Mylan Calls for End to Abusive Practices That Delay Access to Affordable Pharmaceuticals

Mylan Testifies Before Congress on Heels of Introduction of New Authorized Generic Legislation

WASHINGTON, July 20 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) testified before the U.S. Senate Special Committee on Aging today concerning potential solutions for authorized generics, citizen petitions and other issues that delay generic pharmaceutical approvals and put at risk billions of dollars of consumer healthcare savings.

Robert J. Coury, Mylan's Vice Chairman and CEO, commented, "It's been approximately three years since we started down this path, and Mylan has never wavered in our commitment to address the abusive tactics that brand pharmaceutical companies use in an attempt to destroy the natural balance that Congress intended for our industry. This is a significant day for the generic pharmaceutical industry as well as for Mylan."

Heather Bresch, Mylan's Senior Vice President of Strategic Corporate Development testified on behalf of Mylan. Ms. Bresch commented: "Brand pharmaceutical companies are employing multiple tactics in order to delay or block consumer access to affordable pharmaceuticals. We are pleased that a bi- partisan group of congressional leaders has taken the lead on addressing these issues, and we are confident that legislative and other measures can be implemented to restore the unique balance that existed in the United States between brand and generic pharmaceuticals."

Mylan's testimony comes on the heels of the introduction of legislation yesterday to address one of the most important issues: "authorized" generics, which are simply branded products relabeled and sold as generics during the 180-day exclusivity period Congress set aside for the first generic company that successfully invalidates a patent. Sen. John D. (Jay) Rockefeller IV, W.Va., introduced S. 3695 prohibiting authorized generics during the 180-day exclusivity period. The bill was co-sponsored by Sens. Charles E. Schumer, N.Y., and Patrick Leahy, Vt.

"Mylan has done great work in upholding the intent of Hatch-Waxman. Authorized generics should not be allowed during the 180-day period Congress intended for a true generic manufacturer to have exclusive market rights. That is why I have introduced legislation to prohibit the introduction of what are brand name drugs-in-disguise during the 180 days," said Sen. John D. (Jay) Rockefeller IV.

Ms. Bresch commented: "We applaud Sens. Rockefeller, Schumer and Leahy for their leadership on this issue. A soon to be released independent study demonstrates the true facts on authorized generics: consumers do not realize any additional savings from authorized generics, and they put billions of dollars of future healthcare savings at risk."

A complete version of Mylan's written testimony for the Special Committee on Aging's hearing follows.

Mylan Laboratories Inc. is a leading pharmaceutical company with three principal subsidiaries: Mylan Pharmaceuticals Inc., Mylan Technologies Inc. and UDL Laboratories Inc. Mylan develops, licenses, manufactures, markets and distributes an extensive line of generic and proprietary products.

For more information about Mylan, please visit www.mylan.com.

Testimony of Heather Bresch
Senior Vice President of Corporate Strategic Development, Office of the CEO

Mylan Laboratories Inc.

The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs.

United States Senate Special Committee on Aging
Washington, D.C., July 20, 2006

Thank you Chairman Smith, Ranking Member Kohl and Members of the Special Committee on Aging. I am Heather Bresch, Senior Vice President of Corporate Strategic Development in the Office of the CEO of Mylan Laboratories. Mylan has been in

existence for 45 years. We are the largest U.S.-based generic pharmaceutical manufacturer, supplying more than 150 FDA-approved prescription generic drugs, and we are one of the world's leading suppliers of prescription medicines having manufactured more than 12 billion tablets and capsules during the most recent fiscal year. Mylan is also the largest supplier, brand or generic, of prescription transdermal patches, with more than 88 million units dispensed in 2005. Mylan has consistently been recognized by the FDA and by the pharmacy community for the excellent quality of its products.

While I am speaking on behalf of Mylan today, I also served as Chairman of the Generic Pharmaceutical Association for two terms and currently serve as Vice Chair. GPhA represents more than 100 generic manufacturers and distributors of finished generic products, as well as manufacturers and distributors of bulk active pharmaceutical chemicals.

