

**Testimony Before the
Subcommittee on Oversight and Investigations of the
House Committee on Energy and Commerce
“Medicaid Prescription Drug Reimbursement”
December 7, 2004
Submitted by Timothy P. Catlett
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Mr. Chairman, thank you for inviting me to testify today. My name is Tim Catlett, and I am Senior Vice-President of Sales and Marketing at Barr Laboratories, Inc. Barr is pleased to have the opportunity to answer any questions the Subcommittee may have on the company’s role as a manufacturer of generic pharmaceuticals in the context of the Medicaid program.

I would like to make two key points:

First, Barr is in business to offer its customers the *same* medicines as brand name drug manufacturers but at a significantly *lower* cost, and we do. As a result, when Medicaid patients receive a generic prescription product, they receive the same medicine as the counterpart branded product, but at a cost to the Medicaid system that usually is substantially lower.

Second, Medicaid and other prescription drug reimbursement programs should encourage the maximum utilization of lower-cost generic drugs. Any proposed changes must be carefully examined to ensure that they include appropriate incentives for pharmacies to stock and dispense generic products.

An Introduction To Barr Laboratories, A Generic Pharmaceutical Manufacturer.

Barr is one of America's leading manufacturers of generic drugs.¹ A generic drug is a product determined by the Food and Drug Administration ("FDA") to contain the same active ingredients, and provide the same therapeutic value, as its brand-name counterpart. The FDA bases its sameness determination on detailed scientific criteria, including clinical studies. These criteria include showing that the generic product is pharmaceutically equivalent to the branded product (*i.e.*, contains the same amount of the same active ingredient); and that the generic product is bioequivalent to the branded product (*i.e.*, has the same rate and extent of absorption in the human body).

When the FDA determines that a generic product is therapeutically equivalent to its branded counterpart, the FDA grants the generic what is called an "AB" rating. The rating means that the generic product is interchangeable with the branded counterpart. Once an AB rating is granted, the generic product can be substituted for the brand at the pharmacy level, even in response to a prescription written for the branded product, unless the physician writes "dispense as written." When a pharmacy dispenses a generic prescription product to a Medicaid patient, the pharmacy provides the patient with the same medicine as the branded product, but usually at a significantly lower cost to the Medicaid system.

Barr's generic pharmaceutical research, development, and marketing efforts focus on specialty products that are difficult to manufacture or otherwise require our unique development skills. Often, Barr makes available the first low-cost generic alternative for a pharmaceutical product, either by developing generic pharmaceuticals to compete with branded drugs no longer

¹ More information about Barr and its role in the development of the generic drug industry can be found at <http://www.barrlabs.com>.

under patent, or by challenging patents on branded products under the Hatch-Waxman Act when those patents appear to be invalid, unenforceable, or not infringed by our product.²

Patent challenges brought by generic manufacturers under the Hatch-Waxman Act have resulted in \$27 billion in prescription drug cost savings.³ Barr brought several of these cost-saving patent challenges, including the one that resulted in the first marketing of a lower-cost generic form of Prozac more than two years prior to patent expiry. When Barr successfully develops a generic substitute, other manufacturers are thereby encouraged to bring generic products to market when allowed by law. The resulting vigorous generic pharmaceutical competition brings even lower prices and greater cost-savings for consumers and their insurers.

Currently, Barr manufactures and distributes more than 70 generic products in core therapeutic categories, including oncology, female healthcare (including hormone therapy and oral contraceptives), cardiovascular, anti-infective, pain management, and psychotherapeutics. All of Barr's generic products are in tablet, capsule or oral suspension dosage form. We do not sell our generic pharmaceutical products directly to physicians or their patients. Rather, our "customers" for these products are pharmaceutical wholesalers, who in turn sell to pharmacies; large chains with distribution centers and pharmacy operations; mail-order pharmacies; federal, state, and local government institutions; and managed care organizations. Our customers then either dispense our products to patients or sell our products to pharmacies, which then dispense our products to patients pursuant to prescriptions written by physicians.

