United States House of Representatives,
Subcommittee on Commerce, Trade, and Consumer Protection Hearing on
H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007

May 2, 2007

Statement of Michael Wroblewski
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Consumers Union, the Independent, Non-Profit Publisher of *Consumer Reports*

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.[1]

Consumers Union strongly supports H.R. 1902, the "Protecting Consumer Access to Generic Drugs Act of 2007." This legislation ends the use of patent settlements in which the generic applicant receives anything of value in exchange for agreeing not to research, develop, manufacture, market, or sell its generic product.[2] These settlements

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with expert and independent information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of *Consumer Reports* and ConsumerReports.org, its other publications and from noncommercial contributions, grants and fees. Consumers Union's products have a combined paid circulation of approximately 7.3 million consumers. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and ConsumerReports.org regularly carry articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

[2] This compensation can take the form of a cash payment. These types of payments were highlighted by the Federal Trade Commission's enforcement actions involving Hytrin, Platinol, and Taxol. *See Abbott Labs*., Dkt. No. C-3945 (May 26, 2002) (consent order); *Geneva Pharms., Inc*., Dkt No. C-3946 (May 22, 2000) (consent order); *Bristol-Myers Squibb Co*., Dkt. No. C-4076 (Apr. 13, 2003) (consent order). It also could be in the form of the brand-name company agreeing not to launch an "authorized generic drug" prior to expiration of the brand-name drug company's patents claiming the brand-drug product.

with exclusionary payments 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 competitive prices. In light of the recent increased use of these agreements with exclusionary payments,[3] 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 and innovation. The Hatch-Waxman Act (the Act),[4] which governs the approval of generic drugs, inadvertently exacerbates these incentives. Moreover, continued reliance on the courts to provide consumers with timely relief is misplaced.

The testimony also describes Consumers Union's support of the other main provision of H.R. 1902 that updates the regulatory structure governing approval of subsequently-filed generic applications. The provision breaks the bottleneck on FDA approval which can occur when generic applicants cannot obtain decisions on the merits concerning patent infringement.

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[3] *See* Prepared Statement of the Federal Trade Commission before the Committee on Judiciary of the United States Senate, "Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution," (Jan. 17, 2007) at 17, ("More than 80 percent (9 of 11) of the settlements with first generic filers involved a payment to the generic challenger and a restriction on generic entry" in fiscal year 2006.), ("FTC Senate Judiciary Committee Statement") *available at* http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf.

[4] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

Finally, the testimony describes Consumers Union's support of several other legislative changes to speed generic entry, including: (a) clarifying the law to provide for the development of generic versions of complex molecular biologic medicines, (b) clearing the backlog of generic applications at the FDA, and (c) 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.[5] 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.[6]

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 assuming all brand prescriptions were filled with the generic version.[7] This year and in 2008, several brand-drugs are expected to go

[5] *See* Aaron Catlin, et al., "National Health Spending in 2005: The Slowdown Continues," 26 *Health Affairs* 142, 144, Exhibit 2 (Jan./Feb. 2007) (prescription drugs expenditures increased 13.1% in 2003, 8.6% in 2004, and 5.8% in 2005).

[6] David Reiffen and Michael Ward, "Generic Drug Industry Dynamic," 87 *Review of Econ. & Stat.* 37 (2005).

[7] Rachel Brand, Popular Drugs are Getting Cheaper," *The Detroit News* (Dec. 6, 2006), *available at* http://www.detnews.com/apps/pbcs.dll/article?AID=/20061206/LIFESTYLE03/612060326/1040.

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).[8] 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 Drugs*®, a free public education project.[9] 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 17 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.

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[8] FDA, Approved Drug Products with Therapeutic Equivalence Evaluations (Electronic Orange Book) - *via on-line resources* FDC Reports, *The Pink Sheet (*2004-2005).

[9] *Consumer Reports Best Buy Drugs*® is funded by grants from the Engelberg Foundation and the National Library of Medicine. In addition, Consumers Union makes a large in-kind contribution to support this project.

