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January 17, 2007

United States Senate Committee on the Judiciary
"Paying Off Generics to Prevent Competition with Brand Name Drugs:
Should it Be Prohibited?"

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Mr. Chairman, Members of the Committee:

Thank you for the invitation to testify today. Consumers Union is the independent non-profit publisher of Consumer Reports. Consumers Union investigates and reports extensively on the issues surrounding the costs, safety, and effectiveness of prescription drugs so that we can provide consumers with expert, non-biased advice to help them manage their health.

In answer to the question that motivated this hearing, "Whether paying off generics to prevent competition with brand-name drugs should be prohibited?" Consumers Union responds with an emphatic "Yes!" Consumers Union strongly supports prompt Congressional action to create a bright line rule to end the use of patent settlements that include compensation from brand-name companies to generic drug applicants in order to restrict generic market entry. These types of settlements should be declared "unfair methods of competition."

These settlements restrict generic competition at the expense of consumers, whose access to lower-priced generic drugs may be deferred for years. These settlements also jeopardize the health of millions of Americans who have difficulty obtaining safe and effective medicines at affordable prices. In light of the recent increased use of these agreements, we urge prompt Congressional action to end this practice.

This testimony first discusses why generic drugs are critical to affordable health care today and how Consumers Union is educating its readers and the public about the substantial benefits of generic drugs. The testimony then explains how the dynamics of generic drug competition create powerful incentives for brand-name and generic companies to settle patent litigation in a way that harms consumers. The Hatch-Waxman Act (the Act), which governs the approval of generic drugs, exacerbates these incentives. The testimony highlights why continued reliance on the courts to provide consumers with timely relief is misplaced. The testimony also describes Consumers Union's support of several other legislative changes to speed generic entry, including: (a) breaking the bottleneck that can occur when generic applicants cannot obtain decisions on the merits concerning patent infringement, (b) clarifying the law to provide for the development of generic versions of complex molecular biologic medicines, (c) clearing the backlog of generic applications at the FDA, and (d) eliminating the abuse of citizen petitions in the generic drug approval process.

I. Generic Drugs Can Help Dampen High Health Care Costs Now

Health care costs continue to surge at double or triple the rate of general inflation, in part due to the high cost and rate of inflation of brand-name prescription drugs. Generic drugs can dampen health inflation by

providing equally safe and effective medicine at a far lower price—often prices up to 70 percent or less of the brand name drug.

New generic drug entry in 2006 illustrates the substantial savings that generic drugs can have on health-care spending. During 2006, the cholesterol-lowering drugs Zocor and Pravachol, the antidepressants Zoloft and Wellbutrin, and the nasal spray Flonase all went generic. Employers, governments, and patients paid $9.4 billion for these drugs in 2005 (the year before generic entry). Because generic drugs can be up to 70% less expensive than brand-name drug price, there is a potential annual savings of $6.6 billion on those five drugs alone. This year and in 2008, several brand-drugs are expected to go generic, including blockbuster drugs with over $1 billion in annual sales such as Prevacid (used to treat heartburn), Imitrex (to treat migraine headaches), Zyrtex (to treat allergies), and Effexor (to treat depression). The consumer savings once generic versions of these drugs are available will be immense.

Consumer Reports strongly encourages the use of generics as a way for consumers to save money while obtaining quality health care. We have made a major organizational commitment to educate consumers about generic drugs and to help consumers obtain reliable, easy-to-understand advice about the safest, most effective, and lowest cost prescription drugs available. In December 2004, Consumers Union launched Consumer Reports Best Buy Drugssm , a free public education project. Attached to this testimony are two sample Best Buy Drugs summary reports on prescription drugs to reduce cholesterol and to relieve heartburn. We currently provide information for 16 different classes of medicine, and we plan to expand to additional classes in the near future.

The goals of Best Buy Drugs are to:

• improve the quality of care by ensuring people get the safest, most effective drugs with the least side effects;

• improve access by helping consumers choose drugs that are most affordable (taking into account effectiveness, side effects, safety, and price); and

• help consumers and taxpayers by reducing the cost of health insurance, consumers' out-of-pocket expenses, and Medicare and Medicaid.

We estimate that a consumer who switches from a highly advertised, high-priced brand name drug to a Best Buy Drug can often save between $1,000 and $2,000 a year. Approximately 100,000 Consumer Reports Best Buy Drugssm reports are downloaded each month, including about 20,000 in Spanish. In addition to our Web site www.CRBestBuyDrugs.org, we distribute print versions of our reports in five states with the help of pharmacists, senior organizations, doctors, and libraries. The Best Buy Drugs website also provides additional information describing how Best Buy Drugs operates and the rigorous evidence-based review that is used to derive the "Best Buy Drug" in each class of medicine.
Consumer Reports also has been active in reporting on the consumer benefits of generic drugs. Most recent, Consumer Reports published a report in its November 2006 issue that explained how cash prices for generic drugs vary widely at different types of pharmacies. The report concluded that for five highly prescribed generic drugs (fluoxetine, lisinopril, lovastatin, metformin, and warfarin), median prices at mass merchant and online pharmacies were approximately 20 to 50 percent less expensive than prices at supermarket and drug chain pharmacies. We urged our readers to shop around for the best deals.

