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Evaluating Intended and Unintended Consequences of Health Policy and Regulation in Vulnerable Populations

presented by Meredith Joy Chace

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Evaluating Intended and Unintended Consequences of Health Policy and Regulation in Vulnerable Populations

A dissertation presented

By

Meredith Joy Chace

to

The Committee on Higher Degrees in Health Policy
in partial fulfillment of the requirements
for the degree of
Doctor of Philosophy
in the subject of

Health Policy

Harvard University
Cambridge, Massachusetts
November 2012

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Stephen Soumerai Meredith Joy Chace

Evaluating Intended and Unintended Consequences of Health Policy and Regulation in Vulnerable Populations

Abstract

The objective of this dissertation is to evaluate whether two different types of policy interventions in the United States are associated with health service utilization and economic outcomes.

Paper 1: The number of government lawsuits accusing pharmaceutical companies of off-label marketing has risen in recent years. We use Medicare and Medicaid claims data to evaluate how an off-label marketing lawsuit and its accompanying media coverage affected utilization and spending on gabapentin as well as other anticonvulsant medications. In this interrupted time series analysis of dual eligible patients with bipolar disorder, we found that the lawsuit and accompanying media coverage corresponded with a decrease in market share of gabapentin, a substitution of newer and expensive anticonvulsants, and a substantial increase in overall spending on anticonvulsants.

Paper 2: Medicare Part D was a major expansion of Medicare benefits to cover pharmaceuticals. There were initial concerns about how the dually eligible population who previously had drug coverage through Medicaid would fare after transitioning to Part D plans. Using a nationally representative longitudinal panel survey of Medicare Beneficiaries that are dually eligible for Medicaid, we investigated whether differences in generosity of Medicaid drug benefits were associated with differential changes in drug utilization and out-of-pocket spending for duals after they transitioned to Part D. Our finding suggest that those who previously encountered a monthly drug cap prior to Part D implementation experienced a differentially higher increase in annual prescription drug fills compared with those who did not face a cap.

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Paper 3: In this paper we evaluate how Part D may have been associated with antidepressant drug utilization for the disabled and elderly Medicare populations. We found that the prevalence of antidepressant treatment did not change after Part D was implemented. However, we did find that antidepressant treatment intensity increased after Part D among both the elderly and nonelderly disabled subgroups.

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parents proud in finding wonderful partners and succeeding professionally in health care, fashion design, and entrepreneurship. To my extended family, the Chaces and Schroeders, thank you for your constant support and love.

Finally and most importantly, I thank my husband, Jeff Foran, for his awesomeness. You have done everything from making me "dissertating" play lists, cheering for me at my football games, discussing my research topics, and cooking extravagant gifts of deliciousness for me, to driving on long road trips so I could work (or sleep) in the car. You are the best friend I could ever wish for and having you by my side made this entire journey more meaningful.

I would like to dedicate this dissertation in memory of my parents, Fran and Mike "the Senator" Chace. My parents were both hard working and fun loving people. They inspired in me a persistent work ethic, a sense of humor, and an appreciation for life and its highs and lows. Growing up in a warm, comical, and supportive family has given me great confidence to pursue my passions. Since they passed away, I have tried to live my life in a way that would make them proud and to never take anything for granted. I think they would be very proud of me for this accomplishment (although the two football super bowl rings might be a close second for Dad).

I am tremendously grateful to have had the opportunity to be a part of the Harvard Health Policy doctoral program.

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Paper 1

Intended and Unintended Consequences of the Gabapentin Off-label Marketing Lawsuit Among Patients with Bipolar Disorder

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Abstract

Objective: The number of lawsuits accusing pharmaceutical companies of off-label marketing has risen in recent years. The impact of such lawsuits on drug prescribing and spending has not been examined. We evaluated a nationwide sample to determine whether the $430 million gabapentin off-label marketing lawsuit and accompanying media coverage affected gabapentin market share, substitution of other scientifically substantiated and unsubstantiated anticonvulsants, and anticonvulsant spending in Medicare/Medicaid patients diagnosed with bipolar disorder.

Method: Using a national 5% sample of Medicare recipients linked to Medicaid claims, we used an interrupted times series design to evaluate the impact of the lawsuit on monthly market share, utilization, and spending from January 1, 2001, to December 31, 2005.

Results: The start of the lawsuit was associated with a 28% relative reduction in gabapentin market share (from ~21% to ~15%; $p<0.001$), and a reduction in the rate of prescribing from 108 prescriptions per 1000 patients per month before the start of the lawsuit to 90 by the end of follow-up. We also observed increases in market share for three other anticonvulsants. Total anticonvulsant use and spending per 1,000 patients increased by 13% and 74%, respectively, after the intervention. The increase in anticonvulsant spending was equivalent to $8,184 per 1,000 patients per year higher than expected compared with the baseline trend ($p=0.01$).

Conclusions: We conclude that the lawsuit resulted in a reduction in gabapentin market share, increased market share for other anticonvulsants, and substantially increased total anticonvulsant

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spending to approximately half of the settlement amount, not counting substitutions of newer drugs for other illnesses affected by the lawsuit. These findings support the need for further study of the effects of current lawsuits regarding off-label drug marketing.

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Introduction

The number of government lawsuits accusing pharmaceutical companies of off-label marketing has risen in recent years.[1-3] Such lawsuits seek to recover costs of off-label drug use caused by illegal marketing.[4] These lawsuits are often accompanied by widespread coverage in the lay media. Negative media messages about medications have been shown to change prescribing patterns and sometimes reduce inappropriate drug use.[5-7] However, no studies have examined the impact of such lawsuits for off-label marketing (and accompanying media reports) on drug prescribing and spending. Negative publicity from the lawsuits in marketing campaigns can increase market share of competitors' products. We investigated the impact of the gabapentin off-label marketing lawsuit on gabapentin market share, substitution of alternative anticonvulsants with varying levels of evidence of efficacy in treating bipolar disorder, and changes in anticonvulsant spending in a nationwide sample of patients with bipolar disorder.

Off-label prescribing is common in many conditions such as cancer, chronic pain management, and mental illnesses because scientific evidence supporting the use of some drugs for unapproved indications may exist even in the absence of a US Food and Drug Administration (FDA) indication.[8,9] Physicians may judge medications to be effective for off-label indications in their practice despite the absence of scientific evidence because of similarities to other medications that have proven effective in the past. Although physicians can legally prescribe medications for off-label indications, it is illegal for companies to market a product for indications that are not FDA-approved.[4] Regulation of off-label marketing through litigation has become increasingly prominent as pharmaceutical expenditures have grown. Given that policies that restrict use of unsubstantiated medications can increase spending due to substitution of more

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expensive similarly unsubstantiated medications, it is important to examine the intended and unintended consequences to such lawsuits.[10]

Brief History of the Lawsuit

Gabapentin is an anticonvulsant medication that was approved in 1993 for adjunctive treatment of epilepsy and in 2002 for post-herpetic neuralgia. By 2000, gabapentin annual sales had grown to blockbuster status (nearly $1 billion), the vast majority of which were for off-label indications, such as bipolar disorder, various pain disorders, amyotrophic lateral sclerosis, attention-deficit/hyperactivity disorder, migraine, drug and alcohol withdrawal seizures, restless leg syndrome, and monotherapy treatment for epilepsy.[11] In 1998, a former Parke-Davis employee filed a lawsuit against the company for illegally marketing gabapentin for use in off-label indications. According to media reports, through which prescribers and patients would become aware of the lawsuit, the lawsuit was later unsealed in 2002 and the US Department of Justice and several states joined as plaintiffs.[3] The plaintiffs sought reimbursement for the utilization that resulted from the illegal marketing. In 2004 Pfizer, having purchased Parke-Davis, settled the lawsuit for $430 million, the largest off-label marketing settlement up to that time.

Objective

In this study, we hypothesized that the lawsuit, accompanied by widespread media coverage of the case (hereafter referred to as "the lawsuit") from competing manufacturers, resulted in a reduction in prescribing of gabapentin. We chose to test this hypothesis in a population with bipolar disorder because gabapentin's off-label use for this indication was unsupported in the scientific literature.[12-14] In 2000, two randomized controlled trials[12,13] were published that concluded that gabapentin was no different than placebo in the treatment of

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bipolar disorder. We further hypothesized that reductions in use of gabapentin would result in substitution of other anticonvulsants that may or may not have proven efficacy in the treatment of bipolar disorder. Finally, we hypothesized that such medication substitution would lead to increased spending within the anticonvulsant class.

