IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA **1100 Fifteenth Street, N.W.** **Washington, DC 20005** **Plaintiff,** **v.** **KEVIN CONCANNON, in his official capacity as Commissioner of the Department of Human Services for the State of Maine** **221 State Street** **Augusta, Maine 04333** **ANDREW KETTERER, in his official capacity as Attorney General for the State of Maine** **6 State House Station** **Augusta, Maine 04333** **Defendants.**	*	**Civil Action No. _____**

COMPLAINT FOR DECLARATORY, INJUNCTIVE AND OTHER RELIEF

Plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), by its undersigned attorneys, states in support of this Complaint as follows:

INTRODUCTION

1. This is an action for declaratory, injunctive and other relief brought by PhRMA against Defendant Kevin Concannon, the Commissioner of the Department of Health and Human Services of the State of Maine, in his official capacity, and against

Defendant Andrew Ketterer, Attorney General of the State of Maine, in his official capacity. Plaintiff seeks injunctive and declaratory relief barring the implementation and enforcement of specified provisions of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter the "Act," provisions hereinafter cited to Section ____ of 22 M.R.S.A., copy attached as Exhibit A hereto), and declaring them unlawful.

2. The challenged provisions of the Act (1) require drug manufacturers to finance drug discounts to Maine residents, and threaten to restrict Maine Medicaid beneficiaries' access to the manufacturers' drugs; (2) punish drug manufacturers for charging prices and realizing profits that the State deems to be excessive, even in out-of-state transactions; and (3) punish drug manufacturers for rearranging their affairs so as to minimize their exposure to these provisions of the Act while continuing to ensure that their drugs will be available to Maine residents.

3. The challenged provisions of the Act violate the Commerce Clause of the United States Constitution by regulating transactions that occur outside Maine, by tying the discounts that drug manufacturers must provide for drugs dispensed in Maine to price discounts provided in other jurisdictions, and by preventing drug manufacturers from modifying their channels of distribution in response to the Act.

4. The challenged provisions of the Act also violate the Supremacy Clause of the United States Constitution by imposing restrictions on patients' access to manufacturers' drugs in the federal Medicaid program to punish manufacturers who do not participate in the new Maine drug program.

PARTIES

5. Plaintiff, PhRMA, is a non-profit corporation, organized and existing under the laws of the State of Delaware.

6. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA's member companies account for more than 75 percent of brand name drug sales in the United States.

7. PhRMA serves as the pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA is committed to, *inter alia*, advancing public policies that foster continued innovation, educating the public about the drug development and discovery process, and promoting a fair and competitive marketplace. PhRMA has represented its members in connection with the Maine Legislature's consideration of legislation regulating prescription drugs, including the legislation ultimately enacted as the Act challenged here.

8. All of PhRMA's members have their principal places of business outside Maine. By far the greatest part of PhRMA's members' prescription drug sales are to wholesalers and other entities located outside Maine. With limited exceptions, PhRMA's members are not parties to sales transactions occurring in, or with purchasers in or from, the state of Maine.

9. PhRMA brings this suit on behalf of its members. At least one of PhRMA's members possesses standing to sue in its own right; the regulation of

prescription drug pricing is of vital concern to PhRMA's members; and neither the claim asserted nor the relief demanded necessitates the participation of individual PhRMA members.

10. Defendant Kevin Concannon is the Commissioner of the Department of Human Services (hereinafter the "Department") for the State of Maine. Defendant Concannon is sued in his official capacity only.

11. Pursuant to the Act, Defendant Concannon (hereinafter, the "Commissioner") is responsible, directly and through his Department, for the implementation and, in substantial part, enforcement of the Act.

12. Defendant Andrew Ketterer is the Attorney General of the State of Maine. Defendant Ketterer is sued in his official capacity only.

13. Pursuant to the Act, Defendant Ketterer (hereinafter, the "Attorney General") is responsible for the enforcement of the profiteering provisions of the Act.

JURISDICTION

14. Subject matter jurisdiction is founded on 28 U.S.C. §§ 1331 and 1343 because this case arises under the Constitution and laws of the United States.

15. This Court has authority to grant declaratory relief pursuant to 28 U.S.C. §§ 2201 and 2202.

VENUE

16. Venue is proper in this Court under 28 U.S.C. § 1391(b) because the Defendants maintain their offices within this judicial district and because the events giving rise to the claims herein occurred within this judicial district.

