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ROBERT P. GIACALONE

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CAREER SUMMARY

Extensive experience and knowledge in the healthcare industry with an emphasis in legal, regulatory and government-related areas. A pharmacist and lawyer by training, having been involved with or directly handled numerous matters and issues including but not limited to: managing departments and functional groups that include attorneys as well as other professionals; managing internal budgets and expenses (outside counsel and consultant spend); involvement in numerous acquisitions and divesture activities; providing sound and pragmatic legal and business counsel to the business and its leaders; actively working to advance commercial opportunities in areas such as: development of state pharmacy automation regulations; state and federal (PDMA) prescription drug pedigree regulation and legislation development; prescription drug re-importation; development of DEA's centralized pharmacy regulations; establishing a centralized corporate import/export compliance program; creation of the first Political Action Committee (PAC) for Cardinal Health; appointment by state governor for two terms (eight years) to the state drug control agency (Ohio State Board of Pharmacy) and the State Medical Board of Ohio (current member); development of company-wide healthcare privacy program pertaining to HIPAA; regulatory strategies that have advanced commercial positions of various products – specifically in the area of pharmaceutical repackaging; extensive experience in contract drafting and negotiations; FDA promotional and advertising review; and, directly interfacing with customers and trade associations to further joint initiatives on both state and federal levels.

In addition, have actively advised or directly represented or defended various companies in numerous legal and regulatory actions including but not limited to: criminal and civil investigations involving the U.S. Department of Justice, the DEA, the FDA as well as state attorneys general and other state, federal or foreign regulatory agencies or bodies. Such matters included alleged fraudulent activities pertaining to DEA quota letters and diversion; DEA Orders to Show Cause and Immediate Suspensions; FDA consent decree involving infusion pumps; FDA warning letters and Form 483 review and responses; allegations of fraud brought by U.S. Customs and Border Protection; preventing the discontinuance of marketing of products by foreign regulatory bodies; representation before federal and state administrative hearings by agencies such as the DEA, FDA, state pharmacy boards or similar state drug control agencies for alleged violations or misconduct by employees or the business; and, successful prosecution of Lanham Act matters resulting in significant commercial product advantage.

CAREER HISTORY

GIACALONE LAW FIRM, LLC **2018 – Present**

Giacalone Law Firm, LLC is comprised of Robert Giacalone as principal member and has represented and advised clients on a number of matters relating to: pharmacy, pharmaceutical manufacturing and distribution, medical device manufacturing and distribution, and state and federal regulatory agencies. The firm has specific expertise in healthcare regulations and requirements especially in the area of pharmaceuticals, medical devices, pharmacy practice, and controlled substances. In particular, Robert has dealt with matters and issues involving the U.S. Drug Enforcement Administration (DEA); the

U.S. Food and Drug Administration (FDA); state regulatory agencies including state boards of pharmacy, state controlled substance agencies, state medical boards and has been involved with or a member of national organizations including the National Association of Boards of Pharmacy (NABP), the Federation of State Medical Boards (FSMB), the Healthcare Distribution Alliance (HDA) and the National Association of Chain Drug Stores (NACDS).

