

THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, & MODERNIZATION ACT OF 2003: ARE WE PLAYING THE LOTTERY WITH HEALTHCARE REFORM?

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ABSTRACT

With millions of Americans unable to cope with the rising costs of prescription drugs, and many even forced to go without health insurance, the mounting pressure on Congress to enact major healthcare reform culminated in the Medicare Prescription Drug, Improvement, & Modernization Act of 2003. This iBrief examines this legislation, and concludes that it provides elusive benefits for seniors and merely creates a windfall for the pharmaceutical and insurance industries.

INTRODUCTION

¶1 In 2002, aggregate health spending in the United States reached an astounding \$1.6 trillion.² As the second richest country in the world,³ it is even more staggering to find that healthcare spending increased by 9.3% while the gross domestic product increased by only 3.9%.⁴ Retail prescription drug sales, which reached an all-time high of \$162.4 billion, accounted for the largest increase in healthcare spending.⁵ Moreover, when coupled with

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² Katherine Levit, et al., *Health Spending Rebound Continues in 2002*, 23 HEALTH AFFAIRS 147, 147 (2004).

³ GDP (PER CAPITA) (TOP 100 COUNTRIES), NATIONMASTER.COM (2003), at http://www.nationmaster.com/graph-T/eco_gdp_cap (citing figures from the 2002 CIA World Factbook that indicate the United States' per capita gross domestic product is the second highest in the world at \$35,991.96 per person) (last visited Sept. 10, 2004).

⁴ Levit, *supra* note 2, at 147; see also Cynthia Smith, *Retail Prescription Drug Spending in the National Health Accounts*, 23 HEALTH AFFAIRS 160, 166 (2004) (“[T]he rate of [prescription drug] spending growth is expected to continue to outstrip gains in GDP.”).

⁵ Levit, *supra* note 2, at 148, 154. While aggregate growth in spending for prescription drugs has actually decreased slightly because of factors such as state use of preferred drug lists, fewer new drug entities entering the market place, and more generics in the marketplace, increased third party coverage has fueled

chronic care spending, long-term care now represents more than 75% of all healthcare expenditures.⁶ Economists predict this figure will only continue to escalate as the Baby Boomer generation ages.⁷

¶2 While increased expenditures represent a stable economic status and evidence of our nation's ability to pay for life-extending healthcare, it is undeniable that the current healthcare system is inefficient and unsustainable.⁸ Given the high level of healthcare spending and the rising number of individuals who are unable to afford proper healthcare, the uneven and unjust nature of the American healthcare system is patently obvious. More than 40 million Americans are uninsured,⁹ and more elderly patients every year must chose between paying for prescription drugs and paying for rent.¹⁰

¶3 In December 2003, President Bush signed into the law the most recent federal healthcare reform—the Medicare Prescription Drug Improvement, & Modernization Act of 2003 (MMA).¹¹ This iBrief looks at the various components of the MMA and addresses the major implications of this more than 700 page bill. Part I examines the factors that led to healthcare and prescription drug coverage reform. Next, Part II gives a general overview of the MMA. Part III contextualizes these provisions and analyzes their impact on the American healthcare system. Finally, this iBrief argues that while the MMA is well intentioned, it may actually exacerbate the underlying problems of the healthcare system and create a windfall for the pharmaceutical and insurance industries.

I. THE BRAND NAME PHARMACEUTICAL INDUSTRY: THE STRUGGLE TO MAINTAIN POWER

¶4 Brand name prescription retail sales are at an all-time high. In 2002, the brand name pharmaceutical firm Pfizer recorded revenues totaling \$32.4 billion, including over \$8 billion in retail sales of their cholesterol-reducing

continued growth in the demand for and the use of newer, more expensive drugs. *Id.* at 156-57; Smith, *supra* note 4, at 161-62.

⁶ R. Sanders Williams, Address at the Duke Health Law Society Symposium, *Science and Better Medicine: A Changing Perspective* (Feb. 18, 2004) (power point presentation on file with author).

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ Robert Pear & Milt Freudenheim, *Drug Discounts Beginning Tuesday, but Sign-Ups Lag*, N.Y. TIMES, June 1, 2004, at A1. [hereinafter *Sign-Ups Lag*].

¹¹ Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified at 26 USCA §§ 139A, 223, 4980G; 42 USCA §§ 299b-7, 1395b-8, 1395b-9, 1395w-3a, 1395w-3b, 1395w-27a, 1395w-29, 1395w-101 to 1395w-104, 1395w-111 to 1395w-116, 1395w-131 to 1395w-134, 1395w-141, 1395w-151, 1395w-152, 1395cc-3, 1395kk-1, 1395zz, 1395hhh, 1396u-5) [hereinafter MMA].

drug Lipitor.¹² In the same year, companies such as Merck and AstraZeneca grossed retail sales of over \$5.6 billion and \$4.6 billion for their high-demand drugs Zocor and Prilosec, respectively.¹³ For the fifth straight year, pharmaceutical firms ranked as the most profitable industry in the nation.¹⁴

Pfizer led U.S. pharmaceutical companies with \$7.8 billion in profits in 2001, which is more than the profits of all the Fortune 500 companies in the homebuilding, apparel, railroad, and publishing industries combined. Merck was the second most profitable pharmaceutical netting \$7.3 billion, which is more than the profits of all the Fortune 500 companies in the semi-conductor, pipeline, food production, mining and crude oil production, and hotel, casino and resort industries combined.¹⁵

¶5 With such an enormous financial interest in maintaining high prescription drug prices and market exclusivity, pharmaceutical companies have spent millions of dollars to extend patent protection and forestall government regulation of prescription drug prices. From 1999 to 2003, the pharmaceutical industry made campaign contributions of more than \$50 million in an effort to keep drug prices unregulated¹⁶ and from 1996 to 2003 spent \$435 million to influence Congress via the efforts of more than 600 lobbyists.¹⁷

¶6 The increase in both health expenditures and pharmaceutical industry profits has not gone unnoticed. Physicians, consumers, and state governments alike are buying drugs from Canada and Mexico, despite possible legal ramifications, because the difference in the cost of drugs in those countries is drastically lower than in the United States.¹⁸ State and city governments in

¹² Donald L. Barlett & James B. Steele, *Why We Pay So Much for Drugs*, TIME, Feb. 2, 2004, at 45, 47, 51.

