

## MEDICAID “PREFERRED DRUG LISTS”: FLORIDA AS A MODEL FOR ANALYSIS

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*As states continue to struggle with the high costs of their Medicaid programs, some have tried to cut these costs by limiting which prescription drugs are covered. Florida has limited its Medicaid drug coverage by only covering drugs for which the state receives supplementary rebates from the manufacturer. In her Note, Nora Flaherty analyzes this Florida policy and concludes that it is contrary to the Medicaid statute, which requires that drug coverage be dependent only upon medical efficacy. Citing the growing strain that drug prices have put on state Medicaid programs, Ms. Flaherty recommends that, for immediate relief, Medicaid be amended to allow the states to require such rebates for coverage. In the long-run however, Ms. Flaherty cautions that only progressive measures, such as disease management programs and patent-law reform, can eventually save the Medicaid system.*

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## I. Introduction

Juan Andujar died in May 2001.<sup>1</sup> He lived in Orlando, Florida, with his girlfriend Martiza Sierra, and had been battling a congestive heart condition for twenty years.<sup>2</sup> Minutes before his death, Juan told Martiza, "I'm so sick and tired of you having to take care of me. It's time for me to go."<sup>3</sup> Martiza says he died too soon, and was a victim of Medicaid, which limited Juan to four brand-name drugs a month.<sup>4</sup> Juan took seven brand-name drugs and six generic medications, and often had to skip doses as he waited for Medicaid to approve his doctor's request to exceed the Florida-mandated four brand-name drug limit.<sup>5</sup> This process would sometimes take a week or more and Martiza claims the skipped doses weakened Juan's heart and "led to his death."<sup>6</sup>

However, the brand-name drug cap did save money.<sup>7</sup> Unfortunately, it did not save enough.<sup>8</sup> Jerry Wells, the pharmacy program manager in the Florida Agency for Health Care Administration (AHCA), says the most efficient way to save money is to require approval for every drug prescribed to Medicaid recipients.<sup>9</sup> This would allow the state to seek cheaper alternatives and "may serve as a brake on the prescribing of drugs that may not be as necessary as patients believe."<sup>10</sup> As a result, patients like Juan will likely have an even harder time than he did getting the drugs they need.<sup>11</sup>

Florida's new Medicaid law,<sup>12</sup> which went into effect in July 2001, requires pharmaceutical companies to offer supplemental rebates to the state, in addition to the federal rebates they already pay,

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1. Greg Groeller, *New Medicaid Drug Policy Stirs up Fears*, ORLANDO SENTINEL, July 1, 2001, at B1.

2. *Id.*

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

7. Joe Follick, *State Seeks to Ease Pain of Drug Costs*, TAMPA TRIB., Mar. 4, 2001, at 2.

8. *See id.*

9. *Id.*

10. *Id.*

11. *See* Bob LaMendola, *Bush Wins; State Won't Pay for Costly Drugs for Poor*, S. FLA. SUN-SENTINEL, May 8, 2001, at 1A.

12. 2001 Fla. Laws ch. 2001-104 (2001) (codified as FLA. STAT. chs. 409.91195, .912 (2001)).

in order to get on the Medicaid preferred drug list (PDL).<sup>13</sup> The PDL lists prescription drugs covered by Florida's Medicaid program.<sup>14</sup> Pharmaceutical companies must negotiate a rebate in order to have some or all of their drugs placed on the list.<sup>15</sup> If physicians want to prescribe a drug not on the list, they must obtain prior approval from the AHCA.<sup>16</sup> Florida lawmakers hope that the program will save the state \$214 million.<sup>17</sup> Other states are enacting similar laws and watching Florida's program very closely.<sup>18</sup> If successful, similar programs "will go like wildfire through the landscape."<sup>19</sup>

This prospect worries consumer advocate groups and pharmaceutical companies.<sup>20</sup> Consumer groups fear that the new law will confuse Medicaid patients and restrict their access to needed drugs.<sup>21</sup> Meanwhile, the Pharmaceuticals Research and Manufacturers of America (PhRMA), the pharmaceutical industry's main trade group, filed a lawsuit in the Tallahassee, Florida, federal court in August 2001, challenging the new law.<sup>22</sup> PhRMA contended that the new program violated federal law<sup>23</sup> because the Medicaid statute only allows states to exclude drugs from formularies of approved medications that do not have a "clinical or therapeutic advantage."<sup>24</sup> In January 2002, a Tallahassee federal judge dismissed the suit, finding that the program did not establish a formulary, but was a "prior authorization" program.<sup>25</sup> The Eleventh Circuit upheld the decision.<sup>26</sup>

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13. Scott Hensley et al., *Florida Medicaid Program Compiles List of Prescription Drugs to Be Preferred*, WALL ST. J., June 25, 2001, at A2.

14. *Florida Medicaid Drug List Panel Appointed*, MARKETLETTER, Sept. 3, 2001, 2001 WL 908365, at \*1.

15. *Inside the Industry Pfizer: WSJ Examines Florida Medicaid Formulary Program*, AM. POL. NETWORK: AM. HEALTH LINE, July 9, 2001 [hereinafter *Inside the Industry*].

16. *Id.*

17. Greg Groeller, *Health Care*, ORLANDO SENTINEL, Aug. 13, 2001, at 6.

18. *Inside the Industry*, *supra* note 15.

19. *Id.*

20. *See* Groeller, *supra* note 17.

21. *Id.*

22. *Id.*

23. *See* 42 U.S.C. § 1396r-(d)(4)(C) (2001).

24. *Id.* These formularies are preferred drug lists for coverage purposes. *See, e.g.*, FLA. STAT. ch. 409.9115(4) (2001 & Supp. 2003).

25. Joni James, *Drug Firms Lose Fight*, MIAMI HERALD, Jan. 4, 2002, at 1C; *see also* Pharm. Research & Mfrs. of Am. v. Medows, 184 F. Supp. 2d 1186 (N.D. Fla. 2001).

26. Pharm. Research & Mfrs. of Am. v. Medows, 304 F.3d 1197 (11th Cir. 2002). As of this writing, the group has also filed a lawsuit against the Michigan state agency in state court and in a Washington, D.C., federal court against the U.S.

The Florida program is a model for the way that many states are handling the huge increase in Medicaid spending on prescription drugs. Because of its possible magnitude, the Florida program requires an analysis from both a legal and policy-based point of view. This Note will explore whether the new law indeed violates the federal Medicaid statute, what the financial, policy, and social ramifications of the law might be, and what the best solution is for states to achieve cost-efficient, legal, and equitable Medicaid prescription drug programs.

Part II will give a brief history of the federal Medicaid program and some of the programs Florida and other states have used to try to control state Medicaid spending on prescription drugs. In addition, it will give an overview of some of the financial statistics on Medicaid prescription drug spending by the federal government, Florida, and other states. Finally, Part II will detail the new Florida program as well as describe two alternative agreements the state has entered into with pharmaceutical manufacturers Pfizer and Bristol-Myers Squibb.

Part III will analyze the legal, policy, and social arguments for and against the new Florida law. First, it will examine whether the new law is in violation of federal law. Next, it will look at whether the Florida program will indeed save the state money and present an analysis of alternative programs. Finally, the social ramifications of such a program will be examined and compared with those of other alternative programs.

Part IV will recommend, for the immediate future, amending federal and state law to further rein in the costs of pharmaceuticals to state Medicaid programs. For the long-term solution, however, it will urge both state and federal governments to develop incentives for states and pharmaceutical companies to work together on disease management and other innovative, forward-thinking programs.

## **II. Background**

### **A. The Federal Medicaid Statute**

Title XIX of the Social Security Act, the Medicaid Act,<sup>27</sup> was enacted in 1965 to provide medical funds to the “categorically needy.”<sup>28</sup>

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Department of Health and Human Services. See U.S. NEWSWIRE, July 15, 2002, 2002 WL 22069452.

27. 42 U.S.C. § 1396 (2001).

The program is a collaboration between the federal government and state governments, which is financed by both and is administered by the states.<sup>29</sup> Flexible and broad federal guidelines allow states to decide eligible groups, types and range of services, payment levels for services, and administrative procedures.<sup>30</sup> The exact amount of federal funds varies with state income levels.<sup>31</sup>

In 1998, there were approximately 40.6 million beneficiaries of Medicaid services.<sup>32</sup> Of those, about 10.6 million were either aged, blind, or disabled, accounting for approximately twenty-six percent of all beneficiaries.<sup>33</sup> Total Medicaid payments to vendors for all services totaled \$142.3 billion in 1998.<sup>34</sup> A startling \$101 billion was attributed to the aged, blind, and disabled, making up seventy-one percent of the total vendor payments.<sup>35</sup> Although the elderly do not make up the

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28. Elizabeth T. Melady, *Spending Down for Medicaid Eligibility in Section 209(B) States: Should the Procedures Be Changed?*, 1 ELDER L.J. 199, 202 (1993). Effective January 1, 1998, the following levels applied when calculating eligibility under the medically needy and surplus income programs:

TABLE 1  
MEDICAID ELIGIBILITY

Family Size	Monthly Income	Resources
1	\$584	\$3,500
2	\$850	\$5,100
3	\$842	\$5,050
4	\$850	\$5,100
5	\$992	\$5,950
6	\$1,134	\$6,800
7	\$1,275	\$7,650
8	\$1,417	\$8,500

For families larger than eight, one adds \$142 per month in income per person and \$850 in resources per person. The first twenty dollars of monthly income is disregarded per household for aged, blind, or disabled applicants, as is a separate burial fund of up to \$1,500. Douglas J. Chu, *Medicaid for the Elderly, Blind, and Disabled*, in 266 ESTATE PLANNING AND ADMINISTRATION 133, 241 (PLI Tax L. & Estate Planning Course, Handbook Series, 1998).

