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SPECIAL EXPERTISE:

- Scientific, clinical and commercial assessment of drug candidates
- In-depth Key Opinion Leader Interviews
- Planning and executing the development of products from pre-IND through NDA
- Planning and executing pharmacological, preclinical, and clinical research in inflammation, immunology, dermatology, oncology and metabolic disease

QUALIFICATIONS

- Thirty years in the pharmaceutical industry with expertise in basic research, development research, market opportunity assessment and new product planning
- Positions held in the following areas:
 - New Product Planning
 - Project Leader in Skin Biology, Immunology, Inflammation, Cancer, Diabetes
 - Project Management
 - Market Consulting
 - Business Development
- Excellent communication skills--High degree of credibility with scientific and commercial management

EDUCATION

Ph.D. (Biology, Skin Tumor genesis) Syracuse University

BS. State University of New York at Albany

POSITIONS (see below for details)

Genencor International 2003-2004

Vice President New Product Planning

Genencor International 2000- 2002

Senior Director New Product Planning

Calyx Therapeutics, Inc. 1998- 2000

Vice President of New Product Planning and Development

IDEA GmbH, 1997

Vice President of Marketing and Business Development for Startup

Pharmaceutical New Product Planning, 1995-

New Product Planning Consultant

Syntex 1978 - 1995

Medical Marketing Planning Manager, New Product Planning, 1992-1995
Research/Development Project Team Manager, 1990-1992
Project Leader for Anti-Acne Compound 1989-1991
Research Section Leader Immunology and Skin Biology, 1986-1990
Senior Staff Researcher, 1984-1986
Staff Researcher II, 1981-1984
Staff Researcher I, 1978-1981

University of Wisconsin 1976-1978 Postdoctoral fellow at the McArdle Laboratory for Cancer Research

SUMMARY OF INDUSTRY EXPERIENCE

Genencor International

- Major role in planning and strategy for launching Genencor Healthcare Initiative
- Market and technology assessment
- Key Member of Pharmaceutical Strategy Group
- Member of in-licensing team for Epimmune, Johns Hopkins, and Phogen deals
- Integral role in launching therapeutic vaccine program
 - Hepatitis B, Human Papilloma Virus, Hepatitis C
 - Chairman of Genencor/Epimuune steering Committee
 - Principal Contact with Johns Hopkins University
- Led in-licensing team that acquired Bavaraian Nordic MVA Vector
- Key member of therapeutic vaccine out-licensing team that successfully out-licensed program to Innogenetics, N.V.
- Led in-licensing review teams in oncology, enzyme replacement, oral insulin

Vice President of New Product Planning and Development, Calyx Therapeutics, Inc.

- Direct project team for anti-diabetes compound isolated from Ayurvedic medicine extract
 - Establish and manage toxicology, manufacturing, pharmaceuticals, and clinical outsources
- Responsible for New Product Planning and Business Development

Vice President Marketing and Business Development, IDEA GmbH

- Wrote marketing, technology, and competitive section of business plan for transdermal delivery of macromolecules
- Planned development program to maximize commercial success
- Performed all business development functions
- Designed clinical trials

Consultant

- Analyzed unmet needs in market place
- Performed market opportunity assessments including investor due diligence
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|-----------------|---------------------------|
| - Asthma | - Pain |
| - Bone Care | - Cardiology |
| - Dermatology | - Urinary Incontinence |
| - Oncology | - Male Sexual Dysfunction |
| Anti-infectives | Wound Healing |

Medical Marketing Planning Manager, New Product Planning Product Planning - Syntex

- Product Manager for Asthma, Osteoporosis, and Rheumatoid Arthritis programs
 - Member of corporate development team
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- Developed and communicated strategic marketing direction via the Assessment of Clinical and Commercial Attractiveness and the product Lifetime Strategic Plan
- Developed expert level knowledge of worldwide medical practice
- Ensured that development programs were positioned to best meet market needs
- Represented New Product Planning on research and development project teams
- Provided commercial input to research program portfolio planning
- Performed commercial assessment of potential product acquisitions
- Personally conducted primary market research with opinion leaders
- Researched and recommended drug delivery options to enhance product profiles