CARDINAL HEALTH, INC: **1997- August 2017**

Cardinal Health, Inc. ("Cardinal Health") is a multifaceted healthcare concern that employs approximately 50,000 people on five continents and produces annual revenues of approximately one hundred and thirty (130) billion dollars. This Fortune 25 Company's customers include hospitals, managed care, alternative health care facilities, pharmaceutical and medical device manufacturers, and chain and independent retail pharmacies. The Company operates through various subsidiary companies and businesses and is divided essentially into two segments. The Pharmaceutical Segment includes: one of the nation's largest pharmaceutical distributors; a pharmaceutical repackaging business; an international franchiser of retail pharmacies (Medicine Shoppe Internationale and MediCap Pharmacy); and, the nation's largest provider of nuclear pharmacy services and positron emission tomography (PET) manufacturing; and, operates a hospital pharmacy management business. The Medical Segment manufactures and markets a variety of medical devices including surgical gowns, drapes, gloves, suction canister devices and surgical procedure trays. In addition, Cardinal Health added to the Medical Segment by acquiring the Cordis (cardiovascular) business of Johnson & Johnson (October 2015) and the Patent Recovery Business (patient care, deep vein thrombosis and nutritional insufficiency) of Medtronic (April 2017). The Medical Segment business also includes one of the nation's largest medical-surgical distributors. Prior to September 2009, Cardinal Health's Medical Segment was comprised of the following businesses: pharmacy automation cabinets (Pyxis®); medical infusion pumps (Alaris®); ventilators (AVEA®); continuous positive airway pressure (cpap) units; pulmonary diagnostic systems (Vmax® and Jaeger®); surgical skin prep products (ChloraPrep®) and, surgical instruments (V. Mueller®). These businesses were spun off in 2009 and are now known as CareFusion. In addition, until 2007, the Company operated an international pharmaceutical manufacturing segment which was comprised of a pharmaceutical manufacturing business specializing in oral, topical and sterile production; a drug packaging company; and, a contract sales, marketing and continuing medical education (CME) organization. The manufacturing, packaging and development components of those businesses were sold to the Blackstone Group in April 2007 and now operate as Catalent Pharma Solutions.

<u>Senior Vice President, Regulatory Affairs and Chief Regulatory Counsel</u>

- Report directly to Executive Vice President (EVP)/General Counsel who sits on the Company's Operating and Executive Committees. In addition, work closely with Chief Compliance Officer for Cardinal Health.

- Have direct responsibility for legal-regulatory matters in current role as Chief Regulatory Counsel and supervise and direct regulatory attorneys in that capacity;

- In the past, have had responsibility for the Corporate Regulatory Compliance function which includes professionals that audit and address issues related to regulatory

agencies including the U.S. Food and Drug Administration (FDA) and foreign regulatory bodies in terms of pharmaceutical and medical device manufacturing; state regulatory bodies (such as state pharmacy boards or similar entities); and, the U.S. Drug Enforcement Administration (DEA) and state controlled substance authorities as it pertains to controlled substance manufacturing and distribution; In addition, have had responsibility for the Corporate Environmental Health & Safety (EHS) function which includes EHS professionals such as industrial hygienists, environmental specialists and the company's Chief Medical Officer.

- Work closely with and advise Senior Management both in Cardinal Health Corporate and business unit subsidiaries regarding regulatory-legal issues and matters. Work towards establishing strategy and tactics regarding various business initiatives.

- Responsible for overseeing and active involvement at the corporate level as well as the subsidiary level with legal-regulatory and/or government affairs-based issues which impact the various business units.

- Either involved directly or in a supervisory capacity at a state level with various state drug agencies such as boards of pharmacy, departments of health and other state regulatory bodies working to resolve issues which may exist or working proactively to further commercial ventures. Specifically, have worked with subsidiary business units to gain revisions to or develop regulations which have supported and provided a commercial advantage to their activities and product lines. In addition, have represented the Company and its subsidiaries in formal and informal hearings before various agencies including state pharmacy boards.

- Involved at a federal level with agencies such as the United States Food and Drug Administration (FDA), the United States Drug Enforcement Administration (DEA), and other similarly situated healthcare regulatory bodies working to resolve issues which may exist or working proactively to minimize Company risks and further commercial ventures. Specifically, have been involved in activities to prevent FDA action which would have resulted in the closure of one of our business units. In addition, have been involved in FDA consent decree matter relating to infusion pumps; avoidance of criminal charges and resolution of civil case in an alleged fraud matter pertaining to DEA quota requirements; and, DEA suspensions pertaining to pharmaceutical distribution business. Also, have represented the Company and/or its business units before various state attorneys general, the U.S. Department of Justice, U.S. Department of Transportation (DOT), Federal Aviation Administration (FAA), DEA, DEA's Office of Chief Counsel as well as the FDA and FDA's Office of Chief Counsel in formal and informal hearings and meetings.

- Work with customers to further the Company's commercial agenda and strengthen relationships. Specifically, have been involved in joint regulatory efforts with customers to mitigate negative existing and proposed regulations. In addition, have provided educational programs and presentations regarding regulatory-legal matters for the benefit of business unit customers.

