Biotechnology as a Pharmacy Specialty

Growing numbers of biotechnology products offer hope to patients who previously lived with chronic, unremitting disease. How are pharmacists addressing this challenge?

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Suppose you are given a special pencil—a biological correction pencil. It is somewhat chunky, has a big eraser, and its point is rounded. With it, you find you can erase some errors in human biology and rough in new plans. You can redraft the biology of a little boy who is so much smaller than his peers that he is socially maladjusted; your pencil will help him grow. Or you can change the biology of a woman who longs to conceive but can't; your pencil will prompt ovulation. Maybe you can even help an individual who struggles with multiple sclerosis; your pencil will provide some protection for her, decreasing the frequency and severity of serious infection. Because the point is a little blunt and the pencil is somewhat difficult to hold, you can't fix things exactly, but you can make the picture prettier for these people.

How much would your pencil cost? Where would you keep it? Would other people want to use your pencil? Would they use it appropriately, or would they use it for cosmetic or self-serving reasons? Would you? How would you ensure that the pencil wasn't used too much, creating giants or multiple births or adverse effects? How would you ensure that a timid artist didn't waste the lead by using it only sketchily, thus wearing out the point without causing real change? Would some people be afraid of the pencil?

These are the issues of biotechnology, a field that addresses problems of biological blueprint flaws. There are a number of pharmaceutical distributors who

specialize in user-friendly provision of biotechnology and chronic therapy to patients across the United States.

BIOTECHNOLOGY

Biotechnology is a growing industry that presents interesting challenges to pharmacists. While they approach the miraculous in their ability to correct some problems of biology, biotech drugs don't fit well in the traditional pharmacy environment. They are unique in many ways.

First, they generally cost considerably more than most medications, and may be carved out of managed care programs only on a limited basis, or may not be covered by traditional third-party payors at all. Second, administration is generally different, with the oral route an exception rather than the rule. Third, they require precise handling in terms of administration time and method as well as storage, creating the need for specialized counseling for patients. Fourth, misadventure secondary to misuse, be it accidental or intentional, presents a greater probability of disaster than with other drugs. Finally, there is a fear that the complicated nature of these drugs may increase risk and liability for the clinician. Educating pharmacy practitioners about biotechnological drugs in general and each agent specifically could consume an inordinate amount of time, making biotechnology ripe for designation as a pharmaceutical specialty.

The combination of these five factors caused payors and clinicians to

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sequester these drugs initially, thus restricting their availability even for people who needed them. Traditional drug distribution channels sometimes found themselves uncomfortable with the issues, and third-party payors looked for ways to guarantee that biotech drugs were used appropriately and cost-effectively.

Approximately 150 to 200 biotechnological agents are available right now. The overall picture becomes more complicated when examining the potential for increased use of biotech drugs. According to a 1996 survey conducted by the Pharmaceutical Research and Manufacturers of America, approximately 300 drugs are in the development process right now, and the number of new drugs is expected to increase by 20% by the year 2000; payors can expect to spend \$5 billion to \$8 billion annually on biotech agents.

PAYOR CONCERNS

Approximately 1% of the population needs a biotech drug, either for acute treatment or for chronic maintenance. Figure 1 describes the clinical conditions that often require biotechnological or chronic intervention. It clearly shows that there is a significant need now, and potential for profound growth in the coming years. According to the Health Care Financing Administration's (HCFA) Office of Actuary, 45% of Americans, or 100 million people, have chronic condi-

Figure 1. Conditions Responsive to Biotechnology or Self-Injectable Drugs

- ▲ Organ transplants
- ▲ Diabetes
- ▲ HIV/AIDS
- ▲ Multiple sclerosis
- ▲ Hemophilia
- ▲ Growth hormone deficiency
- ▲ Infertility
- ▲ Hepatitis B and C
- ▲ Cancer

Figure 2. Formula to Calculate Estimated Biotech Spending

# lives covered	X	9.94%	X	\$4,500	=	Total plan spending per year (average wholesale price plus 10%)
		Average incidence of patients in the population requiring self-injectable medication		Average annual cost of self-injectable drugs		

tions. Pharmaceutical manufacturers are looking at the potential in this area carefully, recognizing that HCFA statistics show 25% of patients consume 75% of health care dollars, and that many chronic conditions often are responsive to biotechnology.

