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GIVING PHARMACEUTICAL MANUFACTURERS A PILL TO SWALLOW: WHY NORTH CAROLINA SHOULD PROVIDE DISCOUNT PRESCRIPTION DRUGS TO NON-ELDERLY UNINSURED CITIZENS

VADDRICK Q. PARKER*

INTRODUCTION

This casenote discusses the potential impact of the United States Supreme Court decision in *Pharmaceutical Research and Manufacturers of America (PhRMA) v. Walsh*¹ on the State of North Carolina's ability to provide discounted prescription drugs to its 1,125,480 uninsured residents. More specifically, the Supreme Court's decision will be examined with respect to North Carolina's 880,240 nonelderly uninsured residents that fall between the ages of 19-64. Until May 19, 2003 there was no United States Supreme Court decision that allowed states, via the federal Medicaid Act, to force pharmaceutical manufacturers to provide discounted prescription drugs for state residents that did not qualify for the Medicaid program.

North Carolina currently has 1,122,898 nonelderly uninsured residents that fall below the federal poverty level.² Persons in poverty are defined as those who make less than 100percent of the Federal Poverty Level (FPL), referred to as the poverty threshold.³ Studies have shown that total pharmaceutical spending in the United States

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1. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003). Pharmaceutical manufacturers association brought an action challenging the constitutionality of a Maine Act that established fairer pricing for prescription drugs. The Supreme Court, Justice Stevens, held that (1) the district court order preliminarily enjoining State of Maine from implementing its prescription drug rebate program, as allegedly preempted by federal Medicaid law, was an abuse of discretion; and (2) Maine's prescription drug rebate program, under which enrollees could purchase prescription drugs from participating Maine pharmacies at discounted price, with the discount reimbursed out of rebate payments collected from participating drug manufacturers, and under which any drug manufactured by nonparticipating manufacturer could not be dispensed to Medicaid beneficiaries without prior approval of State Medicaid administrator, did not impose disparate burden on out-of-state manufacturers in violation of Commerce Clause. *Id.*

2. *North Carolina: Distribution of NONELDERLY Uninsured by Federal Poverty Level*, Kaiser Family Foundation State Health Facts Online. Data Source: Urban Institute and Kaiser Commission on Medicaid and the Uninsured based on pooled March 2001 and 2002 Current Population Surveys, available at <http://www.statehealthfacts.kff.org>.

3. *Id.* "The federal poverty level for a family of three was \$13,738 in 2000 and \$14,128 in 2001." *Id.*

topped \$141.8 billion in 2001, and increased to an estimated \$160 billion in 2002.⁴ United States spending for prescription drugs is expected to continue to rise rapidly, reaching \$445.9 billion (17percent of personal health care spending) by 2012.⁵

Past North Carolina state legislation affecting prescription drug prices has been focused primarily on providing discounted prescription drugs for children and the elderly. If North Carolina chooses to act, as did Maine, North Carolina will be joined by a dozen other states that are considering required prescription discounts to qualified state residents.⁶

BACKGROUND

Maine's Proposed Prescription Drug Plan (Rx Plan/Program)

Under Maine's Rx program, all qualified uninsured Maine residents would have access to discounted prescription drugs. This is made possible because Maine will pay for the discounts using rebates it gets from the drug makers that participate in the Medicaid program. If a company elects not to pay the rebate, Maine will require doctors to get prior authorization from the state before prescribing that company's drug for Medicaid recipients. Opponents of the Maine Rx program argue that a program such as this would create a cumbersome process that could prevent Medicaid patients from receiving necessary prescription drugs. In addition, the brand name drug manufacturers could suffer revenue losses due to the prior authorization procedure.

In 2000, Maine's state legislature established the Maine Rx Program.⁷ Maine's Rx program is unique because it seeks to assist all qualified residents of the state regardless of their income level or socioeconomic status. Pursuant to Me.Rev.Stat. Ann. tit. 22, § 2681, the state shall act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare.⁸ If a pharmaceutical manufacturer chooses not to enter into a rebate agreement⁹ there are two consequences for this nonparticipation. First, the

4. *Pharmaceuticals: State Policy Overview At a Glance*, National Conference of State Legislatures (June 1, 2003), available at <http://www.ncsl.org/programs/health/pharm.htm>.

5. *Prescription Drug Trends*, Kaiser Family Foundation (March 2003), available at <http://www.kff.org>.

