

# Index

- aging populations, demands on healthcare innovation 45–47
- Amgen FIPCO strategy 123–125
- antisense 122
- Asia, biotechnology sector 153–154, 160–165
- ASP (application service provision) 326, 343–344
- Australia, biotechnology sector 165–166
- Bayh-Dole Act (1980) 107
- Betaseron (beta-interferon) 113
- Biogen RIPCO business strategy 128–129
- bioinformatics databases 126
- biologicals/bioproductions *see* biotechnology products
- biomarkers 62
  - successes and challenges 63–64
  - surrogate end points 62–63, 69
- biotechnology companies
  - challenges for management 150–153
  - challenges to business strategy 190–191
  - entrepreneurial management 150–151
  - evolution 36–37
  - financing 41
  - interaction with other organizations 40
  - magnitude of resources required 151–152
  - managing periods of financial stress 151–152
  - mergers and acquisitions 147–150, 149
  - need for culture of flexibility 152–153
  - ongoing rethinking of business models 190–191
  - operational management 151
- biotechnology–pharmaceutical company alliances 137–150
  - benefits to both parties 139–143
  - Bristol-Myers Squibb deal with Imclone 147
  - changing dynamic of alliances 143–147
  - differences in ways of doing business 137–139, 142–140
  - difficulties in making alliances work 137–139, 142–140
  - influence of genomics technology 145
  - mergers and acquisitions 147–150
  - partial acquisitions 144–145
  - what makes alliances work 139, 142
- biotechnology products 27–29
  - manufacturing and process development 79–80
- biotechnology sector
  - building on accumulated tools and information 215–217, 220–221
  - business and revenue models, definition of 208–209
  - business and revenue models reassessment 208
  - business models and the value chain in healthcare 208–211, 212–221, 353–354
  - business models of technology platform companies 191–193
  - capital raising through pharmaceutical outsourcing 209–210
  - change motivators in business and revenue models 210–211
  - changing relationships between alliance partners 196, 219
  - company definitions and related business models 214–219
  - drivers for individual companies 180–181
  - drivers for the industry 181–183
  - evolution of new business models 215–217, 220–221
  - expanding the position on the value chain 218–219
  - factors affecting business and revenue models 211–212
  - FIPCO development 215–218
  - information transfer problems between partners 219
  - intellectual property issues 218–219
  - investment levels 212–213
  - lack of consolidation despite financial pressure 211–213
  - laws of supply and demand 181–183
  - licensing agreements 213–214
  - systems biology 215–217, 220–221
  - value chain points of participation 208–210
  - vertical integration 212–219
- biotechnology sector (therapeutics)
  - Amgen FIPCO strategy 123–125
  - anemia and erythropoietin 113
  - antisense 122
  - Bayh-Dole Act (1980) 107
  - Betaseron (beta-interferon) and multiple sclerosis 113
  - Biogen RIPCO business strategy 128–129
  - bioinformatics databases 126
  - biotechnology drugs on the market 111
  - blocking single gene functions 122

