

Litigation Impact

By Krista L. Cosner

The biotech explosion has led to an onslaught of potentially blockbuster products that will enter the market at a rate expected to outpace traditional, chemically based drugs.

Are You Prepared to Defend Biopharmaceuticals?

Dramatic changes in defending pharmaceutical product liability cases are on the horizon due to the ever-increasing presence of biologic medicines in the marketplace. While biopharmaceuticals are well established in biomedicine

and have provided therapies for diseases and conditions for which no therapies previously existed, their presence in personal injury lawsuits has been sporadic compared to traditional, chemically based drugs. As more and more biopharmaceuticals gain marketing approval, an increase in product liability lawsuits involving them is sure to follow.

What exactly are biopharmaceuticals? How do they differ from traditional pharmaceuticals? What are the applicable laws and regulating bodies? How will they impact your product liability practice? And more important, are you prepared to defend biopharmaceuticals? This article will attempt to answer these questions, provide a basic working understanding of these products and introduce an exciting yet challenging new direction that your practice might take.

Presence and Expected Growth in the Marketplace

Biopharmaceuticals represent the fastest

growing segment of the pharmaceutical industry. In 2009, traditional, chemically synthesized drugs, also known as small-molecule drugs, accounted for 76.7 percent of pharmaceutical sales, totaling \$396.7 billion. *See Monoclonal Antibodies: 2010, 14 (Table 4) (Datamonitor, Oct. 7, 2010).* Biopharmaceuticals, also known as large-molecule drugs, consisting of therapeutic proteins, monoclonal antibodies and vaccines, accounted for 23.3 percent of industry sales, totaling \$120.4 billion. *Id.* The expected growth rate, however, between these segments of the pharmaceutical industry differs significantly with biopharmaceuticals outpacing traditional chemical drugs over the next six years. *Id.* The small-molecule drug market is forecasted to shrink by 0.3 percent to \$390 billion, whereas the large-molecule market is expected to grow by 6.3 percent to \$168 billion. *Id.* Indeed, some analysts have predicted that by 2013, four of the top five revenue-generating pharmaceuticals will be biologics. *See Table 2; Michael Good-*



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man, *Sales of Biologics to Show Robust Growth Through to 2013*, 8 Nature Reviews Drug Discovery 837 (Nov. 2009).

Protection from exposure to competition from generic manufacturers explains the primary reason for the different projected growth rates. A large number of small-molecule blockbuster therapies will lose patent protection between 2011 and 2013, including the world's largest-selling drug, Pfizer's Lipitor. Forecasters do not predict the same degree of sales erosion from manufacturers attempting to copy innovators in the biopharmaceutical market due in part to the manufacturing challenges of copying biopharmaceuticals, discussed further below.

Major pharmaceutical companies have begun efforts to make up for this expected loss from patent expiry by diversifying their product pipeline with biopharmaceuticals. In recent years, Big Pharma has been acquiring biopharmaceutical companies, developing their own biopharmaceuticals and entering licensing agreements with biotech companies to provide the mass manufacturing and marketing muscle. In the United States and Europe, the top two biopharmaceutical markets in the world, just over 200 products have gained regulatory approval. Gary Walsh, *Biopharmaceutical Benchmarks 2010*, 28 Nature Biotechnology 917 (Sept. 2010). As of 2010, however, the biopharmaceutical pipeline included approximately 360 monoclonal antibodies and therapeutic protein products in clinical trials, with hundreds of other biologics in earlier phases of development. *Id.* at 923.

Differences Between Biopharmaceuticals and Traditional Drugs

Historically, most drugs have been based on the chemical synthesis of small molecules. The last two decades heralded unprecedented advancements in biotechnology. As a result, an increasing number of large-molecule medicines have developed from substances derived from biological sources or produced using biotechnology. Many believe that we have only scratched the surface of potential biopharmaceutical therapies. Rich Ng, *Drugs: From Discovery to Approval*, §§3.1, 4.1, 10.4–10.5 (2nd ed. 2009) (Unless otherwise stated,

the primary source for information in this section, Differences Between Biopharmaceuticals and Traditional Drugs.”).

Fundamental Differences

Traditional pharmaceutical drugs are small molecule drugs which have been chemically synthesized with molecular weights of <500 daltons. They are considered new chemical entities and are produced in manufacturing plants using techniques based on the chemical reactions of various substances. They have well-defined structures and can be fully characterized.