6. Joan Biskupic, *Justices Clear Way For Plan That Cuts Prescription Costs*, USA TODAY, May 19, 2003.

7. Me.Rev.Stat. Ann., tit. 22, § 2681 (2003).

8. *Id.*

9. Pursuant to § 2681, "a drug manufacturer or labeler that sells prescription drugs in the state of Maine through the elderly low cost drug program under section 254 or any other publicly

names of the manufacturers and labelers who do not enter into rebate agreements become public information, and the names of these companies will be released to both health care providers, and to the public.¹⁰ Second, the department shall impose prior authorization¹¹ requirements in the Medicaid program, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers.¹²

To avoid abuse by Maine residents, the state legislature proposed limitations on the plan, and made access limited to individuals who do not have a comparable or superior prescription drug benefit plan.¹³ Despite the fact that Maine seeks affordable prescription drugs for all of its residents, it is clear that the state does not want to discourage employers from providing prescription drug benefits.¹⁴

The Medicaid Act

Medicaid is a joint federal and state program that seeks to provide medical services to those whose income and resources are insufficient to meet the costs of necessary medical services.¹⁵ Congress created the Medicaid program in 1965 by adding Title XIX to the Social Security Act.¹⁶ The program authorizes federal financial assistance to states that choose to reimburse certain costs of medical treatment for needy persons. A state must, in order to participate in the Medicaid program, have a plan for medical assistance approved by the Secretary of Health and Human Services of that state.¹⁷ In 1990 Congress required drug companies to pay rebates to states on their Medicaid prescription drug purchases. Prior to 1990, the Medicaid statute did not specifically address outpatient prescription drug coverage. In an amendment contained in the Omnibus Budget Reconciliation Act (OBRA) of 1990¹⁸ Congress ratified the Secretary of Health and

supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program." *Id.*

10. tit. 22, § 2681.

11. The proposed rules also explain that Maine will appoint a "Drug Utilization Review Committee" composed of physicians and pharmacists who will evaluate each drug manufactured by a company that has declined to enter into a rebate agreement to decide whether it is clinically appropriate to subject the drug to prior authorization.

12. tit. 22, § 2681.

13. *Id.*

14. *Id.* "It is not the intention of the State to discourage employers from offering or paying for prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter." *Id.*

15. *See*, 42 U.S.C. § 1396 (2003).

16. Title XIX appears in the United States Code as §1396-1396v, subchapter XIX, chapter 7, Title 42. Regulations relating to Title XIX are contained in chapter IV, Title 42, and subtitle A, Title 45, Code of Federal Regulations.

17. *See*, 42 U.S.C. § 1396a(b) (2003).

18. 104 Stat. 1388-143 (1990).

Human Services practice of approving state plans containing prior authorizations.¹⁹ Under this new amendment there were two basic parts. First, in order to qualify for Medicaid payments, drug companies must enter into agreements either with the Secretary or, if authorized by the Secretary, with individual states, to provide rebates on their Medicaid sales of outpatient prescription drugs.²⁰ Second, once a drug manufacturer entered into a rebate agreement the law required the state to provide coverage for that drug under its plan unless the state complied with one of the exclusion or restriction provisions in the Medicaid Act.²¹

Under the 1990 OBRA, a state may subject a covered outpatient drug to prior authorization,²² so long as the state's prior authorization program (1) provides a response by telephone or other telecommunication device within 24 hours of a request for prior authorization, and (2) except for the listed excludable drugs, provides for the dispensing of at least a 72-hour supply of a covered drug in an emergency situation.²³ The 1993 amendment to the OBRA reenacted the provisions for state prior authorization programs that had been included in the 1990 OBRA.

THE CASE

Pharmaceutical Research and *Manufacturers of America v. Walsh*

The United States Supreme Court made it clear that the holding in this case will not determine the validity of Maine's Rx program.²⁴ According to the Supreme Court, Maine's Secretary of Health and Human Services could view the Maine Rx program as an amendment to the state's Medicaid plan, therefore requiring the Secretary's approval before the program could become effective.²⁵

In a 6 to 3 decision, the Supreme Court affirmed the Court of Appeals ruling, which stated that the lower court²⁶ was incorrect in hold-

19. See, e.g., *Dodson v. Parham*, 427 F.Supp. 97, 100-101 (N.D.Ga. 1977). Prior to this amendment under plans approved by the Secretary, some state's designed and administered their own formularies, listing the drugs that they would cover. States also employed "prior authorization programs" that required approval by a state agency to qualify a doctor's prescription for reimbursement. *Id.*

20. If the state determines that a drug is essential to the health of a beneficiary, if it has been given a special rating by the Federal Food and Drug Administration, and if a doctor has obtained prior authorization for their use, the statute authorizes payment for the drug even if it is not covered by a rebate agreement. See, 42 U.S.C. § 1396r-8(a)(3) (2003).

21. See *Id.*, 42 U.S.C. § 1396r-8(d) (2003).

22. *Id.* at § 1396r-8(d)(1)(a).

