TESTIMONY OF

BRUCE L. DOWNEY

CHAIRMAN AND CEO, BARR PHARMACEUTICALS, INC.

"ASSESSING THE IMPACT OF A SAFE AND EQUITABLE BIOSIMILAR POLICY IN THE UNITED STATES"

Before the
HOUSE ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH

U.S. HOUSE OF REPRESENTATIVES
MAY 2, 2007

Chairman Pallone, Ranking Member Deal and Members of the House Energy and Commerce Committee Subcommittee on Health. I am Bruce Downey, the Chairman and Chief Executive Officer of Barr Pharmaceuticals, a leading global generic pharmaceutical company.

I want to thank you for convening this hearing and for allowing me to express my company's views on issues so vital to the continued success of the generic pharmaceutical industry – an industry that saves consumers and taxpayers literally billions of dollars each year in prescription drugs costs. Indeed, no other industry has made, or continues to make, a greater contribution to affordable health care than the generic pharmaceutical industry.

While my testimony today is on behalf of Barr Pharmaceuticals, I also serve as Chairman of the Generic Pharmaceutical Association, which represents more than 100 generic manufacturers, distributors and suppliers of bulk active pharmaceutical chemicals worldwide. I mention my role in GPhA because it is important to note that the issue we address today – that of generic biological medicines – is at the top of the association's priority list of legislative and policy initiatives.

INTRODUCTION

Mr. Chairman, this Congress holds the key that will open the door for generic and other manufacturers to provide affordable access to many of the life-saving biological medicines used in the treatment of diabetes, cancer, rheumatoid arthritis, HIV/AIDS and other diseases. Today, the cost of these treatments can put them out of reach of many consumers. The rheumatoid arthritis and psoriasis treatment Enbrel®, for instance, costs an average of $16,000 a year per patient. Biological drugs for multiple sclerosis range in price from $16,000 to $25,000 a year. Neulasta®, used to correct chemotherapy-induced white blood cell deficiency, costs an average $3,500 per chemotherapy cycle.

What becomes frightening from the cost perspective is that not only are the costs of biological treatments getting more expensive each year, but the utilization of these medicines is growing, as well. These two factors coupled together yields exponential growth in the amount we are spending on biologics every year.

According to the 2006 Drug Trend Report released in April by Express Scripts, biotech drug spending increased 21 percent last year, even as growth in traditional prescription drug expenditures slowed. The report showed that growth hormone deficiency spending rose nearly 23 percent in 2006 due to a 10.7 percent increase in utilization, coupled with the increase in product cost.

This dual impact of higher prices and greater utilization presents a recipe for disaster which will end in price controls. The alternative, as we are seeing in the chemical drug sector, is competition.

Thus, creating a pathway that allows for the introduction of safe and affordable generic alternatives to these medicines is vital. It not only will save consumers and taxpayers billions of dollars a year, but, again, will allow more patients access to these important medicines.

This committee is well aware of the role traditional chemical generic drugs play in helping consumers, insurers, and the government in achieving billions of dollars in savings each year. Generic drugs filled more than one-and-a-half billion prescriptions in the U.S. last year. That is nearly 55% of all prescriptions dispensed nationwide. Considering that the average cost of a generic prescription is less than $30, while the average cost of a brand prescription is close to $95, it is easy to see how the Congressional Budget Office estimates the savings generated by generic drug use to be between $8 billion and $10 billion each and every year.

As this Committee knows, Congress made these savings possible over twenty years ago with the 1984 enactment of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. Hatch-Waxman achieves a critical balance between access to less costly generics and innovation of new brand-name drugs. I, and many others, believe that it is time for Congress to take the next step

and let generic companies provide savings in the biological field. Doing so, however, will require brushing aside the current political maneuvering that threatens progress on this issue, and enacting appropriate legislation that would allow FDA to begin approving safe, effective, and affordable generic biologics.

