

Index

- ACCME. *See* Accreditation Council for Continuing Medical Education (ACCME)
- Accreditation Council for Continuing Medical Education (ACCME), 62
- Act on Combating International Bribery, 31
- “Adequate procedures designed to prevent prohibited payments” defense, 233
- Advanced Medical Technology Association (AdvaMed), 61–62
- Adverse employment action, 187–188
- Agency labor compliance advisor (ALCA), 110
- Ajoku v. United States*, 155
- AKS. *See* Anti-Kickback Statute (AKS)
- Alarm bell, 3
- ALCA. *See* Agency labor compliance advisor (ALCA)
- Alcohol and Tobacco Tax and Trade Bureau, 85
- Alternatives to prosecution. *See* Pre-trial diversion agreements
- AMA. *See* American Medical Association (AMA)
- American Medical Association (AMA), 61
- American National Standards Institute, 84
- American Water Works Association, 84
- Amusement park rides, 83–84
- Anti-bribery provisions, 27–29. *See also* Foreign Corrupt Practices Act (FCPA)
- Anti-Kickback Statute (AKS), 55–56
- Anti-trafficking provisions. *See* Human trafficking and other forms of forced labor
- Antitrust violations, 206–207
- APEC. *See* Asian Pacific Economic Cooperation (APEC)
- Arrests and restraining orders, 138–139
- Arthur Anderson, 39n
- Asian Pacific Economic Cooperation (APEC), 120, 122
- ASTM International, 84
- AT&T, 118
- Attorney-client privilege, 124–125. *See also* Legal privilege
- Attorney up-the-ladder reporting obligations, 41–43
- Auditor’s report, 41
- Australia’s Privacy Act, 121
- Avoid liability (review, revise, hire, and submit), 234
- BAA. *See* Business associate agreement (BAA)
- Bank of America, 164
- BNP Paribas SA, 164
- Board of Directors
- D&O liability insurance, 160
 - health care industry, 60
 - personal liability. *See* Personal criminal liability
- Bona fide business expenditure exception, 26, 34
- Breach of warranty, 79–80
- Breuer, Lanny, 49
- Bribery red flags, 38. *See also* Foreign Corrupt Practices Act (FCPA)
- Burlington Northern* standard, 187
- Burlington Northern v. White*, 187
- Business associate agreement (BAA), 58
- Business purpose test, 28
- Business Supply Chain Transparency on Trafficking and Slavery Act, 11
- Cable Communications Policy Act, 115
- California debarment laws, 174
- California Transparency in Supply Chains Act, 10, 16–18, 174
- Carbon copy prosecutions, 34–35, 205
- CCO. *See* Corporate compliance officer (CCO)
- Centers for Medicare & Medicaid Service (CMS), 53–54
- CGL insurance. *See* Commercial general liability (CGL) insurance
- Charities. *See* Nonprofit entities
- Children’s Gasoline Burn Prevention Act (CGBPA), 84
- Children’s Online Privacy Protection Act (COPPA), 115
- Chinese anti-bribery laws, 31–33
- CIA. *See* Corporate integrity agreements (CIA)

- Class actions, 166
- Clawback and hedging provisions, 48
- Clean Air Act, 94, 96
- Clean Water Act, 92, 94, 96
- Clinical trials. *See* Pharmaceutical, medical, and food products compliance
- clinicaltrials.gov, 71
- Closed-ended questions, 192
- CME. *See* Continuing medical education (CME)
- CMS. *See* Centers for Medicare & Medicaid Service (CMS)
- CMS compliance program guidance, 60
- CMS program audits, 64–65
- CMS recovery audit program, 64
- CMS Self-Referral Disclosure Protocol, 67
- Code of conduct
 - AdvaMed code, 61–62
 - AMA code, 61
 - company, 37, 177
 - PhRMA code, 61
- Code on Interaction with Healthcare Professionals*, 61
- Commercial general liability (CGL) insurance, 87–88
- Communications Act, 115
- Company code of conduct, 37, 177
- Complaint validity, 132
- Compliance interviews, 135
- Compliance officer. *See* Compliance officer
- Compliance program. *See* Compliance program
- Conflict mineral rules, 173, 174
- Constructive discharge, 187–188
- Consumer-facing privacy policy, 122–123
- Consumer Product Safety Act (CPSA), 83, 84
- Consumer Product Safety Commission (CPSC), 83, 84
- Consumer reporting agency, 116
- Consumer reports, 116
- Continuing medical education (CME), 62
- Contractors. *See* Government contracts
- Contractual (informal) immunity, 148–149
- Cooperation credit. *See* Mitigation credit
- Cooperation vs. capitulation, 149, 151
- COPPA. *See* Children's Online Privacy Protection Act (COPPA)
- "Cops-and-robbers" stereotypes, 128
- Compliance officer
 - access to senior executives and Board members, 1–2
 - audit committee, and, 3
 - go-to person, 165
 - "jack of all trades," 1
 - mission, 127
 - most challenging compliance roles, 3
 - personal career risk, 3
 - relationship building, 5–8
 - reporting to the Board, 3, 8
 - required skills, 1
 - typical background, 1
 - uncomfortable role, 8
- Compliance program, 58–60
 - anti-trafficking provisions, 20–22
 - checklist of relevant government entities, 170
 - class actions, 166
 - CMS compliance program guidance, 60
 - code of conduct, 37
 - confidential reporting, 37
 - continuous improvement, 38
 - "culture of compliance," 36
 - four easy steps (review, revise, hire, and submit), 234
 - government contracts, 103–105
 - health care industry, 58–60
 - human trafficking, 20–22
 - incentives and disciplinary measures, 37
 - key statutory elements, 166
 - meeting with the regulator, 169
 - mitigation credit, 202. *See also* Mitigation credit
 - OIG compliance program guidance, 59
 - paper-only policy, 36
 - periodic testing and review, 38
 - practical steps to take, 169
 - primary legislation, 165
 - questions to ask, 166
 - regulatory agency meetings, 168
 - risk assessment, 37
 - sanctions compliance program, 164
 - senior management buy-in, 36
 - third party due diligence, 37
 - tort lawsuits, 166–167
 - trade association, 168
 - training and continuing advice, 37
 - U.S. Sentencing Commission guidance, 58–59
- Corporate debarment. *See* Debarment
- Corporate integrity agreement (CIA), 208–209, 219–220, 226–228
 - duration, 228
 - eligibility considerations, 227

