BIOTECHNOLOGY INDUSTRY, STRUCTURE & STRATEGY
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NYU Stern School of Business
MBA Program

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COURSE DESCRIPTION AND GOALS

Biotechnology started as a science, referring to the use of living cells as factories to produce protein through manipulation of genes. Yet today, biotechnology refers to an industry, with the top companies in the sector exceeding some of the major pharmaceutical companies in market capitalization. No longer are biotechnology companies constrained to using recombinant DNA technology alone, as the moniker is assigned today to any small company engaged in any life sciences-related research directed toward developing a commercial product, using any scientific means. Belonging to the sector usually also implies a culture – small, nimble, visionary but practical, cash constrained but willing to risk it all. While some of the above characteristics are more idealized than real, it is certainly the case that, while the key factors for success in a development stage company include the very same scientific, analytic, and/or managerial talents that reside in “big pharma”, the context is different, requiring the organization to incorporate some additional skills to ensure survival, and non-traditional systems to support success.

The foundation of this course will be the core curriculum that you have all mastered during your first year at Stern. You will be at an advantage, in that regard, relative to some of your future colleagues who work in the industry today. The long product development cycles inherent to the industry may minimize the rigor behind decision-making, since there is a long time lag between the action taken, and its ultimate impact. Moreover, paradoxically, there is a “comfort” to operating at a significant loss for many years, spending hundreds of millions of dollars of investors’ money, relieving the incentive to generate incremental revenue or savings that seem insignificant relative to the scale of the investment and the size of the opportunity. Finally, the need to constantly raise money sometimes favors promotion over analysis, and short-term impact on share price, rather than long-term creation of value.

We are going to try to avoid all of those traps, mindful that there is less margin for error built into the “biotech” business model. But we will superimpose a whole other set of considerations that make the industry different from just a smaller version of “big pharma”. Your ability to think across functions will be critical, as will your flexibility and ability to adapt the plan to changing circumstances. Finally, your own personal style will be more prominently displayed while swimming for survival in a small glass fish bowl, sharing the space with the occasional piranha.
COURSE FORMAT

My goal for the course is not to make you experts on the facts and figures of the industry. Instead, the goal is to teach you to identify issues, practice how to analyze and solve them, and then implement your solution from the perspective of a senior manager in a biotechnology enterprise. The focus of the course will not be on starting a biotechnology company, but rather on running one. Therefore, the format will be primarily discussion rather than lecture, anchored around case studies of real situations faced by companies similar to those that you will (hopefully) found and/or join. Within the course, you will be exposed to all of the important functional areas: discovery, development, manufacturing, marketing, and sales. In addition, the more global topics of strategy, financing (including corporate deals), intellectual property, bioethics, and organizational behavior, will be addressed.

Our sessions are a couple of hours long but we have relatively few given the breadth of information to be covered, resulting in some compromises in course content. For example, while there will be some readings assigned and classroom discussion about medical devices and diagnostics, the major focus will be on pharmaceutical applications, as they tend to be more complex. However, there will be a full session dedicated to diagnostics, reviewing a case about Personalized Medicine in light of the increasing attention given to this field by drug developers and regulatory agencies. In addition, there will be a final session on non-medical applications of biotechnology, with an emphasis on creation of biofuels. Similarly, to minimize the need for starting from scratch with each case analysis, I have tried to carry companies and/or markets across multiple topics. For example, I have written three cases about my most recent company, Cypress Bioscience, Inc. – one covering clinical development, the second dealing with negotiating corporate deals, and the last with private and public financing. Given the length of each class, I will intersperse some alternative formats to maintain your interest, while saving my voice. One of these alternative formats, to be used frequently, will be our switching roles, with one or more of you taking on leadership of the class discussion. Other days may include team exercises, videos, and/or guest speakers. Participating guests for each session will be added to the syllabus over time.

HOMEWORK AND GRADING

By way of philosophy, I come into the course with very high expectations of what each of you is capable of achieving, and will do my best to push you to realize that potential. As a result, the first session or two can be a little awkward, as we search to find a happy medium between what is possible and what is realistic. Based on past experience, the process, although perhaps frustrating in the very short term, yields large benefits, as we work together to tailor the rest of the quarter to meet the needs of the class as a whole, and of the individuals therein. My advice: hang in there, and provide me with feedback in real-time as to what works best, since the faster I know, the faster I can adjust.

