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MEDICAID RECIPIENTS DENIED COVERAGE FOR SMOKING CESSATION PHARMACOTHERAPY

KELLY N. REEVES

Forty-six million American adults smoke cigarettes.¹ Of the eighty-one percent of adult smokers who try to quit smoking, only forty percent will abstain for at least one year.² Clinical studies have demonstrated that it is extremely difficult to quit smoking without some form of smoking cessation aid.³ Smoking prevalence is highest among persons with 9 to 11 years of education (37.5%) and among persons living below poverty level (34.7%).⁴ Such demographics help explain the more than 42 percent of Medicaid beneficiaries who are smokers, compared to the less than 30 percent of adult smokers in the general population.⁵ Over the next 25 years, cigarette smoking will cost the Medicaid program an estimated \$39.2 billion dollars in direct and indirect health care delivery costs.⁶ While the Food and Drug Administration (FDA) has approved several prescription and nonprescription drugs for smoking cessation,⁷ states are not required to provide Medicaid coverage for FDA-approved prescription drugs for

1. See Tamar Nordenberg, *It's Quittin' Time Smokers Need Not Rely on Willpower Alone*, FDA CONSUMER NOV.-DEC. 1997 (visited June 12, 1998) <http://www.fda.gov/fdac/features/1997/797_smoke.html> (article on file with the JOURNAL OF HEALTH CARE LAW & POLICY). This article is a reprint of the original article and contains revisions made in February 1998; see also U.S. Dep't of Health and Human Services, Centers for Disease Control Activities in the United States, Initiatives by Organizations to Strengthen National Tobacco Control Activities in the United States; Notice of Availability of Funds for Fiscal Year 1998, 63 Fed. Reg. 20,197, 20,198 (1998) [hereinafter CDC Notice of Availability of Funds].

2. See U.S. DEP'T OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL, THE HEALTH BENEFITS OF SMOKING CESSATION: A REPORT FROM THE SURGEON GENERAL 600 (1990). About one-third of those that successfully abstain for one year may eventually relapse. See *id.* at 610.

3. See *infra* notes 86-90 and accompanying text.

4. See CDC Notice of Availability of Funds, *supra* note 1, at 20,199; see also *Comprehensive Tobacco Control Legislation: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Commerce*, 105th Cong. 2-4 (1998) (statement of Summit Health Coalition) (discussing tobacco industry's deliberate targeting of the African American community and the high smoking-related disease rate in the African American community).

5. See National Center on Addiction and Substance Abuse at Columbia University, *The Cost of Substance Abuse to America's Health Care System* (last modified July 1996) <<http://www.casacolumbia.org/pubs/jul93/heal5.htm>>.

6. See *id.*; see also *infra* notes 101-104 and accompanying text for discussion on direct and indirect costs of smoking.

7. See *infra* notes 69-79 and accompanying text for discussion of FDA-approved smoking cessation drugs.

smoking cessation.⁸ Currently, only 21 states voluntarily provide Medicaid coverage for prescription and nonprescription products indicated for smoking cessation.⁹

To reiterate the incredible irony in this policy: smoking cessation is difficult without the aid of smoking cessation therapy, nearly half of Medicaid beneficiaries are smokers, FDA-approved smoking cessation products are available, the Medicaid program would reap cost savings if there was a reduction in Medicaid smokers, but states do not have to provide Medicaid coverage for smoking cessation drugs. This paper will examine the optional Medicaid coverage provision in the Social Security Act¹⁰ that permits states to exclude Medicaid coverage of smoking cessation prescription drugs, including its legislative history and the availability of FDA-approved smoking cessation pharmacotherapy at the time of its passage in 1990. The paper will then examine the cost of cigarette smoking to Medicaid and the cost effectiveness of extending Medicaid coverage to smoking cessation prescription drugs. The paper will examine current federal government smoking cessation initiatives espoused by several federal agencies and programs to illustrate that smoking cessation is clearly a priority of the national health agenda. Finally, the paper will propose an amendment to the current law to eliminate states' optional coverage of smoking cessation prescription drugs and will examine provi-

8. See Social Security Act § 1927(d)(2)(A)-(J), 42 U.S.C. § 1396r-8(d)(2)(A)-(J) (1971).

9. See *Glaxo Zyban Medicaid Coverage Would Be Required Under the Tobacco Bill*, "THE PINK SHEET," F-D-C REPORTS, June 1, 1998, at 10 (citing a July 1997 survey of state policies on smoking cessation treatment conducted by the National Conference of State Legislatures) [hereinafter "THE PINK SHEET"].

10. 42 U.S.C. § 1396r-8(d)(2)(A)-(J). Section 1927(d)(2) of the Social Security Act states:

The following drugs or classes of drugs or their medical uses, may be excluded from coverage or otherwise restricted:

- (A) Agents when used for anorexia, weight loss, or weight gain.
- (B) Agents when used to promote fertility.
- (C) Agents when used for cosmetic purposes or hair growth.
- (D) Agents when used for symptomatic relief of coughs or cold.
- (E) Agents when used to promote smoking cessation.
- (F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- (G) Nonprescription drugs.
- (H) Covered outpatient drugs which the manufacture seeks to require as a condition of sale that associated test or monitoring devices be purchased exclusively from the manufacturer of it designee.
- (I) Barbituates.
- (J) Benzodiazepines.

(emphasis added).

sions of recently-defeated tobacco legislation that would have accomplished this task, as well as speculate about the likelihood of Congress considering a similar provision in the near future. By eliminating optional coverage, states will be required to extend Medicaid coverage to smoking cessation prescription drugs, thereby making FDA-approved smoking cessation drugs available to Medicaid recipients, increasing rates of smoking cessation among Medicaid recipients, and ultimately reducing the cost to Medicaid of providing care for smokers.

I. MEDICAID'S OPTIONAL EXCLUSION OF COVERAGE FOR SMOKING CESSATION DRUGS

The Medicaid program was born from the Social Security Act Amendments of 1965¹¹ to ensure that low-income Americans receive adequate health care.¹² The Medicaid program is a federal entitlement program that is administered and partially funded by the states, but is subject to federal oversight and regulations.¹³ The federal government allocates to states a percentage of the Medicaid funding, usually ranging from 50% to 83% depending on the wealth of the state, and states contribute the remaining percentage to fund their respective Medicaid programs.¹⁴ Attached to the federal government's allocation of Medicaid funding are requirements that states provide certain services to Medicaid beneficiaries.¹⁵ A state must obtain a waiver from the Department of Health and Human Services if it intends to stray from the federal requirements.¹⁶ States are not required by the Social Security Act to provide Medicaid coverage for prescription drugs.¹⁷ However, if a state does choose to cover prescription drugs, it must cover all prescription drugs and comply with the federal requirements for prescription drug coverage under Medicaid outlined in the Social Security Act.¹⁸ Notably, every state and the

11. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended in scattered sections of 42 U.S.C.).

