

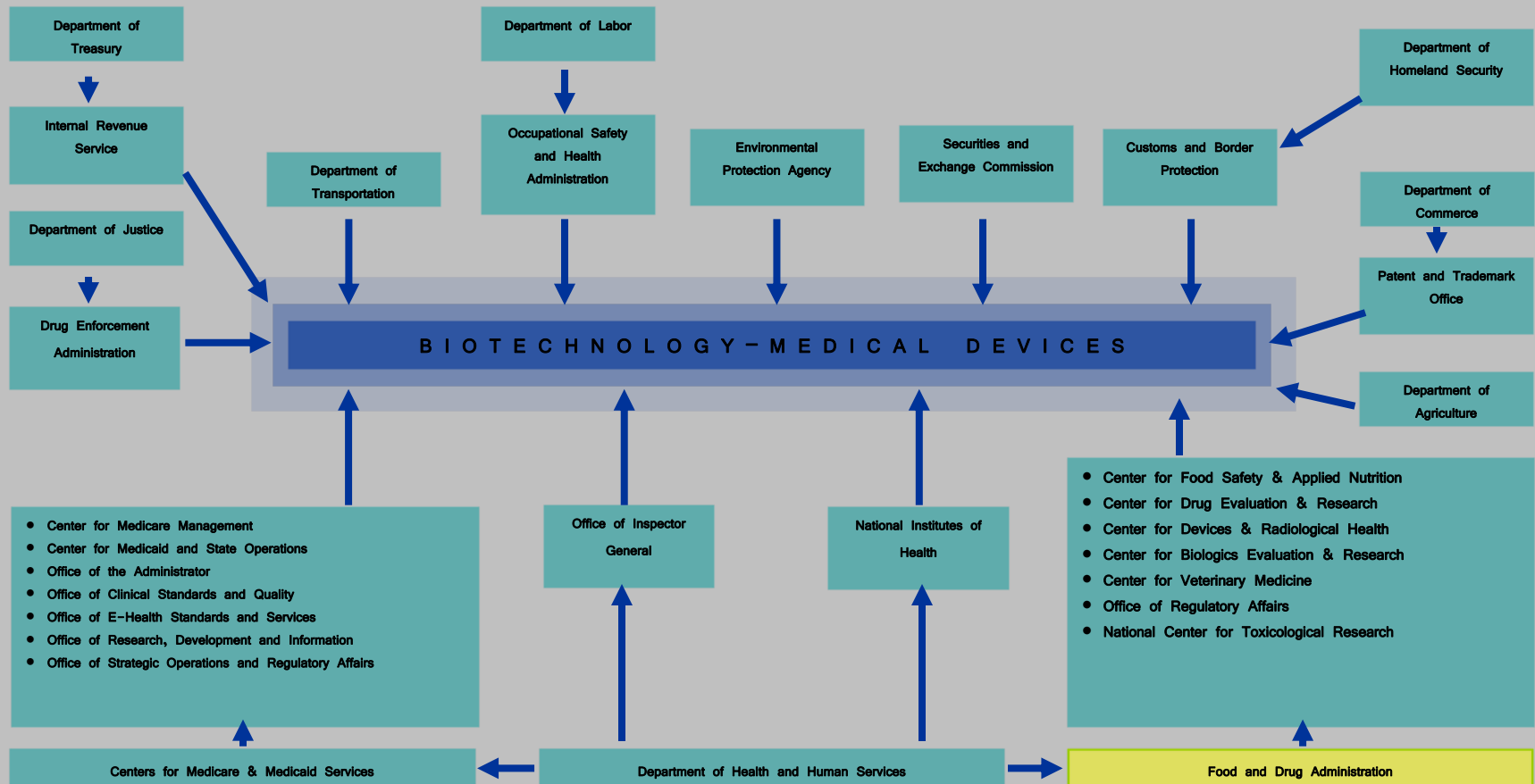
Coming to America

Expectations for U.S. Employees

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USA Regulatory Environment

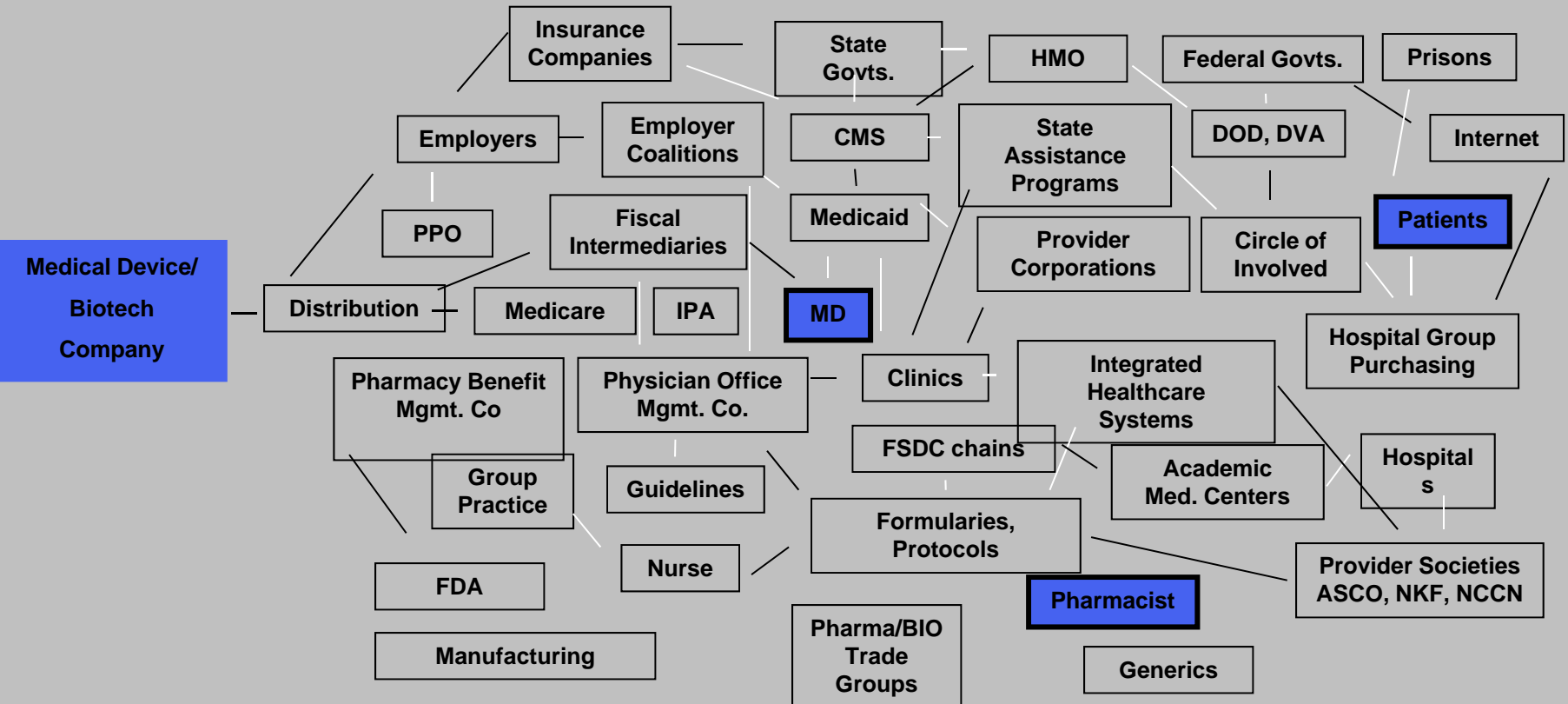


Sample of US federal agencies that regulate medical companies

Laws Enforced by the FDA

- Infant Formula Act of 1980 (summary)
- Orphan Drug Act
- Drug Price Competition and Patent Term Restoration Act of 1984 (summary)
- Prescription Drug Marketing Act of 1987
- Generic Animal Drug and Patent Term Restoration Act of 1988 (summary)
- Nutrition Labeling and Education Act of 1990
- Safe Medical Devices Act of 1990 (summary)
- Medical Device Amendments of 1992 (summary)
- Prescription Drug Amendments of 1992
- Prescription Drug User Fee Act (PDUFA) of 1992
- Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994
- Dietary Supplement Health and Education Act of 1994
- Food Quality Protection Act of 1996
- Animal Drug Availability Act of 1996
- Food and Drug Administration Modernization Act (FDAMA) of 1997
- Best Pharmaceuticals for Children Act
- Medical Device User Fee and Modernization Act (MDUFMA) of 2002
- Animal Drug User Fee Act of 2003
- Pediatric Research Equity Act of 2003
- Minor Use and Minor Species Animal Health Act of 2004
- Food Allergen Labeling and Consumer Protection Act of 2004

