Testimony of
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Subcommittee on Courts and Competition Policy
Committee on Judiciary
U.S. House of Representatives

Pay to Delay: Are Patent Settlements That Delay Generic Drug Market Entry Anticompetitive?

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*.[1] Consumers Union investigates and reports extensively on the issues surrounding the costs, safety, and effectiveness of prescription drugs and other health products so that we can provide physicians and consumers with expert, non-biased information.

Attachment #1 describes our Best Buy Drugs program. This is a major campaign by Consumers Union to use comparative effectiveness research to provide free, unbiased information to doctors and patients on the safest, most effective brand and generic drugs, and then to make a best buy recommendation. These recommendations can save consumers thousands of dollars a year.

To answer the hearing question: Absolutely!

Consumers Union absolutely believes that payments between brand and generic drug companies that delay the entry of generic drugs are bad for consumers and are the very definition of anti-competitive behavior. We support legislation to ban these payments—bills such as HR 1706 by Representatives Rush, Waxman, and others, and S.369 by Senators Kohl, Grassley, and others. That bill clarifies the law to make these agreements illegal and is a necessary step to give the enforcers and the courts the ability to stop this egregious conduct which costs consumers over $12 billion annually in excessive drug prices.

Almost all of 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

[1] Consumers Union, the nonprofit publisher of *Consumer Reports*, is an expert, independent organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. To achieve this mission, we test, inform, and protect. To maintain our independence and impartiality, Consumers Union accepts no outside advertising, no free test samples, and has no agenda other than the interests of consumers. Consumers Union supports itself through the sale of our information products and services, individual contributions, and a few noncommercial grants.

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 hope that you will quickly pass legislation like HR 1706. There is an excellent chance that CBO will score it with savings, perhaps substantial savings, and we hope you will consider adding it to any Health Reform legislation Congress considers this year, as a partial pay-for.

This testimony

> --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 using the most effective drugs, whether brand or generic;
>
> --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;
>
> --urges that other anti-competitive practices, such as abuse of the generic 6-month exclusivity provision and 'authorized generics" be addressed.

The testimony also describes Consumers Union's support of several other legislative changes to help consumers, speed generic entry and improve pharmaceutical research and consumer information, including: (a) creating an incentive for other "later filer" generic firms to successfully challenge patents by permitting them to secure exclusivity, (b) eliminating the abuse of 'authorized generics', (c) clarifying the law to provide for the development of generic versions of complex molecular biologic medicines (biosimilars), (d) clearing the backlog of generic applications at the FDA, (e) eliminating the abuse of citizen petitions in the generic drug approval process, (f) using Medicare to control costs while encouraging innovation, and (g) advancing the pace of drug R&D and consumer safety.

Rapid Entry of Generic Drugs Can Help Dampen High Health Care Costs Now, Assisting Families and Governments in a Difficult Time

Health care costs continue to surge at double or more the rate of general inflation. While drug inflation has moderated in recent years—in large part due to the increased use of generics—it is still a serious burden to consumers and government and private insurers, and the higher rate of inflation is expected to resume in a few years.[2]

High costs impact families: We all know how badly the high cost of health care is hurting America's families, especially now in this time of recession and high unemployment. Because

[2] From AARP's "Rx Watchdog Report," April, 2009: "In 2007, US health care spending growth slowed to its lowest rate since 1998. A majority of this change was due to retail prescription drug spending, which grew 4.9 percent in 2007, the slowest rate of growth since 1963. The deceleration in prescription drug spending, in turn, was largely attributed to generic drugs, including a further increase in the generic dispensing rate and slower growth in prescription drug prices due to the introduction of generic equivalents for several blockbuster drugs."

generics are substantially cheaper than brand name drugs, it is more important than ever that we ensure that generics come to market without collusive, anti-competitive delays.

In a poll of over 2000 households this spring, Consumers Union found 28 percent of the public has tried to reduce health care costs by not filling prescriptions, skipping doses or cutting dosage in half without their doctor's approval—all potentially dangerous actions and bad for the long-term health of those who need drugs like statins, diabetes medicines, etc.[3] In particular, seniors and people with disabilities on Medicare will need extra help in the next several years dealing with high drug prices, because Social Security COLAs are estimated to remain at zero or close to zero, yet Part D premiums are likely to increase, cutting into the net Social Security check.