12. See S. REP. NO. 89-404, at 169 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943, 1943; see also BARRY R. FURROW ET AL., HEALTH LAW 864 (3d. ed. 1997).

13. See FURROW ET AL., *supra* note 12, at 881.

14. See S. REP. NO. 89-404, at 178, *reprinted in* 1965 U.S.C.C.A.N. 1943, 2024.

15. See *id.* at 175, *reprinted in* 1965 U.S.C.C.A.N. 1943, 2021.

16. 42 U.S.C. § 1315 (1998).

17. See S. REP. NO. 89-404, at 175, *reprinted in* 1965 U.S.C.C.A.N. 1943, 2021.

18. See *id.*; H.R. CONF. REP. NO. 101-881 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2107.

District of Columbia provides Medicaid coverage for prescription drugs.¹⁹

A. *Section 1927 (d)(2) of the Social Security Act*

The statutory provision that allows states to exclude smoking cessation prescription drugs from Medicaid coverage is found in section 1927 of the Social Security Act.²⁰ Section 1927 of the Social Security Act was added by the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990),²¹ and amended by the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993).²² With OBRA 1990, Congress focused on reducing spending in the Medicaid program by: (1) reforming the purchase of prescription drugs by the states, and (2) by requiring states to purchase employer group health coverage on behalf of Medicaid beneficiaries where cost effective.²³ With regard to prescription drug reform, OBRA 1990 mandated that drug manufacturers would be limited to charging the Medicaid program the best price given any bulk purchaser for prescription drugs, subject to a minimum discount of 10 percent, with savings returned to the state Medicaid program through a quarterly rebate.²⁴ A drug manufacturer that refused to enter a drug rebate agreement with the Secretary of the Department of Health and Human Services for all the manufacturer's drugs and with all the states would be denied federal Medicaid matching payments for the covered outpatient drugs.²⁵

OBRA 1993 required a drug or biological manufacturer to enter into a master agreement with the Administrator of the General Services Administration (GSA) under which the manufacturer must agree to enter into Federal Supply Schedule (FSS), Department of Veterans Affairs (VA) depot, and Department of Defense (DoD) depot pharma-

19. See H.R. CONF. REP. NO. 101-964, at 821 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2526, 2374.

20. Social Security Act § 1927(d), 42 U.S.C. § 1396r-8(d)(2)(E) (1998).

21. Omnibus Budget Reconciliation Act of 1990 § 4401, Pub. L. No. 101-508, 104 Stat. 1388 (codified as amended in scattered sections of 42 U.S.C.).

22. Omnibus Budget Reconciliation Act of 1993 § 3602, Pub. L. No. 103-112, 107 Stat. 312 (codified as amended in scattered sections of 42 U.S.C.).

23. See H.R. CONF. REP. NO. 101-881, at 4 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2107.

24. See 42 U.S.C. § 1396r-8(c); see H.R. REP. NO. 101-881, at 96-97, *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108-09.

25. See 42 U.S.C. § 1396r-8(a). A "covered outpatient drug" includes all prescription drugs approved by the FDA except those for which Medicaid payments is made as part of payment for the following services: inpatient hospital, hospice, dental, physician office visits, outpatient hospital emergency room visits, and outpatient surgical procedures. See § 1396r-8(k)(2)(a)(i), (k)(3); H.R. REP. NO. 101-881, at 97, *reprinted in* 1990 U.S.C.C.A.N. 2017, 2019.

ceutical pricing agreements as a condition of selling the drug or biological to a federal agency,²⁶ and as a condition for receiving payment for the drug or biological under the Medicaid program, or receiving payment for the drug or biological directly or indirectly from any entity that receives funds under the Public Health Service Act.²⁷

Section 1927 outlines the Medicaid drug rebate program and several prescription drug cost containment methods permissible for states to employ.²⁸ Again, states that choose to extend Medicaid coverage to prescription drugs must cover all prescription drugs, subject to the permissible restrictions outlined in section 1927(d).²⁹ States may employ prior authorization programs,³⁰ drug formularies,³¹ or may limit the maximum or minimum quantities per prescription or on the number of refills,³² or limit drugs not prescribed for a medically accepted indication.³³ In addition to these cost containment measures, a state may exclude a drug, classes of drugs, or their medical uses from Medicaid coverage if it falls under the list of drugs exempted from coverage in section 1927(d)(2).³⁴ States are granted flexibility in determining what medical uses and drugs qualify under the list of exempted drugs.³⁵ The statutory list of drugs ranges from

26. Specifically, selling the products to the VA, the DoD, and the Public Health Service.

27. See S. REP. NO. 102-401, at 46-47 (1993), *reprinted in* 1993 U.S.C.C.A.N. 4113, 4121. The term "depot" means a centralized commodity management system operated by the Department which drugs and biologicals procured for the use of entities of the Department are received and delivered. *Id.* at 43.

28. See 42 U.S.C. § 1396r-8 (1998).

29. See *id.* § 1396r-8(d).

30. See *id.* § 1396r-8(d)(5). A prior authorization program requires the approval of a drug before its dispensing for any medically accepted indication as a condition of coverage or payment for a covered outpatient drug. See *id.* § 1396r-8(d)(5). A state's prior authorization program must be established in accord with federal requirements. See *id.* § 1396r-8(d)(5)(A)-(B).

31. See *id.* § 1396r-8(d)(4). A drug formulary is a cost containment measure that excludes payment coverage of certain prescription drugs that do "not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome for treatment" in pertinent populations over other drugs that are included in the formulary. *Id.* § 1396r-8(d)(4)(C). The state formulary must be established in accord with federal requirements. See *id.* § 1396r-8(d)(4).

32. See *id.* § 1396r-8(d)(6) ("A State may impose limitations. . . on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste.")

33. See *id.* § 1396r-8(d)(1)(B)(i). Medically accepted indication is defined as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. §301 et.seq.]." *Id.* §1396r-8(k)(6).

34. *Id.* § 1396r-8(d)(2)(A)-(J).

