

Index

- Abbott 19, 45, 65, 67, 108, 142, 436–437
- Abele, John 388
- ACO (accountable care organization) 546–547, 554–555
- affordable innovation 529
- AHCA (Agency for Health Care Administration) (Florida) 95
- alliances, definition of 357
- Alzheimer’s 36, 48, 211
- AMC (academic medical center) 175, 176
- American Recovery and Reinvestment Act (2009) 244
- aneurysm treatment 395–396
- angel networks 351
- anti-stenotic drugs 19
- antisense 222–223
- API (active pharmaceutical ingredient) 63, 108–109
- arthritis therapies 36
- ASC (ambulatory surgery center) 549
- assay development 53, 54
- Bakken, Earl 388
- Bayh–Dole Act (1980) 199
- BCG (Boston Consulting Group) 5, 9, 149, 428, 435
- Berg, Marc 472–473
- beta-interferons 207–208
- biogenerics 520
- biologicals 34
- biomarkers 83
- bioproducts 33, 34
- biosimilars 308–309, 314, 315–316, 354
- biotechnology business/revenue models
  - and capital markets 349–350
  - data mining alliances 369–370
  - definitions 348–349
  - genomics technology platform companies 363–366
  - macro/micro factors affecting 353–355
  - motivators for change 350
  - proteomic technology platform companies 363–366
  - specialty drug development model 361
  - technological reintegration and healthcare value chain 361–366
  - technology development alliances 370–371
  - technology platform companies 363–375
  - technology transfer alliances 371–372
    - performance measurement 372–375
    - productivity measurement 372–373
  - therapeutic area alliances 368–369
  - venture capital model 351–352
  - vertical integration 349–350, 355–361
- biotechnology industry 38–39
  - Asia 285–303
  - Australia 297–298
  - Canada 283–285
  - challenges to industry 346–347
  - culture of flexibility in management 274
  - diseases tackled by 205–212
  - drug discovery/development 520
  - drug regulation in US 303–319
  - employment from 211
  - ethical issues 347
  - in Europe 276–283
  - global companies 302–303
  - global structure of 274–303
  - impact on healthcare 205–212
  - innovation gaps 258–260
  - investment risk 195
  - managing biotechnology firms 271–274
  - and merger and acquisition (M&A) 157
  - merger and acquisition (M&A) trends in 124–130
  - molecular diagnostics companies 219
  - monoclonal antibodies 206, 208, 212–215
  - and multiple sclerosis 207–208
  - in multiple technologies 515–516
  - and national healthcare cost constraints 258
  - and pharmaceutical companies 126–130, 204–205, 247–269, 328, 352–353
  - policy 303–326
  - product validation 251
  - productivity gaps 258–260
  - proteomics 2, 219–220
  - RDD (rational drug design) 20, 220–221
  - rDNA (recombinant DNA) 196, 199–201, 202
  - regulation 303–326
  - revenues 517–518

- sector innovation 2
- as seen by pharmaceutical companies 251
- sequencing capability 218–219
- and specialty pharmacy providers 173
- spread of 199–201
- therapeutics sector 25, 201–205
- tool companies 218
- United Kingdom 278–280
- biotechnology products, major issues 68–69
- bioterrorism 318–319
- Biotherapeutics and Bioinnovation Center (BBC) 130
- BLA (biologics licensing application) 315
- blockbuster drugs 119–120, 133, 137, 258, 273, 555
- Blumenthal, David 474
- BMP-2 19
- Booth, Bruce 246
- bottom-up experimentation 8
- Boyer, Herbert 196
- BPR (business process reengineering) 468–469
- brand switching 414
- business models 5, 8, 25–26, 69–73, 520–522
- business strategies 6
- CABG (coronary artery bypass graft) 12
- CAM (complementary and alternative medicine) 549, 550–551
- cancer metabolism 224
- cancer therapies 36
- capability of firms 7
- capital, in-house venture capital 527
- capital markets and finance 236–247, 264, 349–350, 351–352, 365, 370–371, 440–441, 518
- cardiac bypass 12
- care accountability 546–547
- care delivery 546
  - COEs (centers of excellence) 549
  - consumer- and patient-centered care 550–551
  - decentralization 549–550
  - implications for suppliers 552–553
  - mixed payment sources 551–552
- care and disease management IT 488–489
- CDHP (consumer-directed health plan) 489–490
- CDSS (computerized decision-support system) 469
- Centers for Therapeutic Innovation 175
- CenterWatch 150
- CER (comparative effectiveness research) 96, 309, 546, 549, 553
- cGMP (current good manufacturing practice) 62, 67–68
- cGxP (current good practice) 105, 107
- Chakrabarty, Ananda 198