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 Drugs*[sm] 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.[10] 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

[10] *Consumer Reports* (Nov. 2006) at 58-59.

to generic entry *exceed* the total profits of *both* the brand-name and generic applicant after generic entry.[11] 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 the amount of money 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. Indeed, the ability to obtain a cash payment and defer market entry could encourage generic companies to challenge strong patents that it would otherwise not challenge, to the detriment of consumer's interest in continued pharmaceutical innovation. 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 Inadvertently 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 low-cost generic drugs, while at the same time restoring patent life lost due to the length of FDA brand-name drug approval process.[12] This balance recognized two important consumer needs – the need for competitively priced pharmaceutical products and the need for strong patent rights to encourage development of life-saving medicines. Congress created a number of industry-specific incentives to

[11] *See* Robert Kneuper, "Four Economic Principles Underlying the FTC's Position Against Reverse Payments in Patent Settlement Agreements," *The Antitrust Source* (Jan. 2006) at 2, *available* athttp://www.abanet.org/antitrust/at-source/06/01/Jan06-Kneuper1=26f.pdf.

[12] H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1, at 14 (1984).

accomplish these goals. 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.[13] 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

[13] The Act also creates a way for a generic applicant to obtain approval at the expiration of any patent claiming the brand-name drug product (a "paragraph III" certification). The relevant statutory and regulatory framework for the ANDA approval process has been described in *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. at 676-78; *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1063-65, 46 USPQ2d 1385 (D.C. Cir. 1998); and *Bristol-Myers Squibb Company v. Royce Laboratories, Inc.*, 69 F.3d at 1131-32, 1135.

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 can exacerbate 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 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."[14] 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."[15]

[14] S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002).

[15] *See* Statement of Sen. Orrin Hatch, Senate Floor Debates on S. 812, *Cong. Rec*. at S7567 (July 30, 2002).

C. Experience Shows that Brand-Name Companies and Generic Applicants Do Not Need to Use Exclusionary 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.[16] Two observations can be made from this fact. First, public knowledge of the FTC's investigations into these types of settlement arrangements in 1999 effectively ended the use of agreements with these terms. Second, brand-name and generic companies continued to settle patent disputes during this period (roughly from 1999 to 2005). The parties settled their differences on terms that did not include an exclusionary payment. Rather, they settled presumably on the basis of the relative strength of their cases. If they could not settle their differences, a court decided the patent issues. Any contention that exclusionary payments are necessary to settle patent litigation is undermined by these two facts.

Consumers Union believes that in light of the consumer harm that can occur from settlements with exclusionary payments, the public interest is served when a court either upholds the brand company's patent rights or resolves the patent issues so that generic entry can proceed expeditiously.

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 the use of exclusionary payments has upset the delicate balance initially struck within the Hatch-Waxman framework. Moreover, it is unlikely the federal courts will provide consumers relief in a timely manner. Two recent appellate court

[16] Bureau of Competition Report, Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition (Apr. 2006), *available at* http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf. *See also* FTC Senate Judiciary Committee Statement at 17.

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.[17] 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.[18]

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.[19]

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

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[17] *Schering-Plough Corp. v. F.T.C.*, 403 F.3d 1056 (11th Cir. 2005) (cert. denied); *In re Tamoxifen Citrate Antitrust Litig*., 429 F.3d 370 (2d Cir. 2005).

[18] *See* Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III, Address Before the ABA Spring Meeting (Mar. 29, 2006), at 26, *available at* http://www.hhlaw.com/files/News/05ac8357-7511-43c9-a927-2c7e96a0ecde/Presentation/NewsAttachment/fd869e0b-b58a-451d-ad8d-2e110dbb796b/LearyABASpringMeetingSpeech.pdf.

[19] *See Schering-Plough Corp*., No. 9297, 2003 WL 22989651 (F.T.C.) (Commission Decision and Final Order) at 33-35 (the FTC's opinion discussing the practical and public policy limitations on the usefulness of a "mini patent trial" within the conduct of an antirust case).

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.[20]

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.[21] 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.