35. See Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, 60 Fed. Reg. 48,442, 48,455 (1995) (to be codified at 42 C.F.R. pts. 441 & 447) (proposed Sept. 19, 1995).

agents used for cosmetic hair growth to weight loss to prescription vitamins.³⁶ Among the drugs listed for optional coverage in section 1927(d)(2) are “agents for the promotion of smoking cessation.”³⁷ This is the provision states rely upon to exclude Medicaid coverage for all prescription smoking cessation pharmacotherapy.³⁸

The Medicaid optional exclusion provision arose from a movement in Congress to reduce the cost of prescription drugs to the Medicaid program. In developing the cost containment provisions in OBRA 1990, the House Committee on Energy and Commerce was responding to the Budget Resolution of 1990, which assumed reductions of \$2.38 billion in Medicaid outlays over the period FY 1991 through 1995.³⁹ The Committee bill sought to achieve these savings primarily by reforming the purchase of prescription drugs by the states.⁴⁰ Prior to OBRA 1990, drug manufacturers were extending discounts on prescription drugs to the VA and the DoD, as well as to large private sector purchasers, including HMOs and hospital group purchasing organizations.⁴¹ The same discounts were not extended to the Medicaid program.⁴² Congress determined that the Medicaid program, which provided health care for the poor, should have the benefit of the same discounts on drugs that other large public and private purchasers enjoyed.⁴³ With the passage of OBRA 1990, Congress established the drug rebate mechanism that gave Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser.⁴⁴ Prescription drug manufacturers were required to enter into drug rebate agreements in order to qualify for payment as a “covered outpatient drug” under Medicaid.⁴⁵

In addition to the concern that drug manufacturers were not uniformly granting discounts to federal programs, Congress also focused on reforming prescription drug reimbursement within the Medicaid program.⁴⁶ States were required to implement drug utilization review committees to oversee prescribing practices and annually report data on clinical abuse and inappropriate use of prescription drugs to the

36. *See id.*

37. *Id.*

38. *See id.*

39. *See* H.R. Doc. No. 101-881, at 63 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2077.

40. *See id.*

41. *See id.*

42. *See id.*

43. *See id.*

44. *See id.*

45. *Id.* at 97; *see also* 42 U.S.C. § 1396r-8(a)(1) (1998). *See supra* note 24, for definition of “covered outpatient drugs.”

46. *See* 42 U.S.C. § 1396r-8(d).

Secretary.⁴⁷ States were also permitted to employ drug formularies, prior authorization programs, and other permissible restrictions on the dispensing of prescribed drugs, including the optional exclusion of coverage for drugs listed in section 1927(d)(2).⁴⁸

Smoking cessation prescription drugs were included on the statutory list of exempted drugs primarily for two reasons: (1) states already commonly excluded smoking cessation drugs from Medicaid coverage, and (2) FDA-approved smoking cessation pharmacotherapy was not generally available at the time the list was drafted.⁴⁹ Congress drafted the list of optional drugs in section 1927(d)(2) based on drugs that were commonly subject to restriction or exclusion by state Medicaid programs.⁵⁰ When states were still individually selecting which prescription drugs to cover under the Medicaid program prior to 1990, only one FDA-approved smoking cessation prescription drug became available, for smoking cessation products were generally regarded as ineffective.⁵¹ Numerous non-FDA approved smoking cessation products proliferated the market, such as hypnotherapy audio tapes and aqua filters; however, such products were often the subject of Federal Trade Commission sanctions for federal violations of unfair and deceptive trade practices laws.⁵² The effectiveness of these products was clearly questionable, prompting most states to exclude them from Medicaid coverage.⁵³ By including smoking cessation agents on the list of optionally covered drugs, Congress allowed states to con-

47. See *id.* § 1396r-8(d)(3).

48. See *id.* § 1396r-8(d)(4), (d)(5), (d)(6).

49. See *infra* notes 50-59 and accompanying text.

50. See 136 CONG. REC. H12423-02, H12466 (1990).

51. See Nordenberg, *supra* note 1 (describing the prescription drug nicotine gum, a nicotine replacement therapy, which was approved by FDA for aid in smoking cessation in 1984).

52. See, e.g., PhaseOut of America, Inc.; Prohibited Trade Practices and Affirmative Corrective Actions, 62 Fed. Reg. 17,831, 17,831 (1997) (describing consent order issued by the FTC in settlement of alleged violations of federal law prohibiting unfair or deceptive acts for PhaseOut, a "purported stop smoking device", and requiring firms that distributed the product to notify identifiable past purchasers of PhaseOut of the FTC's action and requiring the respondents to have scientific substantiation for claims that PhaseOut reduces the amount of nicotine, tar and carbon monoxide that smokers receive); Taleigh Corporation; Proposed Consent Agreement with Analysis to Smoking Cessation Aid, 60 Fed. Reg. 16,148, 16,148 (1995) (describing proposed consent agreement issued by FTC in settlement of alleged violations of federal law prohibiting unfair or deceptive acts for Nicotain, a "purported smoking cessation product", and charging proposed respondents with representing falsely and without reasonable basis that Nicotain enables smokers to stop smoking quickly and easily and that it works through the same mechanism as a prescription smoking deterrent patch).

53. See generally H.R. Conf. Rep. No. 101-964 (1990), 136 CONG. REC. H12423-02, H12467 (1990).

tinue to decide independently whether to spend Medicaid dollars on potentially ineffective products.

When OBRA 1990 was passed, no nonprescription drugs for smoking cessation were approved by the FDA and only one FDA-approved prescription smoking cessation drug was available.⁵⁴ Prescription nicotine gum, a nicotine replacement therapy, was approved by the FDA for aid in smoking cessation in 1984.⁵⁵ In 1993, after eight years of reviewing various drugs claiming smoking cessation indications, the FDA issued a final regulation stating that no over-the-counter drug indicated for smoking cessation was safe and effective.⁵⁶ The FDA further required any new over-the-counter drug products containing active ingredients for smoking cessation use to be “new drugs,” which must be approved by the FDA prior to marketing.⁵⁷ As will be discussed *infra*, the number of FDA-approved smoking cessation prescription and nonprescription drug products available at the time the statutory list of exempted drugs was drafted was minimal compared to the number of FDA-approved smoking cessation drugs currently available.⁵⁸

54. See Smoking Deterrent Products for Over-the-Counter Use, 58 Fed. Reg. 31,236, 31,240 (1993) (codified at 21 C.F.R. pt. 310); see also Nordenberg, *supra* note 1.

55. See Nordenberg, *supra* note 1, at *5.

56. See Smoking Deterrent Products for Over-the-Counter Use, 58 Fed. Reg. at 31,241; see also Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619, 44,788 (1996) (“After extensive premarket review, FDA concluded that nicotine replacement therapies are efficacious.”).