Generic products are now used to fill more than one-and-a-half billion prescriptions in the U.S. every year, which accounts for about 54 percent of all prescriptions dispensed across the country. Considering that the average cost of a brand prescription is about $95.00, while the average cost of a prescription filled with a generic is less than $29.00, use of generic drugs generates billions of dollars in savings for consumers as well as businesses, and state and federal government agencies. The Congressional Budget Office estimated, for example, that by purchasing generic drugs when available as substitutes for brand-name drugs, consumers save between $8 billion and $10 billion a year on prescription purchases made at retail pharmacies.

Mr. Chairman, our country is facing a crisis in rising healthcare costs and the generic pharmaceutical industry represents one of the few proven solutions to contain those costs. So I am pleased to be here today to discuss ways to improve access to generic drugs and to share our views on the harm done to consumers and government when new generic drugs are delayed. I will specifically address four tactics purposefully used to slow down or block the entry of generic pharmaceuticals into the marketplace. These tactics cost American consumers, businesses, insurers and our government millions of dollars every day.

By way of background Hatch-Waxman - officially "The Drug Price Competition and Patent Term Restoration Act of 1984" - reflected an attempt by Congress to strike a balance between two policy objectives: to incentivize name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products; and also to enable competitors to bring lower-cost, bioequivalent and therapeutically equivalent generic versions of those drugs to market. Hatch-Waxman, is designed to both reward innovation and encourage access to affordable medicines. When the balance is disturbed the system is jeopardized and it is consumers, the government and taxpayers who suffer the economic consequences.

In terms of the branded pharmaceutical side of the scale, this legislation protects intellectual property in a variety of ways. Hatch-Waxman provides the means for innovators to restore up to 5 years of patent life to compensate for time the product underwent regulatory review at the FDA. In subsequent legislation branded pharmaceutical companies were offered 5 years of data exclusivity for new chemical entities, a supplement of 3 years of data exclusivity for clinical trials, 6 months marketing exclusivity for pediatric studies, and an automatic 30-month stay of generic approvals in order to resolve patent disputes.

With respect to the generic pharmaceutical side of the scale, Hatch-Waxman streamlined the generic drug approval processes and provided 180 days of market exclusivity to financially incentivize generic manufacturers to challenge the validity of questionable patents held by brand manufacturers. The marketing exclusivity period allowed the generic companies to gain the significant financial resources necessary to reinvest and continue to develop additional generic products.

Notable examples of the system working the way it was intended occurred when Mylan challenged patents on the name brand drugs Buspar® and Procardia XL® and brought generic versions of those drugs years before patent expiration. Another well known patent challenge by a different generic company invalidated a key patent on Prozac®. Hundreds of millions of dollars in savings were realized by consumers and the government as a result of these successes.

The system worked well until the early 2000s, when branded pharmaceutical companies began to exploit certain legislative loopholes. While Congress put an end to some of these practices in 2003 with the passage of Hatch-Waxman reform in the Medicare Modernization Act (MMA), unfortunately, brand companies were already using new tactics to extend their monopolies.

These tactics include first, authorized generics, which are simply branded products relabeled as generics and then systematically dumped into the generic marketplace during the 180-day exclusivity period. A second tactic is the use of frivolous citizen petitions raising unfounded safety-issues. These petitions are strategically filed with the FDA to delay generic entry. Third, legal maneuvering around Congress's attempt to allow for a declaratory judgment trigger can create a bottle-neck of generic drug approvals. And fourth, exploitation of pediatric exclusivity rules to gain extended monopoly for drugs that should not be used in the pediatric population.

AUTHORIZED GENERICS

Mr. Chairman, in our industry there is no issue more hotly debated than that of authorized generics. This brand tactic is the "authorizing" of a third party to sell the brand product dressed as a generic as soon as the first true generic begins to enjoy its

180 days of statutory exclusivity. This practice can all but eliminate the financial benefit of the market exclusivity for the first generic filer.