- China
  - biotechnology industry 293–296
  - cGxP (current good practice) 105
  - drug discovery/development 204
  - GlaxoSmithKline center of excellence 104
  - hybrid business models 104
  - intellectual property rights 103
  - merger and acquisition (M&A) entry 132
  - multinationals in 103–105
  - National Economic Plans 106
  - pharmaceutical industry 46, 81
  - as pharmaceutical market 102–106
  - political system 106
  - research and development (R&D) 104
  - regulation and quality 321
  - TCM (traditional Chinese medicine) 102, 540
- CHINs (community health information networks) 463
- CHMP (Committee for Medicinal Products for Human Use) 323
- Chorus translational development concept 46–47
- claims management IT 483–488
- Clark, Richard 262
- clinical decision-making 546
- clinical development
  - challenges in 82–85
  - globalization of 82
- clinical genetics 475
- clinical needs, economics of 415–417
- clinical trials *see* research and development
- cloud computing 457
- CME (continuing medical education) credits 90
- CMO (contract manufacturing organization) 121, 136, 552
- CMS (Center for Medicare and Medicaid Services) 15
- COGS (cost of goods sold) 63, 423–424
- Cohen, Stanley 196
- Coleman, Alan 310–311
- collaboration management 528
- collaborative model 26
- combinatorial chemistry 221
- Comité Économique du Médicament 49
- common business model 520–522
- COMP (Committee for Orphan Medicinal Products) 323
- competitive forces 6
- competitive scale 139–140
- competitive scope 139–140
- compound potency 65–66
- computer-based molecular modeling 20
- CON (Certificate of Need) laws 3–4, 11
- concentration ratios in mergers and acquisitions (M&As) 437–439
- conflicts of interest 11

- consumer health ecosystem 556
- consumer and patient centered care 550–551
- consumerism and healthcare 543–544
- convergent product 19
- convergent thinking 8
- convertible debt securities 243
- COURAGE trial 396–397
- CPOE (computerized physician order entry) 468–475
- Crick, Francis 196
- CRM (customer relationship management) 101
- CRO (contracted research organization) 121, 136, 225, 235
- cross-sector technology 19–21
- crystallography 54
- CSL (clinical science liaison) 99–100
- CSO (contract sales organization) 121, 136
- CTD (common technical document) 320
- cyclical financing 237
- data mining alliances 369–370
- de-diversification 122, 166
- de-diversifying 527
- DEB (drug-eluting balloon) 19
- defibrillators 389–391, 392–393, 399–400, 415, 418, 421
- demonstration programs 173
- DES (drug-eluting stent) 12, 19, 383, 431–432
- desperation index 137
- Dickey-Wicker Amendment 312
- digital radiology 476
- disease identification advances 542
- disease and pharmaceutical pricing 47–50
- disease treatment advances 542
- disease trends 51
- divergent thinking 8
- diversification 33, 44–45, 122, 131–132, 166, 524, 525–526, 531
- DM (disease management) program 95
- DMF (drug master file) 321
- DNA 38, 196, 217, 221–222
- donut hole 309
- downstream customers 6
- downstream value chains 546
- Drews, Jürgen 366
- drug delivery devices 533
- drug development, scale effects 154–155
- drug discovery 204, 220, 366, 367–368, 520
- drug fallout 61
- drug insurance tier status 93–94
- drug product 62–69
- drug regulation 303–326
- drug substance 62–69
- drug supplies 13, 15–16
- drug therapy 533
- drug-coated device 33
- drug-hunting 46, 165
- drug/device collaboration 533
- drug/device convergence 431–433
- drugs, pay-for-performance 171
- DTCA (direct to consumer advertising) 16, 90, 100–101, 425–426
- earnings growth and pipeline problems 136–139
- EBM (evidence-based medicine) 546, 547–549
- economies of scale 131, 143–145
- economies of scope 131, 143–145
- EDL (essential drugs list) 106
- efficiency, and scale/scope 152–155
- EFPIA (European Federation of Pharmaceutical Industries and Associations) 320
- EHRs interoperable (electronic health records) 462, 466
- electrophysiology 421
- EMA (formerly EMEA, or European Agency for the Evaluation of Medicinal Products) (European Medicines Agency) 321–325
- EMR (electronic medical record) 453, 468–470, 482–483
- EPI-MEDICS 477–479
- epigenetics 224–225
- EPO (erythropoietin) 226
- ESC (embryonic stem cell) research 309–313
- evidence-based care *see* EBM
- exit options financing 357
- Factor Xa therapies 36, 73
