What Is a *Biopharmaceutical?*

Part 2: Company and Industry Definitions

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Both major US trade associations dilute the use of the word *biopharmaceutical*, especially as it refers to companies, such that the industry no longer exists.

This is the conclusion of a two-part article about basic terminology problems concerning *biopharmaceutical* (and *biotechnology*) products, technologies, companies, and the industry. Part 1 reviewed basic definitions, concentrating on products ~1. Four different views and patterns of use of *biopharmaceutical* were described—each with its own definitions of products and companies. (See "Paradigms of Biopharmaceutical Terminology.") With diverse definitions in use, exercise caution and skepticism whenever encountering *biopharmaceutical* (and *biotechnology*) or related terms. The speaker/author may be referring to biopharmaceutical in the context of

- biotechnology-derived pharmaceuticals
- just new biotechnologies (genetic engineering and later)
- biotech-like companies, including small-molecule and drug R&D service companies
- the entire pharmaceutical industry.

This article examines definitions and (mis)use of *biopharmaceutical* (and *biotechnology*), particularly as applied to companies and the industry. This includes terminology used by the financial community, popular press, industry analytical studies, trade associations (BIO and PhRMA), and various companies and industry sectors claiming to be biopharmaceutical.

BIO IN BIOPHARMA

The broad biotechnology paradigm defines *biopharmaceutical* as involving biotechnology and recognizes that most relevant companies are R&D-intensive and have no marketed products. Based on this, a good working definition of a *biopharmaceutical company* is:

A company primarily (determined as majority of revenue, activity, and so on) involved in the research, development, manufacturing and/or marketing of biotechnology-based pharmaceutical products or surrogates, including gene and protein sequences.

This definition may be broadened to include companies primarily involved with related supplies and services—culture media, bioreac-

The opinions expressed in this article are those of the author. We invite readers to contribute their own ideas on this important subject. Despite the obvious lack of consensus, we believe the effort to define biotechnology accurately is necessary and worthwhile. For more food for thought, see the BEI Company Study on page 22.

—The Editors

Paradigms of Biopharmaceutical Terminology

	Biopharmaceutical	Biotechnology	Pharmaceutical	Drugs	Users
Broad Biotechnology	All biotechnology-based pharmaceuticals	Involves living organism sources/ bioprocessing	All medicinal products (all pharmaceuticals)	Chemical/non-biological source pharmaceuticals	Core biopharma industry (especially in United States); many tech-savvy sources
New Biotechnology	Only new biotech (genetic engineered) pharmaceutcals (primarily rDNA protein and monoclonal antibody-based)	Only new biotech (genetic engineered) products	All medicinal products (all pharmaceuticals)	Chemical/non-biological source pharmaceuticals	Some in biopharma industry (especially in Europe); some tech-savvy sources; EMEA/EU
Biotechnology Business	All pharmaceuticals from biotech-like (small, R&D intensive) life science companies (plus biopharmaceuticals from Big Pharma)	All products from biotech-like companies (plus biotech products from large companies)	All medicinal products (all pharmaceuticals)	Chemical/non-biological source pharmaceuticals	Business/financial communites; popular press; BIO
Pharma Business	All medicinal products (all pharmaceuticals are biopharmaceuticals)	All products from pharmaceutical and biotech companies	Biopharmaceutical used as synonym for pharmaceutical	Term often dropped from usage	Some Big Pharma supporters

At least four conflicting paradigms of biopharmaceutical terminology are in common use: *broad biotechnology, new biotechnology, biotechnology business,* and *pharma business*. Part 1 of this article considered the first two paradigms. Part 2 discusses the second two.

tors, assays and analytical services, and facilities design. Thus is would include companies primarily involved in bioinformatics, genomics, proteomics, and so on, including drug (non-biological molecule) design companies that are substantially using recombinant proteins, phages, nucleotide sequences, or other biological molecules or technologies.