Costs of drugs impact governments and taxpayers: In 2008, the federal government was projected to have accounted for 31 percent of the $235 billion spent on prescription drugs, and the Federal government's share is expected to rise to 40 percent by 2018.[4] The new Part D program added a tremendous future obligation onto the government: $9.4 trillion in present value costs to Medicare over the next 75 years, with Part D outlays estimated to increase from 0.4 percent of GDP to 1.8 percent by 2083. In the short-run, the Part D average annual increase in expenditures is estimated to be 11.1 percent through 2018, while the US economy is projected to grow by only 4.5 percent.[5]

Generics dramatically lower costs: The rapid entry of generic drugs into the market can help dampen health inflation by providing equally safe and effective medicine at a far lower price—often prices up to 80 percent or less of the brand name drug and capturing 44 to 80 percent of sales in the first year of generic launch[6]. In 2007, the average retail price of a generic prescription drug was $34.34, while the average retail price of a brand-name prescription was $119.51 and almost 70 percent of all prescriptions are now for generics.[7] It has been estimated that generic drugs save consumers between $8 and $10 billion each year.

Generics also inflate substantially less than brand name drugs:

> "Prices for generic drugs increase more slowly than prices for brand-name drugs. In 2008, the average price inflation for generic drugs used by Medco members was only

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[3] CU March 17, 2009 Poll, In addition, CMS "posits that the slowdown for prescription spending is likely due to the effects of the recession, which may be causing consumers to shift from more expensive brand-name drugs to lower-cost generics and to fill fewer prescriptions." Quote from 2009 Drug Trend Report, Medco, p. 6. The importance of affordable maintenance medicines can be seen in the fact that a person starting on a generic maintenance drug has a 62 percent better chance of staying on it, than a person started on a non-preferred brand drug, according to ARRP testimony before the Energy and Commerce Committee, 3/31/09.

[4] CMS National Health Expenditures, 2008.

[5] Medicare Trustees Report, pp. 2, 3, and 127.

[6] Testimony of FTC Commissioner Jon Leibowitz, before Senate Judiciary Committee, January 17, 2007.

[7] GPhA Website, Facts at a Glance.

> 0.5%, and unit costs for many generic drugs actually declined as market competition expanded. In contrast, the average price inflation for brand-name drugs was 8.4%.[8]
>
> "In 2008, the average annual increase in manufacturer prices charged to wholesalers and other direct purchasers for brand name prescription drugs widely used by Medicare Part D beneficiaries was 8.7 percent, or about 2.3 [times] the general inflation rate of 3.8 percent. The 2008 average rate of increase in manufacturer prices of specialty drugs (brand and generic) was even greater—9.3 percent. By contrast manufacturer prices of (non-specialty) generic drugs widely used by Medicare beneficiaries *decreased* by an average of 10.6% in 2008." [9]

Many generics about to enter market: What is exciting for consumers is that there are major brand-name medicines about to be available in generic form—if anti-competitive and collusive practices do not block their timely entry. As of the fall of 2007, Hatch-Waxman challenges were pending for over 120 brand name prescription drugs with combined annual sales of over $90 billion, and it is estimated that between now and 2012, about $139 billion in international annual sales of brand-name drugs will face generic competition.[10]

Clearly, it will be a major help to America's consumes and taxpayers if the expected flow of generics to market is not thwarted by anti-competitive, collusive payments between brand and generic drug manufacturers.

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—do nothing--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.

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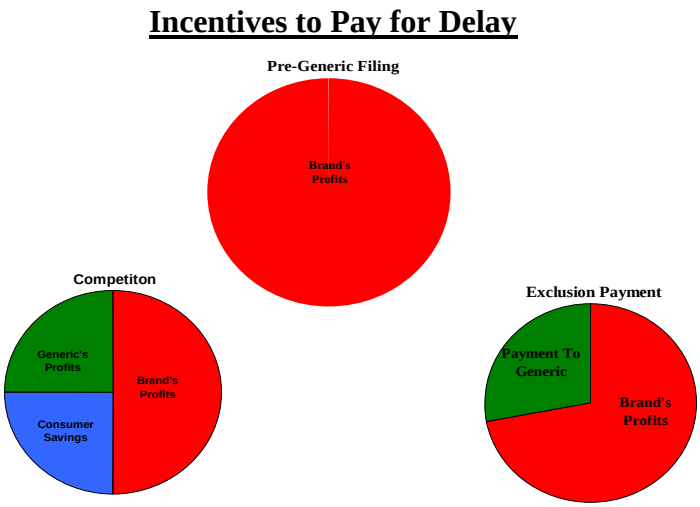
[8] Medco, Drug Trend Report, 2009, p. 22.