A large component of your grade (35%) will be driven by the quality of your classroom participation. Please be sure to read and prepare the assigned cases to the best of your abilities. I would recommend that you do so with your assigned team (~ 4 students). While your informal contributions to classroom discussion may improve your ultimate grade, there will be many occasions where you are assured of more formal feedback, including (each of which will be described further below):
• An opportunity to “lead” class discussion of one of the cases, along with your teammates.
• Active participation in simulations and mock negotiations during our corporate partnering, intellectual property, and pricing sessions.
• Submission of Excel spreadsheet models to reinforce basic industry cost structure, and in preparation for our corporate partnership negotiation.

Including all of the above, each of you will receive feedback in some form (either as individuals or as a team) at a minimum of 6 times during the course. Depending on the nature of the activity, feedback may be verbal or in writing, and may be qualitative or in grade form. Please be proactive in soliciting the feedback if you feel you are not receiving it in a timely fashion.

Before elaborating on some of the assignments above, I would like to make a few comments about the sensitive subject of grades. In my view, grades incorporate a measure of both absolute and relative performance in the course. Most of the grades that you receive along the way during the course will reflect my assessment of your absolute knowledge at that point in time. It is probably safe to assume that you are all taking this course because you believe that there are gaps in your knowledge about the industry that you would like to fill. Therefore, you should not expect to have “mastered” the subject, as reflected by an A+, after limited exposure. Over the weeks, your knowledge and skills will improve, and will be reflected in improved grades. The final grade will not be an arithmetic mean of the individual grades, but will rather represent my view of your performance and effort relative to the class as a whole, and relative to my expectations. Although I have never intentionally used a curve in assigning final grades, my history over the past two years is consistent with the School’s guidelines – that is a clustering of A-/B+, with A/A+ reserved for the top performers, and balanced (albeit biased toward the higher grades) by some B/B- grades. We share the same goals: Every student should aspire to master the material and end up with an A/A+, and my goal, similarly, is to demonstrate effectiveness as a teacher by getting as many of you as possible to the level of proficiency reflected by the top grade bracket. Hopefully, we will all succeed in reaching our respective goals.

FORMAL ASSIGNMENTS

To ensure that everyone has a chance to contribute their ideas in class, the members of each team will lead the case discussion once during the course of the quarter. From a practical standpoint, what that means is that I will count on the individuals within the designated “team of the week” to be especially well prepared in their identification of the issues raised within the case, and with an analysis of the options facing the management team, and will draw on those individuals to get the discussion started. Although the team can choose to be proactive, and start off the class with a formal presentation introducing the case, or an informal set of questions for the class’ consideration, neither is required. More typically, I will direct a few introductory questions to the members of the team, and will use that dialogue to kick off discussion within the broader group. The primary goal is to provide an opportunity for each individual within the class to demonstrate leadership during the course, and to serve as a framework for each student to receive some feedback from the instructors multiple times during the course. Each team member will receive feedback from me within 1 week of the class during which you were a member of the lead team. The feedback will come either in the form of a conversation (at a mutually convenient time and place) or by e-mail.
Depending on the number of students in the class, you will be assigned to teams of ~4. Each team will choose one case from the following list:

- MorphoSys (Strategy & Business Models)
- Wyeth (Drug Discovery)
- Cypress A (Drug Development)
- Teva (IP)
- Nucleon (Manufacturing)
- Cypress C (Financing)
- Prozac vs Paxil (Sales & Marketing)
- Genomic Health (Personalized Medicine/ Diagnostics)
- Metabical (Pricing)
- Gilead (Pricing)
- Khosla Ventures (Biofuels)

Your group team and case study assignments will be emailed to you in early September. In addition to having this opportunity to be a “primary” contributor at least once during the course, you are welcome and encouraged to participate in the give and take of all sessions, even if you are not a member of the designated lead group.

Please be sure to read the assigned articles and prepare the MorphoSys case in advance of our first session. To help guide you on how to analyze a case, I will post an outline of how to structure your discussion/presentation. The teams assigned to present these case studies are encouraged to contact me in advance with any questions. While the document was written to guide the construction of a PowerPoint presentation on a case, it should provide value even to those teams who choose not to prepare a formal presentation by guiding you toward the information that I will expect you to extract from each week’s case analysis.