IV. Break the Bottleneck on Generic Entry

Consumers Union also supports the provision in H.R. 1902 that updates the regulatory structure governing FDA approval of subsequently-filed generic applications. Under current law, there is no way to trigger a forfeiture of the first-filer's 180-day period if a subsequent applicant is not sued, although the FDA may be ready to approve the subsequently filed application. The provision in H.R. 1902 merely updates the regulatory conditions under which the FDA can approve the subsequently-filed generic product.

V. Other Legislative Suggestions to Help Speed Generic Entry.

Congress also may wish to consider three specific actions so that consumers have access to safe and effective generic medicines in a timely manner. First, there is no clear

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[20] Brief for the United States As Amicus Curiae Supporting Petitioner, *MedImmune, Inc. v. Genentech, Inc., et al.*, No. 05-608 (May 2006) at 2, *available at* http://www.usdoj.gov/osg/briefs/2005/3mer/1ami/2005-0608.mer.ami.pdf.

[21] Federal Trade Commission, Generic *Drug Study Prior to Patent Expiration: An FTC Study* (July 2002) at vi, *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

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.[22] Existing FDA law should be clarified to allow the U.S. to do what the Europeans are doing: bringing some relief to consumers.[23] To this end, Consumers Union supports Chairman Waxman's legislation, the "Access to Life-Saving Medicine Act."

We note, however, the possibility of patent settlement agreements that restrict generic entry, which are the subject of today's hearing, are also likely to occur with biogeneric drugs. As a result, we support using the same approach in H.R. 1902 to define these types of agreements as "unfair methods of competition." We also support requiring brand and generic biologic manufacturers to file their patent settlement agreements with the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice, similar to the way in which brand and generic pharmaceutical manufacturers file their agreements under the MMA.

Second, we urge Congress to provide the FDA with sufficient resources to eliminate the backlog in the approval of generics.[24] In a memo to Consumers Union last autumn, the FDA reported that an unduplicated count of pending generic applications

[22] Tsao, Amy. "Seeking a Prescription for Biogenerics." Business Week. October 24, 2003.

[23] *See* Statement of Jim Guest before the Senate Committee on Health, Education, Labor and Pensions on S. 3807, the Enhancing Drug Safety and Innovation Act of 2006 (Nov. 16, 2006) at 20, *available at* http://help.senate.gov/Hearings/2006_11_16/Guest.pdf.

[24] *Id*. at 19.

showed a backlog of 394 drugs pending more than 180 days—drugs which could help lower costs to consumers if they were approved.

Third, we urge Congress to stop the use of phony citizen's 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.[25] We recommend Congress end this abuse.

Respectfully Submitted,

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[25] *Consumer Reports* (Nov. 2006) at 5.

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Drugs to Treat Heartburn, Ulcers, and Stomach Acid Reflux:

The Proton Pump Inhibitors

Comparing Effectiveness, Safety, and Price

IF YOU SUFFER from heartburn, ulcers or gastroesophageal reflux disease (GERD, more commonly known as acid reflux), you may need treatment with a proton pump inhibitor, or PPI. Five medicines in this class are available. One is a nonprescription drug. PPIs range in cost from around $25 to more than $200 a month.

To help you and your doctor choose a PPI, *Consumer Reports* has evaluated the drugs in this category based on their effectiveness, safety, and cost. This 2-page brief is a summary of an in-depth report you can access on the Internet at **www.CRBestBuyDrugs.org.** You can also learn about other drugs we've analyzed on this free Web site. Our independent evaluations are based on scientific reviews conducted by the Oregon Health and Science University-based Drug Effectiveness Review Project. Grants from the Engelberg Foundation and National Library of Medicine help fund *Consumer Reports Best Buy Drugs*.

Do You Need a PPI?

Almost everyone has heartburn once in a while. Periodic bouts can be treated effectively and safely with over-the-counter antacids and acid reducers such as Alka Selzer, Maalox, Rolaids, Tums, cimetidine (Tagamet) or ranitidine (Zantac). But if you have heartburn or acid reflux more than once a week and your symptoms are not relieved by these over-the-counter medicines, you may need a PPI. GERD can be dangerous. If left untreated, it can cause erosion of the lining of the esophagus.

