Susan C. Winckler, BS Pharm, JD, FAPhA

[redacted]

PROFESSIONAL EXPERIENCE

Reagan-Udall Foundation for the FDA, Washington, DC
Chief Executive Officer May 2020 to present

The Reagan-Udall Foundation for the Food and Drug Administration is the non-profit, non-government organization created by Congress in 2007 for the sole purpose of advancing the mission of the FDA.

As CEO, Ms. Winckler leads the Foundation staff in efforts to embody FDA's vision of collaborative innovation to address regulatory science challenges of the 21st century and assist in the creation of new, applied scientific knowledge, tools, standards, and approaches the FDA needs to evaluate products more effectively, predictably, and efficiently, and thereby enhance the FDA's ability to protect and promote the health of the American public. The Foundation serves as a crucial conduit between FDA and the public, providing a means for FDA to interact directly with stakeholders, including industry and consumers. (The Foundation does not participate in regulatory decision-making or offer advice to FDA on policy matters.)

Major responsibilities include:

- Leading the development and execution of the organization's annual budget, including fundraising. More than doubled Foundation budget from 2019 to 2022.
- Recruiting, retaining, and motivating staff and Foundation consultants to deliver on the promise of the Foundation's competence in advancing regulatory science, communicating with consumers, and stakeholder convening. More than doubled staff from nine to nineteen (positions as of July 2023).
- Guiding a 17-member board of directors composed of national leaders from academia, consumer groups, the medical product and food industries, health care providers, and others. (The FDA Commissioner and the Director of the National Institutes of Health serve as non-voting members of the Board.)
- Moderating numerous major meetings of the organization.
- Leading major Foundation projects, including primary staff support to the Independent Expert Panels who providing operational evaluations of FDA's Human Foods program and certain components of its Tobacco program.

Leavitt Partners, LLC, Washington, DC/Salt Lake City, UT
President, Leavitt Partners Solutions July 2018 to April 2020
President, Leavitt Partners Consulting April 2017 to July 2018
Chief Risk Management Officer Sept. 2015 to April 2020
Interim Managing Partner, Chicago Office 2016
Managing Partner, DC Office June 2014 – Sept. 2015
Senior Advisor (part-time) Aug. 2009 – May 2014

Founded by former U.S. Health & Human Services Secretary Michael O. Leavitt, Leavitt Partners is a leading national health consultancy that advises major U.S., multinational and international clients on a range of major health issues.

As President of Leavitt Partners Solutions (LPS), Ms. Winckler led a staff of 65 professionals who conduct in-depth research and analysis on complex business, regulatory and policy issues, and then inform, advise and convene clients on strategy and decision-making. LPS helps clients evaluate new

domestic and international markets, enhance the value of their products, navigate reimbursement systems, and improve health conditions around the world. LPS clients span the health system, and include integrated delivery systems, payors, health care associations, life sciences companies, pharmacies, and health information technology vendors, and organizations outside health care looking to 'break in' to the market.

Major responsibilities included:

- Holding profit-and-loss responsibility, including developing new business and retaining anchor clients.
- Guiding the LPS Board of Directors.
- Effectively deploying staff providing strategic advice to 50+ clients across the health-care spectrum.
- Conducting strategic planning sessions and trainings with client board members, CEOs and C-suite executives on a range of major health care developments, such as medical products and services (from product approval to formulary/coverage structures), and emerging payment systems (including the transition from fee-for-service to value-based systems).
- Managing the work for the largest/highest-profile clients, including $1M+/annual accounts.
- Leading the development and execution of the annual budget.
- Providing subject matter expertise to Leavitt Partners Collaborative Advocates alliance management and legislative/regulatory consulting practices; contribute to business/market evaluation and portfolio company support for Leavitt Equity Partners Management.
- Serving on the Board of Managers for Leavitt Partners, LLC, the parent company of three LP subsidiaries and corporate support structure for two affiliated companies.

Major accomplishments:

- Navigated the consolidation and subsequent separation of LP's consulting business into two wholly owned subsidiaries (creating Leavitt Partners Solutions); instituted new business practices to assure alignment across three practice areas.
- Guided the process of setting the LPS vision and strategy for a 5-year success cycle.
- Recruited five new principals to form the LPS senior management team; built a high-functioning collaborative leadership group.
- Facilitated multiple association and business strategic planning efforts, including work with volunteer leadership and staff for PhRMA, the National Pharmaceutical Council, and the Visiting Nurses Association of America. Corporate clients have included a major retail pharmacy chain, a large multi-national pharmaceutical manufacturer, a multi-state health system, and a provider-sponsored health plan.
- Provided advice to pharmaceutical stakeholders in India on maturing their drug regulatory system, as an international rapporteur.
- Served as the inaugural Executive Director for the then-30+-member Health Care Transformation Task Force, a coalition of patients, payers, providers, and purchasers committed to moving their business to value-based care.

