CHAPTER: INDIA-BM03
DATE: 11/01/13

BIODESIGN GLOBAL SOURCEBOOK: INDIA MARKET DYNAMICS

TOPICS

INDIAN ECONOMY

From independence in 1947 to 1991, India's economy was closed, socialist-leaning, and suffered anemic growth. (See Figure 1 for a map of India.) The Indian government began implementing economic reforms in 1991 as part of a bailout deal with the International Monetary Fund. Since then, India's gross domestic product (GDP), which reached US$2 trillion in 2012,[1] has surged about six percent or more per year on average.[2]

As part of these economic reforms, the Indian government abolished the country's license-based import structure in favor of a restriction-free trade policy for capital goods and intermediates.[3] Although tariff protection rates in India remain among the highest in the developing world, they have declined from 90 percent for certain goods in 1990 to roughly 15 percent for most items in 2010.[4]

India also now allows foreign direct investment in most sectors, including foreign majority stakes of up to 100 percent in all industries except telecommunications, airlines, and banking.[5] Healthcare has traditionally enjoyed high levels of private sector investment, with imports dominating the medical technology sector.

This chapter was prepared by Ritu Kamal as part of a multi-chapter global series for use in Stanford University's Program in Biodesign. These papers can be used individually or as a set. References to other related chapters may refer to the Biodesign Textbook or others in this series.

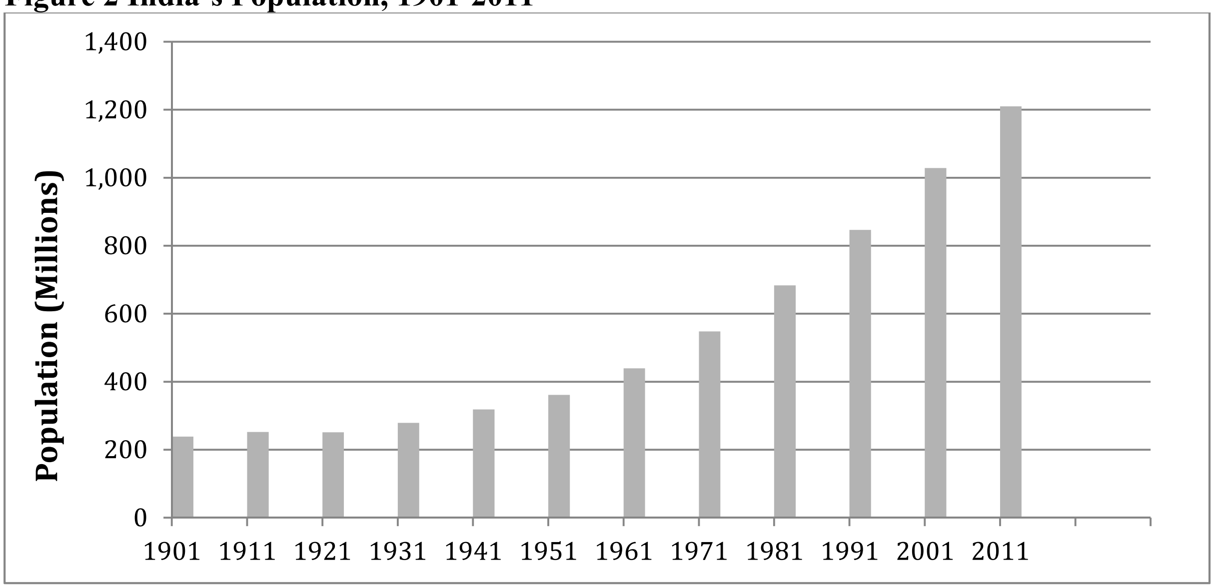
Copyright © 2013 by the Board of Trustees of the Leland Stanford Junior University. All rights reserved. To order copies or request permission to reproduce materials, e-mail the Stanford Biodesign Program. No part of this publication may be reproduced, stored in a retrieval system, used in a spreadsheet, or transmitted in any form or by any means — electronic, mechanical, photocopying, recording, or otherwise — without the permission of the Stanford Biodesign Program.