57. See Smoking Deterrent Products for Over-the-Counter Use, 58 Fed. Reg. at 31,241. This requirement is significant because over-the-counter drugs are not generally subject to pre-market approval, but rather may just comply with FDA published monographs for specific drug ingredients. See 21 C.F.R. § 330.10 (1998). The FDA determined that no data supported safety and effectiveness of any active ingredient for over-the-counter smoking cessation products and therefore was not adequate to support monograph status for any ingredient. See Smoking Deterrent Products for Over-the-Counter Use, 58 Fed. Reg. at 31,241. A “new drug” is “any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling.” 21 U.S.C. § 321(p) (1998). FDA-approval of a drug is significant because it confirms that the drug has been clinically reviewed and approved as safe and effective for the drug’s indication. See Federal Food, Drug, and Cosmetic Act of 1938, § 505(d), 21 U.S.C. § 355(d) (1997). The FDA reviews clinical data from at least two small clinical trials or one large clinical trial of the drug in humans to determine the safety and effectiveness of a drug. 21 C.F.R. § 330.10.

58. See Nordenberg, *supra* note 1.

*B. Only Congress is Authorized to Remove a Drug from
Section 1927(d)(2)*

Per section 1927(d)(3) of the Social Security Act, the Secretary of the Department of Health and Human Services is required to periodically update the list of drugs, classes of drugs, or their medical uses found in section 1927(d)(2).⁵⁹ To update the list, the Secretary must determine, based on data collected by surveillance and utilization review programs of state medical assistance programs, that the drug is subject to clinical abuse or inappropriate use.⁶⁰ In 1995, the Health Care Financing Administration (HCFA) issued a rule interpreting section 1927(d)(3) which concluded that the Secretary could *add* drugs to the statutory list, but did not have the authority to *delete* drugs from the list.⁶¹ HCFA determined that the drugs on the list are statutorily mandated and that the plain language and legislative history of the statute only granted HCFA the authority to add drugs to the statutory list.⁶² In its determination, HCFA pointed to the use of the term “update” in the statutory language, which it interpreted to mean only adding drugs to the list.⁶³ HCFA also relied on the legislative history revealing that Congress developed the statutory list from drugs that were commonly subject to exclusion or restriction by state Medicaid programs.⁶⁴ HCFA determined that both the “tenor of the report” and the statute suggest “that drugs may be added to the list, but that the categories already on the list will remain subject to state restriction.”⁶⁵ HCFA further noted that if it were to determine that a drug on the list was not subject to clinical abuse or inappropriate use, it would have to remove the drug from the list and require all state Medicaid programs to cover the drug, thus conflicting with the statute and the legislative history.⁶⁶ HCFA’s interpretation of the statute has not been explicitly rejected by Congress, and as a result, drugs can only be deleted from the statutory list of optionally covered drugs by Congress via statutory amendment.⁶⁷

59. 42 U.S.C.A. § 1396r-8(d)(3) (West 1998).

60. *See id.*

61. Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, 60 Fed. Reg. 48,442, 48,456 (1995) (codified at 42 C.F.R. pts. 441 & 447) (proposed Sept. 19, 1995).

62. *See id.*

63. *Id.*

64. *See id.*

65. *Id.*

66. *See id.*

67. *See id.*

II. CONGRESS SHOULD NOT DENY MEDICAID COVERAGE OF SMOKING CESSATION DRUGS

A. FDA-Approved Smoking Cessation Pharmacotherapy Available in 1998

Circumstances in the smoking cessation prescription drug market have changed since Congress drafted the statutory list of exempted drugs in 1990. Several pharmaceutical research companies continued developing and testing smoking cessation drugs, and were ultimately successful in demonstrating the safety and efficacy of these products to the satisfaction of the FDA.⁶⁸ By 1998, FDA had approved three nonprescription and five prescription smoking cessation drugs.⁶⁹ Of the prescription drugs now available, four are nicotine replacement therapy drugs and one is a non-nicotine pill.⁷⁰ Nicotine replacement therapy delivers small, steady doses of nicotine in the body, normally delivered by cigarette smoking, to relieve the nicotine withdrawal symptoms that occur when the smoker quits smoking.⁷¹ FDA approved the nicotine gum, Nicorette®, for sale by prescription in 1984, and for sale over-the-counter in February 1996.⁷² The nicotine transdermal patches, Habitrol® and Prostep®, were approved for sale by prescription in 1992, and approved for sale over-the-counter in July 1996.⁷³ Nicotine nasal spray and a nicotine inhaler were approved for sale by prescription in March 1996 and May 1997 respectively.⁷⁴ Few side effects have been reported with the nicotine replacement gum or patches, which account for more than 90 percent of the nicotine replacement market.⁷⁵ The non-nicotine pill, Zyban®, was originally approved as an anti-depressant prescription drug and marketed by

68. See *supra* note 56 for FDA requirements for showing of safety and effectiveness.

69. See Nordenberg, *supra* note 1.

70. See *id.*

71. See *id.* ("As with other addictive drugs, people can experience withdrawal when they get less nicotine than they are used to . . . [S]ymptoms can include irritability, frustration, anger, anxiety, difficulty concentrating, restlessness, and craving for tobacco.")

72. See *id.* Nicorette® is manufactured by SmithKline Beecham. See *Medicaid Coverage of Smoking Cessation Rx, OTC Products Would Be Required Under Senate Floor Version of McCain Tobacco Bill*, HEALTH NEWS DAILY, F-D-C-REPORTS, May 27, 1998, at 1.

73. See Nordenberg, *supra* note 1. Habitrol® is manufactured by Novartis and Prostep® is manufactured by Lederle. See *Medicaid Coverage of Smoking Cessation Rx, supra* note 72, at 1. The over-the-counter smoking cessation transdermal patches are marketed under the names Nicotrol CQ® and Nicoderm®, manufactured by McNeil Consumer Products and SmikthKline Beecham. See *id.*

74. See Nordenberg, *supra* note 1. These products are marketed under the names Nicotrol Inhaler® and Nicotrol Nasal Spray® and are manufactured by McNeil Consumer Products. See Sandra G. Boodman, *Feeding the Nicotine Habit: Finding Safer Substitutes for Cigarettes*, WASH. POST, June 30, 1998 § 2 (Health), at 10.