23. *Id.* at § 1396r-8(d)(5).

24. *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S.Ct. 1855, 1866 (2003).

25. *Id.* at 1866.

26. The federal district court held that the Medicaid Act pre-empted Maine's Rx program insofar as it threatened to impose a prior authorization requirement on nonparticipating manu-

ing that Maine's Rx program was preempted by the federal Medicaid law. The Supreme Court agreed with two of the three reasons given by the Court of Appeals as to why preemption was incorrect. First, since the federal statute expressly authorized the use of prior authorizations, it found "no conflict between the Maine Act and Medicaid's structure and purpose."²⁷ Second, given the absence of an actual conflict, the court found that the mere fact that Maine Rx program "fails to directly advance the purpose of the federal program" is an insufficient basis for "inflicting the 'strong medicine' of preemption" on state statutes.²⁸ The Court of Appeals also reviewed the affidavits submitted in the case and concluded that they fell short of establishing that the Maine Rx program will inflict inevitable or even probable harm on Medicaid patients and thus were insufficient to support a preemption based facial challenge.²⁹

PhRMA had the burden of establishing by a clear showing that there was no Medicaid related goal or purpose served by the Maine Rx program, which it failed to do.³⁰ The Supreme Court held that there are three such goals plainly present in the Maine Rx program. First, the program will provide medical benefits to persons who can be described as "medically needy" even if they do not qualify for AFDC or SSI benefits.³¹ Second, Medicaid expenses may be reduced by enabling some borderline aged and infirm persons better and earlier access to prescription drugs.³² Third, Medicaid's purpose will be fostered whenever it is necessary to impose the prior authorization requirement on a manufacturer that refuses to participate.³³

facturers. The court assumed that the "Department of Human Services will not deny a single Medicaid recipient access to the safest and most efficacious prescription drug therapy indicated for their individual medical circumstances." Civ. No. 00-157-B-H (D.Me., Oct. 26, 2000), App. to Pet. for Cert. 68. In the district courts view, since Maine altered the federal Medicaid program to serve Maine's local purposes that act alone was outside the scope of the Medicaid program and created an obstacle to the administration of the federal program and therefore was preempted by federal law. *Id.*

27. Pharm. Research & Mfrs. of Am. v. Walsh, 249 F.3d 66, 75 (C.A.1 Me 2001). In its view, as long as there was compliance with the federal 24- and 72-hour conditions, the State's motivation for imposing the requirement is irrelevant. *Id.*

28. *Id.* at 76.

29. *Id.* at 78.

30. Pharm. Research & Mfrs. of Am. v. Walsh, 123 S.Ct. 1855, 1867 (2003).

31. *Id.* "Even if the program is more inclusive than the Secretary thinks it should be, the potential benefits for nonneedy persons would nullify the benefits that would be provided to the neediest segment of the uninsured population." *Id.*

32. *Id.* "If members of this borderline group are not able to purchase necessary prescription medicine, their conditions may worsen, causing further financial hardship and thus making it more likely that they will end up in the Medicaid program and require more expensive treatment." *Id.* at 1867-88.

33. *Id.* at 1868. "Private managed care organizations typically require prior authorization both to protect patients from inappropriate prescriptions and to encourage the use of cost effective medications without diminishing safety or efficacy." Under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription

The fact that the Maine Rx program may serve Medicaid related purposes, both by providing benefits to needy persons and by curtailing the state's Medicaid costs, would not provide a sufficient basis for upholding the program if it severely curtailed Medicaid recipients' access to prescription drugs.³⁴ States have substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage, as long as care and services are provided in the best interest of the recipients.³⁵ The fact that a state's decision to curtail Medicaid benefits may have been motivated by a state policy unrelated to the Medicaid Act does not limit the scope of its broad discretion to define the package of benefits it will finance.³⁶ The need to protect the health of the uninsured residents in Maine provides a plainly permissible justification for a prior authorization requirement that is assumed to have only a minimal impact on Medicaid recipients' access to prescription drugs.³⁷

The impact on patient care and access to appropriate drugs far outweighs any adverse impact on the manufacturers of brand name prescription drugs. Under this Supreme Court ruling, the impact on brand name pharmaceutical manufacturers is irrelevant because the transfer of business to less expensive products will produce savings for the Medicaid program.³⁸ Until such time when patient care is directly affected by the prior authorization requirement, the severity of any impediment that Maine's program may impose on a Medicaid patients' access to the drug of her choice is a matter of conjecture, and the Court could not conclude that any patient's medical needs would be adversely affected based on the record before it.³⁹ The Court also concluded that the Maine's Secretary of Health and Human Services is likely to take action with respect to the Maine Rx program, and until such time the fate of the Maine Rx program would remain unknown.⁴⁰

ANALYSIS

Overview of Prescription Drug Prices

Spending for prescription drugs is one of the fastest growing

drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care. H.R.Rep. No. 101-881, p. 98 (1990), U.S.Code Cong. & Admin.News 1990, pp. 2017, 2110.

