Curriculum Vitae

EDWARD J. BUTHUSIEM
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SUMMARY

Mr. Buthusiem is a Managing Director in the BRG Health Analytics practice and a leader of its Corporate Compliance and Risk Management practice. He has over 30 years of experience advising clients on a variety of business, regulatory, operational, intellectual property, litigation, transactional and compliance matters, with particular emphasis in pharmaceutical and medical device product and technology licensing transactions, commercial and strategic transactions, business formation and planning, securities, mergers and acquisitions, compliance, and corporate governance. Since joining BRG in 2013, Mr. Buthusiem has provided expert testimony and support in a number of litigation matters involving, among other things, the interpretation of licensing and development contracts relating to pharmaceutical and medical device product development, deal structures, valuation and pricing, matters involving fiduciary responsibilities, securities disclosure, adequacy of internal controls and pharmaceutical pre-clinical and clinical development and commercialization.

Mr. Buthusiem has served as a government and court-appointed monitor for entities subject to post-settlement and post-acquisition mandates, including on behalf of the US Department of Justice (DOJ), the Securities and Exchange Commission (SEC) and the Office of Inspector General (OIG) in connection with various civil and criminal actions. Mr. Buthusiem has also served as a court-appointed monitor in connection with the disposition of assets in bankruptcy proceedings as well as an independent third party to oversee the implementation of post-closing obligations primarily involving M&A transactions. He has advised healthcare companies and their legal counsel in implementing Corporate Integrity Agreements (CIAs), as well as negotiating CIA terms with the Department of Justice, the OIG, the SEC, and other governmental agencies. Mr. Buthusiem has also developed and overseen all aspects of compliance programs, including auditing and monitoring; interactions and engagements with healthcare professionals; determining fair market value of goods and services provided by and offered to physicians; strategic marketing and sales initiatives; transparency reporting; and clinical, research and development, and post-market surveillance.

Prior to joining BRG, Mr. Buthusiem served as General Counsel and Head of Business Development for KaVo Kerr Group ("KKG"), Danaher Corporation's $2.5 billion global dental and medical device business, from 2010 to 2012. His responsibilities included heading the Business Development, Legal, Compliance, Trade Operations and Environmental Health and Safety Departments and overseeing the provision of these services to KKG's global businesses.

Prior to joining KKG, Mr. Buthusiem was a senior executive at GlaxoSmithKline ("GSK") from 1990 to 2010. GSK is a $45 Billion global pharmaceutical and consumer healthcare company. During my tenure at GSK, Mr. Buthusiem served in various senior capacities, including Vice President Global and Strategic Transactions (1994-2000), Senior Vice President & General Counsel of R&D and Vaccines (from 2000-2008) and Senior Vice President & Special Counsel (from 2008-2010). Among other things, Mr. Buthusiem was responsible for managing the team that drafted and negotiated product and technology licensing agreements on a global basis and head of Business Development for the Vaccines Division. Mr. Buthusiem also served as a member on numerous project and product management teams which were responsible for the discovery and development of new drugs and the lifecycle management of existing products and therapeutic franchises.

Prior to joining GSK, Mr. Buthusiem was an attorney in private practice with two nationally recognized law firms, Fried, Frank, Harris, Shriver & Jacobson LLP (from 1984-1988) and Dickstein Shapiro LLP (from 1988-1990). During his tenure in private practice, he worked in both firms' Corporate and Securities practices, and provided legal advice in areas including, but not limited to M&A due diligence and transactions, as well as corporate agreement transactional drafting, guidance, and review.