- biotechnology sector (therapeutics) (*cont.*)
  - business models 122–131
  - cancer/renal failure anemia and erythropoietin 113
  - combinatorial chemistry 120, 126
  - cost of products 115
  - cumulative losses 109, 110
  - deals with pharmaceutical companies 110–111
  - diseases and conditions which have been impacted 112–115
  - DNA microarrays (DNA chips) 121
  - DNA structure discovery 104
  - driving force of innovation 116–122, 123
  - FIPCO (or FIBCO), fully integrated (bio)pharmaceutical company model 122–125, 131
  - founding of Genentech 104–105
  - founding of the sector 104–105
  - gene therapy 114, 121
  - genetic engineering techniques 106
  - genomics (gene structure and function) 117–118, 126–127
  - growth and investment 110–111
  - history 104–108
  - HTS (high-throughput screening) 120–121
  - impact on healthcare 111–115
  - impact on pharmaceutical sector 115
  - innovative technologies 116–122, 123, 125–127
  - intellectual property law (patents) protection 105–107
  - major employment area 115
  - Millennium Pharmaceuticals business strategy 126–127, 128
  - monoclonal antibodies 116–117
  - monoclonal antibody technology 104–105
  - multiple sclerosis and Betaseron (beta-interferon) 113
  - NRDO (no research development only) companies 122–123, 129–131
  - pioneering companies 104–105, 107–108
  - proteomics (protein structure and function) 118–119
  - rational drug design (RDD, structure-based design) 120
  - recombinant DNA (rDNA) techniques 104–105, 106
  - RIPCO (royalty income pharmaceutical company) strategy 122–123, 128–129, 131
  - RNA interference 122
  - sector development in last 30 years 103–104
  - sector overview 108–111
  - systems biology 122, 123
  - technologies which become commoditized 126
  - technology platform business model 122–123, 125–127, 128
  - technology platforms to advance drug discovery 119–122, 123
  - US biotechnology company revenues 111
- biotechnology sector finance
  - convertible debt securities 135–136
  - cost to develop one drug 132
  - cyclical nature of financing 132–133
  - factors influencing availability of finance 132–133
  - financing alternatives 133, 134, 136–137, 138
  - financing and the capital markets 132–137, 138
  - government grants 136
  - IPO (initial public offering) market 132–133, 134, 136–137, 138
  - PIPEs (private investment in public equity) 134–135, 136–137, 138
  - private placements 133, 136–137, 138
  - R&D limited partnerships 135
  - SBIR (Small Business Innovative Research) grants 136
  - shifts in sources of financing 136–137, 138
  - SWORDs (stock-warrant off-balance sheet R&D financing) 135
  - venture capital funding 129–131, 133, 134, 136–137, 138
- biotechnology sector global structure 153–167
  - Asia 153–154, 160–165
  - Australia 165–166
  - Canada 154, 158–160
  - China 160, 161, 164–165
  - comparing US biotechnology with rest of the world 153–154
  - Europe 153–158
  - Germany 153–154, 155, 157–158
  - global companies 166–167
  - India 160, 161
  - Japan 161–163
  - Korea 160, 161
  - Singapore 153–154, 160, 161, 163–164
  - Taiwan 160, 161, 163
  - UK 153–154, 155–157
- biotechnology sector regulation 167–180
  - biologics approval issues 171
  - bioterrorism 175
  - CBER (Center for Biologics Evaluation and Research) functions 169–173
  - CDER (Center for Drug Evaluation and Research) functions 169–171
  - drug approval in Europe 176–179
  - drug approval in Japan 176–177, 179–180
  - drug development for rare diseases 174, 175
  - drug regulation outside the US 176–180
  - embryonic stem cell research 171–172
  - Environmental Protection Agency functions 167–171
  - FDA (Food and Drug Administration) functions 167–171
  - federal regulatory authorities 167–171
  - generic biologics 173
  - germline gene therapy 173
  - human cloning 172–173
  - ICH (International Conference on Harmonization) 176–177
  - Orphan Drug Law (1983) 174, 175