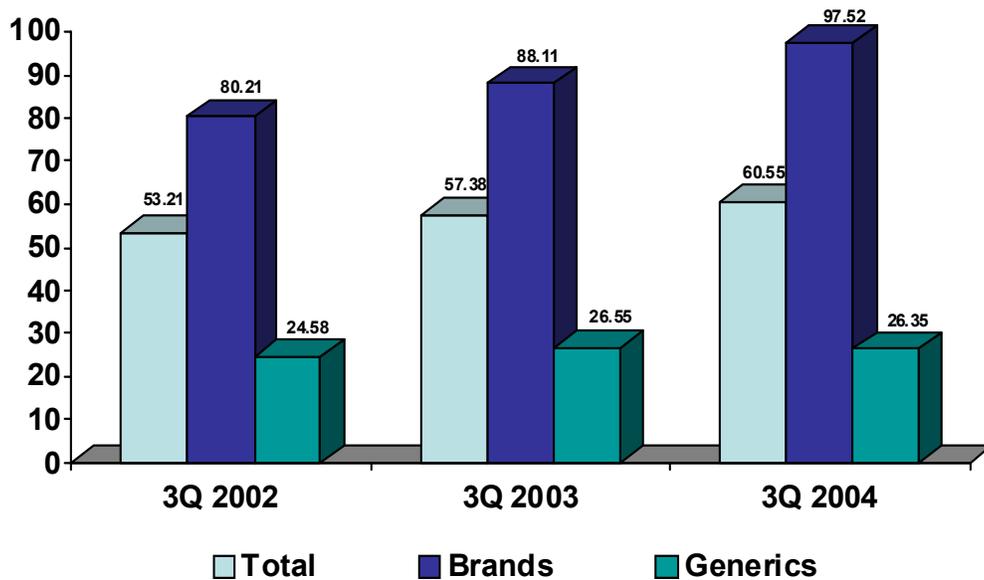
The growth of generic pharmaceutical manufacturers over the last thirty years has resulted in substantial prescription drug cost savings for consumers, private insurers, and public

² Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 (1999 & Supp.).

³ See Kathleen D. Jaeger, Presentation to the HHS Task Force of Drug Importation, April 5, 2004, *available at* <http://www.gphaonline.org/policy/pdf/2004-04-05-testimony.pdf>.

insurers. For example, during the third quarter of 2004, the average prescription cash price to a consumer of a branded pharmaceutical medication was \$97.52, as compared with an average price of only \$26.35 for a generic prescription.⁴

Average Prescription Cash Price at Consumer Cost



Source IMS NPA --- Prices are simple averages not weighted
For product mix or RX size

ims

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Congress and federal agencies recognize that use of generic pharmaceuticals should continue to be promoted, given the magnitude of savings that already have been realized. According to the Centers for Medicare & Medicaid Services (“CMS”), generic substitution is a “best practice” for lowering prescription drug costs.⁵ When Congress passed the Medicare

⁴ IMS Health, National Prescription Audit, November 2004.

⁵ Centers for Medicare and Medicaid Services, Safe and Effective Approaches to Lowering State Prescription Drug Costs: Best Practices Among State Medicaid Drug Programs, *available at* <http://www.cms.hhs.gov/medicaid/drugs/strategies.pdf>.

Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, Title IX §§ 1101-1104, it closed loopholes in Hatch-Waxman that delayed the development and marketing of generic products. According to the Congressional Budget Office, these statutory reforms “would accelerate the availability of generic versions of prescription drugs” and “result in lower total drug spending within the United States by \$7 billion over the 2004-2013 period.”⁶

Pharmaceutical Price Data.

Brand and generic manufacturers provide pricing data to independent publishers, including Red Book, First DataBank, and others, which compile the data for drug manufacturers, wholesalers, retailers, and third-party payors, including state governments and the federal government. These data are used as reference points for numerous purposes, including calculating reimbursement levels under Medicaid and other public and private health insurance programs.