75. See Boodman, *supra* note 74, at 10. While nicotine in replacement products is generally a safe substance and smokers generally consume less nicotine, it still has some side

Glaxo Wellcome as Wellbutrin®.⁷⁶ Zyban® works by suppressing dopamine levels in the brain that are associated with nicotine addiction, reducing nicotine withdrawal symptoms and the urge to smoke.⁷⁷ The FDA approved the smoking cessation indication for Zyban® in May 1997.⁷⁸ Drug companies continue to develop new treatments — at least a half a dozen products are currently being tested, including a nicotine lozenge, a reusable lollipop, and a triple-strength patch.⁷⁹

Smoking cessation prescription drugs are not prohibitively costly, particularly when compared to other prescription drugs currently covered by Medicaid.⁸⁰ Nicotine replacement therapy varies from \$160 to \$300 for treatment and is generally prescribed for six to twelve weeks, depending on the product and the patient.⁸¹ The non-nicotine pill costs \$2.56 per day of treatment, and is generally prescribed for seven to twelve weeks.⁸² The daily cost of using the nicotine replacement gum or patch is roughly equivalent to a cigarette habit of a pack and a half per day.⁸³ But the cost of smoking cessation products may be onerous to low income smokers who buy cigarettes by the pack and are accustomed to only scraping together a few dollars to buy a pack rather than paying \$30 to \$50 at one time for smoking cessation pharmacotherapy.⁸⁴ Unfortunately, the cost of paying for smoking

effects. Nicotine raises the heart rate, and nicotine's effect on fetal development, nursing infants, and individuals with certain heart problems is unknown. *See id.*

76. *See id.*; Nordenberg, *supra* note 1; "THE PINK SHEET," *supra* note 9, at 10.

77. *See* Richard D. Hurt et al., *A Comparison of Sustained-Release Bupropion and Placebo for Smoking Cessation*, 337 NEW ENG. J. MED. 1195, 1201 (1997); *see also* Nordenberg, *supra* note 1, at *3. Dopamine is a neurotransmitter in the central nervous system. MILLER-KEANE ENCYCLOPEDIA & DICTIONARY OF MEDICINE, NURSING & ALLIED HEALTH 443 (5th ed. 1992).

78. *See* Nordenberg, *supra* note 1. Common side effects of Zyban® are dry mouth, difficulty sleeping, shakiness, and skin rash; individuals with pre-existing seizure conditions, such as epilepsy, or with an eating disorder, such as anorexia or bulimia, should avoid using the drug. *See* Hurt et al., *supra* note 77, at 1199, 1201. One positive side effect of Zyban® is the significantly smaller weight gain resulting from smoking cessation with the use of the drug. *See id.* at 1200-01.

79. *See* Boodman, *supra* note 74, at 10.

80. For example, Viagra®, which was recently approved by the FDA for treatment of male impotence, retails for \$10 per pill. *See Kaiser Vetoes Viagra Coverage: HMO Says Popular Impotence Treatment Is Too Costly* (visited June 19, 1998) <<http://www.cbs2.com/news/stories/news-980619-091208.html>>. *See infra* text accompanying notes 80-84 for discussion of retail price of smoking cessation drugs.

81. *See Kicking the Habit. . . With Help*, (visited July 8, 1998) <<http://www.homearts.com/gh/health/0197hcb1.htm>>.

82. *See New Aid to Smoking Cessation Treatment Available to Help Smokers Declare Independence from Cigarettes*, (last modified Aug. 18, 1997) <<http://familymedicine.tqn.com/library/weekly/aa081897.htm>>, reprinted from PR Newswire, July 1, 1997.

83. *See* Boodman, *supra* note 74, at 10.

84. *See id.*

cessation treatment, however nominal, will likely preclude Medicaid recipients from using smoking cessation aids.⁸⁵

Nicotine addiction is almost impossible to overcome without intervention assistance.⁸⁶ Nearly half of smokers who quit “cold turkey” relapse within the first 48 hours.⁸⁷ For many smokers, nicotine is both physically and mentally addictive.⁸⁸ Smoking is a powerful addiction that warrants appropriate medical treatment.⁸⁹ Dr. Michael Fiore, director of the Center for Tobacco Research and Intervention at the University of Wisconsin Medical School explains: “As a rule, people who smoke more than 10 cigarettes a day and want to quit should use an FDA-approved smoking cessation product.”⁹⁰ Studies have shown that the most effective smoking cessation treatment is pharmacotherapy combined with smoking cessation counseling.⁹¹ While adding pharmacotherapy increases the cost of each intervention, it also substantially increases their marginal effectiveness.⁹² Smokers who use the nicotine gum or transdermal patch increase their chances of quitting from about 5 percent to between 10 and 20 percent, depending on motivation and other factors.⁹³ Smokers who are highly motivated and use nicotine replacement therapy products in conjunction with supportive counseling increase their chance of quitting to 30 percent.⁹⁴ While using prescription drugs can ease the symptoms resulting from the physical addiction to nicotine, group or individual counseling as well as encouragement from family members and friends are critical in addressing the mental addiction to nicotine.⁹⁵ State Medicaid programs should provide beneficiaries with access to

85. *See id.* Last year, nicotine replacement products accounted for \$350 million in sales compared to annual U.S. cigarette sales of at least \$25 billion. *See id.* (citing IMS Health, a health care information company that compiles pharmaceutical company sales data).

86. *See* Jerry Cromwell, et al., *Cost-effectiveness of the Clinical Practice Recommendations in the AHCPR Guideline for Smoking Cessation*, 278 JAMA 1759, 1763 (1997); *see also* Boodman, *supra* note 74, at 10.

87. *See* Boodman, *supra* note 74, at 10 (citing John R. Hughes, an addiction expert who is a professor of psychiatry, University of Vermont School of Medicine).

88. *See* Nordenberg, *supra* note 1.

89. *See id.*

90. *Id.*

91. *See* Cromwell et al., *supra* note 86, at 1763 (assuming three quarters of United States smokers tried to quit within a year using transdermal nicotine).

92. *See id.* at 1764.

93. *See* Boodman, *supra* note 74, at 10.

94. *See id.*

95. *See* Nordenberg, *supra* note 1. (statement of Celia Jaffe Wichell, M.D., psychiatrist and FDA’s medical team leader for addiction drug products) (“If someone is serious about quitting, the drugs alone won’t do it . . . [T]hey must have some kind of support, whether it’s from a formal stop-smoking program or at least informal support from their friends and family.”).

smoking cessation prescription drugs and smoking cessation counseling to most effectively facilitate smoking cessation and yield the highest quit rates.