It excludes companies primarily involved with non-biological chemical/drug technologies, including novel chemistries for screening or development of small-molecule drugs. Here is a simple test: If a pharmaceutically oriented company's end products—the agents being screened, designed, delivered, or developed, and/or its core technologies—are biotechnology-based (involve the use of organisms, cells, or derived biological molecules or surrogates), it is a *biopharmaceutical company*. Otherwise, it is almost certainly a *drug company* working with chemical materials and technologies.

Classification of organizations/companies as *biopharmaceutical* (or not) can be more complex than classifying products and technologies. Some biopharmaceutical companies—Biogen, Amgen, and Genzyme—also develop, manufacture, and market synthetic drugs. The reverse is also true: Many large international drug companies—Hoffmann-La Roche, Merck, and others—are also involved in biopharmaceuticals. Thus, when considering parameters such as total industry sales, it is better to total the sales of individual products rather than classify a company with diverse products as either *biopharmaceutical* or *drug*. Also, few biopharmaceuticals can be attributed to a single company. Different companies often deserve credit for research, development, manufacturing, and marketing.

Hype Above All

But few outside the core biopharmaceutical industry use such a definition of *biopharmaceutical* (or *biotechnology*). That is particularly true among the financial community and associated media, downstream popular media, and many drug companies, pharmaceutical industry sectors, and trade associations. Among those people, the biotechnology-business and, to a growing extent, the pharmaceutical-business paradigms predominate. Although authors and analysts commonly base their stories and analyses on technologies, few seem to make relevant distinctions based on them.

In the biotechnology business view, anything that appears high-tech and involves pharmaceuticals (or life sciences), particularly if it is about small companies, is described as *biopharmaceutical* (and/or *biotechnology*). Thus, hundreds of small drug discovery and related service companies that have no involvement in or use of biotechnologies are called *biopharmaceutical*. Similarly, large international drug companies (Big Pharma) are often included. For example, the *BioSpace Glossary* defines a *biopharmaceutical* company as "involved in research of new drugs as well as the manufacturing, marketing, and distribution of pharmaceutical products" ~2. If "drugs" is presumed to mean *pharmaceuticals*, that definition encompasses the entire pharmaceutical industry. Similarly, the NASDAQ Biotechnology Index includes small biotechnology and small pharmaceutical companies ~3.

Articles in the major business/financial periodicals, newspapers, and other popular press often apply *biopharmaceutical* (and *biotechnology*) to products and companies without any real biotechnology involvement. The terms appear where it would be more appropriate to use *emerging, R&D-intensive, biotech-like, startup, new*, or *small molecule*. Misuse is so common that even writers working from sources that have taken care with their terminology often generalize and arbitrarily use other terms, resulting in serious errors and problems for those trying to interpret what is reported.

In terms of sheer volume, the press is dominated by public relations, dumbed-down communications, spin,

Products Before Companies

Many industry analysts consider *biopharmaceutical* to encompass essentially all pharmaceutical (drug and biopharmaceutical) companies and service suppliers except Big Pharma. They sometimes switch to more restrictive definitions when referring to products.

For example, Ernst & Young in its 18th annual study of the US healthcare-related biotechnology industry includes "companies that use modern biological techniques to develop products or services" ~4. But it excludes large pharmaceutical companies and includes many companies with no significant use of biotechnology. **Six of 14 (43%) of the "biotech products" listed as approved in 2003 are actually fully synthetic drugs** (Cialis, Entriva, Rebetol, Lexiva, Gliadel, and Fuzeon), while a list of industry blockbusters is confined to "biologics," a term not defined or used elsewhere but apparently restricted to recombinant proteins, including some regulated as drugs.

Companies such as Gilead Sciences, Vertex, BioCryst, and many others with little or no use of biotechnology or its products are repeatedly discussed as "biotech" companies. Other drug companies—Theravance, Idenix, and Triangle Pharmaceuticals—are included among the top biotech acquisitions and mergers in 2003.

and hype. The main concerns of the great majority of biotechnology companies are financing, stock sales, and prices. Proper use of terminology is a low priority at best. Much of the misuse in the popular press reflects the inconsistent and incorrect use of the words in the hundreds of press releases issued daily, particularly by small companies.