Biopharmaceutical drugs, on the other hand, are protein-based large molecule drugs produced using recombinant DNA technology with molecular weights in excess of thousands of daltons. “Biologics,” as biopharmaceuticals are sometimes called, are produced from living material, complex in structure, and usually they cannot be fully characterized. They include products such as vaccines, blood and blood components, tissues, monoclonal antibod-

ies and recombinant therapeutic proteins. Biopharmaceuticals have been developed to treat a number of common diseases and conditions such as cancer, diabetes, immune deficiencies, cardiovascular disease, metabolic disorders and autoimmune disorders, as well as rare medical conditions such as Pompe disease, Fabry disease and Gaucher disease.

Biopharmaceuticals are considered by some to be more potent and precise than chemically synthesized drugs. Since they are similar to the proteins in the human body, they are more effective at targeting and treating diseases, and have been described as “smart bombs” within the body. Biopharmaceuticals are used in three manners: (1) prophylactically (vaccines), (2) therapeutically (antibodies), and (3) as replacement therapy (hormones, growth factors).

Despite these differences, biopharmaceuticals are indeed “drugs” as defined in the Food, Drug, and Cosmetic Act (FDCA). Section 352 of the Public Health Service

Table 1: Ten Top-Selling Biopharmaceutical Products in 2009

Product	Sales value (\$ billions)	Company
Enbrel (etanercept)	6.58	Amgen, Wyeth, Takeda Pharmaceuticals
Remicade (infliximab)	5.93	Centocor (Johnson & Johnson), Schering-Plough, Mitsubishi Tanabe Pharma
Avastin (bevacizumab)	5.77	Genentech, Roche, Chugai
Rituxan/MabThera (rituximab)	5.65	Genentech, Biogen-IDEC, Roche
Humira (adalimumab)	5.48	Abbott, Eisai
Epogen/Procrit/Eprex/ESPO (epoetin alfa)	5.03	Amgen, Ortho, Janssen-Cilag, Kyowa Hakko Kirin
Herceptin (trastuzumab)	4.89	Genentech, Chugai, Roche
Lantus (insulin glargine)	4.18	Sanofi-aventis
Neulasta (pegfilgrastim)	3.35	Amgen
Aranesp/Nespo (darbepoetin alfa)	2.65	Amgen, Kyowa Hakko Kirin

Source: Gary Walsh, *Biopharmaceutical Benchmarks 2010*, 28 Nature Biotechnology, 917 (Sept. 2010).

Table 2: Top Five Products by Consensus Revenue in 2013

Product	Company	2013 Consensus Revenue (billions)	2012–2013 % Change
Avastin	Roche/Genentech	\$8.90	6%
Advair Diskus	GlaxoSmithKline	\$8.58	–10%
Humira	Abbott	\$7.98	2%
Mabthera/Rituxan	Roche	\$7.56	3%
Lantus	Sanofi-Aventis	\$6.84	7%

Source: Michael Goodman, *Sales of Biologics to Show Robust Growth Through to 2013*, 8 Nature Reviews Drug Discovery 837 (Nov. 2009).

Act (PHSA) defines a “biologic product” as “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide) or analogous product, or arsphenamine or derivative [thereof]... applicable to the prevention, treatment or cure of a disease or condition of human beings.”

42. U.S.C. §262(i)(2005) (corresponding to Public Health Service Act §351(i)). The definition of a biologic product, therefore, is consistent with the definition of “drug” in the FDCA, which is “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man...” or articles “intended to affect the structure of any function of the body of man.” 21 U.S.C. §321(g)(1) (corresponding to the Food, Drug, and Cosmetic Act §201(g)(1) (2002).

Manufacturing Differences

Manufacturing small-molecule and large-molecule drugs differs significantly. The manufacturing process of biopharmaceuticals is more complex and “contributes to product uniqueness.” Basant G. Sharma, *Manufacturing Challenges for Biosimilars—The Process Defines the Product*, 13 European J. Hospital Pharmacy Practice 54 (2007/5), <http://www.ppme.eu/>. Complicated procedures are required in every phase of the biopharmaceuticals manufacturing process to maintain product stability and integrity.