As the first few session introduce you to basic industry structure and strategy, each team will be asked to build an Excel spreadsheet of a “typical” pharmaceutical company P&L, and an “average” pharmaceutical product P&L. You will be provided with more detail when we meet.

In addition, all of you will be active participants in the two-part corporate partnering session (in which you will play the principals in a mock negotiation), and in the pricing session (in which you will present and defend a proposed price for a new product in front of a committee of “payers”). For these exercises, we will merge whatever number teams that are formed into three. More details on the assignments for these sessions will follow. While, in general, your preparation for each session will be self-guided, you will be required to build and submit a financial model (Excel) in preparation for the mock corporate partner negotiation session (case of “Cypress Bioscience, Inc. B: Finding Milnacipran’s Mate”). All of the above activities will be factored into the class participation component of your grade.

Since there are so few sessions, you must attend them all! If for some significant and unavoidable reason you must miss a class, please let me know in advance.
As you will see in the attached bibliography, there is a significant amount of assigned reading, in addition to the cases. Don’t panic! Only those references in BLACK print are required. Those in BLUE are recommended, and those in RED are optional. As you would do on the job as a CEO in a real world situation, you will develop skills individuality and as a team, to determine which information is most important to address the critical issues within the week’s case, and will support that effort with the readings that best fit. Each of you needs to read the black references, but you may want to split the blue readings among team members, so that there will be at least one member of the team who can bring that background information to the team’s case analysis. Remember, you are in the role of the CEO (or other key executive) in each case. You will be expected to have analyzed the situation, identified the key issues, and formulated a plan to address them. I am not looking for general platitudes by way of response. I want to hear the details of your analysis and the specifics of your plan. Perhaps different from the direction given to you in other classes, you are to strive to fully understand all of the available options, the trade-offs between the various solutions, and the implementation needs of the one that you choose. Do not confine yourself to the information included in the cases or the associated readings. You are encouraged to bring as much information as you can to each analysis, from other literature that you identify, company websites and/or public filings, or from discussion with those with relevant first-hand experience. Also, while the cases are meant to be analyzed, the readings are meant to be read, not studied or memorized. You will be evaluated based on your demonstrated problem-solving abilities, rather than on mastery of information. Consistent with this philosophy, no exams are planned.

The remaining 65% of your grade will be based on a short paper to be submitted by our last session. The goal of this exercise is to have you apply what you have learned to the analysis of a local company. You choose the company, but it should be one with which you have no more than a passing familiarity. This is an exercise to be completed as an individual rather than as part of a team. Each of you needs to choose a different company. There will be a sign-up sheet at which you can “stake your claim.” Your task is to read publicly available information, and then interview at least three people related to your company of choice. (The interviewees could include, for example, corporate management, competitors, an expert academic scientist within the field, or a Wall Street analyst who covers the company). Your paper should include some company background (for my sake), but that piece need not be authored by you. You may use, for example, the executive summary from the company’s press kit, the business section from one of their public filings, or an analyst report initiating coverage on the company, that you will attach to your paper when you hand it in (preferably by e-mail). Your assignment is to identify three key issues faced by the company, based on what you have learned during the course. These issues should not be generic, but rather raised within the context of the company’s unique character – its technology, its people, its market, its investors, and the like. Moreover, they may very well be issues that are different from those highlighted by the company within their public filings, or during your interviews. After identifying the issues, select one for further analysis: Describe how the company has addressed the issue (if at all), along with a critique of their plan or actions: Do you agree with their approach to addressing this key challenges? Do you view the challenge and its solution differently than does the company? What action(s) do you think that the company should take to further analyze and/or overcome the challenge? The paper should run 3-5 pages, excluding the company background information. We will discuss this assignment further when we meet in person.
GENERAL BACKGROUND READING

BOOKS:

This book by an HBS professor is the closest to a “textbook” for the course. While there will be no formal reading assignments from the book, I strongly recommend your reading it from cover to cover.

The story of the first drug based on the new paradigm of “pharmaco-genomics”, providing insight on how Genentech became a market leader in cancer by being the scientific innovator.

The former CEO of Amgen provides an insider’s account of the history of the most successful biotechnology company to date.