Average Wholesale Price. It is generally known in the pharmaceutical industry and related government agencies that average wholesale price (“AWP”) is a reference price only, and does not represent the actual selling price charged by a manufacturer for its products. The Department of Health and Human Services has repeatedly recognized that AWP does not reflect an actual wholesale price.⁷ A recent General Accounting Office report confirms that “AWP is not necessarily the price paid by a purchaser,” and that it is “often described as a ‘list price’ [or]

⁶ See, Congressional Budget Office, Analysis of Changes to the Hatch-Waxman Act, August 27, 2003, available at <http://www.cbo.gov/ftpdocs/45xx/doc4513/Hatch-WaxmanLtr.pdf>.

⁷ See Report, Title XIX of the Social Security Act, Limitation on Payment or Reimbursement for Drugs, Medicaid Transmittal No. 84-12, reprinted in Medicare & Medicaid Guide (CCH0 ¶ 34,157, at 10,193 (Sept. 1984); Report, Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program, A-06-89-0037 (Oct. 1989), reprinted in Medicare & Medicaid Guide (CCH) ¶ 38,215 (1990).

‘sticker price.’”⁸ A generic manufacturer typically establishes the AWP for the generic product at 90% of the corresponding brand AWP.

Wholesale Acquisition Cost. Wholesale acquisition cost (“WAC”) is the price that wholesalers and distributors pay on the invoice for a given product, although discounts may be provided after invoice, for prompt-pay or periodic volume purchasing incentives, or as rebates.

Average Manufacturer Price. Average manufacturer price (“AMP”) is the average per tablet price for a product sold to a CMS-designated class of purchasers including wholesalers, retail chains, and mail order pharmacies for resale in the retail pharmacy market after all discounts and rebates to customers are taken into account. Manufacturers report AMP to CMS on a quarterly basis. For generic products, the manufacturer then pays a unit rebate amount of 11% of the AMP to the state Medicaid programs based on utilization of the product by each state Medicaid program. States can readily calculate AMP for a generic product from the unit rebate data they receive from CMS.

Prescription Reimbursements Under Medicaid.

Pharmaceutical manufacturers, including Barr, do not seek or receive any reimbursements under the Medicaid program. It is pharmacies that are reimbursed, under the contracts they negotiate with state Medicaid agencies, for the Medicaid prescriptions they fill.

Because CMS “note[s] the shortcomings of using AWP as a basis for reimbursement,” the agency has agreed to “strongly encourage states to reevaluate their reimbursement methodology for drugs” and to “continue to encourage states to look for an alternate basis for

⁸ United States General Accounting Office, Report to Congressional Committees GAO-01-1118, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers’ Cost*, 9 (September 2001).

reimbursement.”⁹ Despite these admonitions, many States, like many private insurers, choose to use AWP to establish the reimbursement formula for Medicaid prescriptions that they negotiate with retailers during each contract period. Notably, these formulae usually subtract a percentage “off” of AWP (different States negotiate different percentages), reflecting the understanding that AWP is a reference price.¹⁰

CMS can and sometimes does cap the reimbursement of Medicaid prescriptions with a Federal Upper Limit (“FUL”). Because CMS does not always move to set a FUL when additional competitors enter the market, thirty-eight states have established maximum allowable cost (“MAC”) programs to cap reimbursement under Medicaid even absent a FUL. As soon as a FUL or a MAC is set, other reimbursement methods and reference price data -- including AWP and WAC -- diminish in significance.

The Importance of Incentives for Generic Drug Use

In order for Barr and other generic manufacturers to continue providing these dramatic cost-savings, generic medicines must be stocked and dispensed by pharmacies. As a practical matter, wholesalers, drug chains with distribution centers, and pharmacies stock or maintain access to essentially all branded pharmaceutical products. If a physician writes a prescription for a branded product for which no generic exists, or if a physician writes “brand medically necessary,” the pharmacy must be able to dispense the branded product.

Because a full catalogue of brand products already must be stocked or accessible, pharmacies incur extra costs when they stock any generic products. Consequently, pharmacies

⁹ Letter from Thomas A. Scully, Administrator to Janet Rehnquist, Inspector General (March 7, 2002) (Commenting on Department of Health and Human Services Office of Inspector General, Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products, A-06-01-00053 (March 2002)).