II. The Dynamics of Generic Drug Competition Create Powerful Incentives for Brand-Name and Generic Companies to Settle Patent Litigation in A Way that Thwarts the Objectives of the Hatch-Waxman Act.

The economics surrounding generic entry create powerful incentives for brand-name and generic companies to enter into these types of patent settlements. These incentives are created because the total profits available to the brand-name company prior to generic entry exceed the total profits of both the brand-name and generic applicant after generic entry. As a result, the brand-name company has a powerful economic incentive to pay the generic applicant something more than it would earn by entry with its

generic product, because the sum the brand-name company pays will still be less than it would lose if the generic applicant did enter the market. Likewise, the generic applicant who is sued for patent infringement can earn more by entering into a settlement in which it agrees to defer market entry than it could earn by winning its patent challenge and competing in the market. In short, when these payments are allowed, the generic company may obtain more by settlement than it could have obtained by outright victory in the patent case.

A. The Hatch-Waxman Act Exacerbates the Incentive to Settle Patent Litigation with Compensation Paid to the Generic Applicant.

When Congress enacted the Hatch-Waxman Act, it represented a compromise between making available more low-cost generic drugs, while at the same time restoring patent life lost due to the length of FDA brand-name drug approval process. To accomplish this goal, Congress created a number of industry-specific incentives to speed generic entry. In order to see how these incentives work, and their effects on the dynamic of patent settlements, it is necessary to understand three unique features of the Act: a paragraph IV certification, the 30-month stay period, and the 180-day marketing exclusivity provision.

The Act establishes a procedure for accelerated FDA approval of generic drugs through the use of an "Abbreviated New Drug Application" (ANDA). The Act requires a generic applicant to show that its generic drug is "bioequivalent" to the brand-name drug. The generic drug manufacturer does not have to replicate the costly safety and efficacy tests for its drug; rather, the Act permits the generic company to rely on the safety and efficacy tests of the brand-name drug product.

One of the most important features of this application process is if the generic applicant seeks prompt approval of its generic drug, it must certify that its generic drug product does not infringe on the patents claiming the brand-name drug product, or that patents claiming the brand-name drug product are invalid. The Act names this a "paragraph IV" certification.

A generic applicant that makes a paragraph IV certification must notify the patent holder. If the patent holder does not bring an infringement action against the generic applicant within 45 days, the FDA may approve the ANDA, assuming the other regulatory requirements are met. Alternatively, if the brand-name company brings an infringement action during the 45-day period after notification, the patent owner is entitled to an automatic stay of FDA approval of the ANDA for 30 months (the 30-month stay). This process provides the brand-name company and the generic applicant an opportunity to litigate patent issues before the generic drug has entered the market and incurred any damage exposure.

The Act provides that the generic applicant to file the first ANDA containing a paragraph IV certification (the "first filer") for a particular brand-name drug is entitled to 180-days of marketing exclusivity. During this period, the Food and Drug Administration may not approve a subsequently filed ANDA for the same brand-name drug product. The 180-day period starts once the first filed generic applicant begins commercial marketing of its generic drug product. The real effect of this exclusivity period is that the FDA is prohibited from approving any subsequently filed ANDA for the same brand-drug product until the first filer's 180-day period of marketing exclusivity expires. The 180-day exclusivity period is an important incentive Congress provided to would-be generic entrants to encourage them to challenge weak or questionable patents claiming brand-name drug products or to design around a brand-name drug's patent.

This regulatory structure exacerbates the economic incentives underlying patent settlements between brand-name companies and generic applicants discussed above. A settlement between the brand-name company and the first filer will avoid the brand-name company's lost profit potential. In addition, the 180-day marketing exclusivity provision blocks entry by subsequently filed generics until 180 days after the first filer actually begins commercial marketing. Unfortunately for consumers, the first filer has a powerful incentive to accept a settlement because it will not only get the brand name company's compensation, but it retains its 180-day marketing exclusivity when it does enter at a later date. Although both the brand-name company and the generic company are better off with the settlement, consumers lose the possibility of an earlier generic entry, either because the generic company would have prevailed in the lawsuit or the parties

would have negotiated a settlement with an earlier entry date but no payment.

B. These Settlements Are Contrary to the Purpose of the Hatch-Waxman Act.

The irony, of course, is that the purpose of the ANDA application process was to speed the entry of generic drugs. This policy was reaffirmed in 2003 when Congress amended the Hatch-Waxman Act in the Medicare Modernization Act. As the Senate Report explained, those amendments sought in part to stamp out the "abuse" of the Hatch-Waxman Act resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market." Indeed, Senator Hatch, one of the Act's co-authors, stated during the debate over these amendments that "[a]s a coauthor of the Drug Price Competition and Patent Term Restoration Act, I can tell you that I find these types of reverse payment collusive arrangements appalling. I must concede, as a drafter of the law, that we came up short in our draftsmanship. We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition."