THE MAINE Rx LAW

17. The Act, which was not accorded the regular public hearing and public work session processes of the Maine Legislature, enacts a new Chapter 603, entitled "Prescription Drug Access," in Maine Rev. Stat. Ann. Title 22.

18. Chapter 603 includes among its principal components (1) a mandatory prescription drug "rebate" program, and (2) penalties for "profiteering" in prescription drugs (including penalties for taking actions to minimize exposure to the Act).

The Maine Rx Program

19. Subchapter I (§ 2681) of the new Chapter 603 establishes the "Maine Rx Program," a prescription drug rebate program administered by the State (specifically, by the Department) for "qualified" Maine residents.

20. As administered by the Department, the class of "qualified" Maine residents will include the 325,000 Maine residents who do not have prescription drug coverage under other public or private programs.

21. Under the new Maine Rx Program, drug manufacturers are required to remit payments to Maine called "rebates." Maine in turn is required to use these payments to finance discounts provided by retail pharmacies to enrollees in the Maine Rx Program. The Act, through the "rebate" mechanism, thereby effectively transfers to Maine residents a portion of the purchase price received by the manufacturers from their customers (typically wholesalers and distributors). As the Program is being administered by the Department, manufacturers are required to remit these payments regardless of whether their sales occurred outside Maine.

22. In particular, Section 2681(3) requires all prescription drug manufacturers and labelers whose drugs are sold in Maine through publicly supported pharmaceutical assistance programs, such as the federal Medicaid program, to enter into agreements with the Department to provide such "rebates" for their prescription drugs that are dispensed to Maine residents under the Maine Rx Program.

23. PhRMA members participate in Medicaid.

24. PHRMA members also participate in Maine's Elderly Low-Cost Drug Program (hereinafter the "Elderly LCD Program"), a publicly supported pharmaceutical assistance program.

25. The PhRMA members who participate in these publicly supported pharmaceutical assistance program in Maine are thus required by Section 2681(3) to enter into rebate agreements for the Maine Rx Program.

26. The Act directs the Commissioner to negotiate the amount of the rebate required from each manufacturer under the obligatory rebate agreement.

27. The Act directs the Commissioner to use his "best efforts" to obtain an initial rebate for the Maine Rx Program equal to or greater than the manufacturer's nationwide, statutorily-specified federal Medicaid rebate. Such initial rebates are to take effect beginning January 1, 2001.

28. On August 2, 2000 the Commissioner presented pharmaceutical manufacturers with a "Rebate Agreement," for signature no later than November 1, 2000, that requires payment of "the Medicaid Rebate amount" on drugs dispensed under the Maine Rx program.

29. The Act also directs the Commissioner to negotiate for further rebates, to take effect no later than October 1, 2001, that are equal to or greater than any discount, rebate or price the manufacturer gives in connection with any federal program.

30. If a manufacturer does not enter into a Maine Rx rebate agreement, the Department is directed by Sections 2681(7) and 3174-Y to impose a "prior authorization" requirement on the manufacturer's drugs that are dispensed—not under the Maine Rx program—but under the entirely distinct federal Medicaid drug program.

31. Prior authorization is intended to limit access to a drug. It does so by requiring a physician who wishes to prescribe the drug to Medicaid patients to justify his or her reasons for doing so to the state Medicaid Administrator on a case-by-case basis in order to obtain specific prior permission from the Administrator. Absent such authorization, the Medicaid patient will not receive coverage for the prescription.

32. The Act's rebate requirement is conjoined with prohibitions on "profiteering" (discussed *infra* at paragraphs 38-46) that, *inter alia*, prevent manufacturers from rearranging their affairs to minimize their exposure to the rebate requirement while continuing to make their drugs available to Maine residents.

33. With the exception of an initial loan from the Trust Fund for a Healthy Maine in fiscal year 2000-01, which must be repaid in fiscal year 2002-03 using rebate revenues collected from manufacturers, the Maine Rx program is to be funded exclusively by the manufacturers' rebate payments through the establishment of the "Maine Dedicated Fund."

34. Maine Rx is thus a pass-through program, under which the State itself does not purchase prescription drugs or contribute state funds to subsidize prescription drug purchases by residents covered by the Maine Rx Program.