Figure 1 Map of India

With a population of more than 1.2 billion, India is the world's second most populous nation after China. Population growth in the country has been exponential since the 1930s (see Figure 2).[6] Projections suggest that India's population will surpass China's in 2030.[7] The median age in India is only 26.2 years,[8] compared to 35 years in China and almost 40 years in high-income countries.[9] Approximately 70 percent of Indians still live in rural areas.

India's middle class is expected to grow rapidly in coming years, from roughly 50 million people to nearly 600 million between 2007 and 2025.[10] This new and demanding middle class will be a strong catalyst for the development of medical devices.

Figure 2 India's Population, 1901-2011[11]



MEDICAL DEVICE INDUSTRY

India's medical device market was worth US$3 billion in 2010, growing roughly 15 percent over the previous year.[12] It is expected to expand at a 16 percent compounded annual clip during the 2010-2015 period,[13] far better than the two percent to three percent growth forecast for this sector in the United States and Europe. As a result, global medical technology firms view India as one of the most promising emerging markets for direct investment.[14]

Imports currently dominate India's med-tech sector, accounting for approximately 75 percent of the devices sold in the country.[15] GE Healthcare, Siemens, J&J, and other multinational corporations, which normally have extensive sales and service networks, lead India's technology-intensive and high-cost device markets. Indian manufacturers suffer from a perceived lack of quality and traditionally have had trouble entering these markets. Domestic companies are highly competitive in the markets for medical supplies and consumables (sutures, catheters, etc.), which are particularly price sensitive due to low labor and manufacturing costs.[16] Small and medium enterprises manufacture some 60 percent of indigenous devices.[17]

The majority of medical devices sold in India fall on the lower end of product complexity, such as syringes, needles, and so on. Figure 3 shows the volume of sales in each of the major categories of medical devices sold in India. Apart from medical imaging, which has traditionally been a strong sector in India, the market is focused on low tech products like disposables.

Figure 3: Indian Medical Device Sales by Category, 2011[18]

	US$ Millions	As % of Total Market
Consumables	519.1	19.6
Diagnostic imaging	968.1	36.6
Dental products	75.9	2.9
Orthopedic & prosthetic products	152.3	5.8
Patient aids	204.6	7.7
Others	722.6	27.3
Total	2,642.7	100.0

