



A Legislative History of the Medicaid Drug Rebate Law: The Drug Industry and the Crusade of Senator David Pryor

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Abstract: The Medicaid Prescription Drug Rebate Program was enacted in 1990, granting the Medicaid program “most-favored customer” status and requiring drug manufacturers sell their drugs to Medicaid at the “best price” available to any other purchaser. Although drug rebates remain an integral part of Medicaid today, the program’s legislative history is largely unexamined. This paper reveals the political story behind the law, focusing on the dynamic between Senator David Pryor (D-Ark.) and the Pharmaceutical Manufacturers Association, the trade group representing name-brand drug products.

A Legislative History of the Medicaid Drug Rebate Law:
The Drug Industry and the Crusade of Senator David Pryor

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Introduction

In 1990, the Medicaid Prescription Drug Rebate Program was enacted into law, mixed into a massive, 533-page, 5-year Omnibus Budget Reconciliation Act (OBRA 1990).¹ The Medicaid rebate provisions of OBRA 1990 granted the Medicaid program “most-favored customer” status, requiring drug manufacturers sell their drugs to Medicaid at the “best price” available to any other purchaser. In return for accepting the pricing provisions, drug companies would be assured that their products would be covered under each state’s Medicaid prescription drug program.

Legislators promised that the rebate agreement would reduce state and federal Medicaid expenditures by \$3.5 billion across the program’s first five years.² Upon enactment, the bill’s author, Senator David Pryor (D-Ark.) declared victory: “At long last, we have entered a new era, where the program serving the poorest of the poor no longer pays the highest price for prescription drugs but instead gets a fair deal.”³ Likewise, House-sponsor Representative Ron Wyden (D-Ore.) was enthusiastic about the bill’s prospects for cost savings: “The big drug companies have been stiffing Medicaid. We’ve finally made our case for how outrageous this is.”⁴ By nearly all assessments, the government had fought a battle against the big pharmaceutical industry and come out on top.

It has been over thirteen years since the initial passage of the rebate program. In some ways, the Medicaid rebates have realized legislators’ promises and have been worthy of their initial praise. Participation in the rebate program is extremely high with approximately 550 pharmaceutical company participants.⁵ Forty

¹Omnibus Budget Reconciliation Act of 1990, Pub.L. 101-508, Title IV, sec. 4401(a)(3), 104 Stat. 1388-143 (hereinafter OBRA 1990).

²Maura Reynolds, *Medicaid Savings Law Mandating Drug Discounts to Cut Spending by \$3.5 Billion*, L.A. TIMES, Nov. 20, 1990, at A5.

³Michael F. Conlan, *Medicaid Reform Plan Now Law, Manufacturer Rebates Mandated*, DRUG TOPICS, Nov. 19, 1990, at 16.

⁴Reynolds, *supra* note 2.

⁵Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program*, at <http://www.cms.gov/medicaid/drugs/drughmpg.asp> (last visited Jan. 5, 2004).

nine states and the District of Columbia cover drugs according to the rules of the rebate program.⁶ Most importantly, rebates have generated great financial return to the state and federal governments, with a total of \$19.8 billion recouped from drug manufacturers between 1990 and 2000.⁷ Yet in other ways, the drug rebate program has done both much less and much more than it promised.

The rebate program has done less because it has failed to reign in the skyrocketing Medicaid expenditures on prescription drugs. Medicaid outpatient prescription drug costs increased at an average annual rate of 14.8 percent between 1990 and 1997, and 18.1 percent per year from 1997-2000.⁸ In fact, spending for prescription drugs has been one of the fastest growing elements of the Medicaid program.⁹ As a result, by 2003, Medicaid was spending \$27.5 billion on prescription drugs for 50.8 million enrollees.¹⁰ Thus, while the rebate program has “saved” Medicaid significantly, it has had poor to failing results as a cost containment tool.

Difficulties monitoring the drug manufacturers’ best prices have also detracted from the program’s success. There are currently numerous lawsuits pending in which states have charged pharmaceutical manufacturers with overstating their best price and therefore under-rebating the Medicaid program. The Health and Human Services Office of Inspector General has instituted ongoing investigations of pharmaceutical pricing practices.¹¹ Some violations have been detected and remuneration has been made to the states.¹² However, the OIG’s recent audits of state programs suggest that there are many more holes in states’ systems of

⁶Arizona is excluded. *Id.*

⁷BRIAN K. BRUEN, KAISER COMMISSION ON MEDICAID AND THE UNINSURED, STATES STRIVE TO LIMIT MEDICAID EXPENDITURES FOR PRESCRIBED DRUGS, (2002), *available at* <http://www.kff.org/medicaid/4030-index.cfm>

⁸KAISER COMMISSION ON MEDICAID AND THE UNINSURED, MEDICAID AND THE PRESCRIPTION DRUG BENEFIT (2002) *available at* <http://www.kff.org/medicaid/4063-index.cfm>.

⁹KAISER COMMISSION ON MEDICAID AND THE UNINSURED, MEDICAID PRESCRIPTION DRUG BENEFITS: FINDINGS FROM A NATIONAL SURVEY, 2003 i (2003) *available at* <http://www.kff.org/medicaid/4164.cfm>

¹⁰*Id.* at 1.

¹¹The OIG 2004 work plan announced the office’s intent to investigate federal drug pricing to “determine whether drug manufacturers are circumventing the intent of the drug rebate legislation.” See HHS OFFICE OF INSPECTOR GENERAL, WORK PLAN FISCAL YEAR 2004, at 29 *available at* <http://oig.hhs.gov/publications/docs/workplan/2004/Work%20Plan%202004.pdf>.

¹²For example, in 2003, Pfizer Inc. agreed to a \$49 million multi-state settlement for failure to pay states the rebates due for its blockbuster drug Lipitor. *Pfizer Settles Lipitor Case with Pennsylvania*, PITT. BUS. TIMES, Mar. 3, 2003, *available at* <http://pittsburgh.bizjournals.com/pittsburgh/stories/2003/03/03/daily37.html>

internal controls that could allow for violations to arise in the future.¹³ Thus, not only has the program failed to reign in skyrocketing costs, but reliance on the manipulable term “best price” has made it difficult to realize the full benefit of the rebates due.

By contrast, the rebate program has done arguably more than promised because many states have leveraged the power granted in the rebate legislation to negotiate additional rebates and extend the “best price” provisions to large non-Medicaid populations.¹⁴ Several states, including Michigan and Florida, have enacted legislation requiring manufacturers pay rebates above those required by federal law as a condition of gaining inclusion on a “preferred drug list.” Maine has created a more sweeping program, which allows the state to extend the cost benefit of the Medicaid drug rebates to all of its residents who lack prescription drug insurance coverage—more than 200,000 people.¹⁵ Both strategies for expanding the reach of the federal rebate provisions have been challenged in court by the pharmaceutical industry. The efforts to halt the programs, however, have not been successful. Most recently, the Supreme Court upheld the Maine program in the summer of 2003 by a 6-3 vote.¹⁶

The propriety of the courts’ decisions and of the use of the rebate program for non-Medicaid populations has been examined extensively by other articles.¹⁷ However, these explorations of legislative intent, while

¹³**For example, OIG reports found generally poor monitoring systems in place that resulted in poor tracking of outstanding rebates owed and failure to collect interest owed on late payments** *See eg.* HEALTH AND HUMAN SERVICES OFFICE OF THE INSPECTOR GENERAL, REVIEW OF THE MEDICAID DRUG REBATE PROGRAM IN NEW HAMPSHIRE AS OF JUNE 30, 2002, A-01-03-00013 (January 2004); HEALTH AND HUMAN SERVICES OFFICE OF THE INSPECTOR GENERAL, REVIEW OF MEDICAID DRUG REBATE COLLECTIONS STATE OF VERMONT OFFICE OF VERMONT HEALTH ACCESS AS OF JUNE 30, 2002, A-01-03-00012 (December 2003); HEALTH AND HUMAN SERVICES OFFICE OF THE INSPECTOR GENERAL, AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN IDAHO, A-10-03-00008 (October 2003).

¹⁴Approximately 9 states now use the Medicaid rebate system to extract additional rebates from pharmaceutical manufacturers. KAISER COMMISSION ON MEDICAID AND THE UNINSURED, *supra* note 9, at 37.

¹⁵ME. DEP’T HUMAN SERV., HEALTHY SAVINGS ON PRESCRIPTION DRUGS: MAINERx PLUS (2004), *available at* <http://www.maine.gov/dhs/mainerx/brochure.pdf>.

¹⁶Pharmaceutical Research and Manufacturers of America v. Walsh (Concannon), 123 S. Ct. 1855 (2003).

¹⁷The Center for Medicare and Medicaid Services (CMS), the federal agency in charge of administering the Medicaid program, itself has sanctioned the use of the rebate agreement to extract additional rebates for both Medicaid and non-Medicaid populations so long as the state seeks CMS approval and demonstrates that such a program “furthers the goals and objectives

generally accurate, do not aim to (and therefore fail to) capture the richness of the legislative history of the drug rebate law. The legislative history is a story of trench warfare between equally armed foes. It is also a story of what perhaps is the last major blow taken by the prescription drug industry. With people everywhere criticizing the recent Medicare drug bill as a sweetheart deal for drug manufacturers, this paper illustrates how forces once came out against drug industry profits, rather than for them.

Basic Summary of Medicaid and the Medicaid Drug Rebate Law

Before exploring the origins and iterations of the Medicaid Drug Rebate Program, it is useful to review the general terms of the law as it currently reads and its place within the larger Medicaid program.

Medicaid is a cooperative state-federal program that provides medical care to needy individuals. Under this scheme, the states administer the delivery of care, while the federal government retains oversight and contributes matching funds for approved state programs. The federal agency responsible for the Medicaid program is the Centers for Medicare and Medicaid Services (CMS, formerly known as the Health Care Financing Administration or HCFA) within the Department of Health and Human Services (HHS). A state may receive between 50 and 77 percent of the cost of providing care from the federal government depending on the state's per capita income.¹⁸

of the Medicaid program.” Letter from the Centers for Medicare and Medicaid Services to State Medicaid Directors, SMDL #02-014 (Sept. 18, 2002), *available at* <http://www.cms.hhs.gov/states/letters/smd91802.pdf>. Still, this conclusion did not put the debate on the wisdom of this policy to rest. *See* Jagan Nicholas Ranjan, *Medicaid and the Unconstitutional Dimensions of Prior Authorization*, 101 MICH. L. REV. 602 (2002); Conrad J. Barrington, *Pharmaceutical Research Manufacturers of America v. Concanon and Maine's Prescription Drug Rebate Statute: A Twenty-First Century Solution to the Medicaid Crisis*, 23 WHITTIER L. REV. 1127 (Summer 2002); Charles J. Coper, *Medically Necessary Drugs at a Reasonable Cost*, ALI-ABA 479 (2002).

¹⁸DEPARTMENT OF HEALTH AND HUMAN SERVICES, FEDERAL MEDICAL ASSISTANCE PERCENTAGES: FISCAL YEAR 2004 TABLE, *available at* <http://aspe.os.dhhs.gov/health/fmap.htm>. This percentage range does not reflect enhanced federal matching for the State Children's Health Improvement Program. It likewise does not account for the temporary percentage increases for which some states were eligible in 2003 and 2004 pursuant to The Jobs and Growth Tax Relief Reconciliation Act of 2003, Pub. L. No. 108-27, 117 Stat. 752. *Id.*

Families with dependent children and disabled individuals who meet income eligibility guidelines may enroll in Medicaid and obtain medically necessary services. Beyond this basic federally-mandated coverage, states may opt to expand their Medicaid coverage to additional services and populations. Prescription drug coverage is one medical benefit that may be included by a state in its Medicaid plan. Today, all fifty states provide a Medicaid prescription drug benefit. Under Medicaid prescription drug plans, Medicaid enrollees may pick up their prescriptions at any of a number of participating pharmacies. The Medicaid program then reimburses the pharmacies for these prescriptions.

The rebate program, §1927 of the Social Security Act, codified at 42 U.S.C. §1396r-8, was enacted to help contain prescription costs of the State Medicaid programs. In sum, the law requires that drug manufacturers provide a per unit rebate to State Medicaid programs as a condition of continuing Medicaid coverage of a manufacturer's outpatient prescription drugs.¹⁹ The agreements dictating the amount of the unit rebate are established between drug manufacturers and the Secretary of Health and Human Services, acting on behalf of the States.²⁰ Rebate agreements are effective for one-year and are automatically renewed unless otherwise terminated by either the Secretary or the participating manufacturer.²¹

The terms of the rebate agreement are many. Most centrally is the provision dictating the rebate amount. The method for calculating the rebate amount depends upon the drug product in question. For non-innovator,

¹⁹Under the 1992 Veterans Health Care Act, in order to receive reimbursement under the Medicaid program, manufacturers must also enter into pricing agreements with the Public Health Services (PHS) and the Department of Veterans Affairs (DVA). The former agreement must provide that the manufacturers offer PHS covered entities discounts on outpatient drugs that are at least as great as the rebates received by State Medicaid program. The latter agreement with the DVA must provide that prices for these drugs may not exceed annual federal ceiling prices specified for these drugs. Veterans Health Care Act of 1992, Pub. L. No. 102-585, §§ 601-603, 106 Stat. 4943.

²⁰42 U.S.C. § 1396r-8(a). The Secretary may also authorize a state to directly enter into an agreement with a manufacturer if that agreement provides for rebates at least as large as provided for under the law. 42 U.S.C. §1396r-8(a)(1). It is this section that has allowed states to enter into supplemental drug rebate agreements such as those litigated in the Florida and Michigan cases discussed above. See Letter from the Centers for Medicare and Medicaid Services to State Medicaid Directors, *supra* note 17.

²¹42 U.S.C. §1396r-(b)(4).

multiple source drugs²² (a.k.a. generics) the rebate amount per unit is 11% of average manufacturer price²³ (AMP) for the rebate period.²⁴ The rebate calculation for single source²⁵ or innovator, multiple source²⁶ drugs is more complex. The basic rebate per unit is equal to the greater of:

a.

Amount by which the average manufacturer price (AMP) during the quarter for each dosage form and strength of a drug exceeds manufacturer's best price,²⁷ or

b.

The minimum rebate percentage of AMP (currently 15.1% AMP).²⁸

On top of the basic rebate, there may be an “additional rebate” associated with certain single source or innovator multiple source drugs to account for inflation of the AMP since the drug's introduction into the consumer market.²⁹ At the end of each rebate period, states must report the total number of units sold of

²²A non-innovator, multiple source drug is statutorily defined as a covered outpatient drug for which there are two or more drug products which are rated by the Food and Drug Administration (FDA) as therapeutically equivalent, bioequivalent, and pharmaceutically equivalent. 42 U.S.C. §1396r-8(k)(7). A non-innovator drug is one that was not originally marketed under a new drug application approved by the FDA. *Id.*

²³Average manufacturer price (AMP) is statutorily defined as “with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.” §1396r-8(k)(1). Thus, AMP does not include direct sales to HMOs and hospitals. AMP is based on actual retail sales data for drug manufacturers. By contrast, the average wholesale price (AWP) is a published catalogue price put out by the drug manufacturers. Some analogize AWP to the “sticker price for an automobile, in that manufacturers name the AWP, but few physicians actually buy at the full AWP or even 95 percent of it.” Joseph P. Newhouse, *How Much Should Medicare Pay for Drugs?* HEALTH AFFAIRS 89, 95 (2004).

²⁴§1396r-8(c)(3). Prior to January 1, 1994, the rebate was 10% AMP. *Id.* See also, CENTERS FOR MEDICARE AND MEDICAID SERVICES, UNIT REBATE AMOUNT (URA) CALCULATION, available at <http://www.cms.gov/Medicaid/drugs/drug12.asp>.

²⁵A single source drug is a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration. §1396r-8(k)(7).

²⁶An innovator, multiple source drug is a drug that was originally marketed under an original new drug application approved by the Food and Drug Administration but that now faces generic competition. §1396r-8(k)(7).