34. See, 42 U.S.C. § 1396a (a)(19) (2003).

35. *Alexander v. Choate*, 469 U.S. 287, 303, 105 S.Ct. 712, 83 L.Ed.2d 661 (1985).

36. See, *Beal v. Doe*, 432 U.S. 438, 97 S.Ct. 2366, 53 L.Ed.2d 464 (1977).

37. *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S.Ct. 1855, 1869 (2003).

38. *Id.* at 1870.

39. *Id.*

40. *Id.*

components of health care.⁴¹ About 23 million American adults, or 12 percent of the adult population, could not afford to get at least one needed prescription medication in 2001, according to the 2000-2001 Community Tracking Study (CTS) household survey. While most nonelderly adults have prescription drug coverage through employer sponsored health insurance, or the Medicaid program, over 26 million Americans lack health insurance for any kind of medical care.⁴² Based on these facts, there is evidence that an even greater number of nonelderly adults are vulnerable to cost barriers to prescription medications, either due to a complete lack of health care coverage, or limitations in Medicaid prescription drug coverage relative to the needs of the beneficiaries.⁴³ In addition, prescription costs paid by those without prescription drug insurance was on average about 15percent higher than those with insurance in 1996.⁴⁴

Three main factors are driving the increases in prescription drug spending. The first factor is the increasing number of prescriptions, which is responsible for 47percent of the overall increase in prescription spending from 1997-2001.⁴⁵ Second, the changes in the types of drugs used, which accounted for 27percent of the increase.⁴⁶ Third, manufacturer price increases for existing drugs, which accounted for 26percent of the increase.⁴⁷ Despite the fact that there is increased spending, especially on newer and more advanced pharmaceuticals, there is growing evidence that these drugs save money on other health care services.⁴⁸

The Potential Impact of the *Walsh* Decision on the State of North Carolina

North Carolina's Medicaid program⁴⁹ mirrors the Medicaid program of most other states by attempting to address the health and

41. *Prescription Drug Trends*, Kaiser Family Foundation (March 2003), available at www.kff.org. "Although prescription drug spending is a relatively small portion (11percent) of personal health care spending, it is one of the fastest growing components, increasing at double-digit rates in each of the past 7 years." *Id.*

42. Peter J. Cunningham, Ph.D, *Affording Prescription Drugs: Not Just a Problem for the Elderly*, Research Report No. 5 (April 2002).

43. *Id.*

44. *Prescription Drug Trends*, Kaiser Family Foundation (March 2003).

45. *Id.*

46. *Id.* "With newer, higher priced drugs replacing older, less expensive drugs." *Id.*

47. *Id.*

48. *The Best Value in Medicine Today: How Prescription Drugs Account for a Fraction of Health Cost Increases While Helping to Offset Other Health Costs*, Pharmaceutical Researchers and Manufacturers of America (2003).

49. North Carolina Division of Medical Assistance, available at www.dhhs.state.nc.us/dma. Typically, "to be eligible for Medicaid you must be (i) age 65 or older OR Under 65 and unable to work due to a severe disability that is expected to last at least 12 months, (ii) have a monthly income no greater than \$749 for individuals or \$1010 for couples (income includes Social Secur-

long-term care needs of the low income disabled and elderly populations, and their families. As required by the Medicaid Act, all states must have a state plan that is approved by the Secretary of Health and Human Services. Title XIX of the Social Security Act requires that North Carolina provide a plan to administer and manage the North Carolina Medicaid program.⁵⁰ In addition to providing the amount, scope, and duration of services as well as eligibility requirements, the North Carolina plan outlines the organization and function of the Division of Medical Assistance.⁵¹

North Carolina's plan is consistent with the 1990 Omnibus Budget Reconciliation Act and its 1993 amendment, which permits the use of prior authorization for pharmaceutical manufacturers that have not entered into a rebate agreement with the State of North Carolina.⁵² North Carolina's plan also provides for a response by telephone or other telecommunication device within 24-hours of a request for prior authorization, as well as the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation.⁵³

North Carolina has implemented Senior Care and North Carolina Health Choice (NCHC). These programs seek to administer prescription drugs to seniors and children, respectively. Senior Care offers a traditional drug benefit that covers sixty percent of the first thousand dollars worth of the cost of prescription drugs and insulin for the treatment of cardiovascular disease, chronic obstructive pulmonary disease and/or diabetes, while program members pay the remaining forty percent of the cost for covered drugs, and six dollars for each 30-day prescription.⁵⁴

ity, Veteran's Benefits, pensions, etc.) and (iii) resources must be no more than \$2,000 for an individual, or \$3,000 for a couple. Resources include cash, bank accounts, second car, retirement accounts stocks, real estate etc." *Id.*

50. North Carolina Division of Medical Assistance. Administrative and Regulatory Affairs (June 11, 2002).

51. *Id.* The Division of Medical Assistance is a subset of the North Carolina Health and Human Services Department.

