

Rx Watchdog Report

Shining a light on the cost and quality of prescription drugs

Making the Case for the Access to Life-Saving Medicine Act

B iologic drugs can treat some of the most devastating diseases Americans face, like cancer, rheumatoid arthritis and multiple sclerosis. But for too many people, these medicines are simply out of reach because of their exorbitant price tags," said AARP Executive Vice President Nancy LeaMond.

"As we learned when Rep. Waxman and Sen. Hatch championed generic legislation in the 1980s, generic competition can lower drug prices without hindering the development of new, innovative medicines. Now we have an opportunity to encourage the Food and Drug Administration to create a regulatory pathway to approve lower-priced options to these new, very expensive and often breakthrough drugs," LeaMond added.

The Drug Price Competition and Patent Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) allowed for the approval of generic versions of brand name prescription drugs. As a result, generic prescription drugs now save consumers and health care payers billions of dollars each year. The popularity of these lower-cost alternatives continues to grow; approximately 69 percent of all prescriptions dispensed in the United States—or nearly 2.6 billion prescriptions every year—are filled using lower cost generic drugs.

The Hatch-Waxman Act created a regulatory process, also known as an abbreviated pathway, that allowed the Food and Drug Administration (FDA) to approve generic prescription drugs, and the result was that millions of people received access to safe, lower-cost prescription drugs. Now, with the advancement of science and introduction of biologics, many say that we

need to develop an approval process for generic biologics for the same reason.

That is why AARP is supporting the bipartisan legislation titled *Promoting Innovation and Access to Life-Saving Medicine Act* (HR 1427/S726), introduced by U.S. Representatives Waxman, Deal, Pallone, and Emerson; and in the Senate by Senators Shumer, Collins, Brown, and Vitter. These bills will allow the FDA to create a regulatory pathway for the approval of safe, comparable, and interchangeable versions of biologics.

"Generic prescription drugs now save consumers and health care payers billions of dollars each year."

Lowering the cost of prescription drugs is a vital component to health care reform. According to the nonpartisan Congressional Budget Office, creating a clear pathway for approval of biogenerics could save the federal government billions each year. This is in addition to the savings that would accrue to other payers of health care, including private and state employers, employees and consumers.

Biologic treatments can cost tens to hundreds of thousands of dollars per year. For example, the annual cost for Enbrel, used to treat rheumatoid arthritis, is about \$15,000 per year, while the annual cost for Avastin, used to treat cancer, is about \$100,000 per year.

The table above identifies six medical conditions—many of which may be more

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The EU: a Global Leader on Biosimilars

By Britta Berge, AARP, Office of International Affairs, Contributing Editor

The United States could look to the European Union (EU) to learn from their experiences and success with developing a regulatory pathway for approving safe and effective biosimilar medicines.

Biosimilars, known in the U.S. as follow-on biologic drugs, are like "generic" versions of brand name biologic medicines. Biologics are distinguished from chemically based drugs in that they are derived from proteins created from living cells.

"Unlike chemically based drugs, there is no regulatory mechanism for the approval of generic biologic drugs in the United States or in many developed countries."

For the past 25 years, chemically based generic drugs have been saving patients, insurance companies, and government billions of dollars through legislation that has created an abbreviated approval process for generic drugs. However, this law does not apply to biologic drugs. Unlike chemically based drugs, there is no regulatory mechanism for the approval of generic biologic drugs in the United States or in many developed countries. The EU is the noted exception.

In 2003, as part of a larger legislative directive on pharmaceuticals, the EU

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Annual Treatment Costs: Biologics vs. Non-biologic Medicines