[9] AARP Rx Watchdog Report, April, 2009.

[10] Ibid.

The following pie charts from FTC Commissioner Rosch before a House Energy and Commerce Subcommittee this March 31st clearly makes the point:



Let me see if I understand the argument of the brand and generic industries? They say we should allow their for-profit brand members (whose fiduciary duty is to their stockholders to make profits) to pay the for-profit generic companies (whose fiduciary duty is to their stockholders to make profits)—diagram #1. They then say that we should permit this because it will encourage both industries to more quickly bring generics to market--diagram #2—where both for-profit parties will make less money and less profit. The industries say that prohibiting these payments will delay the day that they both voluntarily act together to help the consumer with lower drug prices while reducing their own profits.

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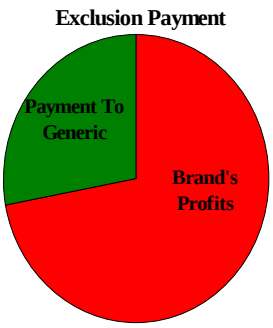
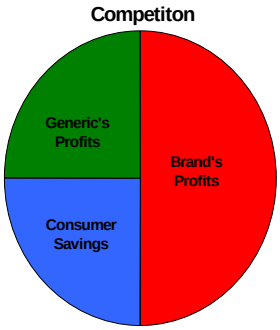
#1



#2



That is their argument. Said with a straight face.

As Columbia University Law Professor C. Scott Hemphill testified before the Energy and Commerce Committee March 31st, "If the brand-name firm paid a rival after patent expiration to abandon its effort to market a competing drug, that transaction would clearly be inappropriate. The same is true when the privately arranged extension postpones an entry date that is prior to patent expiration."

The argument is made that some of these reverse payment settlements have led to bringing more quickly a generic to market. Like a Blue Moon, it is possible. And HR 1706/S. 369 allow the FTC to recognize and accept such settlements in the rare cases they occur.

But in the great majority of cases, it would be extremely naïve to assume that the Diagram #1 above is being done to help speed up the results in Diagram #2. The FTC has provided massive documentation that in most cases, these payments cost the consumer—and the cumulative cost is running in the billions.

As this Committee knows, the courts have not grasped the reality of the anticompetitive effects of these settlements. Absent Congressional action the substantial harm to consumers will

continue. If the law is not clarified pharmaceutical patentees will continue to pay off generic firms to terminate patent challenges that would otherwise generate *billions* of dollars in consumer savings. The costs are substantial: a recent study by Professor C. Scott Hemphill of Columbia Law School found that consumers are paying over $12 billion more annually because of these exclusion payments.2

Attachment #2 is a discussion of how and why these problems arose and why legislative action is needed as soon as possible.

Other Legislative Suggestions to Help Speed Generic Entry.

Congress should also consider several other alternatives to support the effort to assure consumers receive access to safe and low cost generic drugs as quickly as possible.

First, the Hatch Waxman Act should be amended to give "later filers" – generic firms that are not the first to file a patent challenge, the opportunity to secure exclusivity if they successfully challenge a patent. Preventing exclusion payments is a necessary, but not sufficient step to preventing the gaming of the regulatory system to delay generic entry. A subsequent generic patent challenger often is well positioned to successfully challenge and invalidate a patent. Unfortunately, under the current system, there is little incentive for the subsequent filer to take on the burden of expensive patent litigation, since it cannot secure any exclusivity if it succeeds. Congress should address this issue by giving a subsequent filer who successfully challenges a patent a period of exclusivity.

Second, we hope that you can address the problem of 'authorized generics.' The very phrase should raise red flags about the level of competition from an 'authorized' generic. It is just another way to avoid rigorous, meaningful competition. An authorized generic is a generic which enters under a licensing arrangement from the branded firm. These authorized generics occur at the end of patent life and seem intended to undermine the reward system established under the Hatch-Waxman Act which gives the first generic filer a six-month period of exclusivity. Without the rewards of exclusivity the incentive to challenge pharmaceutical patents is diminished. Moreover, branded firms often use the threat of an authorized generic to force generic firms to enter into these anticompetitive settlements.