Method

Study Design

We used an interrupted time series design to evaluate the effect of the lawsuit on changes in level and trend of anticonvulsant market share and spending in patients with bipolar disorder. In a national experiment in which a control group is impossible, interrupted time series is the strongest quasi-experimental design available because it can control for pre-existing levels and trends of outcomes during the pre-intervention period when evaluating immediate changes in trends after the start of an intervention.[15]

Data

Using a merged dataset of a national 5% sample of Medicare (public insurance for the elderly and disabled) recipients and Medicaid (public health insurance for the low-income population) claims data from January 1, 2001, to December 31, 2005 we identified a continuously-enrolled, dually-eligible population over the age 18 years based on monthly enrollment data from Medicare and Medicaid. Continuous enrollment was defined as being enrolled in both Medicaid and Medicare in all months during the study period. We further analyzed Medicaid prescription drug claims for this population to measure anticonvulsant market share, utilization and spending. These claims included a unique patient identifier, National Drug Code, date of dispensing, the number of units provided (number of tablets, for example), days' supply, and amount reimbursed.

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The Harvard Pilgrim Health Care Institutional Review Board approved the study, waiving consent because our study was conducted with de-identified patient data from a large administrative claims data set.

Study population

The study population contains many of the sickest patients with bipolar disorder, a large number of whom qualify as permanently disabled.[16] We limited the cohort to patients who had at least 1 inpatient or 2 outpatient diagnoses of bipolar disorder (ICD-9-CM codes 296.0, 296.1, 296.4–296.7, 296.89, and 301.11) at any point during the study period.[17,18] Diagnoses of bipolar disorder were accepted from the first diagnostic field in a claim.

Information regarding sex, age and race of the study population were taken from the Medicare 5% sample data. Unique medications at baseline included medications for both physical and mental health and were taken from the claims data based on previously validated methods.[19]

Study intervention index date

The intervention was indexed when the lawsuit began in March 2002 (see Figure 1.1).[20] In order to identify trends in media reports of the lawsuit, we conducted a search of the Lexis-Nexis database[20] for newspaper articles and newswires that contained the words Neurontin and off-label between January 1, 1996, and December 31, 2005. The search yielded 196 articles, of which 29 were excluded because they were unrelated to the lawsuit. The first of many reports on this topic appeared in March 2002, shortly after the case was unsealed.[21] Almost all coverage occurred in newspapers or newswires; television coverage was rare.

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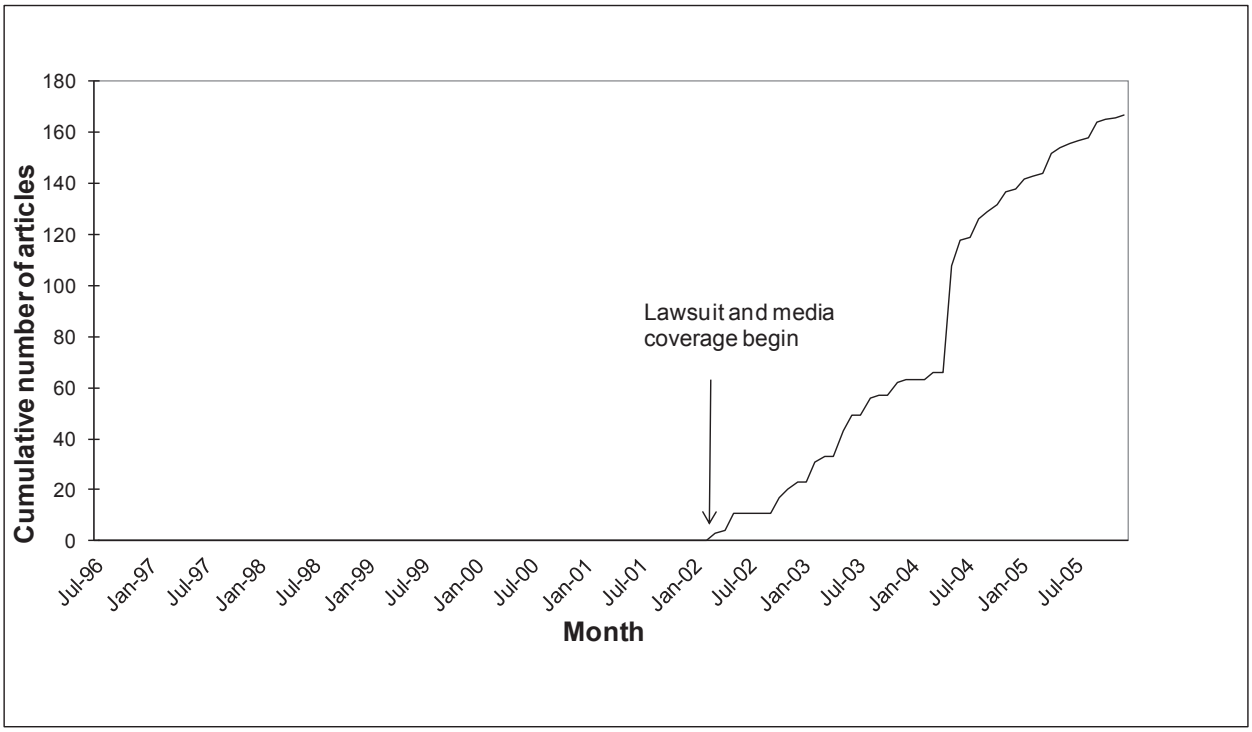
Figure 1.1 Cumulative Number of News Articles in Lexis Nexis National Sample[19] on Gabapentin Off-label Marketing Lawsuit : 1996 to 2005



In June 2003, 15 months following the start of the lawsuit, the anticonvulsant lamotrigine was approved for bipolar maintenance by the FDA.[22] Since this event would most likely affect anticonvulsant market share, we included this new indication in our analysis as a second intervention during the study period.

Outcomes

All study outcomes were calculated at monthly time intervals to allow the use of an interrupted times series design. We measured monthly market share as the fraction of total monthly prescription fills of anticonvulsants that each anticonvulsant represented. We chose to measure market share because it best reflects changes in relative use of individual products within a drug class. We also measured overall utilization of anticonvulsant therapy and utilization of gabapentin. We counted a month as a use month if that month was included

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between the dispense date and through date on a prescription. When looking at utilization, we counted each "use month" as a prescription. In order to characterize the level of scientific evidence of efficacy among the anticonvulsant medications used to treat bipolar disorder, we referred to the treatment recommendations from the National Institute of Mental Health as well as several literature reviews. We identified several older anticonvulsants, including divalproex sodium, valproic acid, and carbamazepine, that were either approved for bipolar disorder or had been scientifically substantiated in the literature through publication of double-blind, randomized control trials that included results of efficacy in bipolar disorder.[23,24] We also classified three anticonvulsants (topiramate, levetiracetam, and oxcarbazepine) as lacking evidence of efficacy for bipolar disorder.[25] Finally, we included lamotrigine, which gained approval as a maintenance treatment in bipolar disorder during the study period.[22-24,26,27]

We defined the following measures to describe spending. Using the pharmacy reimbursed amount, we defined total anticonvulsant spending per 1,000 prescriptions per month, spending for each anticonvulsant per 1,000 prescriptions per month, and anticonvulsant spending per 1,000 people per month.

Analysis

We estimated population-level changes in anticonvulsant market share and spending using interrupted time series regression models.[15] Using 14 months of data prior to the lawsuit, we established a baseline level and slope of market share and spending for anticonvulsants per 1,000 patients per month. We used segmented linear regression to evaluate changes in slopes and levels of anticonvulsant market share, utilization, and spending after the start of the lawsuit (March 2002) and the FDA-approval of lamotrigine for bipolar maintenance (June 2003), controlling for pre-intervention trends in market share and spending. In the segmented

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regression, we controlled for serial autocorrelation and excluded all non-significant ($p > 0.05$) terms from the models by using backward elimination. We used SAS software, version 9.2 (SAS institute, Inc., Cary, North Carolina), to conduct these analyses.