Sales and Distribution

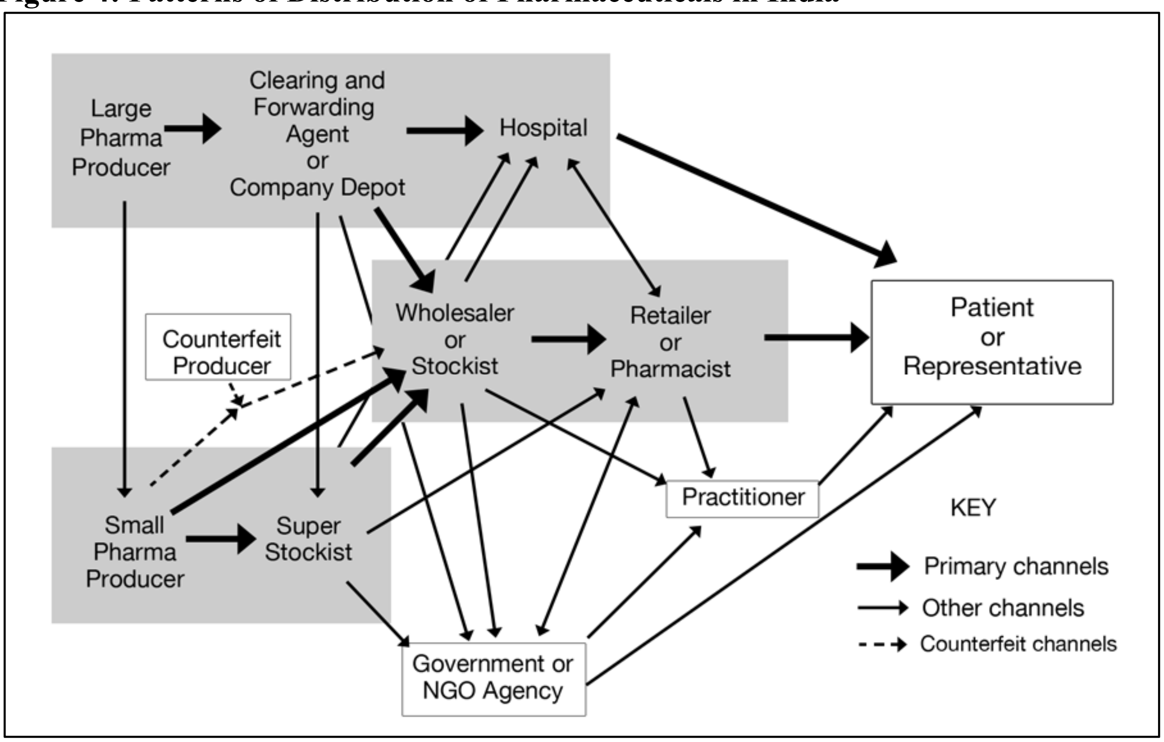
The diversity of the Indian healthcare system presents a particularly thorny challenge to the distribution and sale of medical products. Enormous differences exist between of the various healthcare settings: urban versus rural, public versus private centers and non-profit versus for-profit healthcare ventures, among others. Further, regional differences in economic potential, quality of infrastructure, density of population, and education add to the difficulty of scaling up sales beyond a specific segment of the market.

As in other industries in India, distribution networks for medical products are fragmented, divvied up by region, medical specialty, class of device and product branding. In order to cover that elusive last mile in the healthcare chain, there are several layers of wholesalers, distributors and salesmen involved. Due to the preponderance of Class I devices in the sales pipelines, salesmen may lack the education and training needed to sell more sophisticated products.

Under the current model, manufacturers or multinationals in India typically appoint different distributors for different territories. As in the US, Indian distributors operate on either exclusive or open contracts. Exclusive contracts give sole authorization to the partnering distributor. In contrast, in an open contract, more than one distributor can be authorized to distribute goods. Interviews indicated that medical device fairs currently play a major role in linking distributors with OEMs. Relationships are formed based on a distributor's market focus and portfolio of products[19]. Indian distributors maintain proprietary networks and employees for product distribution. Most also provide after-sale-services to customers and maintain medical equipment under warranty. These value-added functions make OEMs attractive, in particular to small young companies who may not have the resources to provide them on their own and whose products may lack the credibility to be successful commercially without such guarantees.

It is important to note that large distributors, such as those maintained or employed by MNCs, generally do not distribute products to small towns and rural areas. The effort required to reach these territories does not justify the resources required to serve them. As a result, indigenous manufacturers/entrepreneurs focusing on low cost devices that are primarily targeted at the rural market are faced with the daunting task of creating their own channels to distribute in these areas. Figure 4 shows the complexity of the distribution networks of the pharmaceutical sector, an industry with many parallels to the medical device industry as they are both in the diverse healthcare sales space.

Figure 4: Patterns of Distribution of Pharmaceuticals in India[20]



In India, even established companies with deep reserves of capital use a multipronged approach to sales and distribution rather than investing in an end-to-end in-house sales team. Commonly cited examples include the chocolate maker Cadbury, with 60% of market share in India, and toothpaste maker Colgate, with 50% share[21]. These companies have been successful by using multiple distribution channels in order to reach customers in all geographies and social classes. For example, Colgate uses a mixture of stockists, wholesalers and a proprietary sales force to reach 2.8 million retail outlets[22]. However, this strategy can pose challenges for even the largest companies to execute: during a recent analysts call, Apple's Tim Cook[23] cited India's multi-layered distribution as the main reason for his company's small share of the market. The challenge for a smaller startup company can be even more daunting.