DISCUSSION

Today, I want to briefly discuss three points that I hope this committee will consider as you move forward on generic biologics legislation:

(1) legislation must provide a regulatory pathway for approving generic biologics that is free of artificial barriers and unnecessary roadblocks, as well as a mechanism for allowing expeditious resolution of patent disputes that would delay generic market entry;

(2) market competition generated by generic biologics would unleash incentives for further innovation of newer medicines, just as Hatch-Waxman did over twenty years ago; and

(3) generic biologics will provide a market-based mechanism to help manage private and federal expenditures and achieve significant savings.

I. Legislative Framework

Effective generic biologics legislation must include two parts: a regulatory pathway that allows FDA to expeditiously approve safe and affordable generic biologics and a mechanism for allowing generic companies to resolve certain

patent disputes without delaying FDA approval. I will discuss some important aspect about both of these issues.

A. Approval Pathway

Effective biologics legislation must include a regulatory approval pathway that does not impose unnecessary barriers to prompt market entry. Hatch-Waxman was largely successful in achieving this goal for generic drugs regulated under the Federal Food, Drug and Cosmetic Act, and this legislation should do the same for biologics regulated under the Public Health Service Act. An adequate abbreviated pathway must include, for example:

- clearly defined comparability criteria;
- provisions giving FDA discretion to require the needed tests – and only the needed tests – to make safety and effectiveness determinations;
- provisions setting forth the circumstances under which FDA can deny approval;
- provisions setting forth the contents of an abbreviated biological application;
- the ability to obtain an interchangeability rating that is immediately operative;
- no unique names for generic biologics, which is fully consistent with FDA's position that unique biologic names should not be used to differentiate products with the same active ingredient(s) when credible scientific data demonstrate that no pharmacologically relevant differences exist;

- a timely review process that allows a company to discuss with the FDA research and testing and to know when action on the application can be anticipated; and

- an approval process that gives FDA flexibility as to what should be required on the label.

Equally as important, effective biologics legislation must not include provisions like those advocated by groups such as BIO – provisions that would unnecessarily delay approval and/or prevent consumers from receiving the biggest benefit from generic biological products. For example, legislation should *not* include:

- a requirement that all generic applications include full clinical and human trials, or any clinical trials other than those that FDA deems necessary to the relevant scientific issues;

- further legislation, or Congressional authorization/oversight or FDA regulations or guidances before the agency can give an interchangeability rating to a generic product;

- unique names for generic biologics, which would impede interchangeability findings and thus prevent the substitution of generic for brand that is essential for cost savings;

- provisions requiring agency-issued guidance or notice and comment rulemaking, which can take years and years to complete, before FDA can accept or approve a generic biologic application; and/or

- provisions requiring the generic company to have an identical label to the reference product, particularly where the brand has patented certain labeling information.

There is no justification for provisions like these, which will delay generic market entry and the interchangeability rating needed for consumers to benefit most from generic competition. They are entirely unnecessary to ensuring approval of safe and affordable generic biologics.

For example, while today clinical data may be needed for most biological products, Congress should not impose rigid requirements for such testing in all circumstances. Rather, Congress should give FDA the ability to draw on its decades of experience with these compounds by granting the agency the discretion to require such tests only when it determines that such clinical studies are needed.

It is significant that FDA agrees. FDA Deputy Commissioner Janet Woodcock addressed this during Congressman Waxman's Oversight & Government Reform Committee hearings last month, testifying that the "use of human subjects for trials that are not needed but are simply to check a box on a regulatory requirement is not desirable." Dr. Woodcock added that the ability to physically characterize protein molecules and other complex substances "has evolved and is continuing to evolve" and that "flexibility in enabling FDA to incorporate the new science into the regulatory process . . . is in the best interest of the public as well as the agency and the industry." Congress has entrusted FDA to

make scientific judgments regarding drugs and biologics. This scientific advice from the agency should be headed.

Barr urges Congress to pass a regulatory framework for approving generic biologics that is free of unnecessary barriers and roadblocks in the form of artificial requirements, such as clinical studies and agency guidances. Such a framework will give FDA the flexibility it needs to approve safe and interchangeable generic biological products as quickly as possible.