- imposed obligations, 228
- management accountability and certification, 228
- monetary fine, 227
- subsidiaries, 228
- Corporate monitor, 201, 223–226
- Corporate social responsibility (CSR). *See* CSR supply chain compliance program
- Corporate voluntary disclosure, 197–212
 - antitrust violations, 206–207
 - benefits of voluntary disclosure, 198–203
 - culpability score, 198, 202
 - effective compliance program, 202
 - environment crimes, 207–208
 - follow-on litigation, 204–205
 - foreign carbon copy prosecutions, 205
 - fraud against the government (FCA), 209–210
 - good corporate citizen, 199
 - health care fraud, 66–67, 208–209
 - independent discovery of misconduct uncertain, 204
 - non-prosecution agreement (NPA), 200
 - one-year FCPA pilot program, 214
 - Principles of Federal Prosecution of Business Organizations, 198
 - privileged or confidential information, 205–206
 - publicly held companies, 210–211, 212
 - risks of voluntary disclosure, 203–206, 212
 - self-monitoring, 201
 - U.S. Sentencing Guidelines, 198
 - whistleblowers, 202–203
 - Yates Memo, 205
- Corporate whistleblowers, 184–196. *See also* Whistleblower complaints
- Corrupt and illegal payments. *See* Foreign Corrupt Practices Act (FCPA)
- Counterfeit electronics, 105–108
- CPNI. *See* Customer proprietary network information (CPNI)
- CPSC. *See* Consumer Product Safety Commission (CPSC)
- CPSC guide, 84n
- Credit card numbers, 117
- Credit reports, 116
- Crime-fraud exception, 126, 158–159
- Crimes of false certification, 152–161. *See also* False certification crimes
- Criminal investigations. *See* Law enforcement activities
- Cross Border Privacy Rules (CBPR), 122
- CSR supply chain compliance program, 171–183
 - areas of potential liability, 171, 174–175
 - audits, 181–182
 - best practices, 178
 - budget, 176
 - characteristics of successful CSR program, 176
 - code of conduct, 176, 177
 - communicating with directors/employees, 179
 - communicating with external stakeholders, 179–180
 - conflict mineral rules, 173, 174
 - continually reassess and update CSR program, 181
 - CSR policies, 177–178
 - CSR procedures, 178
 - debarment, 174
 - designating a point person, 172
 - designing program to comply with CSR laws, 174
 - enforcement, 181
 - implementation, 178–179
 - internal “resistance” and response, 182
 - legislation, 173–174
 - long-term planning, 181
 - program design and compliance team, 172
 - program priorities and aspirations, 175
 - responding to potential violations, 182–183
 - stand-alone program versus incorporation into other company policies, 177
 - timeline, 176
 - training, 180
 - work plan, 175
- Culpability score, 198, 202
- “Culture of compliance,” 36, 111
- Customer proprietary network information (CPNI), 115
- Cybersecurity, 108–109
- Data analytics, 4
- Data breaches, 123
- Data security provisions, 119–120. *See also* Privacy and data security
- Davis Bacon Act, 110
- Debarment
 - California, 174
 - environmental issues, 96
 - government contracts, 98–100