B. Providing Smoking Cessation to Medicaid Recipients Is Cost Effective

Smokers incur demonstrably higher health care costs than nonsmokers. Tobacco use is linked to 30% of all cancers, 25% of all heart attacks and strokes, and more than 90% of all chronic obstructive pulmonary disorders (COPD).⁹⁶ The Centers for Disease Control and Prevention declared tobacco use the chief avoidable cause of premature death in the United States; it results in nearly 420,000 deaths annually.⁹⁷ In addition, smokers can impact the health of nonsmokers, family members, and others who breathe secondhand smoke.⁹⁸ Passive cigarette smoke causes approximately half of all asthma, chronic bronchitis, and frequent wheezing in children aged two months to two years.⁹⁹ Smokers experience an average of 6% more physician office visits and spend an average of 27% more days in the hospital annually than nonsmokers.¹⁰⁰

The direct and indirect costs to society of cigarette smoking are dramatic: Americans spend an estimated \$50 billion annually on direct medical care for smoking-related illnesses, about 10% of the total health bill in America, and spend another \$47 billion annually on lost productivity and forfeited earnings due to smoking-related disability.¹⁰¹ Tobacco-related illness accounts for \$8.2 billion of the \$18.2

96. See Michael C. Fiore, *The Cost Effectiveness of the AHCPR Smoking Cessation Clinical Practice Guideline*, AMA/American Public Health Ass'n (Dec. 1997) (media briefing) (briefing on file with the *Journal of Health Care Law & Policy*); W. Martin Davis, *Tobacco/Nicotine Dependence and Cessation Therapies*, DRUG TOPICS, Sept. 7, 1998, at 62-63 (describing the link between smoking and lung cancer and coronary artery disease).

97. See *Cigarette Smoking-Attributable Mortality and Years of Potential Life Lost- United States, 1990*, 42 MORBIDITY AND MORTALITY WKLY. REP. 645, 645-49 (1993). In fact, approximately one out of every five deaths in the U.S. is attributed to smoking. See *id.* Tobacco use kills more people each year than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined. See INSTITUTE OF MEDICINE, *GROWING UP TOBACCO FREE: PREVENTING NICOTINE ADDICTION IN CHILDREN AND YOUTHS 3* (Barbara S. Lynch & Richard J. Bonnie eds., 1994).

98. See Nordenberg, *supra* note 1.

99. See *Smoking Cessation: Hearings Before the Senate Labor and Human Resources Committee*, 105th Cong. (1997) (statement of John M. Eisenberg, M.D., Administrator, Agency for Health Care Policy and Research) (citing study by Peter Gergen of the Agency for Health Care Policy and Research) available in www.senate.gov/labor/hear/2108hrg/eisenb.htm.

100. See Cromwell et al., *supra* note 86, at 1763.

101. See Agency for Health Care Policy and Research, U.S. Dep't of Health and Human Services, *Smoking Cessation: A Systems Approach* (visited June 9, 1998) <<http://www.ahcpr.gov/clinic/smokesys.htm>>; see also Jon D. Hanson & Kyle D. Logue, *The Cost of*

billion in substance abuse-related costs to Medicaid.¹⁰² These costs reflect only inpatient hospital costs to Medicaid, and not outpatient hospital costs, emergency room services, payments to physicians, or costs to Medicare or other public programs.¹⁰³ The total cost to Medicaid from smoking is estimated to be \$322 billion over the next 25 years.¹⁰⁴

Smoking cessation improves the health of smokers, thereby reducing their need for treatment for smoking-related illness. When a smoker quits smoking, her risk of heart disease and lung cancer decrease steadily.¹⁰⁵ In fact, three years after quitting, the risk of dying from a heart attack is approximately the same as a nonsmoker.¹⁰⁶ Ten years after quitting, the risk of lung cancer declines about 30% to 50% of a continuing smoker's risk.¹⁰⁷ The 1990 Surgeon General's report, *The Health Benefits of Smoking Cessation*, concluded smoking cessation has major health benefits for men and women of all ages, and these benefits apply to persons with and without smoking-related disease.¹⁰⁸ The health benefits of smoking cessation are somewhat difficult to assess because the benefits are delayed many years, occurring through decreased morbidity and mortality across a wide range of illnesses.¹⁰⁹ However, smoking cessation clearly leads to lower incidence of disease, which in turn leads to lower incidence of utilization of health care services.¹¹⁰ Lower utilization of health care services leads to decreased costs of providing health care to Medicaid smokers.¹¹¹ Smoking cessation intervention such as pharmacotherapy is an inexpensive

Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation, 107 YALE L.J. 1163, 1229-31 (1998) (discussing cost effectiveness of smoking cessation).

102. See National Center on Addiction and Substance Abuse at Columbia University, *supra* note 5. Drug-related conditions account for \$5.6 billion and alcohol-related diseases account for \$4.4 billion in substance abuse-related costs to Medicaid. See *id.*

103. See *id.*

104. See *id.* Since 1980, Medicaid costs have grown at an annual average rate of 13%, as opposed to only a 4.4% annual increase in the Consumer Price Index. See *id.*

105. See Nordenberg, *supra* note 1.

106. See *id.* (quoting the American Heart Ass'n).

107. See *id.* (quoting the American Heart Ass'n).

108. See Smoking Deterrent Drug Products for Over-the-Counter Human Use, 58 Fed. Reg. 31,236, 31,238 (1993) (codified at 21 C.F.R. pt. 310).

109. See Cromwell et al., *supra* note 86, at 1759-60.

110. See *id.* at 1759; see also Steven R. Cummings et al., *The Cost-effectiveness of Counseling Smokers to Quit*, 261 JAMA 75, 75 (1989); Kevin Fiscella & Peter Franks, *Cost-effectiveness of the Transdermal Nicotine Patch as an Adjunct to Physicians' Smoking Cessation Counseling*, 275 JAMA 1247, 1247 (1996); Gerry Oster et al., *Cost-effectiveness of Nicotine Gum as an Adjunct to Physician's Advice Against Cigarette Smoking*, 256 JAMA 1315, 1315 (1986).

111. See National Center on Addiction and Substance Abuse at Columbia University, *supra* note 5.

way to reduce Medicaid costs, particularly when compared to the cost of providing health care for the lifetime of a smoker.¹¹²

In a study examining the cost effectiveness of smoking cessation intervention, researchers assessed the cost and success rates of a smoking cessation program that combined counseling with pharmacotherapy.¹¹³ The study determined that providing patients with smoking cessation counseling without pharmacotherapy was not as successful and therefore not as cost effective as providing patients with a smoking cessation program that combined counseling with pharmacotherapy.¹¹⁴ The study estimated the cost of implementing such a program nationally was \$3,779 per quitter, for which society could expect to gain 1.7 million new quitters.¹¹⁵ The overall cost of providing smoking cessation treatment per year of life saved is estimated to be \$2,587.¹¹⁶ The more intensive the intervention, the lower the cost per year of life saved, which suggests that greater spending on intervention yields more net benefit.¹¹⁷ The study also found that smoking cessation programs that involved more intensive counseling and the nicotine patch had the highest rate of success.¹¹⁸ Smoking cessation intervention is also extremely cost effective when compared to other prevention interventions.¹¹⁹ For example, mammography screening costs about \$26,000 per year of life saved and hypertension screening costs almost \$55,500 per year of life saved.¹²⁰ Other than immunization, smoking cessation is the most cost effective prevention intervention for adults; no other intervention provides the same return on investment as smoking cessation treatment.¹²¹

