Committee	CCHMC	*Promises and Perils of Translational Research at Academic Health Centers: The CCHMC Model*
12/21/06	Report to the Cancer Committee	CCHMC	*Musculoskeletal Tumor Center: Clinical Database: "Sarcobase"*
3/14/07	4th International Conference on Virus Therapy for Cancer	Phoenix, AZ	*Oncolytic HSV Replication in Explant Tissue Cores Correlates With In Vivo Tumor Response in Xenograft Cancer Models*
3/16/07	Divisional Scientific Advisory Committee External Review	CCHMC	*TRTO: An Institutional Core Created by the Divisions of Experimental Hematology and Hematology/Oncology*
5/9/07	Vascular Club	CCHMC	----------*(b)(4)*----------
6/21/07	Masters in Clinical Research Program Orientation	U of Cincinnati	*Masters in Clinical Research: The Translational Track*
8/9/07	Division Chiefs' Meeting	CCHMC	*Translational Research Initiative Grants Program 2008*
8/23/07	Fellow Lecture: DataBlitz	CCHMC	*Targeted Experimental Therapeutics for Pediatric Solid Tumors*
9/4/07	Departmental Faculty Meeting	CCHMC	*Translational Research Initiative Grants Program 2008*
9/24/07	2nd Annual Musculoskeletal Tumor Symposium: Osteosarcoma	CCHMC	*The Role of Intensified Adjuvant Therapy for Poor Histologic Response*

10/23/07	Vector Club	CCHMC	----------*(b)(4)*----------
10/25/07	Tumor Biology Nidus Group	CCHMC	----------*(b)(4)*----------
11/2/07	Van Andel Research Institute (Invited Lecture)	Grand Rapids, MI	----------*(b)(4)*----------
11/29/07	National Cancer Institute Pediatric Oncology Branch (Invited Lecture)	Bethesda, MD	*Excitements and Challenges of Identifying, Enhancing and Translating Targeted Biotherapeutics for Pediatric Cancers*
1/29/08	Children's Tumor Foundation Director's Meeting	Newark, NJ	*Neurofibromatosis Preclinical Consortium: Cincinnati Site*
2/5/08	Fellow Lecture: DataBlitz	CCHMC	*Targeted Experimental Therapeutics for Pediatric Solid Tumors*
3/6/08	Divisional Translational Research Retreat (Kingsgate Marriott)	Cincinnati, OH	*Can Oncolytic Viruses Be Used to Treat Metastatic Disease?*
3/7/08	Departmental Faculty Meeting	CCHMC	*Translational Research Initiative Grants Program 2008*
3/31/08	Immunohematology Seminar Series	CCHMC	*Cancer Virotherapy*
8/26/08	Grand Rounds, Arkansas Children's Hospital	Little Rock, AR	*Challenges and Opportunities of Pediatric Translational Research*
8/26/08	Noon Research Conference, Arkansas Children's Hospital Research Institute	Little Rock, AR	----------*(b)(4)*----------
9/04/08	Pediatric Oncology Program Retreat, Ohio State University Comprehensive Cancer Center	Roberts Convention Centre, Wilmington, OH	*Preclinical and Clinical Development of Oncolytic Virotherapy at CCHMC*
9/12/08	HSV Symposium	CCHMC	----------*(b)(4)*----------
12/10/08	Retinoblastoma Symposium	CCHMC	*Cell Culture and Xenograft Core*
12/11/08	Retinoblastoma Symposium	CCHMC	*Oncolytic Viral Therapy*
2/17/09	Pediatric Hematology-Oncology Grand Rounds	Children's Medical Center, Dallas,	*Oncolytic Virotherapy for Pediatric Cancers*

EXHIBIT 17

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

CURRICULUM VITAE January 2014

NAME: JOHN BRADLEY HOLCOMB, M.D., F.A.C.S.

PRESENT TITLE:

Director, Center for Translational Injury Research
Chief, Division of Acute Care Surgery
Professor of Surgery
Vice Chair, Department of Surgery
Jack H. Mayfield, M.D. Chair in Surgery

ADDRESS:

The University of Texas Medical School at Houston
Department of Surgery
6431 Fannin, Room 4.170
Houston TX, 77030
Telephone: 713.500.7218
Fax: 713.500.7213
Email: John.Holcomb@uth.tmc.edu

CITIZENSHIP: (b)(6)

UNDERGRADUATE EDUCATION:

1977-1981 B.S., Biology with Honors, *Cum Laude*, Centenary College, Shreveport, LA

GRADUATE EDUCATION:

1981-1985 M.D., University of Arkansas Medical School, Little Rock, AR

POST-GRADUATE TRAINING:

1985-1986 General Surgery Intern,
William Beaumont Army Medical Center, El Paso, TX
1987-1991 General Surgery Resident,
William Beaumont Army Medical Center, El Paso, TX
2001-2002 Surgical Critical Care Fellow,
The University of Texas Medical School at Houston, Houston, TX

PAST GRANT SUPPORT:

Laparoscopic Hernia Repair with (b)(4) Mesh™
Principle Investigator 1995-96
Atrium Medical (b)(4)(b)(6)

Dry Fibrin Sealant Dressing for Hemorrhage Control after a Ballistic Injury
Principle Investigator 1995-96
Special forces Operational Detachment - Delta $5,000

Development and Testing of the ------(b)(4)----------
Principal Investigator 1996-97
American Red Cross (b)(4)(b)(6)

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1996-97
Joint Special Operations Command $25,000

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1996-97
USA Medical Research and Material Command $50,000

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1996-97
USA Medical Research and Material Command $94,000

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1996-97
USA Medical Research and Material Command $100,000

Optimal Device for Treating Tension Pneumothorax by Combat Medics
Principal Investigator 1997-98
Marine Corps Combat Development Command $75,000

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1997-98
USA Special Operations Command $182,000

Development of Testing of a Hemostatic Foam for Hemorrhage Control from Non-compressible Hemorrhage
Principal Investigator 1997-99
USA Special Operations Command $186,000

Evaluation of ----(b)(4)------ for Hemorrhage Control in a Simulated Land Mine Injury
Co-Principal Investigator 1999-2000
American Red Cross (b)(4)(b)(6)

PAST GRANT SUPPORT (CONTINUED):

Continuous Physiologic Data Acquisition and Analysis Across the Trauma Spectrum
Principal Investigator 2000-01
US ARMY MRMC $50,000

Continuous Physiologic Data Analysis after Trauma
Principal Investigator 2001-02
US Army MRMC $140,000

Continuous Physiologic Data Analysis after Trauma
Principal Investigator 2001-02
DARPA $200,000

Reducing Mortality from Acute Hemorrhage in Trauma
Consultant 2002-07
Clinical Research Center Grant (National Transfusion Medicine) (b)(4)(b)(6)

TexSHIELD
Co-Investigator 2007-10
US Department of Defense/TATRC $808,111

Prospective Evaluation of ---(b)(4)--- EMS Ultrasound
Principal Investigator 2009-10
Sonosite, Inc. (b)(4)(b)(6)

Pathogenesis of Multiple Organ Failure
Principle Investigator 2010-11
National Institutes of Health/NIGMS $162,474/yr
5P50GM038529

Accelerating Early Weight Bearing Segmental Bone Regeneration
Co-Investigator 2010-11
Extremity War Trauma Research Foundation (b)(4)(b)(6)

ABThera Open Abdomen Negative Pressure Therapy Sys/Barker's Vacuum-Packing Technique
Principal Investigator 2010-12
KCI, Inc (b)(4)(b)(6)

Multicenter study evaluating the use of rapid TEG
Co-Investigator 2010-11
Haemonetics, Inc. (b)(4)(b)(6)

Timing and Mechanism of Traumatic Coagulopathy
Co-Investigator 2011-2012
National Trauma Institute (b)(4)(b)(6)

CURRICULUM VITAE

NAME: JOHN BRADLEY HOLCOMB, M.D., F.A.C.S.