¹³ *Id.*

¹⁴ *Pharmaceutical Industry Ranks as Most Profitable Industry—Again*, PUB. CITIZEN, Apr. 18, 2002 [hereinafter *Pharma Most Profitable*], available at <http://www.citizen.org/pressroom/release.cfm?ID=1088>. Pfizer's profits increased another \$1.3 billion in 2002 to \$9.1 billion. Barlett, *supra* note 12, at 51.

¹⁵ *Pharma Most Profitable*, *supra* note 14 (emphasis in original).

¹⁶ Sheryl Gay Stolberg & Gardiner Harris, *Industry Fights to Put Imprint on Drug Bill*, NY TIMES, Sept. 5, 2003, at A1.

¹⁷ Barlett, *supra* note 12, at 52.

¹⁸ See Julie Appleby, *FDA threatens stores that sell Canadian drugs to U.S. residents*, USA TODAY, Apr. 9, 2003, available at <http://www.usatoday.com/money/industries/health/drugs/2003-04-08canadadrugs-x.htm> (last visited Mar. 10, 2004); Joel Baglolle, *Getting the Gray Out*, Feb. 11, 2003, WALL ST. J. ONLINE, at <http://online.wsj.com/article/0,,SB1044557607157100653,00.html> (last visited Mar. 10, 2004); Tara Parker-Pope, *The Ins and Outs of Buying Legal Drugs Across Borders*, Oct. 22, 2002, WALL ST. J. ONLINE, at

Illinois, Iowa, Minnesota, New Hampshire, Wisconsin, New York, and Massachusetts have all begun investigating or implementing programs to import cheaper prescription drugs from Canada.¹⁹

¶7 As consumer pressure mounts and evidence suggests that the Food and Drug Administration's (FDA) crack-down on the illegal importation of prescription drugs has little to do with actual safety concerns and more to do with the pharmaceutical industry's vast political influence over the FDA,²⁰ various entities have filed lawsuits seeking the right to import prescription drugs.²¹ Most recently, Governor Jim Douglas announced that Vermont expects to be the first state to sue the FDA for their recent "unsubstantiated" denial of a pilot program aimed at lowering prescription drug expenditures for current and retired state employees by nearly \$1 million via a state contract with a Canadian mail-order pharmaceutical company.²²

¶8 Such attempts to find less expensive means of obtaining prescription drugs are the offshoot of a recent shift in the consumer market toward generics. Brand name pharmaceutical companies have been experiencing declining profits as people opt for generic bioequivalents of brand name prescription drugs that cost, on average, 30-60% less than their brand name counterparts.²³ For example, since the expiration of Claritin's patent protection in December 2002, Schering-Plough's retail sales for the drug

<http://online.wsj.com/article/0,,SB1035229711265527711.djm,00.html> (last visited Mar. 10, 2004).

¹⁹ See Julie Appleby, *Boston, N.H. look to Canada for drugs*, USA TODAY, Dec. 10, 2003, at 1A; Monica Davey, *Illinois Might Purchase Drugs From Canada, Saving Millions*, 123 THE TECH 40, Sept. 16, 2003, at http://www-tech.mit.edu/V123/N40/long2_drugs.40w.html (last visited Mar. 2, 2004); Gardiner Harris, *Drug Makers' New Intensity in Defense of U.S. Borders*, N.Y. TIMES, Oct. 30, 2003, at C1 [hereinafter *Defense of U.S. Borders*]; Gardiner Harris, *Cheap Drugs From Canada: Another Political Hot Potato*, N.Y. TIMES, Oct. 23, 2003, at C1; Gardiner Harris & Monica Davey, *U.S. Steps Up Effort Against Drug Imports*, N.Y. TIMES, Jan. 24, 2004, at C1; *Illinois governor pushes for drug-buying program*, CNN.COM, Dec. 22, 2003, at <http://www.cnn.com/2003/HEALTH/12/22/prescription.drugs.ap/index.html>.

²⁰ See, e.g., Pam Belluck, *Vermont Will Sue U.S. for the Right to Import Drugs*, N.Y. TIMES, Aug. 11, 2004, at A13.

²¹ *Id.*

²² *Id.*

²³ Gail Russell Chaddock, *Profits, Politics, and a Drug patent*, THE CHRISTIAN SCI. MONITOR, July 19, 2000, available at <http://search.csmonitor.com/durable/2000/07/19/text/p1s2.html> (last visited Mar. 14, 2004).

declined more than \$1.8 billion in the first half of 2003 and led to a staggering 20% decline in Schering-Plough's stock price.²⁴

¶9 In an attempt to maintain control over the American drug market, pharmaceutical companies have countered reimportation efforts by reducing their overall drug sales to Canadian retailers.²⁵ Pointedly, Pfizer has ordered its Canadian wholesale distributors to provide lists of sales of its products to individual drugstores, warning that Pfizer will halt all drug supplies if drugs are being sold to American sources.²⁶

A. Congress' Initial Attempt to Balance Power in the Industry

¶10 Congress spent six years debating and amending a bill, referred to as the Hatch-Waxman Act of 1984,²⁷ aimed at balancing the interests of consumers in receiving safe and affordable medications with those of both the brand name and generic pharmaceutical companies in protecting patent rights and maintaining profitability.²⁸ Specifically, the Act established three key measures: (1) patent term restoration for brand name patents,²⁹ (2) the ability for generic firms to file an "abbreviated new drug application" (ANDA) for any new generic drug,³⁰ and (3) a 180-day period of exclusivity for sales and

²⁴ Amy Tsao, *Schering-Plough: Drugmaker, Heal Thyself*, BUSINESSWEEK ONLINE, June 11, 2003, at http://www.businessweek.com/technology/content/jun2003/tc20030611_0956_tc055.htm (last visited Mar. 14, 2004).

²⁵ *Defense of U.S. Borders*, *supra* note 19, at C1.

²⁶ Barlett, *supra* note 12, at 49.

²⁷ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b (1994); 21 U.S.C. §§ 301 note, 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

²⁸ See H.R. Rep. 98-857(I), at ¶ 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647-48 (affirming that the Hatch-Waxman Act was enacted "to make available more low cost generic drugs . . . [and] to create a new incentive for increased expenditures for research and development of certain products which are subject to pre-market approval").

