GENIA LONG Analysis Group, Inc.

Phone: (617) 425-8491 111 Huntington Avenue FAX: (617) 425-8001 14th Floor

E-mail: genia.long@analysisgroup.com Boston, MA 02199

Ms. Long is a Senior Advisor at Analysis Group and an expert in the economics and business strategy of innovation, assisting clients as they face novel challenges to growth and profitability. She is a speaker at manufacturer and industry meetings and conferences, where she has facilitated senior management strategic deliberations, recommended changes in portfolio and product strategy and tactics, and analyzed the impacts of policy change in health care on the economics of innovation.

Ms. Long has assisted clients to select, develop, and launch new products and businesses, translating the power of innovation into commercial success in industries from consumer packaged goods, information technology and telecommunications, and biopharmaceuticals.

She is a published author and expert on issues relating to the economics of the biopharmaceutical industry and public policy issues with a potential impact on the pharmaceutical, biotech and medical device industries.

Her clients have spanned the health care industry, from pharmaceutical, biotech and medical device manufacturers, technology providers, venture capital, to academic medical centers, specialty and general hospitals, clinical, research and product marketing joint ventures, and trade organizations. She has assisted executives in addressing research and development, market strategy, pricing and market

access, financial and business planning challenges across all major therapeutic areas, including cardiovascular, metabolic, oncology, respiratory, autoimmune disease, central nervous system, musculoskeletal, and virology.

Her work has included:

- Economic analyses of key public policy health care issues, particularly those with an impact on pharmaceutical, biotech, medical device industries and innovation
- Economic analyses and scenario modeling of changes in the regulatory, technology, and competitive
 environment, applying these insights to optimize market strategies for new and existing brands and
 franchises
- Pricing, reimbursement, market and contracting strategies for new products and established brands in a variety of markets
- Provider and payer segmentation studies
- Market research with payers, key opinion leaders, physicians, and patients to analyze value propositions for new and on-market products
- Market and competitive assessments across numerous therapeutic areas
- Screening and assessment of new product, franchise, technology, and M&A opportunities
- Pharmacoeconomic studies and product strategies

Prior to joining Analysis Group, Ms. Long was Associate Vice President for Finance and Administration at Brandeis University and Assistant Commissioner for Administration and Finance for the Massachusetts Department of Public Welfare, where she was the senior executive responsible for the budget, finance, strategic planning, human resources and operations functions for the largest state agency in Massachusetts. She draws on over thirty years of experience in business strategy, economic analysis, and financial management and modeling.

EDUCATION

1983 M.P.P., Harvard University, Kennedy School of Government, Cambridge MA

1981 S.B., Massachusetts Institute of Technology, Cambridge MA

PROFESSIONAL EXPERIENCE

1997 – Present Analysis Group, Inc., Boston MA Senior Advisor, Managing Principal

Vice President, Manager, Senior Consultant

1991 – 1997 Brandeis University, Waltham MA

Associate Vice President for Finance and Administration, Budget Director

1982 – 1991 Massachusetts Department of Public Welfare, Boston MA

Assistant Commissioner for Administration and Finance

Assistant Commissioner for Budget and Cost Control, Manager,

Senior Analyst, Analyst

Summary of Representative Assignments

- Therapeutic area franchise strategy: Analyses and recommendations for numerous franchise leaders and manufacturers to guide selection and resource investment decisions, in the face of changing technical, competitive and market conditions.
- Long-term strategic planning: Numerous long-term strategic planning efforts for a variety of clients, including manufacturers, specialty and general hospitals and services, and integrated networks.
- **Product portfolio optimization:** Portfolio assessment and recommendations for many brand and franchise area U.S. and ex-U.S. senior executives; recommendations for ongoing multi-functional portfolio review process.
- *Value of therapy studies:* Economic assessment of the value of antihypertensive therapy on U.S. health outcomes, including population blood pressure distribution, stroke and myocardial infarction hospitalization, and premature cardiovascular mortality.
- *Policy and economic simulation studies and analyses:* For various manufacturers and trade organizations, analyses and studies of the impacts of major legal or regulatory changes to the pharmaceutical industry, including the impact of:
 - o Biosimilar entry;
 - o Medicare Part D prescription drug benefit;
 - o proposed commercial importation legislation;
 - o federal supply-side programs;
 - o changes in federal Medicaid and Medicare reimbursement policies and FDA approval policies and practices; and
 - o changes in U.S. public and private payer practices.
- **R&D** and technology strategy: For a value-added-technology platform service firm seeking to migrate upstream and assume risk for drug development, the systematic identification and assessment of potential target compounds.

