

MEDICAL INNOVATION AND GOVERNMENT INTERVENTION

Reconciling Interests to Create Stakeholder Value

*Eds. Raine Hermans – Morton Kamien – Martti Kulvik –
Alicia Löffler – Joel Shalowitz*

The Research Institute of the Finnish Economy (ETLA)
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"It is not from the benevolence of the butcher, the brewer, or the baker that we expect our dinner, but from their regard to their own interest."

and

"People of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices."

Adam Smith, "An Inquiry into the Nature and Causes of The Wealth of Nations"
(1776), Modern Library, New York

PREFACE

Global health care issues are driving the public sector into a balancing act between conflicting and complementary forces of inevitable change: an ageing population, the explosion of new therapeutic technologies, a critical shortage of clinical professionals, the desire to improve clinical outcomes, and economic constraints.

With respect to technology and economic constraints, the public is in a confusing situation as it strives to lower current health care costs, but at the same time, seeks more and better health care technology. Moreover, in developing this new technology it is in the public's interest to foster successful new business development, increasing public wealth by creating jobs and the resulting tax revenues. Also, a healthier workforce is more productive, further enhancing the incentive for technology development.

Biotechnology has been seen as offering promises of breakthrough innovations and hence major business potential. These innovations are not incremental improvements but new and different types of therapy and diagnostics. Consequently, a number of governments have invested significant resources into creating a strong biotechnology industry base, with special emphasis on subsidizing drug development. Despite the success of some individual products, however, the infrastructure has so far not fully met expectations.

This book deals with the complex dynamics of the health care sector, assessing, in particular, the risks inherent with an enforced regulation of an entire industry sector. The major focus is on value creation in general and biotechnology in particular. Since drugs constitute the bulk of biotechnological health care applications, and likewise both drug development and pricing is under particular governmental regulation, the book highlights the pharmaceutical sector whenever possible. Both practitioners and policy makers will find the messages in this book helpful in creating value for their stakeholders.

Dipak Jain

Dean

Kellogg School of Management, Northwestern University

Pekka Ylä-Anttila

Managing Director

Etlatieto Ltd, the subsidiary of ETLA, The Research Institute of the Finnish Economy

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Raine Hermans
Morton Kamien
Martti Kulvik
Alicia Löffler
Joel Shalowitz

Editors

Raine Hermans, Morton Kamien, Martti Kulvik, Alicia Löffler and Joel Shalowitz

Authors

Raine Hermans^{b,c}, Morton Kamien^c, Martti Kulvik^{a,d}, Ismo Linnosmaa^e, Alicia Löffler^c, Joel Shalowitz^c, Scott Stern^c, Antti Tahvanainen^a

^a The Research Institute of the Finnish Economy (Etna) and Etlatieto Ltd.
Lönnrotinkatu 4 B, 00120 Helsinki, Finland
firstname.lastname@etla.fi

^b Helsinki School of Economics (forthcoming Aalto University)
Runeberginkatu 14-16, P.O. Box 1210, 00101 Helsinki, Finland
firstname.lastname@hse.fi

^c Kellogg School of Management, Northwestern University
2001 Sheridan Road, Evanston, IL-60208, USA
initial-lastname@kellogg.northwestern.edu

^d Helsinki University Central Hospital HUCH
Dept. of Neurology, P.O.Box 340, 00029 HUS, Finland
firstname.lastname@hus.fi

^e Kuopio University, Department of Health Policy and Management
Savilahdentie 6, 70210 Kuopio, Finland
firstname.lastname@uku.fi

Professor Morton Kamien is Professor Emeritus of Economics and Decision Sciences. A distinguished scholar, Professor Kamien came to the Kellogg School over 35 years ago from Carnegie-Mellon University. At Kellogg, Kamien served as the School's associate dean for academic affairs for three terms, the Joseph and Carole Levy Distinguished Professor of Entrepreneurship and director of the school's Heizer Center for Entrepreneurial Studies. He retired in 2007.