Results

Descriptive statistics

Table 1.1 describes several baseline characteristics of the study patients (N=3,004). The mean age was 48 years, ranging from 21-92. Women comprised 62% of the population and 83% were white. During the first year of the study period, patients took a mean of 10.8 unique medications.

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Table 1.1 Baseline Characteristics of Study Cohort of Medicare and Medicaid Beneficiaries with Bipolar Disorder

	Study cohort (N=3,004)	
Characteristic	N	%
Female	1,852	62
Age at baseline		
20-34	536	18
35-54	1,665	55
55-64	345	12
65+	458	15
Race: White	2,499	83
Medication use[a]		
Antipsychotics	1,987	66
Lithium	744	25
Anticonvulsants	1,915	64
Antidepressants	2,384	79
Antianxiety	1,874	62
# Unique medications[b]		
Mean (Standard Deviation)	10.77 (0.117)	

[a] Number of people who filled a prescription in each drug class at any point during the study period

[b] Mean number of unique medications filled among the study population during the first year of the observation period

Gabapentin and anticonvulsant market share

During the 14 months prior to the lawsuit, gabapentin was the second most prescribed medication (behind divalproex sodium) to the study population, representing 21.4% of anticonvulsant prescriptions. During this baseline period, gabapentin market share remained

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stable between 21.4% and 22.6%. However, gabapentin market share declined suddenly after the start of the lawsuit (see Figure 1.2) to 15.4% by the end of the study period, representing a relative change of -28% in market share (trend change = -0.16% market share per month, $p<0.001$). In terms of gabapentin utilization among the study population, there was a reduction in the rate of prescribing from 108 prescriptions per 1000 patients per month before the start of the lawsuit to 90 prescriptions per 1000 patients per month by the end of follow-up (data not shown).

Figure 1.2 shows a market share comparison of gabapentin, lamotrigine, and the unapproved anticonvulsants during the study period. Lamotrigine utilization remained stable at 2.5% during the baseline period. After the start of the gabapentin lawsuit, the trend in lamotrigine market share increased immediately by 0.19% market share per month ($p<0.001$) and continued to increase after it received FDA approval for bipolar disorder treatment reaching a market share of 13.5% by the end of the observation period. Figure 1.2 also shows that the market share for the unapproved anticonvulsants (topiramate, oxcarbazepine, and levetiracetam) increased consistently from the start of the study period. The upward monthly market share trend of +0.43% ($p<0.001$) continued after the start of the lawsuit and then decreased after lamotrigine received an FDA indication for bipolar disorder (trend change = -0. 41%, $p<0.001$).

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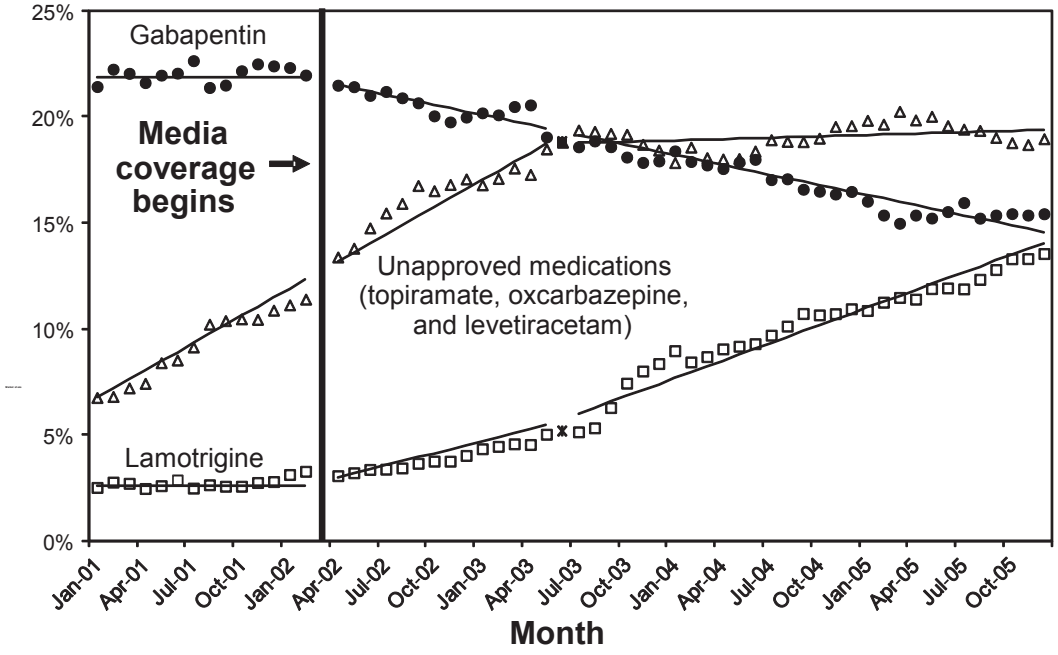
Figure 1.2. Market Share of Selected Anticonvulsants in the Dually Eligible Population with Bipolar Disorder: Gabapentin; Lamotrigine; and Unapproved Drugs



This finding suggests that prescribers did not reduce off-label prescribing within this drug class as a result of the lawsuit. Overall it appears that lamotrigine and the unapproved anticonvulsants offset much of the decline in gabapentin market share. The market share for the older approved anticonvulsants steadily declined during the baseline period (baseline trend=-0.32% market share per month, $p<0.001$) and this decline slowed after the intervention (trend change = 0.24% market share per month, $p=0.01$) (Data not shown).

Anticonvulsant use and spending

Figure 1.3 shows the monthly utilization of anticonvulsants per 1,000 bipolar patients, mean monthly spending per 1,000 anticonvulsant prescriptions, and mean monthly spending on anticonvulsant treatment per 1,000 patients from February 2001 to December 2005. Prior to the start of the lawsuit, monthly spending on anticonvulsants was consistently rising by $655.70 per 1,000 patients each month. This upward trend further increased after the start of the lawsuit (trend change = $629.50 per 1,000 patients per month, $p=0.01$). The dramatic increase in the

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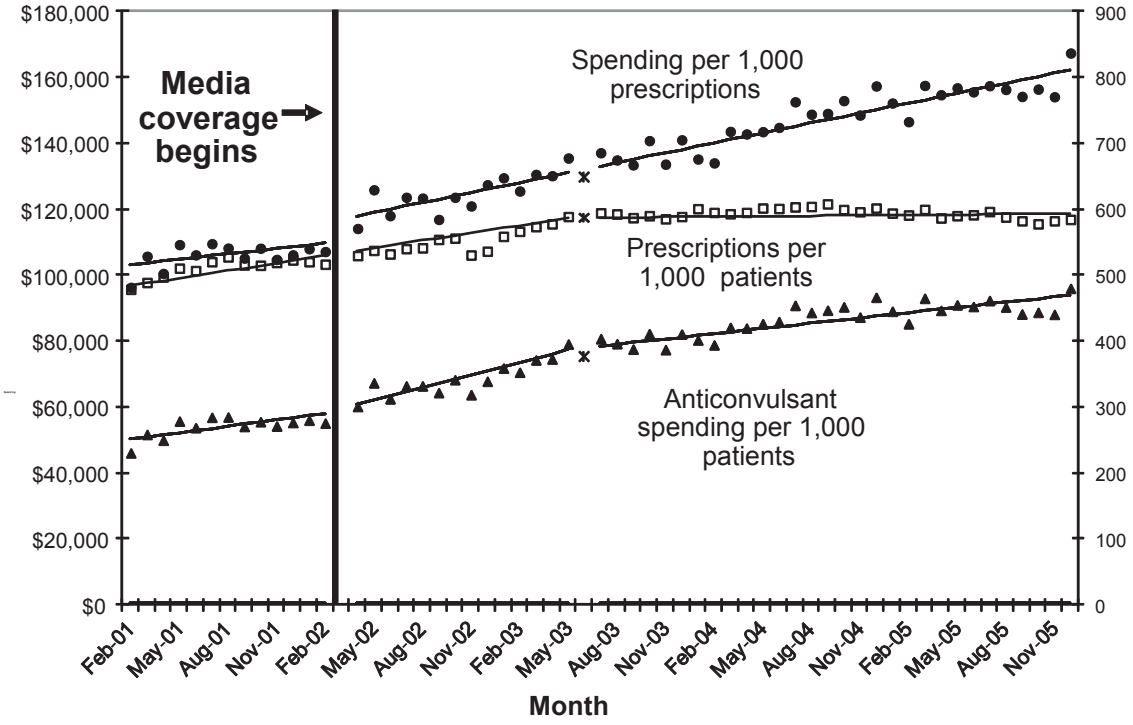
trend of anticonvulsant spending per 1,000 patients continued until lamotrigine was approved 14 months after the start of the lawsuit (See Figure 1.3). This trend change accounts for an $8,184 increase in anticonvulsant spending per 1,000 patients compared with expected spending based on the baseline trend over the 13-month period before lamotrigine was approved for bipolar disorder.