52. Memorandum from Portia W. Rochelle, North Carolina state plan coordinator to state plan e-mail subscribers (August 9, 2002) (on file with author). Section 12(a) Prescribed Drugs Attachment 3.1-A.1 p. 14. "Drugs for which medical Assistance reimbursement is available are limited to the following: (4) Covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under Section 1927(a) of the Act which are prescribed for a medically accepted indication. In addition, prior authorization must be obtained from the Medicaid agency or its authorized agent for any drug on the prior authorization list before Medicaid reimbursement is available." *Id.*

53. *Id.*

54. *North Carolina Senior Care Program—Program Benefits* (June 5, 2003) available at <http://www.ncseniorcare.com/programBenefits.htm>. "Any costs beyond the \$600 covered by the program and cost for drugs that treat illnesses not covered by Senior Care are the member's responsibility." *Id.*

NCHC is a fee-for-service insurance program that provides free or low-cost health coverage, including prescription drugs, to children under the age of nineteen whose families cannot afford private health insurance and that do not qualify for Medicaid.⁵⁵ Unfortunately, there is no comparative program for North Carolina's uninsured nonelderly adult residents.

North Carolina's number of uninsured nonelderly residents is reported based on information from two general surveys, each controlled by a different independent variable. The first survey was controlled by the federal poverty level,⁵⁶ and the second was controlled by the population distribution by insurance status. North Carolina has a total population of 8,049,313.⁵⁷ As stated in the introduction, North Carolina has 1,122,898 nonelderly uninsured residents that fall below the federal poverty level.⁵⁸ Based on these numbers approximately 13.95 percent of North Carolina's population fall below the federal poverty level. A second survey, also conducted by the Kaiser Foundation, shows that approximately 1,125,480, or 13.98 percent of North Carolinians are uninsured.⁵⁹

As indicated, North Carolina provides health and prescription drug programs for children and the elderly. This casenote focuses on those between the ages of 19 to 64 that are not provided with prescription

55. *North Carolina Division of Medical Assistance, North Carolina Health Choice Frequently Asked Questions for Pharmacists* (June 10, 2003) available at <http://www.dhhs.state.nc.us/dma/CHIP/faq/pharmfaq.htm>. "The program was established in October 1998 by the federal government and the state of North Carolina. It is modeled after the State Teachers' and Employees' Comprehensive Major Medical Plan and is administered by BlueCross and BlueShield of North Carolina (BCBSNC) with the exception of pharmacy benefits, which are managed by AdvancePCS. . . . Coverage includes "acute care", preventative care services, hospitalization, prescription drugs, durable medical equipment, medical supplies, and special hearing and vision benefits." *Id.*

56. The results in this survey were based on the federal poverty level for a family of three in 2000, which was \$13,738, and 2001, which was \$14,128. The federal poverty guidelines for 2003 are as follows: for an individual the amount is \$8,980, for a couple the amount is \$12,120, family of three the amount is \$15,260 and for a family of four the amount is \$18,400. 68 Fed. Reg. 6456-58 (February 7, 2003).

57. U.S. Census Bureau, census 2000 profile of general demographic characteristics for North Carolina.

58. The Henry J. Kaiser Family Foundation State Health Facts Online, *North Carolina: Distribution of Nonelderly Uninsured by FPL, state data 2001-2002, U.S. 2002*, available at <http://www.statehealthfacts.kff.org>. "Those individuals who fall under 100percent of the FPL equals 411,563 (37percent of the 1,122,898). Those individuals who fall between 100-199percent equals 314,202 (28percent of the 1,122,898). Those who fall 200percent or more below the federal poverty level equals 397,132 (35percent of the total 1,122,898)." *Id.*

59. *North Carolina: Population Distribution by Insurance Status*, Kaiser Family Foundation State Health Facts Online. Data Source: Urban Institute and Kaiser Commission on Medicaid and the Uninsured based on pooled March 2001 and 2002 Current Population Surveys, available at <http://www.statehealthfacts.kff.org>. The disparity between the 1,122,898 reported as falling below the federal poverty level and the 1,125,480 reported as being uninsured could be due to an instance where a resident is uninsured, yet does not fall below the federal poverty level for whatever reason.

coverage. North Carolina has 4,886,905 residents that are nonelderly,⁶⁰ of which 880,240 are uninsured.⁶¹ Therefore, approximately 18.01 percent of all North Carolina residents between the ages of 19-64 are uninsured. The percentage of uninsured nonelderly is 4.03 percent higher than the total percentage of uninsured residents for the entire state, which is 13.98 percent. It is likely that the vast uninsured nonelderly that lack health insurance also lack prescription coverage.