PRESENT TITLE:
Director, Center for Translational Injury Research
Chief, Division of Acute Care Surgery
Professor of Surgery
Vice Chair, Department of Surgery
Jack H. Mayfield, M.D. Chair in Surgery

ADDRESS:
TheUniversity of Texas Medical School at Houston
Department of Surgery
6431 Fannin, Room 4.170
Houston TX, 77030
Telephone: 713.500.7218
Fax: 713.500.7213
Email: John.Holcomb@uth.tmc.edu

BIRTHDATE: [redacted]

Redacted to comply with LCvR 5.4(f); not redacted on original

CITIZENSHIP: U.S.A.

SECURITY CLEARANCE: Top Secret

UNDERGRADUATE EDUCATION:

1977-1981 B.S., Biology with Honors, *Cum Laude*, Centenary College, Shreveport, LA

GRADUATE EDUCATION:

1981-1985 M.D., University of Arkansas Medical School, Little Rock, AR

POST-GRADUATE TRAINING:

1985-1986 General Surgery Intern,
William Beaumont Army Medical Center, El Paso, TX

1987-1991 General Surgery Resident,
William Beaumont Army Medical Center, El Paso, TX

2001-2002 Surgical Critical Care Fellow,
The University of Texas Medical School at Houston, Houston, TX

CURRENT GRANT SUPPORT (CONTINUED):

Treatment of Adult Severe Traumatic Brain Injury Using Autologous Bone Marrow Mononuclear Cells
Co-Investigator 2011-2014
US Department of Defense/AFIRM $1,722,975

Evaluation of Lyphilized Plasma (LP) in Models of Vascular Injury and Hemorrhagic Shock
Co-Investigator 2011-13
US Department of Defense $1,500,000

PAST GRANT SUPPORT:

Laparoscopic Hernia Repair with Atrium Mesh™
Principle Investigator 1995-96
Atrium Medical $5,000

Dry Fibrin Sealant Dressing for Hemorrhage Control after a Ballistic Injury
Principle Investigator 1995-96
Special forces Operational Detachment - Delta $5,000

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1996-97
American Red Cross $50,000

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1996-97
Joint Special Operations Command $25,000

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1996-97
USA Medical Research and Material Command $50,000

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1996-97
USA Medical Research and Material Command $94,000

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1996-97
USA Medical Research and Material Command $100,000

Optimal Device for Treating Tension Pneumothorax by Combat Medics
Principal Investigator 1997-98
Marine Corps Combat Development Command $75,000

Development and Testing of the Dry Fibrin Sealant Dressing
Principal Investigator 1997-98
USA Special Operations Command $182,000

PAST GRANT SUPPORT (CONTINUED):

Development of Testing of a Hemostatic Foam for Hemorrhage Control from Non-compressible Hemorrhage
Principal Investigator 1997-99
USA Special Operations Command $186,000

Evaluation of Fibrin Dressings for Hemorrhage Control in a Simulated Land Mine Injury
Co-Principal Investigator 1999-2000
American Red Cross $100,000

Continuous Physiologic Data Acquisition and Analysis Across the Trauma Spectrum
Principal Investigator 2000-01
US ARMY MRMC $50,000

Continuous Physiologic Data Analysis after Trauma
Principal Investigator 2001-02
US Army MRMC $140,000

Continuous Physiologic Data Analysis after Trauma
Principal Investigator 2001-02
DARPA $200,000

Reducing Mortality from Acute Hemorrhage in Trauma
Consultant 2002-07
Clinical Research Center Grant (National Transfusion Medicine) $1,490,000

TexSHIELD
Co-Investigator 2007-10
US Department of Defense/TATRC $808,111

Prospective Multicenter Transfusion Study in Trauma Patients
Co-Investigator 2008-10
US Department of Defense/MRMC $9,200,000

Prospective Evaluation of Aeromedial EMS Ultrasound
Principal Investigator 2009-10
Sonosite, Inc. $100,000

Pathogenesis of Multiple Organ Failure
Principle Investigator 2010-11
National Institutes of Health/NIGMS $162,474/yr
5P50GM038529

Accelerating Early Weight Bearing Segmental Bone Regeneration
Co-Investigator 2010-11
Extremity War Trauma Research Foundation $67,500

PAST GRANT SUPPORT (CONTINUED):

ABThera Open Abdomen Negative Pressure Therapy Sys/Barker's Vacuum-Packing Technique
Principal Investigator 2010-12
KCI, Inc $255,000

Multicenter study evaluating the use of rapid TEG
Co-Investigator 2010-11
Haemonetics, Inc. $560,000

Timing and Mechanism of Traumatic Coagulopathy
Co-Investigator 2011-2012
National Trauma Institute $8,613

Characterization and Application of a Large Model of Penetrating Ballistic Brain Injury
Co-Investigator 2011-12
US Department of Defense $1,019,999

Comparative Effectiveness of Clinical Care Processes in Resuscitation and Management of Moderate to Severe Traumatic Injuries
Co-Investigator 2010-2012
National Trauma Institute $62,222

Validation of the Athena Wireless Vital Signs Monitor
Principal Investigator 2009-12
National Trauma Institute $220,000

PUBLICATIONS:

1. Geer D, Arnaud G, Beitler A, **Holcomb JB**, et al. Colonic Volvulus. The Army Medical Center Experience 1983-1987. Am J Surg. 1991 May;57(5):295-300. PMID: 2039127.

2. Hetz SP, **Holcomb JB**. Combined Laparoscopic Exploration and Repair of Inguinal Hernias. J Am Coll Surg. 1996 Apr:364-366. PMID: 8605561.

3. **Holcomb JB**, Pusateri AE, Hetz SP, Harris RA, Hess JR, MacPhee MJ, Tock BB, Drohan WN. Implications of New Fibrin Sealant Technology for Trauma Surgery. Surg Clin North Am. 1997 Aug;77(4):943-52. PMID: 9291993.

4. **Holcomb JB**, Pusateri A, MacPhee M, Hess J. New Technologies in Hemorrhage Control. Curr Opin Crit Care. 1997;3:488-93.

5. **Holcomb JB**, MacPhee M, Hetz S, et al. Efficacy of a Dry Fibrin Sealant Dressing for Hemorrhage Control after a Ballistic Injury. Arch Surg. 1998 Jan;133(1):32-35. PMID: 9438755.

EXHIBIT 18

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

CURRICULUM VITÎ

Part I. General Information

Date Prepared: **7/1/14**

Name: Harold J. Burstein, M.D., Ph.D.