- Work directly with business and technical people within the various business units to assess needs and develop approaches to gain beneficial commercial outcomes. Involved in developing strategies regarding the development of products and the

approach to be taken with such products in light of their regulatory-legal implications. Specific activities include the evaluation on Internet-based healthcare initiatives, centralized pharmacy applications and utilization of pharmacy automation in long term care facilities.

- Led group involved in developing Corporate-based program to address international and domestic import and export matters across various business units and subsidiaries. Instrumental in helping to create Corporate-based import/export compliance program across entire company. Involved in representing Cardinal Health and its subsidiaries in legal-regulatory issues associated with agencies such as U.S. Customs and Border Protection and U.S Bureau of Industry and Security (BIS) and similar foreign regulatory agencies.

- Led Company-wide task force involved in establishing compliance for those business units affected by federal privacy and security regulations derived from the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Instrumental in helping to develop risk assessments, policies and training needed to establish compliance with this law.

- Involved in trade and professional association activities such as the Healthcare Distribution Management Association (HDMA) as well as working with regulatory-based organizations such as the National Association of Boards of Pharmacy (NABP). Have served as Committee Chairperson for HDMA Regulatory Affairs Committee (2004-2006). Have also served on numerous NABP committees and task forces. Have been actively involved in state and federal prescription drug pedigree issues and helping to develop state and federal regulations and policy in that regard.

- Involved in assessing new acquisitions, business opportunities and various commercial programs and/or ventures from a strategic, due diligence and legal-regulatory perspective. To date, have been involved in numerous high profile acquisitions reflected in the Company's growth from $8 billion in revenues (in 1997) to its current status of $108 billion.

- Responsible for activities and development of direct reports including dotted-line responsibility for subsidiary functional groups. Included within this is control and budgetary responsibility for the use of outside counsel and consultants.

- Responsible for advocating and subsequently creating the first political action committee (PAC) for Cardinal Health, Inc. and its subsidiaries. Currently sit on this PAC as a voting member.

MINNESOTA MINING AND MANUFACTURING COMPANY (3M): 1995-1997
(3M Pharmaceuticals Division) Office of General Counsel

Minnesota Mining and Manufacturing Company ("3M") is the multinational manufacturing and technological concern specializing in a number of supply and consumer markets including those of industrial manufacturing including adhesives and abrasives, specialty chemicals, and healthcare areas such as medical and dental products as well as pharmaceuticals. Sales of 3M products are in excess of twenty (22) billion dollars.

Office of General Counsel

- Employed in 3M's Office of General Counsel with primary representation provided to 3M's pharmaceutical business/division, known as 3M Pharmaceuticals. Essentially acted as business unit's general counsel.

- Responsible for advising and providing strategic and legal-technical guidance to Pharma Group's Senior Management with direct reporting relationship to Assistant General Counsel for the 3M Company Worldwide.

- Responsible for litigation issues and general corporate transactions associated with 3M Pharmaceuticals including the drafting and negotiation of a full range of contracts such as: distributor/commercial agency agreements, research and consulting agreements, supply contracts, leases, licensing and joint venture agreements, and managed care contracts.

- Involved in FDA-related/regulatory issues, including but not limited to review of promotional material, filing of citizen petitions, labeling development and review and general counseling. In addition, member of 3M Institutional Review Board (IRB).

- Involved in healthcare issues pertaining to VA (i.e. FSS Contracting), PHS, and CMS, including Medicaid/Medicare Fraud and Abuse as well as OBRA-related matters.

- Responsible for the client educational programs delivered both to pharmaceutical employees as well as customers outside of the organization.

- Worked closely with Sales and Marketing functions as well as technical staff in assessing programs and commercial opportunities. Specifically, involved in helping the business unit obtain additional sales of one of its products by capitalizing upon a regulatory position.

BOOTS PHARMACEUTICALS, INC. **1991-1995**

Boots Pharmaceuticals, Inc. ("BPI") located in Lincolnshire, Illinois was a wholly owned, ultimate subsidiary of The Boots Company PLC of Nottingham, England ("Boots PLC"), a multinational healthcare concern with sales of in excess of seven (7) billion dollars. Boots Pharmaceuticals, a division of Boots PLC, was the prescription pharmaceuticals business unit which operated worldwide, manufacturing and distributing human pharmaceuticals. BPI comprised this division's North American arm which included the United States, Puerto Rico and Canada.