Much, if not most, of what is reported by companies, analysts, and the popular press involves spinning interesting or compelling stories for technologically illiterate audiences. *Biopharmaceutical* and *biotechnology* are buzzwords that attract audience attention and evoke warmer, more positive images than alternatives such as *drugs*. Both companies and journalists often seem to care more about attracting attention and exploiting biotech's positive image than about precise use of particular terms. For many users and uses, lumping all smaller high-tech life sciences and pharmaceutical companies together is appropriate, but this does not warrant labeling them all as biopharmaceutical (or biotechnology) companies.

Worthless Analyses

Misuse of terminology has rendered much biopharmaceutical industry data, market and other analytical reports, and press coverage worthless, misleading, and/or impossible to compare with other data. Nearly all of the widely recognized and presumed authoritative biotechnology and pharmaceutical industry studies use *biopharmaceutical* (or its synonyms) to refer to all small pharmaceutical or life sciences companies or to all pharmaceutical companies. Few of these reports and sources bother to define their terms or their criteria for including some companies and products and excluding others.

To make matters worse, many reports use terminology inconsistently even within the same report and, particularly, between years (with small-molecule drug companies more commonly included in recent reports than in older ones). Many leading industry reports—such as those from Ernst & Young, Burrill & Co., Recombinant Capital and major stock analysts—obviously use fluid definitions and criteria because they discuss different products and companies. Even in the same report or section, authors may use various terms—biopharmaceuticals, biologics, drugs, biotech drugs, and so on. (See "Products Before Companies.") These and other terminology-based problems are further compounded as downstream writers and analysts reinterpret results, often using their own haphazard terminology.

Biopharma Company Wannabes: Analysts are not the only source of the problem. Many pharmaceutical and life science companies that lack any significant use or involvement with biotechnology claim to be *biopharmaceutical*. These companies often describe themselves as "a biopharmaceutical company developing novel chemistries for the development of small molecule drugs." Many of these companies and their technologies are solely chemical based. Terminology abusers include company executives who should spot such mislabeling as errors or incompetence when reviewing market research, competitor analysis, or other information for their own decision-making.

Many executives and companies persist in misusing *biopharmaceutical* and *biotechnology* in presentations, publications, and press releases. Why? Perhaps they rationalize that they are just following the pack. Or maybe they believe (or want to) that *biopharmaceutical* and *biotechnology* need not involve actual biotechnology. Or maybe they hope to avoid the image and other problems facing Big Pharma by redefining themselves as biopharmaceutical.

Unintended Consequences

Incomplete, ill-defined, and misleading BIO and PhRMA product lists have persisted for years. (See "(Dis)Associations.") This has resulted in the widespread promulgation of incorrect and misleading information about biopharmaceutical products and the industry. Despite their caveats and problems, most users look at the titles, take those lists to be authoritative, and use them to report progress and provide statistics concerning biopharmaceutical products and the industry. For example, a recent front-page article in the *Washington Post* about the debate over generic biopharmaceuticals included a bar chart showing by year the number of "biotech drugs" approved in the past decade, based on BIO's data with its many small-molecule drugs from companies with no significant use of or involvement with biotechnology ~9.

How did these lists become so inconsistent and misleading? BIO has vested interests in redefining *biotechnology* and *biopharmaceutical* to be more inclusive of its diverse membership and to bulk up the number of relevant new products. PhRMA and its members have interests in associating themselves with the hard-earned

(Dis)Associations

Those seeking clarity and authoritative information—lists of marketed or recently approved biopharmaceuticals, for example—will find little help and much inconsistency and contrived propaganda from the major US biotechnology and pharmaceutical trade associations: Biotechnology Industry Organization (BIO) and Pharmaceutical Manufacturers and Research Association (PhRMA). Those organizations use varying terminology inconsistently to refer to biopharmaceuticals. Even their lists of approved products are substantially misleading.