As further testament to the cost effectiveness of smoking cessation intervention, 75 percent of private sector managed care covers

112. See Cromwell et al., *supra* note 86, at 1763-64; see also *supra* notes 99-104 and accompanying text for direct and indirect costs of smoking and cost savings from smoking cessation. In addition to direct health benefits for smokers, increasing the rate of smoking cessation for adults may aid in reducing the number of teenagers who start smoking. See Mike Males, *The Influence of Parental Smoking on Youth Smoking: Is the Recent Downplaying Justified?*, 65 J. OF SCHOOL HEALTH 228, 230 (1995). Studies demonstrate that the children of parents who smoke are also more likely to smoke and be resistant to smoking prevention education messages. See *id.*

113. See Cromwell et al., *supra* note 86, at 1766.

114. See *id.* at 1764-65.

115. See *id.*

116. See *id.*

117. See *id.* at 1759.

118. See *id.* at 1765-66.

119. See *id.*

120. See *id.*; see also T. Tengs, et al., *Five Hundred Life-Saving Cost Interventions and Their Cost-effectiveness*, 15 RISK ANALYSIS 369, app. at 378, 383 (1995).

121. See Cromwell et al., *supra* note 86, at 1766.

smoking cessation intervention and treatments.¹²² That the majority of private sector managed care organizations provide coverage for smoking cessation prescription drugs implies managed care recognizes the cost effectiveness of encouraging their members to quit smoking.¹²³ The cost of providing effective smoking cessation treatment is minimal when compared with the cost of treating a heart attack, stroke, or cancer which result from smoking.¹²⁴ Due to the potential for cost savings, smoking cessation has been cited as the "gold standard" by which all other prevention treatments can be compared.¹²⁵

C. Federal Government Smoking Cessation Initiatives in Agencies and Programs

Smoking cessation is clearly a national priority, as evidenced by the federal government's sponsorship of several smoking cessation initiatives through federal agencies and programs. The federal government encourages smoking cessation through the Agency for Health Care Policy and Research (AHCPR), the Centers for Disease Control and Prevention (CDC) and Healthy People 2000, and through other health programs for military personnel.¹²⁶ All military services are required to establish a health promotion program, a component of which must address smoking cessation and prevention.¹²⁷ Military smoking cessation and prevention programs are required to provide smokers with encouragement and professional assistance in quitting, and require military health care providers, as part of routine physical and dental examinations, to advise smokers of the risk of tobacco use and where to obtain help to quit smoking.¹²⁸

Healthy People 2000 is a national health activity sponsored by the CDC to reduce morbidity and mortality, and improve the quality of

122. See *Research Funding: Managed Care Plans Should Enhance Identification of Individual Smokers*, "THE BLUE SHEET," F-D-C REPORTS, May 20, 1998 (citing a 1997-98 Robert Wood Johnson Foundation survey of managed care entities).

123. See *id.* Managed care organizations survive by focusing on providing preventive services to their members and improving cost savings in health care delivery. See FURROW ET.AL., *supra* note 12, at 284.

124. See Cromwell et al., *supra* note 86, at 1766 (referring to author's analysis which indicates very low cost-effectiveness ratios for smoking cessation intervention compared to other medical interventions).

125. David M. Eddy, *David Eddy Ranks the Tests*, 17 HARV. HEALTH LETTER 10, 11 (July 1992).

126. See *infra* notes 139-145 and accompanying text.

127. See 32 C.F.R. § 85.6(a)-(d) (1998).

128. See *id.* at § 85.6(d)(1)(i)-(vii).

life of all Americans.¹²⁹ One of the Healthy People 2000 goals is to reduce cigarette smoking in the United States to no more than 15% of people aged 18 years or over by the year 2000.¹³⁰ The CDC achieves its smoking cessation goals by annually offering grants to national organizations that provide smoking cessation programs to minority populations and youth.¹³¹ The CDC endorses smoking cessation programs that combine nicotine replacement therapy, social support, and skills training/problem solving techniques for achieving and maintaining abstinence.¹³² The CDC has awarded tobacco control cooperative agreements to state health agencies to develop infrastructure and strengthen capacity to implement tobacco control programs, and to collaborate with other national organizations and health agencies in the implementation of local and state tobacco control programs.¹³³

The Agency for Health Care Policy and Research (AHCPR) issued smoking cessation guidelines for clinicians in 1996.¹³⁴ The AHCPR guidelines recommend prevention activities primary care physicians should undertake when they encounter patients who smoke.¹³⁵ In the smoking cessation guidelines, AHCPR recommends that clinicians offer smoking cessation treatments to every person who smokes at every office visit, and further recommends that smoking cessation treatments, both pharmacotherapy and counseling, should be provided as paid services of health insurance.¹³⁶ The AHCPR smoking cessation guidelines were distributed to 200,000 primary care physicians by the American Medical Association (AMA), and were endorsed by the AMA and the American Academy of Family Physicians.¹³⁷ AHCPR notes that smoking cessation pharmacotherapy and counseling are not consistently provided as paid services for subscribers of health insurance packages.¹³⁸ AHCPR further advises that smoking cessation intervention is as cost effective as other covered preventive services, such as treatment of mild or moderate hyperten-

129. See CDC Notice of Availability of Funds, 63 Fed. Reg. 20,197, 20,197 (1998).

130. See *id.* at 20,198.

131. See *id.* at 20,197; see also Initiatives by Organization to Strengthen National Tobacco Control Activities in the United States, 62 Fed. Reg. 36,550, 36,550 (1997).

132. See CDC Notice of Availability of Funds, 63 Fed. Reg. at 20,199.

133. See *id.*

134. See *Smoking Cessation: A Systems Approach*, *supra* note 101.

135. See *id.*

136. See *id.*

137. See *AHCPR Encourages Physicians To Help Smokers Kick the Habit*, MANAGED CARE MAGAZINE (June 1996) (visited June 30, 1998) <<http://www.managedcaremag.com/archiveMC/9606/MC9606.guidelines.shtml>>.

138. See *Smoking Cessation: A Systems Approach*, *supra* note 101.

sion or high cholesterol, and therefore clinicians should be reimbursed for smoking cessation treatment.¹³⁹

Clearly, the optional exclusion of smoking cessation pharmacotherapy from Medicaid coverage does not comport with the federal government's investment in smoking cessation as illustrated by the military guidelines on smoking cessation and prevention programs, the Healthy People 2000 goals, CDC tobacco control funding initiatives, or AHCPR smoking cessation guidelines and recommendations. Medicaid coverage of smoking cessation prescription drugs should not be the exception to this national priority of smoking cessation.