Ms. Winckler also served as Chief Risk Management Officer for all LP companies – LPS, Leavitt Partners Collaborative Advocates, Leavitt Equity Partners Management, Leavitt Partners Insight, and Leavitt Risk Partners, where she enabled their efficient and effective governance of significant risks. She previously served as the Managing Partner of LP's Chicago and DC offices, where she built the

firm's health-intelligence and consulting practices in those markets, oversaw personnel and administration, and led the medical products and services team. She joined Leavitt Partners in August 2009 in a part-time capacity, a position she held throughout her tenure with the Food and Drug Law Institute until she joined LP full-time in 2014.

The Food and Drug Law Institute, Wash., DC
President and CEO Nov. 2009 – May 2014

FDLI is the leading national nonprofit organization that educates professionals and the public about food and drug law issues through conferences, publications, and member interaction. It convenes major stakeholders and provides an open, balanced marketplace of ideas that inform innovative public policy, law, and regulation. Ms. Winckler led 17 staff and hundreds of volunteers who serve FDLI's 10,000+ individual and corporate members from regulated industry, law firms, consultancies, academia, and state and federal government who work across all sectors, including pharmaceuticals, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices, and tobacco. FDLI tracks developments in all these areas of U.S. and international law. It delivers 30+ live educational programs yearly on a wide range of topics, including drug and device regulation, the regulation of products that deliver nicotine, current Good Manufacturing Practices, the evolving global regulation of food, and recent FDA enforcement actions. FDLI also publishes the quarterly *Food and Drug Law Journal*, the bimonthly *Update* magazine, the biweekly *Food and Drug Policy Forum,* and a collection of reference books and other resources that have become standards in the industry.

Major responsibilities included:

- Leading the development and execution of a $3.5 million annual budget.
- Guiding a 15-member board of directors composed of national leaders in food and drug law.
- Overseeing the nation's largest annual food and drug law conference, which most recently attracted 600+ attendees from the bar, industry, regulatory agencies, and consumer groups.
- Moderating numerous major meetings of the organization.
- Representing FDLI at key national and international conferences, such as the September 2012 gathering in São Paulo.
- Serving, in 2012 and 2013, as the international co-rapporteur for the "21st Century Regulatory Agency (Structure and Function)" workstream of the China Drug Administration Law Initiative led by Tsinghua University.

U.S. Food and Drug Administration, Rockville and Silver Spring, MD
Chief of Staff Jan. 2007 – June 2009

At the time, the FDA deployed nearly 11,000 employees and a $2.3 billion budget to regulate tens of thousands of food products and all human and veterinary drugs, medical devices, and other health-care products, which together constituted approximately 20% of goods purchased in the U. S. Ms. Winckler served as the Commissioner's senior-most staff advisor and represented him and the Agency before Congress, the White House, federal, state and local agencies, foreign governments, industry associations, professional organizations, the research community, and consumer groups. She also served as the Agency's principal liaison to HHS. As FDA's liaison to these varied audiences, she informed them about the Agency's key initiatives and actions, ensured they understood FDA's objectives, and garnered their feedback.

The Commissioner tasked Ms. Winckler with the unique added responsibility of overseeing and improving the efficiency and effectiveness of FDA's government affairs, communications, correspondence management, and external affairs offices on a day-to-day basis. The Commissioner also routinely had her coordinate the Agency's response to public health emergencies, major fast-breaking events, and key international efforts. In total, Ms. Winckler had responsibilities in six main areas:

Management
Served in dual capacity as manager of the Commissioner's direct staff and manager of the Agency's government affairs, communication/media relations, correspondence, and external affairs offices. Responsible for more than 100 staff, an operating (non-personnel) budget of over $5 million, and preventing and detecting fraud and abuse in operations. Assisted in the annual preparation and presentation of this budget.

Intergovernmental Liaison and Relations
Daily liaison with the Office of the HHS Secretary, the assistant secretaries of major HHS divisions (including public affairs and legislation), and key HHS operating divisions, including CDC and the Centers for Medicare and Medicaid Services. Primary interface with the White House Domestic Policy Council on all FDA-related issues. Represented the Commissioner in interagency negotiations on key Agency priorities. Shepherded FDA initiatives and numerous proposed rules through the administration-approval process, including OMB review, on such issues as a new FDA Food Protection Plan and an Import Safety Action Plan governing all FDA-regulated imported drugs, devices and other products.

