Jay P. Siegel, M. D.

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Citizenship: United States
Family: Married, 1982, two grown children

Chronology of Employment

2003-pres. Johnson and Johnson

Current positions

- 2009- Chief Biotechnology Officer (CBO), J&J
- 2013- Head of Scientific Strategy and Policy, J&J

Prior J&J positions

- 2009-2013 Head, Global Regulatory Affairs, Jannsen R&D, LLC (J&J Pharmaceuticals)
- 2003-2012 President, Centocor Research & Development, Inc.
- 2006-2009 Group President for Biotechnology, Immunology and Oncology, Research & Development, J&J Pharmaceuticals
- 2005-2006 Group President, Research & Development, J&J Pharmaceuticals

Selected other current functions

- 2010- Exec. Comm., Board of Directors, Biotechnology Industry Organization
- 2012- Exec. Comm., Board of Directors, Alliance for Regenerative Medicine
- 2013- Member, Forum on Microbial Threats, IOM
- 2009- Board of Directors, Lifesciences Org.
- 2010- CoChair, J&J regulatory policy council (pharm, devices, & consumer)
- 2013- Member, J&J R&D Management Committee
- 2009- R&D Development Committee (reviews development plans for all major

projects and critical times)

2011- R&D Investment Committee (advises on all major internal and external product development investments)

- As CBO, serves as J&J lead on policy, business, and scientific issues regarding biotechnology. Through 2013, led an organization responsible for expanding and managing the Company's extensive biotechnology capabilities and applying them to the discovery and development of new products in partnerships across J&J (pharmaceutical sector and device and diagnostic sector) Products include protein and cell-based therapies, drug-device combination products and regenerative medicine therapies.
- As Head of Scientific Strategy and Policy, serves as definitive J&J external scientific spokesperson in various venues with NIH, FDA, WHO, IOM, APEC, and other organizations globally. Plays central role in formulating and/or reviewing R&D / scientific strategy at all levels, eg., licensing and acquisitions, product areas, therapeutic and disease areas, technologies, portfolio investment choices, key product development programs, decision processes. Leadership position influencing global policy on biosimilars, PDUFA, drug approval standards and processes and other scientific matters
- Participates on committees responsible for scientific review of all pharmaceutical advanced development projects and for making funding decisions across our entire pharmaceutical portfolio.

Prior positions at J&J

2009-2013 Head of Global Regulatory Affairs (concomitant with J&J Chief Biotechnology Officer)

- As head of global regulatory affairs, led organization responsible for all pharmaceutical regulatory interactions in over 150 countries. Comprises many thousands of applications, several key drug approvals in all therapeutic areas (incl. Sirturo for resistant Tbc; Zytiga for prostate CA, Edurant for HIV, Incivek (Telaprevir) for HCV, Xarelto for CV disease, Invega Sustenna for some psychoses, Nucynta for pain) large pipeline.

2006-2009 Group President for Biotechnology, Immunology and Oncology Research & Development, J&J Pharmaceuticals

- Led global pharmaceutical R&D activities in oncology, immunology, and biotechnology, annual budget of nearly $ 1 billion and about 2000 employees.
- Continued as President, Centocor R&D, Inc.
- Led successful global development and registration efforts for Simponi and Stelara
- Member: J&J Worldwide R&D Council and the Pharmaceutical R&D Council.
- Partnered closely with commercial, marketing, business development and supply chain functions in leading an integrated organization in biotechnology,

immunology, and oncology pharmaceuticals.

- Created and built Ortho Biotech Oncology Research & Development. – J&Js Oncology R&D organization. I integrated activities, assets, and personnel from 4 R&D companies at multiple sites globally into a single, integrated, high-powered recruited and supervised a highly successful leader (Bill Hait, now head of Janssen R&D); built a strong R&D organization managing and advancing many projects including Zytiga, Velcade, Doxil, Yondelis, Procrit/Eprex.
- Created first biomarkers organization and first informatics organization within J&J; integrated these functions into product development.
- Co-led development of comprehensive long-term strategies for leadership in biotechnology, immunology, and oncology
- Individually, successfully reframed congressional debate on biosimilars through expert testimony.