Office Address: Dana-Farber Cancer Institute
450 Brookline Avenue, Boston, MA 02215
Telephone (direct) 617 632 2624
Telephone (clinic) 617 632 3495

Home Address: (b) (6)

E-Mail: hburstein@partners.org **FAX**: 617 632 1930

Place of Birth: (b) (6)

Education:

1986	A.B.	Harvard College, Cambridge, MA (biochemical sciences)
1994	M.D.	Harvard Medical School, Harvard-MIT Division of Health Sciences & Technology, Boston, MA
1994	Ph.D.	Harvard University, Division of Medical Sciences/Committee on Immunology, Cambridge and Boston, MA
1994	A.M.	Harvard University, Department of the History of Science, Cambridge, MA (history of medicine and biomedical research in the 19th and 20th century)

Postdoctoral Training:

7/1994-6/2000	Clinical Fellow in Medicine, Harvard Medical School, Boston, MA
7/1994-6/1995	Intern in Medicine, Massachusetts General Hospital, Boston, MA
7/1995-6/1996	Junior Assistant Resident in Medicine, Massachusetts General Hospital
7/1996-6/2000	Fellow, Adult Oncology, Dana-Farber Cancer Institute, Boston, MA

Licensure and Certification:

1995	Massachusetts License
1997-2007	American Board of Internal Medicine Certificate
2001-2020	American Board of Internal Medicine, Medical Oncology Certificate

Academic Appointments:

7/1999-6/2002	Instructor in Medicine, Harvard Medical School
7/2002-3/2008	Assistant Professor of Medicine, Harvard Medical School
4/2008-present	Associate Professor of Medicine, Harvard Medical School

Hospital Appointments:

7/1999-present	Medical Staff, Dana-Farber Cancer Institute
7/1999-present	Associate Physician, Brigham & Women's Hospital

1999-present	Journal of Women's Health
1999	The Prostate Journal
2000-present	Psycho-Oncology
2001-present	The Oncologist
2002-present	Nature Reviews Clinical Practice
2003-present	Lancet Oncology
2005-present	Journal of Oncology Practice
2008-present	Lancet

Awards and Honors:

1986	Phi Beta Kappa (Harvard College, Alpha of Massachusetts Chapter); *magna cum laude*
1986-94	Medical Scientist Training Program (MSTP), Harvard Medical School
1988	Harvard Medical Alumni Association Essay Prize
1990	Bowdoin Prize, Harvard University (graduate essays in natural science)
1994	National Institute of Diabetes and Digestive and Kidney Diseases Award for Most Outstanding Medical Students, National Institutes of Health
1998	Merit Award, American Society of Clinical Oncology
2000	Breast Cancer Scholar, Commonwealth of Massachusetts
2000	Dunkin' Donuts Developing Clinical Investigator, Dana-Farber Cancer Institute
2001	George P. Canellos Award for Excellence in Clinical Investigation and Patient Care, Dana-Farber Cancer Institute
2002	Dunkin' Donuts Rising Stars Clinical Investigator, Dana-Farber Cancer Institute
2008	Ellen and Stephen Fine Award for Outstanding Medical Oncology Teaching in Cancer Medicine, Dana-Farber Cancer Institute
2012	Fellow, American Society of Clinical Oncology
2014	Clinical Mentor Award, Dana-Farber Cancer Institute

Part II. Research, Teaching, and Clinical Contributions

A. Narrative Report.

1. Clinical Contributions.

I am a breast cancer specialist in the breast oncology center at Dana-Farber and maintain a busy medical oncology practice in our group. My clinical activities include assessment and treatment of patients with pre-invasive tumors, and early and advanced stage invasive breast cancer. I have developed an international reputation as an expert clinician in breast cancer medicine, and routinely see direct referrals of particularly challenging cases from around the US, as well as international patients. I provide primary oncology care to breast cancer patients from throughout New England.

I provide 4 weeks of inpatient service work on the women's cancers inpatient service at BWH each year.

I am routinely listed as a "top doctor" by US News and World Report, Boston Magazine, Castle Connolly, and other similar rating organizations.

2. Research.

I am a clinical investigator with particular interest in the development and analysis of clinical treatment trials for early and late stage breast cancer. I have served as principal investigator a variety of phase I, II, and III trials, as well as pilot studies conducted at DFCI and in collaboration with other cancer research centers and cooperative groups.

These trials have garnered international attention and recognition. The work is particularly known for developing vinorelbine plus trastuzumab, now a widely used treatment combination for advanced breast

cancer; for the first published reports on the efficacy of neoadjuvant trastuzumab, now established as a standard treatment; and for innovative uses of bevacizumab in breast cancer. I have been lead author or investigator for novel tyrosine kinases, chemotherapy regimens, and anti-angiogenic agents iin breast cancer, and linked these studies to valuable correlative endpoints.

I have been an active member of cooperative group research. I serve on the CALGB/Alliance breast cancer committee, and currently hold the U10 grant for cooperative group research at Dana-Farber / Harvard Cancer Care. We recently rewrote this grant to overhaul the cooperative group structures and integrate more fully the program with MGH and BWH.

In addition to this research as a clinical trialist, I have collaborated with the DFCI outcomes group on several projects related to health care and needs for breast cancer survivors, patterns of clinical care in breast cancer, and decision analyses on optimal use of endocrine therapy for breast cancer. This vein of research has been featured prominently in the international discourse on how best to use novel anti-estrogen therapies in early stage breast cancer.

3. Education.

I am a widely known educator and commentator in breast cancer medicine, and I have an active role in teaching at several levels at Harvard Medical School and DFHCC.

I have developed an international reputation as a breast cancer educator and commentator. I am frequently invited to speak at major international, national and regional breast cancer meetings including the annual ASCO meeting, the St. Gallen meeting, and innumerable national and regional symposia dedicated to cancer care. I have earned a distinguished reputation as a commentator on cancer therapy and have been invited to write several reviews and commentaries in major publications including the New England Journal of Medicine and the Journal of Clinical Oncology, as well as many other periodicals.

My educational contributions also include both new and old media formats, as I participate in a variety of telemedicine CME activities, audio programs, and web based educational efforts. With Gary Lyman, I am editor of the book Breast Cancer: Translational Therapeutic Strategies, published in 2007. I authored a short monograph, Targeted Therapy in Breast Cancer, published by Oxford University Press in 2011.

With colleagues from Massachusetts General Hospital and Dana-Farber, I co-chair our annual 3-day breast cancer CME program held in July in Boston. This multidisciplinary conference draws approximately 250 attendees per year, and has developed a following for its excellent, collaborative and interactive programming. With DFCI colleagues, I serve as the breast cancer track leader for our DFCI Master Class education programs, held around the U.S. and given 3-4 times per year. These are two-day seminars on oncology care, of which the breast cancer track is ½ day. These programs have garnered praise for their outstanding lectures and close faculty interaction.

I am a leader on the HMS Admissions Committee, serving as chair of subcommittee 2, and serving on the main admissions committee. The admissions work takes (b) (4) between September and March, time spent screening applications, interviewing applicants, running the subcommittee meetings, and participating in the subcommittee and main committee meeting work.

At Dana-Farber/Harvard Cancer Center, I have created and organized a novel educational program for senior fellows and junior faculty intent on careers in clinical investigation. This program consists of a weekly seminar led by experts in various aspects of clinical investigation, from principles of clinical trial design to translational oncology to the structures and organizations of clinical research. Faculty are drawn from across the Harvard teaching hospitals. The program attracts roughly 12 to 15 attendees per academic year, and has been recognized as a valuable contribution to the investigator training for our junior faculty/fellows.