Congressional Relations (until April 2009)
Directly oversaw all Congressional-affairs activities, including preparing Agency positions and testimony, negotiating with House and Senate committees and leadership, responding to Congressional requests for information, and analyzing legislation. Routinely briefed the Commissioner, Center Directors, and other top Agency officials prior to their appearances at hearings and Hill meetings. Managed or participated in more than 50 hearings and nearly 100 inquiries, fact-finding efforts, and investigations during the 110th Congress.

Communications and Media Relations
Recruited new leadership team for the FDA press office to improve strategic messaging and media relationships. Supported the staffing and coordinated an annual workload that included responding to 3,250 media inquiries, issuing 180 news releases and statements, and convening 40 media teleconferences. Led the launch of the new FDA.gov website that yielded a 75% improvement in users' ability to find information. Converted FDA's consumer magazine to a series of consumer health articles for the FDA website that were reproduced in numerous other publications through new editorial partnerships, thus greatly expanding the material's reach.

External Relations
Established new relationships with more than two dozen professional and consumer organizations. In 2008, supported the coordination and content of the Commissioner's 22 meetings with regulated entities and organizations representing food, drug, device, cosmetic, and other regulated industries. Provided similar substantive and logistical support for the Commissioner's new listening sessions and other meetings with more than 40 consumer and patient organizations.

International Assignments

- Over five months, led the technical drug and device negotiating team in a series of meetings in China and the U.S. that resulted in the landmark Memorandum of Agreement between HHS and the (then) Chinese State Food and Drug Administration on the safety of drugs and medical devices exported from China to the U.S.
- Represented the HHS Secretary and FDA Commissioner at the World Health Organization's Food Safety Summit in China attended by 20+ nations.
- Helped facilitate the opening of FDA's first-ever overseas offices in Beijing, Guangzhou, and Shanghai.
- Periodically communicated FDA regulatory actions directly to Chinese officials through face-to-face meetings and teleconferences.

U.S. Food and Drug Administration, Rockville, MD
Director of Policy Communications, Office of Policy & Planning, Office of the Commissioner Sept. 2006 – Jan. 2007

Served as a point person for policy development and constituent communications on key issues.

- Actively sought input from a full range of stakeholders, including federal agencies, health and medical organizations, consumer and patient groups, professional associations, industry, and academia.
- Had primary responsibility for developing and implementing the Office of the Commissioner's policies governing the management and operation of all FDA advisory committees, including supervising relevant advisory committee staff to ensure that all committee operations fully complied with applicable federal laws and regulations.

American Pharmacists Association, Washington, DC
Vice President for Policy & Communications and Staff Counsel April 2002 – Sept. 2006
Group Director, Policy and Advocacy July 1999 – April 2002
Director, Policy and Legislation May 1997 – July 1999

After a series of promotions, spent 4½ years managing APhA's policy and communications departments. Reported to the CEO and advised him, the Board of Trustees, APhA's ~400-member House of Delegates, and numerous committees on legislative, regulatory, health/medical policy, communications, and legal-scientific matters. Served on the six-person Senior Management Team and as the point person for developing public policy positions, designing related advocacy and media outreach strategies, and overseeing their implementation. Primary responsibilities grew over eight years in each of the following major functional areas:

Strategic Planning, Staff Management and Budgeting

Initially guided the development of APhA's annual health policy strategy in conjunction with the CEO and Board. As V.P., led the creation of APhA's annual policy plan, communications plan, and their related budget of $3.2 million/yr. Oversaw department finances and financial reporting. Progressed from supervising three staff to 14 plus a public-relations firm and a HRSA-funded project utilizing 20+ contractors. Hired eight staff in final two years. Conducted annual performance/compensation reviews. Regularly mentored younger staff, fellows, and interns.

Public Policy Analysis and Development

Initially tracked numerous complex legislative, regulatory and policy issues. Subsequently

drafted analyses, Congressional testimony, position papers, and other pieces for senior management and volunteer leadership. As V.P., oversaw issue-tracking, analysis, production, and dissemination of written work products on such issues as drug importation, Medicare drug coverage, medication errors, immunizations, compounding, OTCs, pain management, and health information privacy/confidentiality. Wrote numerous articles on public policy issues for professional journals and a regular column for *Pharmacy Today*.