Figure 1.3. Overall Spending (per 1,000 prescriptions and per 1,000 patients) and Utilization of Anticonvulsant Drugs Among the Dually Eligible Bipolar Population



The increase in anticonvulsant spending per 1,000 patients was largely due to substitution of expensive anticonvulsants as well as increased spending per prescription of gabapentin and lamotrigine. The trend in gabapentin spending increased by $2,281 per 1,000 prescriptions per month, $p<0.001$ after the intervention. Lamotrigine spending increased in both trend (trend change = $3,035 per 1,000 prescriptions per month, $p<0.001$) and level (level change= $1,745 per 1,000 prescriptions per month, $p<0.001$) (See Figure 1.4). Figure 1.4 also shows that the

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spending on the unapproved anticonvulsants was increasing $1,356 per 1,000 prescriptions per month before the lawsuit and this trend persisted after the lawsuit began. Spending on the older, commonly used standby anticonvulsants was increasing $748 per 1,000 prescriptions per month ($p<0.001$) and continued to increase after the lawsuit.

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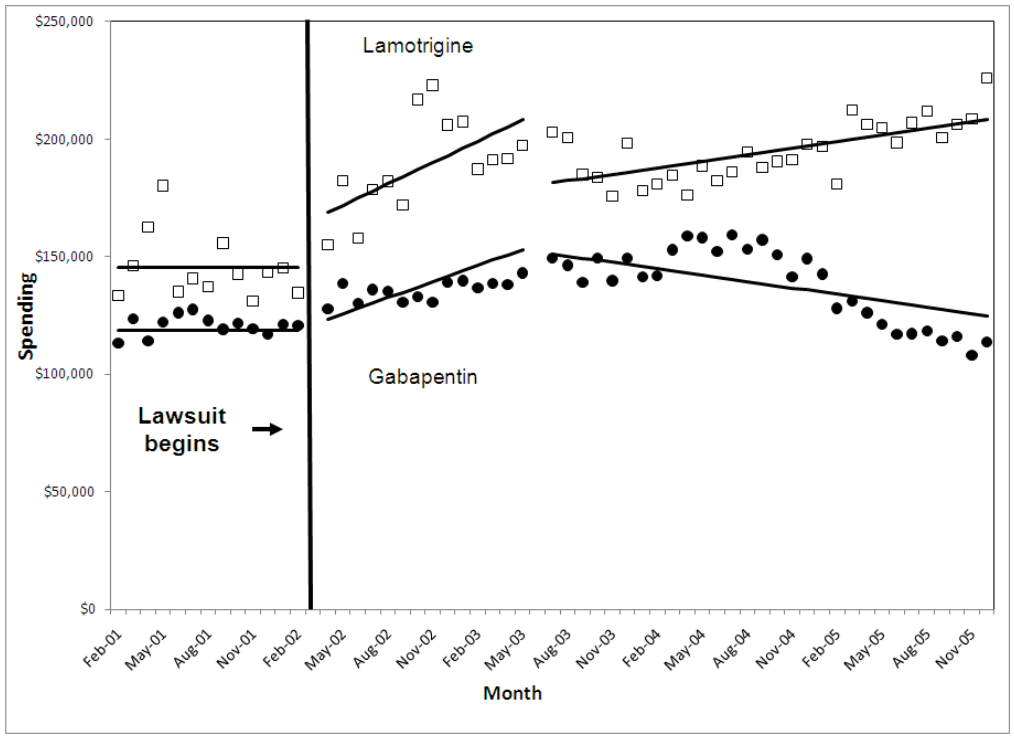
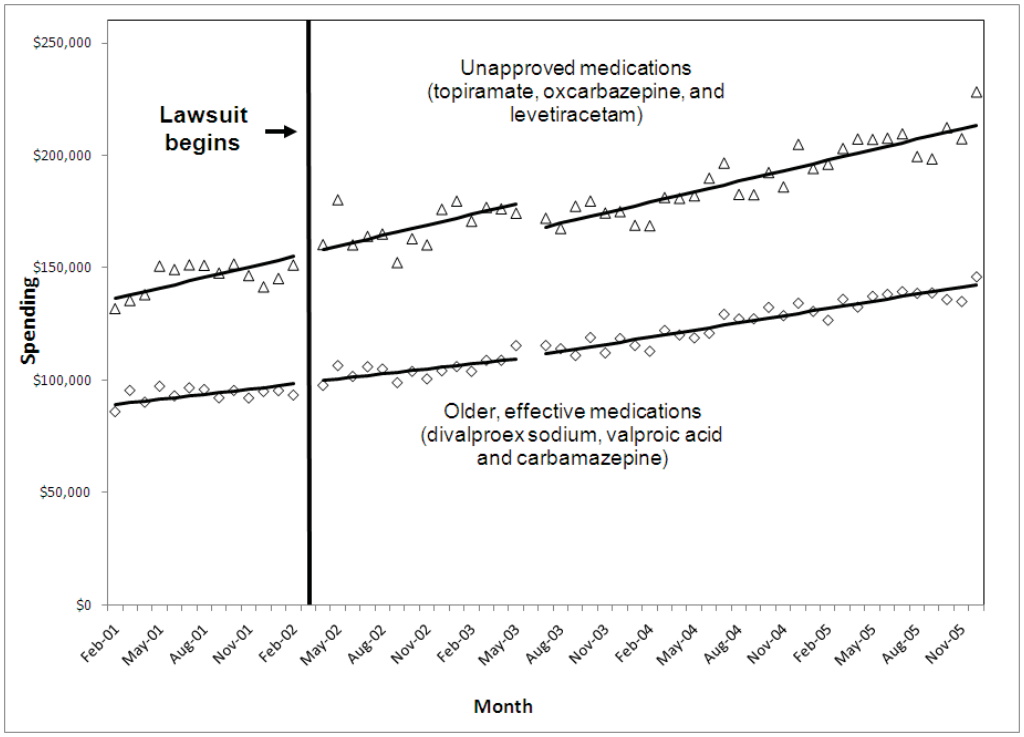
Figure 1.4: Monthly spending per 1,000 prescriptions for all Anticonvulsants in the Dually Eligible Population with Bipolar Disorder: Gabapentin; Lamotrigine; Unapproved Drugs; and Older, Effective Medications





Note: Lamotrigine is displayed separately because it gained an approval for bipolar maintenance during the study period.

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Discussion

The importance of understanding the relationships between off-label lawsuits and media coverage, marketing, prescribing patterns and drug spending grows as off-label marketing lawsuits become more frequent.[28,29] In the case of gabapentin, our results indicate that the lawsuit and accompanying media coverage corresponded with a decrease in market share of gabapentin, substitution of newer and expensive anticonvulsants, and an increase in overall spending on anticonvulsants.

Our results also suggest that illegal off-label marketing lawsuits have both intended and unintended consequences. Consistent with the US Department of Justice's intent to protect public insurers from fraudulent prescribing of gabapentin, the intended consequences of the lawsuit included a decrease in gabapentin market share as well as the substitution of alternative anticonvulsants. However, as soon as information about the lawsuit was made available through media and marketing, there was a long-term, unintended increase in spending on anticonvulsants, which included a mix of scientifically substantiated and unsubstantiated products. In this case, the increase in spending on anticonvulsant use most likely exceeded the settlement amount. On the basis of the national annual prevalence of bipolar disorder (2.6%)[30] and the observed approximate increase in spending immediately following the intervention ($7,554 per 1,000 patients per month) we estimated that the increase in spending on anticonvulsants during the observed post- intervention period was well over $200 million: about half of the $430 million gabapentin settlement amount, not counting many unmeasured substitutions in other illnesses affected by the lawsuit.