B. Patent Provisions and Other "IP" Provisions

A key part of effective generic biologics legislation is a mechanism that allows the generic company to resolve certain patent disputes without that litigation impacting FDA approval. This was also a goal of Hatch-Waxman, although the brand industry has found ways around the law's intent, which was that patent disputes be resolved early, so that the generics can enter the market at the earliest time after valid and applicable patents have expired. Barr submits that any bill providing a pathway for generic biological products should take into account what we have learned from our 20-plus years of experience with the Hatch-Waxman patent provisions and improve upon that system in order to ensure that affordable biological products reach the public as quickly as possible. Thus, an effective generic biologic bill must, at the very least, contain patent provisions like the following:

- First, companies need patent certainty prior to marketing. Without it, companies will not invest in bringing affordable, comparable products to market prior to patent expiration because doing so could subject them to enormous patent infringement damages. Thus, effective legislation must include provisions that allow a generic company to obtain the required certainty – through litigation if necessary – while FDA is reviewing the application.

- Second, equally as important, however, is the fact that generic companies not be forced to litigate every patent relating to the brand product in order to obtain the patent certainty needed to launch. Thus, a biological patent system should provide a mechanism for litigating only those patent disputes that the generic company believes would delay its launch. There will be other patents – for example patents applicable to manufacturing processes that the generic company is not using – for which the only effect of early litigation would be unnecessary delay. I am not suggesting that the brand company should forever be foreclosed from asserting its patents. The brand company should have that opportunity, just not before the generic company markets its product. Accordingly, the system that will allow for the most expeditious generic market entry is one that permits the generic company to select the patents that will be litigated pre-product launch. This system also protects the brand company's intellectual property by allowing for suit on any patent that can reasonably be asserted after the generic company begins marketing.

- Third, generic companies need to be able to resolve patent disputes without those disputes delaying the FDA approval process, as we now experience with small molecule drugs under Hatch-Waxman.

- Fourth, generic companies must be able to litigate patent disputes quickly and efficiently. This will only happen if the generic company is permitted to designate a forum that would allow for more efficient litigation resolution. Right now, the brand company has the ability to bring suit against an ANDA applicant in virtually any district court in the country. Brand companies increasingly have brought suit in districts

with the longest time to trial. In some courts, its takes from three to five years just to get to trial. Where certainty is essential, this means more delayed market entry.

- Fifth, if a brand company refuses to participate in the patent process, as increasingly happens with small molecule applications, the generic company must be allowed to enter the market without risking potentially massive damages. Under proposals such as those found in H.R. 1038, generic companies have some protection in the event that the brand company refuses to participate in the patent process. Brand companies have complained that this takes away substantive patent rights and forces them to give what amounts to a compulsory patent license. Not true. These provisions only apply if the brand company violates its statutory obligation to participate in the patent process. If the brand company follows the law, all of its patent rights would remain in tact.

Finally, part of the so-called "IP" discussion surrounding generic biologics is the idea of exclusivity. On the generic side, the issue is clear: consumers and taxpayers, without question, will see the most significant savings from interchangeable products. Thus, it is essential that any generic biologics bill incentivize generic companies to do the work necessary to achieve an interchangeability rating from FDA. At present, no such incentive currently exists and, therefore, will need to be included in the legislation.

On the brand side, the issue also seems clear: lengthy, new exclusivity periods for brand companies are not necessary because the law currently provides more than enough incentive to continue innovating. For example, brand companies already get significant incentives, including multiple provisions

allowing for patent term restorations, orphan drug exclusivity, and various tax credits. If the brand companies disagree, they are free to come forward and present data to support their argument. Indeed, Representative Waxman has invited discussion on this issue. However, the brands have not yet come forward with any concrete data that would suggest that additional incentives are necessary. It is my view that only if they do come forward with such evidence should Congress consider enacting new exclusivity periods.