- Debarment (*continued*)
- health care industry (exclusion), 226–227
 - Maryland, 174
 - pharmaceutical, medical, and food products compliance, 72
- Defense contractors. *See* Government contracts
- Defense Federal Acquisition Regulation Supplement (DFARS), 97, 105, 173
- Deferred prosecution agreement (DPA), 218–219. *See also* Pre-trial diversion agreements
- Department of Health and Human Services (HHS), 118
- Department of Justice (DOJ), 54, 152
- Department of Justice pilot program for cooperation, 213–216
- declination decision, 215
 - duration of program, 216
 - factors to consider in determining whether to lay a charge, 215–216
 - “full cooperation,” 214
 - limited credit, 215
 - “timely and appropriate” remediation, 214–215
 - voluntary self-disclosure, 214
- Derivative use immunity, 146–147
- Deutsche Bank AG, 164
- DFARS. *See* Defense Federal Acquisition Regulation Supplement (DFARS)
- DFUs. *See* Directions for use (DFUs)
- Directions for use (DFUs), 80
- Directors. *See* Board of Directors
- Directors and officers (D&O) liability insurance, 160
- Disclosure. *See* Corporate voluntary disclosure
- Diversion. *See* Pre-trial diversion agreements
- D&O liability insurance. *See* Directors and officers (D&O) liability insurance
- Dodd-Frank and Sarbanes-Oxley regulation, 39–52
- assessment by management, 40–41
 - attorney up-the-ladder reporting obligations, 41–43
 - auditor's report, 41
 - certification of reports, 41
 - clawback and hedging provisions, 48
 - Dodd-Frank clawback regime, 48
 - Dodd-Frank hedging policy, 48
 - internal controls, 39–40
 - material weakness, defined, 40
 - motivating employees towards first-step internal reporting, 49–52
 - reporting directly to SEC, 43
 - reporting up rules, 41–43
 - sanctions and discipline, 43–44
 - SOX clawback regime, 48
 - whistleblower award program, 44–46
 - whistleblower protection provisions, 46–47
- Dodd-Frank clawback regime, 48
- Dodd-Frank hedging policy, 48
- DOJ. *See* Department of Justice (DOJ)
- DPA. *See* Deferred prosecution agreement (DPA)
- DPPA. *See* Driver's Privacy Protection Act (DPPA)
- Driver's Privacy Protection Act (DPPA), 115
- E&C committee. *See* Ethics and compliance (E&C) committee
- ECPA. *See* Electronic Communications Privacy Act (ECPA)
- Electronic Communications Privacy Act (ECPA), 115
- Enforcement process. *See* Law enforcement activities
- Enron, 39n
- Environmental audit, 92, 95
- Environmental discharge or operations permits, 92–93
- Environmental requirements, 90–96
- accuracy and validity of submissions, 93–94
 - certificates of compliance, 94
 - debarment, 96
 - environmental compliance plan, 90–91
 - EPA incentives policy, 91
 - EPA priorities, 95
 - internal audit (self-audit), 92, 95
 - main areas for criminal prosecution, 95
 - permits, 92–93
 - punishments, 95–96
 - SEC reporting requirements, 95
 - strict liability, 96
 - voluntary reporting of environmental law violation, 94, 207–208
 - whistleblower complaints, 95
- Ethics and compliance (E&C) committee, 131–132
- EU Anti-Bribery Law, 31
- EU Data Protection Directive, 121

- EU Directive on Human Trafficking, 11
- EU-U.S. Privacy Shield, 121–122
- Excluded Parties List System, 96
- Exclusion from participation. *See* Debarment
- Executive Order 13627 (Executive Order on Trafficking in Government Contracts), 10, 12–14, 100, 110
- Express false statement, 154
- Express warranty, 79

- Facilitating/expediting payments exception, 26, 29
- Fail to warn claims, 80. *See also* Warning
- Fair Credit Reporting Act (FCRA), 116
- Fair Labor Standards Act, 110
- Fair Pay and Safe Workplaces, 110
- False certification crimes, 152–161
 - crime-fraud exception, 158–159
 - D&O liability insurance, 160
 - establishing Section 1001 liability, 153
 - example prosecution of individuals, 157–158
 - False Claims Act, 157
 - false statements, 153–154
 - jurisdictional requirement, 155
 - “knowing” and “willful,” 155
 - limiting liability, 159, 160
 - materiality, 154
 - other Title 18 crimes, 156
 - penalties, 160–161
 - plea bargaining, 156
 - statute of limitations, 155
 - tag-along crime to other crimes, 156
- False Claims Act (FCA)
 - charging provision, 23
 - false certification crimes, 157
 - government contracts, 97, 100
 - health care industry, 56–57
 - public disclosure bar, 210
 - qui tam* provisions, 56
 - voluntary disclosure, 209–210
- False statements, 22–23, 153–154
- Family and Medical Leave Act, 110
- Family Educational Rights and Privacy Act (FERPA), 117, 119
- FAPIIS. *See* Federal Awardee Performance and Integrity Information System (FAPIIS)
- FAR. *See* Federal Acquisition Regulation (FAR)
- FAR anti-trafficking provisions, 10, 12–14
- FARO Technologies, 204
- FCA. *See* False Claims Act (FCA)
- FCC. *See* Federal Communications Commission (FCC)
- FCRA. *See* Fair Credit Reporting Act (FCRA)
- FDA. *See* Food and Drug Administration (FDA)
- Federal Acquisition Regulation (FAR), 10, 12–14, 97, 173
- Federal Awardee Performance and Integrity Information System (FAPIIS), 104
- Federal Communications Commission (FCC), 115
- Federal contractors. *See* Government contracts
- Federal Food, Drug and Cosmetic Act (FFDCA), 77, 85
- Federal Hazardous Substances Act (FHSA), 84
- Federal Trade Commission (FTC), 54, 115, 118, 120
- Federal Trade Commission Act, 118
- FERPA. *See* Family Educational Rights and Privacy Act (FERPA)
- FFDCA. *See* Federal Food, Drug and Cosmetic Act (FFDCA)
- Fifth Amendment right against self-incrimination, 144, 145–146, 150
- Financial Services Modernization Act, 117
- Flammable Fabrics Act (FFA), 84
- Flowdown requirement, 97–98, 102, 109
- Follow-on litigation, 204–205
- Food and Drug Administration (FDA), 54, 69–70, 85
- Food or medical products. *See* Pharmaceutical, medical, and food products compliance
- Food Safety Modernization Act (FSMA), 74, 173
- Forced or coerced labor. *See* Human trafficking and other forms of forced labor
- Ford Aviation Investment and Reform Act, 186
- Foreign carbon copy prosecutions, 205. *See also* Carbon copy prosecutions
- Foreign Corrupt Practices Act (FCPA), 25–38
 - anti-bribery provisions, 27–29
 - attempt liability, 28
 - bona fide business expenditure exception, 26, 34
 - bribery red flags, 38
 - business purpose test, 28
 - carbon copy prosecutions, 34–35
 - Chinese anti-bribery laws, 31–33
 - compliance program. *See* Compliance program