²⁹ To appease brand name firms, patent term extensions were made available for losses in patent terms cause by FDA regulatory delays, but only if drug firms employed due diligence in achieving any such patent term restoration. 35 U.S.C. § 156 (2000). Patent term restorations may be obtained that are equal to one-half of the time it takes to run human clinical trials on a new drug plus the period of FDA review. However, the maximum extension is five years and the total length of exclusivity cannot exceed 14 years. *Id.*

³⁰ 21 U.S.C. § 355(j)(2) (2000). As an incentive to expedite the production and approval of generic drugs, the Act also permitted generic firms to submit an ANDA, whereby FDA safety and efficacy testing was no longer mandatory with a demonstration of bioequivalence to a brand name drug. *Id.* However, the Food, Drug and Cosmetics Act did require ANDA applicants to certify that the patent on

marketing given to the first generic firm to file an ANDA with the FDA.³¹ Brand name pharmaceutical companies were also given an additional protection against potential abuses by generic firms. Accordingly, an automatic 30 month stay on FDA approval of any generic ANDA was granted if a brand name firm initiated a legal challenge asserting patent infringement.³²

¶11 Despite the fact that these new provisions increased the availability and use of generic prescription drugs, the Hatch-Waxman Act ultimately failed to achieve its goals or adequately address the problems that Congress originally sought to remedy. In fact, the Hatch-Waxman Act exacerbated the power struggle between brand name pharmaceutical companies, generic firms, and the public. The Act was susceptible to further monopolistic abuses such as antitrust violations, further delays in the release of generic drugs, and significant increases in prescription drug prices.³³ A Federal Trade

the drug or method of use: (I) had not been filed in a previous patent application; (II) had expired; (III) would expire on a particular date; OR (IV) was invalid/would not be infringed by the drug for which the ANDA was being sought. § 355(j)(2)(A)(vii). In the case of a “paragraph IV certification,” the brand name drug company would be given notice, § 355(j)(2)(B); 21 C.F.R. § 314.95(c)(6) (2003), and a 45-day period within which they could bring an action for patent infringement against the ANDA applicant. § 355(j)(5)(B)(iii). Such an action automatically triggered a mandatory 30-month stay on the approval of the ANDA. *Id.*

³¹ 21 U.S.C. § 355(j)(2). The Act also provided a financial incentive for generic drug companies to challenge allegedly invalid patents or market drugs that they believe do not infringe on current brand name patents. The first generic firm to file an ANDA with the FDA would be granted a 180-day period of exclusivity during which no other generic manufacturer may obtain FDA approval or market its version of the drug. § 355(j)(5)(B)(iv).

³² 21 U.S.C. § 355(j)(5)(B)(iii).

³³ See Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements Before the Committee on the Judiciary United States Senate, 107th Cong. (2001) (prepared statement of the Federal Trade Commission) available at <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>; see also NATIONAL INSTITUTE FOR HEALTHCARE MANAGEMENT RESEARCH AND EDUCATIONAL FOUNDATION, PRESCRIPTION DRUG EXPENDITURES IN 2001: ANOTHER YEAR OF ESCALATING COSTS (Mar. 29, 2002), available at <http://www.nihcm.org>; FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002) [hereinafter FTC STUDY], available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (last revised Sept. 10, 2002). After instituting several complaints against some of the leading brand name and generic pharmaceutical companies for alleged antitrust actions including, agreements made by drug companies to (1) intentionally delay generic drug competition in exchange for millions of dollars, (2) tie up key ingredients used in the making of prescription drugs so that demand was increased, and (3) impose unwarranted price increases, the FTC finally proposed an industry-wide study to

Commission (FTC) study conducted in 2002 demonstrated that generic drug entry into the marketplace has been delayed even further by cunning manipulations of the Hatch-Waxman Act.³⁴ For example, the 30-month stay provision, which was designed to protect brand name firms from the improper appropriation of patented drugs, has been abused in several instances to delay the entry of generic drugs into the marketplace for up to 12 years in some cases.³⁵

¶12 The same FTC study also found that the regulations governing the 180-day period of exclusivity granted to generic firms for filing the first ANDA were problematic.³⁶ Although the 180-day marketing exclusivity provision was intended to facilitate and encourage generic firms to bring their drugs to market sooner, it actually delayed the entry of such generics into the marketplace.³⁷ The 180-day exclusivity period only begins to run from the first date of commercial marketing of the generic, or from the date of a court decision declaring the brand name patent invalid or not infringed. As such, the FTC study found multiple instances where generic firms suspended the start of the 180-day exclusivity period (1) as part of a settlement agreement in patent infringement suits brought by brand name firms, or (2) until a court decision had been rendered in their favor.³⁸ Therefore, all generic competition in the marketplace is suspended indefinitely when the first firm to file an ANDA fails to trigger the start of their exclusive rights.³⁹

examine the impediments to a more competitive and less costly drug market. *Id.*; see also, Federal Trade Commission Decision and Order, *In the Matter of Abbott Laboratories*, (Mar. 16, 2000) (No. 981 0395) available at <http://www.ftc.gov/os/2000/03>; Federal Trade Commission Administrative Complaint, *In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation*, (Mar. 16, 2000) (No. 9293), available at <http://www.ftc.gov/os/2000/03>; Federal Trade Commission *In the Matter of Schering-Plough Corporation, et al.*, (Mar. 30, 2001) (No. 9297).

³⁴FTC STUDY, *supra* note 33.

³⁵Debra Z. Anderson, *The Private Sector: Delaying Cheap Pills*, POST-GAZETTE, July 19, 2003, available at <http://www.post-gazette.com/pg/03119/180170.stm>.

³⁶FTC STUDY, *supra* note 33.