A well-known industry consultant explains its workings.

For those of you with aspirations to work on Wall Street covering life sciences companies, this is a handy primer to the complex problem of trying to value biotechnology companies – especially early stage ones.

This book is similar to the Campbell reference above, but more specific to the small company biotechnology setting.

This is probably the best general interest book ever written about biotech. The book follows a company, Vertex Pharmaceuticals, from its inception through its “growing pains”, and ultimately to its success. Like a good thriller, it has it all – good guys versus bad guys, heart-stopping action, and pathos. Enjoy!

WEBSITE:

A useful website, www.evelexa.com, is designed to provide free information, advice, and support to life sciences entrepreneurs. Included on the site is a manual called “The Entrepreneur's Guide to a Biotech Start-up”, by Peter Kolchinsky, which is available for free download. It offers background information on all of the many aspects of the industry, as well as practical, simple, down-to-earth advice.
on the “nitty-gritty” of how to pull it all together (including guidelines for salary, equity split, drafts of standard legal agreements, etc.). All of you should read this! The site also has regular columns on various topics, and a job board, along with other features.

SUPPLEMENTARY ON-LINE COURSES:

Those of you who do not have a background in the life sciences may benefit from one of a number of self-study courses designed to provide an overview of the relevant technical aspects of the business. One such course, entitled “Principles and Practice of Drug Development”, was prepared by Stanford University. The point person at Stanford for the course is Chaitan Khosla, Professor of Chemistry at Stanford. He can be reached at khosla@stanford.edu.

Similarly, there are two different series of courses designed by The Pharmaceutical Institute. The first series, comprised of 9 parts, covers all of the different functional areas within the industry (such as Discovery, Development, Manufacturing, etc.). The second series, also comprised of 9 parts, covers the different therapeutic areas (such as Cardiovascular, Metabolic, CNS, etc.). For more information about any of these modules, I refer you to The Pharmaceutical Institute’s web-site (www.pharmainstitute.com/pi/education.html).

You will receive hard copies of all required and recommended readings, as well as links to those optional readings available on-line. Hard copies of optional readings that are not available on-line will be kept in the library, reserved for your use.
STRATEGY AND BUSINESS MODELS
During this first session, (after an orientation to the logistics of the course), we will discuss the biotechnology industry’s structure and strategies, in the form of examination of various business models – their rationale and sustainability. The session will also stress the economics of the industry as a whole, as well as of individual functions therein. To accomplish this goal, we will use a recently written case about MorphoSys, a Germany based antibody company which must weigh the trade-offs of running their business as a “technology” business versus as a “product” business, with the concomitant tradeoffs of risk versus return.

CASES:


ARTICLES:


INVITED GUESTS: TBD
DRUG DISCOVERY

During this session, we will focus on options available to companies to generate a strong pipeline of novel drug candidates. The focus will be strategic, organizational, and operational, rather than technical.

CASE:

How does a company increase research productivity? Can an intrinsically creative process be managed with metrics? A major pharmaceutical company, Wyeth (now part of Pfizer) gives it a try.

NOTES:
A background piece on the science underlying biotechnology.


ARTICLES:

http://www.kellogg.northwestern.edu.


BOOKS:


INVITED GUESTS: TBD
DRUG DEVELOPMENT
During this part of the session, we will discuss the clinical and regulatory processes. To those trained as scientists, clinical development seems so simple, yet it is the most complex, risky, and expensive part of the business. In this area, the company must make tradeoffs between rigor and practicality, in a process that is ultimately responsible for whether a company will succeed or fail. In development, outstanding execution is necessary but not sufficient for success. Strategic and tactical planning (in advance) is what separates the winners from the losers.

CASE:

NOTES:

ARTICLES:
INVITED GUESTS: TBD
INTELLECTUAL PROPERTY
Today, you will be introduced to both legal and business elements of intellectual property (IP), and how company operations and strategy need to take IP into account. We will use the case of Teva Pharmaceutical Industries, Ltd, the world’s largest generics company, to discuss the relative economics and business systems for generic vs. proprietary pharmaceutical companies, and the blurring of the line between the two which is beginning to occur.

CASE:

ARTICLES:
Carreyrou, John and Barbara Martinez. “Board Members at Bristol-Myers Told to Fire CEO.” The Wall Street Journal (September 12, 2006).