²⁹The additional rebate is calculated as follows: 1. Divide the “baseline AMP” (AMP for first quarter after the date first marketed) by the “baseline consumer price index-urban (CPI-U)” (the CPI-U for the month prior to the first quarter after the date the drug was first marketed); 2. Multiply the result by the CPI-U for the current quarter, providing the AMP based on cost-of-living; 3. Compare the result in 2 with the AMP for the current quarter. If this amount (in 2) is less than the current AMP, then a rebate equal to the difference between current AMP and CPI-U-adjusted AMP (in 2) must be paid to the state

each outpatient drug to the manufacturers (to enable them to compute the rebate) and to HHS (for record keeping and audit purposes).³⁰ Using this information, manufacturers pay the rebates directly to the states. Amounts received by the states are considered a reduction in State Medicaid spending and therefore reduce the amount of federal matching funds received.³¹

Manufacturers are responsible for calculating the rebate amount based on their determination of AMP and best price. To enable HHS to verify the manufacturers' rebate calculation, participating drug manufacturers are required to provide the agency a significant amount of otherwise proprietary pricing information. Section (b)(3)(A) provides that within 30 days after the end of each rebate period, a manufacturer must report the drug's AMP and best price.³² HHS may then survey wholesalers and other direct recipients of a manufacturer's drugs to confirm this information.³³ If a discrepancy is discovered, the manufacturer could face civil penalties of up to \$100,000 for each item of false information.³⁴ HHS may also penalize manufacturers for failure to provide timely information on AMP or best price.³⁵

In return for their cooperation with the rebate agreement, participating manufacturers are guaranteed coverage of their drugs. However, there are certain restrictions which states can place on prescription drug coverage. First, certain drugs, including those used for cosmetic purposes, to promote smoking cessation or fertility, and non-prescription drugs, need not be covered by State Medicaid programs.³⁶ Second, pursuant to

for each unit of the drug sold. If the amount is more than current AMP, there is no additional rebate required.

Note that the methods for calculating baseline AMP and baseline CPI-U has changed across the years. Therefore, for drugs originally marketed on or before September 30, 1990, baseline AMP is the AMP for the quarter of March 1990 and CPI-U is equal to the CPI-U value for September 1990. Between September 20, 1990 and October 1, 1993, the baseline AMP was calculated using the AMP for the first full month the product was marketed and the CPI-U was equal to the CPI-U for the month preceding this month. See CENTERS FOR MEDICARE AND MEDICAID SERVICES, REBATE AMOUNT (URA) CALCULATIONS, *supra* note 24.

³⁰§1396r-8(b)(2).

³¹That is, the rebate savings are shared by both the federal and state governments in proportion to the percentage of costs paid for Medicaid. §1396r-8(b)(1)(B).

³²§1396r-8(b)(3).

³³§1396r-8(b)(3)(B).

³⁴§1396r-8(b)(3)(C).

³⁵*Id.*

³⁶§1396r-8(d)(2). The full list of drugs that may be excluded from coverage is found includes: agents when used for anorexia, weight loss, or weight gain; agents when used to promote fertility; agents when used for cosmetic purposes or hair growth; agents when used for the symptomatic relief of cough and colds; agents when used to promote smoking cessation; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; nonprescription drugs; covered outpatient

1993 amendments to the original law, states may establish drug formularies. Medicaid formularies must meet several requirements, and as such only about half of the states use these “preferred drug lists.”³⁷ Similar to formulary restrictions in practice, but distinguished from formularies under the law, are prior authorization programs. A state may subject any prescription drug coverage to prior authorization.³⁸ All prior authorization programs must guarantee that physician’s drug authorization requests are handled within 24-hours of receipt.³⁹ States must also allow for the provision of a 72-hour supply of the non-authorized drug in an emergency situation.⁴⁰ The final major restrictions states may impose on drug coverage are limitations on the quantities of pills per prescription or on the number of refills.⁴¹ These quantity restrictions must be designed to discourage waste or address fraud and abuse.

Despite the general “no reimbursement without rebate” rule, Medicaid will reimburse “non-rebate agreement” drugs when “the availability of the drug is essential to the health of beneficiaries,” it is rated 1-A by the Food and Drug Administration, and either a doctor has obtained approval under a prior authorization program, or the Secretary of HHS has approved a state’s decision to cover the drug despite the absence of a rebate agreement.⁴²

The drug rebate law contains several other sections addressing issues related, but peripheral, to the rebate itself. For example, the law establishes a detailed administrative structure for reviewing and monitoring drug

drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; barbiturates; and benzodiazepines.

³⁷§1396r-8(d)(4). Although the formulary may not exclude outpatient drugs of any manufacturer which has entered into and complies with a rebate agreement, it may exclude rebate-covered drugs if, based on the FDA-approved labeling, the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for a specific disease or population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion. Still, the state must permit coverage of drugs excluded from their formulary after prior authorization is given. In addition, the formulary must be developed by a Governor-appointed committee of physicians, pharmacists, and other appropriate individuals. PDLs have been the subject of the aforementioned lawsuits and have been met with resistance by some consumer groups who feel the lists restrict access to needed drugs for beneficiaries.

³⁸The prior authorization provisions were included in the original law as passed. OBRA 1990, *supra* note 1, at Sec. 4401, §1927(d)(5), *codified at* 42 U.S.C. §1396r-8(d)(1). Approximately 95 percent of states had prior authorization in 2003. KAISER COMMISSION ON MEDICAID AND THE UNINSURED, *supra* note 9.

³⁹§1396r-8(d)(5).

⁴⁰*Id.*

⁴¹§1396r-8(d)(6).

⁴²§1396r-8(a)(3).

use. The drug utilization review programs, standard for most insurers, were put in place to assess topics such as over and underutilization of drugs, prescribing errors and adverse drug effects, and generic substitution.⁴³ In addition, the issue of pharmacy reimbursement was addressed in the final version of OBRA 1990, with lawmakers placing a moratorium on the reduction of pharmacy reimbursement for covered prescription drugs.⁴⁴ The moratorium was repealed in 1993.⁴⁵

Formidable Opponents

The story of the enactment of the above-summarized provisions cannot be appreciated without an understanding of the characters central to its passage. Because of the multitude of players and constituents involved, a legislative battle can perhaps never be accurately reduced to a contest of two wills. Yet the history of the Medicaid drug rebate program seems suited to such a mythic framing: how the persistent Senator from Arkansas slew the multi-headed Pharmaceutical Manufacturing Association dragon. As such, before going into the details of hearings and floor statements, press releases and phone calls, it is only appropriate to explain the passions ignited on either side of the table.

Senator David Pryor

David Hampton Pryor was born in Arkansas on August 29, 1934. Just three years out of college, he was first elected to public office in 1960, winning a seat in the Arkansas House of Representatives. Building a reputation as a reform-minded liberal, Pryor soon gained attention of the Arkansas voters and was elected to the U.S. House of Representatives in 1966, where he served three terms. In the House, Pryor was known as a “crusader for the elderly.”⁴⁶ In fact, when Pryor tried and failed to establish a House Committee on

⁴³§1396r-8(g).

⁴⁴OBRA 1990, *supra* note 1 at §1927(f). Although pharmacists and their trade representatives were present and active in many of the debates surrounding the drug rebate legislation, this paper will not focus on their claims as related to the prescription drug bills. However, it is important to note that this constituency was impacted by the drug reimbursement changes in OBRA 1990.

⁴⁵Omnibus Reconciliation Act of 1993, *supra* note 28, at Title XIII, § 13602(a)(1).

⁴⁶*David Pryor*, in *POLITICS IN AMERICA: MEMBERS OF CONGRESS IN WASHINGTON AND AT HOME* 67 (Alan Ehrenhalt ed.,

Aging, he “formed his own ‘special’ aging committee in a trailer parked at a nearby gas station, and began issuing news releases.”⁴⁷ Despite this dedication, Pryor lost his reelection bid in 1972. Quick to rebound from defeat, however, Pryor won the Arkansas gubernatorial race in 1974, and before long he was back in Washington, a junior Senator.⁴⁸

Senator David Pryor initially served on the Agriculture, Nutrition and Forestry Committee. In 1984, he gained a seat on the Finance Committee, generally recognized as one of the most prestigious panels in Congress.⁴⁹ Still, in his early Senate years, many felt Pryor had yet to find his niche. The Congressional Quarterly (CQ) publication of *Politics in America* observed, “Pryor is a natural salesman who, after more than eight years in the Senate, has yet to settle on a product to sell that seems worthy of his talents. For all his considerable personal charm and flair for publicity, he has not become a well-known figure on major issues.”⁵⁰ In fact, CQ would later describe Pryor’s early career as one of “relatively low-profile labors and middling success.”⁵¹

But in 1988, Senator Pryor began to get more passionately interested in issues surrounding the elderly that had won him attention in the House. Pryor identified the high cost of prescription drugs as one of the biggest problems burdening seniors. As far as the drug companies went, he had little sympathy. He observed, “I frankly think there’s a lot of greed out there... [Drug companies] say they need to spend all this money on research and I just don’t buy that.”⁵² This distaste for the drug companies, or more neutrally, his rediscovered dedication to lowering drug costs for seniors, landed Pryor in 1989 in the position of Chairman of the

Congressional Quarterly, Inc. 1982).

⁴⁷ *David Pryor*, in *POLITICS IN AMERICA: MEMBERS OF CONGRESS IN WASHINGTON AND AT HOME* 74 (Alan Ehrenhalt ed., Congressional Quarterly, Inc. 1984).

⁴⁸ Pryor was elected to the Senate in 1978 and began serving his term in January 1979. *Id.*

⁴⁹ Pryor was also a member of the Governmental Affairs Committee and the Select Committee on Ethics. *Id.*

⁵⁰ *David Pryor*, in *POLITICS IN AMERICA: MEMBERS OF CONGRESS IN WASHINGTON AND AT HOME* 70 (Alan Ehrenhalt ed., Cong. Q., Inc. 1990).

⁵¹ *David Pryor*, in *POLITICS IN AMERICA: MEMBERS OF CONGRESS IN WASHINGTON AND AT HOME* 81 (Phil Duncan ed., Cong. Q., Inc. 1992).

⁵² Julie Rovner, *Drug Industry Discount to Medicaid Not the Bitter Pill as Prescribed*, CONG. Q. WKLY. REP., Oct. 6, 1990 at 3220.

Senate Special Committee on Aging.⁵³ Leading this group, Pryor continued to drive bills to reduce drug costs, vehemently attacking drug industry leaders. The award for this persistence came in the form of the drug rebate provision of 1990, the focal point of this paper.

To further illustrate the Senator's resolve on this issue, however, it is interesting to explore Pryor's actions vis-à-vis the drug industry even after passage of the drug rebate bill. Pryor was not one to be content with a single legislative win. As one executive in the pharmaceutical industry wrote in October 1991, "Senator Pryor is not at all satisfied with the enactment of the Medicaid Drug Rebate bill and is still after our industry."⁵⁴ In fact, Pryor's rants against the pharmaceutical industry did not stop, but arguably grew more heated across the years following the Medicaid rebates. Only months after the legislation's passage, Pryor hammered away at brand name drug companies, accusing them of shifting their abusive practices to other populations, even "on the backs of our Nation's soldier's and veterans. . . rather than slightly trim excessive profits or cut back on huge marketing budgets."⁵⁵ Pryor painted the drug industry as a deceitful and devious bunch, abusing patent protection and using the profits to "subsidize lavish and extravagant drug manufacturer marketing campaigns which have little or no educational value for health care professionals."⁵⁶ The pharmaceutical manufacturers were "the robber barons of the American health care system."⁵⁷ By 1993, even the Senator himself acknowledged that he "may sound like an old broken record on this subject [of the cost of prescription drugs]."⁵⁸ Still, he persisted.

From 1991 through the end of his legislative career in 1996, Senator Pryor introduced an additional two bills aimed at containing prescription drug costs, and spoke on the Senate floor nearly a dozen times on the topic. Among his varied accomplishments across his 17 year tenure in the Senate, it was the battle against

⁵³David Pryor, in *POLITICS IN AMERICA: MEMBERS OF CONGRESS IN WASHINGTON AND AT HOME* 70 (Alan Ehrenhalt ed., Cong. Q., Inc. 1990).

⁵⁴C. Joseph Stetler, *The Pharmaceutical Industry in Review: How We Got to Where We Are*, 26 *MEDICAL MARKETING & MEDIA* 11 (1991).

⁵⁵137 CONG. REC. S2711-01 (daily ed. Mar. 6, 1991)(statement of Sen. David Pryor).

⁵⁶138 CONG. REC. S17329-02 (daily ed. Oct. 7, 1992)(statement of Sen. David Pryor).

⁵⁷137 CONG. REC. S2711-01(daily ed. Mar. 6, 1991)(statement of Sen. David Pryor).

⁵⁸139 CONG. REC. S11763 (daily ed. Sept. 15, 1993)(statement of Sen. David Pryor).

the drug industry that largely defined his career. “He never stopped fighting to keep drug prices down for elderly patients,” Senator Chris Dodd observed, in a speech on the Senate floor bidding Pryor farewell.⁵⁹ Senator Carl Levin’s “goodbye” comments were similar: “As chairman of the Aging Committee, he fought price gouging by the pharmaceutical companies and pushed legislation to make drug companies give their most favorable prices to Medicare and Medicaid recipients.”⁶⁰ So too the remarks of Senator Jim Exon: “A leader in keeping pharmaceutical prices low, Senator Pryor has fought long and hard to make sure that Americans do not pay for the low prices pharmaceutical companies charge other countries for their products. Because of his leadership, the Medicaid program instituted a prescription drug rebate program so that drugs could be purchased at a more favorable rate.”⁶¹

It was this undying commitment, the belief that the drug companies could always do more for the American consumers, which Pryor brought with him to the drug rebate debate.

Pharmaceutical Manufacturers Association

Senator Pryor’s determination was matched by a formidable opponent. The Pharmaceutical Manufacturers Association (PMA, now the Pharmaceutical Research and Manufacturers of America or PhRMA) was incorporated in 1958 to represent the interests of research-based pharmaceutical companies.⁶² In 1989-90, PMA had a membership of over 100 brand name pharmaceutical companies, or about 60 companies if subsidiaries

⁵⁹142 CONG. REC. S11956-01 (daily ed. Sept. 30, 1996)(statement of Sen. Chris Dodd).

⁶⁰142 CONG. REC. S12252-01 (daily ed. Oct. 3, 1996)(statement of Sen. Carl Levin).

⁶¹142 CONG. REC. S11265-03 (daily ed. Sept. 25, 1996)(statement of Sen. Jim Exon).

⁶²Pharmaceutical Manufacturers Association changed its name to Pharmaceutical Research and Manufacturers Association in 1994 in response to government health reform, which drug manufacturers felt would threaten their research capacity. The name change sought to highlight the importance of the research element of member companies’ work. Victor Ostrowidski, *A New Look at the PMA*, AMERICAN DRUGGIST, June 1994, at 11.

were not included.⁶³ Worldwide sales of PMA companies were \$46.2 billion in 1988 and \$50.1 billion in 1989.⁶⁴ The drug companies' investment in research and development topped that of any other U.S. industry and was increasing steadily, quadrupling in the 1980s to \$8.2 billion in 1990.⁶⁵ By 1988, combined PMA member-company R&D expenditures surpassed that of the National Institutes of Health.⁶⁶

Although individual member companies participated in the rebate debate and testified before Congress, PMA largely served as the mouthpiece for the unified group. Mr. Gerald J. Mossinghoff was the figure atop PMA to direct this assault. Gerald Mossinghoff was a lawyer by training with a background in engineering. He had been named PMA President in 1985 after stepping down as Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.⁶⁷ When PMA selected Mossinghoff as its leader, his credentials in the patent field eclipsed his lack of direct experience in the pharmaceutical industry. What's more, Mossinghoff's deeply held beliefs on the importance of protecting the incentive to innovate meshed perfectly with the goals of the Association. In 1987 he wrote, "For the private sector pharmaceutical industry, which has been the primary source of new therapies for the past four decades, there is little incentive to provide an ever-increasing commitment to research unless there are reasonable expectations of financial return."⁶⁸

More than previous PMA leaders, Mossinghoff was eager to take an activist stance in promoting the PMA agenda. One former PMA executive observed, "His aim was clear—to make PMA one of the most, if not the most, effective trade associations in Washington."⁶⁹ Under his leadership, PMA stepped up its efforts to improve the public image of research based drug companies, launching for the first time an all out public relations campaign. The campaign focused on three themes: the value of R&D, the cost-effectiveness of

⁶³PHARM. MFRS. ASS'N, 1989 ANNUAL REPORT 13 (1990).