Selling medical technology products in India, especially for smaller, younger companies, requires a commitment to business model innovation that is just as important as the technical innovation of their products. Failure to do so can result in limited success or even outright failure. Many, if not most, of the basic business models used in India are similar to those used elsewhere in the world in the medtech industry, but execution strategies differ vastly. Different factors, such as importance of IP, financial requirements and clinical hurdles can vary for each business model. In India, some of the most important factors for choosing the appropriate business model are: 1); price of the product, which is crucial in private pay market; 2) level of sales training required, since distribution networks are extremely fragmented and region specific; 3) level of customer training or skill required, as many healthcare settings in India are staffed with low-skilled healthcare workers; 4) barriers to entry for other companies, as traditional barriers to entry such as IP enforcement or quality regulation tend to be ineffective in India. See Figure 5 for a detailed list of business models generally used in the medtech sector.

Figure 5: Types of Business Models[24]

Type of Model	Price	Sales Investment	Customer Skill	Barriers to Entry	Importance of IP	Clinical Hurdles	Investment Required
Disposable	Low	Low	Low	Low	Low	Low	Neutral
Reusable	Low	Low	Low	Low	Low	Neutral	Low
Implantable	High	High	High	High	High	High	High
Capital Equipment	High	Neutral	Neutral	High	High	High	High
Service	Neutral	Neutral	Low	Neutral	Low	Low	Neutral
Fee Per Use	Neutral	High	High	Neutral	High	High	Neutral
Over the Counter	Low	High	Low	Low	Neutral	Neutral	Neutral
Prescription	High	High	High	High	High	High	High
Physician Sell	Neutral	High	High	High	Neutral	Neutral	Neutral

Startup medical device companies in India have experimented with different types of business models and unique execution strategies to sell their products, as shown in Figure 6.

Figure 6: Types of Business Models in Indian Medtech[25]

Name of Company	Type of Model	Execution of Business Model
Embrace	Reusable	Partnership with multinational company
Brilliance (D-Rev)	Capital Equipment	Partnership with Indian company
Jaipur Knee	Implantable	Partnership with foundations/NGOs
Perfint[26]	Capital Equipment	Direct sales
Cura Healthcare[27]	Capital Equipment	Third party service provider
XCyton Diagnostics[28]	Fee Per Use	Indirect sales

HEALTHCARE AS A MARKET

The Indian healthcare market is a complicated entity, with several different types of market sectors. See **India Overview** for basic information about the Indian healthcare system. The healthcare market in general and the medical device industry in particular can be divided into three main segments, premium, value and the low-cost segment. As India is predominantly a self-pay market in healthcare, these segments are primarily defined by the ability to pay for medical products. The clinical needs, healthcare infrastructure available, and skill and training of healthcare workers also vary by segment.

Premium Segment

Most multinational companies are focused on the premium customer segment, serving it with pre-existing portfolio products and utilizing commercialization strategies similar to those used in developed markets. Ability to pay out of pocket is high in this predominantly urban segment, which comprises of about 6-7% of the total population in the country.[29] Clinical needs in this segment tend to be close to those seen in the US or Europe— non-communicable diseases such as cancer, diabetes, and cardiac issues—and healthcare settings enjoy a high level of resources and trained staff. Currently, majority of the $3 billion medtech market in India is focused on this segment, though many companies are starting to look to the un-tapped mid-tier market.