2005-2006 Group President Research & Development, J&J Pharmaceuticals

- Continued as president of Centocor R&D, Inc.; added oversight responsibility for Alza Corporation and TransForm Pharmaceuticals (company presidents reported to me) and for Johnson & Johnson Pharmaceuticals worldwide regulatory affairs, R&D quality assurance, and Benefit-Risk Management (pharmacovigilance organization).
- Total 3000 employees reported up to me.
- Chair, Development Review Committee, Pharmaceuticals, with responsibility for technical review of all phase 2b and 3 programs from any of the J&J pharmaceutical R&D companies (Alza, Scios, Tibotec, Centocor, PRD)

2003-2012 President, Centocor, R&D, Inc.

- Achieved several approvals for Remicade
- Successfully brought Stelara and Simponi through development to market
- Built and developed organizational capabilities to transition organization from single drug development (with limited discovery and early development capabilities) to a comprehensive, successful R&D organization engaged in discovery and development of biotechnology pharmaceutical products and of new technologies for the efficient manufacture of such products.
- Our successes led to more than doubling of headcount and budget over 5 years.

1982-2002 Center for Biologics Evaluation and Research (CBER and predecessor organizations), FDA, Bethesda, MD

1995-2002: Director, Office of Therapeutics Research and Review (OTRR), CBER

- Led about 250 physicians, scientists, and support personnel responsible for research, review, and regulatory policy development for the vast majority of monoclonal antibodies, other therapeutic proteins, and cell and gene therapies.
- Responsible for regulating investigational studies and product approvals for a

substantial portion of the biotechnology and pharmaceutical industries
    - Actively involved in the development and review of many of the most important pharmaceutical products of our time (e.g., Remicade, Herceptin, Enbrel, Avonex, Rituxan, Avastin).
- Under my leadership, we established rigorous standards ensuring safety and efficacy, none of about 50 products I was involved in approving has ever been recalled for safety concerns.
- Despite this, OTRR review times met all legal standards, times to approval compare favorably for those for less novel and less complex drugs, approvals preceded those overseas in the large majority of cases.
- Managed a high quality research program involving 100 scientists located at NIH.
    - Designed and implemented a rigorous system of annual evaluations of research productivity, research relevance to the CBER mission, and regulatory contributions and thereby ensuring optimal use of scarce resources.
    - Through their research, review and policy activities, OTRR scientists played a critically important role in ensuring that new technologies that offer both promise and safety concerns (e.g., stem cell therapy, xenotransplantation, gene therapy) are developed in a safe and appropriate manner.
    - Helped negotiate and establish joint NCI-CBER laboratories in genomics and in proteomics.
- Developed new approaches to assessing workload and work effort; used those data to support two reorganizations, optimizing regulatory quality and efficiency.
- In concurrent roles as chair of CBER's Medical Policy Coordinating Committee, co-chair of the CBER-CDER Medical Policy Coordinating Committee, clinical topics lead for the International Conference on Harmonization, and other activities detailed below, I made major contributions to policy at the agency, national, and international level – both in the areas of clinical drug development and biotechnology product development (e.g., immunogenicity, comparability, risk of xenozoonosis).

1992-1995 Founding Director, Division of Clinical Trial Design and Analysis

- Made definitive recommendations for biological therapeutics regarding whether proposed clinical trials could proceed and whether safety and efficacy had been demonstrated for potential new products.
- Built essentially from scratch (6 employees) a group of about 35, mostly physicians, that became widely respected for its expertise in clinical trial design and analysis.
- Directly participated in the design of hundreds of clinical trials involving all fields of medicine.

1992-1995 Senior investigator, Division of Cellular and Gene Therapy, Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research, FDA, Bethesda, MD

- Research appointment, concomitant with clinical trial division appointment

1992 Deputy Director (Acting), Division of Cytokine Biology, Center for Biologics

Evaluation and Research, FDA, Bethesda, MD

1988-1992 Chief, Laboratory of Cellular Immunology, Division of Cytokine Biology, Center for Biologics Evaluation and Research, FDA, Bethesda, MD

- recruited and mentored 3 tenure-track independent investigators and developed a coordinated research agenda in cellular immunology. All 3 successfully achieved tenure (through the NIH Board of Scientific Directors); 2 became now FDA Division Directors, and the other an FDA laboratory chief.