⁶⁴PHARM. MFRS. ASS'N, 1991 ANNUAL REPORT 4 (1992); PHARM. MFRS. ASS'N, 1989 ANNUAL REPORT 4.

⁶⁵PHARM. MFRS. ASS'N, 1989 ANNUAL REPORT 4 (1990).

⁶⁶PHARM. MFRS. ASS'N, 1989 ANNUAL REPORT 4 (1990).

⁶⁷Michael Conlan, *PMA Chief Battles Formularies, Wants More Generics Tested*, DRUG TOPICS, Mar. 19, 1990, at 38.

⁶⁸Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: the Need for Improved Patent Protection Worldwide*, 2 J.L.TECH. 307 (1987).

⁶⁹WILLIAM C. CRAY, PHARMACEUTICAL MANUFACTURERS ASSOCIATION: THE FIRST THIRTY YEARS 293 (1989).

drugs, and the need for new medication development to promote the health of all Americans.⁷⁰ By the late 1980s, the communications program was running full throttle, ready to respond to any political criticism or legislative attack on the industry or its members.

Despite its significant money and power, PMA was wary to take on a fight against Senator Pryor. In fact, Pryor was one of the last Senators the drug companies would have wanted to have against them. In the Senate, Pryor was personally popular. He was moderate in politics, Southern in manners, and overall a “hell of a nice guy.”⁷¹ In fact, in 1989 his peers’ elected him Secretary of the Democratic Conference, the third-ranking position in the Democratic leadership. According to one Pryor aide, “everyone loved him. . . and he was not an ideologue. So if he was mad, they all knew that some real substance must be there behind the anger.”⁷² Therefore, when Pryor’s anger came crashing down against the drug companies, most Senators were content to sit back and let him push the issue as far as he could.⁷³ The pharmaceutical companies were intent on making sure he couldn’t push the issue far. There was simply too much at stake.

Thus, long before the first hearing on Pryor’s Medicaid rebate bills, it was clear that any bill would emerge only after a prolonged and bloody battle between two heavily armed opponents.

Legislative History Proper

From the Ashes of a “Catastrophe”

The first hearings about Medicaid prescription drug rebates weren’t about Medicaid at all. Rather, the idea

⁷⁰PMA had used some advertising to advance its public image in the past, but the first coordinated public relations campaign did not occur until 1986 or so. *Id.* at 296.

⁷¹Arkansas Ency., *David Pryor*, available at http://www.geocities.com/arkencyclo/wiki/David_Pryor/

⁷²Telephone Interview with Christopher C. Jennings, Former Deputy Staff Director, Senate Special Committee on Aging, (Feb. 12, 2004).

⁷³*Id.*

for a Medicaid drug rebate arose from the ashes of a Medicare legislative debacle referred to in short as Medicare Catastrophic.

Medicare Catastrophic ironically was not so named because of its horrible demise. Rather, the Medicare Catastrophic Coverage Act of 1988 was conceived as an extension to Medicare insurance coverage, designed to provide protection to Medicare beneficiaries against extremely high (“catastrophic”) costs of severe illness. In addition, Medicare Catastrophic added an outpatient drug benefit to the Medicare program. The drug program had a basic deductible and co-payment structure common in many other Medicare and private insurance plans. Specifically, Medicare enrollees who satisfied an annual deductible would be required to pay a percentage coinsurance on outpatient prescription drugs. In return, Medicare would pick up the remaining cost, namely 50 percent in 1991, 60 percent in 1992, and 80 percent in 1993 and years thereafter.⁷⁴

At first, the bill received support from sponsors and interest groups. Upon passage in the House, Representatives hailed it as “the greatest improvement in Medicare in twenty years,” and a “great bill for the elderly.”⁷⁵ Every major retiree organization, from the American Association of Retired Persons (AARP) to the National Association of Retired Federal Employees, officially threw its support behind the law.⁷⁶ AARP’s *Bulletin* hailed Catastrophic “in most laudatory terms, describing it variously as ‘a watershed,’ ‘a victory for the elderly,’ and protection ‘from the ravages of acute catastrophic illness.’”⁷⁷

The initial praise was short-lived. Soon after enactment, Medicare Catastrophic began its path toward repeal. In an embarrassing turn of events for seniors’ groups who had supported the legislation, wealthy seniors began to vehemently and vocally protest the new legislation. Under the new law, a large percentage

⁷⁴Medicare Catastrophic Coverage Act of 1988, P.L. 100-360, 102 Stat 683.

⁷⁵Spencer Rich, *Catastrophic Care Bill Clears House, 328 to 72; Medicare Expansion Likely to Pass Senate Soon*, WASH. POST, June 3, 1988, at A3.

⁷⁶133 CONG. REC. S15114-01 (daily ed. Oct. 27, 1987)(List of Group Endorsements).

⁷⁷RICHARD HIMELFARB, CATASTROPHIC POLITICS 58 (Penn. St. U. Press 1995).

of wealthier beneficiaries would be required to pay a surtax to maintain their Medicare benefits. In 1989, that surtax could be as much as \$800 per person.⁷⁸ Moreover, these higher premiums did not assure Medicare's solvency: the Congressional Budget Office projected the new drug benefit alone would have a budgetary shortfall of approximately \$2.8 billion over its first four years of operation.⁷⁹

CBO attributed the drug benefit deficit, at least in part, to the increasing price of prescription drugs.⁸⁰ Medicare drug prices were to be based on average wholesale price per unit—a price that, by most all assessments, was far higher than that actually paid by any purchaser. The Health Care Financing Administration would have no authority to negotiate prices below this average.

In an attempt to save the prescription drug portion of the bill, deflate its price tag, and look more generally at drug pricing issues, the Senate Special Committee on Aging, chaired by Senator David Pryor, convened a two-part hearing, entitled, “Skyrocketing Prescription Drug Prices.” Part One was held on July 18, 1989 and was entitled, “Are We Getting Our Money's Worth?” Part Two took place four months later on November 16, 1989 and focused on “Turning a Bad Deal into a Good Deal.” These hearings did nothing to reverse Catastrophic's tumble toward repeal, which eventually occurred on December 13, 1989.⁸¹ By contrast, the hearings were instrumental in laying the foundation for the Medicaid drug rebate legislation.

The Early Hearings: Skyrocketing Prescription Drug Prices

On July 18, 1989, the Senate Special Committee on Aging called on witnesses to help examine drug pricing

⁷⁸Spencer Rich & Tom Kenworth, *Sen. McCain Vows Fight on Medicare 'Catastrophic' Benefits Partially Supported*, WASH. POST, Nov. 19, 1989, at A10.

⁷⁹Julie Rovner, *Panel May Pave Way for Death of Catastrophic-Cost Laws*, CONG. Q. WKLY. REPT., July 15, 1989, Vol. 47, No. 28.

⁸⁰*Id.*

⁸¹Medicare Catastrophic Coverage Repeal Act of 1989, Pub. L. 101-234, 103 Stat. 1979.

issues related to Catastrophic.⁸² The witness panel was comprised of eight people possessing a variety of experiences with drug pricing policy, both inside and outside of Medicare. Presumably, it was the intent of the committee that witnesses with non-Medicare experience might have innovative cost-reducing suggestions that could be applied to Catastrophic Drug Insurance proposal. Yet as each witness spoke, the hearing began to take a different twist. The discussion of drug pricing became more global. Rather than a strategy session to save or strengthen the Catastrophic Drug Insurance proposal, the July 1989 hearings were more like a grand jury trial of the drug industry and their pricing policies.

From the start the drug companies faced an uphill battle. The stark drug price increases of the 1980s screamed out to Pryor. Moreover, the conclusions of a Special Aging Committee majority staff report provided additional backing for this basic complaint. The briefing paper entitled, “Prescription Drug Prices: Are We Getting Our Money’s Worth?” presented nine conclusions of the staff’s research:



The bulk of research and development by prescription drug manufacturers produces insignificant new compounds that add little or nothing to drug therapies already marketed;



Prescription drug manufacturers charge the public high prices for new drugs that duplicate existing and generally less expensive, drug therapies;



Present governmental incentives to spur true innovation by pharmaceutical manufacturers appear to have failed;



Prescription drug price increases more than tripled the rate of inflation in the economy from 1981 to 1988;



Prescription drug manufacturers have opted to expand their market by charging penthouse prices to

⁸² *Hearing on Skyrocketing Prescription Drug Prices before the Sen. Spec. Comm. on Aging*, 101st Cong. 457 (1989)[hereinafter *Aging Hearings*].

compensate for the poverty of their innovation;

♣ Citizens of most countries of the world pay less than U.S. consumers for their prescription drugs;

♣ There are two domestic markets in the U.S. for most big-selling prescription drugs: a price competitive market characterized by deep discounts off the published list price, and a high-priced market where retail customers, Medicare and Medicaid purchase their prescription drugs;

♣ Actions by insurers and Medicaid programs to reduce drug costs by cutting pharmacy reimbursement have hurt pharmacies but have had little effect on prescription drug prices;

♣ Congress has previously granted the Executive Branch authority which may be useful in obtaining fair drug prices from manufacturers that refuse to negotiate single source drug prices or engage in competitive bidding.⁸³

In his opening statement, Pryor candidly described the data and the above conclusions. In sum, he asserted that the American prescription drug consumer was getting a bad deal.

The data amassed in support of his position was not the only thing that fueled Pryor's antipathy toward the drug industry. Pryor was also frustrated by his personal interactions with the industry even before the hearing began. Pryor had invited 18 drug manufacturers to present testimony on the topic of drug pricing. Only one of those companies, Amgen, agreed to appear. Pryor vociferously chastised the drug industry for their lack of cooperation, ticking off the names of each non-participating invitee. "When it comes to boasting of their profits to Wall Street, the drug companies can be heard loud and clear, but hey are awfully quiet when it comes to discussing the prices they charge on Main Street," Pryor stated.⁸⁴

⁸³STAFF OF SENATE SPEC. COMM. ON AGING, PRESCRIPTION DRUG PRICES: ARE WE GETTING OUR MONEY'S WORTH?, (Comm. Print No. 101-49 (1989)). Subsequent to the release of this report after the July hearing, PMA composed a white paper of its own on November 15, 1989, just a day before the second hearing on drug pricing. PMA President Gerald Mossinghoff urged Chairman Pryor to "consider the facts rather than the flawed conclusions of the Committee majority staff." *Aging Hearing*, *supra* note 82, at 457 (letter from Gerald J. Mossinghoff to the Honorable David Pryor, Chairman, Select Committee on Aging). PMA's report, entitled, "America's Pharmaceutical Research Companies—A Cost-Effective Source of Important New Medicine," objected to five elements of the majority staff's analysis and concluded that the report far overstated the "me-too factor" in the drug industry. *Id.* at 458-59.

⁸⁴*Aging Hearings*, *supra* note 82 at 1 (1989)(Opening Statement by Senator David Pryor, Chairman). In an advisory article to the industry published in October 1991, the author noted the leverage Pryor gained by advertising the absence of drug

Luckily, the first witness was friendlier to the interests of the Senator and in fact gave him more fodder for his fight with the industry. Mr. Dennis Styrsky, chief of the Pharmaceutical Products Division at the Department of Veterans Affairs (VA), testified on the VA drug procurement policy. The drug acquisition program had successfully secured discounts on single-source drugs ranging from 22 to 90 percent off of average wholesale price. By contrast, Medicare (under the Catastrophic plan) and Medicaid were required to pay AWP for their drugs. HCFA and the VA therefore represented the two ends of a spectrum of drug prices, with hospitals and other insurers falling somewhere in the middle. Yet, Pryor observed, HCFA and the VA were both government purchasers, were they not? Why did they pay different amounts? Pryor attached to this price differential. He would return frequently to the comparable across the next year.⁸⁵

While the VA testified that it had little difficulty lowering drug prices, State Medicaid offices were largely stuck paying AWP. The next witness, Mr. Winston Barton, Director of the Kansas Medicaid program, explained his state's attempts at reducing drug costs to a more affordable level. New state legislation allowed the Medicaid program to establish a bidding program, under which drug companies were invited to place a price bid for each of their prescription drugs. The company offering the lowest bid price within a class of therapeutically equivalent drugs gained the right to be the sole distributor for that class. Unfortunately, Mr. Barton commented, "the major obstacle in starting this program was the strong resistance from the major pharmaceutical companies," and only a half-dozen drug products had been bid on.⁸⁶ Savings, therefore, were limited. The next witness expressed similar frustrations. An operator of a retail pharmaceutical purchasing

companies at the hearings. In looking forward to possible additional hearings on revisions to the rebate bill, the author stated: "When Pryor schedules these hearings, and he will, I believe it is imperative that, in addition to PMA, representatives of three or four companies be present to testify. If we are afraid to appear, you can be sure that Pryor will exploit our absence and that no one in the Congress is going to give us any support. We do have a great story to tell and some strong points to make. But we have to tell it in person. Not by proxy, not by letter, and not by advertisements." Stetler, *supra* note 54.

⁸⁵There is some question of the wisdom and accuracy of comparing the VA and HCFA-procured prices. The Veterans Administration is not an insurance program, but directly purchases and delivers prescription drugs. By contrast, HCFA in Medicaid (and in Medicare, had Catastrophic been implemented) are the financiers of a program wherein each individual beneficiary obtains drugs from independent pharmacies and the government reimburses the pharmacies for this cost. Some people, including the HCFA administrator, felt that this distinction made the prices procured in the two programs incomparable and felt that Pryor's persistent comparison of Medicaid, Medicare and VA prices was inappropriate. See e.g. *Aging Hearings*, *supra* note 82, at 27.

⁸⁶*Id.* at 41.

group, he too had tried and largely failed in gaining participation of brand-name drug manufacturers. Two innovative strategies to lower drug costs had been thwarted by uncooperative drug manufacturers.

Three witnesses had testified at this point. Two had illustrated the unwillingness of pharmaceutical manufacturer to support cost containment policies, while another had proven that, yes, lower prices existed on the market. This “constructive education of the committee” primed them to receive the head of the Pharmaceutical Manufacturers’ Association.⁸⁷

In his five minutes of testimony, Gerald Mossinghoff, PMA President, touted the benefits of the new drugs being developed by member companies. He highlighted the associated costs for the development process and the fact that PMA member companies devoted a higher percentage of their sales to research and development than any other high-technology industry.⁸⁸ Drug prices may seem high, but the product was worth the cost. Any reduction in these costs would only cut into innovative drug discoveries in the future.

Then he went negative, criticizing the numbers that Senator Pryor and his committee had found in their research. He “respectfully submit[ted]” that the number of me-too drugs was significantly inflated; that the amount spent on advertising by pharmaceutical companies was likewise overstated; and that the comparison of drug prices around the world was misleading when accounting for the average earning power in each of the comparison countries.⁸⁹ He noted that while individual drug prices may have gone up, the share of each health-care dollar expenditure attributable to prescription drug purchases had decreased from 12.4 percent in 1965 to 6.8 percent in 1987. As “respectfully” as he delivered his critique, Mr. Mossinghoff did not please the Committee Chair.

Pryor’s rebuke was harsh and directed at both PMA and the absent member companies. He criticized the general attitude of a drug industry that didn’t feel Congress had “a role in looking at the prices that our con-

⁸⁷*Id.* at 118.

⁸⁸In 1990, PMA members spent \$8.1 billion on research and development. PHARM. MFRS. ASS’N, 1989 ANNUAL REPORT 13 (1990).