35. In addition to establishing the new Maine Rx Program, the Act (Section 254 ss. 8-A) revises the State's existing, voluntary Elderly LCD Program to make participation mandatory for all manufacturers who participate in Medicaid.

36. The Elderly LCD Program receives state funding support.

37. Under the Maine Elderly LCD Program, manufacturers give the State rebates equivalent to those calculated under Medicaid.

Anti-Profiteering

38. Section 2697 declares unlawful the act of "profiteering" in prescription drugs.

39. Manufacturers, labelers, and distributors of prescription drugs are deemed to engage in "illegal profiteering" if they: (1) exact or demand an "unconscionable" price; (2) exact or demand prices or terms that lead to an "unjust or unreasonable" profit; (3) "discriminate[] unreasonably" in selling or distributing drugs dispensed in Maine; or (4) intentionally restrict the sale or distribution of drugs in Maine in retaliation for the Act.

40. The Act's anti-profiteering prohibitions relating to prices, profits, and preferential terms, Sections 2697(A)-(C), are not by their terms confined to transactions occurring in Maine.

41. The Act's fourth anti-profiteering provision, Section 2697(D), precludes manufacturers from rearranging their affairs so as to minimize exposure to the rebate requirement and the anti-profiteering provisions.

42. Violations of the anti-profiteering provisions are punishable by, *inter alia*, injunctive relief, treble damages, punitive damages, and civil penalties of up to $100,000 per violation, plus costs and attorney's fees.

43. Violations of the anti-profiteering provisions of the Maine Rx Law are also deemed to violate the Maine Unfair Trade Practices Act.

44. Violations of the Maine Unfair Trade Practices Act are punishable by, *inter alia*, injunctive relief, damages, restitution, and civil penalties of up to $10,000 per violation.

45. The Attorney General is responsible for investigating suspected violations of the Act's anti-profiteering provisions and the Maine Unfair Trade Practices Act, and for prosecuting civil violations thereof.

46. Violations of the Maine Unfair Trade Practices Act are also subject to private actions for damages, restitution, and equitable relief. Successful plaintiffs may also recover attorney's fees and costs.

THE FEDERAL MEDICAID PROGRAM

47. Medicaid is a federally mandated, state-administered program that operates under federal guidelines to provide medical care to certain low-income populations. The program is jointly funded by the federal and state governments.

48. In 1991 Congress supplemented the federal Medicaid health care program with a rebate program to offset the costs of prescription drug coverage, which states may opt to offer to Medicaid beneficiaries. Omnibus Budget Reconciliation Act ("OBRA") of 1990, enacting § 1927 of the Social Security Act, 42 U.S.C. § 1396r-8.

49. Under the Medicaid drug program, drug manufacturers enter into national rebate agreements with the Secretary of the Department of Health and Human Services. 42 U.S.C. § 1396r-8(a)(1). Pursuant to those agreements, manufacturers pay statutorily-calculated rebates directly to each state for their drugs dispensed to Medicaid beneficiaries in the state. 42 U.S.C. § 1396r-8(b), (c); 56 Fed. Reg. 7049 (1991). The states also receive federal Medicaid reimbursement funds for those drugs, and contribute state funds to make up the balance (such that the Medicaid beneficiary makes no more than a nominal payment).

50. For each drug, a manufacturer pays the same nationwide Medicaid rebate. 42 U.S.C. § 1396r-8(c)(1)(A).

51. The formula for calculation of that rebate is prescribed by statute. 42 U.S.C. § 1396r-8(c)(1).

52. The calculation of the rebate starts with the per-unit Average Manufacturer Price ("AMP") paid by wholesalers, taking into account all discounts and price reductions, for drugs in the "retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1).

53. The manufacturer's Medicaid rebate for brand-name drugs is the greater of: (1) 15.1% of the AMP or (2) the difference between the AMP and the manufacturer's nationwide "best price." 42 U.S.C. § 1396r-8(c)(1). Thus if any U.S. purchaser (with certain statutory exceptions) pays less than 84.9% of the AMP for the brand-name drug, the Medicaid rebate paid by the manufacturer will be based on that best price. The Medicaid rebate for generic and over-the-counter drugs is 11% of AMP. 42 U.S.C. § 1396r-8(c)(3).

COUNT I
VIOLATION OF COMMERCE CLAUSE
Section 2697(2)

54. Paragraphs 1-53 are incorporated by reference.

55. The Commerce Clause of the United States Constitution prohibits a state from regulating transactions occurring outside of the state.