1989-1992 Attending Physician, Division of Infectious Diseases, Department of Internal Medicine, National Naval Medical Center, Bethesda, MD

1986-1988 Senior Investigator, Laboratory of Immunology, Division of Virology, Center for Biologics Evaluation and Research, FDA, Bethesda, MD

1982-1986 Senior Staff Fellow, Division of Virology, Office of Biologics Research and Review, Center for Drugs and Biologics, Food and Drug Administration, Bethesda, MD

1988 Granted tenure by the NIH Board of Scientific Directors

Education

Degrees

1977 MD, Stanford University School of Medicine, Stanford, CA

1973 BS, Biology, *cum laude*, California Institute of Technology, Pasadena, CA

Post-graduate Medical Education

1980-1982 Fellowship, Infectious Diseases, Department of Medicine, Stanford University School of Medicine, Stanford, CA

1977-1980 Internship and Residency, Internal Medicine, University of California, San Francisco

Training in Research and Teaching

1980-1982 Fellow, Immunology and Infectious Diseases, Research Institute, Palo Alto Medical Foundation, Laboratory Director: Dr. Jack Remington

1980-1981 Instructor, Clinical Diagnosis, Department of Medicine, Stanford University School of Medicine, Stanford, CA

1973 Summer Research Fellow, Division of Immunology, Merck Institute for Therapeutic Research, Rahway, NJ, Preceptor: Dr. David Wood

1972-1973 Research Assistant and Teaching Assistant, Department of Biology, California Institute of Technology, Pasadena, CA, Preceptor: Dr. Edward B. Lewis (Nobel laureate).

1971-1972 Research Assistant, Department of Biology, California Institute of Technology, Pasadena, CA, Preceptor: Dr. James Bonner.

Uniformed Service

2003- Medical Director, U. S. Public Health Service, Retired
1992-2002 Medical Director, U. S. Public Health Service, Active Duty
1987-1992 Senior Surgeon, U. S. Public Health Service, Active Duty
1986-1987 Surgeon, U. S. Public Health Service, Active Duty

Selected Honors and Awards

2012 Pharmavoice 100 – Selected as one of the most inspirational leaders in life sciences.
2012 Stelara awarded international Prix Galien for Best Pharmaceutical Product 2011-2012 (schedule prevented my accepting on behalf of Janssen)
2011 Accepted the Prix Galien USA for best biotechnology product - Stelara
2010 Elected to Distinguished Fellowship, Society for Clinical Trials
2005 HHS Secretary's Award for Distinguished Service, for designing and implementing a comprehensive regulatory approach for safety of cell and tissue-based products.
2004 Johnson & Johnson Standards of Leadership Award for leadership in erythropoietin safety efforts
2003 HHS Secretary's Award for Distinguished Service, Gene Therapy Safety Team
2002 Distinguished Service Medal, (highest honor awarded by Public Health Service), "in recognition of his critical contributions to the development of new biological therapies that have saved and will save tens of thousands of lives and improved the health of millions of Americans"
1999 HHS Secretary's Award for Distinguished Service, FDAMA Implementation Team
1998 FDA Commissioner's Special Citation, Outstanding Unit Commendation, Xenotransplantation public health policy
1997 HHS Secretary's Award for Distinguished Service, FDA Reform Legislation Working Group (FDAMA Development)
1997 Meritorious Service Medal, USPHS, for exemplary performance of duty. "exceptional high quality initiative and leadership in designing, building, and implementing the clinical review program at CBER, FDA"
1996 FDA Commissioner's Special Citation, Outstanding Unit Citation, member, National Task Force on AIDS Drug Development Working Group
1993 Meritorious Service Medal, USPHS, for exemplary performance of duty. (cancer/sepsis therapy, cell/gene therapy, research management/supervision)
1992 Elected to Fellowship, Infectious Diseases Society of America
1992 Exceptional Capabilities promotion (before minimum age) to rank of Medical Director, USPHS
1990 Elected to Fellowship, American College of Physicians

Selected Major Policy Efforts

Biosimilars: Substantial leadership in global policy efforts regarding biosimilars including meetings with white house and congressional staff and media (2006-present). These efforts substantially shaped the contents of biosimilars legislation (Biologic Price Competition and Innovation Act (BPCIA) of 2010, and regulatory implementation in U.S. and E.U.). My congressional testimony (Senate HELP committee – before Kennedy, Obama, Clinton, Enzi, et al.) in March, 2006 led to substantial changes in how the safety issues were understood and addressed in legislation. Subsequent lectures and debates on Capital Hill continued to educate and influence. I have been invited to address EU regulatory authorities (EMA) and FDA on development of biosimilar policies on numerous occasions from 2002 through the present. In 2012, I gave invited keynote addresses at the Asia Pacific Economic Cooperation (APEC) Harmonization Conference on Biosimilars and I have been invited back this year.