29. 42 C.F.R. § 430.0 (2001).

30. *Id.*

31. Melady, *supra* note 28, at 203.

32. Health Care Fin. Admin., *Medicaid Beneficiaries and Vendor Payments by Basis of Eligibility of Receipt: Fiscal Year 1998* (R. No. 2082), <http://cms.hhs.gov/Medicaid/msis/2082-98.asp> (last visited Feb. 23, 2003).

33. *Id.*

34. *Id.*

35. *Id.*

majority of Medicaid beneficiaries, they are responsible for the majority of Medicaid expenditures.<sup>36</sup>

Federal law establishes both mandatory services<sup>37</sup> and optional services available to Medicaid patients.<sup>38</sup> Although coverage of prescription drugs is considered optional, if a state adopts a prescription drug program, it must follow federal guidelines.<sup>39</sup> Historically, there have been more limitations on prescription drug programs than on other services.<sup>40</sup> Under the Medicaid Statute, the Health Care Financing Agency (HCFA), the federal agency in charge of Medicaid, must approve all state Medicaid prescription drug programs for compliance with federal rules and guidelines.<sup>41</sup>

#### **B. The Omnibus Budget Reconciliation Acts of 1990 and 1993 and the Mandatory Rebate**

Congress added Section 1927<sup>42</sup> to the Social Security Act when it passed the Omnibus Budget Reconciliation Act<sup>43</sup> (1990 OBRA) in 1990.<sup>44</sup> The 1990 OBRA attempted to reduce \$2.38 billion in Medicaid

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36. *See id.*

37. Mandatory services are: (1) inpatient hospital services, excluding mental institutions; (2) outpatient hospital services; (3) rural health clinic services; (4) federally qualified health center services; (5) laboratory and X-ray services; (6) nursing facility services and home health services, excluding mental institutions for those twenty-one and older; (7) early and periodic screening, diagnosis, and treatment services for those twenty-one years and younger; (8) family planning services and supplies; (9) physician services; and (10) medical and surgical dental devices. Emile L. Loza, *Access to Pharmaceuticals Under Medicaid Managed Care: Federal Law Compiled and State Contracts Compared*, 55 FOOD & DRUG L.J. 449, 456 (2000).

38. 42 U.S.C. § 1396a(a) (2001); *see also* Loza, *supra* note 37, at 456; Carole L. Stewart, *Mandated Medicaid Coverage of Viagra: Raising the Issues of Questionable Priorities, the Need for a Definition of Medical Necessity, and the Politics of Poverty*, 44 LOY. L. REV. 611, 616 (1998).

39. 42 U.S.C. § 1396a(a); *see also* Stewart, *supra* note 38, at 616.

40. David F. Chavkin, *Medicaid and Viagra: Restoring Potency to an Old Program?*, HEALTH MATRIX, Winter 2001, at 199–200.

41. Vernellia Randall et al., *Symposium on Consumer Protection in the Managed Care Mechanism of Consumer Protection—the Marketplace and Regulation Medicaid Managed Care: Section 1115 Medicaid Waivers: Critiquing the State Applications*, 26 SETON HALL L. REV. 1069, 1070–71 (1996). As of July 1, 2001, the Federal Health Care Financing Agency is known as the Centers for Medicare & Medicaid Services (CMS). HCFA, *Acronym List*, at <http://cms.hhs.gov/acronyms/results.asp?Acronym=HCFA> (Jan. 27, 2002).

42. 42 U.S.C. § 1396r-8.

43. Pub. L. No. 101-508, 104 Stat. 1388 (1990).

44. Chavkin, *supra* note 40, at 200.

spending between 1991 and 1995.<sup>45</sup> One key in reducing this spending was the reform of state Medicaid prescription drug programs.<sup>46</sup>

Under the 1990 OBRA, prescription drugs remained an optional service. However, once a state decided to cover prescription drugs, it was now “required to cover all medically necessary prescribed drugs produced by manufacturers with rebate agreements in effect.”<sup>47</sup> This provision created what are frequently referred to as the federal rebates.<sup>48</sup> The 1990 OBRA abolished any form of a state formulary for prescription drugs covered by Medicaid to ensure the success of the federal rebate program and required that state Medicaid programs cover those drugs from manufacturers with rebate agreements unless they were otherwise excluded by federal law.<sup>49</sup> However, the Omnibus Budget Reconciliation Act of 1993<sup>50</sup> (1993 OBRA) again allowed state formularies, but only within specific guidelines, as discussed below in Part III.A.2. In addition, limitations on amount, duration, and scope of coverage were allowed, as well as prior authorization requirements and utilization reviews.<sup>51</sup>

Although the rebates are required by federal law, manufacturers enter into the rebate agreements with the states themselves, not with the federal government.<sup>52</sup> HCFA then approves rebates and the amount of funds to be given to states for reimbursement.<sup>53</sup> Under the

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45. *Id.* at 201.

46. *Id.* In the words of Representative Ron Wyden, the legislation was an effort “to stop the rip-off of the Medicaid program by pharmaceutical manufacturers.” *Id.* at 203–04. Representative Wyden also said “in states which use restrictive formularies, beneficiaries will be given new access to a significant number of prescription drugs for which payment had been prohibited.” *Id.* at 204.

47. *Id.* at 205.

48. *See id.*

49. *Id.* at 206.

50. Pub. L. No. 103-66, 107 Stat. 312 (1993).

51. Chavkin, *supra* note 40, at 207.

52. *Id.*

53. *See* Loza, *supra* note 37, at 463. Several federal and state agencies are involved in the administration and regulation of prescription drug programs. *See id.* at 450–55. The Health Care Financing Administration (HCFA) provides technical assistance to states in the development of language in contracts and establishment of performance standards. *Id.* at 450. The Food and Drug Administration (FDA) regulates the approval and classification of drugs; Medicaid coverage depends on the status of FDA administrative actions and findings under the agency’s Drug Efficacy Study and Implementation program. *Id.* at 451. Sources of federal law that apply to pharmaceuticals are the United States Code, the Code of Federal Regulations, and the State Medicaid Manual, published by the HCFA. *Id.* at 450.

There are private players involved in the Medicaid prescription drug coverage process as well (besides the obvious—pharmaceutical companies). States are increasingly using health maintenance organizations (HMOs) for financing and

1990 OBRA, HCFA can deny matching funds for prescription drugs produced by any manufacturer that has not entered into a rebate agreement with the state.<sup>54</sup> The federal government determines payment and rebate amounts based on three categories, which are dependent upon market availability and approval by the Food and Drug Administration (FDA).<sup>55</sup> These categories are single-source drugs, non-innovator-multiple-source drugs, and innovator-multiple-source drugs.<sup>56</sup>

The inclusion of products in state formularies is dependent upon a pharmaceutical manufacturer's continued compliance with the agreed rebate contracts.<sup>57</sup> Occasionally, under the right circumstances, Medicaid payments can be authorized for single-source or innovator-multiple-source drugs that are not included in a rebate contract.<sup>58</sup> States and manufacturers exchange best price and average manufacturer price information.<sup>59</sup> The basic rebate paid to states for Medicaid use of single-source and innovator-multiple-source drugs is either the difference between state payments and the manufacturer's best price for the numbers of units per dosage and strength per period or a minimum rebate of 15.1% of actual state payments, whichever is greater.<sup>60</sup> The rebate amount for non-innovator-multiple-source drugs is calculated as numbers of units per dosage form and strength times

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delivery of pharmaceuticals to Medicaid patients. *Id.* at 451–52. States also sometimes contract with managed care organizations (MCOs) as fiscal intermediaries and as service providers. *Id.* at 452. MCOs will often subcontract with pharmacy benefit management companies (PBMs), who perform various services including claims processing, drug formulary management, and case management programs. *Id.* at 453.

54. *Id.* at 463.

55. *Id.*

56. *Id.*

Single source drugs are produced or distributed under FDA-approved original new drug applications (NDAs) during the rebate period, i.e., proprietary drugs marketed under original NDAs. Non-innovator multiple source drugs are two or more therapeutically and pharmaceutically equivalent or bio-equivalent drug products, i.e., generic drugs, sold or marketed . . . in the United States during the period . . . by two or more drug manufacturers or labelers. Innovator multiple source drugs are those noninnovator multiple source drugs that also are marketed . . . under original NDAs during the period, i.e., newly approved generic drugs.