The growing number of uninsured residents is a concern not only of the citizens, but also for politicians in North Carolina. In the August 2000 Congressman Robin Hayes served as a conference chair for the North Carolina Regional Healthcare Forum. At this forum Roy Hinson of Stanly Memorial Hospital noted that a lack of insurance ranked second behind a language barrier, as the biggest healthcare concern in North Carolina.⁶² Congressman Richard Burr, representing North Carolina's 5th Congressional District, also noted that North Carolina faces a serious problem in providing quality and affordable health care to its residents.⁶³ Congressman Burr's reasoning was that high insurance costs is the reason for the increased number of uninsured residents in North Carolina⁶⁴, albeit directly reflecting the rising cost of prescription drugs. Congressman Burr proposed that Congress continue to do three things to provide North Carolina citizens with greater access to affordable, high quality health care. First, ensure that employers have the proper incentives to provide health care.⁶⁵ Second, look at alternative solutions that may reduce the number of uninsured and underinsured.⁶⁶ The *Walsh* decision could be a start to thinking about alternative solutions by providing affordable prescription drugs that may prevent existing medical conditions from worsening. Third, increased support for community health care centers across North Carolina.⁶⁷

North Carolina currently provides affordable prescription drugs to the nonelderly uninsured residents through federally qualified community health centers (FQHCs), charitable foundations, and phar-

60. U.S. Census Bureau, census 2000 profile of general demographic characteristics for North Carolina.

61. *North Carolina: Distribution of Adults 19-64 by Insurance Status*, The Kaiser Family Foundation State Health Facts Online. Data Source: Urban Institute and Kaiser Commission on Medicaid and the Uninsured based on pooled March 2001 and 2002 Current Population Surveys, available at <http://www.statehealthfacts.kff.org>.

62. Roy Hinson, Address at the North Carolina Regional Healthcare Forum in Concord, North Carolina. (April 19, 2000).

63. Congressman Richard Burr, *North Carolina Political Review: Expand Health Centers* (August 2002) available at www.ncpoliticalreview.com.

64. *Id.*

65. *Id.* "Majority of health care plans are provided by employers." *Id.*

66. *Id.*

67. *Id.*

macy assistance programs. [For purposes of this casenote, health care centers will be discussed in a manner that details the impact such centers have on prescription drug access, as opposed to general health care.]

In 2001, North Carolina's 20 community health centers cared for more than 700,000 North Carolinians. FQHCs are vital sources of primary health care for underserved populations in North Carolina, providing cost effective quality care for our most vulnerable men, women and children.⁶⁸ A FQHC must adjust its fees based on a patient's income and family size, and it cannot refuse service because an inability to pay.⁶⁹ [The services that are included in primary care may include prescription drugs.] However, since FQHCs funding sources⁷⁰ are limited and focused on new patients and new services, the health centers are not being compensated for increased cost, including prescription drug costs, and the rising burden of uncompensated services.⁷¹ This places a heavy financial burden on North Carolina's community health centers.

Charitable foundations can play several roles in improving access to prescription drugs for North Carolina's nonelderly uninsured residents. For example, the Kate B. Reynolds Charitable Trust in Winston-Salem, North Carolina has provided funding for a variety of pharmacy programs since 1995 by awarding grants to health clinics and health departments. These grants are used to purchase medications, hire staff to work with prescription assistance programs, and salary support for pharmacists.⁷² This method ultimately leads to greater

68. *North Carolina's Health Centers: "Standing in the Gap"*, North Carolina Primary Health Care Association (March 2003).

69. *Id.* "Fees that are unable to be collected are referred to as 'bad debt'. During the period 1998-2001, bad debt losses rose by 62 percent and is projected to show even more significant losses for 2002."