Value Segment

With the rise of the middle class, increased access to care, and improving healthcare infrastructure has created a new class of consumers of medical devices in India. This segment, about 200 million people in urban areas[30], is extremely cost-conscious due to limited ability to pay for healthcare expenses. Traditionally served by de-featured products from the multinationals or cheap products from domestic players, this segment is rapidly being targeted more aggressively by the medtech industry. Several major global companies such as GE Healthcare and Philips Healthcare have set up research centers in India to innovate for this value segment, developing new products that create value at affordable price-points.[31] One example is GE's MAC 400 EKG machine, which is priced at about $1000 and was developed in the John Welch Research Center in Bangalore.[32] Indian companies are also very active in this segment, with orthopedic companies like Indus and INOR challenging multinationals such as Smith and Nephew and J&J's DePuy with "good-enough" products at competitive price points.[33] The value segment is generally believed to be the largest source of growth in the Indian medtech industry in the next decade.[34]

Low-Cost Segment

Often known the "bottom of the pyramid" segment, the low-cost segment is the largest segment of the market, with over 700 million people largely living in rural India.[35] It is also the most under-served part of the Indian healthcare market, with an acute shortage of healthcare facilities, trained medical professionals and resources like medical devices. This segment is largely ignored by multinationals, and is served by low-cost, low-tech domestic manufacturers.

The Indian growth story, which is slated to add 500 million people into the middle class by 2025, up from 50 million today[36], presents enormous opportunities for healthcare innovation, and the medical technology industry is poised to seize them.

REIMBURSEMENT

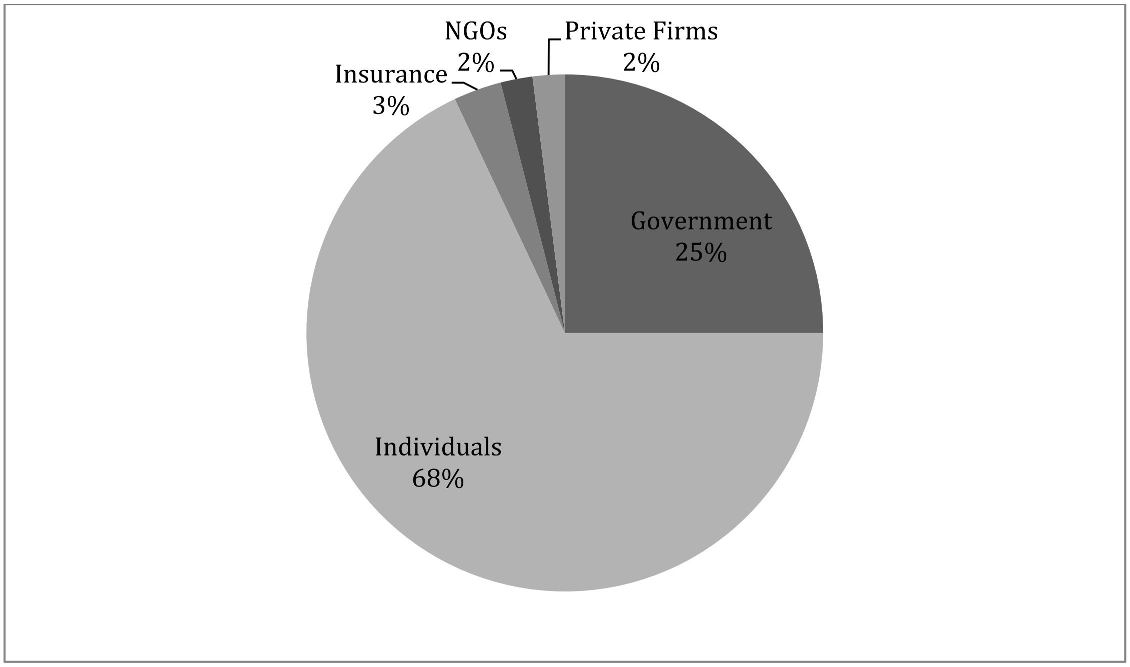
As three quarters of the health expenses paid in India are borne privately, and most are paid direct out-of-pocket, medical device companies do not pursue reimbursement pathways. Instead, they focus on getting their products in front of doctors who will prescribe them and patients who will purchase them. Business models and distribution pathways are thus very important in India.