- FDA (Food and Drug Administration) regulation 9, 56, 59–60, 62, 67–68, 74–75, 77, 83, 85–86, 91, 99, 101, 120, 122, 257–258, 308, 314, 320, 381, 384, 441–445, 532, 535
- FDA pre-market approval (PMA) 442–443
- FDA risk classification system 442–443
- FDAMA (Food and Drug Administration Modernization Act 1997) 16, 99
- FIDDO (fully integrated drug discovery and development organization) 357
- FIH (first in human) starts 119
- finance 5, 236–247, 264, 349–350, 351–352, 357, 365, 370–371, 440–441
- financial resources 523, 524
- FIPCO (fully integrated pharmaceutical company) model 169, 225, 226–228, 236, 357, 360, 517, 520, 537
- FIPNet (fully integrated pharmaceutical network) 169
- first-cycle approval rates 86
- Five Forces framework 6–7

- 510(k) clearances 445
- flexibility, culture of 274
- FOB (follow-on biologics) 314–316
- form/fill/finish (F/F/F) sites 63–64
- Fortune Global 500* firms 23
- free-standing care (care delivery decentralization) 549–550
- French Anderson, William 208–209
- frugal innovation 529
- FSS (Federal Supply Schedule) 49
- fungibility of resources 523–524
- G-CSF (granulocyte-colony stimulating factor) 34
- Garnier, Jean-Pierre 263
- GCP (good clinical practice) guidelines 326
- gene expression 54
- gene therapy 208–209, 222
- General Electric six-sigma/lean management 16
- generic biologics 314–316
- generic drug companies 37–38
- generic drugs 33
- genetics, clinical 475
- Genetics Institute 226–228
- genomics 2, 215–219, 254, 347, 366, 367–368
- genomics technology platform companies 363–366
- germline gene therapy 313–314
- Gilbert, Walter 232–233
- global outsourcing 491
- globalization of clinical development 82
- GMP (good manufacturing practice) 62
- Golub, Todd 219
- government grants 243–244
- GPO (group purchasing organization) 18, 133–134
- GWA (genome-wide association) studies 217
- Hammer, Michael 468–469, 473
- Hatch-Waxman Act (1984) 16, 125, 133, 136, 314
- HDL (high-density lipoprotein) 36
- health communities 500–503
- Health Security Act 124
- health spending benefits 3–4
- healthcare
  - affordability of 543
  - and consumerism 543–544
  - technology convergence in 531–534
  - training needs 544–546
- healthcare courses 1–3, 9–10
- healthcare delivery systems 544–546
- healthcare hedge funds 246
- healthcare innovation
  - demographics 540–541
  - environment 37
  - expanding scientific/technological bases 541
- healthcare intermediaries 1–3
- healthcare IT (information technology)
  - analysis of sector 27
  - benefits of 454–455
  - business models 461
  - care automation 455–458
  - care and disease management 488–489
  - CDHP (consumer-directed health plan) 489–490
  - claims management 483–488
  - cloud computing 457
  - consumer demand for healthcare IT 495–496
  - consumer use of 494–503
  - in England 464–465
  - government spending on 462
  - hardware development 456
  - health communities 500–503
  - and hospital management 504
  - increased connectivity 542–543
  - innovation in 2
  - interoperability 462, 467–468
  - major players 492–494
  - market structure 458–461
  - multiple technologies 515–516
  - national health data access 463–468
  - personal health records 496–497
  - PHR (personal health record) *see* PHR
  - RAND report 454–455
  - remote patient monitoring/management 476, 480–481
  - scale in US 451–453
  - slow progress in 453–454
  - smartcards 463–464
  - system response 455
  - systems integration 490–494
  - in US 466–468
  - virtual primary care 481–482
- healthcare outsourcing 490–494
- healthcare producers, study of 9–19
- healthcare reform 307–309, 445–447
- healthcare value chain 361–366, 544–545, 552
- herbs 33
- high science 9
- high throughput screening 20
- HIPAA (Health Insurance Portability and Accountability Act 1996) 466, 475, 483–485
- HITECH (Health Information Technology for Economic and Clinical Health) Act 452, 454–455, 467, 474
- HMO (health maintenance organization) 93, 133–134
- horizontal integration 157–158
- hospitals
  - chief executive training 12
  - healthcare supply costs 11
- HSA (health savings account) 489, 551

- HTAs (health technology assessments) 96  
 HTS (high-throughput screening) 54, 221  
 human cloning 313–314  
 human genome mapping/decoding 80, 120  
 Human Genome Project 215, 365  
 Human Genome Sciences 254, 368–369  
 hybrid business models 104