**BOOKS:**

**INVITED GUESTS:** TBD
MANUFACTURING\(^1\)
Unlike in other industries, where manufacturing is all about lowering cost of goods, manufacturing plays a more strategic role in the pharmaceutical industry. It is the key element used by regulators to define and approve classic biotechnology products (biologics), and also is critical to establishing barriers to entry of others.

CASE:

ARTICLES:


Thiel, Karl A. "Biomanufacturing, from bust to boom... to bubble?" *Nature Biotechnology,* vol. 22, no.11 (November 2004): 1365-1372. [http://www.nature.com/naturebiotechnology](http://www.nature.com/naturebiotechnology).

INVITED GUEST: TBD

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\(^1\) Before starting our discussion of manufacturing, we will spend a few minutes upfront review the models of industry and product economics which you have prepared.
DEALS: FINANCINGS IN THE CAPITAL MARKETS
It takes years for most biotechnology companies to become profitable. It takes hundreds of millions of dollars of investment to get a company to that point. In this session, we will assume that the technology and/or product is financeable. Yet, even though money may be available to a company, knowing when and how to collect it is a key decision for management. Today, we will discuss the most common vehicles for raising money: private or public financings. (It is assumed that you covered venture capital in your "Lab to Market" course).

VC’s, PIPE’s, IPO’s, Convert’s, Corporate deals – What to do?

CASES:
This case is all about the "who, what, where, when, how, and why” of raising money for an established biotechnology company.

Describes the mechanics of going public.

ARTICLES:


INVITED GUESTS: TBD
DEALS: PARTNERSHIPS AND FINANCINGS

It takes years for most biotechnology companies to become profitable. It takes hundreds of millions of dollars of investment to get a company to that point. In this session, we will assume that the technology and/or product is financeable. Yet, even though money may be available to a company, knowing when and how to collect it is a key decision for management. Today, we will discuss a common vehicle for raising money: corporate partnerships.

CORPORATE PARTNERING:

This week’s session will be a hand-on experience, as you will prepare for and participate in negotiating a corporate deal between four different parties, with different goals and conflicting needs.

CASE:

Kranzler, Jay. “Cypress Bioscience, Inc. (B): Finding Milnacipran's Mate.” (July 30, 2005). This case will serve as the basis for a mock negotiation, complicated by the typical need for a biotech company to renegotiate old agreements to form new ones.

NOTE:


ARTICLES:


INVITED GUESTS: TBD
SALES & MARKETING

If you love scandals, then this is the session that you have been waiting for! Pharmaceutical sales reps do not sell; they educate. Yet, lately, the press has vocally portrayed the industry’s sale techniques as having undue influence on the prescribing habits of physicians. Are the cynics correct? If so, is it truly a problem?

CASE:
The anti-depressant market grew from a small “niche”, to its position today as the largest category in all of pharmaceuticals. This case will give us a chance to discuss how science and marketing came together to effect that transformation, and how the two continue to be used today to differentiate one anti-depressant from another.

ARTICLES:


INVITED GUESTS: TBD
PERSONALIZED MEDICINE
Today we will consider Genomic Health, one of the hottest companies in the “personalized medicine” space, to gain an understanding of the historical differences between the diagnostics and therapeutics industries, and to learn of the convergence now underway.

CASE:

ARTICLES:


PRESENTATIONS:
“The Case for Personalized Medicine”
http://www.personalizedmedicinecoalition.org/sites/default/files/TheCaseforPersonalizedMedicine_5_5_09.pdf

WEBSITE:
www.personalizedmedicinecoalition.org

INVITED GUEST: TBD
PRICING: The Interface of Economic Analysis, Public Policy, and Bio-ethics

Our prior sessions on sales and marketing and intellectual property provide a natural segue into a discussion of the inter-related topics of pricing and reimbursement, which, in turn, requires an analysis of the economic value of the product, tempered by a consideration of the ethical issues around access to care. While focusing on pricing, this session will also serve as an introduction toward the much broader fields of health policy and bioethics. Because of the breadth of today’s subject, we will be using two different cases – Metabical, to provide a little more practice on the process of modeling and analysis, and Gilead, to provide a more strategic perspective on pricing.

CASES:


NOTES:

A great overview on a topic that we will have little time to discuss.