- Project Bioshield 175
- special regulatory issues 171–175
- US Department of Agriculture functions 167–171
- US drug approval process 167–171
- bioterrorism 175
- blockbuster products 81–85
  - effects of patent expiry 145, 146
- Bristol-Myers Squibb 38
  - deal with Imclone 147
- business models, biotechnology sector 122–131
- Canada, biotechnology sector 154, 158–160
- CBER (Center for Biologics Evaluation and Research),
  - biotechnology regulation functions 169–171, 172–173
- CDER (Center for Drug Evaluation and Research),
  - biotechnology regulation functions 169–171
- Certificate of Need (CON) laws 10
- cGMP (current Good Manufacturing Practices)
  - compliance 73, 78–79
- China, biotechnology sector 160, 161, 164–165
- cloning
  - Dolly the sheep (Scotland) 172–173
  - human cloning 172–173
- combinatorial chemistry 120, 126
- convertible debt securities, biotechnology sector 135–136
- CPOE (computerized physician or clinical order entry)
  - systems 330–333
- CRM (customer relationship management) 86–87
- CT (computerized tomography) 335
- diseases, shifting patterns of 46–47
- DNA
  - discovery of structure 104
  - microarrays (DNA chips) 121
  - recombinant DNA (rDNA) techniques 104–105, 106
- drug discovery, history of 44–45
- drug technology, new versus older drug technology 44–47
- drugs, proportion of hospital expenses 10–13
- economic impact of local technology cluster developments 17–18
- e-detailing 87
- electronic medical record (EMR) 330–332
- erythropoietin, and anemia 113
- Europe
  - biotechnology sector 153–158
  - drug approval process 176–179
- FDA (Food and Drug Administration)
  - cGMP (current Good Manufacturing Practices)
    - enforcement 73, 78–79
  - Consent Decrees 78–79
  - NDA (New Drug Application) approval procedure 65–66
  - financing of biotechnology companies 41, 132–137, 138
  - FIPCOs (or FIBCOs)
    - barriers to development of 350
    - fully integrated (bio)pharmaceutical company model 122–125, 131
    - limited prospects for development in biotechnology sector 215–217, 218
    - transition toward fully integrated companies 353
  - France, marketplace regulation 42
  - gene discoveries, licensing 202–203
  - gene functions, selective blocking of single genes 122
  - gene therapy 114, 121
  - Genentech, founding of 104–105
  - generic biologics 173, 174
  - genetic engineering techniques 106
  - genetics, clinical 334
  - genomics
    - gene structure and function 117–118, 126–127
    - genome science, objectives 193–195
  - Germany
    - biotechnology sector 153–154, 155, 157–158
    - marketplace regulation 42–43
  - germline gene therapy 173
  - global biotechnology companies 166–167
  - government grants, biotechnology sector 136
  - Health Insurance Portability and Accountability Act (HIPAA) (1996) 339–341
  - health plans, consumer-directed health plans 341–342
  - healthcare, drivers for advances 45–47
  - healthcare expenditure
    - costs and benefits 3–4
    - reasons for rising costs 3–4
    - technological imperative 3–4
  - healthcare information technology (IT) sector
    - acquisition of healthcare IT firms 327, 328
    - ASP (application service provision) 326, 343–344
    - barriers to user adoption 324–325
    - biometrics technology advances 335–337
    - clinical genetics 334
    - computerized tomography (CT) 335
    - consumer directed health plans 341–342
    - cost of clinical informatics software 326
    - cost reduction progress 325–326
    - CPOE (computerized physician or clinical order entry)
      - adoption constraints 332–333
    - CPOE systems 330–333
    - development cycles of healthcare IT firms 327, 328
    - development toward an “intelligent” clinical record 331–332
    - diagnostic applications 333–334
    - digital image storage and routing 334–335

- healthcare information technology (IT) sector (*cont.*)
  - digital radiology and broadband Internet connectivity 334–335
  - electronic medical record (EMR) 330–332
  - electronic submittal of medical claims 340–341
  - fragmentation of the market 326–327
  - future directions 344–345
  - genetic information usage issues 334
  - GUI (graphical user interface) design 324–325
  - health insurance information systems 339–341
  - Health Insurance Portability and Accountability Act (HIPAA) (1996) 339–341
  - implantable “intelligent” monitoring and medicating systems 337–338
  - integration of diagnostic and therapeutic functions 325
  - “intelligent” monitoring systems 335–339, 337
  - Internet connection between health insurers and subscribers 340–341
  - Internet submission of medical claims 340–341
  - Internet use 326
  - location independent monitoring of unstable patients 335–339, 337
  - major healthcare IT applications 329–344
  - market structure 326–329
  - microchip computing power improvements 325, 325–326
  - MRI (magnetic resonance imaging) 335
  - outsourcing IT applications 343–344
  - outsourcing IT installation and management 342–344
  - outsourcing IT using broadband Internet 343–344
  - outsourcing of healthcare IT activities 329
  - PACS (picture archiving communication and storage) systems 334–335
  - payer applications 339–341
  - remote monitoring of intensive care unit (ICU) patients 338
  - remote monitoring/management of patients 335–339, 337
  - sales of financial software and systems 328–329
  - size and potential 323
  - slow progress due to healthcare system complexity 323–324
  - systems integration consulting 329, 343
  - technological demands on hardware and software 324–326, 325
  - telepresence technology and two-way remote physician visits 338
  - “thin client” architecture 343–344
  - top healthcare software applications providers 328
- healthcare innovation *see also* [innovation](#)
  - demands of aging populations 45–47
  - meta-environment 40
  - role of USA 41
- healthcare innovation across sectors
  - “ambidextrous” approach to managing the balancing act 360
  - balancing “exploitation” with “exploration” 360
  - balancing short-term and long-term objectives 360
  - barriers to development of FIPCOs 350
  - bioinformatics challenges 352
  - biotechnology challenges 352
  - biotechnology RIPCOs 350
  - commercialization challenges 350
  - common business models 353–354
  - convergence of many skills and multiple technologies 348–349
  - convergence of markets or sectors 362–363
  - different forms of diversification 357
  - diversification and integration 356–358
  - financial resources 354–355
  - FIPCOs 353
  - fragmented markets 353–354
  - fungibility of resources 355–356
  - integration of knowledge 356–358
  - intellectual property protection complexities 349–350
  - invention and adoption challenges 348–352
  - M&A diversification strategies 356–358
  - M&A impacts 353–354
  - market capitalization of different sectors 350–351
  - medical device sector business environment 351–352
  - organizational routines and capabilities 356–361
  - pharmaceutical sector managerial structure 357–358
  - platform technology challenges 352
  - portfolio management and optimization 358–359
  - postmerger integration 356–358
  - pressures for affordable innovation 360–361
  - sales force resources 355
  - scale as a resource 355
  - strategic alliances management 359–360
  - strategic capabilities and key success factors 354–361
  - strategic resources 354–356
  - technological convergence across sectors 361–363
  - transition toward fully integrated companies (FIPCOs) 353
- healthcare markets, USA 100–101
- healthcare value chain, effects of changing business models 208–211, 212–221
- hospital expenditure management 10–13
- HTS (high throughput screening) 120–121
  - μHTS (ultra high throughput screening) 56–58
- human cloning 172–173
- Human Genome Project, and technology platform companies 192–193
- Human Genome Services (HGS) alliance with SmithKlineBeecham 198–203
- ICU (intensive care unit) patients, remote monitoring 338
- imaging technologies 64, 69