Professor Kamien made fundamental advances in the use of game theory and dynamic optimization methods in industrial organization theory. Among his many publications are contributions that helped found the modern theory of limit pricing under uncertainty. Other work was instrumental in developing the theory of patent races – how firms compete to develop a new product or production method, the value of patents, mergers and entry deterrence. He has also produced two classic textbooks, co-authored with Kellogg peer Nancy L. Schwartz: *Dynamic Optimization: The Calculus of Variations and Optimal Control in Economics* (first published by North Holland in 1981) and *Market Structure and Innovation* (Cambridge University Press, 1982). For his contributions he was elected Fellow of the Econometric Society in 1996 and bestowed with an Honorary Doctor of Economics Degree in 2001 by Purdue University. At present he serves as an expert witness in anti-trust cases. Indeed, he was an expert witness on behalf of the plaintiff in the American Express vs. Visa and Master Card case which resulted in the largest anti-trust settlement in US history.

Professor Alicia Löffler is globally recognized as a leader in biotechnology education and life science entrepreneurship. She consults widely with start-ups in the US, Asia and Europe. Dr. Löffler is the Director of the Kellogg Center for Biotechnology Management. The center is an educational and research organization focused on management of the biotechnology, pharmaceutical and medical device sector. Dr. Löffler launched the center in 2001 and is responsible for the center's strategies and operations. Previous to this position, she directed the University-wide Northwestern University Center for Biotechnology (sciences, engineering and Medical School). Dr. Löffler created the Center's educational programs including the Master's Program in Biotechnology, the Summer Biotechnology Institute, and career development programs.

Dr. Löffler served as advisor of: Baird Venture Partners; founding Board Member of the Biotechnology Institute, Washington DC; Biopharmaceutical Center at the WHU in Koblenz, Germany and multiple biotechnology companies. She consulted extensively on technology assessment issues for major pharmaceutical companies and Universities in the US. She also served at as the Board Member and Past-Chair, Council for Biotechnology Centers (BIO), and Board Member, Emerging Companies, Biotechnology Industry Organization and the Governor's Edgar Council for

Biotechnology. She was recently named one of the Tech 100 stars by *Crain's Chicago Business* and received the "Women in Black" I-Street award. She is completing her second book, *Rethinking the Biotechnology Model*. Dr. Löffler received her BS from the University of Minnesota, PhD from the University of Massachusetts and post-doctoral in biochemical engineering from Caltech.

Professor Joel I. Shalowitz, MD, MBA, FACP is Professor of Health Industry Management and Director of the Health Industry Management Program at Kellogg as well as a Professor of Medicine and of Preventive Medicine at Northwestern University's Feinberg School of Medicine. He is also Visiting Professor of Health Industry Management at the Schulich School of Business at York University in Toronto.

Dr. Shalowitz received his ScB and MD degrees (Sigma Xi) from Brown University and his MBA degree (Beta Gamma Sigma) from Northwestern University. He also completed post-graduate internal medicine training at Northwestern. He is a Diplomate of the American Board of Internal Medicine and a Fellow of the American College of Physicians. His areas of special interest are health insurance, ambulatory care management, quality improvement and international healthcare systems. In 2004 he was a Fulbright Scholar at the Schulich Business School, York University in Toronto and in 2007 he was a Fulbright Senior Specialist and Visiting Professor at Keio University Medical School in Tokyo. Recent publications include: *Strategic Marketing For Health Care Organizations: Building A Customer-Driven Health System* (Jossey-Bass, 2008) with Philip Kotler and Robert J. Stevens.

Professor Scott Stern is an Associate Professor of Management and Strategy at the Kellogg School of Management at Northwestern University. Stern is the co-organizer of the NBER Innovation Policy and the Economy Working Group and a Senior Fellow of the Searle Center on Law, Regulation and Economic Growth. He is an Associate Editor of *Management Science*, the *Journal of Industrial Economics*, the *International Journal of Industrial Organization*, serves on the Board of Management of the International Schumpeter Society, and has served on the editorial boards of the *Antitrust Law Journal* and the *Journal of Business and Economics Statistics*. In 2005, Stern was awarded the first Ewing Marion Kauffman Prize Medal for Distinguished Research in Entrepreneurship.

Stern explores how innovation – the production and distribution of “ideas” – differs from more traditional economic goods, and the implications of these differences for business and public policy. Often focusing on life sciences industries, this research is at the intersection between industrial organization and the economics of technical change. Recent studies examine the determinants of R&D productivity, the role of incentives and organizational design on the process of innovation, and the drivers of commercialization strategy for technology entrepreneurs.