Condition	Prevalence	Common Biologics and Annual Treatment Costs	Top Non-biologic Medicines and Annual Treatment Costs
Rheumatoid arthritis: an autoimmune disease that causes inflammation (pain, stiffness, swelling, deformity) in the joints.	2.1 million people in the U.S. The age of onset is typically between 20 and 50 years; can also affect young children and people older than 50; incidence increases with age. Affects two to three times more women than men.	Enbrel [®] , Remicade [®] , Rituxan [®] \$15,000–\$22,450	aspirin, ibuprofen, methotrexate, prednisone \$100–\$300
Multiple sclerosis: chronic neurological disorder that affects the central nervous system.	300,000 people in the U.S. The age of onset is typically between 20 and 50 years. Affects twice as many women as men.	Humira [®] , Avonex [®] , Copaxone [®] , Rebif [®] , Betaseron [®] , Tysabri [®] \$12,700–\$28,400	prednisone, dexamethasone, gabapentin, phenytoin \$200–\$1,400
Cancer: a group of diseases characterized by uncontrolled growth and spread of abnormal cells.	About 10.5 million Americans with a history of cancer were alive in January 2003. Nearly 1.5 million new cases are expected to be diagnosed in 2007.	Procrit [®] , Gleevec [®] , Sutent [®] , Herceptin [®] , Avastin [®] , Erbitux [®] , Rituxan [®] \$5,500–~\$32,500*	cyclophosphamide doxorubicin, methotrexate \$100–\$1,600*
Hepatitis C: disease of the liver caused by the hepatitis C virus.	Four million people in the U.S. are affected, making it the most common blood-borne infection in the U.S.	Pegasys [®] , Peg-Intron [®] , ribavirin, Rebetron [®] , Copegus [®] \$6,400–\$15,700	n/a
Osteoporosis: a disease in which bones become fragile and more likely to break.	In the U.S., 10 million people have the disease and an additional 34 million are estimated to have low bone mass, placing them at increased risk. Risk increases with age; from age 75 on, it is as common in men as it is in women.	Forteo [®] \$6,700	Fosamax [®] , Actonel [®] , Boniva [®] \$750–\$1,000
Diabetes: a condition in which the body has trouble breaking down sugars in the blood. If left untreated, it can lead to cardiovascular disease, kidney disease, nerve and blood vessel damage, blindness, and death.	In the U.S., 18 million people suffer from type 2 diabetes, which is the most common form of the disease. Among those age 60 years and older, 23% are estimated to have diabetes (this includes both diagnosed and undiagnosed). Among both sexes, about one-third of people with diabetes do not know they have it.	Novolin [®] , Lantus [®] , Novolog [®] , Humalog [®] \$1,100–\$2,000	glimepiride, glipizide, metformin, Avandia [®] \$190–\$1,100

"Biologics in Perspective: Expanded Clinical Options amid Greater Cost Scrutiny," AARP, Public Policy Institute, June 2007.

**Cancer treatments are rarely used continuously for 365 days/year; therefore, treatment costs in this category represent one course of treatment. Some patients will need more than one course of treatment. Note: Drug names in lowercase indicate that a generic version is available. Sources: Biologic treatment costs are primarily from: C.D. Douglas et al., "Kaiser Permanente's Evaluation and Management of Biotech Drugs: Assessing, Measuring, And Affecting Use," Health Affairs 25(5) (September/October 2006): 1340-46; Caremark, "2006-Focus on Specialty Pharmacy," 2006; and Express Scripts, "2006 Drug Trend Report," April 2007. Non-biologic treatment costs are based on data from drugstore.com.*

common among older adults—for which biologics have become an increasingly important treatment option.

Critics of developing a pathway for generic biologics argue that biologics are more complex than traditional prescription drugs, and that they cannot be easily replicated. However, some biologic drugs—like Epogen and certain forms of insulin—have been on the market for decades. In addition, technology has progressed to

the point where many biologics are better understood. As evidenced by the growing number of generic biologics available in other countries, existing science is more than sufficient to create affordable generic versions of many biologic drugs (see accompanying article on approval of generic biologics in the European Union).

While the high cost of biologics is an obvious concern, AARP's primary focus remains on safety and efficacy. No

prescription drug should be allowed on the market that is not safe and effective for its intended purpose. This is why the FDA is tasked with ensuring the safety and efficacy of all prescription drugs, including biologics.