II. Generic Competition Will Spur Innovation

There is a misconception that market competition from generic biologics would diminish the incentive for originators to innovate new biologics. Generic competition will *not* slow innovation. In fact, just the opposite would be true. Market competition generated by generic biologics would accelerate further innovation of new biological products, while at the same time lowering the cost of treatment with existing medicines.

For example, Dr. Scott Gottlieb, recently the FDA Director of Medical Policy Development and Deputy Commissioner for Medical and Scientific Affairs, has explained: "Legislation to expose today's biologics to easier competition, after legitimate patents have expired, is going to accelerate development of improved products, not just lower-cost. Those making static assumptions . . . about how much savings this legislation is likely to bring are losing sight of the competition

and progress it will have unleashed." [Forbes 4/17/07 edition (emphasis added)]. Similarly, the January 2007 study released by the Pharmaceutical Care Management Association concluded that increased competition from generic biologics would not only create pressure to reduce the cost of these products, but also produce added incentives for further innovation. Thus, generic biologics legislation would provide the dual benefit of increased savings and advancements in medical treatments.

III. Savings

No one can legitimately dispute that generic biologics will provide a market-based mechanism to help manage private and federal expenditures and achieve significant savings. And no one can dispute that the American health care system has ever needed those savings more than it does today.

As the use of life-saving biological drugs continues to increase, so does the amount consumers and taxpayers spend. Indeed, spending on biotech drugs increased 21% in 2006, to approximately $40 billion, according to the 2006 Drug Trend Report. Spending in this sector is expected to grow to $100 billion over just the next four years. By 2010, biological medicines will account for 26% of total drug spending in the U.S. It is particularly important to note that Medicare spending for biological drugs continues to escalate disproportionately to Medicare funding. To put things in perspective, Medicare and Medicaid will spend $2.5

billion this year on just one biological drug – the anemia treatment Epogen® – which is a half-billion dollars greater than the entire FY 2007 budget of the Food and Drug Administration.

The solution to managing this spending is, of course, the use of safe and effective, lower-cost generic biologics. Just as generic chemical drugs have saved billions of dollars so, too, will generic biological drug products. A study released by Express Scripts in February 2007 showed that generic biologics would save payors $71 billion over 10 years. An Engel & Novitt study in January 2007, as well as other independent economic analyses we have seen, show that generic biologics would generate significant savings for Medicare Part B reimbursed medicines. Now, the brand companies take issue with some of these studies. Significantly, though, they do not take issue with the fact that generic biologics will save billions of dollars. They only take issue with how many billions will be saved. But in the end, whether the number is $71 billion or $7.1 billion, we simply cannot afford to lose the savings that, without question, would be achieved through use of generic biological medicines.

Congress should act now and pass legislation giving FDA authority to review abbreviated applications for generic biologics. The agency would be able to begin reviewing those applications as soon as they were submitted and the public would be assured that when the FDA approves a generic version of a

biological product, just as has been the case with traditional drugs over the past 30 years, it will be safe, effective and have the same performance as the innovator product.

CONCLUSION

Chairman Palone and Members of the Committee, Barr always has been deeply committed to providing the public with affordable, safe generic drug products, and to do so as expeditiously as possible under the circumstances. That is why Barr has joined with consumer groups like AARP, Consumers Union, Families USA; employee unions life AFL-CIO and AFSCME; major corporations like Caterpillar, Ford, GM, and Kodak; healthcare providers Aetna, Blue Cross Blue Shield and Kaiser Permanente; pharmacy leaders like CVS/Caremark and the National Association of Chain Drug Stores; and no less than 18 of the nation's governors in calling on Congress to pass legislation creating the framework for the approval of safe, effective and lower-cost generic biological drugs.

Congress has the opportunity this year to create a huge win for patients, for taxpayers and for employers alike. Indeed, effective generic biologics legislation very well could be the most important piece of consumer legislation enacted this year. We urge Congress to move forward in this effort.

Thank you, Mr. Chairman. I am happy to respond to any questions you and the Committee may have.