Professor Stern graduated with a BA degree in Economics from New York University, and received his PhD in Economics from Stanford University in 1996. From 1995-2001, Stern was Assistant Professor of Management at the Sloan School at MIT, and, from 2001-2003, Stern was a Non-Resident Senior Fellow of the Brookings Institution.

Dr. Martti Kulvik is a researcher at ETLA, the Research Institute of the Finnish Economy. Dr. Kulvik holds an MBA from the Helsinki School of Economics and Business Administration, a medical degree from the University of Helsinki, and a clinical appointment at the Department of Neurology at the Helsinki University Central Hospital, the latter being the leading hospital in Finland with a catchment area population exceeding 1 million.

Kulvik has been involved in international multidisciplinary research projects, including those related to gene therapy and boron neutron capture therapy for brain tumors. His present topics include biotechnology management and strategy, as well as healthcare management and process analysis.

Martti Kulvik has consulted with several early-stage biotechnology companies, and he is a lecturer at the Institute of Medical Technology at University of Tampere and at the Department of Biological and Environmental Sciences at the University of Helsinki. Dr. Kulvik has authored and co-authored several medical journal articles as well as articles related to biotechnology management. He has also edited and co-authored two academic books.

Dr. Raine Hermans is the adjunct professor at the Helsinki School of Economics (forthcoming Aalto University). The Helsinki School of Economics (HSE) is the largest and leading business school in Finland and a globally acknowledged player in management education. At HSE, Dr. Hermans explores how the company or industry can create value by utilizing innovation management as a part of their everyday operations, strategic planning and valuation schemes.

Hermans was the visiting professor from 2006-2007 at the Kellogg School of Management, Northwestern University, Illinois, USA. At the Kellogg School of Management he performed studies on forecasting the future sales of the bio-pharmaceutical start-ups, analyzing biotechnologies as a competitive edge of the Forest industry, and simulating the impacts of biotechnology based energy applications together with experts from related fields. He visited Kellogg also in Summer of 2009 and led a research project on the projected economic impacts of the biopharmaceutical industry in Illinois. Before joining Kellogg he worked with ETLA – The Research Institute of the Finnish Economy, where he led multidisciplinary projects on managerial economics of biotechnology. He started with ETLA as a member of the forecasting group, responsible for international trade, and for production forecasts of the chemical, metal and electronics industries.

Raine Hermans works as the Director of Regional operations at Tekes, The Finnish Funding Agency for Technology and Innovation in Helsinki, Finland. Tekes is the main public funding organization for research and development (R&D) and innovation in Finland. In addition to Helsinki headquarters, the regional office network of Tekes employs 90 people and consists of 14 innovation and international business departments all over Finland.

Antti-Jussi Tahvanainen holds a research economist position at ETLA, the Research Institute of the Finnish Economy. He received his M.Sc. degree in economics and business administration from the Helsinki School of Economics in 2003, and is currently a Ph.D. student at the Helsinki University of Technology, Department of Industrial Engineering and Management. Tahvanainen was a visiting scholar at Stanford University in 2007 conducting research on university technology transfer offices and their value creation.

Tahvanainen has committed himself to understanding the role the development and commercialization of technologies play in the growth and prosperity of economies and single organizations. Through the analysis of impediments and key success factors in finance, organizational strategy, knowledge and technology management, technology transfer, and innovation policy, Tahvanainen aspires to contribute to the research of innovation and commercialization processes. He has published several articles in international journals and edited books.

Dr. Ismo Linnosmaa is a senior lecturer at the Department of Health Management and Policy, University of Kuopio. Dr. Linnosmaa received M.Sc. and Licentiate's degrees in economics from University of Joensuu and Ph.D. degree from the Department of Economics at State University of New York at Stony Brook, New York. Linnosmaa has worked as a research director at the Center for Pharmaceutical Policy and Economics, University of Kuopio, visiting lecturer at the Department of Economics, Boston University, and as a visiting research fellow at The Center for Health Economics, University of York. He also serves on the editorial board of *The Open Pharmacoeconomics & Health Economics Journal*.

Linnosmaa's research specializes in the fields of industrial organization and health economics. His research has focused on managerial incentives in oligopolistic firms and competition and incentives in the pharmaceutical industry. In recent years he has published several articles on price competition, regulation and advertising of pharmaceuticals. He has also contributed to evaluations of various pharmaceutical policy measures Finland has implemented in recent years.