USA Healthcare Environment



USA Reimbursement Environment

- The willingness of insurers and other payers to reimburse the cost of medical devices is a primary and fundamental uncertainty.
- The pricing & reimbursement environment is notoriously complex & continuously changing.
- The effort to gain reimbursement is both on a federal and state by state level.

USA Working Environment

- Differences in salary and benefits programs
- Issues regarding equity.
- Differences in the meaning of titles.
- Vacation programs.
- Significant differences regarding labor laws.
- EEO – Equal employment opportunity
- “At Will” vs. “Contract” employee
- Getting fired.

USA Business/Legal Environment

- A more litigious society.
- Differences in corporate law.
- Employment law.
- Tax benefits – state to state differences

USA Funding Environment

- Federal programs
 - NIH – National Institutes of Health
 - DOD – Department of Defense
 - NCI – National Cancer Institute
 - SBIR – Small Business Innovation Research
 - On and on and on and on
- State Programs
 - Vary greatly state to state
 - A decision factor for company location

USA Funding Environment

- Venture Capital
 - A difficult environment, but funding is still happening
- Angel Investing
 - Groups
 - Individuals
- Public Markets
 - IPO – Initial Public Offering
 - PIPE – Private Investment in Public Equity

USA Living Environment

- Differences in life style from one location to another.
- Differences in cost of living.
- The commute.
- Home prices.
- Types of houses.

Key Consideration # 1

Do you need a US
market presence to
achieve business
success?

US R_x Sales

- US \$ 291 billion in 2008
- 43% share of worldwide sales
- 4.5 % growth rate in the US (IMS)

...single largest health care market in the world!

Questions you need to ask...

- What is the strategic vision for the business?
- Does this require global market expansion?
- Will this maximize valuations of IP, product assets, and equity of stakeholders?
- Will you have support of Board and Management Team?
- Will you have adequate financial resources?

Key Consideration # 2

What are the critical
legal and financial issues ?

Differences between US and Domestic market

- Business entity structure
- Intellectual Property protection
- Immigration laws and restrictions (since 9/11)
- Employment law issues
- Executive compensation programs
- Antitrust and trade regulations
- Tax considerations
- Transfer pricing
- Sarbanes-Oxley

Key Consideration # 3

Can you successfully
launch your products
in the US market?

- The US Market is rapidly growing...but changing
- Regulations at the national and state level are more complex
- New rules for promotion and medical education
- Traditional approaches usually mean doing it yourself or **finding a partner/investor**

Questions Often asked by Potential Partners/Investors

- Does the market need the product?
- Will it sell?
- Will it be reimbursed?
- What is the experience of the management team?
- Can we win?

Key Consideration # 4

What are the issues
when deciding on
geographical location for
the business unit?

- Accessibility to skilled talent
- Cost of living / compensation
- Proximity to academic centers of excellence
- Location of strategic partners
- State & Local tax incentives
 - Biotech specific innovation zones
 - R&D tax credit qualifications
 - Employee training grants

Key Consideration # 5

How will you know that
your business is *really*
ready for expansion to
the US market?

Key Operating Principles

- **Assess** your firm's "readiness" to enter the US market. (3rd party review)
- Develop a comprehensive US market *commercialization plan* before committing resources
- **Hire/contract skilled commercial personnel with *US market experience***

Business Goals should be

- Stay “*virtual*” for as long as possible
- Manage expenditures (\$ and time)
 - Accelerate time to market

Summary

- So much to consider.
- The US market is huge.
- So are the barriers to entry.
- Is your funding appropriate?

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