- IND (Investigational New Drug) approval 59–60
- India, biotechnology sector 160, 161
- industrial organization perspective, on corporate strategies 6
- infectious diseases 46–47
- innovation *see also* [healthcare innovation](#)
  - in pharmaceutical companies 249
  - major sectors among producers 2
- innovation flow through the value chain 1–2, 32
- innovation success
  - as driver for commercial success 4–5
  - factors contributing to 4–8
  - industrial organization perspective 6
  - organizational innovation perspective 7–8
  - resource-based view 6–7
  - value chain perspective 7
- innovative technologies, biotechnology sector 116–122, 123, 125–127
- intellectual property *see* [patents](#)
- International Conference on Harmonization (ICH),
  - biotechnology sector regulation 176–177
- Internet
  - broadband connectivity and digital radiology 334–335
  - outsourcing IT using broadband Internet 343–344
  - to connect health insurers with subscribers 340–341
  - to submit medical claims 340–341
  - use by healthcare information technology (IT) sector 326
- IPO (initial public offering) market
  - and M&A activity 313–316
  - biotechnology sector 132–133, 134, 136–137, 138
  - reasons for surge in 313–314
- IT *see* [healthcare information technology \(IT\) sector](#)
- Japan
  - biotechnology sector 161–163
  - drug approval process 176–177, 179–180
  - marketplace regulation 43
- Johnson & Johnson 37–38
- Korea
  - biotechnology sector 160, 161
  - stem cell research 172
- M&As (mergers and acquisitions) *see also* [pharmaceutical sector M&As](#)
  - diversification strategies 356–358
  - effects of 353–354
  - of biotechnology companies 147–150
  - pharmaceutical companies 96–99
  - postmerger integration 356–358
- managing a biotechnology company 150–153
- manufacturing and process development
  - (pharmaceutical) 73–80
  - API (active pharmaceutical ingredient) bulk manufacturing 74
  - API form/fill/finishing (F/F/F) 74–75
  - biotechnology products 79–80
  - cGMP (current good manufacturing practices)
    - compliance 73, 78–79
  - compound potency and manufacturing cost 77
  - costs of FDA Consent Decrees 78–79
  - customer requirements from pharmaceutical suppliers 76
  - making the medicine 74–75
  - manufacturing excellence inputs 76–78
  - manufacturing management 73
  - process optimization 77–78
  - process robustness 77–78
  - process which is “in-control” 77–78, 79
  - quality control (cGMP) 73, 78–79
  - quality systems approaches 79
  - sales forecast accuracy 76–77
  - supplying the medicine 75–76
  - value chain within manufacturing 74–76
- manufacturing sectors *see also* [producer sectors](#)
  - convergent product development 15–17
- marketplace regulation
  - France 42
  - Germany 42–43
  - Japan 43
  - national approaches and effects 42–43
  - USA 42
- medical device sector
  - 510(k) premarket notification 275–276
  - balloon angioplasty catheters 300–301
  - channels for selling 289, 289–291, 292–295
  - characteristics of the sector 271–272
  - clinical feedback on products 291
  - comparisons with other industries 272–273
  - comparisons with pharmaceutical sector 295–297
  - concentration of buyers/customers 292–295
  - contribution of materials sciences 300–302
  - current success 273–274
  - direct selling 289, 289–291, 292–295
  - distributor networks for orthopaedic sales 291–292
  - drug-eluting coronary stents 287–289
  - drug-eluting stent combination technology 302–303
  - drug-device convergence 302–305
  - economics and sustained growth 284–285
  - economics of clinical need 286–289
  - electronics technologies 297–300
  - favorable pricing and high profitability 285–286
  - franchise building by sales representatives 290
  - global vs US sourcing 279–284
  - history and development of the sector 274
  - history of medical device regulation 274–275
  - implantable defibrillators 283–284, 297–300, 299