A study conducted by the Managed Healthcare Market Report revealed that while private health insurance provided 8.8% of funds for prescription drugs in 1975, by 1990 its proportion had increased to 39.9%. With increasing frequency, private payors have been faced with patients' needs for expensive, refined drugs. With use of injectable drugs increasing, payors have had to consider the costs of supplies, nursing visits, and office visits to physicians. HCFA reports that injectables account for between 7% and 12% of total drug expenditures in the United States. And there are the more elusive costs to consider: noncompliance, adverse events, and distress associated with lack of knowledge or poor administration technique. Many payors are unprepared to deal with the issues raised by the advent of biotech drugs.

Specialty pharmacies were developed to offer services, medical products, and pharmaceuticals for individuals who have chronic illnesses, or people with

acute conditions requiring biotechnological intervention. They specialize in high-cost, high-risk conditions and deliver services and products directly to patients or institutions. These pharmacies also work closely with third-party payors to ensure that drugs are prescribed appropriately, used correctly, and discontinued when no longer needed. They offer several advantages to both payors and patients. The mission—cost-effective improvement in quality of life—is important to everyone in the health care chain.

PATIENT CONCERNS

Patients who need biotech drugs have experienced difficulty obtaining them and having their costs covered by private health insurance. Availability always has been an issue, and payment mechanisms have been very complicated. Many patients had their local pharmacy order the medication, which often required immediate payment and later submission of the claim to insurance. The high cost of these drugs presented its own dilemma, and the high rate of rejected claims led to a precarious fiscal situation for all but the wealthiest of patients.

Table 1. Three Most Expensive Biotech Therapies (May 1998)

Drug	Common Trade Names	Indication
Interferon alpha (\$56,117/year)	Roferon	Treatment of malignancies
Somatropin (\$15,790/year)	Genotropin, Humatrope, Nutropin, Nutropin AQ	Long-term treatment of children with inadequate growth
Interferon alpha-2b (\$15,288/year)	Intron	Treatment of chronic hepatitis B and hepatitis C, and treatment of malignancies (circumvents liver transplant)

Table 2. Ten Most Frequently Used Biotech Drugs (May 1998)

Drug	Common Trade Names	Indication
Medroxyprogesterone	Depo-Provera	Prevention of pregnancy, endometrial or renal carcinoma
Interferon beta-1a	Avonex	Biological response mediator which is used in relapsing/remitting multiple sclerosis to decrease frequency and severity of infection
Leuprolide	Lupron	Infertility, endometriosis, prostate cancer, leiomyoma uteri, precocious puberty, breast cancer, ovarian cancer, endometrial cancer
Urofollitropin	Fertinex, Humegon, Metrodin	Various indications related to infertility
Human chorionic gonadotropin	HCG	Infertility, cryorchidism, hypogonadism, luteal phase support
Somatrem	Protropin	Primary growth hormone deficiency
Erythropoietin	Procrit, Epogen	Anemia secondary to renal failure, zidovudine-induced anemia, and anemia secondary to cancer
Filgrastim	Neupogen	Various types of neutropenia
Interferon beta-1b	Betaseron	Biological response mediator which is used in relapsing/remitting multiple sclerosis to decrease frequency and severity of infection
Interferon alpha-2b	Intron	Chronic hepatitis B and C, Kaposi's sarcoma, malignant melanoma

SPECIALTY PHARMACY AS A SOLUTION

A number of specialty pharmacies, including Chronimed, NovaFactor, and Statlanders, now focus on biotech and injectable drugs and their associated disease states. They offer economy-of-scale purchasing as well as expertise in storage, distribution, and administration of each drug. Their ability to purchase the drug at the best price and ensure that none is wasted or accidentally spoiled represents economy to the purchaser. They are familiar not only with the drug, but also with the companion supplies and equipment necessary to use the drug correctly. Most are not constrained by a formulary; they carry any and all products needed by their clientele. Their patient specialists work with clients to ensure that a comprehensive package, including all of the equipment and supplies needed to administer the drug, is delivered directly to their homes.

Payment issues are addressed in

advance. These specialty providers work with third-party payors, including health maintenance organizations, to help them identify and control costs associated with biotech drugs. Chronimed uses the simple formula presented in Figure 2, based on the average incidence of patients in the general population who need biotech drugs and the average cost per year of biotechnology drugs. Although the number of lives affected is small, the cost to an insurer can be great. For example, currently the three most costly biotech therapies are interferon alpha-2a (\$56,117 annually), somatropin (\$15,790 annually), and interferon alpha-2b (\$15,588 annually). Table 1 describes these drugs and their indications. The 10 biotech drugs used most frequently are described in Table 2. These drugs probably are familiar to most pharmacists.