- ICH International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use 319, 320–321
- imaging 20
- in control, concept of 59, 66
- in-house venture capital 527
- in-licensing *see* licensing
- IND (investigational new drug) applications 56, 119
- India  
   animal experiments 107  
   biotechnology industry 298–300  
   cGxP 107  
   drug discovery/development 204  
   generic pharmaceutical companies 108–109  
   internal market 106–107  
   merger and acquisition (M&A) entry 132, 142  
   multinationals in 107, 108  
   pharmaceutical industry 46, 81, 106–111  
   pharmaceutical production levels 108  
   political system 107  
   research and development (R&D) 110–111
- industry concentration 158
- inflammation therapies 36
- information asymmetry 161
- information-based platform technologies 20
- infrastructure costs 134–136
- Infuse spine cage 432
- innovation 2  
   affordable innovation 529  
   ambidextrous firms 528–529  
   business model 5, 73–87  
   from generics base 45  
   from service company base 46  
   frugal innovation 529  
   in healthcare business 27–28  
   medical devices decline 409  
   and mergers and acquisitions (M&As) 522  
   negative innovation 529  
   open source innovation 167  
   organizational 8–9  
   pure innovation models 44–45  
   questions about 5–6  
   reverse innovation 529  
   and value chain 1–3  
   and virtual pharma models 46–47  
   *see also* research and development (R&D)
- innovation challenge 5–9
- innovation factors 8–9
- innovation process, common themes 23–24
- innovation product 5
- innovative pharmaceutical pricing 86–87
- institutional accountability 546–547
- insurance technology 16
- integrated delivery network (IDN) 11
- integrative devices in mergers and acquisitions (M&As) 161–163
- integrative mechanisms 524
- integrative structures 8
- internal co-promoting 139
- investment exit options 357
- IO (industrial organization) perspective 6–7, 130–131
- IP (intellectual property)/patents issues 55, 103, 125, 132, 137, 198–199, 211, 287, 347, 352, 360–361, 367–369, 373–374, 516
- IPO (initial public offering) 237, 238–239, 351, 352, 440–441
- IRB (Institutional Review Board) 326
- IT *see* healthcare IT (information technology)
- Japan  
   biotechnology industry 287–290  
   drug regulation 325–326  
   pharmaceutical industry 41  
   pharmaceutical pricing 50  
   stem cell research 310–311, 312
- Jones, Fletcher 493
- JPMA (Japan Pharmaceutical Manufacturers Association) 320
- junk mail advertising 92
- Kefauver Amendments (1962) 98
- Köhler, George 212, 213
- KOL (key opinion leader) physicians 90, 91
- Koop, C. Everett 494
- Lander, Eric 219
- Lehman, Betsy 473
- Lehman Brothers 370–371
- licensing 154, 166, 167–169, 265, 315–316, 353, 356, 368–369
- Liu, Edison 372–373
- local economies, technology sectors impact 21–23
- long-term exploration 8
- Longman, Roger 150
- merger and acquisition (M&A) 5, 6, 9, 24–25, 77, 126–129  
   absorption approach 164

- biotechnology firms, trends in 124–130, 204–205
- challenges and strategies 118
- concentration ratios 437–439
- consolidation 116
- and converging business models 521
- cost efficiencies and mergers 153–154
- deal sizes 436–437
- deal trends 439–440
- deceleration 122
- defense against acquisition 140–141
- and disruptive change 145–146
- diversification 166
- earnings growth and pipeline problems 136–139
- economies in marketing 154
- economies in sales 154
- execution of 159
- and foreign pharmaceutical markets 141–142
- genomics companies 165
- historical role of 117–118
- as horizontal integration 157–158
- in-licensing 154, 166, 167–169
- and increased profit pressures 133–134
- in industrial organization theory/research 130–132
- industry concentration 158
- informal networks 163
- and infrastructure costs 134–136
- and innovation 522
- and integration 524
- integrative devices 161–163
- internal value chain integration 165
- jumpstarting existing projects 166
- mass-mergers 138
- medical devices industry 434–437
- merger activity, reasons for 170
- multiple motivations 146
- and new markets 132
- offensive rationales 141–146
- pharmaceutical firms 124–130, 132–146, 147–156, 521
- post-merger cooperation 164
- post-merger integration 164
- preservation approach 164
- proactive rationales 141–146
- as productivity problem 156–159
- project reductions 165–166