⁸⁹*Aging Hearings*, *supra* note 82, at 119.

sumers and taxpayers are paying for prescription drugs, which are necessities of life.”⁹⁰ He was unrelenting on the question of the 88 percent rise in drug prices since 1981, demanding an explanation that would satisfy his constituents. He asked about price increases after patent expiration and why after a drug company had its “patent for 17 years, [and] made a lot of dough on that particular drug, and the price still goes up?”⁹¹ When Mossinghoff’s initial replies were unsatisfying to the Senator, the PMA President retreated to the fact that because of antitrust law “PMA cannot get involved in how our companies price.”⁹² This reply of course, only served to egg on Pryor who had expressed to PMA his preference for individual manufacturer testimony over an Association presentation, “as the Association is neither responsible nor accountable for manufacturers’ decisions with respect to pricing of prescription drugs.”⁹³

Although sprinkled with comments from other Senators, the discussion between Senator Pryor and PMA President Mossinghoff continued for some twenty pages of transcript, rehashing the pricing questions and examining the favorable tax treatment of manufacturers’ expensive research and development pursuits. The exhaustive exchange left Pryor confident about one thing: if prices kept going up as they had been, Congress, with his leadership, was going to take action.

Mossinghoff may have been the centerpiece of the hearing, but he was not the last witness of the day. That position was given to the Chairman of Amgen, George B. Rathmann. The Chairman had become more subdued when Mr. Rathmann finally took to speak. The testimony of three other witnesses had put space between the industry rep and the company chair. ⁹⁴ Moreover, Pryor’s appreciation for the sole participating

⁹⁰*Id.* at 154.

⁹¹*Id.* at 167.

⁹²*Id.*

⁹³In a June 14, 1989 letter to Mr. Gerald J. Mossinghoff of the Pharmaceutical Manufacturers’ Association, Chairman Pryor and Ranking Member John Heinz expressed their concerns with PMA representation at the hearing in lieu of individual manufacturers. They wrote, “The Association, in contrast with its member firms, lacks specific knowledge of firms’ pricing policies, or the reasons behind these decisions, and is prohibited by anti-trust statutes from participating in price-setting. Inasmuch as the Association is neither responsible nor accountable for manufacturers decisions with respect to pricing of prescription drugs, we believe the Committee’s limited hearing time will be most fruitfully employed in frank dialogue with company decision-makers, based on actual pricing data.” *Aging Hearings*, *supra* note 82, at 373-74.

⁹⁴The other panelists at the July 18, 1989 hearing included Joseph Thomas II of Purdue University School of Pharmacy; Bruce Laughrey, president of Medi-Span; Louis B. Hays, Acting Administrator of HCFA. *Id.* at 176-219.

drug manufacturer seemed to engulf his negative feelings toward the industry that had been unleashed upon PMA. Mr. Rathmann’s testimony concluded the hearing, and Senator Pryor sent him off with a charge: “I hope that you can talk to some of your colleagues who are in the pharmaceutical business, some of the manufacturers to convince them that we don’t have horns, that we’re looking for answers, that we hope that they will participate with us in some of these future discussions.”⁹⁵

The hearing adjourned at 1:21 p.m., but the issues it raised did not disappear. Instead they hovered over the Capitol like the swampy D.C. summer air. On July 31, Senator Pryor brought his observations from the hearings to the rest of the Senate.⁹⁶ While his floor speech perhaps presented no new revelations, his message was firm. This was something he wasn’t going to quit pushing. “Are we getting our money’s worth?” the hearing had asked. Pryor’s answer resounded: absolutely not.

A Shift to Medicaid Drug Costs

By the second of the two hearings on Prescription Drug Prices on November 16, 1988, the Medicare Catastrophic drug benefit was all but dead. Chairman David Pryor admitted as much and reframed the policy context of the discussion. Instead of analyzing drug prices for the purpose of getting a fair deal for Medicare, he shifted his attention to Medicaid drug spending. The change made good policy sense. After all, approximately 3.1 million Medicare beneficiaries (or 9 percent of all Medicare enrollees) also qualified for Medicaid benefits.⁹⁷ If there was to be no drug benefit through Medicare, Pryor was to assure that the

⁹⁵*Id.* at 229.

⁹⁶136 CONG. REC. S.9058-02 (daily ed. July 31, 1989)(statement of Sen. David Pryor).

⁹⁷These data are based on the number of Medicaid beneficiaries in the 65 and older eligibility group. They do not include individuals who may have received Medicare coverage due to disability. Therefore, the percentage of “dual eligibles” (people on Medicare who also qualified for Medicaid) was probably slightly higher than this figure. See CENTERS FOR MEDICARE AND MEDICAID SERVICES, *Number of Medicaid Persons Served (Beneficiaries), by Eligibility Group: Fiscal Years 1975-1999*, 2001 MEDICARE AND MEDICAID STATISTICAL SUPPLEMENT, available at <http://www.cms.hhs.gov/review/supp/2001/table88.pdf>; CENTERS FOR MEDICARE AND MEDICAID SERVICES, *Number of Enrollees in the Medicare Hospital and/or Supplementary Medical Insurance Programs, By Type of Coverage and Type of Entitlement: July 1, 1966-1999*, 2001 MEDICARE AND MEDICAID STATISTICAL SUPPLEMENT available at <http://www.cms.hhs.gov/review/supp/2001/table5a.pdf>.

states providing drug coverage through Medicaid could continue to finance their programs and support the most desperate segment of the elderly population.

Pryor's concern for the financial viability of State Medicaid drug programs was well placed. Drug coverage under Medicaid was optional, but all but two states, Alaska and Wyoming, elected to offer the benefit. Yet while states covered prescription drugs, the financial security of the programs was unsteady in November 1989. States were in a time of sharp fiscal decline, and 33 states would face budget deficits by 1990.⁹⁸ As the second fastest rising cost in state government budgets in the 1980s, Medicaid was a significant contributor to these deficits.⁹⁹ In turn, the third highest driver of Medicaid expenditures was prescription drugs, estimated at \$3.5 billion in 1989.¹⁰⁰

States were pursuing a variety of strategies to decrease the cost of their Medicaid drug programs. Drug cost-control measures included co-payments, restrictive formularies, annual or monthly limits on number of prescriptions or prescription reimbursement per enrollee, and reduced reimbursement to dispensing pharmacists. By 1988, twenty states had co-payments in effect, twelve states capped the number of annual prescriptions or expenditures per enrollee, and at least 22 used formularies.¹⁰¹

States were also exploring policies to directly force drug companies to lower the sticker price on their drugs. As described in the earlier hearing, Medicaid was paying average wholesale price for its drugs—on the order of 30 to 40 percent more than most other drug purchasers.¹⁰² As of the November hearings, two states—Alabama and Kansas—had passed legislation allowing Medicaid administrators to negotiate lower prices with drug manufacturers.¹⁰³ To provide the states with leverage in negotiating drug rebates, the laws also gave

⁹⁸JEAN DONOVAN GILMAN, *MEDICAID AND THE COSTS OF FEDERALISM*, 1984-1992 163 (1998).

⁹⁹136 CONG. REC. S5811-01 (daily ed. May 8, 1990)(statement of Sen. David Pryor).

¹⁰⁰*Id.*

¹⁰¹Stephen B. Soumerai and Dennis Ross-Degnan, *Experience of State Drug Benefit Programs*, HEALTH AFFAIRS, 40, 41 (Fall 1990). Other studies reported that in 1988 only 4 state drug formularies could be deemed “completely open.” *Id.*

¹⁰²To be precise, Medicaid reimbursement for single source and innovator multiple source drugs was based on pharmacists Estimated Acquisition Cost. In most states, this was equal to Average Wholesale Price minus 10 percent. *Aging Hearings*, *supra* note 82, at 223.

¹⁰³STAFF OF SENATE SPEC. COMM. ON AGING, *SKYROCKETING PRESCRIPTION DRUG PRICES: TURNING A BAD DEAL INTO A FAIR DEAL*, (Comm. Print No. 101-69, at 22 (1990)). Twelve other states were exploring this possibility as of November 1989.

administrators the authority to exclude non-participating drug manufacturers from the Medicaid formularies. Still, the states were having difficulty employing this tactic against drug companies who acted in concert and refused to submit bid prices.¹⁰⁴ In fact, the state threat was somewhat empty: it was politically infeasible to withhold brand-name drugs without generic equivalents from Medicaid enrollees. Drug companies played up this fact in their lobby to prohibit further state action. “Such policies amount to second-class medical treatment for the poor,” they argued.¹⁰⁵ States were having difficulty negotiating rebates, but many didn’t know where else to turn. Costs had to be reduced.

And so, in the November 1989 hearings, the Special Committee on Aging turned to what they could do to help the Medicaid programs. Members heard the plight of Medicaid directors and program administrators. They heard the stories of two seniors who were having trouble covering their prescription drug costs. They listened as directors of organizations dedicated to making drugs more accessible described how any success in gaining lower bulk purchase prices were counteracted by subsequent drug price increases. There were neither drug companies nor PMA representatives testifying at this session. Instead, the Committee Chair drew attention to those in need of help and indicated his intent to provide that support.

“The drug manufacturers may not know it, but they are digging themselves into a very deep hole. The Congress is not going to stand around and watch drug prices in the community . . . go up 400 percent, 238 percent . . . We’re not going to stand here and watch people in Italy pay 41 cents . . . and \$2.38 here. This system is not going to permit that. What we do with this problem is another question, but there is no doubt that something is going to be done.”¹⁰⁶

A Medicaid Drug Rebate Bill

The drafting and introduction of PAPPA (S. 2605)

Georgia would enact similar law before the close of 1989.

¹⁰⁴136 CONG. REC. S5811-01 (daily ed. May 8, 1990)(statement of Sen. David Pryor).

¹⁰⁵Milt Freudenheim, *Price Revolt Spreading on Prescription Drugs*, N.Y. TIMES, Nov. 14, 1989, at D1.

By January 1990, Senator Pryor had begun to delve into legislative strategies to “do something” about the problem of prescription drug costs. Although he remained concerned about escalating drug costs in all sectors, a Medicaid-based proposal seemed the best place to start. Medicaid was the single largest drug purchaser, and it was paying the highest drug prices.¹⁰⁷ The hearings from the previous year informed a January Aging Committee majority staff report that offered three options for legislation.¹⁰⁸ The options were:

1.

“Voluntary Educational Program”: Directs HHS to establish a National Pharmacy and Therapeutics (P&T) Committee to assess drug therapeutic equivalence. The therapeutic equivalence list would be given to the states to assist them, at their option, in negotiating drug prices with manufacturers.

2. “Flexible Mandate”: Requires States to join multi-state buying groups to negotiate prices of single source drugs with manufacturers. These buying groups would be required to accept the low bid in each therapeutic category established by the National P&T Committee. States would pay pharmacies AWP and obtain a rebate from the manufacturer equal to the difference between the negotiated price and AWP. States which have their own negotiating program prior to the statutory deadline for joining a buying group could continue to operate this program (the “grandfather clause”) subject to certain fundamental rules (to be set forth in the final legislation).

3. “Mandatory National Medicaid Buying Program”: Require States participate in a single national buying group that would negotiate drug prices with manufacturers on their behalf. Rebate structure would be similar to that described in Option 2.¹⁰⁹

¹⁰⁷There was some objection to calling Medicaid the “largest drug purchaser” for the program itself was not a direct purchaser of prescription drugs but reimbursed individual retailers. Still, this was the rhetoric that Pryor used in describing the decision to go after Medicaid drug costs. Note also, this reference is to “single purchaser.” Combined other industry sectors were larger purchasers (e.g., HMO sales were 20-30% of drug company sales but any individual company represented only 0.05% to 0.06% of a company’s business). *Id.* at 226.

¹⁰⁸Comm. Print No. 101-69, *supra* note 103.

¹⁰⁹*Id.* at 17-18.

It took some time to hammer out the details and settle on one of the above options. Finally, on May 8, Senator Pryor took the floor to preview his Medicaid drug price legislation. He began:

“Madam President, I rise this afternoon with good news and bad news. The bad news is that we face a smoldering national crisis. The good news is that I believe I have at least part of the solution in a bill I will introduce on Thursday. The crisis I am referring to has been created by years of excessive increases in prescription drug prices. It is a crisis of affordability. I am sure there are many reasons for it, but in my mind one central reason has been the greed of drug manufacturers.”¹¹⁰

Pryor continued, describing his findings from the Aging Committee hearings from 1989, and explaining his change in focus from the drug costs of older Americans to the burden on State Medicaid budgets. His legislative solution to the exploding Medicaid drug prices was entitled “Pharmaceuticals Access and Prudent Purchasing Act of 1990” or PAPPA. PAPPA would give state governments express authority to negotiate directly with drug companies to achieve lower Medicaid drug prices. Details would be forthcoming upon the bill’s official introduction.

While Pryor was sparing on the specifics of the legislation, he took care to spell out his concerns about the legislative battle ahead and the formidable lobbying power of the drug industry. He warned:

“I understand that many Aging and Finance Committee members have heard from drug manufacturers lobbying against this proposal even before the bill’s specifications were written. In all the year I have been in the Senate, I have never seen such an extensive lobbying campaign against an idea that has yet to be formally introduced. . . I ask my colleagues one favor. Please read and evaluate my proposal and not be misled by speculation about my intent or the industry’s dire predictions. . . please remember who is not calling or writing to oppose it. It is not those who have had to carry the burden of difficult cost containment approaches aimed at reducing skyrocketing State Medicaid prescription drug expenditures. . . Rather it is the one participant of the Medicaid prescription drug program that has escaped all cost containment initiatives—the prescription drug manufacturers.”¹¹¹

As promised, PAPPA was introduced formally two days later. PAPPA was virtually identical to “Option

2” from the majority staff report released back in January. The skeleton had been filled in, but the basic structure remained the same. Under PAPPa, the Department of Health and Human Services would establish a National Pharmacy and Therapeutics Committee to evaluate the “relative safety and efficacy, and the comparability, of covered outpatient drugs approved for marketing in the United States.”¹¹² Based upon this information, the Committee would group the drugs into therapeutic classes, and determine which of the drugs within any class had “superior safety and efficacy.”¹¹³ Each state would then be required to solicit bids directly from drug manufacturers for drugs in each federally-determined therapeutic class.¹¹⁴ The low bid within a class would be considered the “preferred” drug and would be used almost exclusively in the state’s Medicaid program.¹¹⁵ Medicaid programs would be entitled to a monthly rebate (per unit dispensed) equal to the difference between the low-bid price and the average manufacturer price.

In other words, PAPPa mandated that each state establish a formulary that included one drug (the lowest bid-price drug) in each therapeutic class. Pharmacists dispensing drugs other than the preferred drug (i.e. dispensing “off-formulary drugs”) to Medicaid patients would not be reimbursed unless the prescribing physician had explicitly indicated that the non-preferred drug was “medically necessary.” If a prescription was for a non-preferred drug, but contained no written “medically necessary” restriction, the pharmacist would be required to use “diligent efforts” to contact the physician and receive permission to substitute the preferred drug. If the pharmacist was unable to contact the prescribing physician, reimbursement for the non-preferred drug would be limited to a 72-hour supply.

¹¹²Pharmaceuticals Access and Prudent Purchasing Act of 1990, S. 2605, 101st Cong. §1927(b)(3) (1990).

¹¹³*Id.*

¹¹⁴States were to create a group by January 1, 1993. States unable to implement such a program by that date would be required participate in a Federal or multi-state buying group. *Id.*

¹¹⁵Note that the lowest bid need not necessarily be the basis for designating a drug as “preferred.” Rather, a drug may be deemed preferred after “taking into account the total cost of medically necessary concomitant drug and or other therapy, the length of time for which a price may be guaranteed, the likelihood of new drug approvals which may create opportunities for lower negotiated prices in the drug use class, and such other business factors as the group or entity deems appropriate.” *Id.* at §1927 (a)(9).