Third, 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.

Fourth, there is no clear pathway, in law or FDA regulation, providing for FDA approval of generic versions of complex molecular biologic medicines which are so important in modern medicine (although the Europeans are moving ahead in this area). To date, the developers of biologics have a de facto monopoly market stretching as far as the eye can see. One such drug on

the market for the past twenty years has probably earned its company $20 billion from Medicare alone, and there is still no generic in the US. These new biologic 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 and the Congressional Budget Office believe that biogenerics could provide billions in savings and can be provided safely, thus helping some of our most severely ill patients. The CBO estimate on Chairman Kennedy's S. 1695 from the 110th Congress (with a 12 year exclusivity compared to Chairman Waxman's proposal of 5 year exclusivity) showed total savings to the economy of $25 billion between 2009-2018 or about 0.5 percent of national spending on prescription drugs at wholesale prices.[11] (Presumably, a 5-year exclusivity bill will show even larger savings.) Existing FDA law should be clarified to allow the U.S. to do what the Europeans are doing: bringing some relief to consumers. Therefore, we hope that as part of health reform, Congress will enact legislation like Chairman Waxman's bill, HR 1427.

Fifth, we urge Congress to provide the FDA with sufficient resources to eliminate the backlogs in the approval of generics. The President's new FY 2010 budget request asks for $36 million to "provide greater access to affordable generic drugs and improve the productivity of generic drug review through a new user fee program." As the FDA testified last month:

> In the coming years, patents will expire on more than a dozen blockbuster brand-name drugs that account for tens of billions of dollars in prescription spending annually. Generic competition for these drugs will likely be very strong. It is imperative that FDA have the resources to ensure the safety, quality, and therapeutic equivalence of generic drugs and allow Americans to benefit from the savings from lower cost generic drugs[12]

We urge Congress to approve this request—consumers must have confidence in generics, and the faster we can move these safe drugs to market, the faster we can help families meet their medical costs.

Finding other ways to help consumers hold down drug costs while promoting drug innovation

Whenever consumers question a pharmaceutical industry policy, no matter how anti-consumer, the industry says that if there is any reduction whatsoever in their profit margins, they won't be able to invent the cures to the diseases we all dread. Even though about 85 percent of new drug approvals are just for me-too drugs and bring little new to the medical world, this threat is always troubling. We believe that there many policies that Congress should consider to encourage the industry to spend more on true R&D while helping consumers obtain access to more generics, faster. We hope that you will join us in considering some of the following types of policies:

[11] Letter of CBO of June 25, 2008 on S. 1695

[12] Statement of Joshua Sharfstein, MD., Principal Deputy Commissioner, FDA, before Senate Appropriations Committee, Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, May 21, 2009.

--require drug rebates to Medicare for drug inflation in excess of population and CPI growth, except no rebates would be required on new breakthrough drugs (as defined in the FDA approval process), thus controlling costs while encouraging drug innovation;

--amend the FDA laws to require that new drugs be tested against the best practice in the field, not just against a placebo;

--increase the world's medical scientific base by eventually making Phase I trial results, both the successful and the unsuccessful, public;

--after ensuring safety, permit the importation of drugs (Berry et al, HR 1298), including biosimilars;

--prohibit drug, device, and other vendor gifts to providers (Physician Payments Sunshine Act by Kohl, Grassly, Stark, DeFazio);

--provide additional rebates from the 20 percent of Part D plans that have the lowest generic drug substitutions rates in cases where a generic is exchangeable with a brand;

--permit Medicare to negotiate on drug prices (Berry et al., HR 684)[13]; special attention should be given to negotiating prices on selected biologics;

--enact a two or three year moratorium on the direct-to-consumer advertising of newly approved prescription drugs, for safety reasons (proposals by DeLauro and others); require rebates for the increased high-cost drug utilization caused by such advertising.

Our Hope that the Judiciary Committee will Examine the Growing Concentration in the Health Insurance Industry, and Why Insurers have been Unable to Control Costs Better. Is it an Argument for a Public Plan Option in Health Care Reform?