Let me be very clear: the generic industry is not opposed to authorize generics per se. Our issue lies only in the marketing of authorized generics during the 180-days of exclusivity as provided under Hatch-Waxman. Following the 180-days of exclusivity granted to the first generic filer, we recognize the right of any company with an FDA-approved product, including the brand company, to compete in the generic marketplace. The issue is when the authorized generic is brought to market. As this committee is aware, it is the timing of the introduction of the authorized generic that has caught the attention of the FTC and is being examined in their pending study.

The words of several brand pharmaceutical CEOs best demonstrate their motives.

- In December 2003 in a Pink Sheet Article Eli Lilly CEO Sidney Laurel was quoted saying that systematically launching authorized generics each time a patent expires would mean the brand industry could "truly eliminate the incentive in the calculation that generic companies would make."
- In June 2006 in a Wall Street Journal article Pfizer's Hank McConnell was asked whether Pfizer subsidiary Greenstone aimed mainly to give generic-drug maker fits or to preserve some sales for Pfizer, he quipped, "Both are good things."
- In April 2003 press release, GlaxoSmithKline announced an authorized generic agreement for Paxil®, the blockbuster antidepressant. The agreement prevented the authorized generic from becoming available until "another generic version fully substitutable for Paxil becomes available." In other words the authorized generic was prohibited from launching until the generic filer with 180 days of exclusivity was launched.
- In February 2004 earnings conference call GlaxoSmithKline CEO J.P. Garner said "The idea was somebody has a six month exclusivity, but we are a king maker; we can make a generic company compete during [the 180- day exclusivity]."

"King maker" doesn't sound like the competitive balance intended by congress when enacting Hatch-Waxman.

Supporters of authorized generics say they reduce prices in the short term, arguing that consumers benefit and that authorized generics are somehow consumer-friendly. They cite a recent report by the Pharmaceutical Research and Manufacturers of America ("PhRMA") saying that there is a 15 percent reduction in price as a result of authorized generics during the 180-day exclusivity period. Nothing could be further from the truth. This study only looked at prices at the wholesale level - not the retail level - where in fact consumers do not realize those savings.

Prescription drugs move through a multi-step pharmaceutical "supply chain" when making their way from manufacturer to wholesaler, to patient (end user or consumer) and prices paid for drugs vary for each entity within the supply chain. For example, large wholesalers, national pharmacy chains and major health insurers - those entities in the middle on the chart -- can negotiate steep price discounts from drugs manufacturers, especially when the market becomes commoditized with multiple generic players. Individual consumers, on the other hand, typically pay retail prices for drugs without negotiating with pharmacists.

Therefore, to measure any discount off the brand drug price - the savings that generics offer - data from the price point between wholesaler/chain and consumer must be used. Using price data obtained at the point between manufacturer and wholesaler does not reflect the any potential discounts available to consumers.

I would be remiss if I did not address the connection between authorized generics and patent settlements between brand and generic companies. There has been increasing attention on the issue of patent settlements, by Congress, the FTC, the press and the public. We are aware, Senator Kohl, of your bill which seeks to prohibit generic drug companies from receiving anything of value from patent settlements. As settlements come under scrutiny, we must remember that patent settlements, in and of themselves, are not bad. In fact, a settlement involving breast cancer treatment Tamoxifen allowed a generic version to enter the market nine years prior to the date when the patent in question expired. The reality is that in almost every other type of case, settling litigation is encouraged as an efficient means of resolving dispute and economizing valuable court resources. The option of settling is particularly important to generic companies attempting to challenge brand patents. These challenges are extremely costly - and the outcomes of even the best cases are uncertain. Generic companies need the ability to settle cases in a way that preserves their ability to fight another day.

But more to the point, brand companies have a stronger bargaining position thanks to authorized generics. Brand companies use authorized generics as a "trump card" in settlement negotiations. Even if the generic company believes it can invalidate the brand's patents, the brand company threatens to release an authorized generic during the 180-day exclusivity period, at prices that gut generic returns. This leaves the generic with little choice and no bargaining power.