*Id.* at 463–64 (internal citations omitted).

57. *Id.* at 464.

58. *Id.*

59. *Id.* at 465.

60. *Id.* at 466.

eleven percent of the average manufacturer price per dosage form and strength.<sup>61</sup>

### C. Prescription Drug Use and Rising Medicaid Expenditures

In a national survey reported by the American Society of Health-System Pharmacists, forty-five percent of the respondents reported taking at least one prescription medication each day, while twenty-eight percent reported taking multiple prescription medications daily.<sup>62</sup> Seventy-nine percent of respondents aged sixty-five and older reported taking at least one prescription medicine a day, eighty-six percent of whom stated it was for a long-term health condition.<sup>63</sup> Eighty percent of those aged sixty-five and older took an average of 2.9 prescription medications in the week before the survey.<sup>64</sup> Respondents from households with the lowest income were more likely to have taken a prescription medication in the past week, with 60.4% of respondents with an income of under \$15,000 annually taking a prescription in the week before the survey.<sup>65</sup>

Between 1994 and 1999, total Medicaid expenditures rose by over \$46.6 billion, from approximately \$137 billion in 1994 to over \$180.9 billion in 1999.<sup>66</sup> The federal share of those expenditures in 1994 was approximately \$78 billion, and \$102 billion in 1999.<sup>67</sup>

Hospitalization costs, which comprise the greatest percentage of all Medicaid expenditures, made up approximately thirty-six percent of all Medicaid expenditures in 1994 at about \$51.8 billion and approximately twenty-five percent of all Medicaid expenditures in 1999, at \$47.6 billion.<sup>68</sup> This represented a decrease in federal and state

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61. *Id.*

62. INTERNATIONAL COMMUNICATIONS RESEARCH, SNAPSHOT OF MEDICATION USE IN THE U.S.: RESEARCH FOR THE AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS (2000), <http://www.ashp.org/pr/snapshot.pdf> (last visited Feb. 23, 2003). One thousand adults took the survey. *Id.*

63. *Id.*

64. *Id.*

65. *Id.*

66. See *Medicaid Expenditures by Category and by Region & State, Total Computable Fiscal Year 1994*, available at <http://cms.hhs.gov/medicaid/mbes/m64.asp> (last modified Aug. 22, 2002) [hereinafter *Medicaid Expenditures FY 1994*]; *Medicaid Expenditures by Category and by Region & State, Total Computable Fiscal Year 1999*, available at <http://cms.hhs.gov/Medicaid/mbes/m64.asp> (last modified Aug. 22, 2002) [hereinafter *Medicaid Expenditures FY 1999*].

67. *Id.*

68. *Medicaid Hospital Expenditures by Type of Service and by State Total Computable Fiscal Year 1994*, available at <http://www.cms.hhs.gov/medicaid/mbes/>

Medicaid hospitalization expenditures of approximately eight percent.<sup>69</sup>

Drug spending is increasing faster than any other component of health care, responsible for forty-four percent of the national increase in health costs in 1998.<sup>70</sup> Even after the 1990 and 1993 OBRA's went into effect, the costs of prescription drugs have continued to skyrocket.<sup>71</sup> In 1994, \$52 billion were spent on prescription drugs, 148 percent more than the \$21 billion in 1985.<sup>72</sup> Medicaid accounted for about seventeen percent of the money spent on drugs in 1994.<sup>73</sup> In that year, drugs accounted for eight percent of all Medicaid expenditures.<sup>74</sup>

Prescription drug coverage is the second most widely utilized benefit in Medicaid.<sup>75</sup> This is due, in great part, to the elderly and disabled population's reliance on pharmaceuticals.<sup>76</sup> In 1998, the elderly and disabled accounted for eighty percent of prescription drug expenditures.<sup>77</sup>

By 1999, Medicaid expenditures on prescription drugs had risen to over \$17 billion, an increase of approximately ninety percent from Medicaid expenditures on prescription drugs in 1994.<sup>78</sup> This too represented an increase in the percentage of total Medicaid expenditures

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m64.asp (last modified Aug. 22, 2002) [hereinafter *Medicaid Hospital Expenditures FY 1994*]; *Medicaid Hospital Expenditures by Type of Service and by State Total Computable Fiscal Year 1999*, available at <http://cms.hhs.gov/medicaid/mbes/m64.asp> (last modified Aug. 22, 2002) [hereinafter *Medicaid Hospital Expenditures FY 1999*].

69. See *Medicaid Hospital Expenditures FY 1994*, *supra* note 68; *Medicaid Hospital Expenditures FY 1999*, *supra* note 68.

70. *Medicaid Prescribed Drug Spending Control Program Annual Report*, Jan. 15, 2001, available at [http://www.state.fl.us/medicaid/prescribed\\_drug/expenditure\\_control\\_program\\_%2661150.pdf](http://www.state.fl.us/medicaid/prescribed_drug/expenditure_control_program_%2661150.pdf) (last visited Jan. 27, 2003) [hereinafter *Florida Medicaid Annual Report*].

71. See Loza, *supra* note 37, at 449.

72. *Id.*

73. *Id.*

74. *Id.*

75. Diane Rowland, *Prescription Drug Benefit for Seniors*, CONG. TESTIMONY, Feb. 15, 2001, available at 2001 WL 2005373, at \*7.

76. *Id.*

77. *Id.*

78. *Medicaid Other Acute Care Expenditures by Service Type, Total Computable Fiscal Year 1999*, available at <http://cms.hhs.gov/medicaid/mbes/m64.asp> (last modified Aug. 22, 2002) [hereinafter *Medicaid Rx Expenditures FY 1999*]; *Medicaid Other Acute Care Expenditures by Service Type, Total Computable Fiscal Year 1994*, available at <http://cms.hhs.gov/medicaid/mbes/m64.asp> (last modified Aug. 22, 2002) [hereinafter *Medicaid Rx Expenditures FY 1994*].

spent on prescription drugs, at almost nine percent.<sup>79</sup> These expenditures were offset by a rebate of approximately \$3.3 billion, representing a savings of 19.5%, to cost a net amount of approximately \$13.7 billion.<sup>80</sup> The five states that spent the most on Medicaid prescription drugs in 1999 were: New York with \$2.08 billion;<sup>81</sup> California with \$2.03 billion;<sup>82</sup> Florida with \$1.07 billion;<sup>83</sup> Texas with \$949 million;<sup>84</sup> and Ohio with \$756 million.<sup>85</sup> Although the rebate percentages remained consistent, the cost of prescription drugs still rose dramatically between 1994 and 1999.<sup>86</sup>

In August 2001, the Office of the Inspector General of the United States Department of Health and Human Services (HHS) issued a report reviewing the pharmacy acquisition costs of brand-name drugs reimbursed under the Medicaid prescription drug program.<sup>87</sup> The memorandum attached to the report explained that most states use the average wholesale price of a drug, less a discount, a percentage that varies from state to state, to reimburse pharmacies for prescriptions.<sup>88</sup> The average discount was a little over ten percent nationally in 1999,<sup>89</sup> although the average discount of the five states that spent the most on prescription drugs was higher, at over twenty percent.<sup>90</sup>

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79. See *id.*; see also *Medicaid Expenditures FY 1999*, *supra* note 66; *Medicaid Expenditures FY 1994*, *supra* note 66; *Medicaid Rx Expenditures FY 1994*, *supra* note 78.

80. See *Medicaid Expenditures FY 1999*, *supra* note 66; *Medicaid Expenditures FY 1994*, *supra* note 66; *Medicaid Rx Expenditures FY 1994*, *supra* note 78; *Medicaid Rx Expenditures 1999*, *supra* note 78.

81. When offset by the rebate of \$356 million, a savings of 17.1%, the net cost was \$1.72 billion. See *Medicaid Rx Expenditures FY 1999*, *supra* note 78.

82. When offset by the rebate of \$533 million, a savings of 26.2%, the net cost was \$1.49 billion. See *id.*

83. When offset by the rebate of \$196 million, a savings of 18.2%, the net cost was \$876 million. See *id.*

84. When offset by a rebate of \$186 million, for a savings of 19.6%, the net cost was \$763 million. See *id.*

85. When offset by a rebate of \$148 million, a savings of 19.6%, the net cost was \$608 million. See *id.*

86. See *Medicaid Rx Expenditures FY 1994*, *supra* note 78; *Medicaid Rx Expenditures FY 1999*, *supra* note 78.

87. DEPARTMENT OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICAID PHARMACY—ACTUAL ACQUISITION COST OF BRAND NAME PRESCRIPTION DRUG PRODUCTS (No. A-06-00-00023, 2001), <http://www.oig.hhs.gov/oas/reports/region6/60000023.pdf> (last visited Feb. 23, 2003) [hereinafter ACTUAL ACQUISITION COST].

88. Memorandum from Michael F. Mangano, Principal Deputy Inspector General, Department of Health and Human Services, to Thomas Scully, Administrator, Centers of Medicare and Medicaid Services (Aug. 10, 2001) (on file with author).