Comparative Effectiveness of PPIs[1]

Generic Name with Dose per Day	Brand Name	Complete Symptom Relief (% of Patients)	Esophageal Healing at 8 Weeks (% of Patients)	Relapse Prevention (% of Patients)
Esomeprazole 40mg	Nexium	60-70%	92%	93%
Lansoprazole 30mg	Prevacid	60-70%	87%	NA
Omeprazole 20mg	Prilosec	60-70%	86%	86%
Pantoprazole 20mg	Protonix	60-70%	91%	86%
Rabeprazole 20mg	Aciphex	60-70%	91%	NA

(1) Effectiveness data presented for those PPI dosage strengths that have been studied and compared to date.

Our Recommendations

You can save money – in some cases $200 a month or more – if you need to take a PPI and your doctor prescribes one of the more expensive ones. That's because all five of the PPIs are quite similar in effectiveness and safety.

Talk to your doctor about other medicines that may relieve your heartburn symptoms, either before you require a PPI or in combination with a PPI. Also talk with your doctor about the role that dietary and lifestyle changes can play in alleviating symptoms – such as eating smaller meals, weight loss and avoiding alcohol.

- If you have no health insurance for prescription drugs, we have chosen **Prilosec OTC 20mg (omeprazole)** as the *Consumer Reports Best Buy Drug.* This proven medicine is sold over-the-counter, without a prescription, and costs 50 to 80 cents a day. It is as effective for most people as the more expensive PPIs.
- If you have drug coverage, find out if your health plan provides a discount coupon for Prilosec OTC. If not, talk with you doctor about choosing the PPI that has the lowest out-of-pocket cost, or co-pay, under your insurance plan.
- If you are one of the 15% of people with GERD who have moderate to severe erosions in your esophagus, you may need a higher dose of a PPI.

SAFETY NOTE: PPIs interact with some other medicines, such as blood thinners and anti-anxiety drugs. Tell your doctor about all the drugs you are taking before you take a PPI. People aged 65 and over, and people with chronic medical conditions, who take a PPI should get vaccinated against pneumonia and get a flu shot every year.

See the cost comparison table on page 2. This information was last updated in November 2004. Go to **www.CRBestBuyDrugs.org** for the latest news and information on the drug classes we examine.

PPI Cost Comparison

Generic Name with Dose per Day	Brand Name[1]	Average Monthly Cost[2]
Esomeprazole 20mg	Nexium	$171
Esomeprazole 40mg	Nexium	$165
Lansoprazole 15mg delayed release lingual tablets	Prevacid	$133
Lansoprazole 30mg delayed release lingual tablets	Prevacid	$126
Lansoprazole 15mg sustained release tablets	Prevacid	$164
Lansoprazole 30mg sustained release tablets	Prevacid	$169
Lansoprazole 30mg enteric coated capsules	Prevacid	$159
Lansoprazole 15mg delayed release suspension packets	Prevacid	$172
Lansoprazole 30mg delayed release suspension packets	Prevacid	$162
CR BEST BUY **Omeprazole 20mg**	**Prilosec OTC[3]**	**$24**
Omeprazole 10mg sustained release capsules	Prilosec	$133
Omeprazole 20mg sustained release capsules	Prilosec	$154
Omeprazole 40mg sustained release capsules	Prilosec	$245
Omeprazole 10mg sustained release capsules	Generic	$120
Omeprazole 20mg sustained release capsules	Generic	$119
Pantoprazole 20mg delayed release tablets	Protonix	$145
Pantoprazole 40mg delayed release tablets	Protonix	$136
Rabeprazole 20mg	Aciphex	$165

UNDERSTANDING GENERICS: A generic drug is one that is sold under its generic name. In this table, only omeprazole is available as a generic. It is also sold under its brand name, Prilosec. A nonprescription version, Prilosec OTC, is also available. The remaining PPIs are sold only as brand name drugs, though their generic or chemical names are also given in the first column.

(1) "Generic" indicates drug sold by generic name, omeprazole.
(2) Prices reflect nationwide retail average for September 2004, rounded to nearest dollar; data provided by NDCHealth, a health care information company.
(3) This is a nonprescription (over-the-counter) version of omeprazole.