Small-Molecule Drugs—

Chemical Synthesis Techniques

Manufacture of small-molecule drugs occurs through chemical synthesis. The particular synthetic route for the production of a small-molecule product is determined during the development phase and includes reactions such as oxidation-reduction, acid-base, halogenation, alkylation and substitution. Chemical reactions are induced using large reaction vessels with commercial production vessels ranging from 1,000 to 20,000 liters in volume. These vessels contain mechanisms that allow mixing, condensing, venting, measuring and sampling of a product throughout the manufacturing process. Raw materials are added to the vessels and heated or cooled to begin the chemical synthesis. Samples are drawn at various intervals to monitor the

reaction progress. Various catalysts, such as enzymes, may be added to direct a reaction in a particular way, and uniformity of the reactive environment is maintained by stirring it. After completing the synthetic reactions, a product is purified through a variety of techniques and then formulated into the finished dosage form.

Large-Molecule Drugs—

Recombinant DNA Methods

“Biopharmaceutical manufacture consists of several key stages, each of which can have a major influence on the characteristic of the end product.... Even minor changes at any stage in the process can have the potential to critically impact clinical efficacy and safety.” Sharma, *supra*. These stages include the development of cell lines, culture mediums and growth conditions, purification, formulation and product storage and handling.

Producing large-molecule drugs starts with producing living cell lines, mostly from microbial cells, such as E. coli cells, and mammalian cells, such as Chinese hamster ovaries and baby hamster kidneys. The recombinant technique involves deliberately introducing DNA into cells that instruct the cells to produce the intended protein. See Exhibit 1 on page 51. This process is called “transfection.” The cells then grow and divide, and the cells that express the protein of interest are used to produce the large-molecule drug. A “master cell bank” is established forming the first generation of these cells and includes hundreds of vials stored in liquid-nitrogen freezers. A vial is taken from the master cell bank to produce a “working cell bank,” and then a vial is taken from the working cell bank for each batch of production. This two-tiered system of cell banks supplies production needs indefinitely and ensures consistency of the protein production.

The culture medium and growth conditions are important factors in the manufacturing process. Cells are cultured in flasks and nutrients are added to promote cell growth under strictly defined conditions. The cells are constantly monitored for viability, density and consumption of nutrients. After the cells grow to an acceptable density and viability, they are transferred into larger vessels called bioreactors. Production is gradually scaled up using larger

and larger vessels and the final production bioreactor may be as large as 10,000–20,000L. This scaling up process may last from weeks to months. As the cells multiply, they are constantly monitored for mutations and to ensure that the intended proteins are expressed. Any slight modifications to the process of scaling up to commercial levels can introduce impurities that are not readily detectable, removable or mitigated. *Id.*

At the end of the growth cycle, the proteins are harvested and then purified, typically through a multistage process using chromatographic techniques. Scientists must delicately balance the removal of impurities—such as host-cell proteins, DNA, medium constituents and metabolic by-products—without damaging the intended proteins. Because the end products are not amendable to sterilization due to their sensitivity to environmental factors, aseptic processes must be used to prevent contamination. *Id.*

Purified active ingredients are then ready to be formulated and placed in their final container, usually vials or prefilled syringes. Selection of the proper container is important given that leachables from the container itself may affect protein activity and immunogenicity. Biologics are highly sensitive to environmental factors such as temperature, light and movement. Strict storage and handling procedures are required to maintain protein integrity and to prevent the introduction of impurities. *Id.*

Generics and Biosimilars

Generic drugs are copies of branded small-molecule drugs with expired patents. They have the same ingredients, routes of administration and dosages of innovator drugs, and they are “bioequivalent,” meaning that the body metabolizes them in the same manner and rate as the innovator drugs. Generics drugs are sold at significantly reduced prices because seeking approval doesn’t require expensive clinical trials. Generic drug manufacturers need only provide clinical data supporting bioequivalence, which typically costs a fraction of the cost of full drug development. Generic drugs are exact copies of branded drugs and are therapeutically interchangeable. Exact duplicates can be made because small-molecule drugs have

relatively simple, definable structures that weigh < 500 daltons.