Legislative and Regulatory Affairs
Began by representing APhA before Congress, FDA, HHS, CMS, CDC, AHRQ, HRSA, and other federal agencies. As V.P., developed and oversaw pursuit of the association's legislative and regulatory agenda on issues including controlled substances, direct-to-consumer advertising, e-prescribing, Medicare Part D, paperless labeling for prescription drugs, and Medicaid pharmacy benefits. Managed the lobbying and regulatory affairs staff. Served as APhA's representative in top-level matters with federal agencies, national and state professional organizations, industry, and other stakeholders. Testified or presented frequently before federal regulatory agencies. Testified before Congress.

External Relations and Alliance-Building
Built and maintained valuable working relationships with scores of professional health and medical organizations, consumer and patient groups, universities, research institutions, and companies. Led or participated in numerous working groups and committees. Delivered approximately 200 formal presentations at professional meetings on new and proposed federal legislation and regulations, as well as complex legal and scientific issues, such as patient privacy and confidentiality requirements, emergency contraception, and conscience clauses.

Media/Public Relations
At first, advised the V.P. for Policy and the CEO on external communications of high-profile health policy matters, such as FDA actions on Rx-to-OTC switches. Served as the association's spokesperson on policy-related matters with many media outlets. Media-trained 45 volunteer leaders. As V.P., served as the association's primary media spokesperson, managed the communications staff, and oversaw the association's media-relations and public-relations activities with national, regional and local media, trade journals, and professional publications. Developed and oversaw major public education campaigns, such as *American Pharmacists Month*. Provided more than 100 interviews and live appearances in final two years with major national media outlets, such as CNN, NPR, ABC, CBS, and the *New York Times*.

Federally Funded Special Project
Led the preparation of successful proposal and negotiated with HRSA to fund a $5+ million, five-year federal contract (at the time, APhA's largest) providing technical assistance to analyze and support better delivery of health-related pharmacy services to underserved populations. Hired and supervised five staff to manage project and oversee 20+ contractors working nationwide.

Legal Counsel
After receiving law degree (pursued while working full-time), appointed Staff Counsel and advised the CEO and board (with outside counsel) on major legal issues, such as responding to subpoenas, joining relevant litigation, and filing amicus briefs. Served as liaison with outside law firm.

American Pharmaceutical Association (subsequently *American Pharmacists Assn.)*, Wash., DC
Director, Professional Practice Affairs Oct. 1994 – May 1997
Interim State Services Director and Manager of Special Projects June 1994 – Oct. 1994
Executive Resident July 1993 – June 1994

As director, monitored, analyzed and evaluated professional issues governing pharmacy and health care. Planned and managed projects on professional and economic issues, including payment for services and the evolving role of the pharmacist. Worked closely with numerous health care organizations on a range of professional, scientific, economic and public policy matters. Developed and managed annual departmental budget and supervised two staff.

- Served as liaison and provided support to the APhA *Academy of Pharmacy Practice and Management*. Led leadership-development program for 34 Academy officers.
- Planned and directed or conducted several special projects on pharmaceutical and health-care issues, including drug-utilization review, immunizations, community-pharmacy residency programs, chemical dependency, pharmaceutical care, and practitioner education. Prepared educational materials and related publicity pieces.
- Began management career in the post-graduate *Executive Residency Program in Association Management* jointly sponsored by APhA and the (then) Natl. Council of State Pharmacy Association Executives. Conducted continuing education programs. Edited articles. Analyzed legislation. Represented associations at national conferences. Assisted membership research project.

State of Iowa Medicaid Program/Paramax Systems Corporation, Des Moines, IA
Drug Prior Authorization Systems Manager Sept. 1992 – June 1993

Developed and implemented the Iowa Medicaid Program's first drug prior-authorization program.

- Interpreted policy and regulations for Medicaid's staff pharmacists and claims-processing professionals. Developed educational materials for physicians, nurses and pharmacists. Prepared and presented testimony to state legislative subcommittees.
- Worked effectively with the Iowa Dept. of Human Services, pharmaceutical companies, and professional societies. Served as state's liaison to committee overseeing implementation of the On-Line Prospective Drug Utilization Review Project, per the federal OBRA of 1990.
- Interviewed, hired, and trained four pharmacist consultants and administrative staff.