ARTICLES:


BOOKS:
It has been a tough couple of years for the pharmaceutical industry. The exposé’s about the side effects of Vioxx®, the off-label sales of Neurontin®, and the suicide risk of anti-depressants have contributed to a public view of the ethical pharmaceutical as not being very ethical at all. For your interest, the list below includes only mass market books published within the past year that deal with the industry. Only two (the book by Hank O’Connell, CEO of Pfizer, and a book about the potential for biological enhancement, by
Naam) present a favorable profile of what we do and how we operate. Unfortunately, while the accounts in all of the other books (which, needless to say, have sold more copies than the favorable ones) are all repetitive, one-sided, and exaggerated, there is, unfortunately, some truth in their arguments, which we need to heed and address.


Hawthorne, Fran. Inside the FDA: The Business and Politics Behind the Drugs We Take and the Food We Eat. Wiley (2005).


WEBSITES:

The American Journal of Bioethics (www.bioethics.net)

Bioethics Research at the Hastings Center (www.thehastingscenter.org)

Bioethics Resources on the Web – National Institutes of Health (www.nih.gov/sigs/bioethics/)

BioethicsWeb- The Gateway for Internet Resources for Biomedical Ethics (www.bioethicsweb.ac.uk)

PharmacoEthics (www.pharmacoethics.com)

The President's Council on Bioethics (www.bioethics.gov)

INVITED GUESTS: TBD
BIOTECHNOLOGY: Non-Healthcare Applications

Biotechnology is not all about drugs (or diagnostics or devices); there are applications across many industries, including consumer goods, industrial chemicals, and agriculture. To give you a little taste for the breadth of applications, we are going to close the course with a case on the newly emerging “cleantech” field, through the use of biotechnology to produce clean “biofuel”.

CASE:

NOTE:

ARTICLES:


WEBSITES:
Food and Agriculture Organization of the United Nations: http://www.fao.org/biotech/


INVITED GUESTS: TBD
GENERAL SOURCES

Journals:
- Nature Biotechnology; http://www.nature.com/nbt (especially the BioEntrepreneur column).
- Nature Reviews Drug Discovery; http://www.nature.com/nrd.
- New England Journal of Medicine; http://content.nejm.org (the most prestigious general medical journal, with frequent articles on policy issues).

Trade Publications:
- Chemical and Engineering News; http://pubs.acs.org/cen.
- In Vivo: The Business and Medicine Report; http://archive.windhover.com (the most sophisticated of all of the trade publications, with feature articles only, backed by detailed analysis).
- Medical Technology Stock Letter; http://www.bioinvest.com/FrontEnd. (biotechnology stock-picking advice by one of the best in the business)
- Modern Drug Discovery; http://pubs.acs.org/journals/mdd.
- Signals; http://www.signalsmag.com (on-line magazine with more of a financial bent. Edited by Recombinant Capital).

1. **Free** resources (of which there are not many) are noted in **bold**.
2. I will try to make sure that as many of the journals and books listed above as possible are available (in some form) at the Library.
3. **ALL ARE OPTIONAL!**

Data Sources:
- Analyst Reports from Investment Banks (*only available to account holders*)
- Ernst & Young Annual Reports on Life Sciences; http://www.ey.com (free to clients).
- Evelexa (advice for bioentrepreneurs); www.evelexa.com.
- IMS; http://www.IMSHealth.com (the best source for data on markets).
- Medscape; http://www.medscape.com (general reviews and on-line continuing education on various medical topics, organized by specialty).
- Pharmaprojects; http://www.pjpubs.com/pharmaprojects (lists status of all drugs in R&D).
- Recombinant Capital; http://www.recap.com (great data source on corporate deals. **Some of the data is free**).
- Think Pharm; http://www.thinkpharm.com (focuses on providing patent expiration dates).
Books:
- Startup to IPO: How to Build and Finance a Technology Company. Donald H Macadam. Xlibris (February 2, 2004).

Government / Industry Sites:
- BIOCOM; http://www.biocom.org (California regional biotechnology industry trade organization).
- FDA; http://www.fda.gov.
- PhRMA.org; http://www.phrma.org (pharmaceutical industry trade organization).
- US Department of Commerce; http://www.commerce.gov (periodically publishes reports on the biotechnology industry).