- medical device sector (*cont.*)
  - “Infuse” spine cage combination technology 303
  - insulin delivery pumps 302
  - interventional cardiology technology 300–301
  - large companies outside the US 280, 281
  - limited consumerism 295–297
  - market breakdown 277–278
  - market size 277–278
  - medical device approval procedures 274–276
  - microprocessor technology 297–300
  - orthopaedics materials technology 301
  - orthopaedics sales by distributor network 291–292
  - PMA (premarket approval) process 275–276
  - predominance of US companies 279–280, 281–282
  - pricing freedom and clinical need 286–289
  - rates of consumption of medical technology 283–284
  - rates of profit generation 292–295
  - reasons for sustainable profitability 295–297
  - sales representatives feedback to the company 291
  - sales representatives educate doctors about products 290–291
  - sales representatives vital role 289–291
  - sector structure 279
  - sector’s unique and defining characteristics 284–297
  - selling efficiencies 292–295
  - separation of consumers, customers and payers 285–286
  - size and diversity of companies 279
  - size and profitability 272–273
  - stent technology 300–301 *see also* drug-eluting stents
  - technologies 297–305
  - US exports around the world 282–283
- medical device sector drivers 305–310
  - aortic aneurysm catheter-based treatment 306–307
  - demographic effects on growth 306
  - investment in franchise building 309–310
  - marketing channels or conduits 309–310
  - pricing effects on growth 308
  - pricing in the orthopaedic market segment 308
  - pricing of new products 308
  - procedure penetration as source of growth 307–308
  - prognosis for the sector 305
  - sources of growth 305–308
  - unmet clinical needs as source of growth 306–307
- medical device sector financing and consolidation trends 310–320
  - acquisition to buy growth 311, 316–317
  - acquisition to increase size, scope, or geographic reach 318–319
  - concentration ratios 312
  - consolidation premise 310
  - corporate strategy and M&A activities 313
  - distribution channel acquisitions 317–318
  - funding restrictions for small innovative firms 319–320
  - IPOs and M&A activity 313–316
  - M&A activity in the last decade 310–312
  - M&A cycles of activity 313–316
  - public market activity and innovation 319–320
  - reasons for combinations 316–319
  - reasons for surge in IPOs 313–314
  - technological–anatomical combinations 318
  - trends in sourcing innovation 319–320
- medical devices, proportion of hospital expenses 12
- medical liability in the USA 41
- medical supplies, proportion of hospital expenses 12
- mergers and acquisitions *see* M&As
- microarrays (DNA chips) 121
- Millennium Pharmaceuticals business strategy 126–127, 128
- money flow through the value chain 1–2
- monoclonal antibodies 116–117
- MRI (magnetic resonance imaging) 335
- NCEs (new chemical entities) 27–28
  - patents 59
- NDA (New Drug Application) 65–66
- NIH (National Institutes of Health), role in healthcare innovation 40
- NPP (new product planning), pharmaceutical sector 80–81
- NRDO (no research development only) companies 122–123, 129–131, 130
- organizational innovation perspective, on requirements for successful innovation 7–8
- Orphan Drug Law (1983) 174, 175
- PACS (picture archiving communication and storage) systems 334–335
- patents (intellectual property) 59
  - patent expiry for blockbuster pharmaceutical products 145, 146
  - patent protection for biotechnology products 105–107
- pharmaceutical commercialization 80–88
  - communicating with customers 85–88
  - coordination of marketing and selling functions 88
  - CRM (customer relationship management) 86–87
  - e-detailing 87
  - focus on blockbusters 81–82
  - launching a blockbuster 82–85
  - marketing input across the value chain 80–81
  - multichannel access to customers 86
  - NPP (new product planning) 80–81
  - sales organization 85–86
  - telephone and video detailing 87–88
- pharmaceutical companies
  - alliance partners changing relationships 196, 219
  - barriers to entry into the industry 99–100
  - biotech companies evolution 36–37
  - biotechnology mergers and acquisitions 147–150, 149