To force drug manufacturers to play and enter “reasonable” rebate bids, S. 2605 required that the negotiated rebate amount provide a “substantial price reduction.” State programs that did not achieve such a reduction would be incorporated into the federal prescription drug negotiating group. The bill dictated that a state would achieve a substantial price reduction when its payments for Medicaid prescription drugs (ingredient costs only) were 85 percent or less than that year’s projected outlay for drugs based on 1990 expenditures. The Special Committee on Aging staff estimated that this bid/rebate plan would save states a combined total of between \$100 and \$200 million annually.¹¹⁶

In introducing the legislation, Pryor paraded the support of fourteen organizations, including three pharmacist associations and eleven consumer groups. Still, the support did not detract from the Senator’s concerns about the intensive pressure on lawmakers from the drug industry. Pryor continued his strike against “red herring arguments the manufacturers have raised,” by distributing a question and answer sheet supplying retorts to manufacturers’ arguments.¹¹⁷

To the rest of the Senate, this was just another bill. With the typical lack of fanfare, PAPPA was referred to the Committee on Finance. It had eight co-sponsors at the time of introduction.¹¹⁸ Nevertheless, PAPPA had set off a firestorm in the drug industry. PMA President Mossinghoff immediately denounced the bill as “misguided” and based on a flawed assumption of therapeutic interchangeability.¹¹⁹ Behind the scenes in strategy sessions, PMA and member companies prepared their countermove.

Drug industry response to S. 2605

¹¹⁶The CBO would later project that S. 2605 would save taxpayers approximately \$1.6 billion over 5 years. 136 CONG. REC. S. 12954 (daily ed. Sept. 12, 1990)(statement of Sen. David Pryor).

¹¹⁷136 CONG. REC. S5982-04 (daily ed. May 10, 1990)(statement of Sen. David Pryor).

¹¹⁸Senators Adams, Bumpers, Burdick, Conrad, Exon, Kerrey and Kohl joined Pryor in introducing the bill. 136 CONG. REC. S5982-02 (daily ed. May 10, 1990).

¹¹⁹Spencer Rich, *Senator Seeks to Stem Rise in Medicaid Drug Costs*, WASH. POST, May 10, 1990, at A13.

PMA's concerns with S. 2605 were easily anticipated based on its interactions with the Aging Committee during the 1989 hearings. Knowing that legislation would be coming down in some way, shape, or form, PMA corresponded heavily with Pryor and his staff from the time of the second hearing in November. In a white paper entitled, "Protecting Medicaid Patients from Restrictive Formularies," PMA blasted "three false assumptions" relied on by the majority staff of the Aging Committee in arriving at their endorsement of the one-drug formulary in PAPP. ¹²⁰ The assumptions and their rebuttals were as follows:



Assumption 1. There are no important differences among drugs in the same therapeutic class.

♣ Retort: This assumption is false because there is no clinical consensus that any two drugs are therapeutically equivalent. Different drugs have different impacts on each individual. ¹²¹

♣ Assumption 2. Restrictive formularies will save Medicaid money.

♣ Retort: Restrictive formularies cause Medicaid expenditures to rise, not fall. Because patients cannot get appropriate drug therapies, states with restrictive formularies have higher physician and hospital expenditures.

♣ Assumption 3: Lower pharmaceutical prices will not hurt innovation.



Retort: Formularies undermine patent protection which is fundamental for ensuring adequate profits for innovation. ¹²²

¹²⁰ *Aging Hearings*, *supra* note 82, at 524 (PMA, *Protecting Medicaid Patients from Restrictive Formularies*, (January 19, 1990)).

¹²¹ PMA would also later argue that the process for determining therapeutic substitutability in PAPP was unconstitutional because the National Pharmacy and Therapeutics Committee decisions were insulated from court or other administrative review. See *Hearing on Medicaid Prescription Drug Pricing Before the Sen. Comm. on Finance*, 101st Cong. 152 (Sept. 17, 1990) [hereinafter *Finance Hearing*].

When S. 2605 was introduced, PMA built on these arguments to mount its protest. To Pryor and his staff, PMA's anti-formulary, anti-therapeutic equivalence arguments seemed motivated purely by the member manufacturers' desire to increase brand-name drug utilization and thereby increase profits. Although profit motives were certainly a factor (if not the dominant one) behind this argument, PMA did have some grounds for their assertions.

Leading scientists and physicians disagreed on the extent to which drugs within a therapeutic class were interchangeable. The American Medical Association agreed with PMA that significant differences between drugs within a therapeutic class made the therapeutic interchange in PAPPA clinically dangerous. But most HMOs and hospitals felt the clinical risks were minor—or at least minor enough to take—and employed policies of drug substitution based on therapeutic equivalence. Little determinative research could be cited by either side in support of their position. The prudence of therapeutic substitution remained a question mark, thereby legitimizing PMA's protest.

The wisdom of restrictive formularies as cost-cutting tools was likewise a matter of policy dispute. Then-current research on the impact of formularies was inconclusive. Some studies supported Pryor's conclusion that formularies could cut costs significantly. For example, in California, authorities estimated that their formulary saved them approximately \$400 million in Medicaid health expenditures per year.¹²³ By contrast, states like Louisiana found that imposing a restrictive formulary actually increased State Medicaid costs by \$27.1 million.¹²⁴ A PMA-sponsored study that found that Medicaid expenditures in states with restrictive formularies would be 4.1 to 30.5 percent higher than if the formulary had been open.¹²⁵ In another study looking specifically at the bid-formulary proposed by S. 2605, PMA determined that the lower prices obtained through the bidding process would not reduce program savings. Compared with Senator Pryor's estimate of

¹²³*Finance Hearing*, *supra* note 121, at 67.

¹²⁴*See Id.* at 69, 74 (testimony the Honorable Alphonse Jackson, Chairman, House Health and Welfare Committee, Louisiana State Legislature, describing the Louisiana restrictive formulary).

¹²⁵*Id.* at 164 (report from the California Department of Health Services, *Open Drug Formularies: Myths and Misconceptions*).

\$200 million a year, a PMA-funded study estimated cost savings of between \$27 and \$135 million in 1993.¹²⁶ PMA's argument that the lower prices would hurt innovation was less substantiated. Medicaid represented only about 10 percent of the market. While the price cuts would hurt the bottom line, it would not do so dramatically. Their claim was further weakened by a much-publicized Wall Street investment group conclusion that "the Pryor bill is not a threat. . . even if passed, the impact of Pryor's bill would be immaterial for the industry."¹²⁷

Concentrating their message on the first two arguments—the dangers of formularies and therapeutic substitution—PMA began an intensive lobbying campaign against S. 2605.¹²⁸ The day after the bill was introduced, PMA printed anti-S. 2605 buttons to be distributed around the country.¹²⁹ It took out a series of advertisements in the Washington Post and Roll Call, a newspaper distributed widely on the Hill and in political circles inside the Beltway. It organized meetings with members of Congress and with interest groups.

PMA focused its inter-organization lobbying on two primary types of interest groups: those who raised money to support disease research, and those that represented minority interests. To the former group, PMA argued that S. 2605 would thwart the disease research by taking money from R&D and impede doctors' ability to match patients with the best drug for them. In speaking with minority advocacy organizations, PMA asserted that Pryor's bill created a system of second-class medicine because drug choice was dictated by low-bid rather than physicians' medical judgments. Since a large percentage of Medicaid beneficiaries were people of color, minorities would be disproportionately be the recipients of this second-class treatment. Medicaid

¹²⁶PMA argued that these savings would be offset by administrative costs, rendering the program budget neutral for Medicaid. Paul E. Freiman, *New Drug Legislation: A Response From the Pharmaceutical Industry*, HEALTH AFFAIRS 112 (Fall 1990).

¹²⁷136 CONG. REC. S5982-04, S5986 (daily ed. May 10, 1990)(statement of Sen. David Pryor).

¹²⁸Pryor would comment on the Senate floor in July that "when added to all the expensive PR, lobbying firms and lawyers PMA and the drug manufacturers have hired, it is easy to understand why I sometimes feel they are spending more money against my bill than the enactment of S. 2605 would actually cost them." 136 CONG. REC. S10497-04 (daily ed. July 25, 1990)(statement of Sen. David Pryor).

¹²⁹*Id.*

recipients could potentially receive their physician's original drug selection, but the process for overriding the formulary was cumbersome. PMA explained that the PAPPa call-back system would lead to "two lines at the pharmacist's counter: one where prescriptions would be filled promptly and a second Medicaid line of persons waiting for the pharmacists to . . . reach the physician to get permission to substitute a low-bid drug for the one originally prescribed."¹³⁰ This message affected minority organizations. Groups including the National Black Caucus of State Legislators and the National Black Nurses' Association became the first to write letters to Pryor, admonishing him for further impeding access to medical care for the poorest of the poor.

OMB's June 20 proposal

As the summer began, it became clearer that the support for changes to Medicaid drug prices extended beyond Pryor and his liberal cronies on the Hill. On June 20, President George H.W. Bush and his White House staff put forth a new proposal to shrink the budget deficit by about \$50.5 billion.¹³¹ Included in these cuts was a provision requiring drug companies cut the prices charged to Medicaid.

The plan, developed by the Executive Branch's Office of Management and Budget (OMB), was nearly identical to PAPPa, but with one notable difference. The therapeutic substitution in the OMB plan was more stringent than that offered in S. 2605. For example, if a physician prescribed a non-formulary drug and did not indicate "brand medically necessary," PAPPa would require that the pharmacist attempt to contact the physician prior to substituting the low-bid, formulary drug. This plan based on therapeutic equivalence properly was called "therapeutic interchange." By contrast, under the OMB proposal, pharmacists would

¹³⁰*Finance Hearing*, *supra* note 121, at 139 (prepared statement of Gerald J. Mossinghoff).

¹³¹Jeffrey H. Birnbaum and David Wessel, *White House Puts Forward Budget Proposal*, WALL ST. J., June 21, 1990, at A2.

be allowed to substitute the therapeutically equivalent drug without contacting the patient's physician. This plan was known as "therapeutic substitution."

Despite the significant difference between therapeutic substitution and therapeutic interchange, the OMB proposal and Pryor's S. 2605 were immediately equated in the minds of the public and those on Capitol Hill. PMA's efforts to enlist support of disease research and minority groups against Pryor's bill took off. On July 9, PMA sent a letter of protest to budget summit negotiators signed by fourteen of these organizations. The letter was also published in a full page advertisement in the *Washington Post*.¹³² The next day, PMA held a press conference where representatives of the National Black Caucus of State Legislators, the National Black Nurses Association, and the League of United Latin American Citizens decried the proposals.¹³³ To shore up its Capitol Hill presence, PMA hired Vernon Jordan, famed civil rights leader, to lobby against S. 2605 on these grounds.

PMA would later deny that it intentionally conflated the two proposals or ever characterized Pryor's bill as a plan for therapeutic substitution.¹³⁴ Yet PMA had not taken great pains to highlight the distinction. The group published a three-volume book of letters, entitled "Leading Organizations Speak Out in Opposition to Restricted Drug List/Therapeutic Substitution," and distributed it to members of the Senate Finance and the Energy and Commerce Committees. The first volume of the publication contained 62 letters and was organized alphabetically within categories based on writer characteristics (Organization, Member of Congress, Organizations of State Legislators, or State Legislators).¹³⁵ As such, there was no physical distinction between the letters of groups that opposed the restricted drug list of Pryor's S. 2605 and those that opposed therapeutic substitution in the OMB plan. The Table of Contents of the book listed several organizations

¹³²THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION, TOWARD OPEN ACCESS: LETTERS AND STATEMENTS FROM THE 1990 DEBATE ON MEDICAID PRESCRIPTION DRUG RESTRICTIONS xii, (1990).

¹³³Julie Kosterlitz, *Washington Update: Drugmakers' Odd Allies*, NTNL. J., July 14, 1990.

¹³⁴*Finance Hearing*, *supra* note 121, at 46.

¹³⁵A second and third volume were later circulated. In total, opposition letters numbered around 156. Pharmaceutical Manufacturers Association, *supra* note 132.

that had not taken a position on the proposed legislation, but only on the policy of therapeutic substitution. Although the book technically did not misrepresent the Pryor bill, the confusion produced by the tactic cannot be understated. Even Representative Ron Wyden, co-sponsor of the final rebate language in the House, would be tricked into equating the OMB and S. 2605. In commenting on an alternative rebate proposal, Mr. Wyden would state that the new legislation “makes a number of changes from the original version of the Pryor bill, S. 2605. [First] there is no therapeutic substitution, so a doctor can control the medicine that the consumer will get.”¹³⁶ If a man so deeply involved in the rebate discussion could make this error, it is abundantly clear the public would too.

Even if Pryor’s bill was equated with the OMB proposal, it is somewhat incredible that the criticism of therapeutic substitution as “second class medicine” carried as much weight as it did. Ironically, by requiring therapeutic substitution, Medicaid was adopting a process employed by the top health insurers. Medicaid was not going second-class; it was adopting a first-class best-practice in drug cost containment. The majority (64%) of the largest health maintenance organizations’ prescription drug plans employed a system based on therapeutic substitution in 1990. As a result, a total of 20 million Americans had health insurance with restricted outpatient formularies.¹³⁷ Moreover, in the inpatient setting, 58 percent of hospitals reported having a “well controlled (closed) formulary with almost no duplication of generic equivalents and minimal duplication of therapeutically equivalent drug products.”¹³⁸

Despite the reality of the situation, Pryor’s S. 2605 was getting a bad reputation as a prescription for second-class treatment of the poor. Although the White House was excited about drug rebates, legislative action would be tougher going if unsupported by traditional allies in the fight for lower drug prices.

¹³⁶*Finance Hearing, supra* note 121, at 10.

¹³⁷*Id.*, at 201(SENATE AGING COMMITTEE STAFF, *Therapeutic Drug Formularies and Therapeutic Equivalence of Prescription Drugs* (Sept. 1990)).

¹³⁸*Id.*

Pharmaceutical company proposals

PMA members were comforted by the traction they were getting with minority groups, but only slightly. To be sure, the support of the White House made federal action more likely. In July, the *National Journal* observed, “To the industry’s dismay, White House interest appears to have made a formerly obscure proposal into a serious contender.”¹³⁹ Fearing the worst, individual pharmaceutical companies attempted to preempt such legislation, or at the very least, get a more palatable version of a federal rebate program on the table. Several drug companies, including Merck, Sharp & Dohme, Pfizer Inc., The Upjohn Company, and Glaxo, Inc., brought their own rebate proposals directly to the states. Many states were eager to accept the olive branch.

Merck, in fact, had developed its rebate proposal before the introduction of S. 2605.¹⁴⁰ The program, entitled “Equal Access to Medicines and Best Price Discounts Act,” offered State Medicaid programs “best price”-based rebates for Merck’s single-source drugs. That is, the rebate would equal the difference between average wholesale price and the best-price offered to any other purchaser. The minimum rebate under the plan would be 10 percent. To start, Merck would impose a ceiling on the rebate amount equal to 15 percent of drug costs; by the end of five years there would be no limit on rebates that could be returned to states.¹⁴¹ Of course, the deal was not without a hitch. In return for the rebate, states were required to reimburse all Merck single-source products without formularies, prior authorization requirements, or other restrictions.¹⁴² The Merck plan officially began on July 1. By the end of August, over half of State Medicaid programs had accepted Merck’s terms and others were simply hammering out the details of their participation.¹⁴³

¹³⁹Kosterlitz, *supra* note 133.

¹⁴⁰Spencer Rich, *Firm Offers Discounts to Medicaid Plans*, WASH. POST, Apr. 21, 1990, at A05. Merck’s motivation for proposing their rebate program many months before other manufacturers is unclear. There has been some suggestion that Merck offered this plan only because it offered low discounts relative to other drug manufacturers. *See e.g.*, Michael R. Pollard and John M. Coster, *UpDate: Savings for Medicaid Drug Spending*, HEALTH AFF., 197, 205 (Summer 1991).

¹⁴¹*Finance Hearing*, *supra* note 121, at 39.

¹⁴²Michael F. Conlan, *Merck Offers Price Cuts to Medicaid—With Strings*, DRUG TOPICS, May 21, 1990, at 42.