In contrast, exact copies of biopharmaceuticals cannot be made given their fundamental nature and manufacturing complexities. Copies of biopharmaceuticals, therefore, are called “biosimilars,” or in some cases “follow-on biologics.” Large molecule drugs weigh thousands of daltons, contain thousands of atoms and have very complex structures that are usually not fully defined. Biopharmaceuticals are also not easily copied due to their sensitivity to the manufacturing process, as discussed above, and due to postproduction modifications such as glycosylation, essentially the occurrence of a carbohydrate attaching to a protein molecule, that affect their behavior.

Differences in Regulations and in Approval Processes Regulating Entities

Pharmaceutical development and manufacturing is regulated by the Food and Drug Administration (FDA) which derives its statutory power from the FDCA. Drug evaluations and approvals are undertaken by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). CDER regulates the development and marketing of small-molecule, chemically based drugs. Both CDER and CBER have regulatory responsibility for therapeutic biologic products, while CBER maintains regulatory jurisdiction over all other biologic products.

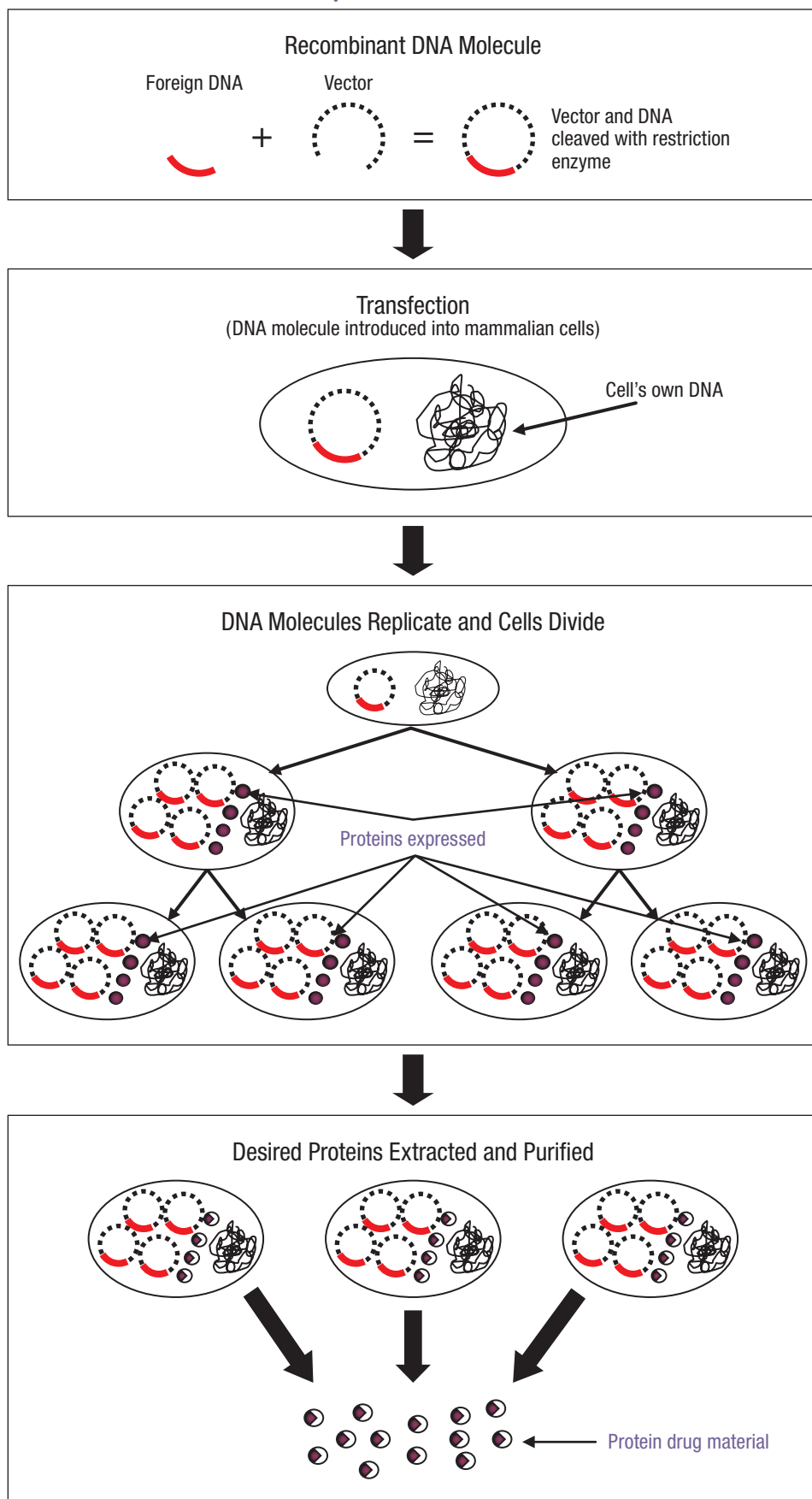
In short, some biopharmaceuticals are regulated by CBER and some are regulated by CDER. The division of regulatory jurisdiction between these two centers seems to stem more from the historical reorganization of responsibilities at the FDA, as well as administrative convenience, than from any fundamental differences in the biologic products.