- Bristol-Myers Squibb 38
- controversies over mergers 97–99
- critical mass concept 97–99
- economies of scale 97–99
- history and character 37–40
- impact of M&As on innovation 249
- innovation influences 249
- interaction with other organizations 40
- Johnson & Johnson 37–38
- large size and “innovation gap” 182–183
- licensing agreement 213–214
- mergers and acquisitions (M&A) 96–99, 249
- patent expiry and “product gap” 182
- question of whether large size is beneficial 92–93, 94, 97–99
- Sanofi-Aventis 39–40
- situations where acquisitions make sense 96–97
- size as a barrier to entry in pharmaceuticals 99–100
- stereotypical views of excessive earnings 13–14
- strategic alliance management 95–96
- strategic alliance need 93–94
- strategic alliance types 93–94
- value strategies as alternatives to M&As 253–256
- pharmaceutical market 29–34
  - changes in major therapeutic areas 32–33
  - generic drug companies 33–34
  - growth predictions 30–32
  - largest pharmaceutical companies 30–32
  - patent expirations 30–34
  - worldwide market size 29–30
- pharmaceutical portfolios
  - business development approach 91–93
  - compensating for drug fallout 89–90
  - in-licensing to improve flow of innovation 91–92
  - internal development approach 89–91
  - monitoring the mix of risk levels 90–91
  - optimization for flow and reduced risk 91
  - outpartnering to keep projects moving 92–93
  - pipeline unlikely to have smooth flow 89–90
  - risk variation among projects 90
  - spinning out assets into a company 92–93
- pharmaceutical research and development
  - biological understanding and productivity 69–72
  - challenge to increase cost effectiveness 67–73
  - critical mass in spending 238
  - cross-functional team approach 72–73
  - factors affecting productivity 67–73
  - fast fail approach to development 70–72
  - flexible organizational structure 72–73
  - reasons for high expense and high risk 67–69
- pharmaceutical research and development (development stage) 59–62
  - biomarkers, 62–63, 69
  - FDA approval procedure 65–66
  - imaging technologies 64, 69
  - IND (Investigational New Drug) approval 59–60
  - NDA (New Drug Application) 65–66
  - phase I testing: first studies of safety in humans 60–61
  - phase II testing: first studies of efficacy 61–62
  - phase III: definitive multicenter trials 64–65
  - phase III: head to head studies 64–65
  - phase IV studies 66–67
  - preclinical and medical development 59–60
  - preregistration 65
  - probability of success at different stages 59–62, 64–65
  - registration 65–66
- pharmaceutical research and development (discovery stage) 51–59
  - assay development and ultra high throughput screening ( $\mu$ HTS) 56–58
  - candidate selection 58–59
  - differences to academic research 53
  - lead generation 56–58
  - lead optimization 54–58, 60
  - patents (intellectual property) 59
  - SAR (Structure-Activity Relationship) 56–58
  - screening to generate leads 56–58
  - target identification 53–55
  - target validation 55–56
- pharmaceutical sector
  - barriers to entry 99–100
  - cost-effective therapies 256–259, 260–261
  - crisis in R&D productivity 239–240
  - criticism of analogue production 36
  - criticism of overpricing 35–36
  - drug development time span 34–35
  - funding a challenging business model 35–36
  - high risk and long time lines for returns 34–35
  - in-licensing 254–256
  - managerial structure 357–358
  - need for greater efficiency 260–261
  - overview 27–37
  - potential shift toward consumer products model 295–297
  - question of value of large size 260–261
  - research and development costs 34–36
  - sector characteristics 34–36
  - value chain alliances with payers and patients 256–259
  - value chain alliances with physicians and hospitals 259–260
  - value creation through value chain alliances 250, 256–260
- pharmaceutical sector M&As
  - adaptive and defensive rationales 229–236
  - clear strategic intent 250–251
  - critical mass in R&D spending 238
  - disruptive change opportunity 229–230, 240
  - economies of scale in sales and marketing 247–249