Corporate Counsel

- Second-in-command reporting directly to the General Counsel/Secretary. Also responsible for overseeing the work and progress of staff attorneys.

- Responsible for BPI's litigation issues and general corporate transactions associated with BPI's operations in North America. This includes issues and matters pertaining to the following North America subsidiaries of Boots PLC: The Boots Company (USA), Inc. (a holding company), Boots Pharmaceuticals PR, Inc. (the Sect. 936 corporation based in Jayuya, Puerto Rico), Boots Pharmaceuticals, Ltd. (a Canadian subsidiary) and Boots Manufacturing, Inc. (a general partner in a joint venture with Hoechst Celanese established to produce bulk ibuprofen in the United States).

- Member of BPI's Senior Management, Pension Administration Committee, Compliance Panel, and Crisis Management team.

- Responsible for significant transactional matters including the drafting and negotiation of a full range of contracts such as: distributor/commercial agency agreements, research and consulting agreements, supply contracts, leases, licensing and joint venture agreements, and managed care contracts.

- Head of litigation for BPI with experience in labor, environmental, false advertising actions, insurance, product liability, and negligence including matters.

- Specifically involved in the following activities:

    - Worked directly with Senior Management and Sales Team in determining and implementing the reduction in force involving BPI's sales department.

    - Involved in handling the legal and legal-regulatory issues associated with the launch and subsequent withdrawal of the cardiovascular prescription pharmaceutical, MANOPLAX® (Flosequinan). Also was subsequently involved in handling existing and threatened litigation stemming from the withdrawal of the product (which was prompted by mortality-related data).

    - Directly involved in Lanham Action matters, one of which has led to the opposing party's placement of remedial advertising in a major medical trade journal coupled with the issuance of "Dear Doctor" letters to physicians, pharmacists and managed care entities. This activity resulted in positive commercial impact in one of our products which had been weakened by this competitor's alleged false advertising claims.

    - Represented Boots' interests in actions brought by the EPA to recover cleanup costs at a number of U.S. Superfund sites, arising out of a 1970's joint venture which involved the manufacturing and distribution of pesticides and agrochemicals.

    - Worked directly on a number of issues dealing with federal, quasi-federal and state agencies including the EPA, FDA, FBI, DEA, EEOC, FTC, USP and various state attorneys general and public health departments.

- Governmental affairs activities including interactions with state drug formulary boards, state boards of pharmacy and the National Association of Boards of Pharmacy (NABP) as well as state and federal legislators.

- Involved in advising Marketing and Sales departments in developing programs geared towards pharmacists. Specifically involved in developing marketing strategy directed towards leveraging legal-regulatory benefits inherent in one of our product lines. The result was a positive growth in one of the Company's significant product lines.

- Awarded Boots Pharmaceuticals President's Award for activities and work performed in conjunction with state regulatory matters. This situation involved preventing the implementation of negative regulations which would have significantly impacted one of the Company's product lines.

MCDERMOTT, WILL & EMERY **1989-1991**

Large Chicago-based law firm with specialty practices in areas which include litigation, taxation, commercial transactions and healthcare.

Associate, Litigation Department: Involved in a number of matters ranging from commercial issues to product liability matters with healthcare-related issues.

WALGREEN COMPANY **1983-1986**

Large Chicago-based retail pharmacy chain. Worked as a Staff Pharmacist prior to entering law school. Provided significant knowledge base in terms of pharmaceutical products and understanding the healthcare system.

EDUCATION

J.D., with Honors - DePaul University, College of Law (1989)
DePaul Law Review
B.S. Pharmacy - University of Illinois, College of Pharmacy (1983)

AWARDS AND ACTIVITIES

Appointed by Governor John Kasich to the *State Medical Board of Ohio* (2013-2018)
- Served as the President of the Board (2018)

Appointed by Governor Bob Taft to the *Ohio State Board of Pharmacy* (1999-2007)
- Served as the President of the Board (2003-2004).