BIO: For *biopharmaceuticals*, BIO primarily uses the terms *biotech(nology) drugs, biotechnology therapeutics* and *biologics* without differentiating among the terms. BIO has a simple definition of biotechnology, citing use of biological processes to solve problems and make useful products ~5. However, in many of its communications, the organization ignores its own definition.

BIO's list of "Approved Biotechnology Drugs, 1982–2003," includes "biologics developed by biotechnology companies and pharmaceutical companies, as well as small-molecule products developed by biotechnology companies, and other selected small-molecule or tissue-engineered products." *Biologics* is defined much the same as *biopharmaceutical* is in the broad biotechnology paradigm. **This list does not claim to be—nor should it be considered—complete or authoritative, but most reporters and writers using it presume that all products included are biopharmaceuticals (and/or from actual biotechnology companies).** Labeling the list *biotechnology drugs* (itself a self-conflicting euphemism) is thus misleading.

BIO's arbitrary inclusion of many small-molecule drugs inflates the number of new biotechnology drugs. A total of 69 of 184 (38%) products listed are clearly drugs (nearly all synthetic). BIO reports 37 FDA product approvals in 2003, more than all new molecular entities (both drugs and biologics) reported by the FDA that year ~6. A source that uses the broad biotechnology paradigm to define biopharmaceuticals reports at most half that many ~7.

Not only does BIO include products in its list that do not use biotechnology in their production, it fails to include a large number of biologics, particularly vaccines and plasma-derived proteins (perhaps because they are from non-member Big Pharma companies). Essentially all relevant nonrecombinant vaccines are omitted, including acellular pertussis (DTaP), hepatitis A, rabies, varicella, pneumococcal conjugate, and haemophilis B vaccines. Similarly, only a few plasma-derived proteins are listed, and several monoclonal antibody-based radiodiagnostics are excluded.

PhRMA's 2004 survey, *Medicines in Development: Biotechnology* lists products in development and those approved in the United States ~8. Hidden in the footnotes is a disclaimer that the lists of products are not comprehensive. In fact, they exclude many relevant products. The lists tend to include products from large (more likely to be member) companies.

The glossary defines *biotechnology* as involving industrial bioprocessing and *biotechnology medicines* in line with EU usage (the new biotechnology paradigm). Buried within the glossary's definition of biotechnology is a note that for this publication, "only those products that involve recombinant DNA, monoclonal antibody/hybridoma, continuous cell lines, cellular therapy, and gene therapy are included."

Thus only users who examine the appended glossary and footnotes in detail would ever realize that only recombinant, monoclonal antibody, and a few other products are included, and nonrecombinant cultured proteins, vaccines, blood-derived, and other biopharmaceuticals are excluded. Continuous cells lines are within the report's own criteria, but many relevant products are omitted—poliovirus, hepatitis A, rabies, and varicella vaccines. PhRMA's biotechnology listings also include some small-molecule drug products.

and well-deserved good will and public image of *biotechnology* and *biopharmaceuticals* and with new, thoroughly innovative technologies.

Neither BIO nor PhRMA has incentive to use clearly defined terms and criteria nor to provide comprehensive lists of approved biopharmaceuticals. For BIO, it would mean significantly paring down its list and including many products from Big Pharma (nonmembers). For PhRMA, it would mean including products not genetically engineered, particularly vaccines and blood products, which many perceive as old or low-tech and/or which evoke negative images (such as vaccines with their unending safety controversies and plasma protein products with their historical contamination with HIV and hepatitis C virus).

BIO and the biotechnology industry were long dominated by biopharmaceuticals, particularly in terms of companies. That may no longer be true. BIO now takes in and represents any life-sciences–based or small-pharmaceutical companies, including a relatively recent influx of small-molecule drug, drug-design, and other R&D service companies. Many of those do not actually use biotechnology, and most of them primarily serve Big Pharma.