INTRODUCTION BY EDITORS

Health care market conditions and regulation

Growing welfare systems have resulted in health care costs occupying a rising proportion of countries' GDP. Fifty years ago a relatively large proportion of workers' income was used for food and other basic necessities; since health care technology did not offer extensive diagnostic or treatment options, costs were not a major issue. As these technologies rapidly emerged, their costs have increased by at least an order of magnitude.

In addition to technological capabilities, the rise in health care consumption also reflects the changing values in virtually all Western societies: population surveys repeatedly indicate that health is the most valued component of welfare, ranking even higher than such highly prized wants as happiness, peace, and wealth. This demand is steady and strong in all Western countries and becomes more important as Third World countries continue to develop.

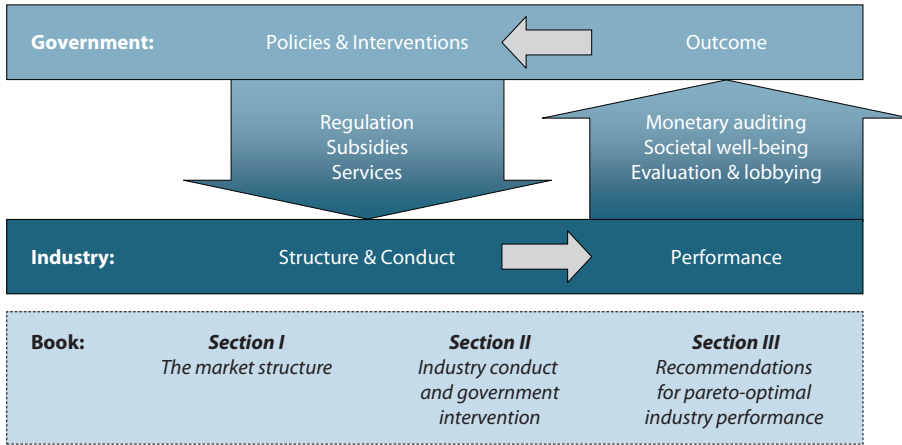
In a conventional market the customer's choices are strongly influenced by the perceived utility balanced by budget constraints. In the treatment of illnesses, however, a major distortion shapes the market: the payer is often someone other than the consumer of the service or product, for example, an insurance company or the government, and the individual no longer has a budget constraint. Consequently, the consumer benefits with increasing consumption [paid by someone else], and individual budget constraints and treatment prices no longer dominate consumer choice. Without regulation, health care customer preference should lead to a steady and significant raise in demand. This outcome holds true for any health care market where the majority of costs are paid by an insurance company or the public sector.

Further, while private health care providers have an incentive to increase profits, in almost all countries their fees are limited by government schedules. Even in the U.S., private insurers follow Medicare guidelines to determine their fees. Providers have, therefore, used volume and, especially, new technology to leverage increases in revenue.

The combination of provider-induced demand and public expectation for improved health care leads to strong pressure on expanding health care spending. This situation has led to extensive government interventions in virtually all health care systems, as the issue of affordability has become a key issue.

These interventions can be summarized in the following fashion (Figure 1):

Figure 1 Industrial organization and government interventions



The industry structure is influenced by such factors as the number of companies, the nature of the competitive environment, culture and judicial and political systems. The structure, in turn, will influence conduct, that is, how the players act individually and interact with each other – for example, do they innovate or imitate? Reciprocally, conduct can also influence the structure of the industry. For instance, companies can decide on vertical or horizontal integration strategies, which can reshape the industry structure. Moreover, conduct will directly influence performance as measured in monetary terms, or in other ways, like efficiency or quality of life. Based on performance, the industry will alter or maintain its structure and/or conduct.

If government desires to shape outcomes, it enacts policies (or laws) that change industry structure and/or conduct. For example, antitrust laws affect industry structure and policies that regulate prices limit industry pricing conduct. These effects can be far-reaching. Government pricing policies can for example cause a restructuring of the industry through such mechanisms as mergers, acquisitions or enhanced outsourcing. Government interventions can also enhance company profitability. Good examples are patents creating time-limited monopolies that provide incentives to invent.