- Foreign Corrupt Practices Act (FCPA) (*continued*)
- criminal prohibitions, 25
 - CSR supply chain compliance, 173
 - enforcement agencies, 25
 - enforcement trends, 34
 - facilitating/expediting payments exception, 26, 29
 - foreign official, defined, 28
 - German anti-bribery laws, 31–33
 - India's Prevention of Corruption Act, 31–33
 - internal controls, 27
 - "knowing" about misconduct, 29
 - local law exception, 26, 29
 - one-year DOJ pilot program, 213–216
 - overview (anti-bribery matrix), 31–33
 - overview (flowchart), 26
 - penalties, 35
 - recordkeeping, 27
 - Travel Act, 26, 35–36
 - UK Bribery Act, 30, 31–33
- Foreign official, 28
- Form 990 annual reports, 112
- Formal (statutory) immunity, 147–148
- Four easy steps (review, revise, hire, and submit), 234
- FPCA. *See* Foreign Corrupt Practices Act (FCPA)
- Fraud against the government, 209–210. *See also* False Claims Act (FCA)
- FSMA. *See* Food Safety Modernization Act (FSMA)
- FTC. *See* Federal Trade Commission (FTC)
- FTC Safeguards Rule, 119
- General counsel, 5
- German anti-bribery laws, 31–33, 234
- GIDEP. *See* Government-Industry Data Exchange Program (GIDEP)
- GLBA. *See* Gramm-Leach-Bliley Act (GLBA)
- Government contracts, 6–7, 97–111
- certification requirement, 102–103
 - compliance plans, 103–105
 - continuing cycle of updates and improvements, 111
 - counterfeit electronics, 105–108
 - "culture of compliance," 111
 - cyber compliance issues, 108–109
 - False Claims Act (FCA), 97, 100
 - flowdown requirement, 97–98, 102, 109
 - human trafficking, 100–102. *See also* Human trafficking and other forms of forced labor
 - labor and related issues, 109–110
 - mandatory disclosure, 98
 - overview, 97–98
 - paycheck transparency, 110
 - prime contractor "police" function, 97–98, 102
 - regulatory developments, 100
 - subcontractors, 102, 103, 109
 - suspension and debarment, 98–100
- Government-Industry Data Exchange Program (GIDEP), 106n, 107
- Gramm-Leach-Bliley Act (GLBA), 117, 119
- Halliburton Amendment, 166
- Health Breach Notification Rule, 120
- Health care industry, 53–68
- Anti-Kickback Statute (AKS), 55–56
 - Board of Directors, 60
 - CIA. *See* Corporate integrity agreement (CIA)
 - clinical trials. *See* Pharmaceutical, medical, and food products compliance
 - CMS program audits, 64–65
 - CMS recovery audit program, 64
 - CMS Self-Referral Disclosure Protocol, 67
 - code of conduct, 61–62
 - compliance officer's keys to success, 68
 - continuing medical education (CME), 62
 - compliance program, 58–60
 - emerging risk areas, 62–63
 - False Claims Act (FCA), 56–57
 - HIPAA, 57–58
 - hospitals. *See* Nonprofit entities
 - OCR pilot audit program, 65
 - OIG Advisory Opinions, 63
 - OIG Provider Self-Disclosure Protocol, 66–67, 208
 - OIG Special Advisory Bulletins, 63
 - OIG Special Fraud Alerts, 62–63
 - overpayments, 65–66
 - physician self-referral law, 57
 - regulators, 53–55
 - Stark Law, 57
 - voluntary self-disclosure, 66–67
- Health Information Technology for Economic and Clinical Health (HITECH), 55, 57
- Health Insurance Portability and Accountability Act (HIPAA), 57–58, 117–118
- Hedging provision, 48
- HHS. *See* Department of Health and Human Services (HHS)