As recently noted by *BioCentury*, "BIO can best be viewed as a powerful megaphone that collects and amplifies the voices of groups of relatively small and highly disparate entrepreneurial companies united more by attitude than technology. PhRMA's task is to put a human face on companies that, because of their size, success, and the essential nature of their products, are easy to dislike. In both cases, the ability to influence public policy is directly determined by the quality and strength of their communications" ~10. With both BIO and PhRMA under new leadership, it will be interesting to see whether and how they fix their terminology problems. Perhaps it is time for the core biopharmaceutical industry to start its own trade association, and/or for BIO to be renamed something else—perhaps the Biological Industries Organization.

Pharma–Biopharma Fiction

The idea—associated with the pharmaceutical industry paradigm—that the pharmaceutical industry is converging, morphing, or being reborn as the *bio*pharmaceutical industry has been repeated in many studies, articles, and meetings. The pharmaceutical industry's adoption of biotechnologies for drug screening, discovery, and other preclinical R&D—largely based on outsourcing and in-licensing from

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small companies—is the basis for this supposed transformation.

The Ernst & Young 2000 biotechnology industry report used convergence as its theme and claimed that "the lines between biotech and pharma [are] inextricably intertwined" ~11. A more recent report, *Biopharmaceutical Industry Contributions to State and US Economics*, published by the Milken Institute with partial sponsorship from PhRMA, further illustrates that idea ~12. That report uses Bureau of Labor employment statistics covering the entire pharmaceutical and parts of the biotechnology industry and renames the whole thing biopharmaceutical (with more than 400,000 employees).

PhRMA's Pharmaceutical Industry Profile 2005 appears to be part of a concerted disinformation or propaganda campaign to redefine and rebrand the pharmaceutical industry, particularly its members (Big Pharma), as the biopharmaceutical industry ~13. PhRMA's industry profile report follows that of the Milken Institute in laying the groundwork (public relations-wise) for the idea of industry convergence. Both reports were hyped in widely disseminated press releases.

As crudely explained without support or documentation, the pharmaceutical industry has undergone a transformation and morphed into the biopharmaceutical industry, becoming more research-driven through adoption of biotechnologies for research (particularly, lead identification) and ties to high-tech R&D service and biotechnology companies. Also, computational chemistry and other breakthroughs have altered the basic nature of the industry. Biopharmaceutical is defined as the combination of biotechnology and (Boolean OR) pharmaceuticals—add a little biotechnology into the mix and the industry is now biopharmaceutical.

As defined in the report and the accompanying Burrill & Co. press release ~14, a biopharmaceutical company need only be involved in R&D of medicines for healthcare. Biotechnology companies are defined as not members of PhRMA (Big Pharma). That usage follows the pharmaceutical industry paradigm or view of biopharmaceutical. Throughout PhRMA's Pharmaceutical Industry Profile 2005, which switched its terminology just this year, biopharmaceutical is used where it would be better to use pharmaceutical. What's next? Will PhRMA rename itself BiophRMA?

What is particularly troublesome about this paradigm for the actual biopharmaceutical industry is that biopharmaceutical products and companies are not mentioned and seemingly do not exist. Instead, everything formerly pharmaceutical is suddenly biopharmaceutical. Biotechnology and pharmaceutical are defined as subsets of biopharmaceutical, with biotechnology companies generally subservient to Big Pharma. That is unlike the traditional, generally accepted paradigm in which biopharmaceutical is a distinct subset of pharmaceutical, with biopharmaceutical being the intersection, not the union, of biotechnology and pharmaceutical.

A Google or other broad Internet search now results in a number of recent reports, articles, and meetings about the convergence of information-, bio- and nanotechnologies. So the fad of pharmaceutical and biopharmaceutical convergence may already be passé.

In any case, the pharmaceutical industry has not morphed into the biopharmaceutical industry. Biopharmaceutical and drug products, technologies, R&D, companies, and industries can be readily distinguished. As discussed in part 1 of this article, research methods do not define industries. Products and their methods of production—

biological or chemical—define industries. Nothing has altered these two industries' basic business models or the big picture.