- and research and development investment 150
- Roche/Genentech relationship 227, 241, 269–270
- and scale 150–152
- and stock market activity 132
- string of pearls strategy 164
- symbiotic approach 164
- McClellan, Mark 535
- MacMillan, Ian 527
- MAD (multiple ascending dose) study 56–57
- Mallory, Steve 501
- management of strategic alliances 528
- managing the balancing act 528
- managing knowledge 524
- manufacturers *see* producers
- manufacturing management 62
- market barriers and technology convergence 535–538
- market dynamics and technology convergence 535–538
- market share and scale 150–152
- market structures, fragmented 521–522
- marketing
  - across the value chain 87–88
  - biological targets 87
  - candidate selection 87
  - high-risk period 88
  - junk mail advertising 92
  - payer marketing organizations 94–95
  - pharmaceutical promotion 90–92
  - stakeholder complexities 88–89
- mass-mergers 138
- MCO (managed care organization) 15, 172–173
- me-too drugs 133
- Medicaid 15, 89, 173, 411, 552
- Medical Device Act (1976) 381
- medical devices 26–27
  - atrial fibrillation 402
  - cardiac rhythm management sector sales 418
  - cardiovascular area 36, 383–384
  - channel efficiency 426
  - company operating margins 410–411
  - comparison with other industries 379–380
  - comparison with pharmaceutical industry 424–426
  - consumer/customer/payer separation 411–415
  - consumerism limitations 424–426
  - convergent technology 533
  - coronary artery bypass graft 396–397
  - costs 14–16, 415–417
  - coverage ratio 408
  - decline in innovation 409
  - defibrillators 389–391, 392–393, 399–400, 415, 418
  - Department of Justice inquiry 377
  - in diabetes 402
  - direct selling 417–419
  - drug/device convergence 431–433
  - economics of clinical needs 415–417
  - education by sales reps 419–420
  - electronics 427–428
  - financing 440–441
  - firm clusters 21–22

- medical devices (cont.)
  - franchises 419
  - growth drivers 395–400, 434
    - demographics 395
    - geographic reach 398–399
    - perennial products 398, 399
    - pricing 397
    - procedure penetration 396–397
    - recent 399–400
    - unmet clinical needs 395–396
  - growth projection rates 403–405
  - growth slowing consequences 405–409
    - corporate structural changes 407–408
    - segment shuffling 405–407
  - historical perspective 380–381
  - immunity to price pressures 414
  - industry analysis 382–391
  - industry consolidation 433–434
  - industry growth rates 391–395
  - industry as oligopoly 522
  - industry overview 376–378
  - industry revenues 379–380, 382–384
  - industry structure 384–386
  - information playback to manufacturer 420–421
  - innovation and commercialization challenges 518–519
  - interventional cardiology products 396–397
  - market size 382–384
  - materials sciences 428–431
  - mergers and acquisitions (M&As) 434–437
  - misapplications/errors 380–381
  - neurological area 384
  - neuromodulation 402
  - neurovascular/stroke occlusion 401
  - orthopedic extremities 401
  - orthopedics sales 420
  - percutaneous coronary interventions 396–397, 401
  - physicians as customers 411, 421, 518–519
  - profits 423–424
  - research and development (R&D) 26–27, 422
  - robotic surgery 402
  - sales 421–424
  - target company valuation 434–435
  - taxation on 446
  - technology 426–433
  - US production/revenues 386–391
  - ventricle assist device (VAD) 401
  - world production/revenues 386–391
- Medical Technologies Innovation Scorecard 22
- Medicare 15, 89, 308, 411, 552
- Medicare Modernization Act (2003) 16, 171
- medicine supply 64
- MEP (market exclusivity period) 136
- merger activity, reasons for 170
- microarrays 221–222
- Milstein, Cesar 212, 213
- mixed payment sources 551–552
- molecular diagnostics companies 219
- monoclonal antibodies 206, 208, 212–215
- Moore, Gordon 456
- Morgan Stanley financial report 261–262, 263
- multinationals 103–105, 107, 108
- multiple disciplines (silos) 8
- multiple sclerosis 207–208
- multiple treatment interference 147
- Munos, Bernard 77
- Myhrvold, Nathan 457
- national economies, technology sectors impact 21–23
- NCE (new chemical entity) 33–34, 44, 55, 61
- NDAs (new drug application) 58, 59–60, 85, 119, 314
- negative innovation 529
- neuroscience 36, 211
- NEWbio (new biotech company) 38–39