PDUFA V: I conceptualized a new approach to regulatory interactions in drug development and successfully led efforts to bring that approach into law (Food and Drug Administration Safety and Innovation Act (FDASIA), 2012) drafted proposals to redesign the review process to ensure better communications and more rapid and appropriate resolution of issues and successfully persuaded BIO and PhRMA to adopt nearly all proposals into their negotiating position. I then joined the PDUFA negotiating team and helped promote adoption of our proposals. Most recently, I coauthored an article (see bibliography) to provide support of our positions when Congress considered them.

Through Executive Committee membership for Clinical Trials Transformation Initiative (a pulic-private partnership co-sponsored by FDA), seeking solutions to improve efficiency and effectiveness on clinical research enterprise in many areas (e.g., monitoring, handling adverse events)

Worked on an Institute of Medicine Expert Panel (2006-10) requested by FDA to advise on best approaches for handling missing data in clinical trials. We published report in 2010 that has had substantial impact on clinical research, and I have participated in many panels discussing and dissemination information.

International Conference on Harmonization (ICH): I participated in negotiations for, and signed, the following international guidelines (*denotes those for which I had the most direct and intensive involvement in negotiations, however, I contributed significantly to all listed.)

E1: The Extent of Population Exposure to Assess Clinical Safety, 1994
E2A: Definitions and Standards for Expedited Reporting, 1994
E2B: Data Elements for Transmission of ADR Reports, 1997
E2C: Periodic Safety Update Reports, 1996
E3*: Structure and Content of Clinical Study Reports, 1995
E4: Dose-Response Information to Support Drug Registration, 1994

E5*: Ethnic Factors In the Acceptability of Foreign Clinical Data, 1998
E5 implementation working group 2001-2002.
E6*: Good Clinical Practice: Consolidated Guideline, 1996
E8: General Considerations for Clinical Trials, 1997
E9: Statistical Principals for Clinical Trials,1998
E10*: Choice of Control Group in Clinical Trials, 2000
E11: Guidance of Pediatric Drug Development, 2000
E12: Guidance on Drugs for Hypertension
CTD-E*: Guidance on the Common Technical Document – Efficacy

I gave plenary talks for the 3rd (Yokohama, 1995), Fourth (Brussels, 1997), and Fifth (San Diego, 2001) International Conferences on Harmonization and authored chapters in books of the proceedings.

Food and Drug Modernization Act of 1997, negotiations, development, congressional briefings, implementation (lead responsibility for implementation of radiopharmaceuticals and fast track provisions)

Development and Implementation, FDA Proposed Approach to the Regulation of Cellular and Tissue-Based Products, 1996-2002 . I formulated the basic approach to risk-based regulation of these products, published in 1997, and implemented since.

Extensive Involvement and Leadership in HHS response to public health concerns regarding gene therapy. (incl. testifying before the Senate, forming and chairing the Gene Therapy Action Plan Core Team, coordinating efforts with NIH and HHS, planning development of gene therapy safety conferences and a gene therapy safety database, and developing, implementing, and assessing many new policies and approaches.)

Extensive Involvement and Leadership in HHS and FDA policies regarding human subjects protections. Chaired working group writing proposed new regulations regarding sponsor-investigators, monitoring, and conflicts of interest and represented CBER on the FDA Good Clinical Practices/Human Subject Protections Steering Committee.

Extensive Involvement and Leadership in FDA development of policy and guidance regarding clinical drug development and clinical labeling of drugs (e.g., effectiveness standard, supplemental indications, abbreviated study reports, data monitoring committees, adverse event and pregnancy labeling.)

I have led FDA intercenter efforts in developing Good Review Practice standards for IND review. These standards were formally published as FDA guidance in 2013.

I have participated directly in over 50 meetings of 13 different FDA Advisory Committees that were giving input either regarding policy or regarding regulatory approval decisions that set important precedents.