- High-level personnel bar, 231
- HIPAA. *See* Health Insurance Portability and Accountability Act (HIPAA)
- HIPAA Breach Notification Rule, 57
- HIPAA Privacy Rule, 118
- HIPAA Security Rule, 119
- HITECH. *See* Health Information Technology for Economic and Clinical Health (HITECH)
- Hospitals. *See* Nonprofit entities
- Human resources department, 7
- Human trafficking and other forms of forced labor, 9–24, 100–102
- anti-trafficking compliance program guidelines, 20–22
- big three forced labor regimes, 9
- Business Supply Chain Transparency on Trafficking and Slavery Act, 11
- California Transparency in Supply Chains Act, 10, 16–18
- due diligence requirements, 14–15
- EU Directive, 11
- false claims, 23
- false statements, 22–23
- FAR anti-trafficking provisions, 10, 12–14
- flowdown requirement, 102
- forced labor, sex trafficking, 22–24
- “naming and shaming” campaigns, 16
- obstruction of justice, 23
- overview (laws & regulation comparison matrix), 10–11
- smuggling, 23
- Trade Facilitation and Trade Enforcement Act, 15–16
- “traditional” anti-trafficking prohibitions, 22–23
- UK Modern Slavery Act, 11, 18–20
- Iceberg analogy, 192
- Immunity issues, 144–151
- clarify precise content of agreement, 150
- contractual (informal) immunity, 148–149
- cooperation vs. capitulation, 149, 151
- derivative use immunity, 146–147
- failure to cooperate, 149, 151
- Fifth Amendment right against self-incrimination, 144, 145–146, 150
- memorializing information shared with government, 150
- overlapping federal/state immunity systems, 149
- perjury/false statements, 149
- practical considerations, 149–151
- proffer agreements, 148–149
- queen-for-the-day letters, 149
- seek legal assistance, 150
- statutory (formal) immunity, 147–148
- transactional immunity, 147
- use immunity, 146–147
- what is not covered by immunity agreements?, 149
- Implied false statement, 154
- Implied warranty, 79
- Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations Policy* (EPA), 91, 94, 207
- India’s Prevention of Corruption Act, 31–33
- “Individual Accountability for Corporate Wrongdoing” (Yates Memo), 205, 221–222
- Individual liability. *See* Personal criminal liability
- Informal (contractual) immunity, 148–149
- Insurance
- D&O liability, 160
- privacy and data security, 123
- product safety and liability, 87–89
- Section 1001 prosecutions, 160
- Internal audit group, 5–6
- Internal controls
- Dodd-Frank and Sarbanes-Oxley, 39–40
- FCPA, 27
- Internal investigation. *See* Matter intake process
- Internal reporting mechanisms, 49–52
- International data transfer, 123
- International privacy and data security regimes, 120–122
- International transactions compliance (OFAC sanction), 162–164
- examples of recent enforcement actions, 164
- mitigating the penalty, 164
- OFAC website, 163
- penalties, 163–164
- sanctions compliance program, 164
- scope of U.S. sanctions, 163
- SDN list, 162
- SSI list, 163
- Interviewing whistleblowers, 191–194
- Inventory of records being seized, 130
- Investigation plan, 133
- Investigation report, 136–137
- Investigations or searches, 140–142

- ISO. *See* Organization for Standardization (ISO)
- ISO CGL policies, 87–88
- Issuer, 40n
- “Knowing” about misconduct, 29
- Labeling/branding, 77–78, 85
- Labor/anti-trafficking issues, 9–24. *See also* Human trafficking and other forms of forced labor
- Lacey Act, 174
- Law enforcement activities, 127–143
 - arrests and restraining orders, 138–139
 - CCO's initial appearance at site, 129
 - copying documents, 141
 - employee interview responses, 129–130
 - employee rights and obligations, 142–143
 - internal investigation. *See* Matter intake process
 - interview guidance, 142–143
 - inventory of records being seized, 130
 - investigations or searches, 140–142
 - pre-enforcement steps, 128
 - process server, 138–139, 143
 - search warrant, 129, 138, 139
 - service of legal process, 138–139, 143
 - site entry and records seizure responses, 129
 - subpoena, 138–139
 - summons, 138–139
 - wage withholding, 138–139
- Legal privilege, 124–126
 - attorney-client privilege, 124–125
 - corporate voluntary disclosure, 205–206
 - crime-fraud exception, 126
 - how to protect privilege?, 125–126
 - information available from another source, 125
 - purely factual information, 125
 - purpose of obtaining legal representation, 126
 - work product privilege, 125
- List of Excluded Individuals and Entities, 227
- Local law exception, 26, 29
- Management accountability and certification, 228
- MAO. *See* Medicare advantage organization (MAO)
- Maryland debarment laws, 174
- Material violation, 41
- Material weakness, 40
- Matter intake process
 - case management ledger, 137
 - close-out and follow-up, 137
 - collection of relevant information, 133–135
 - company code of conduct, 136
 - complaint validity, 132
 - compliance interviews, 135
 - corrective action, 137
 - ethics and compliance (E&C) committee, 131–132
 - fact-finding, 134
 - factual and legal analysis, 135–136
 - intake, 131–132
 - investigation plan, 133
 - investigation report, 136–137
 - investigatory principles, 136
 - level of resources to be deployed, 133
 - overview, 131
 - planning, 132–133
 - reporting to stakeholders, 136–137
 - securing documents, 134–135
 - steps in process, 131
 - Upjohn advertisements, 134
- McKessy, Sean, 40
- Medicaid fraud control units (MFCUs), 55
- Medicare advantage organization (MAO), 60
- Meeting with the regulator, 169
- MFCUs. *See* Medicaid fraud control units (MFCUs)
- Mitigation credit
 - government contracts, 104
 - health care industry, 58–59
 - OFAC violations, 164
 - one-year FCPA pilot program, 213–216
 - three-level offense reduction, 230–231
 - voluntary disclosure. *See* Corporate voluntary disclosure
- Monetary fine. *See* Penalties
- Monitorship, 201, 223–226
- Motivating employees towards first-step internal reporting, 49–52
- “Naming and shaming” campaigns, 16
- Natale v. United States*, 155
- National Defense Authorization Act (NDAA), 105
- National Highway Safety Administration, 85
- Nature's Sunshine Products, 204
- NDAA. *See* National Defense Authorization Act (NDAA)