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Despite evidence from physician self-report that off-label use of gabapentin in bipolar disorder was unaffected by the lawsuit,[31] our results show a reduction in use of gabapentin from 21.4% to 15.4% market share (28% relative reduction) after the lawsuit, following a period of stable use during the baseline period.

The relative decrease in gabapentin use did not coincide with a decline in overall anticonvulsant use; we showed that the market share of other anticonvulsants increased or continued to grow after the intervention. This increase is not surprising because of previous studies that show the decline in use of 1 drug after regulatory changes is often offset by increasing utilization of other substitute drugs.[10,32,33] Lamotrigine, an off-label, brand-name anticonvulsant that later received an indication for bipolar disorder in 2003 (more than a year after the gabapentin lawsuit), was 1 of the drugs that experienced the highest increase in market share. The use of the unapproved anticonvulsants, which included three brand name medications with no indication for bipolar disorder also continued to increase substantially after the intervention. Thus, many prescribers shifted from 1 scientifically unsubstantiated product to both substantiated and unsubstantiated products. The continued use of off-label prescribing indicates that the negative coverage did not result in a generalized reduction in off-label medication use. It is not surprising that the lawsuit was not associated with an increase in market share of older, generic medications that are not generally promoted as intensely as branded medications by the pharmaceutical industry.[34]

Monthly anticonvulsant spending per 1,000 patients increased 74% after the start of the lawsuit. Since a major driver of the lawsuit was state Medicaid program reimbursement of excess spending for off-label gabapentin use from 1994-2002, the increase in spending for anticonvulsants was unexpected.

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This study has several limitations. Our datasets did not allow us to measure pharmaceutical spending on marketing for anticonvulsants. Marketing to psychiatrists for gabapentin was essentially discontinued after the publication of the 2 negative randomized controlled trials [35] and may have contributed to the stability in use of gabapentin during the initial period of this study. However, there was most likely an increase in marketing of other anticonvulsant drugs in anticipation of decreased gabapentin use. We also could not account for changes to state Medicaid pharmacy benefits. For example, several State Medicaid Programs implemented prior authorization policies that included gabapentin, but these programs were implemented near the end of our study period after the lawsuit was settled in 2004 and were unlikely to affect our results.[35] Like lamotrigine, several antipsychotics (risperidone, quetiapine, ziprasidone, and aripiprazole)[36] were approved for bipolar disorder during the study period. Since these approvals could potentially influence our outcomes, we conducted a sensitivity analysis in which we included new bipolar medication approvals that occurred during the study period as interventions and evaluated changes in drug-specific market share and spending using all bipolar drugs in the denominator for market share. This analysis did not change our conclusions with regard to the anticonvulsant drug class, so we chose to exclude these interventions in the study. Also, we recognize that the publication of 2 studies[12,13] suggesting that gabapentin was not efficacious may have affected prescribing of gabapentin; however, these studies occurred before our baseline period when gabapentin use was flat and stable. Spending was based on pharmacy reimbursement, so we could not account for rebates. We did not have any information about physician specialty, so we were unable to distinguish between anticonvulsants prescribed by psychiatrists and those prescribed by general practitioners. However, other studies of this population indicate that most patients with bipolar illness are

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generally treated by mental health specialists.[37] Another limitation was that the pre-intervention period was relatively short; however, use of all medications was very stable and easy to model with the available data. We recognize that the dually eligible population with bipolar disorder is a particularly vulnerable subpopulation among those diagnosed with the disorder. While we believe that the general pattern of substitution effects in the general population may be similar, further study is needed to generalize our findings beyond this population.

In 2006 a year after our study period ended, Medicare Part D, the largest change to Medicare coverage since its inception, was implemented. Under this policy, the dually eligible population was transitioned from state Medicaid pharmacy benefits to regional Part D drug plans. Since both state Medicaid pharmacy benefits and Part D Plans vary widely in their formularies and cost-containment strategies, we believe it would be very interesting to evaluate a more recent lawsuit to observe whether similar intended and unintended consequences of this type of litigation would occur during the Part D era.

The US Department of Justice continues to sue pharmaceutical companies for off-label marketing practices. AstraZeneca, Pfizer, and Serono recently settled cases for hundreds of millions of dollars.[28,29,38] In 2010, Novartis settled a lawsuit accusing Novartis of marketing oxcarbazepine for off-label use in bipolar disorder.[1] The impact of these later lawsuits and their accompanying media coverage on prescribing practices remains unknown. On the basis of these results, the gabapentin lawsuit was associated with both intended and unintended changes in drug utilization and spending. This finding highlights the need for more comprehensive consideration of potential consequences when the US Department of Justice and states negotiate these important settlements. We found that both on-label and off-label anticonvulsants substituted for gabapentin use, and spending increases for other anticonvulsants eclipsed the reimbursement to

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states for off-label gabapentin use. These findings suggest the need for further study of lawsuits for the pharmaceutical marketing of off-label indications. We suggest that in these types of lawsuits, the US Department of Justice communicates with relevant health care provider and specialty organizations rather than rely on media reports as a primary means of disseminating information about an illegal marketing case. With knowledge of such a case, the health care provider organizations could inform prescribers about the litigation and reinforce that prescribers should refer to treatment guidelines for the disease of interest when making decisions about off-label prescribing. A narrow regulatory approach that does not consider the prescribing needs and substitution behavior of clinicians may not be effective in decreasing the use of scientifically unsubstantiated drugs and may increase rather than decrease overall spending.

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Paper 2

Dual Enrollees and the Transition to Medicare Part D: The Influence of Prior State Medicaid Benefits on Changes in Use of Medications

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Abstract

Objective: In this study, we evaluate how transitioning from state Medicaid drug benefits with and without drug benefit limits differentially affected changes in medication use and out-of-pocket drug costs among Medicare/Medicaid dual eligibles after their transition to Medicare Part D in 2006.

Methods: Using the Medicare Current Beneficiary Survey (MCBS) from 2000 to 2007, we identified annual cohorts of community-dwelling dual eligibles. Outcome measures were average annual prescription drug fills and out-of pocket drug costs per person. We constructed time-series regression models using pre-Part D data (2000-2005) to establish a baseline trend and intercept. We used these models to estimate predicted values to compare with observed values for each outcome in 2007.

Results: Dual enrollees in states with no Medicaid caps had an average of 4.4 more prescription drug fills in 2007 than expected given baseline trends for 2000-2005. In contrast, dual enrollees in states with Medicaid caps had an average of 10.5 more prescription drug fills in 2007 than expected. Both state groups experienced decreased total out-of-pocket spending on medications after Part D (absolute decreases –$143 and –$40, respectively).

Conclusions: Our study indicates that the dual eligibles in states with caps on the number of covered fills per month prior to entering a Part D plan experienced larger increases in annual fills compared with those in states where pharmacy benefits, like Part D plans, were not capped. This suggests that state Medicaid caps impose substantial constraints on the use of prescription

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medications for dual eligibles, which in turn may lead to under treatment of illness and adverse health consequences for individual patients.