89. *Id.*

90. See *Medicaid Rx Drug Expenditures FY 1999*, *supra*, note 78.

However, HHS believes that drug manufacturers are not giving states a sufficient discount to ensure that a reasonable price is paid for drugs.<sup>91</sup> Further, HHS expressed the “critical need for States to better control the costs of their Medicaid drug program because expenditures are rising at a dramatic rate.”<sup>92</sup> Medicaid drug expenditures increased almost ninety percent from 1994.<sup>93</sup> This increase affected both the federal government’s budget and the states’ budgets.<sup>94</sup> HHS encouraged states to develop reimbursement methods that are more in line with actual drug costs.<sup>95</sup>

The review conducted by HHS drew pricing information from 216 pharmacies in eight states.<sup>96</sup> HHS estimated that nationally the pharmacies’ actual acquisition cost was an average of twenty-two percent below the average wholesale price.<sup>97</sup> HHS further estimated that as much as \$1.08 billion could have been saved if reimbursement had been based on pharmacies’ actual acquisition cost.<sup>98</sup>

#### D. Prescription Drugs and Florida’s Medicaid Program

By the end of fiscal year 2002, Medicaid drug expenditures are expected to approach \$1.87 billion just in Florida.<sup>99</sup> Florida’s Medicaid prescribed drug costs have increased 138% in the past five years from \$609 million in the fiscal year 1996 to an estimated \$1.45 billion in fiscal year 2001.<sup>100</sup> In 2001, Florida spent almost as much on prescription drugs as it did on hospital stays.<sup>101</sup>

The average number of prescriptions per Medicaid-eligible recipient has increased from 12.8 in 1993 to a projected 18.7 in 2002, with the annual drug cost per Medicaid-eligible recipient rising from \$318 in 1993 to a projected \$1,357 in 2002.<sup>102</sup> The average Medicaid cost per

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91. ACTUAL ACQUISITION COST, *supra* note 87.

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. *Florida Medicaid Annual Report*, *supra* note 70.

100. *Id.*

101. The Florida Medicaid program spent \$1.46 billion on hospitalization in fiscal year 2001. *Id.*

102. *Id.*

prescription drug rose from \$24.91 in 1993 to a projected \$72.51 in 2002.<sup>103</sup>

The Florida legislature passed a number of measures, effective in 2002, that attempted to reduce the cost of prescription drugs to the Medicaid program, including the Preferred-Drug List (PDL) rebate program.<sup>104</sup> The Medicaid-prescribed drug budget reduction resulting from the Florida legislation totaled approximately \$243 million.<sup>105</sup>

As discussed in this Note's introduction, Florida had previously passed a law that limited Medicaid patients to four brand-name prescription drugs per month.<sup>106</sup> Patients exceeding this four drug per month limit were required to have their physician obtain prior authorization.<sup>107</sup> The institution of the PDL does not replace this requirement; any brand-name drug on the preferred drug list is still subject to the four drug monthly limit.<sup>108</sup> The statute also requires a telephone response to the request for prior authorization within twenty-four hours after the receipt of the request.<sup>109</sup> In addition, a seventy-two-hour supply is provided in an emergency or when the agency does not provide a response within twenty-four hours.<sup>110</sup>

The new statute refers to the federally mandated rebates of 15.1% of the average manufacturer price for the manufacturer's generic products.<sup>111</sup> If a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a rate below 15.1%, the manufacturer must provide a supplemental rebate to the state to make up the difference.<sup>112</sup>

The new Florida legislation authorizes the state, "pursuant to 42 U.S.C. § 1396r-8," to establish a "preferred drug formulary" and au-

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103. *Id.*

104. FLA. STAT. ch. 409.912(38) (2001 & Supp. 2003). Some of the provisions limited the number of brand-name prescriptions permitted, reduced the pharmacy ingredient payment rate, created a voluntary preferred drug list, mandated use of a secure prescription pad, required prior authorization of certain drugs consistent with FDA guidelines, limited duration of drug therapies, increased rebates for generic drugs, adjusted HMO capitation rates to compensate for lost rebates, created controls and limits on the pharmacy providers network, and performed case management for high utilizing recipients. *Id.*; see also *Florida Medicaid Annual Report*, *supra* note 70.

105. *Florida Medicaid Annual Report*, *supra* note 70.

106. FLA. STAT. ch. 409.912(38)(a)(1) (2001 & Supp. 2003).

107. *Id.*

108. *Id.*

109. *Id.* ch. 409.912(38)(a)(1)(a).

110. *Id.* ch. 409.912(38)(a)(2)(b).

111. *Id.* ch. 409.912(38)(a)(6).

112. *Id.*

thorizes the state to negotiate supplemental rebates from manufacturers in addition to those required by federal law.<sup>113</sup> The statute defines “supplemental rebates” as cash rebates and other program benefits provided at the AHCA’s discretion that offset a Medicaid expenditure.<sup>114</sup> The supplemental rebate can be no less than ten percent of the average manufacturer price unless the federal or supplemental rebate, or a combination of the two, equals or exceeds twenty-five percent.<sup>115</sup> The state agency is authorized to determine whether specific products, brand-name or generic, are competitively priced at lower rebate percentages.<sup>116</sup> An agreement to pay the minimum supplemental rebate percentage will guarantee that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the PDL; however, this does not guarantee actual placement on the list.<sup>117</sup> The AHCA makes decisions based on the clinical efficacy of the drug, the recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, and the price of competing products with federal and state rebates.<sup>118</sup> The Medicaid Pharmaceutical and Therapeutics Committee is appointed by the governor and is comprised of five doctors, five pharmacists, and a university professor, who act as an advisory committee for the PDL.<sup>119</sup> In addition, the Florida statute authorizes the state to contract with private firms to negotiate the rebates with pharmaceutical manufacturers.<sup>120</sup> The plan has been approved by HHS.<sup>121</sup>

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113. *Id.* ch. 409.912(38)(a)(7).

114. *Id.*

Such other program benefits may include, but are not limited to, disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments with guaranteed savings to the Medicaid program in the same year the rebate reduction is included in the General Appropriations act.

*Id.*

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.*

119. Joni James, *Florida Governor Picks Doctors, Pharmacists for Panel Concerning Drug Costs*, KNIGHT-RIDDER TRIB. BUS. NEWS, Aug. 23, 2001, available at 2001 WL 26627178, at \*1.

120. FLA. STAT. ch. 409.912(38)(a)(7) (2001).

121. Robert Pear, *Drug Cost Program Gets U.S. Approval*, TIMES UNION ALBANY, Sept. 19, 2001, at A5.

Pfizer and Bristol-Myers Squibb have already entered into agreements with the State of Florida not to pay cash rebates and to get all of their drugs on the formulary.<sup>122</sup> Before the law was even passed, Pfizer representatives approached state health officials with the idea of substituting such services as disease management initiatives, public health education, and free drugs in exchange for the cash rebates.<sup>123</sup> Under Pfizer's agreement, signed shortly after the new Florida law was passed, the company plans to train doctors, nurses, and other health care providers in addition to instituting new education programs at some preselected community health centers and paying up to sixty case representatives to work with Medicaid recipients who have asthma, congestive heart failure, and hypertension.<sup>124</sup> Pfizer has guaranteed the state a savings of \$33 million over two years; if the goal is not met, the company has promised to pay the state "about double" what it would have had to pay in cash rebates.<sup>125</sup>

Bristol-Myers Squibb entered into a similar agreement with Florida.<sup>126</sup> The company agreed to set up two disease management programs.<sup>127</sup> In one, Bristol-Myers Squibb will pay health professionals and social workers to serve Hispanic and African American Medicaid patients suffering from depression and HIV/AIDS and patients with breast, cervical, and lung cancer in order to improve compliance with health regimens such as taking drugs as prescribed.<sup>128</sup> The other plan is for the company to fund the hiring and training of community residents to assist in overcoming language and cultural barriers that prevent many Medicaid patients from getting access to needed care.<sup>129</sup> Bristol-Myers Squibb has guaranteed that it will save the state \$16.3 million over two years or pay the state the balance of the cash rebate.<sup>130</sup>

The rationale behind both manufacturers' programs is that this care will prevent emergency room trips and hospitalizations.<sup>131</sup> Cur-

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122. Russell Gold, *Bristol-Myers Signs Florida Deal for Medicaid Health Initiatives*, WALL ST. J., Sept. 6, 2001, at B2; *Inside the Industry*, *supra* note 15.

123. Editorial, *Secrecy Is Troubling*, S. FLA. SUN-SENTINEL, June 29, 2001, at 24A.

124. *Id.*

125. *Inside the Industry*, *supra* note 15.