CDER

Regulation of therapeutic biologics was transferred from CBER to CDER in 2003. CDER has regulatory responsibility for the following biologics:

- Monoclonal antibodies for in vivo use;
- Proteins intended for therapeutic use, including cytokines, enzymes and other

Exhibit 1. Recombinant DNA Technique



novel proteins except those specifically assigned to CBER such as vaccines and blood products, for example;

- Immunomodulators, which are non-vaccine and nonallergenic products intended to treat disease by inhibiting, or “downregulating,” a preexisting, pathological immune response;
- Growth factors, cytokines and monoclonal antibodies intended to mobilize, stimulate, decrease or otherwise alter the production of hematopoietic cells in vivo.

See, FDA, Frequently Asked Questions About Therapeutic Biological Products, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm> (last visited June 24, 2011).

CBER

CBER regulates all other biologics, specifically including the following:

- Allergens;
- Blood, blood components (*i.e.*, red blood cells, plasma, platelets) and pharmaceutical products derived from blood (*e.g.*, clotting factors and immunoglobulins);
- Gene therapy products used to replace a patients’ faulty or missing genetic material;
- Human tissues and cellular therapeutics;
- Vaccines;
- Xenotransplantation products, that is, live animal cells, tissues or organs used to treat human diseases.

Drug Development and Marketing

The FDCA governs both small- and large-

molecule drugs. Although the same rules and regulations govern drug development and clinical trials for both categories, their courses diverge at the marketing approval phase.

If initial laboratory and animal studies reveal that investigational use of either a small- or large-molecule drug is reasonably safe, then a drug is studied in clinical trials using human subjects under an “investigation new drug application.” 21 C.F.R. §312. If the data from these clinical trials demonstrates the safety and efficacy of a product, the data are submitted as part of a marketing application. Most practitioners are familiar with the “new drug application” (NDA), the marketing application for small-molecule drugs under the FDCA. The criteria used by the FDA for approval of an NDA are contained in 21 C.F.R. part 314.

Biologics, however, obtain marketing approval after a developer submits a biologics license application (BLA) under the PHSA and governing regulations in 21 C.F.R. part 601.

Issuance of a biologics license is a determination that the product, the manufacturing process, and the manufacturing facilities meet applicable requirements to ensure the continued safety, purity and potency of the product. Among other things, safety and purity assessments must consider the storage and testing of cell substrates that are often used to manufacture biologics. A potency assay is required due to the complexity and heterogeneity of biologics.

FDA, Frequently Asked Questions About Therapeutic Biological Products, *supra*.

Because biologics are more complex and less well defined than traditional chemical drugs and because manufacturing changes could profoundly alter the safety or efficacy of a biologic, the PHSA establishes more control over all aspects of the manufacturing process for biologics than for traditional chemical drugs. *Id.*

An important exception exists to the marketing approval process discussed above. Some of the first biopharmaceuticals on the market were hormones such as insulin. Hormones received marketing approval under NDAs before the explosion of scientific advancement in biotechnology. Because the early generation of hormones received approval through the NDA process, and because the FDA regulated them as drugs under the FDCA, they continue to be regulated as such today. *Id.* Therefore, some biologics receive approval for marketing with an NDA rather than a BLA.

Relevant regulations for drug development and marketing are listed in Table 3.