The underlying source of the pharmaceutical industry's products, R&D, technologies, and revenues remains primarily chemical, with the industry dominated by drugs at all levels. Depending on the criteria used, at most 15–20% of pharmaceutical products, sales, and R&D involve biopharmaceuticals ~15. Only a small portion of Big Pharma is substantially involved in biopharmaceuticals—has one or more internally developed and/or manufactured product(s). A few Big Pharma companies are the source for nearly all older biopharmaceuticals—primarily vaccines and plasma proteins. More large drug companies will be manufacturing and/or marketing biopharmaceuticals in the coming years, particularly recombinant monoclonal antibodies. However, other than in terms of the number of companies, drugs have and will continue to clearly dominate the pharmaceutical industry.

Outsourcing = Biopharma? Big Pharma has become more dependent on outsourcing services—most recently drug screening, design, and other R&D—and in-licensing technology. That has resulted in the creation of hundreds of new support and services companies. However, that does not constitute a revolution nor warrant renaming the industry *biopharmaceutical*. It is simply a continuation of trends evident in the 1990s with industry consolidation and outsourcing of clinical trials, IT, and other activities.

PhRMA members spend more than $38.8 billion annually on US-based R&D ~13. Outsourcing of just a small percentage of R&D can easily account for hundreds of new small companies. Also, most of the drug screening/discovery technologies heralded as *biopharmaceutical* and *revolutionary* are not fundamentally new. The industry adopted similar chemical modeling, structure–activity relationships, and automated drug screening/discovery technologies as early as the 1970s.

Some people argue that biotechnology is now involved in the discovery and early R&D of just about every pharmaceutical product. But one could also argue that chemistry and chemical technologies are comparably essential to the R&D and manufacture of every biopharmaceutical. Computers and information technology have fundamentally altered pharmaceutical R&D and the industry as much as or more than biotechnology, but no one proposes changing the name of the industry based on that.

Strategic Considerations

Removing the link between *biopharmaceutical* (and its synonyms) and biotechnology devalues and eliminates its utility for those truly involved with biopharmaceutical products, technologies, companies, and industry. *Biopharmaceutical* and *biotechnology* evoke positive images in comparison with *drug* and *pharmaceutical*. Redefining the pharmaceutical industry to be biopharmaceutical is simply wrong and purposely misleading. Everyone wants to gain advantage, get in on, and be associated with a good thing. Because of their hard-earned, well-deserved reputation for advanced technology, innovation, and high value to society, biopharmaceutical terms are already being abused and co-opted. Terminology obfuscation is also a common way to influence regulations. For example, how better to complicate the public debate and delay generic biopharmaceutical regulations than to take over, muck up, or obfuscate the underlying terminology?

Terminology used incorrectly or without definition becomes useless among a jumble of other terms and meanings. Then others can adopt, co-opt, or redefine it. If these terms continue to be (mis)used to refer to anything biotech-like or pharmaceutical, they could well be used to rebrand (in name only) the entire pharmaceutical industry—Big Pharma becoming Biopharma. Those who stand to gain from rebranding themselves may find these terms irresistible for marketing and image reengineering, to the detriment of companies actually using biotechnology to create human therapeutic products.

Research methods do not define industries. Products and their methods of production—biological or chemical—define industries.

Use It or Lose It

This article recommends adoption of the broad biotechnology paradigm of *biopharmaceutical* as involving biotechnology-derived pharmaceuticals. *Biopharmaceutical* has significant advantages over other terminology: It has a long history of use; appears to be the predominant term (particularly in the United States); allows use of the abbreviations biopharma or biopharm, which fits well with other common terminology (pharma); uses *bio-*, which provides a well-understood link to biotechnology; sounds better than terms such as *biotechnology medicine*; and is not self-conflicting, (*biotech drugs*). Regulatory-based terms, such as *biologics* and *drugs* have their own specific and convoluted definitions and are best avoided for general use.

To prevent the loss of its unique identity, the biopharmaceutical industry and its supporters must be mindful of terminology. They should adopt and consistently use *biopharmaceutical* (or a synonymous term) and define the terms they use, or at least make their meaning clear in context.

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