Research Project Manager (Drug Development from IND to NDA) - Syntex

- Planned drug evaluation/development programs
- Primary Syntex contact with numerous partners
- Responsible for ensuring good communication between R&D and marketing
- Responsible for coordinating foreign filings

Staff Researcher and Research Section Leader (Drug Discovery and Basic Research) - Syntex

- Principal Investigator on the novel anti-acne agent basic research program
 - Designed and directed the laboratory program leading to patented compounds
 - Wrote pharmacology section of IND.
 - Coordinated drug synthesis program with Syntex Canada
 - Project Team Leader pre- and post- IND project team.
 - Directly supervised 7 employees.
- Basic research in the biology, biochemistry and pathology of the skin,
 - Developed the P. acnes model of inflammatory acne
 - Over 30 publications

ADVANCED TRAINING CLASSES AND CONFERENCES

Project Management Course, Pharmaceutical Manufacturers Association, Washington, D.C., 1990.

International Price Control & Pricing Strategies for Pharmaceutical Companies, September 21-22, 1992, IBC USA Conferences Inc., Georgetown University Conference Center.

Clinical Trials, European Registration and Global Development Programs, September 23-24, 1992, IBC USA Conferences Inc., Georgetown University Conference Center.

Medical Marketing Program, October 25-30, 1992 John E. Anderson School of Management, UCLA.

Asthma (Focusing on Current Development and Strategic Implications for the Pharmaceutical Industry), London, January 25-26, 1993.

Molecular Pharmacology and the Therapy of Osteoporosis, William Harvey Research Conferences, London, July 12-13, 1993.

Fundamentals of Finance and Accounting for Nonfinancial Executives, American Management Association, San Francisco, March 30 - April 1, 1994.

Executive Effectiveness Course, American Management Association, Carmel, Ca. November 15 - 20, 1994