70. "Grants from the Bureau of Primary Health Care provide less than 30 percent of the total support needed to operate a health center. The balance must come from patients service revenues through Medicaid, Medicare, and private insurance. . . Many FQHCs have historically used revenue from other patients, such as Medicaid, to offset some of the costs associated with caring for the uninsured. However, the potential of increased managed care revenue has made Medicaid more attractive to providers that have not traditionally served that population within North Carolina. Consequently, many of North Carolina's community health centers have lost Medicaid income and have fewer resources available for their uninsured patients. The total effect is an increase in uninsured patients while the number of Medicaid patients seen at FQHCs decreases." *Id.*

71. *Id.* "The President's Health Center Initiative focuses on new patients and new services. No additional funding has been offered to health centers to compensate them for the increased cost and the rising burden of uncompensated services. FQHCs have not received a cost adjustment to their base funding in two years. This leaves many health centers in North Carolina bursting at the seams with patients, yet struggling payroll to payroll to maintain their operations." *Id.*

72. *Access to Prescription Medications for the Uninsured: Findings from the Grantmakers in Health Resource Center*, Grant Makers Health (GIH Annual Meeting 2003).

access to prescription drugs. In addition to providing funding to health clinics and health departments, charitable foundations have developed programs to fund co-payments for people who cannot afford them.⁷³

Several states have also developed pharmacy assistance programs for their low-income populations funded from general revenues and direct subsidies or discounts. Many of the existing prescription assistance programs fail to provide for the nonelderly by only providing drug coverage for people ages 65 or older that do not have supplemental Medicare coverage.⁷⁴ Often pharmaceutical companies provide medicines free of charge to consumers and to physicians whose patients might not otherwise have access to necessary medicines.⁷⁵ Most often, a patient's physician would refer them to the pharmaceutical assistance program or make an application on their behalf.⁷⁶ The Pharmaceutical Research and Manufacturers of America has compiled a directory of prescription drug patient assistance programs.

Compared to North Carolina, Maine has a total population of 1,274,923 of which 756,036 are nonelderly.⁷⁷ Of the 756,036 between the ages of 19 and 64, 113,090 are uninsured.⁷⁸ Therefore, approximately 14.95 percent of Maine's nonelderly residents are uninsured compared to North Carolina's 18.01 percent. That equates to a 3.06 percent difference between the number of nonelderly uninsured residents in North Carolina as compared to Maine. If providing affordable prescription drugs was important to the State of Maine and its residents, then it should be equally important for North Carolina.

Maine's prescription plan seeks to provide affordable prescription drugs to all of its qualified residents. North Carolina could use this same methodology to provide affordable prescription drugs to its nonelderly uninsured residents. There are several reasons why North Carolina should follow in Maine's footsteps. First, enacting a prescription drug plan consistent with Maine's prescription drug plan would compliment North Carolina's Health Choice program for children and North Carolina's Senior Care program for the elderly,

73. *Id.* "The Health Foundation of Greater Cincinnati, for example, provided a grant to establish a co-payment bank to provide co-payments for patients who were not able to fill prescriptions because they could not afford the co-payments." *Id.*

74. *Id.*

75. Pam Silberman, *A Consumer's Guide to Health Insurance and Health Programs in North Carolina* (May 2003).

76. *Id.*

77. U.S. Census Bureau; census 2000 profile of general demographic characteristics for Maine.

78. *Maine: Distribution of Adults 19-64 by Insurance Status*, Kaiser Family State Health Facts Online, Data Source: Urban Institute and Kaiser Commission on Medicaid and the Uninsured estimates based on pooled March 2001 and 2002 Current Population Surveys available at <http://www.statehealthfacts.kff.org>.

thereby providing affordable prescription drug access to a larger percentage of the population. Second, a prescription drug plan could lower future health care costs by addressing serious health problems at their outset, before the problems have a chance to worsen. Third, a prescription drug plan would reduce the strain placed on North Carolina's community health centers. Finally, a prescription drug plan would compliment pharmacy assistance programs, which usually cater to older individuals.

If North Carolina were to enact a prescription drug plan similar to Maine's Rx program, then it would compliment both North Carolina's Senior Care program for the elderly, as well as NCHC. While NCHC provides for children and Senior Care provides for the elderly, an independent prescription drug plan would provide for not only children and seniors without a comparable or superior prescription drug plan, but also for the nonelderly uninsured population. There are no age limits under Maine's proposed plan⁷⁹, therefore unlike NCHC and Senior Care the nonelderly population would be allowed to purchase prescription drugs at a discounted rate. This would in effect provide a dual benefit.

Second, a prescription drug plan such as Maine's Rx program, could possibly lower future health care costs in North Carolina. The Supreme Court noted the impact that such a plan could have on a state's ability to lower future health care costs by ruling that it is possible to lower Medicaid expenses by enabling some borderline aged and infirm persons better access to prescription drugs before their condition worsen.⁸⁰ If a patient's condition is allowed to worsen, it will inevitably lead to more expensive treatment. For the uninsured population the worsening effect would mean increased reliance on state and government funding. By analogy, allowing better access to prescription drugs for the borderline aged and infirm to reduce future medical costs could also apply to the nonelderly uninsured residents of North Carolina. By providing nonelderly uninsured residents of North Carolina better access to prescription drugs it would logically follow that future health care costs among this group could be lowered. This theory is also supported by an article from the Pharmaceutical Researchers and Manufacturers of America in which it is stated that "there is growing evidence that increased spending on medicines, especially

79. The most important limitation is the program would apply to those individuals who to do have a comparable or superior prescription drug insurance plan.