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Introduction

In 2006 Medicare expanded its benefits to offer pharmaceutical coverage (Medicare Part D) to its beneficiaries, many of whom had no insurance coverage for prescription drugs.[1,2] Low-income elderly and persons with disabilities who are enrolled in both Medicare and Medicaid-received drug benefits through their state Medicaid pharmacy program. As part of the implementation of Part D in 2006, these dual eligibles were automatically transitioned from their state Medicaid pharmacy benefits to a regional Part D prescription drug plan (PDP).[3] At the time of Part D implementation there were approximately 6.6 million duals assigned to a Part D PDP.[4]

While it seemed likely that Medicare beneficiaries who transitioned from no insurance to Medicare Part D would experience increased access to medicines, it was not clear what the impact would be for the dual population who had previously had Medicaid drug coverage. Because these dual beneficiaries are among the sickest and poorest of the Medicare beneficiaries, many policymakers and others were concerned that they might experience reduced access to essential medicines from this change. Policymakers and others raised concerns that dual enrollees might have difficulties navigating the new system; cease use of essential medications because of increased cost sharing; and have trouble accessing essential medications under new formulary restrictions.[5-7] Previous studies of the impact of Medicare Part D on access to medicines for the dually eligible population have found that, on average, dual eligibles experienced either the same or increased utilization of medicines after Part D compared with their utilization before Part D.[8,9] However, no study has examined the impact of Medicare Part D on the duals while considering differences among the Medicaid pharmaceutical benefits from which they transitioned.

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State Medicaid pharmacy programs commonly use several utilization management strategies in order to minimize excess prescribing and control drug spending. These strategies include copayments, restricted formularies, prior authorization (requiring approval from the program before a particular drug can be dispensed), and prescription drug caps.[10,11] A drug cap is a limit on the number of prescriptions per person that a Medicaid program will pay for each month. When dual beneficiaries transitioned into a Medicare PDP in 2006, they encountered modest copayments for each medication they filled ($1-$5; the maximum copayment has since increased to $6.30),[12,13] drug formularies, and some prior authorization requirements depending on their PDP. But there are no drug caps under Part D. Previous studies have found that cap implementation in state Medicaid programs was associated with an immediate drop in drug utilization.[14] Removal of the cap was also associated with a dramatic and immediate increase in medication use.[14]

In this study we evaluated how transitioning from Medicaid programs with and without drug caps affected prescription drug utilization for dual eligibles entering Medicare Part D. We also evaluated overall changes in out-of-pocket (OOP) spending before and after Part D. We hypothesized that in state Medicaid programs with prescription drug caps, the dual eligibles would experience a differentially larger increase in utilization once enrolled in PDPs in 2006 compared with dual eligibles in states that had previously had no Medicaid drug caps.

Methods

Study Design

We used time series regression on the data from 2000 to 2005 to establish baseline intercepts and trends for our outcomes during the pre-policy period. Using bootstrap models we predicted post-policy outcomes in order to evaluate the effects of the transition to Medicare Part

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D on prescription drug use and OOP costs among dually-enrolled beneficiaries in states with drug benefit programs that varied in generosity.

Data and study population

Using the Medicare Current Beneficiary Survey (MCBS) from 2000 to 2007, we identified annual cohorts of community-dwelling respondents who were enrolled in both Medicare and Medicaid for 12 months in each calendar year of participation. The MCBS is a nationally representative panel survey that selects beneficiaries from Medicare enrollment records according to a multi-stage sampling plan. The Cost and Use subsample has a three-year rotating panel design with a portion of the sample replenished each year. Survey data include a wide range of information based on both administrative records and self-reports, including demographics, health status, insurance, services utilization, prescription fills, and payments from all sources. We required that respondents in years 2000-2005 (pre-Part D) have at least one prescription with a payment from Medicaid to be included in our sample for a given year. In 2006 and 2007 (post-Part D), we required respondents to have at least one prescription with a payment from a Medicare Part D plan.

We determined state Medicaid pharmacy benefits policies, including caps on fills per month, based on the annual report of the National Pharmaceutical Council in 2005.[15] We found that 21 states (including the District of Columbia) reported having caps and 30 states reported no caps. The specific details of the caps varied, ranging from limits of 3 to 15 per month for all prescriptions, to separate limits for branded and other drugs, to a monetary cap rather than a cap on the number of prescriptions. We excluded sample respondents living in Tennessee and Illinois because both states implemented a drug cap during 2005. We disregarded changes in cap policies (i.e., addition or removal of caps) that may have occurred between 2000 and 2004, and

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state differences in other cost-containment policies. For more details about Medicaid pharmacy benefits, see Table 2.1.

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Table 2.1. Description of States with a Prescription Drug Cap Policy

State	Cap	Brand Cap	Monetary Cap	Notes
Alabama		4		
Arkansas	3			Also can receive extension of three more per month.
California	6			Some rxs are exempted
Delaware	15			
District of Columbia			$1,500	Prior Authorization override
Georgia			$2,999.99	>$2,999.99 requires an override. >$9,999.99 requires paper claim and a copy of the prescription.
Illinois		3		Did not go into effect until October 2005. Over 65 excluded, no cap on generics and certain drug categories including chemotherapy, anticonvulsants, and antipsychotics.
Kansas		5		
Kentucky	4	3		3 brand cap (when no generic equivalent available). Many rx categories excluded 1. For any of the following conditions: a. Acute infection or infestation; b. Bipolar disorder; c. Cancer; d. Cardiac rhythm disorder; e. Chronic pain; f. CHD or CVD g. Cystic fibrosis; h. Dementia; i. Diabetes; j. End stage lung disease; k. End stage renal disease; l. Epilepsy; m. Hemophilia; n. HIV or AIDS o. Hyperlipidemia; p. Hypertension; q. Major depression; r. Metabolic syndrome; s. Organ transplant; or t. Psychotic disorder; or 2. As part of: a. Acute therapy for migraine headache or acute pain; or b. Suppressive therapy for thyroid cancer.
Louisiana	8			
Maine		5		
Mississippi	5	2		Can apply for 2 additional per month
New York	3.6			43 rxs annually. Overide process.
North Carolina	6			
Oklahoma	6	3		
Pennsylvania	6			
South Carolina	4			allowed based on a list of conditions. Including: ♦ Acute sickle cell disease ♦ Behavioral health disorder ♦ Cancer ♦ Cardiac disease (including high cholesterol) ♦ Diabetes ♦ End stage lung disease ♦ End stage renal disease ♦ HIV/AIDS ♦ Hypertension (i.e., high blood pressure) ♦ Life threatening illness (not otherwise specified) ♦ Organ transplant ♦ Terminal stage of an illness
Tennessee	5	2		Cap inplemented in mid-2005, so excluded from study
Texas	3			
Utah	7			Review when filling more than 7 in a month
Washington		5		Review of pharmacist when requesting 5th brand rx within month

Sources: Pharmaceutical Benefits Under State Medical Assistance Programs, 2005. National Pharmaceutical Council

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Study variables

Our outcome measures were mean annual self-reported prescription drug fills and out-of-pocket drug costs. Demographic characteristics of interest were age and gender (from enrollment files), and race and education (self-reported). All drug costs were converted to 2007 US dollars using the consumer price index.[16]

Statistical Analyses

For the full dually-enrolled study sample and separately for the two subgroups defined by state cap policies, we examined the survey-weighted characteristics in all study years (2000-2007) to check for discontinuities over time. We calculated mean annual fills per person and OOP drug costs per person with 95% confidence intervals, applying annual cross-sectional survey weights supplied by the MCBS as well as our own standardizing weights based on the characteristics of the two subgroups, separately, in 2007.

To model changes in drug utilization after Part D, we constructed time-series regression models on the pre-Part D data (2000-2005), establishing a baseline intercept and trend for each stratum of states. We then used parametric bootstrapping techniques previously used to evaluate the study outcomes in a different study of the MCBS population.[17] We conducted 10,000 simulations, sub-setting the pre-Part D annual population means to estimate predicted outcome values in 2007, with 95% confidence intervals, assuming no transition to Part D. We compared these predicted values to observed outcomes in 2007 to evaluate whether we could be 95% confident that they were different, while controlling for minor changes in demographic characteristics. We further compared the differences in predicted and observed values between the two study groups using a difference-in-difference approach. Our primary analysis focused on 2007, because 2006 was a transitional year. However, we also compared predicted and observed

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values for 2006 in a sensitivity analysis. We used SAS software, version 9.2 (SAS institute, Inc., Cary, North Carolina); this study was approved by the Human Subjects Committee of Harvard Pilgrim Health Care.

Results

The demographic characteristics of the study population in 2000, 2005, 2006, and 2007 are described in Table 2.2. Population characteristics were fairly stable over time; though there were slight shifts in age and education level over time in the states with caps, our statistical models accounted for these shifts.