- *R&D process improvement and business integration:* Many assignments for diverse manufacturers involving improving the alignment between R&D and marketing functions, defining the transition between early stage research and later stage development, technology platform selection and alignment with long-term market needs.
- *Early phase commercial screening:* Development of global corporate process by which to screen early phase (pre-clinical and early clinical) leads and potential opportunities; specific investment recommendations.
- **Research target scanning:** For a global pharmaceutical company, scanning of pre-clinical research targets for potential research investment and partnerships.
- **Product value proposition:** For the manufacturer of a pre-launch injectable product in late stage development, primary market research with a range of clinical care, formulary management, case management, and insurance plan stakeholders to understand and quantify key drivers of demand for new product, segmentation of key accounts, and development of account targeting recommendations.
- **Product launch preparation:** Review and assessment of product launch plans and tactics, clinical study sequencing schedule, and account segmentation scheme for a major new branded medication.
- **Brand copositioning:** Copositioning strategy for a portfolio of cardiovascular products, based on analysis of underlying patient population dynamics and treatment patterns, and primary market research with physicians.
- *Pricing and contracting strategies:* Optimal pricing and contracting studies for oral and injectable pharmaceutical agents in diverse managed care, retail, and institutional markets.
- *Managed markets lifecycle strategy:* For the manufacturer of late-stage blockbuster oral drug, recommended modifications to historical managed markets contracting strategy, based on analytical assessment of share response to contracted formulary position for each segment of managed market health insurance plans.
- *Patent expiry strategy:* For a manufacturer of a late lifecycle blockbuster drug, modeling of the likely impact of loss of market exclusivity, given unique features of the drug, the underlying technology, and clinical care in the indication, and market transition strategy recommendations.
- Analogue assessments: For a variety of manufacturers, structured analyses of diverse on-market product analogues, in order to identify potential success and failure modes, key drivers of share, revenue and profit, in comparison with products in development, seeking changes in indication or labeling, or targeted towards market areas where manufacturers have limited on-market experience.
- Competitive and market assessments: Numerous analyses of current and emerging market environment and competitors, competitive pipeline assessments for pharmaceutical/medical device manufacturers, service providers, venture capital investors.
- *Business forecasting:* Numerous assignments involving forecasting business results (e.g., share, revenue, profit) under technical, market, or competitive uncertainty.
- New business creation: Market entry strategy for a major food manufacturer entering health and nutritionals market; new venture organization design within established global manufacturer in order to access high-growth, high-risk opportunities in new product markets distinct from legacy business.
- **Joint venture designs:** Funds flow, governance model, and supporting business forecasts and recommendations to optimize results for teaching, clinical, and research joint ventures involving academic medical centers, general and specialty hospitals, and physician groups.
- *Network governance model design:* Governance and operating models for emerging and established integrated delivery networks.

PUBLICATIONS

Articles

Henry Grabowski, Genia Long and Richard Mortimer, "Recent Trends in Brand Name and Generic Drug Competition," *Journal of Medical Economics* (2013) 1-8.

Anna Kaltenboeck, Genia Long, Eleanor Hayes-Larson, and Gilberto de Lima Lopes, "Assessing the Impact of Substandard Copy Medicines in Developing Countries: The Experience with Imatinib Copies," *Expert Reviews in Clinical Pharmacology* (2013) 6(6).

Genia Long, Carla Mulhern, "Recently Released FDA Guidance and Biosimilar Development: Implications for the Litigation Environment," Food and Drug Law Institute *Update* (March/April 2012) 19-21.

Henry Grabowski, Margaret Kyle, Richard Mortimer, Genia Long, and Noam Kirson, "Evolving Brand- Name And Generic Drug Competition May Warrant A Revision Of The Hatch-Waxman Act," *Health Affairs* (2011) 30:2157-2166.

Henry Grabowski, Genia Long, Richard Mortimer, "Implementation of the Biosimilar Pathway: Economic and Policy Issues", *Seton Hall Law Journal* (2011) 41(2): 511-557.

Patricia Danzon, Scott Johnson, Genia Long, and Michael Furukawa, "Commercial Importation of Prescription Drugs in the United States; Short-Run Implications," *Journal of Health Politics, Policy and Law* (2011) 36(2): 295-316.

Henry Grabowski, Genia Long, Richard Mortimer, "Data Exclusivity for Biologics", *Nature Reviews Drug Discovery*, Vol. 10, January 2011.

Genia Long, David M. Cutler, and Ernst R. Berndt, "Antihypertensive Drugs: A Perspective on the Value of Improved Blood Pressure Control in the USA," *European Heart Journal Supplements* (2007) 9 (Supplement B): B19-B22.