¹⁴³By the September Subcommittee hearings, 32 states had adopted the Merck proposal and another ten were near acceptance.

The cost savings from the Merck plan were noteworthy, but not mind blowing. For example, in Georgia, researchers were projecting cost savings to amount to only 0.25% to 0.4% of the state's annual Medicaid drug expenditures.¹⁴⁴ Projected across all 50 states, Merck predicted cost savings of over \$20 million per year.¹⁴⁵

Other drug manufacturers were more hesitant to volunteer rebate programs.¹⁴⁶ Come August, however, with OMB pressing its proposal and Congressional observers predicting action on Pryor's bill, more companies threw their hats into the ring.¹⁴⁷ Pfizer, Glaxo and Upjohn were among those that offered their variations on a Medicaid rebate plan.¹⁴⁸

Pfizer's plan was closest to Merck's, likewise offering rebates based on "best market price" of their single-source drugs.¹⁴⁹ Also similar was the requirement that participating states do away with prior authorization. Unlike the Merck five-year phase in, which capped percentage rebate per drug product, Pfizer offered three years for ramping up. States would receive only 1/3 of the rebate payments authorized under the plan during the first year and 2/3 in the second. The full amount would be realized in year three. To leave no question as to the motivation behind the plan, Pfizer stated outright that the program was predicated on the requirement that the federal government would not implement a federal Medicaid formulary.

The Glaxo proposal differed slightly in its approach toward calculating Medicaid rebates, basing rebates not on "best price" but rather on the best price in the managed care market.¹⁵⁰ The Glaxo "managed care"

Martha Glaser, et al., *Majority of States Give Nod to Merck Discount Plan*, DRUG TOPICS, Aug. 20, 1990, at 63; see also *Finance Hearing*, *supra* note 121, at 39.

¹⁴⁴Glaser, *supra* note 143.

¹⁴⁵Linda Darnell, *More Firms Give Medicaid Breaks on Drug Prices*, L.A. TIMES, Sept 17, 1990, at 1.

¹⁴⁶Beginning in July, two other "major drug companies" had been speaking with Pryor about potential rebate alternatives. These plans were not formally introduced to the states until the end of August. 136 CONG. REC. S10497, 10499 (daily ed. July 25, 1990)(statement of Sen. David Pryor).

¹⁴⁷Timothy Noah, *Drug Concerns Seek to Block Medicaid Curbs*, WALL ST J., Aug. 8, 1990, at B1.

¹⁴⁸Several smaller drug companies, including G.D. Searle & Co. also had begun to develop their own rebate program. PMA reported on September 17, that more than a dozen PMA companies, or over one-half of the Medicaid single-source drug market, were negotiating discounts and rebates with Medicaid officials. *Finance Hearing*, *supra* note 121, at 40. Forty-two states were rumored to be involved in these negotiations. *Id.*

¹⁴⁹*Finance Hearing*, *supra* note 121, at 38-40.

¹⁵⁰*Id.*

model was further limited to independent practice association (IPA) purchasers rather than a group model HMO. Therefore, these rebate amounts were likely to be smaller than those in the Merck and Pfizer plans. States participating in the Glaxo plan could not exclude their single-source drugs from Medicaid formularies. Finally, the Upjohn model offered a rebate plan entirely different from the rest. Upjohn proposed a rebate on single source drugs of three percent of prescription cost, plus 75 cents for claims processing.¹⁵¹ The manufacturer estimated this would result in average rebates of \$1 to \$2.48. Upjohn asserted that this model's administrative simplicity and easy calculations rendered it superior to the plan's offered by its sister manufacturers.

Despite the states' eager acceptance of the rebate proposals, Pryor felt the manufacturers' models would not achieve satisfactory cost savings and were susceptible to manipulations. He observed: "Any program that gives the drug manufacturers free reign to reduce or eliminate the discounts or manipulate their 'best prices' cannot be counted on to achieve significant savings for the multi-billion dollar Medicaid drug program."¹⁵² Because, in the case of the Merck and Pfizer plan, the companies would have control over their best price, they could eliminate discounts over time while still managing to secure listing on the Medicaid formulary. The Glaxo plan was equally objectionable as, "in the scheme of things, these HMOs receive only very small discounts as compared to discounts offered by manufacturers to other purchasers."¹⁵³ Pryor held the Upjohn plan in the lowest regard, calling it a "poorly thought out and totally unacceptable plan."¹⁵⁴ Moreover, the plans applied only to single-source innovator drugs while data showed much of the costs were driven by high-priced multiple-source non-innovators.¹⁵⁵

¹⁵¹ *Id.*

¹⁵² *Id.* at 214 (SENATE AGING COMMITTEE STAFF, *Analysis of Drug Manufacturer Medicaid Drug Discount Proposals and Necessary Elements of Medicaid Drug Price Negotiation Plan* (Sept. 1990)).

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ PMA studies projected that Medicaid drug expenditures in 1991 would be divided: \$1.5 billion on single source drugs, \$1.6 billion on retail/wholesale markups and dispensing fees; and \$1.9 million on multiple-source drugs (including multiple source innovator drugs and generics). *Id.* at 143.

Analysts too were skeptical about the impact of the drug rebate proposals. Economists predicted the discounts would have little direct cost for manufacturers and may in fact expand their Medicaid market. As many states had already implemented restrictive formularies, many felt drug manufacturers were simply using their discounts to entice states to reopen their program to manufacturer's products.¹⁵⁶ Still, others on Wall Street feared that by offering a rebate off of AWP, manufacturers were opening the door to additional criticism of their drug pricing policies. One analyst observed that because "the issue has unearthed a whole question about how drugs are priced," the rebate plans may just increase pressure to discount for other purchasers, such as HMOs and private insurers.¹⁵⁷ Ultimately, the long-term impact of the pharmaceutical-offered plans would never be known. Although PMA President Mossinghoff contended that the discount programs made "further federal action. . . unwarranted," Senator Pryor disagreed and kept the issue alive on Capitol Hill.¹⁵⁸

Another federal option: S. 3029

As the conversation progressed between the drug companies and the states, Senator Pryor did not wish to be left out of the loop. The Senator felt strongly that any state plan would fall short of a federal solution, at least insofar as guaranteeing that the negotiated prices be locked in for some period of time. Pryor needed to refocus the debate on the federal level before the drug company plans diffused the issue's firepower. His staff began busily drafting a new piece of Medicaid rebate legislation. PAPP had been hit hard by the consumer groups as a racially discriminatory system of second class medicine. These were organizations the

¹⁵⁶For example, if Alabama were to accept either the Merck or Upjohn proposals, the State Medicaid program would have been required to add more expensive drugs to its formulary. On balance, the state decided this increased cost would not be offset by the rebate amount and rejected the two plans. Tim Brightbill, *Bills Push Medicaid Drug Discount*, HEALTHWEEK, Sept. 17, 1990, at 9.

¹⁵⁷Linda Darnell Williams, *More Firms Give Medicaid Breaks on Drug Prices*, L.A. TIMES, Sept. 17, 1990, at D1.

¹⁵⁸Brightbill, *supra* note 156.

Senator needed on his side. Pryor needed a fresh, new approach that could not be maligned on the issue of therapeutic substitution.

The new bill was S. 3029, the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990.¹⁵⁹ S.3029 was officially introduced on September 12. Pryor insisted that S. 3029 was “not a substitute for nor an amended version of S. 2605” but rather “one other option that can be considered.”¹⁶⁰ Nevertheless, S.3029 quickly became the focal point of the debate. By addressing some of the criticisms that had been leveled against S. 2605, S. 3029 seemed to move the sides a bit closer together.

The Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act required that drug manufacturers provide Medicaid the best price it offered to any other purchaser in order to be covered by a State Medicaid program. These discounts would apply to both single source and innovator multiple source drug products. For non-innovator multiple source drugs, manufacturers would be required to provide a flat rebate of 10 percent of the aggregate expenditures for those drug products. The contract for the rebate program would be negotiated between the Secretary of Health and Human Services and the individual manufacturers. In practice, State Medicaid programs would pay pharmacists the average manufacturer price (AMP) for each unit of a drug sold. Then, on a quarterly basis, drug manufacturers would be required to reimburse State Medicaid programs a per unit dollar amount equal to the difference between the best price the manufacturer offered to any other purchaser and AMP. To prevent manufacturers from hiking their best price to reduce the rebate amount, S. 3029 would require drug manufacturers’ best price be no greater than the best price in place on September 1, 1990, indexed to the consumer price index. In an attempt to allay the concerns of manufacturers who had steep (e.g., over 60 percent) discounts as of September 1, the bill would cap the rebate amount at 25 percent of the state expenditures attributable to that drug. Rebates could be no less than the 10 percent required of generic drugs.

¹⁵⁹Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act, S. 3029, 101st Cong. §1927 (1990).

¹⁶⁰136 CONG. REC. S12954-01 (daily ed. Sept. 12, 1990)(statement of Sen. Pryor).

States receiving rebates were required to reimburse for all rebate-covered drugs. However, states could use a prior authorization system so long as that system was available to physicians 24 hours a day, 7 days a week and provided an immediate response to the authorization request.

Pryor 1 versus Pryor 2: A comparison of S. 3029 and S. 2605

S. 3029 appeared to address concerns surrounding therapeutic interchangeability that had allowed PMA to unite many consumer groups against S. 2605. Medicaid-covered drugs under S. 3029 would not be chosen simply based on a low-bid within a given therapeutic class. Rather, S. 3029 allowed a state to reimburse for any drug which had negotiated a rebate plan. Therefore, on its face, S. 3029 presented a less restrictive formulary than S. 2605. Still, the fact that states *could* reimburse for any rebate drug did not mean that they were required to do so. States were still free to subject rebate-covered drugs to a prior-approval system. As such, drug manufacturers were not assured that Medicaid enrollees would have freewheeling access to their drugs even if they offered a rebate. This contrasted significantly with the agreements that drug manufacturers had been securing with individual states, which guaranteed that rebate-covered drugs would be part of the State Medicaid formulary. This “improvement” in S. 3029 therefore would only slightly detract from concerns about formularies and prior approval.

The difference in formulary structure also created a difference in the rebate calculation. While S. 2605 anchored the rebate amount to the bid price of the manufacturer, S. 3029 introduced a new reference point: the “best price.” Of course, this term was not in fact new but lifted directly out of the plans proposed by the drug manufacturers themselves. Both Merck and Pfizer had based their discounts to the states on their best price offered to any other purchaser. Pryor thus was able to state that “this legislation simply builds

on the proposals already put forth by the drug industry.”¹⁶¹

Most people knew that companies like Merck and Pfizer were able to offer a best price term because they did not in fact have very steep discounts in any of their markets. In short, their best price was not so good.¹⁶² By contrast other companies with steep VA discounts, such as Upjohn, disliked the best price anchor. Therefore, the move to a best price metric worked mixed results on the pharmaceutical manufacturers. Knowing the varied acceptance of the best price idea throughout the industry, Pryor nevertheless attached to the concept. In fact, by splitting the industry in this way, Pryor weakened the resolve of his biggest opponent. Certain firms were just not going to push as hard against the legislation. Moreover, because the best price idea was scored to provide more savings than S. 2605 (\$1.3 billion versus \$2.5 billion over five years for S. 3029) Pryor was able to onboard Senators attracted to the rebate legislation solely for its budget hook.

A final significant difference between the two Pryor bills was the locus of negotiating power. S. 3029 explicitly shifted the negotiation power from the various states to the federal government. Although S. 2605 did call for HHS to form a purchasing group for prescription drugs, such an option was only a back up if the states could not take the initiative on its own. It was the hammer for drug companies who would not undertake real negotiation with the states. By contrast, the contract in S. 3029 would be established on the federal level.

In praise of the free market: September hearings, panels 1 & 2

Even before the introduction of S. 3029, plans had been made to continue the Senate debate on “modifying Medicaid’s drug reimbursement program.”¹⁶³ On August 17, the Senate Finance Subcommittee on Health

¹⁶¹ *Id.*

¹⁶² See Pollard and Coster, *supra* note 140.

¹⁶³ *Finance Hearing*, *supra* note 121, at 1.

for Families and the Uninsured announced plans to hold a September 17 hearing. The new Pryor approach—introduced just five days before the hearing—would be an integral part of the discussion.

The Finance Subcommittee hearing was the first Senate examination of Medicaid drug pricing to occur outside of the Aging Committee. Senator Pryor did not sit on the Subcommittee, but attended as a Member of the full Committee. Control of the hearing was in the hands of Subcommittee Chairman Donald W. Riegle (D-Mich.)—at least to start.

A whopping fourteen witnesses were scheduled to appear. Gerald Mossinghoff of PMA would be in the middle of the pack, accompanied by representatives from member manufacturers Merck, Pfizer, Glaxo, and Upjohn—the four major pharmaceutical firms that had proposed their own state-level rebate programs. But on September 17, it was friendly fire of fellow Democratic Senator Bill Bradley who began the attack of S. 3029. Bradley was from New Jersey, home to several large pharmaceutical companies that had been pressuring him on the Pryor bill. In his opening statement, Bradley aligned with his constituents. S. 3029, he said, looked like a dangerously “rigid system of price controls.”¹⁶⁴

This characterization of S. 3029 would stick. It would be leveled as a criticism of S. 3029 throughout the hearing—by HCFA Administrator Gail Wilensky (“My concern about the explicit way of ensuring that you keep the best price over time is that it sounds an awful lot like a price control to me...because it pegs a price at a given point in time.”)¹⁶⁵; by the Director of the Pharmaceutical Economics Research Center at Purdue University, Mr. Stephen Schondelmeyer (“I do not feel that it is in the best interest to index the best price over time.”)¹⁶⁶, and by PMA President Mossinghoff (“[The] idea of price controls is inimical to this country’s free market economy... A quintessential feature of world-wide developments is that free-market forces serve society far better than centrally planned and administered controls.”)¹⁶⁷ Still, with the exception of Mr.

¹⁶⁴*Id.* at 7.

¹⁶⁵*Id.* at 29.

¹⁶⁶*Id.* at 36.

¹⁶⁷*Id.* at 38.

Mossinghoff, these witnesses were generally receptive to Pryor's proposal and saw possible remedies to the price-indexing prescribed by S. 3029.¹⁶⁸

By contrast, the price control element was not the only one that continued to disturb PMA. Mr. Mossinghoff expressed concern that the attempt to improve the single-drug formulary offered by S. 2605 was unsatisfactory because it continued to allow individual states to implement a prior-approval system, which he saw as amounting to a de facto restrictive formulary. He also submitted that S. 3029 was "inherently unfair" for two reasons. The first inequity was that it had a greater negative economic impact on companies offering steep discounts than those with less "friendly" discount policies. The second was that the proposal required higher rebates of drugs no longer under patent (innovator multiple source drugs) than their generic competition. S. 3029 was not going to make the research-based pharmaceutical companies happy. Mr. Mossinghoff instead continued to advocate for the individual company plans in lieu of federal action.

After only one question of his constituent-company Upjohn, Senator Riegle excused himself from the hearing and invited Senator Pryor (who had "graciously agreed to chair the rest of this hearing") to assume the chair position.¹⁶⁹ The show was again largely Pryor's affair to run. He got off to a galloping start. "Mr. Mossinghoff, you talk about a free market economy," he began. "Well, what the free market economy has brought to us is that chart, the highest priced drugs anywhere today are paid for by those least able to afford them. That is what the free market economy you speak of has brought us. We cannot stand it. It does not make sense. It is unjustified."¹⁷⁰

Despite the permeating animosity reflected in this opening comment, the conversation on S. 3029 was in fact somewhat more productive. By assuming the best price construct as a baseline, the drug manufacturers

¹⁶⁸For example, HCFA suggested taking an index of the manufacturer's sole source drug prices over time, with additional rebates required only if the index goes above CPI or MCPI increases. Mr. Schondelmeyer recommended the bill "index the average manufacturer's price at a certain point in time and then require that the price that be given to the Medicaid program be the lower of the best price or that indexed manufacturer's price minus 10 percent or the current manufacturer's price minus 10 percent." *Finance Hearing*, *supra* note 121 at 29, 36.