During his tenure at GSK and KKG, Mr. Buthusiem was responsible for directly drafting and negotiating, as well as managing the support for all global transactions, including mergers and acquisitions, joint ventures, pharmaceutical product and R&D licensing and development transactions, pharmaceutical product divestitures, investment banker and broker deals, venture capital partnerships, academic and scientific collaborations, commercial joint ventures, marketing, supply and distribution agreements and a variety of other corporate and commercial transactions. Altogether, Mr. Buthusiem has acted as 'first chair' and/or managed the support for well over a thousand pharmaceutical and medical device transactions, involving billions of dollars of value. Mr. Buthusiem's expertise includes, but is not limited to the following types of transactions:

- Product and technology licensing and research collaboration agreements
- Research consortia agreements
- Intellectual property in-licensing, out-licensing, and cross-licensing agreements involving pharmaceutical and medical device products and projects
- Drug, device, vaccine, and biological product research and development agreements
- Mergers and acquisitions involving businesses, pharmaceutical and medical device products
- Early stage drug, device, vaccine, and biological product research development agreements
- Co-promotion and co-marketing agreements
- Manufacturing, supply and distribution agreements
- Business broker and venture capital investment transactions

- Grant agreements
- Pre-clinical research agreements
- Government contracts
- CRO services agreements
- Clinical trial agreements

Throughout his career both as a General Counsel and as a compliance consultant, Mr. Buthusiem has advised numerous companies and institutions, their executive management and Boards of Directors on corporate governance issues involving fiduciary duties, and conflicts of interest. In particular, Mr. Buthusiem has rendered such advice in connection with the sale of pharmaceutical products to current and former employees, and has also advised on similar situations while serving as a director on external Boards. In each case, through his advice Mr. Buthusiem has sought to ensure that any conflicts of interest, whether in the context of transactions or generally, were appropriately addressed and proper safeguards implemented and followed accordingly.

EDUCATION

J.D. University of Pennsylvania School of Law, 1985
Activities: Member of Jessup Moot Court, 1984-1985 (Captain of the 1985 Team)

B.A. Temple University, 1982 (*magna cum laude*)

AWARDS

Recipient of the Temple University 2003 Diamond Achievement Award

Delivered the 2004 Commencement Speech, Temple University College of Liberal Arts

EXTERNAL BOARDS

Chairman, Temple University Board of Visitors for the College of Liberal Arts

Member, Temple University President's Council

Chairman, Temple University Law School Advisory Board for the Center for Ethics and Compliance

EDITORIAL BOARDS

Editor, Compliance and Risk Management eJournal, Legal Scholarship Network

Editor, the Lifesciences Compliance Update

EMPLOYMENT HISTORY

Temple University Beasley School of Law
Adjunct Professor
August 2015 – Present

Berkeley Research Group, LLC
Managing Director
January 2013 – Present

Kavo Kerr Group, a Danaher Company
General Counsel, Head of Business Development, Trade Operations and Environmental Health & Safety
November 2010 – January 2013

GlaxoSmithKline plc (formerly SmithKline Beecham plc)
October 1990 – October 2010

Senior Vice President and Special Counsel
January 2009 – October 2010

Senior Vice President, General Counsel of Global R&D and Vaccines Divisions, Business Development (Vaccines) and Risk Management
January 2001 – January 2009

Vice President & Associate General Counsel, Strategic & Scientific Transactions Department
January 1995 – January 2001

Senior Counsel, Licensing and Commercial Transactions
October 1990 – December 1995

Dickstein, Shapiro & Morin
Associate
January 1987 – October 1990

Fried, Frank, Harris, Shriver & Jacobson
Associate
September 1985 – December 1987

OVERSIGHT POSITIONS AND SPECIAL PROJECTS

Monitorships:

- Appointed by the FTC as a Monitor to review and periodically report on compliance with mandates contained in two Decisions and Orders issued by the FTC, each requiring the divestiture of multiple products, plants, and other tangible and intangible assets in connection with the approval by the FTC of 2 global mergers in the Lifesciences industry.

- Appointed by the DOJ and OIG to act as IRO for the largest Imaging Service Provider in Texas in connection with their CIA. As part of this process, was asked to assess the overall effectiveness of the company's compliance program in conformity with applicable State and Federal regulations, including the OIG Seven Elements. Was also required to test the company's billing and coding policies and procedures and to conduct a statistically relevant sampling of claims submitted for reimbursement under State and Federal health plans to ensure that licensed physicians were present at and provided direct supervision on all imaging tests conducted with contrast dye in compliance with CMS regulations.