The FTC has recognized the crucial role authorized generics play in settlement negotiations. FTC Commissioner Jon Leibowitz noted in a recent speech at the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust in Philadelphia, that

"the profits to be made in the 180-day exclusivity period are reduced substantially [by authorized generics], perhaps even cut in half. So the generic firm's calculus in the fight-versus-settle equation may now be more heavily weighted towards settling. Rather than gamble on winning in court, a generic may decide that a fixed entry date and guaranteed revenue stream is a better value than rolling the dice." Mr. Chairman any consideration of patent settlements reform must take authorized generics into account.

CITIZEN PETITIONS

Mr. Chairman, the second tactic being used by brand companies to delay access to generic drugs is the abuse of the citizen petition process.

The brand industry is misusing the citizen petition process to improperly delay generic competition. As intended, the citizen petition mechanism provides a formal opportunity to request the FDA to take or not take a particular administrative action about very specific issues, such as scientific concerns about a particular product's safety or bioequivalence. However, when the process is abused, a citizen petition can become a tool for the brand industry to delay timely entry of safe and effective generic drugs.

Frequently, a brand company will file a frivolous petition on the eve of FDA approval of a generic equivalent. This despite the fact that the FDA may have already granted a tentative approval, meaning that FDA already determined the generic product is safe and effective. The brand strategy is that it will take several months for the FDA to decide the petition, during which time approval of the generic drug is held in limbo. The brand is not required to submit petitions with merit. What the brand company can do is block competition for several months beyond the life of the 20-year patent, thereby extending its monopoly on the market.

The submission of these "eleventh-hour" petitions has caught the attention of the FTC and of the FDA as far back as 1999. That year, the FDA issued a proposed rule to address the problem that would have decoupled the approval process from the process for addressing citizen petitions. The proposed rule, unfortunately, was withdrawn in 2003.

Examples of egregious abuses of the citizen petition process are many. In the case of the drug Arava®, Aventis filed a citizen petition requesting that the FDA deny approval for generic leflunomide unless the generic could demonstrate that 5x20 mg tablets were bioequivalent to 1x100mg tablet. The FDA ultimately denied the petition, noting in its reasons that the "petition was submitted approximately one year after [expiration of brand exclusivity]. [...] This would be at the end of the normal ANDA review cycle for an ANDA submitted on or near the date ANDAs were first eligible for submission, suggesting that the petition intends (at least in part) to delay generic competition." The petition was successful in this regard - it resulted in approximately 6-months delay to generic entry and economic harm to consumers and the government.

In an ongoing example, Wyeth filed a petition to delay approval of generic Effexor XR® two weeks before the patent expired. For each day that the brand succeeds in delaying generic entry, it benefits from approximately $7 million in sales. The delay to generic entry is over three months, and counting.

Yet another example may currently be seen at Mylan Laboratories. Our company is currently experiencing a delayed generic approval solely because of an eleventh hour citizen petition filed by the branded drug company. In September of 2005, we successfully defended a patent infringement suit and invalidated a patent covering the name brand drug Ditropan XL®. Mylan's generic version of the drug had already been tentatively approved by the FDA, meaning the lawsuit was the only thing standing in the way of our ability to launch our product. On the eve of a decision from the district court invalidating the patent, Ortho McNeil Pharmaceuticals filed a citizen petition requesting that FDA re-think its standards for approving generic versions of this drug. The petition raised no new information that had not been long known to Ortho-McNeil and certainly appears to have been timed to delay final approval of our generic drug. Ten months later, the patent stands invalid but we are still unable to obtain final approval from the FDA to launch our product because of the citizen petition.

Frivolous citizen petitions give brand companies an undeserved patent extension, at no cost and with no consequences. These extensions provide anywhere from a few months to over a year of additional monopoly. In contrast, a generic applicant must invest considerable resources on bioequivalence studies, incur significant development costs to design around patent, and legal costs to challenge brand patents in the hopes of benefiting from what was supposed to be 180 days of exclusivity.