¹⁶⁹*Id.* at 42.

¹⁷⁰*Id.* at 42.

and Pryor were closer to operating on the same page. The sides began to debate the principle of the best price reference point on its economic merits. Both agreed that the Veteran's Administration price would in most cases be the best price for any given drug. But was using this price, the price offered to only 1 percent of the market, an appropriate "barometer" for a fair market price? What would happen if the best price accounted for drug prices in Europe? In sum, while no problems were solved in this segment of the hearing, the conversation had been elevated, if only slightly, from the name calling and finger pointing of earlier days.

Consumer groups, states highly divided: September hearings, panels 3 & 4

Senator Pryor's day of defending his rebate proposals did not end after PMA and manufacturers took their seats among the public. Next to testify were three consumer groups. Their feelings on the new Pryor bill were generally positive. In fact, Families USA was effusive, urging adoption of the "rare opportunity to achieve savings and improve quality of care in the Medicaid program."¹⁷¹ By contrast, the American Medical Association and the Epilepsy Foundation of America were more cautious in their praise.¹⁷² These organizations had been among those who had allied with PMA against therapeutic substitution. S. 3029 provided some comfort that therapeutic substitution was off the table for the moment. Still, patient access remained of concern. The prior authorization system did not adequately provide for a timely appeal or a rational process for determining whether authorization would be given to cover the requested drug.

The state reaction to the various legislative proposals concluded the hearing. Even more than the consumer groups, the states reacted in different ways to the Pryor proposals. California supported national action similar to Pryor's second proposal, so long as the state could maintain its current restrictive formulary.¹⁷³

¹⁷¹*Id.* at 57-58.

¹⁷²*Id.* at 58-63.

¹⁷³*Id.* at 64-67.

Louisiana would only support legislation that would *not* require a restrictive formulary of any sort.¹⁷⁴ A legislative proposal could allow the preferred approach of both states if it left the door open for states to have restrictive formularies without requiring them. Sanctioning restrictive formularies or prior authorization would buy Pryor a host of enemies in PMA and consumer groups. Without either tactic, however, much of the cost savings might not be realized.

Counting the votes: Toward OBRA 1990

The ideas vocalized in the September hearing had hardly been digested before the larger legislative current of 1990 grabbed hold of the rebate bill's fate. Congress was in the throes of a debate on a deficit-reducing budget package. The discussion had been initiated in April, and it had been determined that the process of reconciliation would be used.

Budget reconciliation is a creature unto itself. It begins with the passage of a budget resolution, which establishes budget targets in each major expenditure category. Committees with jurisdiction over the spending programs are then required to work within the budget constraint to determine program spending, devising budget-cutting or revenue-generating measures as needed to meet the target. When the combined reports from all committees are melded into an omnibus bill, no substantive changes are generally permitted. The full omnibus measure is submitted to the floor for passage with limited time for debate.¹⁷⁵ With so much wrapped up in the package, reconciliation measures generally pass without a hitch.

Some have described the reconciliation process as an “express train” that allows the party in control of the

¹⁷⁴*Id.* at 69-71.

¹⁷⁵In the Senate, floor debate is limited to twenty hours. In the House, the rules committee establishes the extent to which debate can be heard and amendments can be proposed.

Congress to “promote the adoption of measures that members managed to pack into it, which were less likely to be authorized if considered alone.”¹⁷⁶ With the Democrats firmly in charge in 1990, they were able to do just that. For Pryor, this meant it would be far easier to make some version of the rebate plan into law.

To devise a budget plan acceptable to the House, Senate and White House, representatives of each body had been working vigorously throughout the summer of 1990. It was at this summit that the OMB proposal was first released, so a drug rebate plan was clearly on the table. The question had always been what version would emerge from these conversations. Finally on September 30 a budget deal was reached. The rebate provisions of the agreement were drawn largely from S. 3029, basing the rebate on the best price metric and setting a floor and ceiling for rebate amounts.

Inclusion in the budget negotiators’ plan did not seal the deal for the rebate program, of course. In fact, the budget summit agreement failed, with the House rejecting it on October 5. The two chambers now had more flexibility to pass their own budget bills. Then it would again take more work to reconcile the two.

The House passed their reconciliation bill first on October 16.¹⁷⁷ Under the leadership of Representatives Ron Wyden and Jim Cooper, the House version not only incorporated rebates but was tougher on the drug companies than the Senate-approved plan.¹⁷⁸ The House plan was based on a best-price scheme with “best price” defined as the lowest price offered to any purchaser or the best price offered to these entities on September 1, 1990 increased by the percentage increase in CPI-U between 1990 and the rebate period in question. Rebates would be capped at 25 percent AMP in 1991 and 1992 and 50 percent in 1993 and 1994. Significantly, the bill explicitly allowed formularies, providing that states could restrict the “amount, duration, and scope of coverage” of any rebate-covered prescription drug. The House version was projected

¹⁷⁶Gilman, *supra* note 98, at 122.

¹⁷⁷Final Vote Results for Roll Call 475, Vote on Passage of H.R. 5835, Omnibus Budget Reconciliation Act of 1990, (Oct. 16, 1990), available at <http://clerk.house.gov/evs/1990/roll475.xml>.

¹⁷⁸Timothy Noah, *Medicaid Would Receive Drug Discounts Under House, Senate Budget Packages*, WALL ST. J., Oct. 19, 1990, at A16.

to save \$2.1 billion over five years.¹⁷⁹ With only three hours of general debate allowed for the full omnibus measure, the topic of drug rebates was never raised. The House’s budget reconciliation bill, H.R. 5835, passed by a vote of 227 – 203.¹⁸⁰

For all his toil, Pryor saw a more lenient version of the rebate plan come out of the Senate than that offered in the House. While the details of the Finance Committee negotiation are unclear, the measure seems to have been worked out primarily among five major players: Senators Bentsen, Packwood, Riegle, Hatch and Pryor.¹⁸¹ The plan required drug companies to provide a fixed 15 percent rebate on single-source and multiple-source innovator during the first three years. Only after this time would the best price mechanism come into play, with manufacturers required to rebate 15 percent or the difference between AMP and best price, whichever was larger. Interestingly, the “best price” definition was exclusive of the price of drugs sold to Veterans Affairs depots.¹⁸² Although Pryor had gravitated to the VA price as a comparable throughout the prior year, the Senate version abandoned the notion of matching Medicaid prices with VA prices. The bill did attempt to prevent drug manufacturers from raising their prices in response to the best price provision (Pryor’s primary concern with the individual drug company plans) by directing the Secretary of HHS to establish a method of adjusting the basic rebate “to ensure that a manufacturer’s price for such drugs...do not increase by percentage that is greater than the increase in the Consumer Price Index for all urban consumers from October 1, 1990 to the month before the beginning of the calendar quarter (or other period) involved.”¹⁸³

¹⁷⁹*Id.*

¹⁸⁰Final Vote, *supra* note 177.

¹⁸¹*See* 136 CONG. REC. S15777, 15858 (daily ed. Oct. 18, 1990)(statement of Sen. Orrin Hatch).

¹⁸²VA medical centers got their drugs through various sources. Approximately 35-45 percent of VA drugs in 1990 were purchased from VA depots. The prices received by federal depots were explicitly excluded from the Medicaid best price definition. However, VA medical centers also obtained drugs based on catalog prices in the Federal Supply Schedule and from direct negotiation with drug manufacturers. These prices were to be taken into account when determining best price. Thus, to say that OBRA did not require matching of Medicaid and VA prices is not entirely accurate. Still, the least expensive VA drug prices—those referred to by Pryor throughout the hearings—had always been the federal depot prices. *See Hearings on H.R. 2890—To Establish Limits on Prices of Drugs Procured by the Dep’t of Veterans’ Aff. Before the Subcomm. On Hosp. and Health Care of the House Comm. on Veterans’ Aff.*, 102nd Cong. 12 (1991) (statement of Anthony J. Principi, Deputy Secretary, Department of Veterans Affairs)[hereinafter *Veterans’ Affairs Hearing*].

¹⁸³136 CONG. REC. S15777-02, 18586 (daily ed. Oct. 18, 1990).

Also unlike the House version, the Senate plan would forbid formularies that did not permit coverage of all drugs for which a rebate existed. Prior authorization was allowed (if operated in accordance with the same terms found in Pryor's second bill), but a state could not subject a new drug to prior authorization during its first year on the market. The cost savings of the Senate plan were scored at \$1.8 billion over five years.¹⁸⁴

Senator Orrin Hatch explained that the Senate version was “not precisely what Senator Pryor would like, it is not all that patients would like, it is certainly not what the research-based pharmaceutical industry would like—but it is, as it stands, something that most of us can and should support. . . In short. . . the legislation would achieve a delicate balance between cutting program costs, improving the access of Medicaid patients to needed medicines, and preserving the incentives necessary to encourage continued pharmaceutical research and development.”¹⁸⁵ The Senate reconciliation bill was passed on October 18 by a vote of 54-46.¹⁸⁶

The conference on the reconciliation bill began on October 19. The negotiations between the conferees from the Senate Finance and House Energy and Commerce Committees were kept largely under wraps.¹⁸⁷ The high-profile nature of the rebate element made discussions easier behind closed doors. On October 31, the House and Senate had worked out their differences and were able to send the measure to the White House.¹⁸⁸ The bill was signed into law on November 5.

As passed, the drug rebate elements of OBRA reflected a compromise between the House and Senate reconciliation proposals. To the pleasure of the drug manufacturers, formulary restrictions in the House version were out; to their chagrin, prior authorization was still in.¹⁸⁹ As far as the rebate amount was concerned, the

¹⁸⁴Noah, *supra* note 178.

¹⁸⁵136 CONG. REC. S15777, 15858 (daily ed. Oct. 18, 1990)(statement of Sen. Orrin Hatch).

¹⁸⁶*Id.* at S18567-8.

¹⁸⁷Julie Rovner, *Conferees Take \$43 Billion from Medicare Programs*, CONG. Q. WKLY, October 27, 1990.

¹⁸⁸*Id.*

¹⁸⁹No prior authorization could be required for newly approved drugs during their first six months on the market. OBRA 1990, *supra* note 1.

Senate “best of percentage or best-price” option was adopted. For 1991 and 1992, drug prices after rebate would be 87.5 percent of AMP or best price, with maximum rebates of 25 percent in the first year and 50 percent in the second. Beginning in 1993, the drug price after rebate would be 85 percent AMP or best price. The bill would account for inflation, but without the harsh indexing in S. 3029 or the House-proposed version of the reconciliation. Instead, OBRA offered a formula for calculating additional rebates for single source and innovator multiple source drugs.¹⁹⁰ The final version of the rebate program was to save the federal government \$1.9 billion and the states’ Medicaid programs \$1.4 billion across the first five years.¹⁹¹

The Aftermath

Heated discussion of Medicaid drug rebates did not end when OBRA was signed by the President. The law was to be implemented on January 1, 1991. Drug companies would be required to sign rebate agreements with HHS by March 1, or, starting in April, federal matching funds for their products would not be available.¹⁹² OBRA grandfathered in previously negotiated state rebate agreements if they were as favorable as the statutory rebate requirements, but the old deals generally were not. Manufacturers opted to forego renegotiating these individual rebate deals in favor of signing on to a national rebate agreement.

PMA and its members did have other work to do in the states, however. The group began to canvass the

¹⁹⁰(i) For calendar quarters (or other periods) beginning after December 31, 1990 and ending before January 1, 1994—
(I) the total number of each dosage form and strength of a single source or innovator multiple source drug dispensed during the calendar quarter (or other period); multiplied by
(II) (aa) the average manufacturer price for each dosage form and strength, minus
(bb) the average manufacturer price for each such dosage form and strength in effect on October 1, 1990, increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. average) from October 1, 1990, to the month before the beginning of the calendar quarter (or other period) involved.

For periods beginning after December 31, 1993 the calculation was identical except that instead of accounting for inflation on a drug-specific basis, the equation would account for inflation based on the price increases of a market-basket of a specific manufacturer’s single source and innovator multiple source drugs. OBRA 1990, *supra* note 1. In 1993, the law would be amended to preserve the original drug-by-drug calculation. OBRA 1993, *supra* note 28.

¹⁹¹Karen Southwick, *Medicaid Drug Rebate Gets Flak from Two Sides*, HEALTH WEEK, Nov. 12, 1990, at 13. PMA estimated the cost to the industry to be closer to \$3.4 billion over five years. *Despite Problems, US Pharmaceutical Industry Is in Good Shape*, FINANCIAL TIMES, Mar. 1, 1991.

¹⁹²Those who failed to comply by that date would be excluded from Medicaid participation for three months (i.e., until the next rebate period). See Pollard and Coster, *supra* note 140, at 198.

country working to convince State Medicaid administrators of the costliness and dangers of prior-approval programs.¹⁹³ On this issue, PMA received some degree of support from the government: the Department of Health and Human Services warned states against using prior authorization heavy-handedly such that it “unfairly den[ies] access to medically necessary drugs.”¹⁹⁴

As PMA shifted its lobbying to the developing state-by-state regulatory structure, Pryor and others in the Congress eagerly awaited the results of the first round of rebate negotiations. Unfortunately, legislators quickly learned that the rebate amounts did not seem as favorable as expected. Manufacturers’ reported best prices, the foundations of the rebate calculation, had increased.¹⁹⁵ Not only were Medicaid savings smaller, but other purchasers, notably the VA, were facing higher prices.¹⁹⁶ Numbers were not yet available to substantiate these claims, but anecdotal evidence indicated that the increase in cost to other purchasers far offset the Medicaid savings.

In January, Senator Pryor expressed his concerns in a letter to HCFA Administrator Gail Wilensky:

“...I am seriously disturbed by the wholesale changes that appear to be occurring in the market in an attempt to circumvent the Medicaid law...I strongly believe that such financial ‘arrangements’ made by the drug manufacturers must be taken into consideration for the purposes of determining the Medicaid discount.”¹⁹⁷

¹⁹³Gerald J. Mossinghoff, *How Will the Industry Respond to Increasing Government Pressure to Curb Drug Costs?* HEALTH-WEEK, Dec. 10, 1990, at 28.

¹⁹⁴Michael Conlan, *Sullivan Warns States on Misuse of Medicaid’s Prior Authorization*, DRUG TOPICS, Mar. 11, 1991, at 114.

¹⁹⁵As long as manufacturers kept the increase below inflation, they could avoid the “additional rebate,” while capturing revenue from the higher prices. Firms’ process for determining the proper price increase that would serve to maximize revenues has been studied extensively. See, e.g. Fries, T.L., *Most-Favored-Nation Pricing Policy and Negotiated Prices*, 9 INT’L J. OF INDUS. ORG., 209-223 (1991); I.P.L. Png, *Most-Favored-Customer Protection versus Price Discrimination Over Time*, 99 J. OF POL. ECON., 1010-1028 (1991). In one of the only non-government sponsored economic analysis of the impact on prices of the Medicaid drug rebate law, Fiona Scott Morton found that about half of the drug manufacturers increased their best price to a level where the flat percentage AMP discount was larger than discounting to best price (and thus was the rebate calculation applied). A firm would make the decision by calculating the profits under both alternatives and making a price decision to maximize profit. See Fiona Scott Morton, *The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules*, 28 RAND J. OF ECON., 269, 275 (1997).

¹⁹⁶In an unfortunate coincidence of timing, the VA five-year drug contracts were up for renewal in 1991, providing an immediate opportunity for drug manufacturers to eliminate VA discounts. Karen Southwick and Merit C. Kimball, *Other Buyers May Pay Price for Medicaid Drug Discount*, HEALTH WEEK, Feb. 25, 1991, at 1. One report indicated that the VA saw its drug costs increase by \$60 million across the first 11 months of 1991. Craig Havighurst, *Drug price law goes to the fix-it shop—Congress tinkers with Medicaid discount as Pryor preps new bill*, HEALTH WEEK, Nov. 4, 1991, at 12.