- Negligence, 80–81
- New York and Presbyterian Hospital and Columbia University, 118
- Non-prosecution agreement (NPA), 200, 219.
See also Pre-trial diversion agreements
- Nonprofit entities
- Form 990 annual reports, 112
 - fraud detection and deterrence, 112
 - loss of reputation, 113
 - loss of tax-exempt status, 113
 - malpractice liability, 112
 - penalties, 113
 - personal criminal liability, 113
- Notice of Inspection forms, 129
- NPA. *See* Non-prosecution agreement (NPA)
- Obama, Barack, 100
- Obstruction of justice, 23
- Obstruction of justice statutes, 156
- OCR. *See* Office of Civil Rights (OCR)
- OCR pilot audit program, 65
- Office of Civil Rights (OCR), 55
- Office of Foreign Assets Control (OFAC), 162. *See also* International transactions compliance (OFAC sanction)
- Office of Inspector General (OIG), 54–55
- compliance resource materials, 60
 - List of Excluded Individuals and Entities, 226–227
 - OIG Advisory Opinions, 63
 - OIG compliance program guidance, 59
 - OIG Provider Self-Disclosure Protocol, 66–67
 - OIG Special Advisory Bulletins, 63
 - OIG Special Fraud Alerts, 62–63
- OIG. *See* Office of Inspector General (OIG)
- OIG Advisory Opinions, 63
- OIG compliance program guidance, 59
- OIG Provider Self-Disclosure Protocol, 66–67, 208
- OIG Special Advisory Bulletins, 63
- OIG Special Fraud Alerts, 62–63
- Online Privacy Protection Act (Cal.), 119
- Open-ended questions, 192–193
- Opposition clauses, 185–186
- Organization for Standardization (ISO), 84
- Organizational chart, 2
- Organized Crime Control Act, 147, 148
- Paper-only policy, 36, 202
- Paraphrasing, 194
- Participation clauses, 185, 186
- Paycheck transparency, 110
- PayPal, Inc., 164
- PCAOB. *See* Public Company Accounting Oversight Board (PCAOB)
- PDP. *See* Prescription drug plan (PDP)
- Peanut Corporation of America, 74
- Pen register and trap and trace provisions, 115, 116
- Penalties
- corporate integrity agreement (CIA), 227
 - criminal prosecution of executives. *See* Personal criminal liability
 - environmental issues, 95–96
 - false certification crimes, 160–161
 - FCPA, 35
 - mitigation. *See* Mitigation credit
 - nonprofit entities, 113
 - OFAC violations, 163–164
 - pre-trial diversion agreements, 223
 - privacy and data security, 118
 - product safety and liability, 78–79
- Perjury, 149
- Perjury statutes, 156
- Personal criminal liability. *See also* Penalties
- environmental issues, 96
 - false certification crimes, 157–158
 - nonprofit entities, 113
 - pharmaceutical, medical, and food products compliance, 71, 74
- Personal Information Protection and Electronic Documents Act (PIPEDA), 121
- Personally identifiable information, 114–115
- PetroTiger, Ltd., 200
- Pharmaceutical, medical, and food products compliance, 69–75. *See also* Health care industry
- adverse effects reporting, 73
 - compliance and submission quality, 74–75
 - criminal punishment of executives, 71, 74
 - debarment, 72
 - FDA, 69–70
 - food issues, 74
 - Food Safety Modernization Act (FSMA), 74
 - fraud and conscious omissions, 71–72
 - product marketing claims, 72–73
 - reports about clinical trials, 71
 - strict liability, 69
- Pharmaceutical Research and Manufacturers Association (PhRMA), 61
- PHI. *See* Protected health information (PHI)
- PhRMA. *See* Pharmaceutical Research and Manufacturers Association (PhRMA)