126. Gold, *supra* note 122.

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.*

131. *Id.*

rently, Florida is negotiating with other manufacturers for alternatives to supplemental rebates; however, the more agreements there are, the more difficult it becomes for manufacturers to come up with innovative plans that do not duplicate others already in effect.<sup>132</sup>

#### **E. Other States' Programs to Reduce the Cost of Medicaid Prescription Drugs**

Florida is not the only state battling high Medicaid prescription drug costs.<sup>133</sup> Connecticut has attempted to pass legislation similar to the rebate negotiation program passed in Florida, but has failed; Hawaii has legislation still pending.<sup>134</sup> Some states are engaging in bulk purchasing to achieve greater price discounts for all eligible groups.<sup>135</sup> These bills authorize the states to join a multistate or multigovernmental purchasing consortium for pharmaceuticals and other medical supplies.<sup>136</sup> Arkansas, Colorado, Idaho, Louisiana, New Mexico, Oregon, Pennsylvania, Rhode Island, Texas, Washington, West Virginia, and Wyoming have bills passed or pending for bulk purchasing.<sup>137</sup> Many other states have passed or attempted to pass legislation that attempts to impose price controls or state maximum prices on prescriptions.<sup>138</sup> Alabama, Arizona, Arkansas, Hawaii, New Mexico, New York, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Virginia, Colorado, Connecticut, Louisiana, Massachusetts, and Wyoming have a form of this legislation which has passed or is pending.<sup>139</sup>

The state legislative sessions of 2001 and 2002 have produced laws in eleven other states creating Medicaid rebate programs similar to Florida's.<sup>140</sup> Louisiana, Michigan, Hawaii, Illinois, Minnesota, Mississippi, New Mexico, North Carolina, Ohio, Vermont, and West Vir-

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132. *Bristol-Myers Follows Pfizer with Fla. Medicaid Pact*, DRUG TOPICS, Sept. 17, 2001, at 5.

133. *See infra* Part II.C.

134. NAT'L CONFERENCE OF STATE LEGISLATURES, 2001 PRESCRIPTION DRUG DISCOUNT, BULK PURCHASING, AND PRICE-RELATED LEGISLATION (2002), <http://www.nslc.org/programs/health/drugdisc.01.htm> (last updated Oct. 18, 2002).

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.*

139. *Id.*

140. *See Janelle Carter, Drug Makers Sue over State Lists; Medicaid Policy Aims to Curb Costs*, S. FLA. SUN-SENTINEL, July 2, 2002, at 3A.

ginia all have rebate programs on the books.<sup>141</sup> At the time of this writing, litigation is pending over the Michigan program in state and federal district courts in Washington, D.C.<sup>142</sup> This litigation may also determine whether states may mandate rebates from drug manufacturers in order to be on a Medicaid preferred-drug list.

### III. Analysis

#### A. Supplementary Rebate Programs

A state-created supplementary rebate program, in and of itself, is likely permissible under the federal Medicaid statute. A state may create its own rebate program subject to the approval of the Secretary of HCFA.<sup>143</sup> The program in Florida did not acquire such approval.<sup>144</sup> However, the program claims not to supplant, but to supplement, the federal rebate program.<sup>145</sup> There is nothing in the federal Medicaid statute that either authorizes or prohibits a state-created supplementary rebate program.<sup>146</sup>

State action may be foreclosed by express language in a congressional enactment, by implication from the depth and breadth of a

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141. *Id.*

142. U.S. NEWSWIRE, July 15, 2002, 2002 WL 22069452, at \*1. While not directly related to Medicaid PDL programs, a Maine program to curb the costs of pharmaceuticals has been getting a lot of legal attention. The "Healthy Maine" program requires pharmaceutical manufacturers to extend the discounts given to the state for Medicaid patients to a state program for patients with slightly higher incomes than the "categorically needy." Garry Boulard, *The War on Drug Prices: States Are Taking up the Fight to Reduce Prescription Drug Costs*, STATE LEGISLATURES, Mar. 1, 2002, at 12; *see also* Chu, *supra* note 28. The First Circuit has upheld the program, and the U.S. Supreme Court has granted certiorari, but has not yet heard the case. *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001), *cert. granted*, No. 01-188, 2002 WL 1393606 (U.S. June 28). Meanwhile, PhRMA challenged the federal government's approval of the program in a Washington, D.C. District Court, and in March 2002, a federal judge dismissed that case. *Pharm. Research & Mfrs. of Am. v. Thompson*, 2002 WL 262037 (D.D.C. 2002), *petition for cert. filed*, 70 U.S.L.W. 3092 (U.S. July 31, 2001). *See United States Supreme Court Docket*, available at <http://www.supremecourtus.gov/docket/01-188.htm> (last visited Feb. 23, 2003). For a more detailed explanation and analysis of the Maine program, see generally Conrad J. Barrington, *Pharmaceutical Research and Manufacturers of America v. Concannon and Maine's Prescription Drug Rebate Statute: A Twenty-First Century Solution to the Medicaid Crisis*, 23 WHITTIER L. REV. 1127 (2002).

143. 42 U.S.C. § 1396r-8(a)(4) (2001).

144. *Pharm. Research & Mfrs. of Am. v. Medows*, 184 F. Supp. 2d at 1191 (N.D. Fla. 2001).

145. *See* FLA. STAT. ch. 409.912(38)(a)(1)(a)(7) (2001 & Supp. 2003).

146. *See generally* 42 U.S.C. §1396r-8.

congressional scheme that occupies the legislative field, or by implication because of a conflict with a congressional enactment.<sup>147</sup>

There is no express language in the federal Medicaid statute regarding state-created supplementary rebate programs.<sup>148</sup> Nor does the breadth of the statute contemplate the prospect of such programs.<sup>149</sup> In addition, courts have traditionally given states much leeway in defining the scope of their Medicaid programs.<sup>150</sup> Therefore, a state-created rebate program, in and of itself, seems not to conflict with federal law.

## **B. Preferred Drug List**

### **1. FORMULARY REQUIREMENTS**

The more complex issue is whether a preferred-drug list, contingent upon compliance with a supplementary state rebate program, like the one in Florida, violates federal Medicaid law because it does not meet the requirements states must follow in creating a formulary. Under the federal Medicaid statute, a state may establish a formulary if it meets certain requirements.<sup>151</sup> The formulary must be developed by a committee of physicians, pharmacists, and other “appropriate” individuals appointed by the governor.<sup>152</sup> The formulary must include all covered outpatient drugs of any manufacturer who has entered into a rebate with the federal government, except those drugs that do not have a “significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment.”<sup>153</sup>

The Florida law creates a Medicaid Pharmaceutical and Therapeutics Committee (the Committee), which is comprised of eleven members appointed by the governor.<sup>154</sup> Four members are physicians, five members are pharmacists, one is a consumer representative, and one member represents the interests of pharmaceutical manufactur-

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147. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001) (citations omitted).

148. *See generally* 42 U.S.C. § 1396r-8.

149. *See generally id.*

150. *See Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 72–74 (1st Cir. 2001); *Fla. Ass’n of Rehab. Facilities v. Fla. Dep’t of Health & Rehab. Servs.*, 225 F.3d 1208, 1211 (11th Cir. 2000).

151. 42 U.S.C. § 1396r-8(d)(4).

152. *Id.*

153. *Id.*

154. FLA. STAT. ch. 409.91195 (2001 & Supp. 2003).

ers.<sup>155</sup> One of the stated purposes of the Committee is to create a preferred drug list based on medical effectiveness and cost savings.<sup>156</sup> The Committee meets all requirements of federal law to create a Medicaid prescription drug formulary.<sup>157</sup>

The same legislation authorizes the Florida AHCA to establish a preferred drug formulary in accordance with 42 U.S.C. § 1396r-8.<sup>158</sup> “[P]ursuant to the establishment of such formulary, it is authorized to negotiate supplemental rebates . . . at no less than 10 percent of the average manufacturer price.”<sup>159</sup> If a manufacturer agrees to pay the minimum supplemental rebate percentage, it guarantees the manufacturer that the Committee will consider a product for inclusion on the PDL.<sup>160</sup> This guarantees consideration for placement on the PDL, but not actual placement, and only drugs that comply with the supplemental rebate provisions will be considered.<sup>161</sup> The final decision for inclusion on the PDL is determined by the clinical efficacy of the drug, recommendations by the Committee, and the price of competing products.<sup>162</sup>

The language of the Florida statute calls for the establishment of a formulary contingent upon a manufacturer giving the state a rebate. The statute clearly shows the legislative intent that the PDL operate as a formulary. The PDL is even called a “formulary” several times within the statute.<sup>163</sup> Moreover, part of the stated purpose in the creation of the Committee was to establish a preferred drug list,<sup>164</sup> the federal Medicaid statute requires the creation of such a committee when

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155. *Id.* ch. 409.91195(1).

156. *Id.* ch. 409.91195. This is also referred to as a “preferred drug formulary” within the same section. *Id.*

Upon recommendation of the Medicaid Pharmaceutical and Therapeutics Committee, the agency shall adopt a preferred drug list. To the extent feasible, the committee shall review all drug classes included in the formulary at least every 12 months, and may recommend additions to and deletions from the formulary, such that the formulary provides for medically appropriate drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.

*Id.* ch. 409.91195(4).

157. *See* 42 U.S.C. § 1396r-8(d)(4).