Pryor charged the manufacturers with several “bad faith” tactics including breaking long-term contracts in order to increase drug prices, masking discounts and rebates, and giving purchasers other needed services and products in lieu of discounts.¹⁹⁸ He urged Wilensky to account for these hidden discounts in negotiating rebates.

By March 1 all rebate agreements for the first quarter of the program were completed. The results remained disappointing. Senator Pryor took to the floor to register his protest, “The ink was not dry on the Medicaid legislation before drug companies decided the best response to this legislation was to begin a massive cost shift to other vulnerable populations, rather than slightly trim excessive profits or cut back on huge marketing budgets.”¹⁹⁹ Still, many found Pryor’s disdain naive. As one news article observed, “They [drug manufacturers] seem to be telling the government, ‘What did you expect? Welcome to the world of big business.’”²⁰⁰

Frustrations on the Hill led many to call for immediate hearings to examine the unintended consequence of cost-shifting. But these hearings would be delayed. On April 16, Senator Pryor suffered a heart attack. The author of the rebate bill was sidelined until June at the earliest.²⁰¹ Unfortunately, Pryor’s recuperation ultimately would take longer than expected. The Senator did not return full time to work until September 1991.

As Pryor’s hiatus from the Senate dragged on, hard data was compiled to support the stories of inflation in drug prices facing other drug purchasers. The General Accounting Office (GAO) released a report on the impact of the Medicaid rebate program on VA and Department of Defense drug prices.²⁰² GAO found that

¹⁹⁸For example, Kaiser Permanent reported that it was being asked to renegotiate multiyear contracts that hadn’t expired. Karen Southwick and Merit C. Kimball, *supra* note 196. See also, Conlan, *supra* note 197.

¹⁹⁹137 CONG. REC. S2711-01.

²⁰⁰Valentine Cardinale, *Medicaid Law: Broken Promise?*, DRUG TOPICS, Mar. 11, 1991, at 8.

²⁰¹Michael F. Conlan, *Some Pharmacy Issues May Be Delayed by Senate Tragedies*, DRUG TOPICS, May 6, 1991, at 104.

²⁰²UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT ON MEDICAID: CHANGES IN DRUG PRICES PAID BY VA AND DOD SINCE ENACTMENT OF REBATE PROVISIONS, GAO/HRD-91-139 (Sept. 1991).

VA costs in 1991 would increase 20 percent over 1990 expenditures while DOD would have a 14 percent increase.²⁰³ Although GAO officially stated that it could not definitively attribute the price increases to OBRA, most took the study results to confirm that cost-shifting was occurring. Government purchasers demanded a Congressional response, with VA representatives stating that without either additional funding or changes to the Medicaid law “we will have to cut back on the delivery of health care.”²⁰⁴

In Pryor’s absence, the response to the outcry was fielded by several players who floated corrections for the perceived cost shifting problem:²⁰⁵



Representative G.V. “Sonny” Montgomery (D-Miss.) introduced legislation to exempt VA prices from best-price calculations and to roll back VA prices to their 1990 levels.²⁰⁶

♣ Representative Ron Wyden discussed two possibilities. First, he proposed making the rebate equal to a percentage of manufacturers’ average retail price, thereby hoping to discourage increases in that price. Second, he proposed to roll back Medicaid and all governmental drug prices to their 1990 level, and index future price increases to overall health care inflation.²⁰⁷

♣ Senator Edward Kennedy introduced legislation requiring Public Health Service Act clinics receive rebates at least as large as those procured by the Medicaid program.²⁰⁸

♣ A stop-gap amendment was added to the Veterans Administrations appropriation bill, excluding Veterans Administration prices from the best price calculation for Medicaid rebates. The measure was to sunset on June 30, 1992 or upon passage of superceding drug price legislation related to the Department of Veterans Affairs.²⁰⁹

²⁰³*Id.* at 2.

²⁰⁴*Veterans’ Affairs Hearing, supra* note 182.

²⁰⁵Several other bills would subsequently be introduced that proposed to amend the Medicaid drug rebate law. The list below reflects only those in play by the end of September 1991.

²⁰⁷Havighurst, *supra* note 196.

²⁰⁸S. 1729 was introduced on September 19, 1991. Hearings on the bill were held in October 1991. *Hearings on the Public Health Clinic Prudent Pharmaceutical Purchasing Act before the Senate Comm. on Labor and Hum. Resources*, 102nd Cong. 1 (1991).

²⁰⁹Departments of Veterans Affairs, and Housing and Urban Development, and Independent Agencies Appropriations Act of 1992, Pub. L. No. 102-139, §519, 105 Stat. 736 (1991).

Upon his return to the Senate, Pryor lent support to the developing efforts of the other Congressmen but was not eager to focus on the nitty-gritty of rebate amendments.²¹⁰ Instead, he had moved on to “Phase Two” of his attack on pharmaceutical pricing. “Phase Two” would be a more comprehensive approach to containing prescription drug costs. The industry’s reaction to the Medicaid rebate bill evidenced that “squeezing one part of the balloon” would only cause it to “pop out somewhere else.”²¹¹ Consequently, pricing practices needed to be addressed head on and drug companies punished for raising prices at a rate in excess of inflation.

Pryor’s Phase Two strategy was put into legislative language in “The Prescription Drug Cost Containment Act (S. 2000),” introduced on November 21, 1991.²¹² The centerpiece of the plan called for a reduction of pharmaceutical manufacturers’ non-research tax credits if they raised drug prices above the rate of inflation.²¹³ The specific credits in question were found in Section 936 of the Internal Revenue Code and granted manufacturers a tax credit per person employed in Puerto Rico.²¹⁴ Pryor’s Aging Committee research indicated that drug companies received more than \$1.4 billion from these tax credits in 1987 alone, thereby lowering companies’ effective tax rate by an average of 9 percent.²¹⁵ While a boon to the drug industry, the Committee concluded that the credits provided “little if any benefit to the American public.”²¹⁶ By reducing the tax credits if drug prices increased too steeply, Pryor’s S. 2000 would link the “financial rewards” to “acceptable and achievable performance standards.”²¹⁷

²¹⁰Although Pryor proposed amending the Medicaid rebate legislation to tie the best price provision to a specific date (as it was in his original bill), this suggestion was never reduced to legislative language. *Hearings on the Public Health Clinic Prudent Pharmaceutical Purchasing Act*, *supra* note 208, at 10.

²¹¹*Id.*

²¹²S. 2000, 102nd Cong. (1991).

²¹³*Id.* at §3. S. 2000 also would have established: a Medicare outpatient prescription drug demonstration project; a “Medicare Outpatient Prescription Drug Trust Fund” financed by the extra tax money received from the pharmaceutical companies; and a Prescription Drug Policy Review Commission to report on national and international drug policy issues, among other minor provisions. *Id.*

²¹⁴§936 I.R.C.

²¹⁵STAFF OF SENATE SPEC. COMM. ON AGING, THE DRUG MANUFACTURING INDUSTRY: A PRESCRIPTION FOR PROFITS 11-12, 17 (Comm. Print No. 102-50 (1991)).

²¹⁶*Id.*

²¹⁷*Id.* Pryor’s S. 2000 did not make much headway, but it did cause quite a stir with PMA and its members who deemed it the “most critical” federal legislative issue of 1992. PHARM. MFRS. ASS’N, 1992 ANNUAL REPORT 6-7 (1993). Senator Pryor

Pryor's more ambitious and perhaps longer-term cost-containment goal did not eliminate the more immediate need to make some fixes to the OBRA rebate program. Still, the Senator's greater distance from the rebate amendments removed the heightened emotional element from these discussions with PMA. In fact, Pryor's unforeseen success seemed to make PMA more wary of the man than of the bill he had enacted. "It must be clear to everyone by now that Senator Pryor has a vendetta against the pharmaceutical industry," PMA representatives stated.²¹⁸ Fearing further Pryor activity, PMA's fight largely followed Pryor and his price limiting tax-based legislation, not the rebate amendments.

This is not to say that PMA did not attend to the amendments proposed to the rebate bill. Nevertheless, once the rebate law was in place, the inconsistent impact of the best price provisions on the different manufacturing companies made it more difficult for PMA to present a united front. For example, some companies supported bills that would replace the best price provision with a flat percentage rebate for Medicaid. By contrast, other companies were dead set against the flat percentage proposals and felt the program contained in OBRA 1990 was working just fine.²¹⁹ The one proposal that was universally unpalatable to PMA members was an attempt to counter VA price increases by rolling back drug prices to their 1990 level.²²⁰ However, the rollback provision failed to gain much traction, as many in Congress agreed with PMA that a rollback would be "inherently unfair and unprecedented."²²¹

Thus, while hospital, HMO, nursing home, and government purchasers clamored for changes to OBRA 1990, PMA rode along somewhat quietly. OBRA revisions were slow to come. Legislators were wary of acting too

attempted to offer the 936 tax credit provision as an amendment to the tax legislation for 1992. After eight hours of floor debate on the Pryor amendment, the proposal was defeated by a vote of 61 to 36 on March 11, 1992. *Id.* See also, 138 CONG. REC. S3179-03 (daily ed. Mar. 11, 1992)(statement of Sen. David Pryor). Nevertheless, the Section 936 tax credit for drug manufacturers was scaled back in the Omnibus Budget Reconciliation Act of 1993. The reduction in the credit was not linked to drug manufacturers pricing policy, however. Instead, the change scaled back the credit by \$3.8 billion over five years. OBRA 1993, *supra* note 28.

²¹⁸Julie Rovner, *Prescription Drug Prices*, CQ RESEARCHER ONLINE, July 17, 1992, available at <http://library.cqpress.com/cqresearcher>.

²¹⁹*Veterans' Affairs Hearing*, *supra* note 182.

²²⁰*Id.*

²²¹*House Panel Ponders Medicaid Drug Solution*, HEALTH LEGISLATION & REGULATION, Aug. 5, 1992.

quickly, lest they “produce unintended consequences like best price did.”²²² Moreover, the dominant legislative responses to the cost-shifting problem—amendments either to exclude government purchasers from best price calculations or to eliminate best price in favor of a flat rebate percentage—had significant political problems. State Medicaid directors had seen substantial cost reductions due to the rebate provision, and exclusion of government purchasers from best price calculations would reduce the state share of Medicaid rebates by approximately \$13.5 million in 1993 alone.²²³ A full repeal of the best price provision in favor of a flat rebate percentage would be even more costly to the states unless the rebate percentage was increased substantially.²²⁴ Thus, as Pryor observed early on, the process of revising the rebate program served only to “pit one group who pays slightly less ridiculous prices for prescription drugs against those groups that pay more ridiculous prices for the same drugs.”²²⁵ That is, the discussion was no longer a fight about reducing prices charged by drug companies, but rather about creating winners and losers among purchasers.

After two years, three hearings, and many more bills addressing the perceived OBRA-stimulated cost-shifting, the Medicaid drug rebate law was amended for the first time. President George H. W. Bush signed “The Veterans Health Care Act of 1992” on November 4, 1992.²²⁶ Title VI took up drug pricing agreements and, in brief, required drug manufacturers enter drug pricing agreements with entities covered by the Public Health Service Act and with the Veterans’ Affairs to continue receiving Medicaid outpatient drug reimbursement; increased slightly the minimum rebate percentages beginning October 1, 1992;²²⁷ and excluded prices charged to government entities from the best price calculation. The Veterans Act amendments ignored the

²²² *Drug Rebate Debate Heats Up*, HEALTH LEGISLATION & REGULATION, Sept 9, 1992.

²²³ *The Prescription Drug Rebate Program: Hearing on H.R. 2890, H.R. 3450, and H.R. 5614 before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 102nd Cong. 31 (1992)(letter from the Congressional Budget Office to the Honorable John D. Dingell).

²²⁴ To retain budget neutrality, a flat rebate would have to rise to 22 percent in 1993, 19 percent in 1994, 17 percent in 1995 and 16 percent thereafter. *Id.* Congressional desire to engage PMA in a fight over this large increase was low.

²²⁵ *Hearings on the Public Health Clinic Prudent Pharmaceutical Purchasing Act before the Senate Comm. on Labor and Hum. Resources*, *supra* note 208, at 10 (statement of Senator David Pryor). The federal government would also lose significant rebates estimated at \$18 million in FY 1993, \$13 million in FY 1994 and \$8 million in FY 1995.

²²⁶ Veterans Health Care Act of 1992, *supra* note 19.

²²⁷ The minimum rebate of 15 percent beginning January 1, 1993 was replaced with a sliding scale for years 1993 through 1995. Rebates required were: 15.7% from September 30, 1992 through December 31, 1993; 15.4 percent January 1, 1994 through December 31, 1994; 15.2 percent January 1, 1995 through December 31, 1995; and 15.1% beginning January 1, 1996. *Id.*

cost-shifting concerns of large non-government purchasers, and left HMOs and hospitals continuing the call for a repeal of the best price provision. However, a GAO report released in January 1993, which concluded that “we could not determine the extent to which the price increases were attributable to (the 1990 law),” diffused the power of these purchasers’ complaints.²²⁸

The only other substantive amendments to the Medicaid drug rebate law came on the heels of the first change, incorporated into the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993).²²⁹ OBRA 1993 gave states permission to use drug formularies under the rebate law. It also eliminated an exemption that forbade states from imposing prior authorization on new drugs within six months of FDA approval. Other smaller changes in the rebate calculation method were also included. PMA predictably fought the formulary provision more vigorously than it did the amendments of the Veterans Affairs bill. Nevertheless, because prior authorization systems were already largely being used as de facto formularies in many states, the change was less harmful to PMA members than it appeared on its face.

Epilogue

In 1995, Senate Finance Committee Republicans included in their Medicaid reform proposal a provision to sunset the Medicaid drug rebate program by 1998.²³⁰ PMA (by then renamed PhRMA) cheered the plan, lambasting the rebate program and the “billions” of dollars it had cost drug manufacturers since 1990.²³¹

Political observers speculated that President Clinton would have vetoed any Medicaid reform package containing such language, but the proposal did not get that far.²³² Instead, the drug manufacturers’ old foe

²²⁸UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT ON MEDICAID: CHANGES IN DRUG PRICES PAID BY HMOs AND HOSPITALS SINCE ENACTMENT OF REBATE PROVISIONS, GAO/HRD-93-43 (Jan. 1993).

²²⁹OBRA 1993, *supra* note 28, at Sec. 13602.

²³⁰Mary Agnes Carey, *Medicaid Rebate Plan Repeal Would Save Drug Cos. ‘Billions,’* DOW JONES NEWS, Sept. 27, 1995, at 11.

²³¹*Senate Vote Continues Rebates by Pharmaceutical Manufacturers*, DRUG STORE NEWS, Oct. 23, 1995, at 21.

²³²Carey, *supra* note 230.

that cut them down at the pass. In the Finance Committee markup of the reform plan, Senator David Pryor introduced an amendment preserving the rebates. Pryor shrewdly passed his amendment by using a voice vote so to allow “GOP Senators to support the rebate program without risking retaliation from the politically powerful pharmaceutical industry.”²³³ Since this defeat, a sunset of the rebate provision has never again come close to materializing.

And thus the Medicaid rebate law remains on the books today. Interestingly, both its proponent and opponent remain unsatisfied with its work. Fearing widespread use of the rebate program to gain discounts for non-Medicaid populations, PhRMA would still be enamored if the provision were to disappear. For his part, David Pryor still worries about drug prices and the pricing practices of the pharmaceutical industry. Today, retired and back in Arkansas, Senator David Pryor continues to believe the drug companies are giving American consumers a raw deal. To most observers, the Medicaid drug rebate program was one of the biggest legislative defeats suffered by the pharmaceutical industry. By contrast, Pryor remains less enthusiastic, “I never saw this [Medicaid rebates] as a major victory. I never saw this as a big bill.”²³⁴ He continues to hope, albeit skeptically, that a big victory may be just around the corner.

²³³DRUG STORE NEWS, *supra* note 231..

²³⁴Telephone Interview with David Pryor, retired Senator from Arkansas (Feb. 4, 2003).