

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

INDUSTRY EXPERIENCE

- 2009 – Present **Regeneron Pharmaceuticals, Inc., Tarrytown, NY**
2009 – 2012 Executive Director and Head, Regulatory Affairs
2013 - Present VP and Head, Regulatory Affairs
- Manage and Lead the Regulatory Development Department
 - Grow department and establish sub-departments with expertise in Regulatory affairs, Regulatory operations and coordination, labeling, Regulatory CMC, Regulatory intelligence, and Promotions
 - Lead the development and implementation of regulatory strategy consistent with business objectives
 - Ensure compliance with regulations worldwide pertaining to the conduct of clinical studies and the maintenance of marketing licensure
- Notable accomplishments to date:
- Growth of department from (b) (4) to (b) (4) individuals
 - FDA approval of EYLEA worldwide
 - FDA advisory committee presenter for EYLEA (safety presentation); (b) (4) (clinical and regulatory presentation); ARCALYST for gout (safety presentation)
- 2006 - 2009 **Merck & Co., Inc.**
Executive Director, Global Human Health
- Development of web-based solutions to provide scientific information to external advisors to scientific teams
- 1999 - 2006 **Merck & Co., Inc. (Merck Research Labs)**
Senior Director and Director, Alternating responsibilities in Global Regulatory Affairs and Clinical Research
- 1999 – 2004 Direct line reporting: Regulatory affairs; Dotted line: Clinical Research.
 - 2004 – 2006 Direct line reporting: President, Merck Research Labs; responsibilities
- Senior Director
Product team leader for Vioxx (pre-withdrawal)
Merck Research Labs point person to work with FDA on VIOXX withdrawal
Led special projects team reporting to president of Merck Research Labs
Management of FDA liaisons for specific products (anti-inflammatory/pain/immunology, bone/osteoporosis, oncology)
- Director
FDA liaison for specific products (anti-inflammatory/pain/immunology)
Member: Immunology Review and Licensing Committee
Medical review of promotional material for specific products
Author and/or review regulatory documents and product labeling

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ACADEMIC APPOINTMENTS

- Academic
 - Adjunct Associate Professor of Medicine, Columbia University, New York, NY 2000 - 2012
 - Associate Professor of Medicine, Columbia University, New York, NY 1995 - 1999
 - Assistant Professor of Medicine, Columbia University, New York, NY 1987 – 1995

- Hospital
 - Associate Attending Physician, Presbyterian Hospital, New York, NY; Physician-In-Charge Arthritis/Lupus Clinic 1995 - 2012
 - Director/Associate Director, Rheumatology Fellowship Program, Presbyterian Hospital, New York, NY 1998 - 1999
 - Director, Thursday Arthritis Clinic, Presbyterian Hospital, New York, NY 1998 - 1999
 - Assistant Attending Physician, Presbyterian Hospital, New York, NY 1987 - 1995

TRAINING

- Medical Staff Fellow, Laboratory of Immunology, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD (mentor: (b) (6), M.D., Ph. D.) June 1983 – June 1987
- Clinical Fellowship, NY Presbyterian Hospital, New York, NY, Rheumatology July 1982 - Dec. 1982
- Residency, NY Presbyterian Hospital, New York, NY, Internal Medicine July 1981 - June 1983
- Internship, NY Presbyterian Hospital, New York, NY, Internal Medicine July 1980 - June 1981

EDUCATION

1974 - 1980	6-Year Honors Program in Medical Education. This program consisted of:
1980	Doctorate of Medicine Northwestern University, Chicago, Illinois
1978	Bachelor of Science in Medicine Northwestern University, Evanston, Illinois

AWARDS AND AFFILIATIONS

- **Professional Organizations and Societies**
 - Drug Information Association 2000
 - American Association of Immunologists 1988
 - American Association for the Advancement of Science 1988
 - Alpha Omega Alpha 1978

- **Honors**
 - Golden and Lamport Award, College of P&S, Columbia University 1994
 - Hirschl Career Scientist, College of P&S, Columbia University 1992