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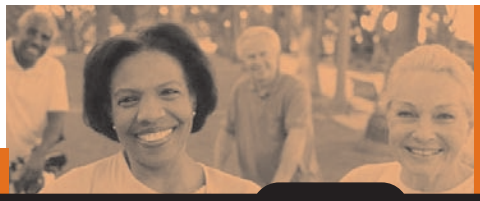

Treating Elevated Cholesterol and Heart Disease

The Statins

Comparing Effectiveness, Safety, and Price

If you have high cholesterol or are at risk of heart attack or stroke, your doctor may prescribe a "statin" – the most widely used type of cholesterol-lowering drug. There are six statins. Three are now available as less expensive generics – lovastatin, pravastatin and simvastatin. One new combination drug – Vytorin – combines simvastatin with another type of cholesterol-lowering drug.

To help you and your doctor choose the statin that is right for you, *Consumers Reports* has evaluated the drugs in this category based on their effectiveness, safety, and cost. This 2-page brief is a summary of an 18-page report you can access on the Internet at www.CRBestBuyDrugs.org. You can also learn about other drugs we've analyzed on this free Web site. Our independent evaluations are based on scientific reviews conducted by the Oregon Health and Science University-based Drug Effectiveness Review Project. Grants from the Engelberg Foundation and National Library of Medicine help fund *Consumer Reports Best Buy Drugs.*

DO YOU NEED A STATIN?

If your cholesterol is only marginally elevated and you're not at risk for heart disease, heart attack, or stroke, dietary and lifestyle changes may be enough to lower your "bad" (LDL, or Low Density Lipoprotein) cholesterol to a healthy level. So you might try that before taking a medicine. But if your LDL is too high and/or you are already at risk for heart disease and stroke (for example, if you smoke, have diabetes, or have coronary artery disease), your doctor is likely to prescribe a statin.

Latest advice on LDL cholesterol reduction

Risk level and criteria*	Reduce LDL to:
Low - No current heart disease - No or only one risk factor	- Below 160mg/dl - Below 130mg/dl is better
Moderate - No current heart disease - Two risk factors	- Below 130mg/dl - Below 100mg/dl is better
Moderate High - Two or more risk factors	- Below 130mg/dl - Below 100mg/dl is better
High - Known heart disease - Diabetes - Multiple Risk Factors	- Below 100mg/dl - Below 70mg/dl is better

* In addition to having an elevated LDL and/or low HDL, the most important risk factors for heart disease, heart attack and stroke are cigarette smoking and having diabetes or high blood pressure. Other risk factors include being overweight, getting little or no exercise; having elevated triglycerides or C-reactive protein levels, and having a family history of heart disease.

Our Recommendations

Statins are highly effective and generally safe medicines. In people at risk for heart disease or who have heart disease, they substantially lower the chances of a heart attack, stroke, and death.

The statins differ in their ability to reduce cholesterol and there is stronger evidence for some when it comes to reducing your risk of heart attack or death from heart disease or stroke. The statins also vary widely in cost – from about $30 a month to $170 a month. (See page 2)

Taking the evidence for effectiveness, safety, and cost into account, we have chosen four statins as *Consumer Reports Best Buy Drugs:*

- *Generic lovastatin* – if you need to lower "bad" (LDL) cholesterol by less than 30%
- *Generic pravastatin* – if you need to lower LDL cholesterol by less than 30%
- *Generic simvastatin* – for some people who need less than 30% LDL reduction; for people who need 30% or greater LDL reduction and/or have heart disease or diabetes; and for some people who have had a heart attack or have acute coronary syndrome (chest pain and signs of coronary artery disease)
- *Atorvastatin (Lipitor)* – for some people who have had a heart attack or have acute coronary syndrome; use for two years

Lovastatin is much less expensive than the other statins. Pravastatin and simvastatin have only recently become available as generics. Their cost will decline in the fall of 2006 and in early 2007. Lipitor is not available as a generic and is more expensive than the three generics.