158. FLA. STAT. ch. 409.912(38)(a)(7).

159. *Id.*

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.*

164. *Id.* ch. 409.91195(4).

a state establishes a formulary;<sup>165</sup> and the Committee meets the federal Medicaid statute's requirements for a Medicaid Pharmaceutical and Therapeutics Committee created to establish a formulary.<sup>166</sup> The explicit language of the Florida statute calls for the establishment of a formulary in accordance with 42 U.S.C. § 1396r-8, the section of the Medicaid statute that regulates creation of formularies.<sup>167</sup>

Although the PDL complies with all of the formal requirements for state formularies, it has one fatal flaw: inclusion on it is not based on clinical efficacy. A logical reading of the language of the Florida statute, "pursuant to the establishment of such formulary, [the agency] is authorized to negotiate supplemental rebates,"<sup>168</sup> renders the understanding that inclusion on the formulary is contingent upon entry by the manufacturer into a rebate agreement with the Florida AHCA. Although other factors, such as medical efficacy, are also considered in the determination of whether the drug is placed on the PDL,<sup>169</sup> federal law clearly states that a covered drug<sup>170</sup> may be excluded "only if . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage."<sup>171</sup> Exclusion from a formulary can only be made for lack of clinical effectiveness. Failure to enter into a rebate agreement with a state agency clearly has nothing to do with clinical effectiveness. Exclusion from a formulary for not entering into a rebate with a state is plainly contrary to federal law.

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165. 42 U.S.C. § 1396r-8(d)(4) (2001).

166. *Id.*

167. 2001 Fla. Laws ch. 2001-104; FLA. STAT. ch. 409.912(38)(a)(7) (2001 & Supp. 2003).

168. FLA STAT. ch. 409.912(38)(a)(7).

169. *Id.*

However, a pharmaceutical manufacturer is not guaranteed placement on the formulary by simply paying the minimum supplementary rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates.

*Id.*

170. 42 U.S.C. § 1396r-8(k)(2) (2001). Generally, "covered" drugs include those drugs which have been approved on the federal Medicaid formulary. *See id.*; *see also id.* § 1396d(a)(12). In order to be included on the federal Medicaid formulary, and therefore any state formulary, the manufacturer must have entered into a rebate agreement, discussed *supra* Part II.B, with the federal Medicaid program. *See id.* § 1396r-8(a)(1).

171. *Id.* § 1396r-8(d)(4)(C) (emphasis added).

## 2. PRIOR AUTHORIZATION REQUIREMENTS

The U.S. District Court for the Northern District of Florida in Tallahassee, as well as the Eleventh Circuit Court of Appeals, had another view, and interpreted the statute differently.<sup>172</sup> The district court found that the Florida statute does not “authorize the creation of a ‘formulary’ as that term is used in the federal Medicaid law,” but calls for the creation of a “preferred drug list” and a “‘prior authorization program’ expressly permitted by the federal Medicaid law.”<sup>173</sup> The court contended that because the terms “preferred drug list” and “preferred drug formulary” are used interchangeably, the choice of words holds little weight.<sup>174</sup>

The courts held that the Florida program more closely resembled a “prior authorization” program than a formulary.<sup>175</sup> Federal law permits a “prior authorization” program, which requires, “as a condition of coverage or payment for a covered outpatient drug[,] . . . the approval of the drug before its dispensing for any medically accepted indication.”<sup>176</sup> Under the federal Medicaid law, “[a] State may subject to prior authorization any covered outpatient drug.”<sup>177</sup> The prior authorization program must provide a “response by telephone or other telecommunication device,” within twenty-four hours of the request and provide for the dispensing of at least a seventy-two-hour supply of “a covered outpatient prescription drug in an emergency situation.”<sup>178</sup> The sections of Florida law that authorize the creation of a PDL and the Committee do not provide these safeguards.<sup>179</sup> However, the section that authorizes a four-brand-name limit per month, as discussed above in Part II.D, does comply with the federal prior authorization requirements for drugs which exceed the limit.<sup>180</sup> In the implementation of the program, the Florida AHCA claims that prior

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172. *Pharm. Research & Mfrs. of Am. v. Medows*, 184 F. Supp. 2d 1186 (N.D. Fla. 2001).

173. *Id.* at 1188.

174. *Id.* at 1195.

175. *Id.*

176. 42 U.S.C. § 1396r-8(d)(5) (2001).

177. *Id.* § 1396r-8(d)(1)(A).

178. *Id.* § 1396r-8(d)(5)(A), (B) (2001). An “emergency situation” is defined by the Secretary. *Id.* § 1396r-8(d)(5)(B).

179. See FLA. STAT. ch. 409.912(38)(a)(7) (2001 & Supp. 2003); see also *id.* ch. 409.91195.

180. *Id.* ch. 409.912(37)(a)(1).

authorization for drugs not on the PDL is automatic and that this is why the statutory language is missing.<sup>181</sup>

Although it is clear that, generally, a prior authorization program is acceptable under federal law, it is not clear that the Florida legislature intended such a program. Even if they did, the program fails to guarantee statutory safeguards necessary under a prior authorization program. In the section that deals with the PDL, there is no mention of a “prior authorization” program. In addition, the required safeguards of a prior authorization program are not included in that section.

Under the Tallahassee district court’s analysis, a program allowing some drugs to be obtained through a preferred drug list, with the drugs not included on the list to be obtained through prior authorization, is a “prior authorization” program.<sup>182</sup> However, such an interpretation would allow any state-created formulary to mask itself as a “prior authorization” program in order to bypass federal restrictions and would render useless the federal Medicaid provision regarding creation of state formularies. It is unlikely this was the intent of Congress.

The legislative history regarding state Medicaid formularies reinforces this view. Cost control by way of restrictive state formularies is not new to Medicaid.<sup>183</sup> By 1990, at least nineteen states had established “restricted” or “closed” formularies for prescription drugs under the Medicaid program.<sup>184</sup> In 1990, with OBRA, Congress abolished restrictive state Medicaid drug formularies at the same time it adopted its own rebate program.<sup>185</sup> In the 1993 OBRA, Congress again gave states the power to establish formularies, but also added the present restrictions on the creation of such formularies.<sup>186</sup> This demon-

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181. *Pharm. Research & Mfrs. of Am. v. Medows*, 184 F. Supp. 2d 1186, 1195 (N.D. Fla. 2001). “Automatic” approval is not provided for in the Florida statute. See FLA. STAT. chs. 409.912(37)(a)(7), .91195, .912(37)(a)(1) (2001).

182. *Medows*, 184 F. Supp. 2d at 1195.

183. See *Medicaid Prescription Drug Pricing: Hearing on S. 2605 and S. 3029 Before the Subcomm. on Health for Families & the Uninsured of the Senate Comm. on Fin.*, 101st Cong. 26 (1990) [hereinafter 1990 Senate Hearing].

184. 1990 Senate Hearing, *supra* note 183, at 254; Senate Comm. on Fin., *Explanatory Material Concerning 1990 Reconciliation Submission*, 136 CONG. REC. 515629–04, 515658 (1990), 1990 WL 158328.

185. 42 U.S.C. §§ 1396a(a)(54), 1396r-8(a)(1) (2001).

186. *Id.* § 1396r-8(d)(4); see *Medicare and Medicaid Budget Reconciliation: Hearings Before the Subcomm. on Health & the Env’t of the House Comm. on Energy & Commerce*, 103d Cong. 453 (1993) (statement of Rep. Waxman) (arguing that the new legislation should prevent the states from undermining OBRA’s guarantee of patient ac-

strates that Congress fully contemplated action by states to create lists of covered drugs and intended to regulate such behavior closely. In addition, by initially taking away the power of the states to create their own formularies and then amending the statute to allow only the creation of a formulary based on the medical efficacy of different drugs, Congress clearly intended to maintain control over such formularies. It did not intend to allow creation of formularies under the name “prior authorization” programs and to circumvent the law regarding Medicaid formularies. Although federal courts have traditionally given the states broad latitude in defining the scope of covered services,<sup>187</sup> a formulary program predicated on rebates to states is in conflict with federal law.

Essentially, the Florida law is attempting to devise a formulary with a prior authorization program. The Florida law follows the federal Medicaid guidelines for state formularies exactly, except in one very important way: inclusion on the PDL is contingent on a rebate given to the state, not on medical efficacy. Prior authorization requires certain safeguards: to provide a telephone response within twenty-four hours and to provide a seventy-two-hour medical supply. These safeguards are not in the statute, so even if this was a prior authorization program, it is invalid for this reason alone. Although Florida may claim approval is automatic, nothing in the law requires the approval to be automatic. Florida is attempting to gain from the economic benefits of the federal formulary and prior authorization programs without providing any of the mandated safeguards. Congress did not intend for states to have this much power over their Medicaid programs.

### C. Policy Issues

Even if PDL programs like Florida’s are never invalidated by the courts, they raise many other policy and social issues. Such programs raise questions about their effectiveness as cost-saving programs,

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cess to prescription drugs and protections for those manufacturers who had entered into rebate agreements with the federal government); *see also* SENATE COMM. ON THE BUDGET, 103D CONG., RECONCILIATION SUBMISSIONS OF THE INSTRUCTED COMMITTEES PURSUANT TO THE CURRENT RESOLUTION ON THE BUDGET 139–40 (Comm. Print 1993), H.R. CONF. REP. NO. 213, 103-61, at 213 (1993).