SHORT BIO

Harold J. Burstein, M.D., Ph.D

1. Clinical Contributions.

I am a breast cancer specialist in the breast oncology center at Dana-Farber and maintain a busy medical oncology practice in our group. My clinical activities include assessment and treatment of patients with pre-invasive tumors, and early and advanced stage invasive cancer. I have developed an international reputation as an expert clinician in breast cancer medicine, and routinely see direct referrals of particularly challenging cases from around the US, as well as international patients. I provide primary oncology care to breast cancer patients from throughout New England.

2. Research.

I am a clinical investigator with particular interest in the development and analysis of clinical treatment trials for early and late stage breast cancer. I have been principal investigator a variety of phase II, phase III, and pilot studies conducted at DFCI and in collaboration with other cancer research centers and cooperative groups.

These trials have garnered international attention and recognition. The work is particularly known for developing vinorelbine plus trastuzumab, now a widely used treatment combination for advanced breast cancer; for the first published reports on the efficacy of neoadjuvant trastuzumab, now established as a standard treatment; and for innovative uses of bevacizumab in breast cancer.

In addition to this research as a clinical trialist, I have collaborated with the DFCI outcomes group on several projects related to health care and needs for breast cancer survivors, patterns of clinical care in breast cancer, and decision analyses on optimal use of endocrine therapy for breast cancer. This vein of research has been featured prominently in the international discourse on how best to use novel anti-estrogen therapies in early stage breast cancer.

3. Education.

I am a widely known educator and commentator in breast cancer medicine, and I have an active role in teaching at several levels at Harvard Medical School and DFHCC.

I have developed an international reputation as a breast cancer educator and commentator. I am frequently invited to speak at major international, national and regional breast cancer meetings including the annual ASCO meeting, the St. Gallen meeting, and innumerable national and regional symposia dedicated to cancer care. I have active roles on the two guideline panels that articulate the most widely followed breast cancer guidelines in the world – the National Comprehensive Cancer Network Breast Panel and the St. Gallen International Panel for Early Stage Breast Cancer. I have been a member of multiple expert working groups through ASCO and NCCN centering on a variety of aspects of cancer treatment. For the past several years, I have served as co-chair for the ASCO guideline on adjuvant endocrine therapy.

I have earned a distinguished reputation as a commentator on cancer therapy and have been invited to write several reviews and commentaries in major publications including the New England Journal of Medicine and the Journal of Clinical Oncology, as well as many other periodicals. I serve on the editorial boards of several oncology journals, and since 2008 have been editor-in-chief of the Journal of the National Comprehensive Cancer Network.

My educational contributions also include both new and old media formats, as I participate in a variety of telemedicine CME activities, audio programs, and web based educational efforts. With Gary Lyman, I am editor of the book Breast Cancer: Translational Therapeutic Strategies, published in 2007. I authored a short monograph, Targeted Therapy in Breast Cancer, to be published by Oxford University Press in 2011.

I am a leader on the HMS Admissions Committee, serving as chair of subcommittee 2, and serving on the main admissions committee. The admissions work takes 6+ hours per week between September and March, time spent screening applications, interviewing applicants, running the subcommittee meetings, and participating in the subcommittee and main committee meeting work.

At Dana-Farber, I have created and administered a novel educational program for senior fellows and junior faculty intent on careers in clinical investigation. This program consists of a weekly seminar led by experts in various aspects of clinical investigation, from principles of clinical trial design to translational oncology to the structures and organizations of clinical research.

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Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

MAY 2011

SCOTT P. BRUDER, MD, PhD

----------(b)(6)----------
PHONE -------(b)(6)------- • E-MAIL ----------(b)(6)----------

EXPERIENCE

2007 - Present **Becton, Dickinson & Company** **Franklin Lakes, NJ**

Senior Vice President and Chief Science and Technology Officer

As an Executive Officer of the Company, and Member of the Office of the CEO, this role provides technology, strategy and development leadership across all three Segments of Medical Devices, Diagnostics and Biosciences. The position is further responsible for identifying and cultivating new growth opportunities, leading the Corporate Research Center, and integrating Worldwide Research & Development, including allocation of a ~$(b)(4) million operating budget. Lastly, the role is accountable for enhancing the Company's ability to identify or create innovative solutions to address unmet healthcare needs and emerging life science research trends.

Accomplishments:

- Established the Company's first enterprise-wide portfolio management system based on optimization of financial metrics, resource allocation & strategic alignment criteria
- Instituted a global, stage-gate product development process to improve cycle time, reduce errors and rework, and facilitate efficient portfolio decision making
- Identified and implemented programs to drive innovation, fostering entry into several new business areas with revenue potential exceeding $1 billion annually
- Designed the integrated expansion of R&D in China, India and Singapore to address local needs and regional capabilities

2000 – 2007 **Johnson & Johnson** **Raynham, MA**

2005 – 2007 *Worldwide Vice President, Johnson & Johnson Regenerative Therapeutics, LLC*

Developed a J&J corporate-wide strategic plan, and successfully led the capitalization and management of a new business unit known as *Johnson & Johnson Regenerative Therapeutics, LLC.* Garnered J&J Board-level support to dedicate further resources to "Regenerative Medicine", including the staffing of a team of ~(b)(4) professionals. Reported to the Chief Science & Technology Officer, Medical Devices & Diagnostics.

Accomplishments:

- Created and executed business plans for product development across multiple J&J operating companies, including active programs in support of DePuy (Musculoskeletal), Ethicon (General Surgery, and Women's Health & Urology), Codman (Neurobiology) and Cordis (Cardiovascular)
- Commercialized numerous products whose revenues exceeded $700 million
- Established a track-record of cultivating talented, ingenious, productive and loyal personnel
- Managed the New Business Development, Clinical & Regulatory Affairs, Research & Feasibility, Process Development, Quality, Human Resources and Finance functions
- Identified and coordinated links with universities and other research institutions in areas such as combination products, biomaterials, cell therapy and tissue engineering

2003 – 2005 *Worldwide Vice President, DePuy Biologics*

2002 – 2003 *Worldwide Vice President, Orthobiologics, DePuy Spine, DePuy Orthopaedics/ACE, and Mitek*

2000 – 2002 *Vice President, Orthobiologics, DePuy Inc.*

Systematically created the musculoskeletal tissue regeneration (Orthobiologic) capabilities from conception to a (b)(4)-person, multi-disciplinary division within the DePuy franchise, eventually evolving into a separate organization known as DePuy Biologics (ultimately acquired by J&J Regenerative Therapeutics, LLC). Served as a member of multiple Johnson & Johnson Corporate Committees that establish policies and strategies related to Stem Cells, Tissue Engineering, Cell and Gene Therapy, and Drug-Device Combination Products. Assessed complementary & competitive technologies, built collaborative relationships with key universities, and coordinated & validated DePuy research in the area of Orthobiologics.