Both government and industry agree that performance must be achieved in a pareto optimal fashion.¹ Nevertheless, friction may occur between the parties when deciding upon the distribution of the spoils of performance. For example, large profits are good for industry but the government may see them as excessive and harmful to public welfare. Government and industry may also disagree on what is the nature of the pareto optimal state. For example, government wants to maximize the health status of the entire population, while the industry desires to maximize profitability that may accrue from a smaller segment. These conflicts can cause further complications when government desires more than one optimal state, like lowering prices and fostering innovation. Lowering prices may help increase access to medications and improve population health status. In the long run, however, removing a profit motive may stifle innovation and worsen prospects for population health improvement.

Technology development under distinctive contexts

This book uses the above framework to assess the relation between health care market conditions, technology supply, and impacts of the government intervention. Broadly put, it analyzes the value creation mechanisms of technology development and commercialization from each of the health care stakeholder's perspectives. To offer an in-depth comparison, the focus here is on the impacts of biotechnology and drug development in the U.S. and Finland, countries with radically different health care system structures and very different environments for technology suppliers.

A government wants to accentuate the benefits of technology but eliminate the disadvantages through its interventions on structure and conduct. However, the government's dilemma lies in the inherent trade-off between two opposite effects. On one hand, it attempts to provide incentives for developing and adopting new technologies in order to create prosperous and profitable businesses by, for instance, allowing patent protection and thus creating monopoly power. On the other hand, it strives to distribute benefits to customers by boosting competition through generic introductions, cutting monopoly profits.

The development of biotechnologies has led to intensive patenting activity and, as a consequence, investment interest in innovative biotechnology companies.

¹ In the simplest Pareto optimum or efficient state, any changes will result in one person being better off while another is worse off.

However, this intensity of proprietary technology has also become a clear obstacle for the development of new ventures. If a venture requires the licensing of dozens of previous patents, further development is discouraged as the early stage sunk costs become too high for a sound business. An individual IPR can form a gridlock in the value chain of developing a new technology (Heller and Eisenberg, 1998; Heller 2008). The IPR owner can exploit the entire value of a venture despite his or her property being a crucial but small sub-section of the value chain (Vanneste et al., 2006). This can lead to underuse of innovations and thereby forgone opportunities.

One way out of the gridlock is to pool intellectual property rights. There is a need for such pooling especially in biotechnology, where technologies are interdependent but tied to several independent patents. Governmentally controlled property right pools are one way to offer an increased total value for both society and business.

STRUCTURE OF THE BOOK

This book aims to shed light on the controversial issues discussed above. We use a framework that draws on the relationships in the above figure. Throughout we include discussions of governmental intervention in the forms of regulations and policies. Particular emphasis is on the effects of government efforts and tools to control the impacts of technology development on health care markets.

Section I The market structure

In any health care system, the large number of stakeholders generates a great degree of complexity. **Chapter 1** “Blueprint for Understanding Complex Health Care Systems” presents some initial definitions and two working models that will help the reader understand how and why different countries structure their health care systems the way they do, deal with and prioritize relevant stakeholders, and understand the effects of their strategic decisions on other elements of the health care marketplace. This chapter compares different health care systems, drawing on different features of these countries, for example, economics, politics, culture and population characteristics. This approach is taken because technology, and particularly the pharmaceutical industry, has experienced extensive cross-national integration, resulting in fewer but larger global giants.

Findings presented in **Chapter 2** indicate that health care technology-related applications are developed all over the world, and that they have received vast subsidies. This chapter utilizes biotechnology patent analysis as a measure for specialization and agglomerations. It suggests that while the origins of the value chains are globally dispersed large-scale actors at the downstream end of the chain (which require extremely high R&D and marketing expenditures) are spatially agglomerated across and within countries.

Section II Industry conduct and government intervention: policies and results

Chapter 3 assesses the juxtaposition between the government and the global pharmaceutical companies in the U.S., the world’s largest pharmaceutical market. As is the case elsewhere, the American government’s policy is Janus-faced: it tries to stimulate innovative activity of new drug development, but at the same time it exercises significant power aiming at reducing costs. This chapter, and the one that

follows, deal with the delicate balancing act between the pharmaceutical companies, on one hand, and the government, on the other. Chapter 3 discusses three acts meant to stimulate innovation and foster competition, each of which has had unforeseen consequences that can frustrate these good intentions. It also suggests a patent pooling system as a means of preventing a single patent owner, monopolizing a specific part of the value chain, to form a gridlock for any further innovation by setting the out-licensing price too high.