Societies

Society for Clinical Trials

2010- Honorary Fellow

2001-5: Board of Directors

Various other committees and associate editorship

American College of Physicians, Associate 1980, Member 1982, Fellow 1990

Infectious Diseases Society of America, Fellow, 1992

Key J&J Committee Responsibilities

2013-	Enterprise wide R&D Management Committee
2011-	Member, Investment Committee
2010-	Member, Regenerative Medicine Scientific Advisory Board
2010-2012	Member, Corporate Office of Science and Technology Science Advisory Board
2010-2013	Executive Sponsor, Convergence Products Team
2009-	Biotechnology Advisory Council, J&J, Chair (2009-2013)
2009-2013	Chair, Biotechnology Leadership Team, J&J
2009-	Member, Development Committee, Janssen (J&J) Pharmaceuticals
2009-	Member, J&J Medical Devices & Diagnostics Research & Development council
2009-2013	Chair, Pharmaceutical Global Regulatory Leadership Team, J&J
2005-	Member, Global Safety Council
2006-	Member, J & J enterprise-wide Research & Development Council(replaced by R&D Management Committee
2009-2011	Member, Cross-Portfolio Management Committee, J&J Pharmaceuticals (replaced by investment committee)
2003	Member, J & J Pharmaceutical Research & Development Leadership Team
2004-2006	Chair, Development Review Committee, Johnson & Johnson Pharmaceuticals
2004-2007	Executive Sponsor, Projects Harmony and Concerto (optimized development in China, Japan, rest of Asia and Latin America)
2003-2009	Chair, Biotechnology, Immunology and Oncology (prior to 2006, Centocor) Research & Development Management Board
2003-2009	Chair, Biotechnology, Immunology and Oncology (prior to 2006, Centocor) Research & Development Review Board
2003-2006	Member, J & J Biotech Management Committee
2003-2004	Member, J & J Drug Development Council
2003-2006	Member, J & J New Products Development Committee

Selected Other Professional Memberships and Activities

2013-	Member, Institute of Medicine Forum on Microbial Threats
2011-	Member, Board of Directors, Life Sciences Institute
2011-	Member, Executive Committee, Board of Directors, Biotechnology Industry Organization
2010-	Member, Executive Committee, Board of Directors, Biotechnology Industry Organization & member of its Regulatory Environment and Global Reimbursement Committees
2010-	PDUFA negotiator
2009-2010	Member, Institute of Medicine expert panel on handling missing data in clinical trials
2007-	Member, Executive Committee, Clinical Trials Transformation Initiative
2003-2009	Member, Executive Oversight Committee (with Schering-Plough), Remicade

	and Simponi
2001-2002	Member, CBER International Policy and Activities Coordinating Committee
2001-2004	Member, Board of Directors, Pharmaceutical Education and Research Institute (PERI)
2001-2002	Member, FDA Steering Committee, Human Subjects Protection and Good Clinical Practice
2000-2002	Co-chair, joint CDER/CBER Medical Policy Coordinating Committee
1999-2003	Associate Editor, *Controlled Clinical Trials*
1998-2002	Chair, CBER Medical Policy Coordinating Committee
2001	Member, Secretary's Advisory Committee on Xenotransplantation
2000	NIH Working Group on Good Clinical Practices for Intramural Research
1997-2000	Faculty, Masters' course in clinical research, Duke Univ.
1997-1999	Co-chaired Fast Track Drug Development Policy Implementation Committee
1993	Completed course on Principles of Epidemiology offered by the CDC (42 credit hours)
1993-5	National Task Force on AIDS Drug Development: member of planning committee and the working group on development
1995-1998	FDA Modernization Act and PDUFA development and implementation team

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Committee on Energy and Commerce
U.S. House of Representatives
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)

1. Your Name: Jay Philip Siegel		
2. Are you testifying on behalf of the Federal, or a State or local government entity?	**Yes**	**No** X
3. Are you testifying on behalf of an entity that is not a government entity?	**Yes** X	**No**
4. Other than yourself, please list which entity or entities you are representing: Johnson & Johnson		
5. Please list any Federal grants or contracts (including subgrants or subcontracts) that <u>you or the entity you represent have received</u> on or after October 1, 2011: Johnson & Johnson, the parent company, does not receive any US Government funding. Johnson & Johnson subsidiaries supply numerous products and services to the Federal Government and as a result have a multitude of contracts with and grants from U.S. Federal agencies/departments.		
6. If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing: Chief Biotechnology Officer and Head, Scientific Strategy and Policy Johnson & Johnson		
7. If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?	**Yes** X	**No**
8. If the answer to the question in item 3 is "yes," please list any Federal grants or contracts (including subgrants or subcontracts) that were received by the entities listed under the question in item 4 on or after October 1, 2011, that exceed 10 percent of the revenue of the entities in the year received, including the source and amount of each grant or contract to be listed: Based on a recent analysis, Crucell Holland B.V. is the only entity in the Johnson & Johnson family of companies that has received in excess of 10% of its total revenue from a combination of U.S. Federal government contracts and grants, including direct and indirect funding.		
9. Please attach your curriculum vitae to your completed disclosure form.		

Signature [redacted] **Date: July 8, 2014**