The Promoting Innovation and Access to Life-Saving Medicine Act does not mandate that the FDA approve a certain number of generic biologic drugs—only that the FDA be given the ability to evaluate and

Making the Case for the Access to Life-Saving Medicine Act continued

approve them. And the legislation leaves the scientific determinations up to those who are best equipped to address them—the FDA. AARP believes that the FDA is the agency that has the scientific knowledge to approve an innovator biologic drug and also has the ability to evaluate a generic version of the same drug.

Prescription drugs play a vital role in the development of health reform. They help to manage and cure diseases, and allow people to maintain or enhance their health. So it makes common sense for Congress to promote options to make prescription drugs more affordable for all Americans. ■

What are Biologic, Generic and Biosimilar Drugs?

When scientists and other professionals try to explain why a pathway needs to be created in order for the Food and Drug Administration (FDA) to approve generic biologic prescription drugs, many people get lost in the details and unfamiliar meanings. A healthy dose of understanding the vocabulary often used in this debate may be useful.

Biologic Drugs: unlike traditional chemical-based prescription drugs, biologic medicines are derived from living organisms, such as yeasts or bacteria. These drugs tend to be administered by infusion or injection. Many of these biologic drugs are prohibitively expensive and are often used to treat chronic and sometimes life threatening diseases, such as diabetes, rheumatoid arthritis, multiple sclerosis, and cancer.

Generic Biologic Drugs: are generic (e.g., similar) forms of biologic drugs. Unlike in other countries, currently the FDA lacks the authority to approve generic forms of biologic drugs. Also referred to as “biosimilars,” “biogenerics,” or “follow-on biologics.” ■

Legal Front News

Exclusion Payments: The Biggest Losers—Consumers

Courts and Congress are currently scrutinizing the increasingly common practice by brand name pharmaceutical manufacturers to pay large sums of money to generic manufacturers to keep generic drugs off the market. These agreements—commonly referred to as “exclusion payments” or “reverse payments”—have prohibited consumers from getting lower-cost generic alternatives. According to a recent study by the Columbia University School of Law, these exclusion payments cost consumers over \$12 billion annually.

AARP, along with several consumer organizations, has asked U.S. Attorney General Eric Holder to urge the Administration to “immediately make known to the federal courts its position on whether these payments are anti-competitive and violate anti-trust laws.

This request was sent after the Court of Appeals for the Second Circuit invited the Administration to inform the court of its opinion on whether exclusion payment agreements violate federal law before the court decides the case *In re Ciprofloxacin Hydrochloride Antitrust Litigation*. This case provides a real opportunity to reverse the trend of exclusion agreements nationwide.

The Ciprofloxacin cases, in which purchasers of the blockbuster antibiotic Cipro sued the brand name and generic name manufacturers of the drug, are currently pending before the U.S. Supreme Court and the Court of Appeals for the Second Circuit. The lawsuits were filed after the brand manufacturer, Bayer, paid its generic competitor, Barr Labs, \$398 million in exchange for the generics’ agreement to stay out of the market for six and one-half years of the remaining seven-year life of the patent. The purchasers alleged that the agreement is a restraint of trade that violates the Sherman Antitrust Act prohibiting contracts in restraint of trade.

If exclusion payments are deemed lawful, pharmaceutical companies holding patents will use them to terminate any patent challenges. As the FTC stated, “[These agreements result in] increased costs ... that delay generic competition harm all those who pay for prescription drugs: individual consumers, the federal government, state governments trying to provide access to health care with limited public funds, and American businesses striving to compete in a global economy.”

AARP filed *amicus* briefs in several cases opposing exclusion payment agreements, including most recently the *Cipro* cases in the U.S. Supreme Court, Second Circuit and Federal Circuit, and *In re Cardizem CD Antitrust Litigation* (6th Circuit), *FTC v. Schering-Plough* (U.S. Supreme Court), *Valley Drug Co. v. Geneva Pharmaceuticals* (11th Circuit), and *In Re: Tamoxifen Citrate Antitrust Litigation*, (2nd Circuit and U.S. Supreme Court). ■