80. *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S.Ct. 1855, 1867 (2003).

newer, more advanced pharmaceuticals, save money on other health care services."⁸¹

In Governor Mike Easley's 2003 State of the State Address he argued for, and encouraged preventive health care procedures for North Carolina residents. Providing affordable prescription drugs to prevent serious illnesses and diseases from worsening later in a patient's life could very well serve this purpose. In many cases the preventative health care procedure that Governor Easley mentioned is in fact preventative prescription drugs.

Third, providing a prescription drug plan similar to Maine's Rx plan could also reduce the strain on North Carolina's community health facilities. According to the North Carolina Primary Health Care Association, North Carolina health care centers are having financial problems maintaining their operations.⁸² This is a direct result of community health centers not being compensated for increased health care cost and the rising burden of uncompensated services. The facts also indicate that prescriptions drugs account for a large percentage of health care expenses in past years. Therefore, if pharmaceutical companies were forced to comply with a prescription drug plan, such as the Maine Rx plan, the cost of prescription drugs will decrease along with a decrease in health care costs. The community health centers would see a decline in prescription drug costs thereby easing the burden of payroll to payroll expenses.

Finally, a prescription drug plan similar to Maine's Rx plan would compliment pharmacy assistance programs, which usually cater to older individuals. Unlike the typical pharmacy assistance program, which generally targets people ages 65 or older and most often requires a patient's physician to refer them to the pharmaceutical assistance program or make an application on their behalf, a prescription drug plan would not limit an individual from receiving discount prescription drugs due to age or physician references. So long as the individual resident does not have a comparable or superior prescription drug plan, then they are eligible to receive the discounted prescription medication.

CONCLUSION

The United States Supreme Court ruling in *Pharmaceutical Researchers and Manufacturers of America v. Walsh* could have a posi-

81. *The Best Value in Medicine Today: How Prescription Drugs Account for a Fraction of Health Cost Increases While Helping to Offset Other Health Costs*, Pharmaceutical Researchers and Manufacturers of America (2003).

82. *North Carolina's Health Centers: "Standing in the Gap"*, North Carolina Primary Health Care Association (March 2003).

tive impact on the State of North Carolina and its ability to provide affordable prescription drugs to the 18.01percent of nonelderly uninsured residents between the ages of 19 and 64. If North Carolina were to follow in Maine's footsteps and enact a prescription drug plan, that plan would compliment North Carolina's Health Choice program and North Carolina's Senior Care program, it could possibly lower future health care expenses in North Carolina, the plan would reduce the strain on North Carolina's community health facilities, and finally it would compliment any existing pharmacy assistance program.

As noted above, the United States Supreme Court did not decide whether the Maine Rx program was valid, only that it did not violate the federal Medicaid Act. North Carolina's Secretary of the Department of Health and Human Services could view such a plan, if proposed, as an extension of the state's Medicaid plan. Therefore, the Secretary's approval of such a plan would be required before it is held to be valid. *Walsh* gives states the opportunity to provide affordable prescription drugs under the guise of the federal Medicaid Act.

Opponents of the Maine Rx program will seek to prove that ultimately the Medicaid recipients will suffer because the individual states will dictate what prescription medication will be subjected to prior authorization. Spokesperson for Pharmaceutical Researchers and Manufacturers of America, Marjorie Powell, stated that PhRMA feels that the core issue under Maine's Rx program is that government officials rather than doctors and patients will decide which medicines will be available to patients and that a better solution is to pass a plan which provides prescription drug benefits for seniors and disabled persons in 2003 because over 1400 brand name medicines are available free to patients without prescription drug coverage through pharmacy assistance programs⁸³ and seniors qualify for a variety of discount programs.⁸⁴ These comments by Powell came after the Supreme Court effectively discounted PhRMA's contentions and ruled that despite of these possible effects, there is no evidence to support such assertions.

Only time will tell if indeed Medicaid patients are being affected by such a prescription drug program as Maine Rx. Until such time, North Carolina should follow in Maine's footsteps and attempt to force pharmaceutical manufacturers to lower prescription drug prices for qualified state residents.

83. Previous findings show that these programs usually cater to older individuals.

84. Press Release, Marjorie Powell, spokesperson for PhRMA remarks regarding the Supreme Court's ruling in *Pharm. Research & Mfrs. of Am. v. Walsh* (May 19, 2003) (on file with author).