Accomplishments:

- Obtained FDA clearance for over (b)(4) "musculoskeletal tissue regeneration" products through successful in-licensing, co-development, or internal development programs, growing annual product sales from ----------(b)(4)----------
- Identified external partnership opportunities, conducted due diligence, and successfully negotiated terms and conditions for several Agreements including: 1) worldwide exclusive license of a bioactive molecule (rhGDF-5) from BioPharm GmbH; 2) acquisition of Orquest, Inc., a development stage orthobiologics company; 3) worldwide exclusive license of stem cell patents from the ---(b)(4)----------; 4) product marketing, distribution and co-development with -(b)(4)- Corp.; 5) product marketing, distribution and co-development with Harvest Technologies; 6) product marketing, distribution and co-development with LifeNet

1998 – 2000 **Anika Therapeutics, Inc** **Woburn, MA**

Vice President, Research & Development

Conceived and directed the overall strategic plan for the Company's Research and Development programs in "Tissue Repair, Protection and Healing", based on a hyaluronic acid biomaterial platform technology. Evaluated and organized relationships with academic and industrial partners, including new technology assessment and intellectual property. Reported to the Chief Executive Officer.

Accomplishments:

- Designed and executed a 385-subject, 23-center, pivotal clinical study contributing to the FDA approval of OrthoVisc™ (Hyaluronic acid viscosupplementation)
- Implemented all basic scientific, applied pre-clinical and product feasibility studies in implantable/injectable biomaterial development, dermal fillers, drug delivery, anti-adhesion, cartilage and bone repair, and osteoarthritis treatment

1994 – 1998 **Osiris Therapeutics, Inc** **Baltimore, MD**

1997 – 1998 *Director, Bone & Soft Tissue Regeneration*

1996 – 1997 *Director, Bone Regeneration*

1994 – 1996 *Senior Research Scientist & Manager, Bone Product Development*

Ensured comprehensive technology transfer from the founding academic laboratories at CWRU, to the Company (as its third employee). Translated the hypothetical tissue reparative applications of mesenchymal stem cells into reproducible therapies that effectively scaled up from rodents to large animals and ultimately humans.

Accomplishments:

- Designed and championed the fundamental technology shift from autologous to allogeneic cell therapy, including drafting and defense of landmark patents as primary inventor
- Constructed and implemented the Orthopaedic Division's programs in Bone, Tendon and Ligament Research and Development

FEBRUARY 2013

SCOTT P. BRUDER, MD, PhD

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PHYSICIAN-SCIENTIST EXECUTIVE

LEADERSHIP & PERSONAL PROFILE

Insightful and energetic healthcare leader with a 20-plus year history of bridging basic science, clinical medicine, and industrial development expertise to deliver innovative, commercially successful products that improve patients' lives around the world. Experience in medical devices, diagnostics, biotechnology, and life science research tools fortify an expansive analytical skill set for this resilient, poised and influential C-Suite executive. An award-winning scientist and clinician, equally comfortable in the laboratory, at the lectern, in the Boardroom or on Capitol Hill, he delivers impactful results by inspiring multi-disciplinary teams to be collaborative, rigorous and decisive. This seasoned Senior Executive, University Professor, and FDA Advisory Committee Member provides a unique bench-to-bedside perspective on unmet needs, development strategy and the path to commercialization. An avid long-distance runner, jazz pianist, devoted husband and dedicated father, his core beliefs are based on the principles of passion, commitment and discipline.

EXPERIENCE

2013 - Present **Stryker Corporation** **Mahwah, NJ**

Chief Medical & Scientific Officer

In this newly created role, the overarching responsibility is to manage the clinical and scientific efforts across the Corporation, including academic, industrial and governmental scientific partnerships to support product development and future growth. Additionally responsible to represent Stryker as the leading medical authority at regulatory agencies, scientific conferences, trade associations and various other entities as necessary. The role also leads company-wide efforts related to the innovation, evidence generation and intellectual property strategies. Stryker is one of the world's leading medical technology companies and offers a diverse array of innovative medical technologies, including reconstructive, medical and surgical, and neurotechnology and spine products to help people lead more active and satisfying lives.

2007 - 2012 **Becton, Dickinson & Company** **Franklin Lakes, NJ**

Senior Vice President and Chief Science & Technology Officer

This role provided technology, strategy and development leadership across the Corporation, including the Medical Device, Diagnostics and Bioscience businesses. Additionally responsible for identifying and cultivating new growth opportunities, leading the Corporate Research Center, and integrating Worldwide Research & Development, including allocation of a ~$500 million operating budget with almost 2,000 R&D associates. Altogether, the role was accountable for enhancing the Company's ability to identify or create innovative solutions to address unmet healthcare needs and emerging life science research trends.

Accomplishments:

- Identified and implemented programs to drive innovation, fostering entry into several new business areas, each with revenue potential exceeding $1 billion annually
- Established the Company's first enterprise-wide portfolio management system based on optimizing resource deployment, strategic alignment and financial returns
- Instituted a global, stage-gate product development process to improve cycle time, reduce errors and rework, and facilitate efficient portfolio decision making
- Designed and managed the charter and agenda of the new Science, Innovation and

Technology Committee of the Board of Directors

- Integrated the expansion of R&D in China, India and Singapore to address local needs and regional capabilities

2000 – 2007 **Johnson & Johnson** **Raynham, MA**

2005 – 2007 *Worldwide Vice President, Johnson & Johnson Regenerative Therapeutics, LLC*

Developed a J&J corporate-wide strategic plan, garnered Board-level support for incremental investment, and successfully led the capitalization and management of a new Business Unit known as *Johnson & Johnson Regenerative Therapeutics, LLC.*

Accomplishments:

- Managed the New Business Development, Clinical & Regulatory Affairs, Research & Feasibility, Process Development, Quality, Human Resources and Finance functions
- Created and executed business plans for product development across multiple J&J operating companies, including dynamic programs in support of DePuy (Musculoskeletal), Ethicon (General Surgery, and Women's Health & Urology), Codman (Neurobiology) and Cordis (Cardiovascular)
- Established a track-record of identifying, developing and exporting talented, ingenious, productive and loyal personnel to Business Units throughout J&J

2003 – 2005 *Worldwide Vice President, DePuy Biologics*

2002 – 2003 *Worldwide Vice President, Orthobiologics, DePuy Spine, DePuy Orthopaedics/ACE, and Mitek*

2000 – 2002 *Vice President, Orthobiologics, DePuy Inc.*

Systematically created the musculoskeletal tissue regeneration (Orthobiologic) capabilities from conception to a multi-disciplinary team within the DePuy franchise, eventually evolving into a separate Division known as DePuy Biologics. Led, or served on, multiple J&J Corporate Committees to establish policies and strategies related to Stem Cells, Tissue Engineering, Cell and Gene Therapy, and Drug-Device Combination Products.

Accomplishments:

- Obtained FDA clearance for over 10 "musculoskeletal tissue regeneration" products through successful in-licensing, co-development, or internal development programs, growing annual product sales from $10 million to over $100 million
- Identified external partnership opportunities, conducted due diligence, and successfully negotiated terms and conditions for acquisition of, or licenses from, BioPharm GmbH, Orquest, Inc., Cleveland Clinic Foundation, ETEX Corp., Harvest Technologies, and LifeNet

1998 – 2000 **Anika Therapeutics, Inc** **Woburn, MA**

Vice President, Research & Development

Conceived and directed the overall strategic plan for the Company's Research and Development programs in "Tissue Repair, Protection and Healing", based on a hyaluronic acid biomaterial platform technology. Evaluated and organized relationships with academic and industrial partners, including new technology assessment and IP.