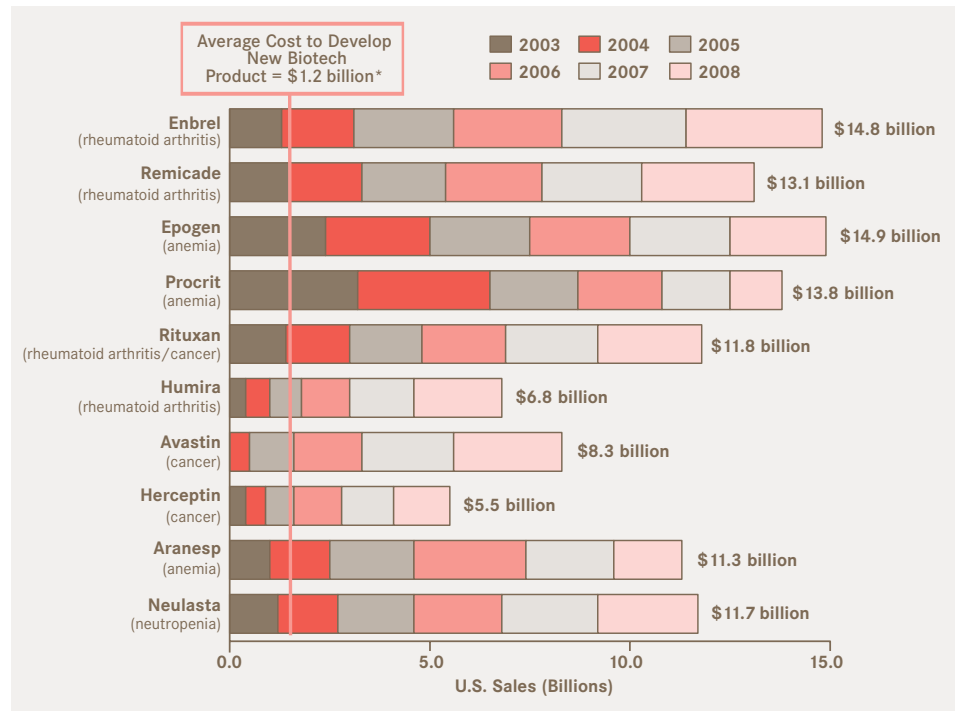
Would Generic Biosimilars Keep Manufacturers From Recouping Their R&D Costs?

Would a streamlined process to approve biosimilars prevent biologic drug manufacturers from recovering their development costs and therefore slow innovation? That's the claim of some drug manufacturers, who assert that the average cost of developing a new biologic drug is \$1.2 billion, including the costs of drugs that fail in testing as well as the time costs associated with bringing a new biologic drug to market.

But a recent AARP study suggests that this should not be a concern. The study shows that, based on U.S. sales alone, a majority of top-selling biologic drugs have recouped their manufacturer's investment several times over in the past six years. Indeed, sometimes the investment is recouped *within a single year*. For example, as shown below, U.S. sales for 10 top-selling biologic drugs between 2003 and 2008 ranged from \$5.5 billion to \$14.8 billion—much more than the estimated \$1.2 billion costs of production—and five of the nine drugs that were on the market in 2003 recovered all of the costs of development in that year alone.

Annual and Total U.S. Sales for Top Selling Biologic Drugs, 2003–2008

Based on U.S. sales alone, a majority of top-selling biologic drugs have recouped their manufacturer's initial investment several times over in the past six years, often within a single year.



To view the report, "Biologics in Perspective: The Case for Generic Biologic Drugs," by Leigh Purvis, AARP Public Policy Institute, go to www.aarp.org/ppi

Source: L. Purvis, "Biologics in Perspective: The Case for Generic Biologic Drugs," AARP Public Policy Institute, May 2009.

AARP Federal Advocacy

AARP has endorsed the "Protecting Consumer Access to Generic Drugs Act of 2009" (HR 1706) and "Preserve Access to Affordable Generics Act" (S. 369). These bills help to bring lower cost generic drugs to market sooner by preventing abuses in patent settlements between generic and brand name prescription drug companies.