Generics and Biosimilars

Generics

The Drug Price Competition and Patent Term Restoration Act of 1984, often referred to as the Hatch-Waxman Act, allows the marketing of generic brand products under an abbreviated approval process. Marketing approval of a generic product is obtained through the Abbreviated New Drug Application (ANDA) process codified in section 505(j) of the FDCA. Generic products are approved more quickly under an ANDA because the manufacturers of these products are expressly allowed to bypass significant

Table 3: Drug Regulations

21 C.F.R. Part 11	Electronic Records, Electronic Signatures	All FDA Regulations
21 C.F.R. Part 50	Protection of Human Subjects	Clinical trials
21 C.F.R. Part 56	Institutional Review Board	Clinical trials
21 C.F.R. Part 58	Good Laboratory Practices for Non-clinical Laboratory Studies	Preclinical studies
21 C.F.R. Part 210	Current Good Manufacturing Practice in Manufacturing, Processing, Packaging or Holding of Drugs; General	Manufacturing, general
21 C.F.R. Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals	Manufacturing, including quality control
21 C.F.R. Part 312	Investigational New Drug Applications	Clinical trials
21 C.F.R. Part 314	Applications for FDA Approval to Market a New Drug	Approval process
21 C.F.R. Part 320	Bioavailability/Bioequivalency	Preclinical studies
21 C.F.R. Part 600	Biological Products; General	Biologic products
21 C.F.R. Part 601	Biologics Licensing	Approval process
21 C.F.R. Part 610	General Biological Products Standards	Manufacturing

research and development. It is believed that the innovator company has already demonstrated the safety and efficacy of the generic drug with its clinical trials on the innovator drug. Therefore once approved, generic drugs can be automatically substituted for brand-name drugs by physicians or pharmacists because they are considered safe and effective exact duplicates.

Biosimilars

After considerable discussion and debate, the United States Congress passed legislation establishing an approval pathway for biosimilars on March 23, 2010, with the Biologics Price Competition and Innovation Act of 2010. 42 U.S.C. §262(k) (corresponding to Public Health Services Act §351(k)). Legislators decided that the FDA could not adopt the ANDA abbreviated approval process under the Hatch-Waxman Act to biologics because, unlike small-molecule drugs, large-molecule drugs do not allow for exact duplication. More controls and oversight were needed for generic biologic products. In order to obtain the benefit of abbreviated approval under the new legislation, therefore, an applicant for a BLA must show that the product is “biosimilar” or “interchangeable” compared to the innovator product.

A “biosimilar” product is defined as a biologic that “is highly similar to the reference product notwithstanding minor differences in clinically inactive components,” and “there is no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product.” 42 U.S.C. §262(i)(2). In contrast to generic drug applicants under Hatch-Waxman, demonstrating “biosimilarity” under the new legislation requires analytical data, animal testing and clinical studies unless the FDA deems this requirement unnecessary. 42 U.S.C. §262(k)(2)(A)(i)(I).

A manufacturer demonstrates that a biologic product is “interchangeable” biologic by showing that (1) the product meets the criteria for biosimilarity; (2) the product will produce the same clinical result as the brand product in all patients; and (3) when compared to the reference product, the biosimilar does not pose additional safety risks or diminished efficacy. 42 U.S.C. §262(k)(4). If a manufacturer

meets these criteria, the interchangeable biosimilar product may be substituted for the brand product without the intervention of the health-care provider who prescribed it.

Given the act’s recent passage, the FDA has not promulgated any specific proposed regulations. Developing the full regulatory framework is expected to take up to three years, and the appearance of the first waive of biosimilars under the new legislation is expected around 2014.

Impact of Biopharmaceuticals on Product Liability Litigation

Defending litigation involving a biopharmaceutical product will present several new challenges to the product liability lawyer. The first will be the need to obtain a solid understanding of the relevant laws and to determine which FDA center has regulating jurisdiction. Detailed analysis and understanding of the differences between the requirements for marketing under an NDA and BLA will be required as you undertake an investigation of the drug’s history, development and submission to the FDA for approval. Finally, a firm understanding of the fundamental differences between traditional chemically synthesized drugs and biopharmaceuticals will lay the foundation for your review of the medical literature and discussions with your company witnesses, consultants and experts.

Manufacturing Issues Will Become More Significant

Perhaps the most significant issue impacting the way that you defend product liability cases involving biopharmaceuticals will be that you can expect opponents to focus on the manufacturing processes, and you must as well.