EDUCATION

Georgetown University Law Center, Wash., DC
Juris Doctor, magna cum laude, 2001

- Selected to serve as a writing instructor (Law Fellow) for first-year students
- *Dean's List* every semester
- *Order of the Coif (*top 10% of graduating class), Georgetown University Law Center, 2001

The University of Iowa, Iowa City, Iowa
Bachelor of Science in Pharmacy, 1992

- *Outstanding Collegiate Scholar,* University of Iowa, 1992
- *Outstanding Performance in Clinical Communications,* Univ. of Iowa College of Pharmacy, 1992
- *Top Ten Finalist,* National Patient Counseling Competition, 1992

PROFESSIONAL AWARDS/HONORS

- *Thomas R. Temple Legacy of Leadership Award*, United States Pharmacopeia, 2025
- *Osterhaus Medal for Lifetime Achievement,* Univ. of Iowa College of Pharmacy, 2023
- *Distinguished Alumni Award*: *FDA*, FDA Alumni Association, 2023
- *Jacob W. Miller Award,* American Pharmacists Association Foundation, 2021
- *Zada Cooper Leadership Symposium Opening Keynote,* Univ. of Iowa College of Pharmacy, 2016
- *William H. Zellmer Lecture,* American Society of Health-System Pharmacists, 2014
- *Fellow*, American Pharmacists Association, 2013
- *Distinguished Alumni Award*, University of Iowa College of Pharmacy, 2012
- *Distinguished Fellow in Public Policy*, Pharmacy Academy, National Academies of Practice, 2011
- *FDA Commissioner's Special Citation*, China Agreement Negotiating Team, 2008
- *Woman of Distinction*, Alpha Xi Delta Women's Fraternity, 2007
- *Distinguished Young Alumni Award,* University of Iowa Alumni Association, 2003
- Named *One of the 50 Most Influential Pharmacists,* American Druggist Magazine, 1998

BOARD AND PROFESSIONAL ACTIVITIES

Secretary, Board of Directors, Purgo Scientific	2019-present
Member, VCU School of Pharmacy National Advisory Committee	2018-present
Chair, Board of Trustees, United States Pharmacopeial Convention	Nov. 2019 – June 2025
Member, Board of Trustees, United States Pharmacopeial Convention	2015-2020, 2020-2025
Member, Board of Directors, Partnership for Safe Medicines	2018-2020
Board Observer, PAI Pharmaceuticals	2019-2024
Board Observer and Compliance Committee Chair, SCA Pharmaceuticals	2017-2020
Co-Chair, Membership Committee, FDA Alumni Association	2016-2018
Board Observer, Veridicus Rx	2015-2016
Member, Univ. of Iowa College of Pharmacy Executive Leadership Board	2010-2014
Member, Board of Directors, American Society for Pharmacy Law	2003-2006
Member, Heart Healthy Magazine Advisory Board	2005-2006
Preceptor, American Medical Student Assn.'s Summer Health Policy Fellow Program	1996-2006
Preceptor, Pharmacy Student Externs	1996-2006
Volunteer, University of Iowa ASIST Program	1995-2006
Mentor, University of Iowa *Student Interns in Washington DC* Program	1995-2001
Participant, Tri-State Pharmacy Leadership Conference	1993

PROFESSIONAL MEMBERSHIPS

American Pharmacists Association	1987-present
Iowa Pharmacy Association	1987-present
Virginia Pharmacists Association	2002-present

PROFESSIONAL LICENSURE

Iowa Pharmacist License No. 17887
Virginia State Bar Member No. 46503

MEDIA APPEARANCES

Television and Radio

Have made over 40 live and taped television appearances, and over 25 live and taped radio appearances, on such programs as:

CBS Evening News	*Dateline NBC*
ABC Nightly News	*Fox News*
CNN	*Good Morning America*
Today Show	*C-SPAN Washington Journal*
CNN Financial New	*Wall Street Journal Report*
Wolf Blitzer Report	National Public Radio
CBS Radio Network	*Diane Rehm Show*

Newspapers and Wire Services

Have provided well over 200 interviews with national newspapers, wire services, and state and local newspapers, such as:

New York Times	*Wall Street Journal*
Washington Post	Associated Press
Washington Times	*USA Today*
Reuters	*Christian Science Monitor*
Boston Globe	*Los Angeles Times*
Chicago Tribune	*Baltimore Sun*

General Circulation Magazines

Have provided over 50 interviews with general-circulation magazines, such as:

Reader's Digest	*Better Homes and Gardens*	*SELF*
People	*Men's Health*	*Cooking Light*
Glamour	*Vitality Magazine*	

PUBLICATIONS

Have authored more than 100 columns for industry publications, as well as a collection of book chapters on emerging health issues, particularly in the pharmaceutical policy arena.

PRESENTATIONS

Have delivered over 250 formal presentations and speeches to professional societies, associations, consumer groups, research institutions, companies, universities, and others in the United States and globally (Austria, Brazil, China, India).

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