- Appointed by the DOJ/OIG to act as IRO for an acute care hospital in the mid-Atlantic region in conjunction with its CIA. The CIA addressed issues related to the coding of outpatient medical records, billing for ambulance claims, and submission of claims to the appropriate payor. Additionally, the CIA referred to internal procedures utilized by the system to review bills and claims submitted to payers for reimbursement. As set forth in the CIA, produced annual reports that detailed the accuracy of the statistically-valid sample selections for each category and an assessment of the internal control processes surrounding billing controls.

- Served as a court-appointed monitor for a large international mining company in connection with a consent decree related to violations of the Foreign Corrupt Practices Act. As part of the process, was asked to assess the entity's supply chains and ensure that sufficient internal controls were put in place to prevent and detect bribes to government officials overseas.

- Appointed by the DOJ/OIG to act as IRO for one of the largest national Durable Medical Equipment companies in conjunction with their CIA. Was further engaged to perform IRO services related to Non-Contractual Arrangements, which included a review of the internal system tracking mechanisms and recording of expenditures by physicians to ensure compliance with their Stark and Anti-Kickback policies.

Licensing Deals:

- Drafted, negotiated and completed numerous product and technology in-licensing and out-licensing and collaborative R&D ventures in the Biotech, Medical Device and Pharmaceutical industries.

Special Projects:

- Structured and negotiated a joint venture with the Chinese Academy of Science to form GSK's R&D Institute for Neurodegenerative Diseases in Shanghai, China.

- Formed and led a crisis management team for Danaher responding to a New York Times front page article linking its Cone Beam CT scanner to radiation overexposure in children. Issues involved FDA regulatory, congressional interaction, legal risk mitigation and media and communication management.
- Successfully represented Danaher Corporation's Dental Division in connection with criminal investigations involving alleged bribery and corruption in Russia and in the EU.
- Was responsible for establishing the CIA and IRO processes for GSK in connection with 2 DOJ settlements involving off-label promotion and falsification of cGMP data at its Ciera, Puerto Rico manufacturing facility.
- Negotiated a settlement with the NY AG in connection with Paxil consumer fraud relating to data falsification. As part of this settlement, was responsible for submitting all quarterly reports under the Consent Decree as well as interacting with the IRO appointed to oversee this matter.
- Formed and led the GSK crisis management team on pandemic vaccines, which managed all aspects of responding to the pandemic vaccine crisis in 2010, including negotiations with NGOs, government agencies, legal risk mitigation, licensing and development. As part of this process negotiated an indemnity from the U.S. government against product liability exposure as a result of the emergency approval of the pandemic vaccine in in vitro data.
- Was legal counsel to the GSK Avandia crisis management team responsible for preparing for and delivering GSK' Congressional testimony to the House Oversight Committee convened to investigate claims of Avandia liability associated with a Meta-Analysis published by Dr. Steve Nissen of the Cleveland Clinic which linked Avandia to elevated CV risk.
- Led GSK Legal's cost reduction and efficiency project that resulted in substantial improvements in the delivery of global legal services as well as a rationalization of external counsel management and utilization, which yielded over $60M in savings over 3 years. Implemented the same program at Danaher and yielded comparable results over a 2-year timeframe.
- Responsible for coordinating the antitrust approvals in connection with the merger of SmithKline Beecham and GlaxoWellcome, including the Federal Trade Commission and European Commission approvals. Led the settlement negotiations with the FTC and the EC which resulted in the FTC Consent Decree and the EC Mandate. As part of this process, was responsible for working with the FTC Monitor Trustee with respect to post-merger obligations. Also led the team that divested the various products mandated by the FTC and the EC to be sold as a pre-condition to approving the merger, most notable of which was the $1.1. Billion global sale of Kytril to Roche Pharmaceuticals and the $1.68 Billion global divestiture of Famvir to Novartis.
- Member of a special R&D 'Blue Ribbon' task force whose mandate is to develop a comprehensive political, socioeconomic and scientific strategy for developing life-saving medicines to combat third world diseases. The other three members of the task force are the head of drug discovery, the head of project management, and the head of business development.