187. *See* Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 72–74 (1st Cir. 2001); Fla. Ass’n of Rehab. Facilities, Inc. v. Fla. Dep’t of Health & Rehab. Servs., 225 F.3d 1208, 1211 (11th Cir. 2000).

about their effect in preventing access to needed drugs, and about the viability of alternatives.

As discussed earlier, Medicaid expenditures have risen dramatically in the last decade.<sup>188</sup> This has been due in great part to the rising costs of prescription drugs.<sup>189</sup> Although this presents an obvious need for reform of prescription drug spending by state Medicaid programs, it is not clear whether a preferred drug list is the best way to achieve this.

Rising prescription costs have also been a source of concern for private insurance companies.<sup>190</sup> Prescription drugs used to account for a much smaller percentage of health care costs.<sup>191</sup> However, this has changed and expenditures for prescription pharmaceuticals are increasing at a faster rate than any other component in private health care.<sup>192</sup> In the private sector, most pharmaceuticals are sold through health maintenance organizations (HMOs), which in turn usually leave the management of prescription drug purchasing to pharmacy benefit managers (PBMs).<sup>193</sup> PBMs represent a very large portion of the market for prescription drugs.<sup>194</sup> These organizations also use formularies, which are the lists of drugs that the PBMs "prefer." They use various incentives to get doctors to prescribe drugs on the formulary, ranging from a requirement that doctors prescribe those drugs or risk being dropped from the plan to the requirement that patients make a higher co-payment for drugs not on the formulary.<sup>195</sup> Because of the large market share the PBMs hold, pharmaceutical manufacturers want to make sure their products are on the HMO's formulary, in order for PBMs to get significant price discounts on many drugs.<sup>196</sup>

State Medicaid formularies follow the same principles. Due to their large market share of purchasers of prescription drugs, the logic is that they also should be able to have some leverage with pharmaceutical companies to negotiate discounts like the HMOs and PBMs

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188. See *infra* Part II.C.

189. See BRIAN K. BRUEN, KAISER COMM'N ON MEDICAID & THE UNINSURED, STATES STRIVE TO LIMIT MEDICAID EXPENDITURES FOR PRESCRIBED DRUGS 1 (2002), <http://www.kff.org/content/2002/4030> (last visited Feb. 23, 2003).

190. See Andrew S. Krulwich, *The Response to Health Care Reform by the Pharmaceutical Industry*, 50 FOOD & DRUG L.J. 1 (1995).

191. *Id.*

192. *Id.*

193. *Id.* at 2.

194. *Id.*

195. *Id.*

196. *Id.* at 3.

do. However, many Medicaid beneficiary advocate groups object to this, arguing that those in the private market have more means and information to purchase drugs not on a formulary than Medicaid beneficiaries.<sup>197</sup>

In addition, the private formulary system is not without criticism. First of all, there are concerns about delays and denials in needed care. Many find that they cannot get needed drugs within a reasonable time frame.<sup>198</sup> In addition, formularies often cause confusion among patients about what is covered and what is not.<sup>199</sup> When beneficiaries are denied prescription coverage by the pharmacy, many do not know to contact their doctor to get prior authorization, and they see their choice as to either pay for the drugs themselves or do without the medication.<sup>200</sup>

These problems will likely be accentuated with Medicaid beneficiaries. First, they are typically less educated than HMO clients.<sup>201</sup> Studies of Medicaid managed-care programs have revealed patients have a difficult time understanding changes in their Medicaid services.<sup>202</sup> In addition, many Medicaid beneficiaries do not speak English, presenting another hindrance in understanding how a PDL works.<sup>203</sup> Also, because their income is significantly lower than HMO participants, they are less likely to be able to pay for the prescription drug, and it is more probable they will leave the pharmacy without the needed drug if they are refused coverage.<sup>204</sup>

In fact, PDLs or formularies may increase costs. The Medicaid population is, in general, a sicker population.<sup>205</sup> Thus, when Medicaid beneficiaries do not get needed prescription drugs, it is more likely

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197. CATHY BERNASEK ET AL., KAISER COMMUN ON MEDICAID & THE UNINSURED, FLORIDA'S MEDICAID PRESCRIPTION DRUG BENEFIT: A CASE STUDY (2002), <http://www.kff.org/content/2002/20020213/4031b.pdf> (last visited Feb. 23, 2003).

198. See *New Jersey Rule Adoptions*, STATE REG. ALERT, Jan. 2, 2001, 2001 WL 735035, at \*34-35.

199. See *id.*

200. See *id.*

201. See *Making Sense of Medicaid Managed Care*, TRUSTEE, 2001 WL 10488954, at \*1.

202. See *id.*

203. *Id.*; see also BERNASEK ET AL., *supra* note 197, at 22.

204. Groeller, *supra* note 1.

205. See Teresa A. Coughlin et al., *Commercial Health Plan Participation in Medicaid Managed Care: An Examination of Six Markets*, 38 INQUIRY 22, 34, 2001 WL 222839249, at \*11; Larry Wheeler, *States Watching Florida Drug Controls*, GANNETT NEWS SERV., Feb. 7, 2002, 2002 WL 5256029, at \*1.

they will have to be hospitalized.<sup>206</sup> Hospitalization costs still make up the largest percentage of state Medicaid expenditures.<sup>207</sup> If hospitalization costs go up as a result of less Medicaid beneficiaries getting the drugs they need, it would impose a great burden on the Medicaid program—possibly greater than if no cuts were made to the prescription drug programs.

In addition to the effect on Medicaid beneficiaries, a Medicaid formulary also imposes burdens on others. To handle additional prior authorizations, the state must set in place a system to process requests. Without such a system, there is less chance that beneficiaries will be able to obtain, in a timely manner, the medications requested for prior authorization.

There are also increased administrative costs for doctors and pharmacists. There is no set program in place to educate Medicaid beneficiaries about the PDL.<sup>208</sup> Medicaid patients will not know how to use available services without a communications and education strategy.<sup>209</sup> With doctors and pharmacists having the most direct contact with patients, they will likely be left to educate Medicaid beneficiaries about changes in prescription drug coverage.<sup>210</sup> Also, the new program will inevitably lead to another increase in paperwork and phone calls—extra time doctors and pharmacists will not necessarily be willing to spend. Finally, many claim that demanding discounts from pharmaceutical manufacturers will inhibit creativity by limiting the money available for research for new, innovative drugs.<sup>211</sup>

Unfortunately, there are not many attractive alternatives to a PDL. If the state programs stay as they are, then they will surely go bankrupt. A few states have already imposed a brand-name drug limit like that in Florida.<sup>212</sup> Another option is to decrease the dispensing fees for pharmacies, but this has been met with much opposition (as might be expected) from pharmacists, and may be why they are in

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206. *See id.*

207. *See, e.g., Medicaid Rx Drug Expenditures FY 1999, supra note 78.*

208. BERNASEK ET AL., *supra* note 197, at 22.

209. *Id.*; *see also Making Sense of Managed Care, supra note 201, at \*2.*

210. BERNASEK ET AL., *supra* note 197, at 22.

211. *Medicare Prescription Drug Benefit: Hearing Before the Senate Comm. on Fin., 106th Cong. (2000)* (statement of Sen. Bill Frist, M.D. (R-TN)).

212. *See, e.g.,* ARK. CODE ANN. § 20-77.101 (Michie 2001); ME. REV. STAT. tit. 22, § 3173-C (1992).

support of a preferred-drug list.<sup>213</sup> In addition, reduced fees for pharmacies may end up effectively restricting access to Medicaid beneficiaries because pharmacies may refuse to dispense Medicaid drugs.<sup>214</sup> Another alternative is changing Medicaid eligibility standards or otherwise limiting enrollment. Florida has already passed a recent law reducing eligibility by \$14 per month.<sup>215</sup> Over five thousand people were dropped from Medicaid coverage.<sup>216</sup> It is likely these people have no other way to get needed prescription drugs, and further decreases in eligibility will only compound the problem.

Some states have proposed legislation for cooperative buying agreements between states in order to achieve better market share.<sup>217</sup> The only such program to go into effect so far is one between Maine, Vermont, and New Hampshire.<sup>218</sup> Instead of using a formulary, these states use their combined strength to give them greater negotiating power when buying prescription drugs from pharmaceutical companies. It appears to be a better option than a formulary based on rebates because this approach puts no limits on the prescribing power of doctors and, if successful, saves the states money.