Henry Cade Memorial Award (May 2015) from the National Association of Boards of Pharmacy (NABP) for creation and development of NABP's "Red Flags" Video that supported state efforts to educate pharmacists on how to identify the warning signs of prescription drug abuse and diversion when dispensing controlled substance prescriptions. See https://nabp.pharmacy/initiatives/awarxe/pharmacist-resources/ and https://nabp.pharmacy/nabp-honors-leaders-at-the-forefront-of-public-health-protection-at-associations-111th-annual-meeting/

Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances (Active participant in a coalition of stakeholder organizations that released a consensus document representing the medical, pharmacist, and supply chain spectrum highlighting the challenges and "red flag" warning signs related to prescribing and dispensing controlled substance prescriptions) See https://nabp.pharmacy/nabp-stakeholders-release-consensus-document-on-the-challenges-and-red-flag-warning-signs-related-to-prescribing-and-dispensing-controlled-substances/
(March 2015)

Participant member on *Ohio Attorney General Mike DeWine's Cybersecurity Advisory Board* (a group of industry experts and business leaders that provide guidance for the Attorney General's Office initiatives on cybersecurity) See http://www.ohioattorneygeneral.gov/Media/News-Releases/September-2016/Attorney-General-DeWine-Launches-CyberOhio-Initiat (September 2016)

PRESENTATIONS AND PUBLICATIONS

Presentation and Panel Discussion: NABP 114th Annual Meeting (May 6, 2018) – MAT: The Next Generation in Combatting the Opioid Epidemic

Presentation and Panel Discussion: American Association of Physicians of Indian Origin (AAPI) Annual Meeting (July 6, 2018) – The National AAPI Opioid Summit Program: State Medical Board of Ohio Regulatory Aspects

Panel Discussion: Ohio and Kentucky Societies of International Pain Specialists (OHSIPP and KYSIPP) Joint Annual Conference (August 9, 2018) – State Medical Board and Board of Pharmacy Updates (Steps taken by Ohio to help address the Opioid Epidemic and Medical Marijuana laws in Ohio)

Drug Wholesaling and Importation: Challenges and Opportunities, Cal. W. L. Rev./Int'l Law J. (Special Edition - Summer 2005) and to be republished in 42 Cal. W. Int'l Law J. Number 1 (Fall 2005).

HIPAA and Its Impact on Pharmacy Practice, 60 American Journal of Health-System Pharmacy 433 (March 1, 2003) and 51 Ohio Pharmacist 7 (July 2002).

The Pharmacist's Duty to Warn and the Potential for Liability, 134 Drug Topics 48 (April 6, 1990) and 52 Illinois Pharmacist 10 (May 1990)

Note, Kirk v. Michael Reese Hospital & Medical Center: The Treatment of a Third Party Plaintiff in a Medical Context, 38 DePaul L. Rev. 749 (1989)

Course Material and Presentation: San Diego Health Policy Conference: International Drug Importation: Issue in Public Policy, Patient Safety and the Public Health - Drug Wholesaling and Importation: Challenges and Opportunities? (San Diego, May 2005)

Presentation and Panel Discussion: ASHP Midyear Clinical Meeting – Drug Diversion and Counterfeiting: Prevention and Detection; The Wholesaler's Role in Preventing Drug Counterfeiting (New Orleans, December 2003)

Course Material and Presentation: Ohio Pharmacists Association Annual Conference – HIPAA Overview – Are You Ready for April 14th? (Columbus, April 2003)

Course Material and Presentation: VHA Conferences – HIPAA Overview (Perdido Beach, September 2002) and HIPAA Overview & Compounding Issue (Lake Tahoe, September 2002)

Course Material and Presentation: Pharmaceutical Care Management Association (PCMA) Conference: Regulatory Issues Surrounding Internet Pharmacy (San Diego, February 22, 2000)

Course Material and Presentation: National Association of Boards of Pharmacy (NABP) District Meetings (1999): The Next Generation of Pharmacy Practice and Regulation

ASSOCIATIONS

American Society for Pharmacy Law (ASPL)

Federation of State Medical Boards (FSMB)
- Previously elected to and served on the FSMB Nominating Committee

National Association of Boards of Pharmacy (NABP)

Ohio State Bar Association

Columbus Bar Association

ADMITTED TO PRACTICE

Law - Ohio Bar 2001(active), Illinois Bar 1989 (inactive), and Minnesota Bar 1996 (inactive).
Pharmacy - Ohio 1998 (active) and Illinois 1983 (inactive)