As recent studies have shown, with the downturn in the economy consumers are having a harder time paying for their health care expenses and some are cutting back on their prescription drugs. Generic drugs offer consumers a lower-cost alternative to brand name drugs whose manufacturer prices continue to rise at nearly twice the rate of inflation each year. The popularity of generic drugs is increasing every year, and now account for nearly 70 percent of all prescriptions filled in the U.S. Unfortunately, delays in getting some generic drugs to market mean that consumers—and other health care payers such as federal and state governments, employers, and insurers—don't realize important savings.

When the patent for a brand name drug has expired or is ruled invalid, generic manufacturers are able to bring their product to market. However, there has been a trend of controversial settlements between generic and brand name prescription drug manufacturers. Several of these settlement agreements have resulted in some form of payment to the generic manufacturer and a delay of market entry of the generic drug. When brand and generic drug manufacturers wrongly conspire to delay market entry of a generic drug, consumers, health plans, and taxpayers are forced to continue to pay for the higher cost brand name drug for a longer period of time.

These bills seeks to prevent these abuses by prohibiting generic manufacturers from accepting anything of value from a brand name prescription drug manufacturer in exchange for delaying introduction or research of a generic product. If a generic manufacturer violates this provision, it forfeits its 180-day exclusivity period (i.e. the period when no other generic versions of the drug can be sold) that is awarded to the first generic manufacturer to obtain FDA approval. The House bill goes further and also grants the Federal Trade Commission the authority to exempt certain agreements if it finds that it furthers market competition and benefits consumers. ■

AARP State Advocacy

The very difficult financial condition of state governments has driven an increased focus on prescription drug costs. In some cases, this has led to proposals to reduce state expenditures on state prescription drug assistance programs, which will likely be very expensive in the long run as people suffer the complication of uncontrolled chronic conditions.

It has also led several states to initiate efforts to improve the marketplace for prescription drugs. For example, Maryland, Minnesota, Iowa, and California have initiated legislative efforts to create academic detailing programs that give prescribers independent information about prescription drug options to counter efforts by pharmaceutical manufacturers to market the latest, most expensive drugs. New York recently implemented a prescription drug discount card for people 50–64 years of age and for people with disabilities. Massachusetts just adopted rules implementing a law requiring disclosure of gifts from pharmaceutical manufactures to prescribers, a subject now also pending in a number of other state legislatures as well as in Congress.

The most creative initiative this year has been in Connecticut, where years of groundwork by the AARP state office enabled the enactment of an improvement in drug coverage along with savings to the state. This was done by making people who have been receiving assistance under ConnPACE, a state-funded pharmaceutical assistance program, eligible for the state's Medicare Savings Program, which is partially funded by the federal government. Thus, instead of the 70 percent reduction in the ConnPACE budget originally proposed by the governor, benefits to low-income residents are projected to increase by nearly \$50 million and state spending will be reduced by over \$4 million a year. ■

From Personal Experience

By Bonnie Cramer, Board Chair, AARP Board of Directors



I've lived with severe rheumatoid arthritis for more than 40 years and I've tried just about every treatment option available. For a long time, nothing worked very well.

I was one of those people who scrutinized the Internet, queried doctors, pored over medical journals, and generally spent time most days in search of something that would help me function normally.

My research eventually led me to one of the biologic drugs, Enbrel. It was new, and it was unspeakably expensive, but I was one of the lucky ones. My health insurance paid for it.

Shortly after beginning to take the drug, I had no sign of the disease for the first time in decades.

As fortunate as I felt, I was heartbroken to see many people at my physician's office who were suffering as much or more than I had from the same disease simply because they could not afford the same treatment. One unforgettable woman was so affected by the disease that her fingers were gnarled, she had difficulty walking, and like many who suffer from chronic illness, she used all her energy just to get through the day. She told me she had gone through every treatment option but was still getting worse. She was trying to find a way to

get access to Enbrel since there was no way she could afford it on her own.

I knew so well what she was going through. The pain can be unbearable, and you watch in disbelief as you grow more incapacitated day by day. And to know that this lovely woman was denied a drug that might have helped simply because she couldn't afford it made the situation that much worse.