Acquisitions and Divestitures:

- 1994 $2.3 Billion acquisition of Diversified Pharmaceutical Services from United HealthCare.

- 1995 $1.45 Billion divestiture of SmithKline Beecham's Animal Health Business to Pfizer.
- 1995 $2.2 Billion acquisition of Sterling HealthCare from Kodak and related $1 Billion spin-off of North American part of the business to Bayer AG.
- Represented Belgium-based SmithKline Beecham ("SB") Biologicals SA in connection with its bid on the vaccine business of German-based Behringwerke AG division of Hoechst AG.
- Represented SB in connection with 1998 merger discussions with American Home Products and Glaxo Wellcome. In this capacity, was directly involved in strategic planning, substantive negotiations, legal due diligence and antitrust analysis.
- Represented SB in connection with the divestiture of SB's clinical laboratories business to Quest Diagnostics for $1.3 Billion; and SB's pharmaceutical benefits management business, Diversified Pharmaceutical Services, to Express Scripts for $700 million.
- Represented SB in connection with the 2001 $124 B merger with Glaxo Wellcome.
- Represented GSK in the FTC-mandated divestitures in connection with the GSK merger, including the $1.2 B sale of Kytril to Roche and the $1.4 B sale of Famvir to Novartis.

Joint Ventures:

- Drafted and negotiated a joint venture with Rite Aid Corp. and SB's Diversified Pharmaceutical Services division for the creation of a new company that will dispense prescription pharmaceuticals through use of mail.
- Newly formed UK joint venture Company with Holland-based Royal Gist brocades BV for the global production of certain penicillin bulk products.
- Represented Belgium-based SB Biologicals in formation of U.S. joint venture Company with, and related equity investment in, Microcarb Inc. relating to the worldwide development and commercialization of human bacterial vaccine products.
- Represented SB Consumer Healthcare in connection with restructuring of $2 Billion North American consumer healthcare partnership with Hoechst Marion Roussel.

Marketing Alliances:

- Completed a series of worldwide country-specific marketing arrangements between SB and German-based Boehringer Mannheim AG for the global commercialization and marketing of the cardiovascular drug carvedilol.
- Various U.S. Co-Promotion Agreements: with Janssen relating to Paxil and Risperdal; with Merck relating to Zocor; with Schering-Plough relating to a number of pipeline products; with TheraTech relating to Androderm; with Bayer relating to Baycol. Drafted and negotiated numerous marketing alliances for Danaher's MedTech business involving a variety of medical device products throughout the world.

RECENT TESTIMONY EXPERIENCE

Case No. 13-md-2460
In Re Niaspan Antitrust Litigation
United States District Court for Eastern District of Pennsylvania

Case No. 3:16-cv-0132
SEC v. Edward J. Kosinski
United States District Court for the District of Connecticut

Case No. 1:10-cv-03864
Jones et al. v. Pfizer, Inc. et al
United States District Court for the Southern District New York

Case No. 111CV203554
Glenridge Pharmaceuticals LLC. v. Questcor Pharmaceuticals, Inc.
Superior Court of the State of California for the County of Santa Clara
.
Docket Number 650908/14
Sybron Canada Holdings, Inc. v. Niznick,
Supreme Court, New York County

Case No. 1:13-cv-01475
Thermo Fisher Scientific, Inc. v. OpenGate Capital Group LLC
United States District Court for the District of Delaware

Case No. 8:12-cv-01623
In re: Questcor Securities Litigation
United States District Court for the Central District of California