Table 2.2 Demographic Characteristics of Community- dwelling Medicare and Medicaid Dual Beneficiaries, 2000, 2005, 2006, and 2007

	% (95% Confidence Interval)			
Characteristics	2000 (n=968)	2005 (n=1,039)	2006 (n=1,079)	2007 (n=946)
No caps	311	401	434	359
Caps	657	638	645	587
No caps				
Under 65[1]	45.9% (41.5-50.2)	44.5% (38.6-50.4)	42.7% (37.3-48.0)	43.4% (37.8-49.0)
65+	54.1% (49.8-58.5)	55.5% (49.6-61.4)	57.3% (52.0-62.7)	56.6% (51.0-62.2)
Sex (female)	61.1% (55.1-67.1)	65.2% (59.4-71.0)	64.3% (53.3-69.3)	59.6% (53.6-65.6)
Race (white)	72.2% (67.0-77.3)	71.4% (65.4-77.4)	72.7% (67.4-78.1)	67.9% (62.1-73.8)
Race (other)[2]	27.8% (22.7-33.0)	28.6% (22.6-34.6)	27.3% (21.9-32.6)	32.1% (26.2-37.9)
No high school diploma	62.1% (55.0-69.2)	49.8% (43.2-56.3)	52.9% (47.3-58.6)	53.5% (47.3-59.8)
At least high school diploma	37.9% (30.8-45.0)	50.2% (43.7-56.8)	47.1% (41.4-52.7)	46.5% (40.2-52.7)
Caps				
Under 65	37.3% (32.6-42.0)	41.3% (36.1-46.6)	38.7% (34.3-43.2)	41.5% (35.8-47.2)
65+	62.7% (58.0-67.4)	58.7% (53.4-63.9)	61.3% (56.8-65.7)	58.5% (52.8-64.2)
Sex (female)	67.7% (63.8-71.7)	63.9% (60.3-67.4)	65.2% (61.2-69.1)	64.7% (61.0-68.4)
Race (white)	56.1% (50.3-62.0)	55.6% (48.6-62.5)	55.3% (48.1-62.4)	54.7% (47.4-62.0)
Race (other)	43.9% (38.0-49.7)	44.4% (37.5-51.4)	44.7% (37.6-51.9)	45.3% (38.0-52.6)
No high school diploma	67.4% (61.3-73.4)	56.4% (52.0-60.9)	60.4% (56.1-64.7)	57.5% (53.0-62.1)
At least high school diploma	32.6% (26.6-38.7)	43.6% (39.1-48.0)	39.6% (35.3-43.9)	42.5% (37.9-47.0)

Source: Medicare Current Beneficiary Survey Cost and Use data from 2000 to 2007.
Survey estimates re-weighted to represent the national Medicare/ Medicaid duals population.
[1]The population under 65 is assumed to have qualified for Medicare via the disability entitlement.
[2]The Other Race category includes Black, Other, Asian, Hispanic, and North American Native.

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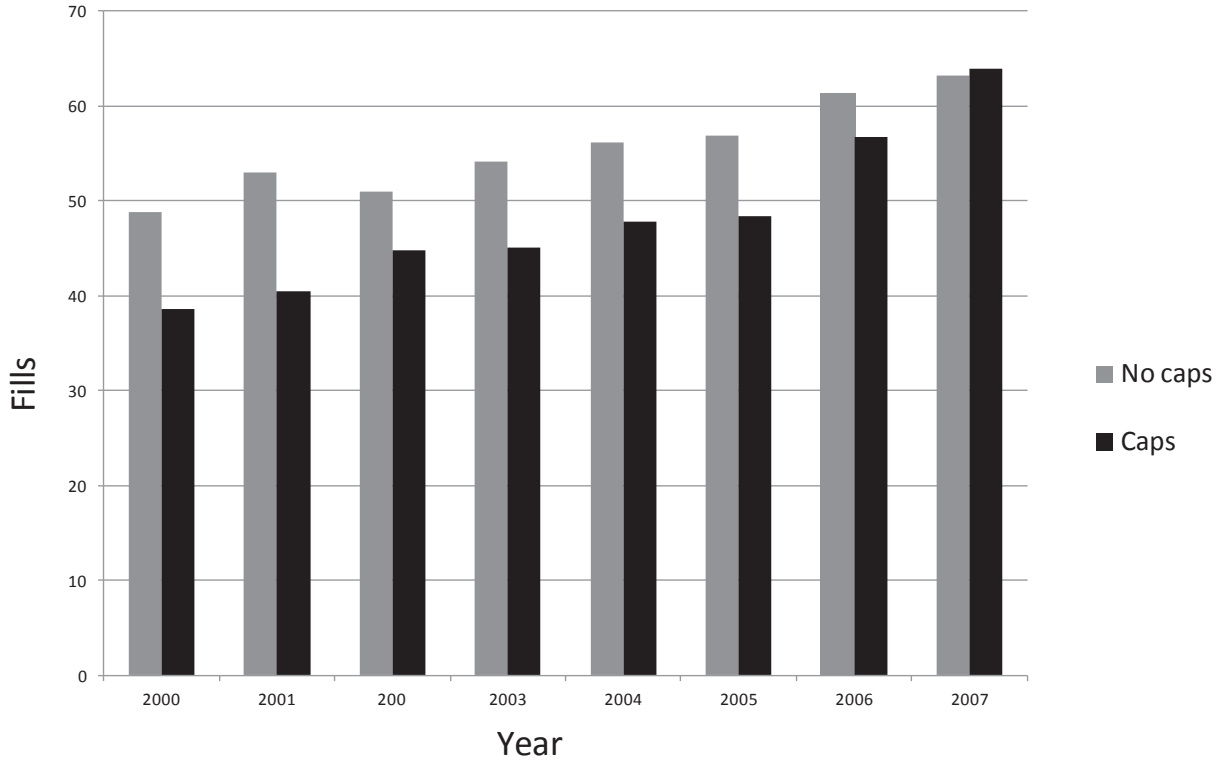
Figure 2.1 shows mean annual drug fills for dual enrollees in the two groups of states defined by the presence or absence of a drug cap. In the no-cap states, drug utilization increased during the baseline from an average of 48.4 fills in 2000 to 56.8 in 2005, and then rose to 65.2 fills in 2007. In the states with drug caps, average fills increased from 38.5 to 48.4 during the baseline years, and then rose to 63.9 fills in 2007.

Figure 2.1. Annual Average Prescription Drug Fills for Dual Beneficiaries by State Medicaid Program Cap Status



Source: Medicare Current Beneficiary Survey Cost and Use data from 2000 to 2007.
Note: Estimates weighted to represent the national Medicare/ Medicaid duals population. Individuals residing in states with a monthly limit on the number of prescriptions covered by Medicaid in 2005 were assigned to the Caps group.

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Table 2.3 displays estimated changes in annual fills after Part D based on time-series modeling of the six baseline years and our bootstrapped estimates of predicted values in 2007. In the states with no caps, we found the observed average in 2007 was 4.4 (95% CI: 0.3-8.2) fills higher than expected. In the states with caps, the 2007 observed average was 10.5 (95% CI: 7.7-13.3) fills above the predicted level. These results lead to a difference-in-difference estimate of 6.2 fills (95% CI: 6.17, 6.21) between the cap and no cap groups (data not shown).

Table 2.3 also presents observed and predicted values for average annual out-of-pocket drugs costs. We found that, in the no-cap states, observed OOP costs per person were $143.22 (95% CI: -$239.30, -$45.90) lower than predicted in 2007. In states with caps, we found that observed OOP costs per person were $40.71 (95% CI: -$66.1, -$15.90) lower in 2007 than predicted.