PAPERS

1. 1974. Argyris, TS, C Nevar, S Mueller, LM De Young, and G Gordon. Ribosome Fractions from Normal and Methylcholanthrene-Treated Mouse Epidermis. *Jour. Invest. Dermat.* 63:262.
 2. 1977. De Young, LM, TS Argyris, and G Gordon. Epidermal Ribosome Accumulation during Two-Stage Skin Tumorigenesis. *Cancer Res.* 37:388.
 3. 1977. De Young, LM, RA Mufson, and RK Boutwell. An Apparent Inactivation of Initiated Cells by the Potent Inhibitor of Two-Stage Mouse Skin Tumorigenesis, Bis (2-chloroethyl) sulfide. *Cancer Res.* 37:4590.
 4. 1977. Mufson, RA, LM De Young, and RK Boutwell. Microwave Irradiation: A New Rapid Technique of Separating Epidermal Tissue from Mouse Skin Preserving, RNA, DNA, Protein, and Phorbol Ester-Induced Ornithine Decarboxylase Levels. *Jour. Invest. Dermat.* 69:547.
 5. 1978. De Young, LM and RK Boutwell. Localization and Significance of Gamma Glutamyl Transpeptidase in Normal and Neoplastic Mouse Skin. *Cancer Res.* 38:3697.
 6. 1978. Boutwell, RK, TG O'Brien, AK Verma, RG Weekes, LM De Young, CL Ashendel, and EG Astrup. The Induction of Ornithine Decarboxylase Activity and Its Control in Mouse Skin Epidermis. *Adv. Enzyme Regul.* 17:89.
 7. 1979. Boutwell, RK, TG O'Brien, AK Verma, RG Weekes, LM De Young, CL Ashendel, and EG Astrup. On the Biochemical Mechanism of Tumor Promotion in Mouse Skin. In: *Naturally Occurring Carcinogens-Mutagens and Modulators of Carcinogenesis*, EC Miller et al (eds.). Japan Sci. Soc. Press, Tokyo/Univ. Park Press, Baltimore, p. 287.
 8. 1981. De Young, LM, CT Helmes, W Chao, JM Young, and V Miller. Paradoxical Effect of Anthralin on 12-O-Tetradecanoylphorbol-13-acetate - Induced Mouse Epidermal Ornithine Decarboxylase Activity, Proliferation, and Tumor Promotion. *Cancer Res.* 41 :204.
 9. 1982. De Young, LM and S Ballaron. The Effect of Topical Drugs on Mouse Ear Epidermal Transglutaminase Activity. *Jour. Invest. Dermat.* 79:189.
 10. 1984. De Young, LM and S Ballaron, and W Epstein. Transglutaminase Activity in Human and Rabbit Ear Comedogenesis: A Histochemical Study. *Jour. Invest. Dermat.* 82:275.
 11. 1984. Young, JM, DA Spires, CJ Bedord, B Wagner, SJ Ballaron, and LM De Young. The Mouse Ear Inflammatory Response to Topical Arachidonic Acid. *Jour. Invest. Dermat.* 82:367.
 12. 1984. De Young, LM, JM Young, SJ Ballaron, DA Spires, and SM Puhvel. Intradermal Injection of *Propionibacterium acnes*: A Model of Inflammation Relevant to Acne. *Jour. Invest. Dermat.* 83:394.
 13. 1985. De Young, LM, DA Spires, SJ Ballaron, CS Cummins, JM Young, and AC Allison. Acne-like Chronic Inflammatory Activity of *Propionibacterium acnes*: Correlation with Ability to Stimulate the Reticuloendothelium System. *Jour. Invest. Dermat.* 85:255.
 14. 1987. De Young, LM, DA Spires, J Kheifets, and TG Terrell. Biology and Pharmacology of
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Recombinant Human Interleukin-1 β -Induced Rat Ear Inflammation. Agents and Actions, 21 :325.

15. 1989. De Young, LM, JB Kheifets, SJ Ballaron and J M Young. Edema and Cell Infiltration in the Phorbol Ester-Treated Mouse Ear are Temporally Separate and can be Differentially Modulated by Pharmacologic Agents. Agents and Actions, 26:335.
16. 1989. Killackey, JFF, BJ Bonaventura, AL Castelhana, RJ Billedeau, W Farmer, L De Young, A Krantz, and D H Pliura. A New Class of Mechanism-Based Inhibitors of Transglutaminase Enzymes Inhibits the Formation of Cross-Linked Envelopes by Human Malignant Keratinocytes. Molecular Pharmacology, Mol. Pharmacol, 35:701.
17. 1991. Goldsmith, LA, LM De Young, V Falciano, SJ Ballaron, W Akers. Inhibition of Human Epidermal Transglutaminases In Vitro and In Vivo by Tyrosinamidomethyl Dihydrohaloisoxazoles. Jour. Invest. Dermat. 97:156.
18. 1991. Gumina, RJ, J Freire-Moar, LM De Young, DR Webb, BH Devens. Transduction of the IFN-g Signal for HLA-DR Expression in the Promonocytic Line THP-1 Involves a Late Acting PKC Activity. Cell Immunol. 138(2):265-79.

PATENTS

1. 1987. Castelhana, A, A Kranz, D Pliura, M Venuti, and L De Young. Transglutaminase Inhibitors. Case 25420 Serial No. 07/ 025,451.