III. PROPOSED LEGISLATIVE CHANGE TO LAW GOVERNING MEDICAID OPTIONAL DRUG EXCLUSIONS

As discussed previously, HCFA has refuted its authority to delete drugs from the statutory list of exemptions in section 1972(d)(2), and therefore drugs can only be removed if Congress statutorily amends the list.¹⁴⁰ As long as smoking cessation prescription drugs appear on the list of exemptions, states will have the option of providing Medicaid coverage regardless of the evidence of cost effectiveness of smoking cessation intervention. Congress should therefore repeal line (E), "Agents which promote smoking cessation", of section 1927(d)(2) of the Social Security Act to ensure that states extend Medicaid coverage for smoking cessation prescription drugs. By this legislative action, states would be required to treat smoking cessation drugs the same as all other prescription drugs under the law governing Medicaid.¹⁴¹ States would retain the ability to subject smoking cessation prescription drugs to state drug formularies, prior authorization programs, and other permissible limitations on prescription drugs employed by state Medicaid programs.¹⁴² However, states would not be permitted to dismiss from coverage the entire class of smoking cessation drugs, as the law currently permits. Medicaid beneficiaries would at last have access to some form of smoking cessation treatment.

Recent Senate legislation on the tobacco litigation settlement sponsored by Senator John McCain (R-Ariz.) contained an amendment that would have eliminated smoking cessation drugs from the statutory list of exempted drugs by repealing line (E) of section

139. *See id.*

140. *See supra* notes 59-67 and accompanying text.

141. *See supra* notes 15-19 and accompanying text.

142. *See supra* notes 28-33 and accompanying text.

1927(d)(2).¹⁴³ The McCain Bill met its demise on the Senate floor on June 17, 1998, and the manager's amendment to section 1927(d)(2) died with it.¹⁴⁴ Several bills pertaining to tobacco control are still active, but none as comprehensive or with the same level of support maintained by the McCain Bill.¹⁴⁵ The remaining tobacco-related bills are narrowly focused on juveniles, minorities, or veterans, and are therefore not a likely vehicle for an unrelated provision repealing a section in the Medicaid law.¹⁴⁶ When the McCain Bill was still active, the provision removing smoking cessation drugs from the list of exemptions received support from the American Medical Association (AMA) and from pharmaceutical companies that market smoking cessation products.¹⁴⁷ The AMA announced its support in the media for coverage of FDA-approved pharmacotherapy for smoking cessation by Medicaid and by private insurers.¹⁴⁸

It is unlikely that Congress will soon consider this issue again. The opinion polls show that voters are not particularly interested in anti-tobacco legislation, diminishing the likelihood that any anti-tobacco legislation will be considered by the full Congress this year.¹⁴⁹ Because the nature of repealing one line in the Social Security Act is

143. Universal Tobacco Settlement Bill, S. 1415, 105th Cong. § 261 (1998); see also *Medicaid Coverage of Smoking Cessation Rx, OTC Products Would Be Required Under Senate Floor Version of McCain Tobacco Bill*, HEALTH NEWS DAILY, F-D-C REPORTS, May 27, 1998. The language in the McCain bill would also have included coverage for smoking cessation OTC treatments as well as prescription drug treatments. See *id.* Many states balk at the notion of covering OTC therapies for smoking cessation because of the fear of expanding coverage to all OTC drugs. See *Smoking Cessation Therapies Approved by FDA Should Be Covered by Medicaid and Private Insurers*, HEALTH NEWS DAILY, F-D-C REPORTS, June 16, 1998. This legislative proposal discussed herein is limited to prescription drugs for smoking cessation for that reason.

144. See *Bill Summary and Status for the 105th Congress*, S.1415, (visited July 6, 1998), <<http://thomas.loc.gov/cgi-bin/bdquery/d105 query.html>>; 144 CONG. REC. S72471-02 (1998); *Tobacco Bill Dies in Senate After a Fierce Four-Week Floor Fight; Settlement Between Big Tobacco and States is Stalled*, ST. LOUIS POST DISPATCH, June 18, 1998, at A1.

145. See, e.g., Youth Protection from Addition Act of 1997, H.R. 762, 105th Cong. (1997); Bipartisan No Tobacco for Kids Act of 1998, H.R. 3868, 105th Cong. (1998); Healthy Kids Act, S. 1638, 105th Cong. (1998); Minority Community Tobacco Reduction Act, H.R. 4189, 105th Cong. (1998); Veterans Tobacco Trust Fund Act of 1998, H.R. 4188, 105th Cong. (1998); Veterans Benefit Restoration Act of 1998, H.R. 4220, 105th Cong. (1998); H.R. 4159, 105th Cong. (1998) (proposing amendment to Public Health Service Act to waive sanctions against states that enact driver's licence-related sanctions for minors who purchase or possess tobacco products for personal consumption).

146. See *supra* note 145.

147. See *Smoking Cessation Therapies Approved by FDA Should Be Covered by Medicaid and Private Insurers*, *supra* note 143; "THE PINK SHEET," *supra* note 9, at 10.

148. See *Smoking Cessation Therapies Approved by FDA Should Be Covered by Medicaid and Private Insurers*, *supra* note 143.

149. See *GOP Leaders Put Smoking Bill on Back Burner, Officials Say Republicans Believe The Teen Smoking Issue Isn't A Concern Among Voters*, GREENSBORO NEWS & REC., Aug. 1, 1998, at

comparatively minor legislative action, Congress is not likely to independently move to pass a bill focused solely on this issue. Rather, this legislative action is best suited for a small provision in a larger bill related to the issue, and therefore will require a vehicle to be considered again by Congress.

IV. CONCLUSION

Repealing the provision permitting states to optionally exclude Medicaid coverage for smoking cessation pharmacotherapy is a simple action Congress could undertake to help Medicaid recipients who want to quit smoking. Five smoking cessation prescription drug products approved by the FDA are currently available, and the safety and efficacy of these products has been demonstrated. However, under the current law, Medicaid recipients are at the mercy of their respective states for access to FDA-approved smoking cessation drugs. Smoking cessation pharmacotherapy can vastly improve the health and quality of life of Medicaid smokers, while simultaneously reducing the overall cost to the Medicaid program of providing health care to treat tobacco-related illness. By repealing a single line from section 1927(d)(2) of the Social Security Act, Congress can have a profound positive effect on the lives of millions of Medicaid smokers.