In addition to product expertise, biotech specialty pharmacies offer an array of services that contribute to financial and administrative efficiency. They promote exceptional product availability,

with in-house inventory of all products. They may have distribution centers across the country to ensure prompt delivery regardless of the patient's location. Typically, these pharmacies offer extremely fast service, with delivery within 24 to 48 hours, recognizing that these products often must be administered quickly during an appropriate biological cycle. Many are linked to a chain of retail stores across the country to accommodate same-day dosing requirements.

Often, these types of pharmacies use a team of insurance verification specialists who work closely with the insurer, creating a hassle-free process for patients and insurers as well. For example, Chronimed screens each order for diagnosis, and verifies in advance that the indication is appropriate and covered by the insurer. They are able to produce clinical and financial reports for insurers as a result.

Like all pharmacies, these biotech specialty pharmacies provide completely confidential services. In addition, biotech specialty pharmacies offer home delivery,

Table 3. Future Biotech Drugs*

Drug	Indication
Neurotrophic factor (BDNF)	Treatment of amyotrophic lateral sclerosis
RhIGF-1	ALS
Human platelet-derived growth factor	Wound healing
Recombinant human growth hormone-releasing peptide	Pediatric short stature and adult growth hormone deficiency
Interferon Alpha-n3	ARC, AIDS
Consensus Interferon	Hepatitis C
Human anti-CMV antibody	CMV infections in AIDS and bone marrow transplant patients
Recombinant human glucagon	Hypoglycemia, gastrointestinal motility inhibition
Recombinant human leutinizing hormone	Follicular support stimulation of follicular development
Recombinant human thyroid-stimulating hormone	Adjunct in procedures used for detection and treatment of recurrent thyroid cancer

*Identified as being in Phase III of FDA testing in a 1996 survey completed by the Pharmaceutical Research and Manufacturers of America.

which makes the process anonymous. For many patients, this is the most important aspect of a specialty pharmacy's service. Many of the conditions treated with biotech drugs are unusual or terminal. Many patients prefer not to discuss their health issues with others, and appreciate the discreet service they receive from these providers.

Home delivery adds an element of convenience, but the patient's information needs are not ignored or neglected in the absence of face-to-face contact. Patient education is extremely important in ensuring the best possible use of these medications. Patients and their caregivers or family members have access to counseling from trained patient specialists and pharmacists during extended hours (e.g., from 7 a.m. to 7 p.m.) five days a week to answer questions or address problems. Typically, pharmacists are available around the clock for problems that require their unique expertise. Other services available through specialty pharmacies include refill reminders, compliance monitoring, and communication of improvement, decline, or compliance issues to the prescriber when necessary.

This level of personal service is not usually found in traditional drug dispensing systems. Chronimed also offers a selection of booklets, charts, and administration guidelines.

One provider assesses customer satisfaction by sending feedback cards with every order. Patients return approximately 10%–12% of these cards; 98.9% of these patients indicate that they are extremely pleased with services, in particular with the confidentiality and convenience of home delivery. One of the reasons for the high satisfaction rate may be the use of specialized personnel who are trained intensely in injectable medications. For example, at Chronimed, patient specialists attend educational programs on new injectable drugs, new client contacts, and telephone skills. Each specialist is certified annually to ensure quality of care and good interaction skills. Calls are monitored periodically to ensure consistency and quality.

A quality assessment component adds an element of safety for patients not possible in a less-specialized environment. For example, the success of these drugs often rests on the prescriber's ability

to manage side effects and the patient's ability to cope with them. Many specialty pharmacies offer assistance to both prescriber and patient.

Specialty providers also should track problems by product and provide feedback to the manufacturer. These efforts help identify trends that eventually may clarify drug interactions, designate individuals or groups of people as high risk, or determine conditions under which adverse events are more likely to occur.

In the near future, many additional biotech drugs will be available; Table 3 lists those that are closest to approval. Following developments in the field closely, specialty pharmacies must prepare for these newest biotech drugs.

CONCLUSION

Designation of biotechnology as a pharmacy specialty has been beneficial to everyone involved in the process. Prescribers have access to trained experts in the field who can address their concerns and problems prospectively. Insurers are assured that biotech drugs are being used appropriately, and in keeping with their policies and procedures. Patients and their families have a resource to help them through health problems efficiently and effectively.

In the near future, the biological correction pencil will change. It will be easier to hold. It will erase problems more cleanly. It will be sharper, letting us redraw the picture more precisely. Who do you think should hold that pencil? We think it should be a specialist who can perform electronic adjudication of claims, consolidate reporting, ensure responsible use, and promote improved quality of life for patients.