Accomplishments:

- Implemented all basic scientific, pre-clinical, product feasibility and human clinical studies in implantable/injectable biomaterial development, dermal fillers, drug delivery, anti-adhesion, cartilage and bone repair, and osteoarthritis treatment

1994 – 1998 **Osiris Therapeutics, Inc** **Baltimore, MD**

1997 – 1998 *Director, Bone & Soft Tissue Regeneration*

1994 – 1996 *Senior Research Scientist & Manager, Bone Product Development*

Ensured comprehensive technology transfer from the founding academic laboratories at

EXHIBIT 20

Declaration of Rachel Clattenburg
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REGENERON

CURRICULUM VITAE

Ned S. Braunstein, MD
Vice President and Head, Regulatory Affairs

INDUSTRY EXPERIENCE

2009 – Present **Regeneron Pharmaceuticals, Inc., Tarrytown, NY**

2009 – 2012 Executive Director and Head, Regulatory Affairs

2013 - Present VP and Head, Regulatory Affairs

- Manage and Lead the Regulatory Development Department
  - Grow department and establish sub-departments with expertise in Regulatory affairs, Regulatory operations and coordination, labeling, Regulatory CMC, Regulatory intelligence, and Promotions
- Lead the development and implementation of regulatory strategy consistent with business objectives
- Ensure compliance with regulations worldwide pertaining to the conduct of clinical studies and the maintenance of marketing licensure

Notable accomplishments to date:

- Growth of department from (b) (4) to (b) (4) individuals
- FDA approval of EYLEA worldwide
- FDA advisory committee presenter for EYLEA (safety presentation); (b) (4) (clinical and regulatory presentation); ARCALYST for gout (safety presentation)

2006 - 2009 **Merck & Co., Inc.**

Executive Director, Global Human Health

- Development of web-based solutions to provide scientific information to external advisors to scientific teams

1999 - 2006 **Merck & Co., Inc. (Merck Research Labs)**

Senior Director and Director, Alternating responsibilities in Global Regulatory Affairs and Clinical Research

- 1999 – 2004 Direct line reporting: Regulatory affairs; Dotted line: Clinical Research.
- 2004 – 2006 Direct line reporting: President, Merck Research Labs; responsibilities

Senior Director

Product team leader for Vioxx (pre-withdrawal)

Merck Research Labs point person to work with FDA on VIOXX withdrawal

Led special projects team reporting to president of Merck Research Labs

Management of FDA liaisons for specific products (anti-inflammatory/pain/immunology, bone/osteoporosis, oncology)

Director

FDA liaison for specific products (anti-inflammatory/pain/immunology)

Member: Immunology Review and Licensing Committee

Medical review of promotional material for specific products

Author and/or review regulatory documents and product labeling

EXHIBIT 21

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

CURRICULUM VITAE

Brian S. Appleby, M.D. September 8, 2011

DEMOGRAPHIC AND PERSONAL INFORMATION

Current Appointments

Active Staff, Lou Ruvo Center for Brain Health, Neurological Institute, Cleveland Clinic
Active Staff, Department of Psychiatry and Psychology, Neurological Institute, Cleveland Clinic

Personal Data

Cleveland Clinic
Lou Ruvo Center for Brain Health
9500 Euclid Avenue/U10
Cleveland, Ohio 44195
Phone: 216-445-7132
Email: APPLEBB@ccf.org

EDUCATION AND TRAINING

1999, B.A., Goucher College, Majors: Biology and Philosophy
2003, M.D., Georgetown University School of Medicine
2004, Internship, Georgetown University School of Medicine, Psychiatry
2007, Residency, The Johns Hopkins Hospital, Psychiatry
2008, Fellowship, The Johns Hopkins Hospital, Geriatric Psychiatry

PROFESSIONAL EXPERIENCE

7/2008-6/2011, Assistant Professor, Johns Hopkins University School of Medicine
7/2008-6/2011, Active Staff, The Johns Hopkins Hospital
7/2011-present, Active Staff, Lou Ruvo Center for Brain Health, Neurological Institute, Cleveland Clinic
7/2011-present, Active Staff, Department of Psychiatry and Psychology, Neurological Institute, Cleveland Clinic

RESEARCH ACTIVITIES

Publications

1. Hall RC, **Appleby BS**, Hall RC. Atypical Neuroleptic Malignant Syndrome Presenting as Fever of Unknown Origin in the Elderly. *South Med J* 2005; 98 (1):114-117.
2. **Appleby BS**, Wise TN, Isaac A. A Case of Refractoriness to Lithium Therapy Following Its Discontinuation in a Previously Responsive Patient. *Harvard Rev Psychiatry* 2006; 14 (6):330-332.

3. **Appleby BS**, Roy P, Valenti A, Lee HB. Diagnosis and Treatment of Depression in Alzheimer's Disease: Impact on Mood and Cognition. *Panminerva Med* 2007; 49(3):139-150.
4. **Appleby BS**. Are Anti-Nuclear Antibodies Common in Affective Disorders? A Review of the Past Thirty-Five Years. *Psychosomatics* 2007; 48 (4):286-289.
5. **Appleby BS**, Duggan PS, Regenberg A, Rabins PV. Psychiatric and Neuropsychiatric Adverse Events Associated with Deep Brain Stimulation: A Meta-Analysis of Ten Years' Experience. *Mov Disord* 2007; 22(12):1722-1728.
6. Lee HB, Hanner J, Yokley J, **Appleby BS**, Hurowitz L, Lyketsos CG. Clozapine for Treatment Resistant Agitation in Dementia. *J Geriatr Psychiatry Neurol* 2007; 20:178-182.
7. **Appleby BS**, Appleby KK, Rabins PV. Does the Presentation of Creutzfeldt-Jakob Disease Vary by Age or Presumed Etiology? A Meta-Analysis of the Past Ten Years. *J Neuropsychiatry Clin Neurosci* 2007; 19(4):428-435.
8. **Appleby BS**. Trace and Transference: Therapy in a Post-Structuralist Era. *Am J Psychother* 2008; 62(2):103-115.
9. **Appleby BS**, Appleby KK, Rabins PV. Predictors of Depression and Anxiety in Patients with Intracranial Neoplasms. *J Neuropsychiatry Clin Neurosci* 2008; 20(4):447-449.
10. **Appleby BS**, Appleby KK, Crain BJ, Onyike CU, Wallin MT, Rabins PV. Characteristics of Established and Proposed Sporadic Creutzfeldt-Jakob Disease Variants. *Arch Neurol* 2009; 66(2):208-215.
11. Bahroo LB & **Appleby BS**. Behind the Masked Face: Depression and Parkinson's Disease. *Minerva Psichiatr* 2009;50:45-53. (Invited Review)
12. Rabins PV, **Appleby BS**, Brandt J, DeLong MR, Dunn LB, Gabriels L, Greenberg BD, Haber SN, Holtzheimer PE, Mari Z, Mayberg HS, McCann E, Mink SP, Rasmussen S, Schlaepfer TE, Vawter DE, Vitek JL, Walkup J, Matthews DJH. Scientific and Ethical Issues Related to Deep Brain Stimulation for Disorders of Mood, Behavior, and Thought. *Arch Gen Psychiatry* 2009; 66(9):931-937.
13. **Appleby BS**. Psychotropics and the Treatment of Human Prion Diseases. *CNS Neurol Disord Drug Targets* 2009; 8:353-362.
14. **Appleby BS**, Appleby KK, Hall RCW, Wallin MT. D178N-129Val and N171S-129Val Genotype in a Family with Creutzfeldt-Jakob Disease. *Dement Geriatr Cogn Disord* 2010; 30(5):424-431.
15. **Appleby BS** & Lyketsos CG. Rapidly Progressive Dementias and the Treatment of Human Prion Diseases. *Expert Opin Pharmacother* 2011; 12(1):1-12.
16. ----------(b)(4)----------[In Press].