³⁷*Id.*

³⁸*Id.*

³⁹*Id.* The FDA has recently enacted new regulations that attempt to address these concerns. 21 C.F.R. § 314, *et. seq.* The new regulations which became enforceable on December 18, 2003, limit brand name firms to a single automatic 30-month stay to resolve any allegations of false “paragraph IV certifications” and curtail the late filing of frivolous patents in an effort to delay generic drug entry into the marketplace. §§ 314.52, 314.95, 314.107(b)(3)(i)(A). Instead, the FDA will now require pharmaceutical firms to submit detailed patent information regarding the active ingredients, the drug composition, the approved uses of the drug, and a signed affidavit that certifies the validity of such information. §§ 314.94-95, 314.101. False submissions to the FDA will also result in strict

¶13 Due to the problems created by the Hatch-Waxman Act and continued negative press about the high costs of prescription drugs, the MMA was touted as problem-solving reform and was strong-armed into law. Yet, even before the ink from Bush's signature could dry, the bill was already being criticized for its elusive benefits.⁴⁰

II. CONGRESS' SECOND ATTEMPT AT REFORM: THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT & MODERNIZATION ACT OF 2003

A. Provisions for Seniors

¶14 The MMA has been touted as a solution for elderly people with low incomes and very high drug bills. For the first time since the inception of the Medicare program in 1965, seniors will be given the opportunity to have prescription drug coverage under a new voluntary "Medicare Part D" benefit plan. Coverage is scheduled to take effect in two stages. Beginning in June 2004, Medicare participants were able to buy discount drug cards for use at retail pharmacies.⁴¹ The second phase of the MMA, scheduled to begin in 2006, will permit Medicare beneficiaries to sign up for a stand-alone drug plan or join a private health plan with drug coverage.⁴²

1. Discount Drug Cards—§ 101

¶15 Under Title I, § 101 of the MMA, the Department of Health & Human Services must establish a temporary prescription drug discount plan.⁴³ Under the plan, Medicare participants who are not already given drug benefits under Medicaid are eligible to purchase discount drug cards for \$30 a year.⁴⁴ In addition, the Act requires the Centers for Medicare and Medicaid Services (CMS) to ensure that each geographic area offers at least two alternative

criminal penalties. §§ 314.80, 314.81, 314.170, 314.630. Although the new FDA regulations address two of the primary abuses of the Hatch-Waxman Act, they ultimately fail to remedy the loopholes in the 180-day exclusivity period.

⁴⁰ See Robert Pear, *Medicare Law's Costs and Benefits Are Elusive*, N.Y. TIMES, Dec. 9, 2003, at A1 [hereinafter *Costs and Benefits Are Elusive*].

⁴¹ Robert Pear, *Coalition Promoting Drug Discount Cards*, N.Y. TIMES, May 24, 2004, at A1.

⁴² *The Skinny On The Medicare Bill*, CBSNEWS.COM, Nov. 25, 2003 [hereinafter *The Skinny*], at

<http://www.cbsnews.com/stories/2003/11/25/politics/main585469.shtml> (last visited Sept. 29, 2004).

⁴³ MMA § 101 (1860D-31) (codified as amended at 42 U.S.C. §§ 1395w-141).

⁴⁴ *Id.*; ARENT FOX, HEALTHCARE ALERT: MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 1 (2003); Alan M. Schlein, *Medicare Reform Bill—Loved, Hated, Hailed and Decried. What's in it for you?*, FIFTY PLUS, Jan. 2004, at 6, 7.

choices and publicizes the coverage—i.e. prices, fees, & formularies—for these discount card programs.⁴⁵

Card sponsors also will have to (1) ensure acceptance of their cards at a sufficiently large network of retail pharmacies located throughout their service area (i.e., access may not be provided solely through mail-order pharmacies); (2) require that pharmacists at participating outlets routinely explain price differences between brand and generic products; and (3) disclose to CMS “the extent to which negotiated price concessions... by a manufacturer are passed through to enrollees through pharmacies or otherwise.”⁴⁶

Discount cards entitle holders to privately negotiated discounts ranging from 10-25% on those prescription drugs listed under the chosen card plan.⁴⁷

2. New Drug Benefit—§ 101

¶16 In January 2006, discount drug cards will give way to the second phase of the MMA, which aims to provide two more comprehensive options to reduce the cost of prescription drugs for seniors.⁴⁸ Eligible seniors can enroll in either a “qualified” Prescription Drug Plan or a Medicare Advantage plan.⁴⁹

¶17 Under these qualified plans, beneficiaries will pay a \$35 per month premium in exchange for either “standard prescription drug coverage” or an out-of-pocket plan with deductibles, both of which are equivalent in coverage.⁵⁰ Standard prescription drug coverage has a \$250 annual deductible and covers 75% of all costs associated with those drugs listed under the plan up to \$2,250 (or a total annual benefit of \$1,500).⁵¹ However, where drug costs exceed \$2,250, there is no additional benefit until out-of-pocket expenses reach \$3,600.⁵² If prescription drug costs reach \$5,100, said plans

⁴⁵ MMA § 101 (1860D-3(a)(1)) (codified as amended at 42 U.S.C. § 1395w-103(a)(1)).

⁴⁶ ARENT FOX, *supra* note 44, at 2.

⁴⁷ Barlett, *supra* note 12, at 46; ARENT FOX, *supra* note 44, at 2 (“To facilitate discounting, the legislation expressly exempts price concessions that manufacturers extend to Medicare-endorsed card sponsors from Best Price determinations under the Medicaid Drug Rebate Statute.”).

⁴⁸ MMA §§ 101 (1860D-1—4) (codified as amended at 42 U.S.C. §§ 1395w-101—4).

⁴⁹ *Id.* at § 101 (1860D-1) (codified as amended at 42 U.S.C. §§ 1395w-101).

⁵⁰ *The Skinny*, *supra* note 42.

⁵¹ *Id.* at §§ 101 (1860D-2(b)(1)(A), (b)(2)(A), (b)(3)(A)) (codified as amended at 42 U.S.C. §§ 1395w-102(b)(1)(A), (b)(2)(A), (b)(3)(A)).

⁵² *Id.* at § 101 (1860D-2(b)(4)(B)) (codified as amended at 42 U.S.C. §§ 1395w-102(b)(4)(B)).

will cover 95% of any additional costs.⁵³ Supplementary aid is also available for catastrophic expenses or when participants' yearly income and assets fall below a certain level.⁵⁴

B. Provisions that Benefit all Americans

1. Individual importation of drugs from Canada—§ 1121

¶18 While the MMA does not permit the importation of prescription drugs from Canada by pharmacies and wholesalers, it does provide for the development of regulations that would allow for such importation on a limited basis by individuals.⁵⁵ Those with a valid prescription would be entitled to a 90-day supply of a pre-approved drug, in proper dosage form, from a registered Canadian seller.⁵⁶ Moreover, the Secretary of DHHS would be permitted to enact any other restrictions on drug importation that he or she deemed "necessary to ensure public safety."⁵⁷

2. Health Savings Accounts (HSAs)—§ 1201

¶19 Title XII of the MMA provides for the establishment of Health Savings Accounts (HSA) for those individuals who have high deductible insurance plans.⁵⁸ HSAs differ from the pre-existing Archer Medical Savings Accounts (MSAs) provided for in 26 U.S.C. § 220 in that they are not limited to individuals who are self-employed or work for a small employer.⁵⁹ In addition, HSAs permit individuals or families to establish a tax free fund for the entire amount of their health insurance deductible over \$1,000 (or \$2,000 for families) and up to \$2,250 (or \$4,500 for families), unlike MSAs which

⁵³ *The Skinny*, *supra* note 42.