PATENT APPLICATIONS

File No	Ctry	Status	Short Title	Application No.	Application Date	Inventor
GC795P	US	PEN	PAPILLOMAVIRUSES	60/ 466,235	28-Apr-03	Stickler Marcia*Harding Fiona*Babe Lilia Maria*Huang Manley A.*Power Scott D.*De Young Larry
GCL5023-3	US	PEN	0139.50 Multi-epitope constructs	10/677,754	3-Oct-03	Sette Alessandro D.*Sidney John C.*Livingston Brian D.*Southwood Scott*Cellis Esteban*Kubo Ralph T.*Grey Howard M.*Chesnut Robert W*Chen YiYou*Power Scott D.*Estell David A.*Babe Lilia Maria*De Young Larry

GCL5023-3-PCT	WO	PEN	0139.50 Immune responses to hepatitis B	US03/31303	3-Oct-03	Sette Alessandro D.*Sidney John C.*Livingston Brian D.*Southwood Scott*Cellis Esteban*Kubo Ralph T.*Grey Howard M.*Chesnut Robert W*Chen YiYou*Power Scott D.*Estell David A.*Babe Lilia Maria*De Young Larry
GCL5023-3-TW	TW	PEN	0139.50 Immune responses to hepatitis B	92127711	3-Oct-03	Sette Alessandro D.*Sidney John C.*Livingston Brian D.*Southwood Scott*Cellis Esteban*Kubo Ralph T.*Grey Howard M.*Chesnut Robert W*Chen YiYou*Power Scott D.*Estell David A.*Babe Lilia Maria*De Young Larry
GCL5023P4	US	ABD	0139.40 Optimized Multi-Epitope	60/419,973	22-Oct-02	Sette Alessandro D.*Chesnut Robert W*Newman Mark J.*Livingston Brian D.*Chen YiYou*De Young Larry*Huang Manley A.*Power Scott D.*Babe Lilia Maria
GCL5025-2	US	PEN	0161.20 Immune response to papillomavirus	60/533,211	31-Dec-03	Southwood Scott*Chesnut Robert W*Baker Denise M.*Newman Mark J.*Mothe Bianca*Huang Manley A.*Babe Lilia Maria*De Young Larry*Chen YiYou*Power Scott D.
GCL5028P2	US	PEN	0141.30 Multi-epitope constructs	60/465,229	25-Apr-03	Sette Alessandro D.*Chesnut Robert W*Newman Mark J.*Livingston Brian D.*Babe Lilia Maria*Chen YiYou*De Young Larry*Huang Manley A.*Power Scott D.

BOOK CHAPTERS

1. 1989. De Young, LM, DA Spires, SJ Ballaron, and JM Young. Intradermal Injection of *Propionibacterium acnes*: An Animal Model of Acne-like Chronic Inflammation. In: Models in Dermatology, Maibach and Lowe, eds., Basel, Karger. Vol. 4, p. 260.
2. 1989. Young, J.M. and De Young, L.M. Cutaneous Models of Inflammation for the Evaluation of Topical and Systemic Pharmacological Agents. In: Pharmacological Methods in Inflammation. Chang and Lewis, eds., Alan R. Liss, Inc., New York, p. 215.
3. 1991. De Young, LM. NSAID's in Psoriasis. In: Psoriasis, 2nd edition. Maibach and Roegnik, eds., Marcel Dekker, Inc., New York, p. 871.

BOOK REVIEWS

1. 1992. De Young, LM. Review of *Dermatotoxicology*, 4th edition. Cited by Francis N Marzulli and Howard Maibach, eds., in Jour. Invest. Dermat. 99:884.