Extramural Funding Activities

1. 07/01/2007-06/30/2008
   Longitudinal Study of Alzheimer's Disease and Other Memory Impairing Disorders
   P50-AG005146-249001
   NIA

Principal Investigator: Constantine Lyketsos, M.D., M.H.S.
Role: Co-Investigator
Notes: This is a longitudinal study of memory disorders that examines characteristics and neuropathology of patients with Alzheimer's disease and related dementias.

2. 11/27/2007-06/07/2011
   Prospective, Randomized, Multi-Center, Double-Blind, 26 Week, Placebo Controlled Trial of Memantine (10mg BID) for the Frontal and Temporal Subtypes of Frontotemporal Dementia
   Forrest Research Institute
   Total Direct Cost: ----(b)(4)(b)(6)----
   Principle Investigator ----------(b)(4)(b)(6)----------
   Principal Investigators: ----------(b)(4)(b)(6)----------
   Role: Co-Investigator, 0.24 Calendar
   Notes: This is a phase IV prospective, randomized, multi-center, double-blind, placebo-controlled trial of the effect of memantine on the rate of behavioral decline in frontotemporal dementia.

3. 07/01/2008-06/30/2010
   Loan Repayment Program
   NIH
   Total Direct Cost: $70, 000.00
   Principal Investigator: Brian S. Appleby, M.D.
   Role: Principle Investigator, 6 Calendar
   Notes: The NIH LRP contributes up to $35,000/year towards loan repayment for investigators who devout at least 50% of their time to clinical research. My project proposal was the characterization of sporadic Creutzfeldt-Jakob disease phenotypes.

4. 07/01/2010-06/07/2011
   Loan Repayment Program
   NIA
   Total Direct Cost: $35,000.00
   Principal Investigator: Brian S. Appleby, M.D.
   Role: Principle Investigator, 6 Calendar
   Notes: The NIH LRP contributes up to $35,000/year towards loan repayment for investigators who devout at least 50% of their time to clinical research. The renewal project proposal was determining the biological determinants and epidemiological risk factors of sporadic Creutzfeldt-Jakob disease variants.

Research Program Building/Leadership
7/2008-6/2011; Johns Hopkins Creutzfeldt-Jakob Disease Program, Director
7/2011-Present; Cleveland Clinic Creutzfeldt-Jakob Disease Program, Director

EDUCATIONAL ACTIVITIES

Curriculum Vitae

Gary A. Giovino

January 2015

Work Address: Department of Community Health and Health Behavior
School of Public Health and Health Professions
University at Buffalo
State University of New York
310 Kimball Tower
Buffalo, New York 14214-8028
Telephone: (716) 829-6952
Facsimile: (716) 829-6040
E-mail: ggiovino@buffalo.edu

Professional Interests:

Lifestyle and environmental factors in health and disease;
Population research on patterns, determinants and control of tobacco use in adolescents and adults, using state, national and international surveys;
Suboptimal nutrition as a risk factor for the development and maintenance of nicotine addiction;
Adverse childhood experiences as risk factors for the development and maintenance of nicotine addiction.

University Education:

1987	Ph.D., Experimental Pathology - Epidemiology State University of New York at Buffalo
1979	M.S., Natural Sciences - Epidemiology State University of New York at Buffalo
1974	B.A., Psychology University of Notre Dame; Notre Dame, Indiana

Employment:

2009 - present	Chair, Department of Community Health and Health Behavior, School of Public Health and Health Professions, University at Buffalo, State University of New York
2007 - 2009	Acting Chair, Department of Health Behavior, School of Public Health and Health Professions, University at Buffalo, State University of New York
2006 - present	Professor, Department of Community Health and Health Behavior, School of Public Health and Health Professions, University at Buffalo, State University of New York
2001 - 2006	Director; Tobacco Control Research Program; Department of Cancer Prevention, Epidemiology, and Biostatistics; Roswell Park Cancer Institute; Buffalo, New York

1999 - 2006	Senior Research Scientist (Full Member); Department of Cancer Prevention, Epidemiology, and Biostatistics; Roswell Park Cancer Institute; Buffalo, New York
1998-1999	Senior Epidemiologist; Epidemiology Branch; Office on Smoking and Health; Centers for Disease Control and Prevention; Atlanta, Georgia
1991 - 1998	Chief; Epidemiology Branch; Office on Smoking and Health; Centers for Disease Control and Prevention; Atlanta, Georgia
1990 - 1991	Acting Chief; Epidemiology Branch; Office on Smoking and Health; Centers for Disease Control; Rockville, Maryland/Atlanta, Georgia
1988 - 1991	Epidemiologist; Office on Smoking and Health; Centers for Disease Control; Rockville, Maryland/Atlanta, Georgia
1985 - 1988	Research Associate; University of Rochester; Department of Psychology; Smoking Research Program; Rochester, New York
1984	Assistant Research Scientist; New York State Department of Health; Buffalo, New York
1983 - 1984	Counselor and Assistant to the Director; Roswell Park Memorial Institute Stop Smoking Clinic; Department of Cancer Control and Epidemiology; Buffalo, New York
1982 - 1983	Research Affiliate; Roswell Park Memorial Institute; Department of Cancer Control and Epidemiology; Buffalo, New York
1980 - 1982	Senior Medical Records Clerk; Roswell Park Memorial Institute Tumor Registry; Buffalo, New York
1977 - 1979	Can-Dial Operator; Roswell Park Memorial Institute; Cancer Information Service; Buffalo, New York

University Appointments:

2006 - present	Professor; Department of Community Health and Health Behavior; School of Public Health and Health Professions; University at Buffalo; State University of New York
2006 – present	Professor of Oncology; Graduate Faculty of the University at Buffalo, Roswell Park Division; State University of New York
2002 - 2006	Associate Professor; Graduate Faculty of the University at Buffalo, Roswell Park Division; State University of New York
2001 - present	Research Professor, Department of Social and Preventive Medicine, School of Public Health and Health Professions, University at Buffalo, State University of New York
1987 - 1988	Assistant Professor; Department of Psychology; University of Rochester; Rochester, New York

24) Robert Wood Johnson Foundation (Substance Abuse Policy Research Program)
Individual- and Policy-Level Influences on the Use of Various Cessation Strategies and Abstinence from Cigarettes Among Adult Smokers
10/1/07 – 1/31/10; Direct/Total costs: (b)(4) and (b)(6)
Principal Investigator.