A review of the citizen petitions filed with the FDA since MMA reveals a clear picture. Since MMA brand companies have filed 45 petitions requesting delay in FDA approval of a competing generic drug. Of these 45 petitions, the FDA has ruled on 21, denying 20 of them - or 95% - but not before causing delay anywhere from a few months to over a year. Of these, ten were identified as "eleventh hour petitions" (defined as petitions filed 6 months prior or 4 months after the earliest estimated generic entry date). Since MMA, no eleventh hour petitions have been approved by the FDA.

We are pleased that the Senate and House Appropriations Committees insisted that the FDA inform Congress of actions being taken to improve the citizen petition process. In April of this year, the FDA delivered its report stating that, going forward,

objectionable citizen petitions would be sent to the FTC for review. We do not believe forwarding citizen petitions to the FTC improves the process. In fact, it merely adds more time to the already delayed generic entry. Therefore, we urge Congress to support legislation like the bipartisan Stabenow-Lott bill to bring a meaningful resolution to this problem.

DECLARATORY JUDGMENTS

Third, I want to discuss the declaratory judgment provision in the current regulatory scheme.

At the urging of the generic industry, Congress included language in MMA to the effect that if a brand company refused to sue a generic applicant, the generic could seek a judgment declaring the patent in question to be invalid, unenforceable or not infringed. This is important because there are times when a brand company will decide, for strategic reasons, to sue on some but not all of its patents.

This leaves the generic with two options, even if the generic prevails on the particular patents at issue in the suit: stay off the market, or enter the market "at risk" of treble damages for infringing the remaining patents. This could be a 'bet your company' decision for a generic manufacturer. The problem is that the US Court of Appeals for the Federal Circuit, which has jurisdiction over all patent cases, has held that the courts do not have jurisdiction to hear these declaratory judgment suits.

Declaratory judgment can be fixed. In order for a court to accept jurisdiction to grant a declaratory judgment, it must determine that the generic has a "reasonable apprehension of suit". So far, the courts have refused to hold this. Congress can legislate that a reasonable apprehension does exist, even if the brand fails to sue. This would effectively give courts jurisdiction to determine the patent questions and allow generic companies to clear patent issues much earlier without having to launch their product at risk.

PEDIATRIC EXCLUSIVITY

The fourth tactic is securing unwarranted extensions of monopolies through misuse of pediatric exclusivity rules. Under current interpretations of the regulations, almost all drugs are eligible for an additional period of exclusivity in which generics cannot be approved if pediatric studies are completed. This gaming was illustrated recently when Bristol Myers Squibb got six months of additional patent protection in exchange for conducting pediatric studies on Pravigard PAC® (pravastatin and aspirin), even though the FDA requires that the product be labeled with a caution against use in children less than 18 years of age. Affordable generic versions of this product will be blocked from the market for an additional half year because the brand company conducted studies in children using a drug that FDA said shouldn't be given to children in the first place.

In summary, Mr. Chairman, we believe that Congress cannot remain passive in the face of such threats to the US healthcare system.

Authorized generics launched into the 180 day exclusivity period can only be eliminated through legislation. As for citizen petitions, the FDA has full authority to reinstate its own rule from 1999 and separate generic approvals from the citizen petitions process.

The time is now for Congress to take action to ensure timely access to affordable drugs. This is all the more important as we stand to move into the world of biotechnology drugs. Generic biologics, such as insulin, are a reality and a pathway to their approval is critical for our healthcare system to survive. The branded versions of these biologic drugs can cost tens and even hundreds of thousands of dollars a year to treat a single patient, and there is currently no regulatory pathway for approving generic versions of these drugs. Patients and insurers cannot afford to pay for the branded versions of these medications, often used to treat cancer and other serious illnesses, so it is crucial that the current loopholes in Hatch-Waxman be closed and the balance reconfigured before their consequences inhibit generic biologics as well.

I want to thank the committee again for its time and interest in making sure seniors and all Americans have access to affordable, safe generic pharmaceuticals. I am happy to answer any questions you might have.

SOURCE Mylan Laboratories Inc. 07/20/2006 CONTACT: Patrick Fitzgerald of Mylan Laboratories Inc., +1-724-514-1811, or Patrick.Fitzgerald@mylanlabs.com Web site: http://www.mylan.com (MYL)