⁵⁴ *The Skinny*, *supra* note 42.

⁵⁵ *Id.* at § 1121(j)(2) (codified as amended at 21 U.S.C. § 384(j)(2)). Despite the fact that § 1121(b) appears to usher in the importation of drugs from Canada by retailers and wholesaler, such a program is not likely because of the language of the MMA. MCDERMOTT, WILL & EMERY, HEALTH LAW UPDATE: CONGRESS APPROVES MEDICARE PRESCRIPTION DRUG AND MODERNIZATION ACT OF 2003, 34 (2003) ("Prior similar authority granted to the secretary was never effectuated because neither the former secretary, nor the current one would conclude that importation posed 'no additional risk to the public's health and safety' and/or that it would 'result in a significant reduction in the cost of covered products to the American consumer.' The [MMA] contains a nearly identical certification requirement, therefore making it unlikely that it will be lawful to import drugs from Canada any time soon.")

⁵⁶ *Id.* at § 1121(j)(3) (codified as amended at 21 U.S.C. § 384(j)(3)).

⁵⁷ *Id.*

⁵⁸ *Id.* § 1201 (223-24) (codified as amended at 26 U.S.C. §§ 223-24).

⁵⁹ *See* 26 U.S.C. § 220(c)(1)(A) (2000).

only permit a tax deduction of 75%.⁶⁰ Individuals 55 years or older are also permitted to increase their tax deductible contribution to HSAs by \$500 in 2004, \$600 in 2005, and by annual \$100 increases not exceeding \$1,000 by 2009.⁶¹

¶20 Additionally, Congress has ensured that eligible individuals will not be able to double-count such health-related tax deductions by coordinating benefits of HSAs with those from previously existing MSAs; individuals who make contributions to HSAs must annually deduct the aggregate amount paid to MSAs for the same taxable year.⁶²

C. Provisions for The Insurance Industry: The Move Toward Private Plan Coverage

¶21 Prior to the MMA, Medicare beneficiaries were permitted to enroll in a managed care plan under Part C, or “Medicare + Choice plans,” and receive the benefits of both Part A and Part B services.⁶³ While Medicare + Choice plans are already provided by private insurance companies under government contract, the MMA increases the role of private insurance by attracting more private companies via the creation of a more competitive fee structure for reimbursement under Medicare Advantage plans (MA).⁶⁴ In addition, the MMA permits the establishment of regional plans that will permit smaller insurance companies to provide MA coverage and will likely encourage better discounts for plan participants via increased competition.⁶⁵

D. Provisions that Benefit the Drug Industry

1. Brand Name Drug Companies—§§ 101, 1102, 1121

¶22 Brand name prescription drug companies will receive several benefits under the MMA. First, all of the prescription discounts that the

⁶⁰ MMA §§ 1201 (223(b)(2)(A)-(B)) (codified as amended at 26 U.S.C. §§ 223(b)(2)(A)-(B)) (eligible individuals or families may only deduct the lesser of their annual health insurance deductible or \$2,250 or \$4,500, respectively).

⁶¹ *Id.* at §1201 (223(b)(3)(B)) (codified as amended at 26 U.S.C. § 223(b)(3)(B)).

⁶² *Id.* at § 1201 (223(b)(4)(A)) (codified as amended at 26 U.S.C. § 223(b)(4)(A)).

⁶³ See MEDICARE, MEDICARE PLAN CHOICES OVERVIEW, at <http://www.medicare.gov/Choices/Overview.asp> (last visited Mar. 13, 2004).

⁶⁴ ARENT FOX, *supra* note 44, at 8. The fee structure created by the MMA will initially compensate participating private insurance companies by the same amount currently awarded under Medicare’s fee-for-service plans, but will incrementally increase by either 2% annually or by the additional per capita growth of the new plan. *Id.*

⁶⁵ *Id.*

elderly will receive under the bill will remain privately regulated.⁶⁶ Second, in an effort to forestall abuses of patent monopolies by generic companies, the bill eliminates the 180-day exclusivity period that competing bioequivalent generic drugs were awarded under the Hatch-Waxman Act.⁶⁷ Third, the MMA provides for a study on the safety and cost-effectiveness of importing drugs from Canada, including a provision that *might* enable the enactment of such regulations—it does not, however, make such importation legal for pharmacists or wholesalers.⁶⁸ As such, brand name drug companies still remain largely in control of prescription drug prices for American consumers.

2. Generic Drug Companies—§§ 1101, 1103

¶23 Last year the FDA enacted new regulations that addressed abuses to the Hatch-Waxman Act.⁶⁹ The new regulations, which went into effect on December 18, 2003, limit brand name firms who challenge abbreviated new drug applications (ANDAs) for patenting generic drugs to a single, automatic 30-month stay to resolve any allegations of false “paragraph IV certifications.”⁷⁰ The new regulations also curtail the late filing of frivolous

⁶⁶ *The Skinny*, *supra* note 42.

⁶⁷ MMA § 1102(a)(2)(D) (codified at 21 U.S.C. § 355(j)(5)). Although the forfeiture of the 180-day exclusivity provision does not appear to benefit brand name prescription drug companies on its face, it has the effect of permitting them to keep their monopoly on the market for a longer period of time. In addition, forfeiture of the exclusivity period may even be provoked by brand name companies who cause generic companies to violate these provisions. For example, the exclusivity period may be forfeited by generic companies for a failure to market or entering into an agreement with another applicant/patent owner to forestall bringing their drug to market. *Id.* Yet, the penalty specified for brand name drug companies who induce generic companies to act in such a manner may not be much more than a drop in the bucket compared to continued monopolies on sales of blockbuster drugs. *See* MMA § 1115 (codified at 21 U.S.C. § 355 note) (citing civil penalties of not more than \$11,000 each day that a brand name drug company fails to file any such agreements with the FTC. Thus, a brand name drug company such as Pfizer could potentially induce a generic firm to contract with them to delay the release of a bioequivalent drug to Lipitor for an entire year and later only be fined a mere \$4,015,000 (\$11,000 x 365 days) as compared to the additional retail sales of over \$8 billion; making their net profit worth such infringements.).