Healthcare Financing

Low spending levels plague India's healthcare system. Healthcare expenditure per capita was only US$56 in India in 2010 compared to US$208 in China and US$964 in Brazil that same year.[37] India's private and public sector combined spent only about four percent of GDP on healthcare in 2010. The government is planning to increase its share from 1.4 percent to 2.5 percent of GDP over the next five years.[38] Total healthcare spending is projected to increase from roughly two percent to six percent of GDP over the next decade.[39] This woefully inadequate level of spending is the lowest among all BRICS nations (Brazil, Russia, India, China, and South Africa).[40] In contrast, the United States spends 17.6 percent, Germany 11.6 percent, and Mexico 6.2 percent of GDP on healthcare.[41]

Although the Indian government plans to boost its healthcare outlays going forward, it only accounts for some 25 percent of total healthcare spending in India.[42] Individuals and institutions contribute the remainder, making India's healthcare system one of the world's most privatized (see Figure 7).[43]

Figure 7 Breakdown of Total Healthcare Expenditures in India[44]



Health insurance is rare but growing in India. Only 55 million people had health insurance in 2003. By 2010, 300 million people, mostly below the poverty line, gained access to some partial form of health insurance. Still, only three percent to five percent of patients have full or substantial coverage.[45]

Both government and private insurers are working to increase access to insurance. Analysts estimate that about half the population will enjoy some level of health insurance coverage by 2020.[46] The National Rural Health Mission (NHRM), which the Indian government rolled out in 2005, will account for some of this increase. NHRM is an ambitious and wide-ranging public health program that seeks to improve healthcare delivery in rural India.[47] The *Rashtriya Swasthya Bima Yojna* (RBSY, translated as National Health Insurance Program) also strives to increase health insurance access for poor families that make less than US$100 per year.[48]

Domestic insurance providers, such as Cholamandalam, L&T General, and HDFC, as well as foreign providers in joint ventures, such as Bajaj Allianz, Tata AIG, and ICICI Lombard, are starting to become more active in the private healthcare insurance sector. Private insurance players currently serve just one percent of the Indian market, but account for more than two percent of total healthcare expenditures in the country.[49]

Reimbursement

Less than a quarter of Indians have any kind of health insurance and only a sliver enjoy substantial coverage. As a result, patients usually pay out-of-pocket for healthcare purchases and are extremely cost-sensitive. Most insurance providers require patients to file claims after receiving service, causing them to bear the cost up front. Insurance normally does not cover many routine primary and secondary care visits, adding to households' out-of-pocket healthcare expenses. Health insurance providers cap the amount they reimburse insured patients for surgeries and other hospital visits. They do not reimburse medical technology separately. Rather, the cost is covered in the reimbursement for the procedure, either to the hospital or to the patient directly.

Public healthcare facilities use central government or state level tender processes to procure medical supplies. These processes vary from state to state and can be very bureaucratic and difficult to break into for new companies. In the private healthcare sector, procurement processes for medical devices differ depending on a facility's size, location, and purchasing power.

DOING BUSINESS IN INDIA

India is a difficult country to start and run a business. In 2013, the World Bank ranked India 177 from among 189 countries in the ease of starting a business and a dismal 186 in enforcing contracts.[50] The country is notorious for high rates of corruption and bribery in the government sector. Regulations such as IP laws or product quality monitoring are often not enforced broadly, which can hinder the success of a startup company. Innovators should be prepared for many routine tasks, such a setting up bank accounts, to take weeks instead of days, and build their plans accordingly. As in many other emerging markets, the key to successfully doing business in India can be to engage the right local partner or hire a leadership team with deep expertise in the sector who can navigate many of these challenges associated with medtech innovation in India.