C. Experience Shows that Brand-Name Companies and Generic Applicants Do Not Need to Use Payments for Delay to Settle Patent Litigation.

As noted above, the FTC has reported that these types of patent settlements reappeared in 2005, after a six year hiatus. Two observations can be made from this fact. First, the FTC reported that in 1999 its investigations into the legality of these types of settlement agreements became public. The result of this public knowledge was that brand-name and generic companies stopped entering into patent settlement agreements with these terms. Second, brand-name and generic companies continued to settle patent disputes during this period (roughly from 1999 to 2005), when many industry participants believed it to be anticompetitive to enter into these types of patents settlements. This fact undermines any contention now that these payments are necessary to settle patent litigation.

III. The Courts are Unlikely to Provide Timely Relief to Consumers.

We encourage Congress to act now to end the use of these types of settlement agreements because it is unlikely the federal courts will provide consumers relief in a timely manner. Two recent appellate court decisions have taken a lenient view of these types of patent settlements, with one of the courts rejecting the reasoned antitrust analysis of these settlements put forth by the FTC. Both courts have, in essence, held that these settlements are legal unless the patent was obtained by fraud or that the infringement suit itself was a sham. These courts relied on the presumptive validity of a patent to support the conclusion that any settlement which does not exceed the exclusionary scope of a patent also must be valid. The upshot of these court rulings is that a patent holder can pay whatever it takes to buy off a potential challenger during the life of the patent. In one sense, court approval of these types of payments will convert Hatch-Waxman into a vehicle for facilitating the collection of "greenmail" by generic applicants.

These rulings are based on two faulty premises. First these courts seem to require that unless the patent can be proved to be invalid or not infringed, a court cannot declare a settlement illegal. This test, as the FTC discussed in its Schering opinion, may be good in theory but, it is nearly impossible to make work from a practical point of view.

The second faulty premise is that these courts have elevated the generally held principle that public policy favors settlements above the statutory mechanisms that Congress put in place to encourage generic applicants to challenge weak patents and, hence, speed generic entry. This reasoning also lacks an appreciation of the view, as recently articulated by the U.S. Department of Justice Antitrust Division, that public policy also strongly favors ridding the economy of invalid patents, which impede efficient licensing, hinder competition, and undermine incentives for innovation.

Indeed, the industry experience under Hatch-Waxman between 1992 and 2000 shows that Congress struck the right balance when it established these incentives. During this period, generic challengers that had used paragraph IV certifications won their patent challenges in 73% of the cases. Indeed, these challenges have

resulted in generic entry earlier than what otherwise would have occurred absent the generic challenge. These patent challenges and subsequent generic entry have yielded enormous benefits to consumers.

Although the FTC remains vigilant in searching for appropriate ways to take enforcement action against these types of patent settlements, administrative law enforcement actions and appeals take several years to complete. During this time, consumers will be denied access to affordable drugs.

IV. Other Legislative Suggestions to Help Speed Generic Entry.

Congress also may wish to consider four specific actions so that consumers have access to safe and effective generic medicines in a timely manner. First, we urge Congress to address a way to break the bottleneck that occurs if the brand-name company does not sue a subsequent generic applicant. Under current law, there is no way to trigger a forfeiture of the first-filer's 180-day period, even through a subsequently filed generic drug application is ready to be approved. To address this issue, Consumers Union supports the FTC's recommendation for Congress to clarify that dismissal of a court action brought by a generic applicant seeking a declaratory judgment on patent infringement or invalidity constitutes a forfeiture event for the 180-day exclusivity period.

Second, there is no clear law providing for the development of generic versions of complex molecular biologic medicines. These new products are the most expensive medicines on the market—some costing as much as $100,000 to $250,000 for a course of treatment. Consumers Union believes that biogenerics could provide some savings and can be provided safely, thus helping some of our most severely ill patients. Existing FDA law should be clarified to allow the U.S. to do what the Europeans are doing: bringing some relief to consumers.

Third, we urge Congress to provide the FDA with sufficient resources to eliminate the backlogs in the approval of generics. In a memo to Consumers Union last autumn, the FDA reported that an unduplicated count of pending generic applications showed a backlog of 394 drugs pending more than 180 days—drugs which could help lower costs to consumers if they were approved.

Fourth, we urge Congress to stop the use of phony citizens petitions to delay generic entry. According to the FDA, only 3 of 42 petitions answered between 2001 and 2005 raised issues that merited changes in the agency's policies about a drug. For example, Flonase, a commonly used prescription allergy medication, went off-patent in May 2004. But GlaxoSmithKline stretched its monopoly window by almost two years with citizen petitions and a legal challenge to the use of generics. We recommend Congress end this abuse.