⁶⁸ MMA § 1121 (codified as amended at 21 U.S.C. §§ 355 note, 381 note, 384 note, 535); *The Skinny*, *supra* note 42. There is also criticism of the provision of the MMA that allows for a study on the effects of importing drugs on a larger scale from Canada because of the manner in which such studies will be carried out. *See* Robert Pear, *U.S. to Study Importing Canada Drugs but Choice of Leader Prompts Criticism*, N.Y. TIMES, Feb. 26, 2004, at A16. However, this section did make it legal for individuals to import prescription drugs on a limited basis. *Id.*

⁶⁹ 21 C.F.R. § 314; *See supra* text accompanying note 39.

⁷⁰ §§ 314.52, 314.95, 314.107(b)(3)(i)(A).

patents by brand name drug companies trying to delay generic drug entry into the marketplace.⁷¹

¶24 Although the new FDA regulations addressed two of the main problems that generic drug companies experienced under the Hatch-Waxman Act, Title XI of the MMA (“Access to Affordable Pharmaceuticals”) expressly amends the 1984 provisions in a similar fashion.⁷² Moreover, the bill adds a new provision that makes bioequivalence of generic drugs easier to prove.⁷³

III. ANALYSIS OF MMA: BIG BENEFITS FOR BIG PHARMA & THE PRIVATE INSURANCE INDUSTRY AT THE EXPENSE OF REAL BENEFITS FOR SENIORS

¶25 With so many provisions in the MMA, it would seem that there is something for everyone. However, the bill is receiving much more criticism than praise, especially from those who initially spearheaded the efforts to reform Medicare. Many Congressional representatives who strongly favored a Medicare reform bill voted against the MMA, arguing that it was a false reform designed to make Republicans look good.⁷⁴

A. *The MMA: A Product of Bad Law-Making?*

¶26 Signs of what may be termed “irresponsible politics” abound in the passage of the MMA. As late as November 18, 2003, less than a month before President Bush signed the bill into law, much of the text of the MMA was still unavailable to most legislators.⁷⁵ For such a complicated and lengthy bill with far reaching implications, it is highly problematic that legislators may have been signing off on many provisions that they either did not know were included or whose potential effects they did not have the opportunity to understand.

¶27 Many of the bill’s supporters openly acknowledged its many imperfections prior to approval but failed to push for changes, either because

⁷¹ §§ 314.80, 314.81, 314.94-.95, 314.101, 314.170, 314.630.

⁷² MMA § 1102 (codified as amended at 21 U.S.C. § 355(j)).

⁷³ MMA § 1103 (codified as amended at 21 U.S.C. § 355(j)(8)).

⁷⁴ See Schlein, *supra* note 44, at 6 (“‘Who do you trust,’ [Senator Edward] Kennedy argued. ‘The HMO—coddling, drug-company-loving, Medicare-destroying, Social Security-hating Bush administration? Or do you trust Democrats, who created Medicare and will fight with you to defend it every day of every week of every year?’”).

⁷⁵ Robert Pear & Robin Toner, *Medicare Plan Covering Drugs Backed by AARP*, N.Y. TIMES, Nov. 18, 2003, at A1.

they wanted to be able to say that they had passed a discount drug bill or out of fear of defying those who had contributed millions to their campaigns.⁷⁶

¶28 In addition, accusations exist that the Bush administration concealed the actual costs of the bill—between \$500 and \$600 billion—prior to Congress' vote on the matter.⁷⁷ Some representatives have claimed that cost estimates of the MMA were repeatedly and expressly withheld by the Bush administration.⁷⁸ These claims were recently confirmed by the Department of Health and Human Services' (DHHS) internal investigation.⁷⁹ The report on the investigation, issued July 6, 2004, found that the top Medicare administrator, Thomas A. Scully, threatened to fire the program's chief actuary, Richard S. Foster, if he were to tell Congress that the drug benefits in the MMA would likely cost much more than the White House had originally estimated.⁸⁰

¶29 Amplifying the feeling that political wrangling will leave Americans to pay the high costs of the MMA is the fact that the Department of Veterans Affairs (VA) has been able to create a similar prescription drug discount plan on a large scale that, according to a National Academy of Sciences study, has “meaningfully reduced drug expenditures without a demonstrable adverse [effect] on quality” and without a large effect on the federal budget.⁸¹ Not only was the VA plan ignored as a model for the new Medicare benefit plan, but other plausible money saving alternatives were also ignored, including vouchers for the purchase of health insurance and proposals to only aid low income individuals.⁸²

⁷⁶ *Id.* (Consider the following comments: “This is not a perfect bill, but America cannot wait for perfect”; “‘Getting a large benefit for lots of people that didn’t exist before is very alluring,’ said Senator Charles E. Schumer, Democrat of New York. Yet Mr. Schumer said he had grave concerns about other parts of the bill that he called ‘a total sellout to the pharmaceutical industry.’”).

⁷⁷ Robert Pear & Edmund L. Andrews, *White House Says Congressional Estimate of New Medicare Costs Was Too Low*, N.Y. TIMES, Feb. 2, 2004, at A14 [hereinafter *Congressional Estimate Too Low*]; Robert Pear, *Inquiry Confirms Top Medicare Official Threatened Actuary Over Cost of Drug Benefits*, N.Y. TIMES, July 7, 2004, at A1 [hereinafter *Official Threatened Actuary*].

⁷⁸ *Congressional Estimate Too Low*, *supra* note 77, at A14; *Official Threatened Actuary*, *supra* note 77, at A1.

⁷⁹ *Official Threatened Actuary*, *supra* note 77, at A1.

⁸⁰ *Id.* In February 2004, Representative Nick Smith of Michigan was accused of voting for the MMA in exchange for support for his son’s congressional campaign. Carl Hulse, *Inquiry Sought in House Vote on Drug Plan for Medicare*, N.Y. TIMES, Feb. 2, 2004, at A13.