Endnotes

[1] World Bank, "GDP," 2012, http://data.worldbank.org/indicator/NY.GDP.MKTP.CD (March 5, 2013).
[2] World Bank, "GDP Growth," http://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG (February 22, 2013).
[3] Ahluwalia, Montek Singh, "Economic Reforms in India since 1991," *Journal of Economic Perspectives,* Summer 2002, p. 1, http://planningcommission.nic.in/aboutus/speech/spemsa/msa008.pdf (February 22, 2013).
[4] "India Tariff Rates," IndexMundi 2012, http://www.indexmundi.com/facts/india/tariff-rate (February 22, 2013).
[5] Ahluwalia, loc. cit.
[6] "Decadal Population Growth in India: 1901 to 2011 Census," IndiaStat 2011, http://www.indiastat.com/demographics/7/growth/116/stats.aspx (February 22, 2013).
[7] "India Set to Overtake China as World's Most Populated Country After Adding 180 Million People in a Decade," *Daily Mail* (London), March 31, 2011, http://www.dailymail.co.uk/news/article-1371996/India-set-overtake-China-worlds-populated-country-adding-180m-people-decade.html?ito=feeds-newsxml (February 22, 2013).
[8] "India Demographics Profile," IndexMundi 2012, http://www.indexmundi.com/india/demographics_profile.html (February 22, 2013).
[9] "Median Age of the Population in China, India, Europe, and USA from 1950-2100," China Profile Data, June 12, 2011, http://www.china-profile.com/data/fig_WPP2010_Median-Age.htm (February 5, 2013).
[10] "Taking Advantage of the Med-Tech Market Potential in India," PWC, 2012, p. 4, http://www.pwc.com/en_GX/gx/pharma-life-sciences/publications/asia-pharma-newsletter/assets/taking-advantage-of-the-medtech-market-potential-in-india.pdf (February 27, 2013).
[11] "Decadal Population Growth in India: 1901 to 2011 Census," loc. cit. Data for 2011 is provisional.
[12] "India: Medical Device Market," Espicom Report 2012, http://www.espicom.com/india-medical-device-market (March 5, 2013)
[13] "Taking Advantage of the Med-Tech Market Potential in India," op. cit, p. 9.
[14] "Ibid.
[15] "Introduction to Medical Devices in India," Pacific Bridge Medical, http://www.pacificbridgemedical.com/business-services/medical-device-consulting/india/ (February 22, 2013).
[16] Espicom 2012, loc. cit.
[17] E. Saneesh, "The Emerging Role of Small and Medium Enterprises in the Indian Medical Devices Market," *Frost and Sullivan*, September 17, 2012.
[18] "Overview of Medical Device Market in India," Espicom Report, 2011, p. 7
[19] Private interviews with author, 2012
[20] Jeffery R. "Pharmaceuticals Distribution Systems in India". Working Paper 1a, 2007. http://www.csas.ed.ac.uk/__data/assets/pdf_file/0003/38829/PharmaDistributionIndia.pdf
[21] Oburai, M. "A Grounded Exploration of Sales and Distribution Channel Structures in 13 Industries in India". IIM Ahmedabad Working Paper, 2004
[22] Ibid.
[23] "Apple: No Signs of Economic Issues in US, China," Tech Trader Daily, July 24, 2012, http://blogs.barrons.com/techtraderdaily/2012/07/24/apple-conference-call-mountain-lion-out-tomorrow/ (January 4, 2013)
[24] Yock, P. Zenios S. Makower, J. "Biodesign: The Process of Innovating Medical Technologies", Cambridge University Press, 2009
[25] Private interviews with author, 2012
[26] http://www.thesmartceo.in/Industries/healthcare-and-pharma/devising-medical-innovation.html
[27] http://www.cura.in/organisation.php
[28] http://www.xcyton.com/company_profile.html
[29] "Emerging Consumer Demand in India", McKinsey Global Institute 2007, http://www.mckinsey.com/tools/Wrappers/Wrapper.aspx?sid={FE9A4B81-FF97-472F-B14C-87A3C87FA8E0}&pid={47CB8519-28C9-431B-9FE5-036888E06091} (October 20, 2013)
[30] Sumit Gupta, "The Bird of Gold: The Rise of India's Consumer Market," *McKinsey Global Institute,* May 2007, http://www.mckinsey.com/insights/mgi/research/asia/the_bird_of_gold (March 6, 2013)
[31] "Medtech Giants Philips and GE fight over India," Forbes India, September 26, 2013
[32] "GE Healthcare innovates in India for the bottom of the pyramid," Business Standard, May 4, 2009
[33] Nicholas Donoghue, Ajay Gupta, Rob Linden, Palash Mitra, and Ingo Beyer, "Medical Device Growth in Emerging Markets: Lessons from other Industries," *In Vivo*, June 2012, p. 6