- pharmaceutical sector M&As (*cont.*)
  - environmental pressures which prompt consolidation 226–227
  - evidence from academic studies and consulting firms 242–248
  - financial outcomes 244–246, 248–249
  - future of M&As 254–256
  - global market control by industry leaders 227–229
  - horizontal integration effects 249
  - impact on growth in sales and operating profits 245–246, 248–249
  - impact on innovation 249
  - impact on market share 246, 248–249
  - impact on performance of pharmaceutical firms 241–242
  - impact on stock price 244–246, 248–249
  - impacts 223–224
  - implementation difficulties due to multiple rationales 240–241
  - leapfrog competition in mergers 234
  - low R&D productivity as prompt for M&As 248–249
  - measuring the impact of a merger 241–242
  - merger partner selection 251
  - mergers as defense against acquisition 235–236
  - mergers to maintain national ownership 235–236
  - multiple rationales and lack of clear goals 240–241
  - negative results of M&As 249
  - postmerger integration process 251–253
  - proactive and offensive rationales 229–230, 236–240
  - rationales from industrial organization theory and research 224–226
  - rationales stated by pharmaceutical companies 224–226
  - rationales which may not have direct benefits 225–226
  - relationship between scale and R&D inputs 242, 248–249
  - relationship between scale and R&D outputs 243–244, 248–249
  - sales force increase in size 234–235, 238–239
  - scale and scope relationship with efficiency 246–249
  - serial consolidators 234–235
  - strategic alliances as alternative to M&As 254–256
  - to achieve economies of scale 225, 238–239, 242–248
  - to achieve economies of scope 239
  - to combat increased profit pressures 2, 230–231
  - to compensate for low pipeline productivity 232–234
  - to cut infrastructure costs 231–232
  - to extend capabilities to new therapeutic areas 237
  - to gain access to foreign markets 236–237
  - to improve R&D productivity 239–240
  - to maintain competitive scale and scope 234–235
  - to maintain earnings growth 232–234
  - trends among pharmaceutical and biotechnology companies 226–229, 230
  - value creation through value chain alliances 250, 256–260
  - value sources in the M&A process 250–254
  - value strategies as alternative to mergers 253–256
- pharmaceutical therapy
  - adverse effects 44–45
  - aging populations 45–47
  - better targeting by newer drugs 44–45
  - care gains and productivity improvements 43–44
  - drivers for advances 45–47
  - history of drug discovery 44–45
  - new vs older drug technology 44–47
  - value proposition 43–44
- pharmaceuticals
  - biologicals/bioproducts 27–29
  - definition of 27–28
  - estimates of potential demand 47–51
  - future demand and company strategy 50–51
  - large molecules (bioproducts) 28–29
  - NCEs (new chemical entities) 27–28
  - pricing variables 49–50
  - research and development process 51–62
  - small molecules (NCEs) 28–29
  - world market size and growth predictions 48–49
- physicians, relationships with vendors 9–10
- PIPEs (private investment in public equity), biotechnology 134–135, 136–137, 138
- PMA (premarket approval) process, medical device sector 275–276
- poor countries
  - high need for medicines 46–47
  - shifting patterns of disease 46–47
- Porter, Michael 6, 17–18
- portfolio management and optimization 358–359
- private placements, biotechnology sector 133, 136–137, 138
- producer sectors *see also* manufacturing sectors
  - capital requirements 18
  - development cycles timescales 18–19
  - domestic to global business scales 19
  - economic importance 14, 31
  - financial support for other parts of the value chain 15
  - high risk 18
  - innovation in 2
  - sector age and strategic behavior 18–19
  - short-term and long-term impact of innovations 3–4, 8
  - similarities and differences across 18–19
  - size and diversity of operations 19
  - stereotypical views of excessive earnings 13–14
  - timescales of development cycles 18–19
- product development, combined technologies 15–17
- Project Bioshield 175
- proteomics (protein structure and function) 118–119
- providers
  - controlling diffusion of new technology 10–13
  - lack of focus on upstream supply costs 10–13
  - provider–vendor strategic partnerships 13