- Physician self-referral law (Stark Law), 57
- PIPEDA. *See* Personal Information Protection and Electronic Documents Act (PIPEDA)
- Plea bargaining, 156
- Plumbing codes, 84
- Plumbing-Heating-Cooling Contractors Association, 84
- Poison Prevention Packaging Act (PPPA), 84
- Police investigations. *See* Law enforcement activities
- Post-sale duty to warn, 85–86
- Pre-trial diversion agreements, 217–229
 - CIA. *See* Corporate integrity agreement (CIA)
 - definitions, 218–220
 - eligibility considerations, 220–222
 - factors to consider when deciding whether to prosecute, 221
 - front-end probation agreements, 217
 - internal reform requirements, 223
 - monetary fine, 223
 - monitoring, 223–226
 - obligations imposed by DPAs/NPAs, 222–226
 - revocation of agreement, 226
 - work product protection/attorney-client privilege, 221
 - Yates memo, 221–222
- Prescription drug plan (PDP), 60
- Prevention of Corruption Act (India), 31–33
- Prime contractor “police” function, 97–98, 102
- Principles of Federal Prosecution of Business Organizations, 198
- Privacy and data security, 114–123
 - APEC, 122
 - Australia’s Privacy Act, 121
 - Canada’s PIPEDA, 121
 - comprehensive privacy/data security policies, 122
 - consumer-facing privacy policy, 122–123
 - data breaches, 123
 - data security provisions, 119–120
 - EU-U.S. Privacy Shield, 121–122
 - EU’s Data Protection Directive, 121
 - insurance, 123
 - international data transfer, 123
 - international provisions, 120–122
 - legislation, 115–119
 - penalties, 118
 - personally identifiable information, defined, 114–115
 - practical pointers, 122–123
 - privacy, defined, 114
 - privacy audit, 122
 - states, 119, 120
 - third parties, 123
- Privacy audit, 122
- Privilege rules. *See* Legal privilege
- Proactive steps (review, revise, hire, and submit), 234
- Process server, 138–139, 143
- Procurement department, 6
- Product design and manufacturing, 81–83
- Product liability endorsement, 88
- Product liability insurance, 88
- Product line approach, 87
- Product marketing claims, 72–73
- Product safety and liability, 76–79
 - amusement park rides, 83–84
 - breach of warranty, 79–80
 - CGL insurance policy, 87–88
 - civil money damages exposure, 79–81
 - CPSC, 83, 84
 - criminal liability, 78–79
 - directions for use (DFUs), 80
 - fail to warn claims, 80
 - FFDCA, 77
 - insurance, 87–89
 - labeling/branding, 77–78, 85
 - legislation, 84
 - mandatory product standards, 83–84
 - marketing and distribution practices, 85
 - misbranding/adulteration, 77
 - negligence, 80–81
 - post-sale duty to warn, 85–86
 - product design and manufacturing overview, 81–83
 - product liability endorsement, 88
 - product liability insurance, 88
 - product line approach, 87
 - product standards, 83–84
 - product withdrawal expense insurance, 89
 - recall insurance, 88–89
 - regulatory agencies, 84, 85
 - Restatement of Torts, 86, 87
 - sistership exclusion, 88–89
 - standard-setting bodies, 84, 85
 - strict liability, 81
 - successor liability, 87
 - types of harm, 78
 - voluntary product standards, 84
 - warning, 80, 85–86

- Product standards, 83–84
- Product withdrawal expense insurance, 89
- Proffer agreements, 148–149
- Protected activity, 185–187
- Protected health information (PHI), 57, 117–118
- Provider Self-Disclosure Protocol, 66–67, 208
- Public Company Accounting Oversight Board (PCAOB), 41, 119–120
- Public disclosure bar, 210
- Publicly held companies, 210–211, 212
- Queen-for-the-day letters, 149
- RAC. *See* Recovery auditor contractor (RAC)
- Recall insurance, 88–89
- Recordkeeping
FCPA, 27
sanctions-related records, 164
- Recovery auditor contractor (RAC), 64
- Refrigerator Safety Act (RSA), 84
- Regulation S-K, 95
- Regulatory agency meetings, 168
- Regulatory relations program, 169
- Relationship building, 5–8
auditors, 5–6
corporate counsel, 5
government contracts team, 6–7
human resources teams, 7
procurement teams, 6
sales teams, 6
- Remedies. *See* Penalties
- Report of the Securities and Exchange Commission on Questionable and Illegal Corporate Payments and Practices*, 38
- Reporting up rules, 41–43
- Resource Conservation and Recovery Act, 93, 166
- Restatement of Torts, 86, 87
- Retaliation claims, 185. *See also* Whistleblower complaints
- Review, revise, hire, and submit, 234
- Sales department, 6
- Sanctions compliance program, 164
- Sanctions programs, 162–164. *See also* International transactions compliance (OFAC sanction)
- Sarbanes-Oxley Act (SOX), 39, 119, 173, 188. *See also* Dodd-Frank and Sarbanes-Oxley regulation
- Satellite Home Viewers Extension and Reauthorization Act (SHVERA), 118
- SCA. *See* Stored Communications Act (SCA)
- Schlumberger Oilfield Holdings, Ltd., 164
- SDN list. *See* Specially Designated Nationals and Blocked Persons List (SDN)
- SDOs. *See* Suspension and debarment officials (SDOs)
- Search warrant, 129, 138, 139
- SEC Rule 10b-5, 211
- Section 1001 prosecutions. *See* False certification crimes
- Sectoral Sanctions Identification (SSI) list, 163
- Self-incrimination, right against, 144, 145–146, 150
- Sentencing Guidelines. *See* U.S. Sentencing Guidelines
- Service Contract Act, 110
- Service of legal process, 138–139, 143
- Sex trafficking, 22–24
- Shareholder derivative suits, 210–211
- SHVERA. *See* Satellite Home Viewers Extension and Reauthorization Act (SHVERA)
- Sistership exclusion, 88–89
- Smale, John, 71
- Smuggling, 23
- SOX clawback regime, 48
- Specially Designated Nationals and Blocked Persons List (SDN), 162
- SSI list. *See* Sectoral Sanctions Identification (SSI) list
- Standards for Commercial Support: Standards to Ensure Independence in CME Activities*, 62
- Stark Law, 57
- State Medicaid fraud control units, 55
- Statutory (formal) immunity, 147–148
- Stevens, Laura, 156–157
- Stock drop case, 211
- Stolt-Nielsen, 226
- Stored Communications Act (SCA), 115, 116
- Strict liability, 69
environmental issues, 96
pharmaceutical, medical, and food products compliance, 69
product safety and liability, 81
- Subordinate attorney's reporting obligations, 42
- Subpoena, 138–139
- Successor liability, 87