56. The "anti-profiteering" provisions of the Act subject manufacturers to penalties with respect to prices, profits, and terms of sales occurring outside Maine.

57. These provisions (Section 2697(2)) violate the Commerce Clause.

58. PhRMA has no adequate remedy at law.

COUNT II
VIOLATION OF COMMERCE CLAUSE
Sections 2681(3) and 254 ss8-A

59. Paragraphs 1-58 are incorporated by reference.

60. The Commerce Clause of the United States Constitution prohibits a state from regulating transactions occurring outside of the state.

61. The rebate provisions of the Act effectively regulates the prices received by drug manufacturers from their customers in transactions occurring outside of Maine.

62. The rebate provisions (Sections 2681(3) and 254 ss8-A) violates the Commerce Clause.

63. PhRMA has no adequate remedy at law.

COUNT III
VIOLATION OF COMMERCE CLAUSE
Section 2681(4)

64. Paragraphs 1-63 are incorporated by reference.

65. The Commerce Clause prohibits a state from tying in-state prices to prices charged in other jurisdictions.

66. The rebate provision of the Act ties prices in Maine to prices paid in other jurisdictions by using as benchmarks for the Maine Rx program rebates the nationwide, federal Medicaid rebate, and nationwide rebates and discounts under other federal programs.

67. The rebate provision (Section 2681(4)) violates the Commerce Clause.

68. Plaintiff has no adequate remedy at law.

COUNT IV
VIOLATION OF COMMERCE CLAUSE
Section 2697(2)(D)

69. Paragraphs 1-68 are incorporated by reference.

70. The Commerce Clause prohibits a state from interfering with "the mobility of [interstate] commerce."

71. The "anti-retaliation" profiteering provision of the Act prohibits drug manufacturers from arranging their interstate distribution channels in response to the Act.

72. The "anti-retaliation" profiteering provision (Section 2697(2)(D)) violates the Commerce Clause.

73. PhRMA has no adequate remedy at law.

COUNT V
VIOLATION OF THE SUPREMACY CLAUSE
Sections 2681(7) and 3174-Y

74. Paragraphs 1-73 are incorporated by reference.

75. The Supremacy Clause prohibits state laws that conflict with federal laws and programs.

76. The prior authorization provisions of the Act conflicts with federal Medicaid law and the federal Medicaid program by curtailing Maine Medicaid beneficiaries' access to a manufacturer's drugs to punish its failure to finance discounts under the Maine Rx Program.

77. The prior authorization provisions (Sections 2681(7) and 3174-Y) violates the Supremacy Clause.

78. PhRMA has no adequate remedy at law.

COUNT VI
VIOLATION OF 42 U.S.C. § 1983

79. Paragraphs 1-78 are incorporated by reference.

80. The Commissioner and the Attorney General are State officials acting within the scope of their authority in implementing the Act.

81. The Act deprives Plaintiff's members of the rights, privileges, and immunities secured by the Commerce Clause and the Supremacy Clause of the U.S. Constitution.

82. The Commissioner and the Attorney General are liable to Plaintiff for proper redress under 42 U.S.C. § 1983.

RELIEF REQUESTED

WHEREFORE, Plaintiff, Pharmaceutical Research and Manufacturers of America respectfully requests the following relief:

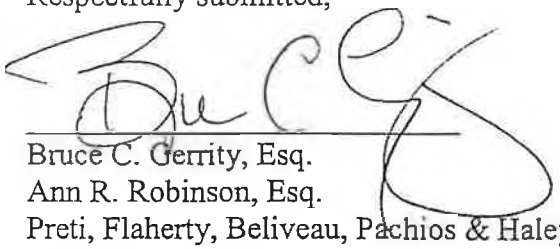
A. A declaratory judgment, pursuant to 28 U.S.C. § 2201, that Sections 254 ss8-A, 2681(3), 2681(4), 2681(7), 2697, and 3174-Y of the Act violate the United States Constitution and are unenforceable;

B. A preliminary and permanent injunction enjoining the Defendants from implementing or enforcing the Act;

C. An order awarding PhRMA's costs and attorneys' fees pursuant to 42 U.S.C. § 1988; and

D. Such other and further relief as the Court deems just and proper.

Respectfully submitted,



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