

**Comments by the  
Coalition for a Competitive Pharmaceutical Market (CCPM)  
to the Senate Judiciary Committee**

**Hearing On The Law Of Biologic Medicine**

**June 23, 2004**

The Coalition for a Competitive Pharmaceutical Market (CCPM) respectfully submits these comments to the Senate Judiciary Committee on the issue of generic biopharmaceuticals. CCPM believes that it is time for Congress to ensure that price competition occurs in the biopharmaceutical sector. We believe that the socioeconomic considerations that resulted in the landmark Hatch-Waxman Act 20 years ago are as significant for biopharmaceuticals today, as they were for traditional pharmaceuticals in 1984.

CCPM is uniquely positioned to speak on the merits of competition, as we are an organization of employers, insurers, generic drug manufacturers and others committed to improving consumer access to affordable pharmaceuticals. The principles to which CCPM are committed include: establishing a definitive, efficient approval pathway for affordable pharmaceuticals (including biopharmaceuticals) that will provide significant savings to consumers and public and private purchasers; implementing market-driven solutions that address the skyrocketing costs of prescription drugs within our nation's health care system; and increasing the utilization and awareness of the safety and efficacy of affordable drugs, and their value to state, federal and private programs.

The Drug Price Competition and Patent Restoration Act of 1984 (Hatch/Waxman) has been a tremendous success. Hatch/Waxman has resulted in a strong, vibrant and highly profitable branded pharmaceutical industry where success is driven by the new product

innovation that competition creates. It has also resulted in a strong and vibrant generic pharmaceutical industry that continues to bring more affordable generic versions of brand medicines to consumers every day.

Of great interest, is the fact that more than one-out-of-every two prescriptions today are filled with generic pharmaceuticals, yet less than eight cents of every dollar spent on medicines is spent on generic drugs. The savings that have resulted from Hatch/Waxman allow more consumers to afford the medicines they need. It also enables employers, insurers and government agencies to ensure that more people have access, while allowing scarce financial resources to be more efficiently allocated.

CCPM believes that solidifying a regulatory process that will enable generic competition for biopharmaceuticals can, and will, have the same effect as Hatch/Waxman. Specifically, competition will: (1) increase access to more affordable versions of biopharmaceuticals; and (2) provide an incentive for biopharmaceutical developers and manufacturers to stoke the engines of innovation and new biopharmaceutical product development. Finally, CCPM believes that the technology to develop and manufacture safe, effective and more affordable generic biopharmaceuticals exists for certain products today and in no way serves as a barrier to these products coming to market. As sophisticated technologies continue to evolve, even more biopharmaceuticals will be candidates for competition in the future.

CCPM asserts that competition for biopharmaceuticals is critical. In 2003, six of the top selling biopharmaceuticals had sales of more than 9.5 billion dollars. In contrast to conventional drugs, some biopharmaceuticals exceeded \$2,800 per patient per year, according to a Forbes Magazine article.<sup>1</sup> And there are other examples that are even more extreme. Patients taking Neupogen paid approximately \$23,000 last year; Epogen patients paid about \$10,000 for a single year of treatment<sup>2</sup>; and Intron A patients paid

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<sup>1</sup> [www.Forbes.com/2003/07/25/cx\\_mh\\_0725drugstore\\_print.html](http://www.Forbes.com/2003/07/25/cx_mh_0725drugstore_print.html)

<sup>2</sup> December 15, 2002; Deseret News; January 2., 2001 Red Herring; April 28, 2002 Reuters News; Feb. 4, 2002 Medical Letter: Vvol. 44 (Issue 1123).

about \$5,000. While these drugs provide treatment for a wide variety of diseases, from cancer to arthritis, the burden on the average consumer, employers and health plans is devastating. Moreover, this burden is shared extensively and excessively with taxpayers who are underwriting the funds for public health programs providing prescription drug coverage.

It is interesting to note that at least 8 biopharmaceuticals used to treat hepatitis, diabetes, cancer, multiple sclerosis and human growth hormone deficiency are already off patent. Another eight drugs used to treat heart disease, kidney failure, and human growth hormone deficiency, among others, will go off patent in the near future. Yet, there is no way for consumers to take advantage of savings once the patents expire, because the approval pathway and requirements remains uncertain. FDA has yet to approve generic versions of these drugs.

High prices and lack of competition are fueling strong growth. Expenditures for biopharmaceuticals are growing at more than twice the rate of all pharmaceuticals (20 percent versus 8 percent), with biologics costing this Nation's health care system about \$33 billion this year. Expenditures for biopharmaceuticals are expected to reach \$60 billion by 2010.<sup>3</sup> Thus, given that the number of new biopharmaceuticals approved each year continues to grow, and given their exceedingly high costs, without biopharmaceutical competition, providers and consumers will be faced with even graver health care cost containment decisions tomorrow.

In summary, CCPM congratulates this committee for taking the first step along the road to ensuring generic biopharmaceutical competition. We call on Congress to work diligently to solidify a flexible, definitive, affordable biopharmaceutical approval process to ensure price competition and universal access to quality health care.

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<sup>3</sup> Bloomberg.com (Oct. 31, 2003).

Today, the blend of brand and generic pharmaceuticals allows Americans to live longer, healthier lives. The Hatch/Waxman Act has simultaneously created billions of dollars in savings on important medicines, while continuing to fuel strong growth and investment in the development of new traditional brand pharmaceutical products. We are convinced that the application of generic competition in the biopharmaceutical environment will have the same results. We believe that ensuring timely access to generic biopharmaceuticals will result in a healthier nation at a more affordable cost.

Thank you.