⁸¹ Robert Pear & Walt Bogdanich, *Some Successful Models Ignored as Congress Works on Drug Bill*, N.Y. TIMES, Sept. 4, 2003, at A1.

⁸² *Id.*

B. The MMA Provides Elusive Benefits for Seniors

¶30 The provisions aimed at lowering prescription drug costs for seniors are inherently uncertain. Although President Bush has promised discounts of up to 25%,⁸³ the text of the MMA makes such discounts anything but certain. For example, the Act expressly prohibits government “interference” in the negotiations of such discounts.⁸⁴ Although the rationale expressly stated in this provision, “to promote competition,” seems logical, it effectuates a privately controlled and unallied system. Medicare is left without any leverage as a government entity because private entities are able to negotiate discounts and establish drug formularies based solely on what the drug companies deem proper. Moreover, there are no standards for determining either the actual discounts or the lists of drugs that will be covered by the discount plans.

¶31 In addition, MMA provisions that appear to create basic rules regarding the structure of discount drug plans may backfire and make discounts even more elusive and more difficult for providers to attain. For example, plan providers are required to make at least two comparable drugs for every treatment category available to beneficiaries.⁸⁵ However, this may not have the effect of creating options for plan users because plan providers will likely be forced to create set formularies to ensure compliance with this provision and to be able to negotiate any substantial discounts. Discounts may be decreased even further because some smaller insurance companies—such as those who agree to participate as regional providers—may be forced into a position marked by a lack in bargaining power. Pointedly, drug companies will be able to gain a higher price for those drugs they know are required for plans to comply with MMA provisions.

¶32 An inability to bargain for significant drug discounts could also lead to an increase in the \$35 per month premium for plan participants and ultimately to participant drop out. The ripple effect extends even farther when one notes that the discount drug plans provided for in the MMA are exactly what they are called—voluntary—⁸⁶ and only a very small fraction of all seniors have chosen to enroll.⁸⁷ The voluntary nature of these plans makes enrollment and the promise of negotiated discounts even more elusive when one recognizes that not only is there a great deal of confusion surrounding the

⁸³ Schlein, *supra* note 44, at 6.

⁸⁴ MMA § 101 (1860D-11(i)) (codified as amended at 42 U.S.C. § 1395w-111(j)).

⁸⁵ MMA § 101 (1860D-4) (codified as amended in 42 U.S.C. § 1395w-104(b)(3)(C)(i)).

⁸⁶ *Id.* § 101 (1860D-1) (codified as amended in 42 U.S.C. § 1395w-101).

⁸⁷ *Sign-Ups Lag*, *supra* note 10, at A1 (“[I]t appears that fewer than one million people in the traditional fee-for-service Medicare program have signed up for cards.”).

MMA and what senior's choices actually are,⁸⁸ but a large number of Medicare beneficiaries may be unable to make informed healthcare choices due to Alzheimer's disease and other incapacitating ailments.⁸⁹ Adding to the current healthcare coverage crisis, the MMA is predicted to lead employers to reduce or eliminate their employer-sponsored prescription drug coverage for an estimated 1/3 of all retirees as soon as Medicare begins to offer coverage in 2006.⁹⁰

¶33 Another concrete example of the deceptive nature of drug discount benefits stems from the very real, very large gaps in coverage. As discussed *supra*, drug costs that exceed \$2,250 are shifted to participants as out-of-pocket expenses until they reach the catastrophic level and such individuals have paid over \$3,600.⁹¹ However, these discount drug plans do not provide coverage for any drugs excluded from their plans (i.e. those that they are not able to negotiate discounts for) and out-of-pocket expenses paid to obtain such drugs are also not applied to the \$3,600 limit required for additional coverage.⁹²

¶34 Furthermore, as per capita drug expenditures under Medicare increase over time, the costs associated with plan premiums, deductibles, as well as out-of-pocket expenses will also increase.⁹³ "By 2013, for example, the out-of-pocket spending required before a person qualifies for catastrophic coverage will probably be \$6,400, well above the \$3,600 required in the first year."⁹⁴

⁸⁸ See *Older patients unaware of new Medicare law*, CNN.COM, Feb. 26, 2004, at <http://www.cnn.com/2004/HEALTH/02/26/medicare.survey.ap/index.html> (last visited Mar. 14, 2004); *Confusion surrounds new Medicare law*, CNN.COM, Dec. 22, 2003, at <http://www.cnn.com/2003/HEALTH/12/22/medicare.confusion.ap/index.html> (last visited Mar. 14, 2004).

⁸⁹ *Costs and Benefits Are Elusive*, *supra* note 40, at A1; Schlein, *supra* note 44, at 6. Others cite a lack of Internet access as another reason why it may be difficult for the elderly to choose the appropriate drug card program. *Sign-Ups Lag*, *supra* note 10, at A1 ("Lucy E. Utt, director of the health insurance assistance program at the Tennessee Commission on Aging and Disability, said it was 'almost impossible to make a card selection,' without access to the Internet, either directly or through a friend, a relative or counselor.").

⁹⁰ Robert Pear, *Drug Law is Seen Leading to Cuts in Retiree Plans*, N.Y. TIMES, July 14, 2004, at A1 [hereinafter *Cuts in Retiree Plans*].

⁹¹ MMA § 101 (1860D-2(b)(1)), (codified as amended at 42 U.S.C. § 1395w-102(b)(1)).

⁹² See Robert Pear, *New Medicare Plan for Drug Benefits Prohibits Insurance*, N.Y. TIMES, Dec. 7, 2003, at 1.

⁹³ *Patches for the Drug Program*, N.Y. TIMES, Jan. 25, 2004, § 4, at 14 [hereinafter *Patches for the Drug Program*].