“As fortunate as I felt, I was heartbroken to see many people at my physician's office who were suffering as much or more than I had from the same disease simply because they could not afford the same treatment.”

How do we as a society hold out the hope of miracle drugs, then turn around and tell people with deadly and crippling diseases that they can't have the treatment that could help them?

We can't. We need to give the FDA the authority to approve safe, effective generic biologic drugs that more people can afford. As the number of biologic drugs continues to grow, it's going to become more and more difficult to say no to the millions of Americans with cancer, multiple sclerosis, rheumatoid arthritis, and other conditions that can be treated using these drugs. ■

Did You Know?

- Generic drugs have saved the U.S. health care system more than \$734 billion over the past 10 years.
- More than half of the top 20 biologics drugs have either gone off patent or will do so by 2012.
- U.S. sales of biologics increased by 20 percent in the past year to \$40.3 billion.
- Worldwide, biologics account for about one out of eight prescriptions written. ■

The Tier 4 Phenomenon

By Bill Walsh, Senior Strategic Advisor, AARP, Contributing Editor

Insurers and employers have long sought ways to shift the rising cost of prescription drugs to consumers. One of the fastest-growing strategies is to charge them a percentage of the bill for some of the most expensive drugs on the market. Almost all Medicare plans and some 10 percent of commercial plans place the costliest drugs on so-called “fourth tiers” of their drug formularies.

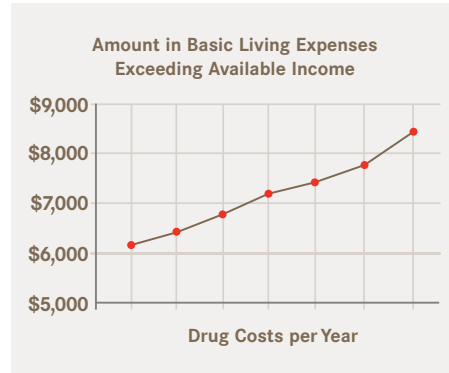
Invariably fourth tiers include expensive biologic drugs, such as breakthrough treatments for cancer, kidney disease, and arthritis. To get the drugs, in most plans, consumers must pay a percentage of the cost (i.e., co-insurance) rather than a predictable, fixed-dollar co-payment. In 2009, fourth-tier cost sharing in Medicare prescription drug plans is typically 25

“With the cost of biologics rising at three times the rate of inflation, fourth tiers are a “double whammy for consumers,” according to a recent report by AARP.”

percent to 35 percent of the drug cost. And the consumer share has been on the rise. One of the biggest Medicare plans increased cost-sharing from 25 percent in 2008 to 43 percent in 2009 for its Tier 4 drugs. In addition, an estimated 20 million Americans are in commercial plans with Tier 4 pricing. With the cost of biologics rising at three times the rate of inflation, fourth tiers are a “double whammy for consumers,” according to a recent report by AARP.

“To get their drugs, (consumers) are forced to pay a growing share of an ever-growing price,” according to the report, *The Tier 4 Phenomenon: Shifting the High Cost of Drugs to Consumers*,

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A Rising Burden: A Medicare beneficiary’s annual income of \$30,000 could force them to forego basic living expenses at various levels of drug costs



Sources: *Pharmaceutical Research and Manufacturers of America, 2007 Annual Report, August 2007*; and *Generic Pharmaceutical Association, “Facts At A Glance,” 2009.*

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which AARP released March 9, 2009. The financial burden for Medicare beneficiaries can be substantial, especially those who don’t qualify for low-income subsidies. According to an analysis by AVOS Life Sciences for AARP, the annual out-of-pocket expenses for someone on Medicare with \$25,000 in drug costs would be \$5,012, not including monthly premiums. For a beneficiary making \$30,000 a year, such a drug cost could mean foregoing basic living expenses such as food, clothing or rent, the analysis found.