- NHE (national health expenditure) 172
- NHI (National Health Insurance) (Japan) 50
- NHIN (National Health Information Network) 462–463, 467–468
- NICE (National Institute of Health and Clinical Excellence) (UK) 96, 121
- Nicholas, Peter 388
- Nicholson, David 262
- NIH (National Institutes of Health) 37, 199–201, 244, 311–312, 541
- NME (new molecular entity) 24, 33, 44–45, 77, 119, 149, 158, 260–261, 271
- non-clinical development 60
- NPfIT (National Programme for IT) 464–465
- NRDO (no research, development only) model 225, 233–235
- Nutt, Roy 493
- Obama, President Barack 244, 307, 311–312, 446, 452, 466
- OCP (Office of Combination Products) 535
- off-label promotion 99
- on-label promotion 99
- open source innovation/research 167, 169
- OPPAGA (Office of Program Policy Analysis and Government Accountability) (Florida) 95
- organizational innovation perspective 8–9
- organizational slack 8
- Orphan Drug Act (1983) 316–318
- OTC (over-the-counter) medications 33
- OTC (over-the-counter) shift 426
- out-licensing *see* licensing



- pacemakers 388
- PACS (picture archiving communication and storage) 476
- Pandemic and All-Hazard Preparedness Act 318–319
- Parkinson, Jay 481–482
- passive pharmaceuticals 20
- patent cliff 98
- patents *see* intellectual property/patents
- patient monitoring/management, remote 476, 480–481
- Patient Protection and Affordable Care Act (2010) 307
- patients, as consumers 411
- payer activism 170–171
- payer organizations 92–96
  - applications 486–490
  - claims management 483–488
  - cost 93
  - cost-containment 172
  - and medical devices 411–415
  - payer integration 93
  - payer marketing organizations 94–95
  - payer size 92–93
  - structure 93
  - value chain alliances with pharmaceutical 174–175
- PBM (pharmacy benefit management) 16, 133–134
- PBMs (pharmacy benefit managers) 89
- PDL (preferred drug list) 95
- period, definition of 356
- Perot, H. Ross 492–494
- PET (positron emission tomography) scanners 20
- pharmaceutical industry 33–41
  - Asia 41, 46, 81
  - and biologics 129–130
  - biotechnology alliances 126–130, 204–205, 328, 352–353
  - biotechnology product issues 68–69
  - business challenges 72–73
  - business model 69–73
  - cash-flow model 70
  - cGMP (current good manufacturing practice) and compliance 62, 67
  - challenges to 111–112
  - comparison with medical devices industry 424–426
  - compound potency 65–66
  - conglomerate models 45
  - customer-focused culture 65
  - diversification 33, 44–45, 122, 131–132
  - drug discovery 175
  - DTC (direct to consumer) advertising 16, 90, 100–101, 425–426
  - efficiency in procurement 176–177
  - efficiency and scale/scope 152–155
  - example of 39–41
  - expansion into therapeutics 142–143
  - financing 37
  - forecast accuracy 65
  - generic drug companies 37–38
  - and government budgets 174
  - government development of 21–23
  - in-licensing 154, 166, 167–169
  - infrastructure costs 134–136
  - innovation *see* innovation and managed care organizations 172–173
  - manufacturing performance 64
  - mergers and acquisitions (M&As)
    - as productivity problem 156–159
    - trends in *see* merger and acquisition (M&A)
  - in multiple technologies 515–516
  - OTC (over-the-counter) shift 426
  - outsourcing non-core functions 176–177
  - patent cliff 98
  - process robustness 66
  - product markets 41–47
  - product safety withdrawals 137
  - profit structure 425–426
  - promotional techniques 90
  - quality culture 67–68
  - reach and frequency model 97–98
  - reliability of companies 64–65
  - revenue 517–518
  - revenue stream shocks 137
  - risk 46, 69–73
  - Russia 46
  - segments 41–47
  - and specialty pharmacy providers 173
  - system integration 64
  - transaction automation 176–177
  - value chain alliances with payers 174–175
  - West–East redeployment 78
  - see also* drug; individual companies; innovation; research and development
- pharmaceutical insurance coverage 49
- pharmaceutical manufacturers *see* pharmaceutical industry
- pharmaceutical markets 35–36, 141–142
- pharmaceutical pricing 47–50, 86–87
- pharmaceutical promotion 90–92
  - regulation 91–92, 97, 98–101
  - technological advances 101
- pharmaceutical strategy
  - challenges to industry 117
  - drivers of 119–124
    - deconstruction of the pharmaceutical industry 121



- pharmaceutical strategy (cont.)