⁹⁴ *Id.*

¶35 These large gaps in coverage might not place as large of a financial burden on participants if the MMA did not have an additional restriction on supplemental insurance coverage.⁹⁵ Under the bill, plan participants will not be permitted to extend or purchase new Medigap (or similar private supplemental) insurance, count payments by former employment health plans toward the \$3,600 limit on out-of-pocket expenses, or supplement any drug coverage from these Medicare plans with Medicaid drug coverage.⁹⁶

C. The MMA Provides Big Benefits to the Pharmaceutical and Insurance Industries

¶36 The most criticized aspect of the MMA is that it provides the greatest benefits to two already thriving industries: the drug and insurance industries. The unparalleled financial focus that the drug industry has placed on political lobbying, *supra*, has led to essentially “tailor-made” provisions that may be worth the huge sums paid.⁹⁷

¶37 Three provisions of the MMA exclusively benefit the drug and insurance industries: (1) privately administered benefit plans, (2) express prohibition of government participation in the negotiation of discounts, and (3) an increase in HMO reimbursements. Because the MMA’s new discount drug plan will be privately administered, the insurance industry will benefit directly from an estimated \$46 billion that will be “pumped” into managed care by the government over the next ten years.⁹⁸ Moreover, greater government reimbursement—upwards of 25%—and increases in the number of enrollees in participating insurance plans will lead to greater overall revenues.⁹⁹ In fact, investors seem to already be placing their bets that HMOs will experience a 2-5% increase in after-tax profits: shares of Humana have jumped from \$8.81 to \$21.53 in just 2 years—an increase of nearly 41%.¹⁰⁰ What is more troubling is that as buying power and profits increase, so too will the insurance industry’s political bargaining power with the government, making future cut backs or changes to the law difficult and unlikely.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ Stolberg & Harris, *supra* note 16, at A1.

⁹⁸ See Milt Freudenheim, *Using Medicare Billions, H.M.O’s Again Court Elderly*, N.Y. TIMES.COM, at <http://www.nytimes.com/2004/03/09/business/09CARE.html?ex=1079873862&ei=1&en=f7fcbb44df723040> (last visited Mar. 9, 2004).

⁹⁹ *Id.*; Schlein, *supra* note 44, at 6 (“Fewer than five million of the 40 million Medicare beneficiaries, about 12 percent, are in private plans. The administration predicts that the proportion will grow to 35 by 2007, as beneficiaries enroll in HMOs and PPOs.”).

¹⁰⁰ Freudenheim, *supra* note 98, at A1.

¶38 As discussed *supra*, barring the government, and more specifically Medicare, from using its power to leverage lower discount prices against the drug industry will effectively keep prices higher and may make discounts much lower than anticipated.¹⁰¹ The precise monetary benefit to the drug industries, while unknown, is troubling in light of the extremely high price tag already placed on the MMA and has caused many to wonder if we aren't paying twice for this bill—once as taxpayers and then again as consumers.

D. The MMA May Be Fiscally Imprudent

¶39 In addition to providing elusive benefits to seniors and helping to keep big industry profits high, the MMA has been described as a “fiscal train wreck.”¹⁰² Initially, financial estimates for the bill topped \$395 billion over the next ten years.¹⁰³ However, less than a month after President Bush signed the MMA into law, estimates suddenly rose to \$540 billion.¹⁰⁴ Moreover, this high estimate may escalate further if the level of drug discounts attained is lower than predicted. With the federal deficit increasing to over \$520 billion, its highest dollar level ever, tacking on at least another \$145 billion to the price tag of this legislation¹⁰⁵ has some legislators outraged and many Americans worried.

¶40 Despite the fact that President Bush has promised to cut the federal deficit to \$365 billion over the next five years, these estimates do not include the costs of the war in Iraq—more than \$87 billion thus far—or the \$162 billion that it will cost to restructure the alternative minimum tax.¹⁰⁶ Moreover, it seems a bit underhanded that amidst all of his proclaimed efforts to provide affordable healthcare to those who need it, President Bush is planning on cutting back on federal Medicaid funding. Vowing to restore the “fiscal integrity” to Medicaid, President Bush says that he will save Americans over \$1.5 billion next year and \$23.6 billion over the next ten by

¹⁰¹ See section II, A *supra*.

¹⁰² *The Medicare Choice*, N.Y. TIMES, Nov. 19, 2003, at A1.

¹⁰³ *White House raising estimated cost of Medicare overhaul*, CNN.COM, Jan. 29, 2004, at <http://www.cnn.com/2004/ALLPOLITICS/01/29/bush.budget.ap/index.html> (last visited Feb. 26, 2004) [hereinafter *White House raising estimated cost of Medicare overhaul*].

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Congressional Estimate Too Low*, *supra* note 77, at A14; *White House raising estimated cost of Medicare overhaul*, *supra* note 103 (“Major priorities Bush proposed last year included: . . . \$87 billion this year for wars in Iraq and Afghanistan, \$500 million less than he got.”). For more information on what the Alternative Minimum Tax is see Kaye A. Thomas, *Alternative Minimum Tax 101*, FAIRMARK PRESS, INC. (2004), at <http://www.fairmark.com/amt/amt101.htm> (last visited Mar. 14, 2004).

requiring stricter recording of state spending.¹⁰⁷ It seems that this is a zero sum game—spending billions on Medicare just to cut back on Medicaid is like starving one hand to feed the other.

CONCLUSION

¶41 The costs of the MMA will likely far outweigh its advantages. The majority of the MMA funds will be spent on satiating the drug industry's desire to keep costs privately regulated and fattening the insurance industry's bankroll by further privatizing Medicare—both at a higher cost to taxpayers and to the detriment of the average American, who will see only modest benefits in the form of larger tax breaks from HSAs and the *possibility* of being able to import drugs from Canada.¹⁰⁸ Moreover, the estimated \$540 billion price tag on the MMA will have far-reaching economic effects that will likely force legislators to make fundamental changes to the tax system in the future and may ultimately cause the healthcare system in the United States to falter.¹⁰⁹

¹⁰⁷ Robert Pear, *U.S. Nears Clash With Governors on Medicaid Cost*, N.Y. TIMES, Feb. 16, 2004, at A1. While it may be true that states have begun to disproportionately utilize federal funds for their Medicaid programs, stricter policies that threaten to disturb the very existence of Medicaid may create an even more detrimental effect on the federal budget—requiring a larger federal remedy farther down the road. *Id.*

¹⁰⁸ See, Elizabeth Becker & Robert Pear, *Trade Pact May Undercut Inexpensive Drug Imports*, N.Y. TIMES, July 12, 2004 (discussing an international trade agreement set to be approved by Congress which would narrow the MMA's provisions for the importation of drugs by allowing “pharmaceutical companies to prevent imports of drugs to the United States and also to challenge decisions by Australia about what drugs should be covered by the country's health plan, the prices paid for them and how they can be used”).

¹⁰⁹ See, e.g., *Patches for the Drug Program*, *supra* note 93, § 4, at 14.