¹⁰ Quarterly reports of state reimbursement formulae are available at <http://www.cms.hhs.gov/medicaid/drugs/prescriptions.asp>.

must have an economic incentive to carry and dispense generic products. Such an incentive exists when the pharmacy can purchase the generic product for sufficiently less than the branded product and then dispense the generic product at a lower price than the branded product and still make a “profit” on the generic product that is greater than the pharmacy could make on the branded product. If the profit to the pharmacy is greater on the branded product than on the generic product, the pharmacy is not likely to stock or sell the generic product. Moreover, because prices on generic products are almost always lower than prices on the equivalent branded products, third-party payors (including Medicaid) will almost always pay a lower reimbursement amount for the generic product even though the pharmacy makes a larger “profit” on that generic product.

As long as Medicaid agencies or other third party reimbursers continue to use AWP-based reimbursement systems, AWP could be a factor in a pharmacy’s decision as to which generic manufacturer’s product to purchase and dispense. If a generic manufacturer unilaterally reduced its AWP for a given product relative to the AWPs of other generic manufacturers for the same product, pharmacies would have an incentive to purchase another manufacturer’s drug that did not reduce its AWP.

If any changes to Medicaid prescription reimbursement are considered, these changes must maintain Medicaid’s practice of promoting the use of lower cost, therapeutically equivalent, generic drugs by providing pharmacies with financial incentives to carry and dispense generic drugs.

Barr’s Fluoxetine Product.

Barr incurred millions of dollars in costs and years of patent infringement litigation in order to bring a low-cost Prozac substitute to market. When Barr ultimately prevailed in the

litigation, we were entitled to 180 days of exclusivity for our fluoxetine product under the Hatch-Waxman Act, because we were the first to file an Abbreviated New Drug Application challenging the patents on Prozac.¹¹ Barr brought this important generic medication to market more than two years prior to patent expiry.

As is customary for generic products, Barr's fluoxetine was a lower-cost alternative to the brand, Prozac. This provided pharmacies with an incentive to purchase and dispense generic fluoxetine. The incentive Barr provided was effective: by the end of the exclusivity period, generic fluoxetine products had gained more than 80% of the prescription market for 20 mg Prozac. The early introduction of a generic fluoxetine, and the incentives provided to pharmacies through a lower purchase price for the generic medication, encouraged substitution of the generic for the brand.

The day that Barr's fluoxetine exclusivity period ended, nine other generic manufacturers entered the market, each establishing virtually the same AWP for fluoxetine as Barr's. Prices for generic fluoxetine dropped quickly and dramatically. Of course, the establishment of a FUL or a MAC for fluoxetine immediately following the launch of multiple generics (January 29, 2002) would have effectively eliminated the use of AWP as a reference point for reimbursement. Notably, this is exactly what did happen with private third party payors (which account for approximately 87% of the market), almost all of which placed a MAC on generic fluoxetine either before or immediately after January 29, 2002. CMS did set a FUL for Prozac on December 1, 2002.¹²

¹¹ Press Release, Indiana District Court Clears Way for Barr's Generic Prozac(R) Launch, available at <http://www.barrlabs.com/pages/nprpr.html>.

¹² Centers for Medicare and Medicaid Services, Federal Upper Limit (FUL) Changes to Transmittal No. 37 at 17. (showing that CMS added fluoxetine hydrochloride to the FUL product list for implementation on December 1, 2002). *See also* Department of Health and Human Services Office of Inspector General, Omission Of Drugs

Conclusion.

Barr is proud to be part of a highly competitive industry that offers generic products at a lower cost than the brands. In 2003, through the enactment of Hatch-Waxman reforms, Congress recognized the importance of generic drugs and their role in easing the financial strain that prescription drug costs often impose on the budgets of many in our society, including federal and state budgets under Medicaid. For the very same reasons, Congress should ensure that any potential changes to Medicaid reimbursement will encourage, rather than discourage, the continued substitution of generic drugs.

From The Federal Upper Limit List in 2001, OEI-03-02-00670 (discussing delays in establishing FULs in a timely manner.)