- R&D limited partnerships, biotechnology sector 135  
RDD (rational drug design, structure-based design) 120  
recombinant DNA (rDNA) techniques 104–105, 106  
resource-based view, of distinctive capabilities and strategic alliances 6–7  
RIPCOs (royalty income pharmaceutical company) biotechnology sector 122–123, 128–129, 131, 350  
RNA interference 122  
  
Sanofi-Aventis 39–40  
SBIR (Small Business Innovative Research) grants, biotechnology sector 136  
Scotland, cloning of Dolly the sheep 172–173  
Singapore  
    biotechnology sector 153–154, 160, 161, 163–164  
    stem cell research 172  
stem cell research  
    outside the US 172  
    within the US 171–172  
strategic alliances  
    biotechnology-pharmaceutical company 137–150  
    management of 359–360  
    technology platform companies 197–208  
strategic partnerships, vendor–provider 13  
structure–activity relationship (SAR) 56–58  
SWORDs (stock-warrant off-balance sheet R&D financing), biotechnology sector 135  
systems biology 122, 123  
    future role in biotechnology 215–217, 220–221  
  
Taiwan, biotechnology sector 160, 161, 163  
technological convergence across sectors 361–363  
technological imperative in healthcare expenditures 3–4, 9–10  
technological innovation, biotechnology sector (therapeutics) 116–122, 123, 125–127  
technologies  
    convergence across sectors 15–17  
    which become commoditized 126  
technology cluster developments  
    competitive benefits 17–18  
    impact on local and national economies 17–18  
technology platform companies  
    and the Human Genome Project 192–193  
    business and revenue models reassessment 208  
    business model 122–123, 125, 125–127, 128, 191–193  
    changes in focus due to failure of alliances 207–208  
    current changes in biotechnology and investment focus 207–208  
    data-mining alliances 198, 203  
    factors for operationally effective alliances 205  
    failure of genomics–proteomics strategic alliances 206–207  
    genomics–proteomics companies emergence 197–208  
    genomics–proteomics for target discovery and validation 195–197, 198, 199  
    history of the biotechnology sector 192–193  
    Human Genome Services (HGS) alliance with SmithKlineBeecham 198–203  
    innovation gap in pharmaceutical discovery 195–197  
    licensing of gene discoveries 202–203  
    measuring alliance performance 205–208  
    objectives of genomics 193–195  
    origins 191–192  
    proteomics 193–195  
    roles in the value chain 199, 201, 203–204  
    specialized methods and technology 197, 198, 199  
    strategic alliance components 200–202  
    strategic alliances 197–208  
    strategic alliances model 198–202  
    technology development alliances 199, 201, 203–205  
    technology transfer alliances 205  
    therapeutic area alliances 202–203  
    “toolbox companies” 192–193  
    transfer of discovery between alliance participants 204–205  
technology platforms, to advance drug discovery 119–122, 123  
telephone and video detailing 87–88  
  
ultra high throughput screening ( $\mu$ HTS) 56–58  
UK, biotechnology sector 153–154, 155–157  
universities, role in healthcare innovation 40  
USA  
    healthcare market 100–101  
    marketplace regulation 42  
    medical liability 41  
    role in healthcare innovation 41  
  
value chain  
    in healthcare 1–2  
    levels of returns in different blocks 15  
    within manufacturing 74–76  
value chain perspective, on business models and trading relationships 7  
value chain roles of technology platform companies 199, 201, 203–204  
vendor–provider strategic partnerships 13  
vendors, relationships with physicians 9–10  
venture capital funding, biotechnology sector 129–131, 133, 134, 136–137, 138  
  
Wharton School curriculum 1–19