Case No. 1:14-cv-20050-MGC
Direct General Insurance Co. v. Indian Harbor Insurance Co. et al.
United States District Court for the Southern District of Florida, Miami Division

Consolidated Case No. 1:14-cv-03547-RMB-KMW
AstraZeneca Pharmaceuticals LP et al. v. Sandoz Inc. et al.
United States District Court for the District of New Jersey

Case No. 16 Civ. 3241 (ER) (JLC)

Impax Laboratories, Inc. v. Turing Pharmaceuticals AG
United States District Court for the Southern District of New York

AAA Case No. 01-15-0006-0746
Torreya Partners LLC v. Mimetogen Pharmaceuticals, Inc.
American Arbitrators Association

Claim No. HC 2015 003978
Norgine B.V. v. Salix Pharmaceuticals, Inc.
High Court of Justice, Chancery Division (UK)

PUBLICATIONS

1. "Using Data Analytics and Enhanced Monitoring Techniques to Avoid Government Enforcement and Individual Liability," *Pharmaceutical Compliance Monitor,* July 16, 2015
2. "Drug Serialization Trends and Developments," *Pharmaceutical Compliance Monitor,* May 6, 2015
3. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* March 2015
4. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* February 2015
5. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* January 2015
6. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* December 2014
7. "Regulatory and Compliance Implications of Orphan Drugs," *Pharmaceutical Compliance Monitor,* November 24, 2014
8. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* November 10, 2014
9. "Recent Trends in Whistleblower Protection under Dodd–Frank," *Pharmaceutical Compliance Monitor,* October 20, 2014
10. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* October 2014
11. "Global Investigations and Compliance Services Enforcement Roundup," *BRG Newsletter,* September 2014
12. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* August 2014
13. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* July 2014

14. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* May 2014
15. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* April 2014
16. "Compliance Officers: Three Common Mistakes to Avoid," *Pharmaceutical Compliance Monitor,* March 19, 2014
17. "Six Strategies to an Effective Risk Assessment and Mitigation Program," *Pharmaceutical Compliance Monitor,* January 8, 2014
18. "Here Comes le Soleil Français: The French Sunshine Act Has Arrived," *Corporate Compliance Insights,* July 3, 2013
19. "PODs: Proceed with Extreme Caution," *Orthoworld,* June 10, 2013
20. "Five Steps to Sunshine: Strategies for Complying with CMS' Reporting Requirements," *Orthoworld,* May 9, 2013
21. "A Practical Guide to Anti-Corruption Compliance for the Medical Device Industry," *Pharmaceutical Compliance Monitor,* April 19, 2013
22. "Here Comes the Sun," *Pharmaceutical Compliance Monitor,* March 18, 2013

SEMINARS AND SPEAKING ENGAGEMENTS

Sixth Annual West Coast Compliance Congress
November 15-16, 2016

Current Trends in Compliance and Enforcement
April 7, 2016

Pharmaceutical Compliance Congress
January 26 – 27, 2016

Current Trends in Ethics and Compliance Law
November 9, 2015

DTA Business Essentials: Determining Fair Market Value for the Dental Industry
August 4, 2015

Pharmaceutical Compliance Congress
March 3 – 4, 2015

Fifth Annual West Coast Compliance Congress
November 13 – 14, 2014

Forum on Transparency and Aggregate Spend
August 18, 2014

FMV of HCP and Investigator Payments
May 20 – 21, 2014

Instruments Compliance and Ethics Synergy Conference
April 14, 2014

Sunshine Act 3.0
March 20, 2014

10th Annual Regulatory and Compliance Congress for Medical Device and Diagnostics
February 25 – 26, 2014

Latin America Compliance Conference
February 11 – 13, 2014

11th Annual Pharmaceutical Compliance Congress
January 28 – 29, 2014

Forum on Sunshine and Aggregate Spend
August 19 – 21, 2013

Here Comes the Sun
February 28, 2013