David M. Cutler, Genia Long, Ernst R. Berndt, Jimmy Royer, Andrée-Anne Fournier, Alicia Sasser, and Pierre-Yves Crémieux, "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs* (2007) 26(1): 97-110.

Henry Grabowski, Iain Cockburn, and Genia Long, "The Market for Follow-On Biologics: How Will It Evolve?," *Health Affairs* (2006) 25(5): 1291-1301.

Book Chapters

Henry Grabowski, Genia Long, Richard Mortimer, "Chapter 12.8: Biosimilars," in Encyclopedia of Health Economics, Patricia Danzon (Ed.), Elsevier Limited, Oxford, England (forthcoming).

Pierre-Yves Crémieux, Denise Jarvinen, Philip Merrigan, and Genia Long (2007) "Pharmaceutical Spending and Health Outcomes," in Pharmaceutical Innovation: Incentives, Competition and Cost-Benefit Analysis in International Perspective, Frank A. Sloan and Chee-Ruey Hsieh (Ed.), Cambridge University Press, New York.

Circulated White Papers and Reports

Genia Long and Justin Works, "Innovation in the Biopharmaceutical Pipeline" (2013), available at: http://www.phrma.org/sites/default/files/pdf/2013innovationinthebiopharmaceuticalpipeline-analysisgroupfinal.pdf.

Henry Grabowski, Iain Cockburn, Genia Long, Richard Mortimer, "Data Exclusivity Periods and Next Generation Improvements to Innovator Biologics: Key Issues" (2009), WP No. 2009-05, available at: http://www.econ.duke.edu/Papers.

Henry Grabowski, Genia Long, and Richard Mortimer, "Data Exclusivity Periods for Biologics: Updating Prior Analyses and Responding to Critiques" (2008), WP No. 2008-10, available at: http://www.econ.duke.edu/Papers.

Henry Grabowski, Iain Cockburn, Genia Long, Richard Mortimer, and Scott Johnson, "The Effect on Federal Spending of Legislation Creating a Regulatory Framework for Follow-on Biologics: Key Issues and Assumptions" (2007), WP No. 2007-09, available at: http://www.econ.duke.edu/Papers.

Filed Reports

Robert N. Stavins, Genia Long, and Judson Jaffe, "Assessment of the Economic Impact of Additional Combined Sewer Overflow Controls in the Massachusetts Water Resources Authority Service Area," August 1, 2004. Submitted by MWRA to Massachusetts Department of Environmental Protection, U.S. Environment Protection Agency (December 2004), filed with U.S. District Court, District of Massachusetts, as part of MWRA Quarterly Compliance and Progress Report as of December 15, 2004.

Conference Presentations and Panels

"Biopharmaceutical Pipeline and Orphan Diseases: A Multidimensional View of Pipeline Innovation," National Institutes of Health, Bethesda, Maryland, Rare Disease Day, February 2014.

"Innovation in the Biopharmaceutical Pipeline: A Multidimensional View," Colorado BioScience Association, Denver, Colorado, February 2013.

"Antitrust and the Rise of Biologics," American Bar Association Antitrust Section, annual spring meeting, Washington D.C., 2012.

"Rare No More: The Possibilities of Rare Disease Research," PhRMA annual meeting, Boston, Massachusetts, April 2012.

"Biosimilars: An Economic Perspective," The Change Imperative: Navigating the Post-Reform Era, Annual Yale Healthcare Conference, New Haven, Connecticut, March 2011.

"Preparing for the Economics of Biosimilars," Biosimilars and Follow-On Biologics Americas Visiongain Conference, Boston, Massachusetts, March 2011.

"Health Care Payment Reform and Innovation in the Medical Tech Industry," Health Care Payment and Delivery Reform: Challenges and Opportunities for Medical Technology, AdvaMed Annual MedTech Conference, Washington, D.C., October 2010.

"Making Risk-Sharing and Clinical Performance Contracts Win-Win," CBI Conference: Risk-Sharing and Innovative Contracting Models for Bio/Pharmaceuticals, Philadelphia, Pennsylvania, March 2010.

"Shaping Follow-on Biologics Policy: The Interplay of Date Exclusivity, Patient Safety and Patents." BIO annual meeting, Atlanta, Georgia, May 2009.

"The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," Alliance for Aging Research briefing, Washington D.C., February 2007.

"Prospects for U.S. Biogenerics," Piper Jaffray 18th annual Investor Healthcare Conference, New York New York, November 2006.

"Innovation and Health Outcomes in Cardiovascular Disease: The Value of Antihypertensives," 2nd World Aging and Generations Congress, World Demographic Assocation, St. Gallen, Switzerland, September 2006.

Other Professional Activities

Served as reviewer for *Health Economics*

Board Memberships

Tufts Medical Center

New England Quality Care Alliance