  - decrease in research and development (R&D)
    - productivity 119–121
  - diversification in business approach 122
  - diversification in capabilities 122–123
  - expansion in developing markets 123–124
  - synergistic combinations of businesses 123
- pharmaceutical venture funds 245
- pharmaceuticals 229–231
  - cancer trials 34–35
  - cost effectiveness 34–35
  - customer enthusiasm 48
  - definition 33
  - demand drivers 50–51
  - development 56–60
  - healthcare innovation environment 37
  - therapeutics 36
  - value of 34–35
- pharmacogenomics 228
- phases in research and development *see* research and development
- PHR (personal health record) 496–497
  - employer-sponsored 498–499
  - health communities 500–503
  - independent 499–500
  - insurer-sponsored 497–498
- PhRMA (Pharmaceutical Research and Manufacturers of America) 99, 101, 320
- physician organizations 96–97
- Physician Payments Sunshine Act (2010) 11
- physicians
  - access to IT 457
  - and CPOE (computerized physician order entry) 468–470, 472–473
  - as customers 411, 421
  - and Kefauver Amendments (1962) 98
  - practice management 482–483
  - product control quotient 421
  - and research 176
  - shortages of 544–545, 552
- PICC (peripherally inserted central catheter) 406
- picks and shovels companies 365
- pipeline NPV (net present value) 149–150
- pipeline problems and earnings growth 136–139
- PIPE (private investment in public equity) 239–241
- Primal Life Sciences 45, 108, 142
- platform technology business models 26, 228–231, 518
- PoCs (proof-of-concept) declarations 119, 120, 165
- Porter, Michael 6–7, 22
- portfolio management and optimization 526–527
- post-merger integration 164
- PPACA (Patient Protection and Affordable Care Act 2010) 446
- PPAR (peroxisome proliferator-activated receptor) 45–46
- PPI (physician preference item) 12
- PPO (preferred provider organization) 93
- practice management 482–483
- preregistration in research and development (R&D) 58–59
- PricewaterhouseCoopers, Medical Technologies Innovation Scorecard 22
- private placements 239
- procedures costs 413
- process of change 8
- producer–provider alliances 16–17
- producers 1–3, 17, 23–24
- product competition 555
- product development cycles 23, 25
- product innovation 5
- product safety withdrawals 137
- product sector margins 18–19
- product sector prominence 17–18
- productivity cliff 119
- profitability and scale 150–152
- programs of change 8
- promotional techniques 90
- Prospective Payment System (1983) 3
- proteomic technology platform companies 363–366
- proteomics 2, 219–220
- providers 1–3
- public sector insurance schemes 89
- purchasers 1–3
- pure innovation models 44–45
- QALY (quality-adjusted life year) 416
- Quintiles 46
- research and development (R&D)
  - annual spending 260–261
  - in Asia 104, 110–111
  - biotechnology costs 354–355, 517–518
  - budgets 139
  - candidate selection 55
  - cash-flow model 70
  - declining productivity 121
  - development issues 56–60, 61, 69–73, 520
  - discovery stage 52, 69
  - dry well projects 69
  - economies of scale/scope in 143–145
  - genomics companies 165
  - governance 9
  - in-licensing 154, 166, 167–169
  - integrative devices in mergers and acquisitions (M&As) 161–163
  - intellectual property/patents 55

- investigational new drug (IND) application 56
- investment 5, 17, 45–46
  - and mergers and acquisitions (M&As) 150
  - per employee 21
- lead generation 53–54
- lead optimization 54–55
- in medical device sector 26–27, 422
- limited partnerships 241–243
- merger and acquisition (M&A) problems 156–159
- in multiple technologies 515–516
- NME (new molecular entity) spending 271
- non-clinical development 60
- pharmaceutical/biotechnology alliances 126–130
- phase I 53, 56–57, 61, 69, 176, 266, 315
- phase II 53, 57, 61, 62, 69, 83–85, 87, 143–144, 149, 165, 167, 175
- phase III 58, 61, 69, 83–85, 87, 91, 119, 137, 143–144, 149, 165, 167, 260, 274, 315, 364
- phase IV 58, 60, 171
- preclinical development 69
- preregistration 58–59
- productivity 125, 145
- proof-of-concept studies 69
- registration 59–60, 69, 85–86
- research challenges 78–81
- research density 148
- research funding 37
- risk 61–62, 69–73
- Roche/Genentech relationship 135, 141, 269–270
  - and scale 143–145, 147–148, 148–150
  - and slowing growth 407, 408
- spending as risk management 143–144
- target identification 52
- target validation 52–53
- in value chain 51–62
- RAC (Recombinant DNA Advisory Committee) 222
- radiopharmaceutical tracers 20
- RAND report 454–455
- RBV (resource-based view) 7
- RDD (rational drug design) 20, 220–221
- reach and frequency model 97–98
- refusal to file letters 85
- registration in research and development (R&D) 59–60