Chapter 4 provides information about how different price-regulation environments affect the price-cost margins of the pharmaceutical industry; or conversely, how pharmaceutical companies adapt to highly varying and changing regulatory environments. The U.S. pharmaceutical industries' price markups, or price-cost margins, are estimated against Finland's highly regulated governmental price-setting system. The results show that differences in regulatory environments have not historically altered the price markups in the pharmaceutical industry in these two countries. This finding indicates that in all but completely regulated markets the drug companies are able to adopt a market-specific pricing strategy that yields similar overall markups. From a governmental perspective, the results imply difficulty in setting up and sustaining an efficient price regulation system.

The previous chapters address the obvious trade-off between government subsidy programs for innovative health care technology and the expressed need for regulating rising health care costs. In the following two chapters, the aim is to add further perspective to the issue by drawing on the experience in one nation's quest to create a prosperous new industry: Finland's biopharmaceutical business.

Chapter 5 uses a simulation to analyze the future earnings of drug development projects of the Finnish bio-pharmaceutical small and middle-sized enterprises (SMEs), emphasizing the overall economic impacts and government and private venture financing requirements. The results of the simulation suggest that, because of rapidly growing R&D costs, high failure potential, and distant future earnings, early-stage drug development does not seem to be profitable. This finding implies a need for government intervention to facilitate or sponsor early-stage R&D efforts to bring along seed technologies for later stage technology development and trials. Developing funding and business affiliations with pharmaceutical giants has proven to be another way biotech companies can approach a balance between risks and return on a more sustainable basis.

While Chapter 5 explains why a government might want to support startup projects that present a negative net present value, **Chapter 6** elaborates on the consequences of governmental interventions/support in early and late phase drug development. It assesses how the use of the infant industry argument (IIA) could affect entrepreneurial strategies via injections of government financing. First how

the IIA-based subsidies and financing extend a conventional financial pecking order is shown in theory. Then the Finnish biopharmaceutical industry is empirically investigated. The results reveal the framework to be a relevant tool reflecting IIA-based policies in two primary ways: (1) Government subsidies are the most highly preferred financial instrument, favored even over companies' internal financing and (2) Government equity financing as a last resort and a relevant option only for companies with clearly non-market-oriented technology push strategies. The findings indicate that late stage support tends to cultivate losers instead of market-oriented, vital companies, contrary to the original intentions of any government policy.

Section III Recommendations for optimal industry performance

In Chapter 7 the prior analyses are expanded by scrutinizing the impact of yet another much-debated government-initiated measure – the U.S. Bayh Dole Act, passed in 1980. This law promotes the diffusion of knowledge created in academic research by facilitating university-industry technology transfers. Specifically, the focus is on the role that American university technology transfer offices (TTOs), play in connecting and matching the substance of academic research with the need-driven demand of commercial markets.

The previous chapters have dealt with companies' responses to contradictory government intentions within the health care market. **Chapter 8** aligns the interests of the technology developers and other stakeholders in health care. These aligned interests are expressed in a model that creates a link among technology pricing, efficiency of treatment, and long-term health care costs. These aspects are contrasted with patient utilities received from acute and long-term care. The model serves as a tool for a health care planner, as well as a pricing starting point for a health care provider, with transparency being the embedded denominator.

Chapter 9 aims at realigning overall innovation policies and corporate strategies. Drawing on recent economic analyses, interviews with 89 business leaders, and seminar discussions within academia, government, and industry, a “bio-information based pharmaceutical” cluster is identified. It utilizes Finland's unique and voluntarily donated comprehensive patient data base and tissue banks as tools for creating domestic intellectual property pools. Such pools are attractive to the international pharmaceutical industry as part of their global value chain. By guarding the original data and material sources and opening cooperation and trade of extracted knowledge thereof, the government can not only act in line with the original interests of the donors to support domestic public health but even push it to a new level of international competitiveness.

We believe that this book's research and recommendations can be successfully employed in small open economies, where many regulations are local, despite nationally mandated guidelines. Examples of small open economies include some U.S. states, Canadian Provinces, and European regions, including all the Nordic countries. Application of these findings can result in industry specialization within global value chains, providing a way to success through international trade that will boost regional growth. The end result will be delivery of the best value for all concerned stakeholders.