[34] "Contribution of emerging market should double in next three-four years: Omar Ishrak, Medtronic", Economic Times, April 22, 2013
[35] "Succeeding in the India healthcare market", Bain and Company Insights, January 17, 2012, http://www.bain.com/publications/articles/succeeding-in-the-india-healthcare-market.aspx (October 26, 2013)
[36] Sumit Gupta, "The Bird of Gold: The Rise of India's Consumer Market," *McKinsey Global Institute,* May 2007, http://www.mckinsey.com/insights/mgi/research/asia/the_bird_of_gold (March 6, 2013)
[37] "Taking Advantage of the Med-Tech Market Potential in India," op. cit., p. 9.
[38] "Healthcare Spending to Rise to 2.5 Percent," *Indian Express*, March 1, 2012, http://www.indianexpress.com/news/healthcare-spend-to-rise-to-2.5--of-gdp/918380 (February 22, 2013).
[39] "The Outlook for Medical Devices in Brazil, Russia, India and China," Espicom Market Reports 2011, http://www.espicom.com/medical-devices-outlook-bric (February 22, 2013).
[40] Ram Prasad, "Medical Device Industry," *The Hindu,* April 15, 2012, http://www.thehindubusinessline.com/industry-and-economy/article3317902.ece?homepage=true&ref=wl_home (February 22, 2013).
[41] "India Healthcare Expenditure," OECD report, 2012, http://www.oecd.org/health/healthpoliciesanddata/oecdhealthdata2012-frequentlyrequesteddata.htm (February 22, 2013).
[42] Parvathi K. Iyer and Dinesh Abrol, "Science and Technology Financing," *India Science and Technology,* 2008, http://www.nistads.res.in/indiasnt2008/t2finance/t2fin2.htm (February 22, 2013).
[43] Nishant Jain, "Analysis of Public Expenditure on Health Using State Level Data," IIM Ahmedabad, June 2004, p.4, http://www.iimahd.ernet.in/publications/data/2004-06-08rbhat.pdf (February 22, 2013).
[44] Iyer and Abrol, loc. cit.
[45] "Government Sponsored Health Insurance in India: Are you covered?" World Bank, October 11, 2012, http://www.worldbank.org/en/news/2012/10/11/government-sponsored-health-insurance-in-india-are-you-covered (February 22, 2013).
[46] "Indian Pharma 2020: Propelling Access and Acceptance, Realizing Potential," McKinsey and Company, 2010, p. 18, http://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/Pharma%20and%20Medical%20Products/PMP%20NEW/PDFs/778886_India_Pharma_2020_Propelling_Access_and_Acceptance_Realising_True_Potential.ashx (February 22, 2013).
[47] Ajay S. Mahal, Bibek Debroy, and Laveesh Bhandari, *India Health Report 2010*, Business Standard Books, (ISBN:978-8074-000), p. 138.
[48] Jackie Range, "India's Poor Get Health Card to Fund Medical Treatment," *Wall Street Journal*, August 26 2008, http://online.wsj.com/article/SB121971773721671817.html (March 3, 2013).
[49] "Taking Advantage of the Med-Tech Market Potential in India," op. cit., p. 4.
[50] "Ease of Doing Business in India," World Babk Data, 2013, http://www.doingbusiness.org/data/exploreeconomies/india/ (October 20, 2013)