- regulation restrictions 98–101
- regulatory forces 6
- related diversification 526
- remote patient monitoring/management 476
- revenue model and value capture 357
- reverse innovation 529
- RFID (radio frequency identification) 20
- RHIO (regional health information organization) 462–463
- rifle medicines 82
- RIPCO (royalty-income [*also* research-intensive] pharmaceutical company) 225, 231–233, 236, 357, 517
- risk participation 46
- risk, and research and development (R&D) 61–62
- RNAi (RNA interference) 222–223
- ROI (return on investment) 143–144, 236
- ROI (return on investment) calculus 553–555
- royalties *see* IP
- SaaS (software as a service) 455
- SAD (single ascending dose) study 56–57
- Safe Medical Devices Act (1990) 535
- sales channels 523
- sales and scale 150–152
- SAR (structure–activity relationship) 53–54
- SBIR (Small Business Innovative Research) grants 243–244
- scaffolds (protein structures) 214–215
- scale 131, 143–145, 149, 150–155, 523
- scope, and efficiency 152–155
- screening 53
- SEC (Securities and Exchange Commission) 240
- service company base, and innovation 46
- SESAM-Vitale smartcard 463–464
- SFDA (State Food and Drug Administration) (China) 104
- SFE (sales force effectiveness) 101
- SG&A (selling, general, and administrative) expenses 143
- shareholder value maximization 8
- Sharp, Phillip 232–233
- sheep cloning 313–314
- short-term efficiency 8
- silos (multiple disciplines) 8
- SinoFDA (Chinese Food and Drug Administration) 105
- SKU (stock-keeping unit) 63
- Smart House monitoring 478
- SOC (standard of care) 82–83
- sourcing ideas 8
- specialized company proximity 22
- speed to market 66
- Starr, Paul 546
- Steere, Bill 138
- stem cell research 303–319
- stock market activity, and merger and acquisition (M&A) 132
- stock price and scale 150–152
- strategic alliances, management of 528
- string of pearls strategy 164

- STTR (Small Business Technology Transfer) 244
- suppliers
  - care delivery implications 552–553
  - and downstream value chains 546
- supply chain management 12
- supply/demand disequilibria 64
- surrogate endpoints 83
- Swanson, Robert A. 196
- SWORD (stock warrant offer for research and development) financing 241–243
- synergies 131, 160–161
- systems biology 20, 223–224, 362
- Taylorism 157
- TCM (traditional Chinese medicine) 102
- TCT (transcatheter cardiovascular therapeutics) 416
- technological imperative
  - in healthcare 3–5
  - non-appreciation of 10–11
- technology convergence
  - across sectors 19–21, 531–538
  - and combination products 532–534
  - and differentiation 531
  - and diversification 531
  - in healthcare 531–534
  - importance of 531
  - market barriers to 535–538
  - market dynamics and 535–538
  - and productivity 531
  - types of 533
  - and World Economic Forum (Davos) 532–534
- technology development alliances 370–371
- technology platform companies 363–375
- technology platform model 26, 228–231
- technology sectors, impact on economies 21–23
- technology spending 3–4
- technology transfer alliances 371–375
- technology zealots 327
- therapeutic area alliances 368–369
- therapeutic pharmaceutical pricing 48
- therapeutically active devices 533
- therapeutics 246
  - and biotechnology 25
  - Biotherapeutics and Bioinnovation Center (BBC) 130
  - economic importance of 36
  - neuroscience therapies 36
  - pharmaceutical industry expansion into 142–143
  - research and development (R&D) scale economics 149
  - TCT (transcatheter cardiovascular therapeutics) 416
  - therapies, in absence of standard of care 82–83
  - tool companies 218
  - toolbox companies 365
  - top-down strategy 8
  - total cost arguments 171
  - tPA (tissue plasminogen activator) 273, 307
  - TPS (Toyota Production System) 548
  - transgenic mice 213
  - Turner, Merv 262
- Ubl, Steve 444–445
- uHTS (ultra high-throughput screening) 80
- United Kingdom, biotechnology industry 278–280
- United States of America, pharmaceutical pricing 49
- upstream supply costs 11–16
- value analysis committees 11–16
- value chain 7
  - alliances in 174–175
  - delivery product 554
  - disruptions to 546
  - and innovation 1–3
  - internal 24
  - and marketing 87–88
  - perspective on 7–8
  - positioning 357
- VBP (value-based purchasing) 553
- VCs (venture capitalists) 38–39
- Viehbach, Chris 262
- Vincent, James 232–233
- virtual model 235
- virtual pharma models, and innovation 46–47
- virtual primary care 481–482
- Wanless, Derek 464
- Warner-Lambert 67, 137, 138, 139–140, 154
- Watson, James 109, 196–201
- Wears, Robert 472–473
- Wharton School Healthcare Management courses 1–3, 9
- Wilmot, Ian 313–314
- Witty, Andrew 262
- World Economic Forum (Davos), and technology convergence 532–534