Another possible solution is to target the underlying cost producer and decrease the market price for pharmaceuticals by encouraging competition. Many in Congress are looking for reform of current patent law.<sup>219</sup> The Hatch-Waxman Act, enacted in 1984, limited the duration of patents for prescription drugs to allow creation of generics, thus lowering the market price for prescription drugs.<sup>220</sup> Prescrip-

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213. BERNASEK ET AL., *supra* note 197, at 12; Rebecca Cook, *Pharmacy Groups, States Face Off over Medicaid*, FORT WORTH STAR-TELEGRAM, Mar. 12, 2002, 2002 WL 15684525, at \*1; see also Mark Niquette, *Medicaid Cuts Mean Closings, Pharmacies Say*, COLUMBUS DISPATCH, Mar. 13, 2002, at 1A; Jeremy Olson, *Proposed Medicaid Cuts Concern Pharmacists—Plans to Trim State Budget Could Force Independent Stores to Close*, OMAHA WORLD HERALD, Mar. 12, 2002, at 8B.

214. Cook, *supra* note 213.

215. David Damron, *Florida Medicaid Plan Drops Thousands of Elderly and Disabled; A Change in Eligibility, Made to Save up to \$63.3 Million in the State's Nearly \$10 Billion Medical-Aid Plan Budget, "Hit Some People Hard,"* ORLANDO SENTINEL, July 18, 2002, at A1.

216. *Id.*

217. *Prescription Drug Coverage, The Uninsured Top 10 Agendas of State Legislatures, BCBSA's Annual States Report Released*, U.S. NEWSWIRE, Feb. 14, 2002, at 2002 WL 4574412, at \*2.

218. *Id.*

219. Naomi Aoki, *Governors May Seek Wider Use of Generics—Drug Firms Say '84 Law Needs No Alteration*, BOSTON GLOBE, Feb. 23, 2002, at C1.

220. See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§ 156, 271, 282 (1984)).

tion drug companies have found a loophole in the law, which allows the manufacturers to extend patents.<sup>221</sup> That way, they can keep the patent on the drug current, and eliminate competition from generics, thus keeping prices high.<sup>222</sup> So far, reform of the Act has been unsuccessful.<sup>223</sup> As with any decrease in intellectual property protection, pharmaceutical industry advocates claim that this would stifle creativity and research, and the overall progress of medicine.<sup>224</sup> However, reform of the Hatch-Waxman Act would assist state Medicaid programs greatly to reduce the prices they pay for pharmaceuticals, as well as increase access to prescription drugs.

#### IV. Recommendation

Although a formulary masked as a “prior authorization program” conflicts with current federal Medicaid law, there is a definite need for curtailment of the enormous costs prescription drugs impose on state Medicaid programs. As noted in Part II.C, above, the cost of prescription drugs has skyrocketed in the last two decades. In addition, many states are facing a budget crisis.<sup>225</sup>

The elderly and disabled cost the state Medicaid programs the most money for prescription drugs.<sup>226</sup> It is estimated that in 2020, fifty-four million Americans will be sixty-five or older, and that number will grow to ninety million by 2060.<sup>227</sup> This will create a heavier

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221. Aoki, *supra* note 219.

222. *Id.*

223. *Id.*

224. *Id.*; see also *U.S. Governors/Business Group Clashes with PhRMA over Hatch-Waxman Reform*, MARKETLETTER, Mar. 4, 2002, 2002 WL 7178366.

225. See, e.g., Brian E. Crowley, *Budget Crisis Mirrors 1991 Economic Crunch*, PALM BEACH POST, Oct. 16, 2001, at 17A (discussing Florida’s budget crisis); Aaron Deslatte, *Opinions Differ on Cause of Money Crunch*, NEWS-LEADER, Jan. 25, 2002, at 2 (discussing Missouri’s budget problems); Keith Richman, *Governor’s Budget Bodes Ill for State’s Future*, L.A. DAILY NEWS, Jan. 25, 2002, at N19 (discussing California’s budget crisis); *Running in an Altered State*, PORTLAND OREGONIAN, Feb. 4, 2002, at C6 (discussing Oregon’s budget crisis); Mark Schreiner, *Ballantine Speaks Out on Budget Crisis*, MORNING STAR, Aug. 25, 2001, at 1A, 4A (discussing North Carolina’s budget crisis); Yvette Shields, *Illinois Budget Official: Curb Spending or Face Fiscal Crisis*, BOND BUYER, Mar. 4, 2002, at 48 (discussing Illinois’s budget problems); Ralph Thomas & Andrew Garber, *Budget Crisis: Locke Makes Hard Choices: Jobs, Programs, Face Elimination as Part of \$566 Million in Cuts*, SEATTLE TIMES, Dec. 19, 2001, at A1 (discussing Washington’s budget crisis); David G. Tuerck, *Budget Crisis Is a Looking-Glass War*, BOSTON HERALD, Nov. 15, 2001, at 37 (discussing Massachusetts’s budget crisis).

226. Rowland, *supra* note 75.

227. Christine L. Himes, *Elderly Americans*, POPULATION BULL., Dec. 1, 2001, at 3.

burden on the Medicaid system. In addition, because the costs of prescription drugs are so high, Congress and many state legislatures are trying to pass bills to provide a prescription drug benefit to a greater percentage of elderly people.<sup>228</sup> If this is to be accomplished, it almost surely will take money away from Medicaid. Medicaid needs serious reform. Next to hospitalization, prescription drug costs account for the greatest percentage of state Medicaid expenditures. Unlike hospitalization costs, prescription drug costs can be easily isolated and targeted. Therefore, because of expense and the ease in cost analysis, reform will need to start with pharmaceuticals.

It is obvious that something further needs to be done to keep Medicaid budgets under control, but programs such as those in Florida are not permitted under the current law. Under the current Medicaid statute, the Florida legislation conflicts with federal law. A state cannot create a formulary based on entering into rebate agreements with the state.

Florida has attempted to combine the cost benefits of a prior authorization program and a formulary without implementing any of the safeguards. The language of the Florida legislation points too much towards creating a formulary. A formulary can only be based on medical effectiveness. The purpose of the federally mandated Medicaid Pharmaceutical and Therapeutics Committee is to make this determination. The committee's job, as foreseen by Congress, was not to determine the medical efficacy of only the drugs made by pharmaceutical manufacturers that entered into rebate agreements with the states.

There was a congressional purpose behind only allowing states to create formularies on the basis of medical effectiveness. Any manufacturer that entered into a rebate agreement with the federal gov-

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228. See, e.g., Associated Press, *G.O.P. Wants to See Bigger Rx Benefit/60 Percent More Sought for Seniors*, HOUSTON CHRON., Mar. 5, 2002, at 13 (discussing a proposed federal prescription benefit for seniors); Peter DeCoursey, *Casey Unveils Drug Plan; Candidate Would Change PACE Guidelines, Use Federal Money*, HARRISBURG PATRIOT, Mar. 8, 2002, at B1 (discussing a proposed prescription drug benefit for the elderly in Pennsylvania); Eric Dyer, *Drug Subsidy Critical; Easley Says; the Governor Tells a Commission to Develop a Program by the End of This Year to Help the Elderly Afford Medicine*, GREENSBORO NEWS & RECORD, May 17, 2001, at B1 (discussing North Carolina's governor's proposal for a prescription drug benefit for the elderly); Paul Sloca, *Lawmakers Working on Compromise for Prescription Plan*, ASSOCIATE PRESS STATE & LOCAL WIRE, Sept. 12, 2001 (discussing proposals in Missouri for prescription drug benefit).

ernment would have its drugs covered by the state Medicaid programs unless there was an issue of therapeutic value.

States must lobby Congress to amend the Medicaid statute. They must urge Congress to do one of two things. First, Congress could raise the amount of required rebates so that the rebates better benefit the states. Otherwise, Congress could authorize the states to create rebate programs modeled after the Florida program: allow the states to enter into supplemental rebates with manufacturers, which may be a condition for consideration for placement on the state's Medicaid formulary.

However, these repairs are only temporary. In five to ten years, there will be a need to make further cutbacks in Medicaid. If Medicaid budgets are in trouble now, they will be much worse once the largest percentage of beneficiaries of Medicaid beneficiaries—the elderly and disabled—multiplies nearly threefold. Therefore, more forward-thinking programs need to be instituted.

The Hatch-Waxman Act should be amended to help decrease the astronomical costs of pharmaceuticals. In addition, more programs need to be instituted to improve the overall health of Medicaid beneficiaries. Pfizer and Bristol Myers Squibb have said that they will continue their Florida disease management programs even if the supplementary rebates are ruled illegal. If these programs are successful in saving Florida money, then they should serve as a model for all states and the federal government. Both the federal and state governments should pass legislation sponsoring disease management programs and creating incentives for private companies to get involved in active disease management and education programs. Although preferred-drug lists may be necessary for the short term, the only way to save Medicaid is by amending patent laws and implementing disease management programs.

## V. Conclusion

State Medicaid programs need to find ways to cut costs, or Medicaid as a whole will eventually go bankrupt. A formulary contingent upon state supplementary rebates, like that in Florida, conflicts with current Medicaid law. However, for the near future, federal law should be changed in order to facilitate savings provided by such programs. As a long-term solution, these amendments should be made in conjunction with federal- and state-sponsored disease man-

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agement programs and reform of current patent law. Medicaid will only survive if all of these reforms are put in place.