Most people who need a statin should take the lowest dose that reduces their LDL cholesterol to an acceptable level. High doses of statins pose greater risk of muscle and liver problems. But some people – such as those who have had heart attacks – may need higher doses.

No matter what dose you take, if you have muscle aches and pains when taking a statin, contact your doctor immediately. Also, ask your doctor about splitting your statin pills. This can save you money.

This information was last updated in July 2006.

Statins – Comparative Effectiveness and Cost[1]

Generic Name And Dose Per Day	Brand Name[2]	Average Monthly Cost[3]	Average Expected LDL Reduction	Reduces the Risk of Heart Attack?[4]	Mortality Reduction?
Atorvastatin				Yes	Yes
CR BEST BUY Atorvastatin 10mg	Lipitor	$90	34-38%		
CR BEST BUY Atorvastatin 20mg	Lipitor	$129	42-46%		
CR BEST BUY Atorvastatin 40mg	Lipitor	$129	47-51%		
CR BEST BUY Atorvastatin 80mg	Lipitor	$128	46-54%		
Ezetimibe/simvastatin				Yes[5]	Yes[5]
Ezetimibe/simvastatin 10mg/10mg	Vytorin	$105	45%		
Ezetimibe/simvastatin 10mg/20mg	Vytorin	$104	52%		
Fluvastatin				Likely	Likely
Fluvastatin 20mg	Lescol	$77	22%		
Fluvastatin 40mg	Lescol	$75	25%		
Lovastatin				Yes	Likely[6]
CR BEST BUY Lovastatin 10mg	Generic	$32	21%		
CR BEST BUY Lovastatin 20mg	Generic	$36	24-27%		
CR BEST BUY Lovastatin 40mg	Generic	$56	31%		
Lovastatin 10mg	Mevacor	$43	21%		
Lovastatin 20mg	Mevacor	$81	24-27%		
Lovastatin 20mg longacting	Altoprev	$99	30%	Yes[7]	Likely[7]
Lovastatin 40mg longacting	Altoprev	$108	36%		
CR BEST BUY **Pravastatin**[8]				Yes	Yes
Pravastatin 10mg	Pravachol	$120	18-25%		
Pravastatin 20mg	Pravachol	$114	23-29%		
Pravastatin 40mg	Pravachol	$168	26-34%		
Rosuvastatin				Likely	Likely
Rosuvastatin 10mg	Crestor	$106	43-50%		
Rosuvastatin 20mg	Crestor	$105	52-55%		
CR BEST BUY **Simvastatin**[8]				Yes	Yes
Simvastatin 10mg	Zocor	$98	26-33%		
Simvastatin 20mg	Zocor	$169	30- 40%		
Simvastatin 40mg	Zocor	$170	35-45%	Yes	

UNDERSTANDING GENERICS: A generic is a copy of a brand drug whose patent has expired. For example, in this table lovastatin is the generic version of the brand name drug Mevacor. As explained on page 1, generic pravastatin and simvastatin only recently became available so we don't yet have the monthly costs for those two drugs. The prices given in this table are for the brand versions, Pravachol and Zocor. Generic drugs are less expensive. If you are prescribed a brand name drug that is available as a generic, ask your doctor or pharmacist why.

(1) Because of space limitations this table does not contain all dosage forms. For a full list, please see the full 18-page statin report at www.CRBestBuyDrugs.org.
(2) "Generic" indicates drug sold by generic name.
(3) Prices reflect nationwide retail average for April 2006, rounded to nearest dollar; information derived by *Consumer Reports Best Buy Drugs* from data provided by Wolters Kluwer Health, Pharmaceutical Audit Suite
(4) Nonfatal and fatal heart attack plus deaths attributed to heart disease.
(5) The combination of these two drugs has not been proven but simvastatin has. The benefit is assumed for the combination.
(6) Lovastatin has not been proven to reduce deaths, but the evidence strongly points in that direction.
(7) Based on the results for shorter-acting versions of the drugs.
(8) A generic version of pravastatin became available in April 2006. A generic version of simvastatin became available in June 2006. Future updates of our statin report and this brief will include the monthly costs for these medicines.