Manufacturing Defect Claims

In product liability lawsuits involving chemically synthesized drugs, we rarely investigate the manufacturing details of the products because the stability of these compounds makes them insensitive to manufacturing process changes. Therefore, although frequently alleged in complaints, plaintiffs’ lawyers rarely pursue manufacturing defect claims except, for example, in cases alleging contamination. It is fair to say that for the last several decades, the

primary claims pursued in pharmaceutical product liability lawsuits have been failure-to-warn and design-defect claims.

Large-molecule drugs, however, are sensitive to even minor changes in the manufacturing process. Subtle changes can drastically affect the safety and efficacy of these products. In addition, the complexity of the manufacturing process itself and the increased regulatory oversight by the FDA of this phase of biopharmaceutical drug development serve to compound and emphasize the manufacturing issues that can serve as the basis for product liability lawsuits. These new issues will require a comprehensive understanding of controlling regulations, including the “Good Manufacturing Practices” applicable to all drugs and those specific to biologics in 21 C.F.R. parts 210, 211, 610. Moreover, investigating all aspects of a company’s manufacturing procedures early on, and thoroughly reviewing all relevant compliance and quality manuals, as well as retaining manufacturing consultants will be important steps as you begin building your defenses to manufacturing defect claims.

Design Defect Claims

Manufacturing issues may begin to serve as the basis for design defect claims involving biologics. It is often stated that biopharmaceutical products are defined by the process—that the product is the process. *See, e.g., Sharma, supra*. Because of the critical role that manufacturing plays in the development of a biopharmaceutical product, innovator companies consider information about their manufacturing processes highly proprietary and often seek patent protection. Therefore, it makes sense that creative plaintiffs’ counsel will begin to assert claims that the manufacturing process itself is part of the product’s overall design and that the product design is defective as the result of a manufacturing issue. Since design defect claims apply to every product sold and therefore allow for greater overall recovery (as opposed to standard manufacturing claims which only apply to individual products or lots), the odds are good that we will begin to see this hybrid cause of action as more and more lawsuits involve biopharmaceuticals.

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Uncertain Impact of Biosimilars

Biosimilars are not expected to impact brand-name biologic companies' profit margins as dramatically as generic drugs due to their decreased competitive edge. When compared to small-molecule drugs, biosimilar manufacturers face significantly increased costs in attempting to copy innovator large-molecule drugs because they themselves must pay for increased expertise in manufacturing processes and for building or leasing complex manufacturing facilities. As a result, a decreased number of biosimilar competitors is expected for individual drugs. Analysts predict the overall cost savings from biosimilars will amount to 25–45 percent, not the 60–80 percent discounts common among chemically based generic drugs. Deena Beasley & Lisa Richwine, *Drugmakers Gear Up to Copy Biotech Drugs in U.S.*, Reuters, May 11, 2011, <http://www.reuters.com/article/2011/05/11/us-summit-biotechnology-generics-idUSTRE74A83G20110511>; Bruce Japsen,

Law Change Allows Cheaper Versions of Biotech Drugs, Chicago Tribune, May 24, 2011. In fact, brand-name biologic manufacturers may actually enter the biosimilar game and benefit from their development. Current brand-name biopharmaceutical companies may leverage their existing manufacturing capabilities and marketing machinery by partnering with developers of biosimilar products. Beasley, *et al.*, *supra*.

Nevertheless, given the recent passage of the approval pathway for biosimilars, they are not expected to be a significant presence in the marketplace for another three to five years. Many ambiguities in the new legislation need to be addressed and a regulatory framework approved before a reasoned assessment can be made about their potential impact on product liability litigation. Biosimilars are also going to face a deluge of patent litigation early on as determinations are made regarding what does and does not constitute “biosimilarity.” Over the next few years, however, product

liability lawyers should monitor the developments surrounding the requirement that biosimilar applicants submit new clinical trial data along with their marketing applications. When, why and how this new clinical data will require information on the label of the biosimilar that differs from the label on the innovator product will be interesting to watch for defending future failure-to-warn claims.

Conclusion

The effects of the biotech revolution are about to hit the product liability litigation sector. The explosion in biotechnology over the last two decades has led to an onslaught of innovative and potentially blockbuster products that will enter the market over the next few years at a rate expected to outpace traditional, chemically based drugs. This kind of growth and market impact in the pharmaceutical industry inevitably triggers an increase in product liability litigation. Are you ready?