- Sulzbach, Christi, 157
- Summons, 138–139
- Suppliers. *See* CSR supply chain compliance program
- Suspension and debarment. *See* Debarment
- Suspension and debarment officials (SDOs), 98
- Syncor International Corporation, 204
- Technischer Überwachungsverein (TUV), 84
- Telephone Records and Privacy Protection Act (TRAPPA), 118
- Testimonial communication, 145
- Third party due diligence, 37
- Three-level offense reduction, 230–231
- Title 18 crimes, 156. *See also* False certification crimes
- Tort lawsuits, 166–167
- Toxic Substances Control Act, 93
- Trade association, 168
- Trade embargo, 163. *See also* International transactions compliance (OFAC sanction)
- Trade Facilitation and Trade Enforcement Act, 15–16
- Trafficking in persons. *See* Human trafficking and other forms of forced labor
- Transactional immunity, 147
- TRAPPA. *See* Telephone Records and Privacy Protection Act (TRAPPA)
- Travel Act, 26, 35–36, 173
- Trusted supplier, 108
- Turkish Criminal Code, 234
- UBS, 226
- UK Bribery Act, 30, 31–33, 173, 233–234
- UK Modern Slavery Act, 11, 18–20, 173, 233
- UL, 84
- Underwriters Laboratories, 84
- United States v. Shah*, 154
- United States Attorney's Manual* (USAM), 198, 220, 221
- Upjohn v. U.S.*, 130
- Upjohn advertisements, 134
- U.S. Department of Agriculture, 85
- U.S. Sentencing Commission, 58
- U.S. Sentencing Guidelines, 58, 198, 230–234
- appropriate response to criminal conduct, 231–232
- four-part eligibility test, 231
- general counsel, 232
- high-level personnel bar, 231
- outside counsel, 232
- privilege, 232
- questions raised by amendments, 232
- three-level offense reduction, 230–231
- U.S. Travel Act, 26, 35–36, 173
- USAM. *See* *United States Attorney's Manual* (USAM)
- Use immunity, 146–147
- Video Privacy Protection Act (VPPA), 118
- Virginia Graeme Baker Pool and Spa Safety Act (VGBA), 84
- Voluntary self-disclosure. *See* Corporate voluntary disclosure
- VPPA. *See* Video Privacy Protection Act (VPPA)
- Wage withholding, 138–139
- Warning, 80, 85–86
- Whistleblower award program, 44–46, 184n, 203
- Whistleblower complaints, 7–8, 184–196
- adverse employment action, 187–188
- bounty program, 44–46, 184n, 203
- Burlington Northern* standard, 187
- causation, 188
- constructive discharge, 187–188
- corporate voluntary disclosure, 202–203
- dual functions of whistleblower investigations, 184–185
- environmental issues, 95
- factors affecting whistleblower's award, 46
- going directly to SEC, 203
- intake systems. *See* Whistleblower intake systems
- “magic words,” 186–187
- opposition clauses, 185–186
- participation clauses, 185, 186
- protected activity, 185–187
- training and coaching managers, 195–196
- whistleblower protection provisions, 46–47
- wrongful termination claims, 186–188
- Whistleblower intake systems. *See also* Whistleblower complaints
- fact-finding, 191–194
- follow-up questions, 193
- iceberg analogy, 192
- intake documentation, 188–189
- interviewing whistleblowers, 191–194

- open-ended questions, 192–193
- paraphrasing, 194
- responsiveness, 190–191
- triage process, 189–190
- Whistleblower interviews, 191–194
- Whistleblower protection provisions, 46–47
- Wiretap Act, 115, 116
- Work product privilege, 125
- Wrongful termination in violation of public policy tort, 186–188
- Yates, Sally, 205
- Yates Memo, 198, 205, 221–222