23) Robert Wood Johnson Foundation (Substance Abuse Policy Research Program)
Impact of Smoke-Free Air Policies on Young Smokers' Demand for and Use of Treatment
10/1/06 – 12/31/09; Direct/Total costs: (b)(4) and (b)(6)
Co-Investigator (Dianne Barker, PI).

22) National Cancer Institute
Evaluating Low Ignition Propensity Cigarette Legislation
9/1/06 – 7/31/10; Direct/Total costs: $1,161,418/$1,479,582
Principal Investigator on the original grant and Co-investigator after I left Roswell Park in 2006 (Richard O'Connor, PI).

21) National Science Foundation
Collaborative Research: Social Networking Tools to Enable Collaboration in the Tobacco Surveillance, Epidemiology, and Evaluation Network (TSEEN)
9/1/06 – 12/31/12; Direct/Total Costs: $101,793/$161,341
Principal Investigator of the Buffalo site (Noshir Contractor, Northwestern University, PI of the Coordinating Center).

20) Battelle Memorial Institute (from NCI)
Tobacco Surveillance, Epidemiology and Evaluation Network
10/15/05-05/31/07; Direct/Total Costs: $23,738/$29,785
Principal Investigator.

19) National Cancer Institute
Global Variation in Lung Cancer and Other Diseases Caused by Smoking. Developmental Research Project partially funded by "Building the Evidence Base for Tobacco Control Policies
(1 P50 CA111236-01)
9/30/05-9/29/06; Direct/Total Costs: $80,000/$80,000
Principal Investigator.

18) National Cancer Institute
Compiling and Evaluating Tobacco Surveillance Measures. Developmental Research Project partially funded by "Building the Evidence Base for Tobacco Control Policies"
(1 P50 CA111236-01)
9/25/05-12/24/06; Direct/Total Costs: $57,588/$98,000
Principal Investigator.

17) National Cancer Institute
Studies to Evaluate Consumer Reactions to Marlboro UltraSmooth. Developmental Research Project partially funded by "Building the Evidence Base for Tobacco Control Policies"
(1 P50 CA111236-01)
9/1/05-7/31/06; Direct/Total costs: $35,000/$36,035
Principal Investigator.

16) National Cancer Institute
TSNA Exposure from Cigarettes with Differing TSNA. Developmental Research Project partially funded by "Building the Evidence Base for Tobacco Control Policies"
(1 P50 CA111236-01)
10/1/04 – 9/30/05; Direct/Total costs: $22,425/$33,598
Principal Investigator.

15) National Cancer Institute
Policy Effects on Cigarette Design, Emissions, & Behavior
9/1/2004 – 8/31/2009; Direct/Total Costs: $927,310/$1,327,967
Page Principal Investigator of Project 3 of Transdisciplinary Tobacco Use Research Center Grant - Building the Evidence Base for Tobacco Control Policies; K. Michael Cummings, Principal Investigator ($7,218,947/$8,193,121). Co-investigator after I left Roswell Park in 2006 (Richard O'Connor, PI of Project 3).

14) American Cancer Society
The Relationship Between Media Advocacy and Tobacco Attitudes and Use
7/01/04-6/30/05; Direct/Total Costs: (b)(4) and (b)(6)
Principal Investigator of Roswell Park component; Katherine Clegg Smith was the Principal Investigator at the University of Illinois at Chicago.

13) New York State Department of Health
A Stop Smoking Campaign Aimed at African American Smokers in Western New York
6/1/03 – 8/3/05; Direct/Total costs: $300,000/$300,000
Principal Investigator.

12) Robert Wood Johnson Foundation
Tobacco Surveillance System, (subcontract with University of Illinois at Chicago on Project ImpacTeen)
3/1/03 – 1/31/09; Direct/Total Costs: (b)(4) and (b)(6)
Principal Investigator of Roswell Park Cancer Institute/SUNY at Buffalo Sub-contracts to the University of Illinois at Chicago (Frank Chaloupka, PI of Project ImpacTeen).

11) American Legacy Foundation
Surveillance Project: Population-based Study of Harm Reduction and the "Hard-Core" Smoker; Project 2 in Tobacco Epidemiology, Surveillance, and Intervention Center of Excellence
1/1/03 – 12/31/07; Direct/Total costs: (b)(4) and (b)(6)
Principal Investigator of Project 2.
Andrew Hyland is the Principal Investigator of the Center of Excellence (Direct Costs/Total Costs: (b)(4) and (b)(6)

10) Robert Wood Johnson Foundation
Assessing Youth Smoking Cessation Needs and Practices
3/1/02 – 6/30/08; Direct/Total costs: (b)(4) and (b)(6)
Principal Investigator.

9) Robert Wood Johnson Foundation
Evaluating SmokeLess States (subcontract with University of Illinois at Chicago on Project ImpacTeen)
1/1/02 – 4/30/06; Direct/Total costs: (b)(4) and (b)(6)
Principal Investigator of Roswell Park component of this project.
Frank Chaloupka is the Principal Investigator of the Evaluating SmokeLess States project.

8) Robert Wood Johnson Foundation
Innovations to Enhance Tobacco Surveillance (from the Innovators Combating Substance Abuse program)
11/1/01 – 1/31/06; Direct/Total costs: (b)(4) and (b)(6)
Principal Investigator.

7) National Cancer Institute
Follow-up of the COMMIT Cohort Participants 13 Years Later
5/1/02 – 4/30/05; Direct/total Costs: $1,542,373/$1,955,255
Co-Investigator; K. Michael Cummings was the Principal Investigator of this grant.

6) Centers for Disease Control and Prevention
Intergovernmental Personnel Act of 1970
10/1/01 – 9/30/03; $39,600/$39,600
Principal Investigator (provided partial salary coverage).

5) Robert Wood Johnson Foundation
Research Network on the Etiology of Tobacco Dependence
1/1/01 - 9/30/04; Direct/Total Costs: (b)(4) and (b)(6)
Core Group Member (funding provided partial salary coverage).

4) Robert Wood Johnson Foundation
Survey of Youth Cessation Needs and Practices: Planning Grant Proposal
7/1/00 – 5/15/02; Direct/Total Costs: (b)(4) and (b)(6)
Principal Investigator.

3) Robert Wood Johnson Foundation
Informing Consumers About the Relative Health Risks of Different Nicotine Delivery Products
11/1/99 - 10/31/03; Direct/Total costs: (b)(4) and (b)(6)
Co-Investigator; K. Michael Cummings was principal investigator of this grant.

2) Centers for Disease Control and Prevention
Intergovernmental Personnel Act of 1970
10/1/99 - 9/30/01; Direct/Total Costs: $47,138/$47,138
Principal Investigator (provided partial salary coverage).

1) Robert Wood Johnson Foundation
Tobacco Surveillance System, (subcontract with University of Illinois at Chicago on Project ImpacTeen)
4/15/99-2/28/03; Direct/Total costs: (b)(4) and (b)(6)
K. Michael Cummings was the Principal Investigator of the original Roswell Park sub-contract; I became the Principal Investigator of that sub-contract on 4/15/99; Frank Chaloupka is Principal Investigator of Project ImpacTeen.

Peer-Reviewed Journal Articles:

126) (b)(4) Giovino GA, (b)(4) (b) (4) (b)(4) (b) (4) (b) (4) (b)(4) (In Press).

125) (b)(4) Giovino GA, (b)(4) (b) (4) (b)(4) (In Press).