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- R. J. Reynolds-Nabisco Scholar 1988
- Daniel Silberberg Assistant Professorship, College of P&S, Columbia University 1988
- Alpha Omega Alpha 1978
- **Boards and Certification**
 - American Board of Internal Medicine 1983
 - Board Eligible in Rheumatology 1983

PROFESSIONAL ACTIVITIES

- Medical and Scientific Committee, Arthritis Foundation, New York Chapter 1998 - 2012
- Medical Advisory Board, NY chapter SLE foundation 1989 - 2002
- American Cancer Society, immunology study section, permanent member 1997 - 1999
- Reviewer, Journal of Immunology 1987 - 1999
- American Cancer Society, immunology study section, ad hoc member 1994, 1996
- Grant study section, N. Y. Chapter Arthritis Foundation 1991 - 1995
- NIH Immunobiology Study Section, ad hoc member 1989, 1992
- NIH NIDDK special study section
- Co-chair, “Cellular routes in antigen processing & presentation”

TEACHING/MENTORING EXPERIENCE

- Lecturer on Drug Development, NYU Medical School 2005 - 2008
- Merck mentoring program (mentor) 2001 - 2003
- Teaching Attending Physician, Outpatient Rheumatology Clinic (NY Presbyterian Hospital) 1998 - 1999; 2001 - 2008
- Immunology and Autoimmune Disease Pathophysiology Course lecturer and preceptor (co-director 1991-1999) (College of P&S) 1988 - 1999; 2003 - 2005
- Acting/Associate Director, Rheumatology Fellowship Program (NY Presbyterian Hospital) 1998 - 1999
- Other Graduate Teaching: Pharmacology Course, Genetics Course, Topics in Biology (Graduate School of Arts & Sciences and College of P&S) 1989 - 1999
- Post-graduate Courses: Update in Internal Medicine (Columbia University and Harvard Medical School combined course); NYU Seminar in Advanced Rheumatology (NYU) 1989 - 1999
- Grand Rounds & Guest Lectures: NY Presbyterian Hospital (Columbia and Cornell Campuses), NYU, Univ. Chicago, Univ. Texas Galveston 1989 - 1999
- Teaching Attending Physician, Inpatient Medical Service (NY Presbyterian Hospital) 1989 - 1999
- Faculty advisor to medical students (4 students per year) in the classes of 1993, 1997, and 2001 (College of P&S) 1989 - 1999

PUBLICATIONS

Lechler, R.I., Ronchese, F., **Braunstein, N.S.**, and Germain, R.N. I-A-restricted T cell antigen recognition. Analysis of the roles of A α and A β using DNA-mediated gene transfer. *Journal of Experimental Medicine*. 1986. 3:678-696.

Braunstein, N.S. and Germain, R.N. The mouse E β 2 gene: A class II MHC β gene with limited