Those in private health insurance plans enjoy none of the low-income subsidies that Medicare offers. While most private plans have out-of-pocket spending limits, the vast majority of these don’t apply to drug costs, leaving enrollees extremely vulnerable to high co-insurance charges such as those found on fourth tiers.

Commercial plans have not been as quick as Medicare to adopt fourth tiers in their drug formularies. But a survey of 28 large employers conducted for AARP by AVOS Life Sciences found that those that had created specialty drug tiers were motivated primarily by the

high cost of drugs. As drug prices continue to rise, adoption of fourth tiers by commercial plans is also expected to increase, the survey found.

One of the most troubling trends in Medicare Part D plans has been the increased presence of cancer drugs on fourth tiers. A recent study by Avalere Health and the American Cancer Society found that in 2009, 84 percent of Part D beneficiaries were in plans that put Gleevec in a high-cost specialty tier, up from 39 percent in 2006. Over the three-year period, the average co-insurance charged for cancer drugs Gleevec, Stutent, and Tarceva rose from 27 percent to 33 percent, the study found, putting an escalating financial load on some of the sickest patients.

“While most private plans have out-of-pocket spending limits, the vast majority of these don’t apply to drug costs, leaving enrollees extremely vulnerable to high co-insurance charges such as those found on fourth tiers.”

The financial burden on consumers could be offset by generic versions of biologic drugs, but the United States lacks a system for approving generic biologics. AARP has endorsed HR 1427, a bipartisan bill by Rep. Henry Waxman, D-Calif., the “Promoting Innovation and Access to Life-Saving Medicine Act.” “I believe this bill will lead to healthy competition and long-term savings for patients and payers, and will preserve innovation in the biotech marketplace,” said Rep. Waxman, Chairman of the House Energy and Commerce Committee. To read the full Tier 4 report visit www.aarp.org/research/health/drugs/tierfour.html. ■

The EU: a Global Leader on Biosimilars continued

agreed on a regulatory pathway for the approval of “similar biological medicinal products” that are as safe and effective as their brand name biologic counterparts.

The EU directive establishes a biosimilar approval mechanism and contains specific guidelines for the European Medicines Agency (EMA), which, like the FDA in the U.S., regulates brand name biologic drugs. This regulatory approval framework ensures safety and efficacy for the manufacture and sale of biosimilar medicines in the EU.

The comparability standard has been widely accepted internationally as a means of approving revisions of brand name biologic drugs if they undergo changes in the manufacturing process. The EU simply extended this accepted standard to biosimilars. Generally, two biotech drugs are considered to be comparable if they are demonstrated to have “highly similar quality attributes” with “no adverse impact on the safety or efficacy, including immunogenicity.”

Companies seeking approval of biosimilars must undergo a rigorous scientific framework for approval to ensure safety and efficacy:

“[W]e have promoted and developed with the European Medicines Agency a special biosimilars framework. So we are confident that if a product meets all the requirements and gets a marketing authorization from the commission, it means that the product is as safe and effective as any other product authorized by the commission.”

“The comparability standard has been widely accepted internationally as a means of approving revisions of brand name biologic drugs if they undergo changes in the manufacturing process.”

Nicolas Rossignol, former Administrator, Medicinal Products for Human Use, European Commission Enterprise & Industry-Pharmaceuticals.

The EU’s approval process was finalized in 2005; within the first three years, 13 biosimilar applications had been

approved. This demonstrates the enormous success of the EU’s framework. Further, the EU has had no safety or quality problems with biosimilars. This is attributable to the scientific rigor of the framework and the EMA’s expertise in biotech medicines.

The experience of the EU also shows that biosimilars can offer great cost-savings through increased competition and lower prices. One study indicates biosimilars were expected to save up to \$80 million in Germany alone in 2008.

After biologic patents expire, the U.S. market will lack generic versions of biotech medicines and will not benefit from the market competition and savings they could provide.

The success of the EU framework underscores the benefits of biosimilars. Most importantly, it illustrates that great cost savings can be achieved through the introduction of biosimilars while maintaining the highest standards of safety and efficacy and further fueling continued research and development of the biotech medicines industry. ■



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