Finally, switching topics, in this year of health care reform debate, we urge the Subcommittee and Committee to consider an investigation into why the health insurance industry has failed so badly to control health care costs, and whether our experience with this increasingly-concentrated industry doesn't argue for a public plan option as part of health care reform.

For decades, the health delivery marketplace has been inflating roughly twice as fast as the rest of the economy, creating special burdens for American businesses and taxpayers, and raising rates of un-insurance, under-insurance, personal bankruptcy and increased morbidity and even mortality for uninsured consumers.

Recently, there have been rumors of possible further mergers among some of the nation's largest health insurers.

[13] This provision receives an amazing 86 percent support in the Kaiser Family Foundation Health Tracking Poll of April, 2009.

We believe it would be useful for Congress to investigate the level of market concentration in the health insurance versus health provider sectors to determine if there are steps that should be taken in health reform to bring us a system which is better at reducing the cost of health insurance for employers, employees and their families.

A Congressional investigation could address the following kinds of questions:

It is often thought that a large buyer can demand discounts and be able to control costs better than many small purchasers. At the same time, it is usually feared that a monopolist will collect excessive profits from their market dominance. There are reports that in a sixth of our large metropolitan areas, a single insurer/purchaser has enrolled 70 percent or more of the local consumer-patient population. It would seem that in such a situation, the insurer could both control costs and reap windfall or oligopolistic profits. Obviously the insurers are not doing a good job controlling costs, but are they collecting higher than expected profits? That is, do we have the worst of both worlds: higher profits being added to failure to control costs?

But at the same time that insurers have been consolidating, there are reports that in many markets, hospital and physician practices have been merging and have formed a dominant countervailing force. Has the consolidation of providers been a contributing factor in the crippling rate of health inflation? Yet while oligopolistic or even monopolistic behavior among providers is a source of concern, so is quality of care. And there is strong data that smaller hospitals, which do limited numbers of procedures, often have a difficult time delivering quality outcomes. In general, consumers needing complex treatments are well-advised to seek out hospitals and practices which do large volumes of such treatments (centers of excellence) and which coordinate care. From a quality, medical education, and research point of view, a larger health care provider can often be a good thing.

The March 2009 Medicare Payment Advisory Commission report to Congress provides a remarkable chart showing that an eighth of the nation's larger hospitals which deliver the highest quality care have, on average, positive Medicare margins and are below average cost hospitals. The other seven-eighths of the hospitals have poorer quality and higher costs. It is MedPAC's thesis that while Medicare is paying approximately 100% of the costs of an efficient provider, the private insurers (who have become relatively consolidated and may be planning further consolidation) are paying about 132 percent of cost at most hospitals. Basically, MedPAC is saying that the private insurers, despite their growing consolidation, have become toothless buyers, and are often turning a blind eye to the unacceptable rate of medical inflation.

This raises a fundamental question: if large private buyers, who for marketing reasons feel a need to maintain a broad network of health care providers, cannot control costs, what is the alternative? As we consider health care reform, doesn't this argue for a public plan option (like Medicare) that can set rates at the approximate level of cost that an efficient provider can deliver quality care?

If the current situation does not argue for a public plan option, then why are these large insurers not doing a better job in controlling health care inflation, and what hope is there that they will do

a better job in the future? What kinds of amendments would Congress need to make to ensure that the private payers can hold inflation down to at least Medicare's past rates of growth?

Attachment #1

Best Buy Drug Campaign

Consumer Reports strongly encourages consumers to talk to their doctor about the use of generics as a way 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 brand or generic, and lowest cost prescription drugs available. In December 2004, Consumers Union launched Consumer Reports Best Buy Drugs , a free public education project. Attached is a sample Best Buy Drugs summary report on prescription drugs to relieve heartburn. We currently provide information for 40 different medical conditions, 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—brand or generic--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 costs.

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—or even as much as $3,000 a year. If all Americans took advantage of the best buy generics, the economy would save billions of dollars. Approximately 100,000 Consumer Reports Best Buy Drugs 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.

Attachment #2

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 claimed by the brand-name drug product, or that patents claimed by 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.

It is important to note that the first generic competitor usually shadows prices the brand. Consumers usually do not really see sharp, dramatic drops in price until there are several generic competitors.

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.

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 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."

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.

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. At least 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.