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- intraspecies polymorphism and an unusual pattern of transcription. *EMBO Journal*. 1986. 5:2469-2476.
- Braunstein, N.S.** and Germain, R.N. Allele specific control of Ia surface expression and conformation: Implications for a general model of Ia structure-function relationships. *Proc. Natl. Acad. Sci.* 1987. 84 (9):2921-2925.
- Sant, A.J., **Braunstein, N.S.** and Germain, R.N. Predominant role of amino-terminal sequences in dictating efficiency of class II major histocompatibility complex $\alpha\beta$ dimer expression. *Proc. Natl. Acad. Sci.* 1987. 84 (22): 8065-8069.
- Lechler, R.I., Sant, J., **Braunstein, N.S.**, Sekaly, R., Long, E., and Germain, R.N. Cell Surface Expression of Hybrid Murine/Human MHC Class II $\beta\alpha$ Dimers: Key Influence of Residues in the Amino-Terminal Portion of the β 1 Domain. *Journal of Immunology*. 1990. 144 (1):329-333.
- Braunstein, N.S.**, Germain, R.N., Loney, K., and Berkowitz, N. Structurally interdependent and independent regions of allelic polymorphism in class II MHC molecules: implications for Ia function and evolution. *Journal of Immunology*. 1990. 145 (6):1635-1645.
- Shreeniwas, R., Ogawa, S., Cozzolino, F., Torcia, G., **Braunstein, N. S.**, Butura, C., Brett, J., Lieberman, H. B., Furie, M., and Stern, D. M. Macrovascular and microvascular endothelium during long-term exposure to hypoxia: alterations in cell growth, monolayer permeability and cell surface coagulant properties. *Journal of Cellular Physiology*. 1991. 146(1):8-17.
- Lederman, S., DeMartino, J. A., Daugherty, B. L., Foeldvari, I., Yellin, M. J., Cleary, A. M., Berkowitz, N., Lowy, I., **Braunstein, N. S.**, Mark, G. E., and Chess, L. A single amino acid substitution in the CD4 molecule ablates binding of the monoclonal antibody, OKT4, in a common African allele. *Journal of Molecular Immunology*. 1991. 28(11):1171-1181.
- Liu, Z., **Braunstein, N. S.**, Suci-Foca, N. T cell recognition of allo-peptides in context of syngeneic MHC. *Journal of Immunology*. 1992. 148 (1): 35-40.
- Berkowitz, N. and **Braunstein, N.** T cell responses specific for subregions of allogeneic MHC molecules. *Journal of Immunology*. 1992. 148 (2): 309-317.
- Braunstein, N. S.**, Weber, X.C., Wang, D. A., Long, E. O. and Karp, D. Sequences in both class II MHC alpha and beta chains contribute to the binding of the superantigen TSST-1. *Journal of Experimental Medicine*. 1992. 175 (9):1301-1305.
- Hong, S.-C., Chelouche, A., Lin, R.-H., Shayitz, D., **Braunstein, N. S.**, Glimcher, L., and Janeway, C. A., Jr. The amino terminal half of the variable domain of the T cell receptor alpha chain influences the specificity of MHC recognition. *Cell*. 1992. 69 (6): 999-1009.
- Ware, R., Jiang, H., **Braunstein, N.S.**, Kent, J., Wiener, E., Pernis, B., and Chess, L. Human CD8+ T Lymphocyte Clones Specific for T Cell Receptor V β Families Expressed on Autologous CD4+ T Cells. *Immunity*. 1995. 2:177-184, February, 1995.
- Weber, D.A., Terrell, N.K., Zhang, Y., Strindberg, G., Martin, J., Rudensky, A., and **Braunstein, Ned S.** Requirement for peptide in alloreactive CD4⁺ T cell recognition of class II MHC molecules. *Journal of Immunology*. 1995. 154(10):5153-5164.
- Itoh, Y., Kajino, K., Ogasawara, K., Katoh, M., Namba, K., Takami, K., Iwabuchi, K., **Braunstein, N. S.** and Onoe K. 1996. Determination of the allele-specific antigen-binding site on I-Ak and I-Ab molecules. *Eur. J. Immunol.* 26(6):1314-21
- Eastman, S., Deftos, M., DeRoos, P. C., Hsu, D.-H., Teyton, L., **Braunstein, N. S.**, Hackett, C. J., and Rudensky, A. A study of complexes of class II invariant chain peptide: major histocompatibility complex class II molecules using a new complex-specific monoclonal antibody. 1996. *Eur. J. Immunol.* 26(2):385-93
- Patrick, S. M., An, H., Harris, M. B., **Braunstein, N. S.**, Leonard, E. F. Controlling Receptor-Ligand