ABSTRACTS

1. 1973. Argyris, TS, S Mueller, and LM De Young. Ribosomes from Mouse Epidermis, Anat. Record 175 :497.
 2. 1973. Argyris, TS, C Nevar, S Mueller and LM De Young. Polyribosomes from Normal and Damaged Mouse Epidermis. Jour. Cell Biol. 59:10A.
 3. 1975. De Young, LM, TS Argyris, and GB Gordon. Epidermal Ribosome Increases in the Early Phases of Two-Stage Mouse Epidermal Tumorigenesis. Jour. Invest. Dermat. 64:213.
 4. 1976. De Young, LM, TS Argyris, and GB Gordon. Ribosome Accumulation in Mouse Interfollicular Epidermis and Epidermis of Papillomas During Promotion with Tetradecanoyl-Phorbol-Acetate. Proc. Am. Assoc. Cancer Res. 17:20.
 5. 1979. De Young, LM and V Sun. Anthralin Mediated Suppression of Tetradecanoylphorbol-Acetate Induced Mouse Epidermal Ornithine Decarboxylase Activity and DNA Synthesis. Clin. Res. 27:A524, 1979.
 6. 1980. De Young, LM, C Tucker Helmes, V Miller, and W Chao. A Paradoxical Effect of Anthralin on 12-O-Tetradecanoyl-Phorbol-13-Acetate-Induced Mouse Epidermal Ornithine Decarboxylase, Proliferation and Tumor Promotion. Proc. Am. Assoc. Cancer Res. 21:58.
 7. 1982. De Young, LM, C Tucker Helmes, and E Knowlton. A "Window Effect" in the Ability of Anthralin to Reverse Initiation in Two-Stage Mouse Skin Tumorigenesis. Proc. Am. Assoc. Cancer Res. 23:88.
 8. 1982. Helmes, CT, LM De Young, and EM Knowlton. The Apparent Reversal of Initiation by Anthralin in Two-Stage Skin Tumorigenesis. Proc. XIII International Cancer Congress. Abstract 3462.
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9. 1984. De Young, LM, JM Young, SJ Ballaron, DA Spires, and SM Puhvel. Rat Ear Injection of *Propionibacterium acnes*: A New Model for Cystic Acne. Clin. Res. 32:137A.
 10. 1984. De Young, LM, JM Young, SJ Ballaron, DA Spires, and SM Puhvel. Rat Ear Injection of *Propionibacterium acnes*: An Acne-Relevant Model of Chronic Inflammation. Jour. Invest. Dermat. 83:412.
 11. 1985. Spires, DA, LM De Young, and SJ Ballaron. Chronic Hypersensitivity in *Propionibacterium acnes* Induced Rat Ear Inflammation. Jour. Invest. Dermat. 84:322.
 12. 1985. Young, JM, CJ Bedord, DVK Murthy, MC Venuti, GH Jones, LM De Young, WA Akers, and JR Scholtz. The Biological Activities of the Novel Topical Antipsoriatic Agent, 6-Chloro-1,4-diacetoxy-2,3-dimethoxynaphthalene (RS 43179). Jour Invest. Dermat. 84, 355.
 13. 1986. De Young LM, DA Spires, J Kheifets, and TG Terrell. Biology and Pharmacology of Recombinant Human Interleukin-1 β (rIL1)-Induced Rat Ear Inflammation. Presented at Third International Conference. Inflammation Research Association.
 14. 1988. Goldsmith, LA, V Falciano, and LM De Young. Novel Transglutaminase Inhibitors Decrease Cell Envelopes in Human Keratinocyte Cultures. Jour. Invest. Dermat. 90, 564.
 15. 2003, Huang M, Lilia Bab¹, Larry De Young , Brian Livingston , Denise McKinney, Scott Power, Alessandro Sette and Mark Newman. Development of therapeutic DNA vaccines for oncogenic viruses, Keystone Conference, February, 2003.
 16. 2003. L Babé, E Bowers, B Fox¹, E Lee¹, R Rao, L de Young, M Huang, S Power, B Livingston, C Crimi, D McKinney, A Sette, M Newman. Multi-Epitope DNA-Based Therapeutic Vaccine for Chronic Hepatitis B Infection. Hep Dart Meeting, Kauai, December 2003.
 17. 2003. Brian D. Livingston, Lilia Babe, Denise McKinney, Manley Huang, Larry De Young, Robert Chesnut¹, Scott Power, Alessandro Sette and Mark Newman. Development of a DNA-Based Therapeutic Vaccine for Chronic HBV. International Symposium on Viral Hepatitis and Liver Disease. 04/06/2003, Sydney, Australia
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