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- Contact to Examine Kinetics of T cell Activation. 1997. *Ann. Biomed Eng.* 25: 1072-1080
- Jiang, H., Kashleva, H., Xu., L.-X., Forman, J., Flaherty, L., Pernis, B., **Braunstein, N. S.**, and Chess, L. T cell vaccination induces TCR V β specific, Qa-1 restricted regulatory CD8⁺ T cells. 1998. *Proceedings of the National Academy of Sciences*, 95: 4533-4537
- Tau, G. Z., Wang, Y., von der Weid, T., Wang, Y., Lu, B., Cowan, S., Kvatyuk, M., Pernis, A., Cattoretti, G., **Braunstein, N. S.**, Coffman, R. L. and Rothman, P. B. Interferon gamma signaling alters the function of T helper type 1 cells. 2000. *J. Exp. Med.* 192(7):977-86.
- Patrick, S. M., Kim, S., **Braunstein, N. S.**, Thomas, J. L., and Leonard, E. F. Dependence of T cell Activation on Area of Contact and Density of a Ligand-Coated Surface. 2000. *J Immunol Methods*. 241(1-2):97-108.
- Patrick, S. M., Kim, S., **Braunstein, N. S.**, Maldarelli, C., Thomas, J. L., and Leonard, E. F. Controlled Cell deformation Produces Defined Areas of Contact between Cells and Ligand-Coated Surfaces. 2001. *Ann. Biomed Eng.* 29(1):1-8.
- Kim, S., **Braunstein, N. S.**, Leonard, E. F., and Thomas, J. L. Controlling duration of contact between T cells and antigen-presenting cells. 2001. *J. Immunol Methods* 249(1-2):73-84
- Kim S., Patrick, S. M., **Braunstein, N. S.**, Thomas, J. L., Leonard, E. F. Modelling of early events in T cell signal transduction after controlled T cell activation by peptide-major histocompatibility complex. 2001. *Ann. Biomed Eng.* 29(5):373-83.
- Jiang, H., **Braunstein, N. S.**, Yu, B., Winchester, R., and Chess, L. CD8⁺ T cells control the phenotype of MBP-reactive CD4⁺ T cells in EAE mice. 2001. *Proc. Natl. Acad. Sci. (USA)* 98(11):6301-6.
- Tau, G. Z., Cowan, S. N., Weisburg, J., **Braunstein, N. S.**, and Rothman, P. B. Regulation of IFN-gamma Signaling Is Essential for the Cytotoxic Activity of CD8⁺ T Cells. 2001. *J Immunol* 167: 5574-5582
- Agrawal, S., Reemstma, K., Bagiella, E., Oluwale, S. F., and **Braunstein, N.S.** Role of TAP-1 and TAP-2 antigen presentation defects in tumorigenicity of mouse melanoma. 2004. *Cellular Immunology* 228:130-137.

ABSTRACTS AND PRESENTATIONS

- Curtis, S.P., Braunstein, N., Sperling, R., Bergman, G., Ng, J., and Shingo, S. Renovascular Safety Profile of Etoricoxib, *American Journal of Hypertension*, **15**: 4 (Supplement 1): A16

LETTERS

- Sperling, R., **Braunstein, N.**, Melin, J., Reicin, A. Cyclooxygenase 2 inhibitors and thrombogenicity production: comment on the article by Crofford et al. 2001. *Arthritis Rheum* 44(5):1229-30
- Braunstein, N.** and Polis, A. Report of Specific Cardiovascular Outcomes of the ADVANTAGE Trial. 2005. *Annals Int. Med.* 143(2): 158-159

REVIEWS

- Germain, R.N., **Braunstein, N.S.**, Brown, M.A., Glimcher, L.H., Lechler, R.I., McCluskey, J., Margulies, D.H., Miller, J., Norcross, M.A., Paul, W.E., Quill, H., and Ronchese, F. 1986. The structure and function of murine class II MHC genes. *Mt. Sinai J. Med.*, 53:194-201.
- Germain, R.N., **Braunstein, N.S.**, Lechler, R.I., Miller, J., Ronchese, F., and Sant, A.J. 1988. Ia structure and immune recognition. In *Processing and Presentation of Antigens*. B. Pernis, S.C.

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Silverstein, and H.J. Vogel, eds. Academic Press, New York.

Braunstein, N.S., Ronchese, F., Sant, A.J., Schwartz, R.H., Lechler, R.I., and Germain, R.N. 1988. DNA-mediated gene transfer as a tool for analyzing Ia structure-function relationships and antigen presentation. In *Antigen Presenting Cells*, L.B. Schook, ed., Alan R. Liss, Inc., New York.

APPEARS THIS WAY ON ORIGINAL.