Table 2.3. Estimated Changes in Average Annual Prescription Drug Fills, and Out-of-Pocket Drug Costs (OOP) After Part D Implementation among Community-Dwelling Medicare/ Medicaid Dual Beneficiaries by Medicaid Pharmacy Benefit Cap Status

	Observed				Predicted[1] Mean (95% Confidence Interval)		Difference between Observed and Predicted (95% Confidence Interval)	
Outcome Measures	2000	2005	2006	2007	2006	2007	2006	2007
Average number of fills								
No caps	48.8	56.8	61.4	63.3	57.9 (54.7-61.0)	58.9 (55.0-63.0)	3.5 (0.4-6.7)	4.4 (0.3-8.2)
Caps	38.5	48.4	56.8	63.9	53.5 (50.7-56.2)	53.5 (48.6-58.3)	5.5 (3.1-8.0)	10.5 (7.7-13.3)
Average OOP drug costs								
No caps	$155	$288	$184	$171	$285 (189-378)	$315 (217-411)	-$101 (-194- -5)	-$143 (-239- -46)
Caps	$152	$191	$166	$181	$211 (189-234)	$221 (197-247)	-$46 (-68- -23)	-$41 (-66- -16)

Source: Medicare Current Beneficiary Survey Cost and Use data from 2000 to 2007.

[1] Predicted using autoregressive models based on 2000 to 2005 historical trends. Confidence intervals were constructed by creating 10,000 simulated values per outcome using the bootstrap method.

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Discussion

Before 2006, dually-enrolled Medicare and Medicaid beneficiaries received pharmacy coverage through their state Medicaid programs, and this coverage varied in generosity across states. Our study found that both study subgroups experienced increases in fills per person, as well as reductions in patient drug spending, after transitioning to Medicare Part D plans. The point estimate for the increase in fills in the cap states was substantially larger than that found in the no-cap states. These findings are consistent with our a priori hypothesis that dual beneficiaries would experience different impacts depending on the state in which they resided. We expected larger increases in medication use in capped states based on earlier research establishing that removal of Medicaid drug caps in the 1980's led to marked increases in utilization of medicines.[14]

Our results suggest important geographic disparities in access to medication prior to Part D. These disparities and problems of access remain highly relevant today, as many states continue to employ caps to control the costs of healthcare for vulnerable Medicaid beneficiaries, most of whom do not have Medicare eligibility. After Part D, some convergence in terms of levels of medication use appears to have occurred for the dual enrollees.

A priori, we had no hypothesis about a differential impact of transitioning to Part D on out-of-pocket spending, because of the variety and complexity of other cost-containment policies in place in both state Medicaid programs and PDPs. These policies included copayment amounts (Medicaid), copayment enforcement (Medicaid), and prior authorization requirements (Medicaid and PDPs). Moreover, the lack of available data on these other cost-containment policies meant it was not possible to control for them in our analyses. We know that prior to Part D, Medicaid could not deny prescriptions for beneficiaries if they could not afford to pay,[18] but once the dual

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eligibles transitioned to Part D, they were required to meet the copayment in order to obtain their prescriptions. We elected to focus this paper on pharmacy benefit caps because there is relative clarity on what policies were in place prior to Part D, as well as prior evidence of particularly strong effects. We found significant drops in OOP spending after Part D, in both cap and no-cap states. Together, our results indicating increased fills and lowered costs suggest substantial improvements in access to treatment and reductions in the financial burden of treatment for dual enrollees after Part D.

Our study fills an important gap in the literature on the effects of Part D, on dual enrollees in particular, and on geographic variations in impact. Moreover, our study has the advantage of using self-reports of drug use and spending. The bulk of the existing empirical evidence on Part D is based on claims data alone. These studies cannot account for purely out-of-pocket purchase or free samples (which the MCBS does), and copayment amounts in claims for dual enrollees may not reflect uneven enforcement of these copayment policies.

This study has several limitations. There were changes over time in the relative sizes of the two subgroup samples, in the composition of individual states making up the subgroups, as well as secular changes in demographic characteristics. These changes could potentially compromise the comparisons. Consequently, we adjusted for these changes by using weights that standardized the population to match the demographic composition of the 2007 cohort. All outcomes were self-reported and might be at risk for recall bias. However, previous validations of the self-reported drug use measure in 1999 and 2006 suggested undercounting of medications by 17.7 and 16.8 percent, respectively, of the samples[17,19] which suggests the self-reported drug measure is likely consistent across the study period. Also, because of the small samples, we were not able to distinguish further among the range of cap policies seen in the group of cap

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states. Since we included both highly restrictive and less restrictive cap states in this group, our results regarding the differential impact of Part D for duals coming from capped benefits can be considered conservative. It would be informative to investigate how the coverage transition affected specific drug choices for beneficiaries with specific chronic illnesses with high medication needs, but we did not have sufficient sample size to address these questions.

Our study found that transition from Medicaid pharmacy benefits to PDPs among dually enrolled beneficiaries coincided with substantial increases in utilization and decreased out-of-pocket spending. Notably, we found substantially larger point estimates for the increased utilization among states with capped Medicaid benefits. Further analyses are warranted focusing on other changes in cost-containment strategies (whether implemented by state Medicaid or specific PDPs), and using larger datasets to investigate effects among more specific clinical populations. Such analyses would create a more detailed picture of the gains and set-backs that may have occurred. There is some evidence that utilization management policies have become more stringent over time (e.g., increases in copayment amounts).[13] Continued research to monitor utilization and spending patterns over time will be important to evaluate the impact of changes to utilization management policies. This kind of knowledge will be critical to guiding future adjustments to pharmacy coverage arrangements for this population.

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Paper 3

National Estimates of the Impact on Antidepressant Treatment Prevalence and Treatment Intensity of Medicare Part D

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Abstract

Objective: We evaluated how Medicare Part D implementation affected the prevalence of antidepressant medication use and treatment intensity among nonelderly disabled and elderly Medicare beneficiaries.

Methods: Using the Medicare Current Beneficiary Survey (MCBS) from 2001 to 2007, we identified annual cohorts of community-dwelling respondents and stratified the study population into nonelderly disabled and elderly subgroups. Outcome measures were annual prevalence of antidepressant treatment and treatment intensity (average number of fills among those with any fills in a year). We constructed time-series regression models based on pre-Part D data (2001-2005) to estimate predicted values in 2007 for comparison with observed outcomes. We also estimated effects among subgroups of beneficiaries who self-reported depressive symptoms.

Results: Among both elderly beneficiaries and the nonelderly disabled overall, we detected no change in antidepressant treatment prevalence attributable to Part D. However, in both groups, those receiving any antidepressant treatment experienced a higher than expected number of fills in 2007 (a relative difference of 11.9% (95% CI: 6.8-17.6%) and 11.1% (95% CI: 5.8-17.0%) for the elderly and non-elderly disabled, respectively). In subgroup analyses, we found that non-elderly disabled beneficiaries reporting symptoms of depression had no increases in either prevalence of treatment or intensity of treatment.

Conclusions: Our study suggests that Part D had no effect on whether Medicare beneficiaries accessed any antidepressant treatment in a year. Treated patients, however, received more intense treatment after Part D. Potential explanations of these findings include the presence of patient-level barriers (e.g., inadequate understanding of Part D) as well as insurance administrative barriers to treatment initiation under Part D. Our findings suggest that both elderly and nonelderly beneficiaries still have difficulties overcoming obstacles to necessary psychotropic therapies, even in a context of expanded coverage.

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Introduction

In 2006, the Medicare Part D drug benefit became available, enabling many Medicare beneficiaries to gain such coverage. Policymakers' expectation in creating Part D was that it would improve access to medications for Medicare beneficiaries, especially those who previously had lacked prescription drug coverage.[1,2] While research has shown the implementation of Part D to be associated with increased utilization of medications among beneficiaries overall,[3-5] more focused evaluations of Part D impacts are needed for specific types of medications, such as antidepressants. Antidepressant medications are an effective and recommended treatment modality for depression.[6,7] Depression affects 10% to 18% of Medicare Beneficiaries and is associated with higher total health care spending compared with beneficiaries who do not suffer from depression.[8-10] Those suffering from depression are more likely to have other chronic illnesses, such as diabetes and cardiovascular disease, which can also be affected by appropriate treatment of depression.[11,12] Therefore, antidepressant medications are an important component of treatment for this population.

Private prescription drug plans compete to sell coverage to Medicare beneficiaries under the Part D program. Before Medicare Part D went into effect, there were widespread concerns about whether beneficiaries would be able to obtain appropriate antidepressants from these plans. The worry was that plans might limit the drugs on their formularies so as to discourage people with depression from enrolling in their plan, as people with depression frequently have higher total prescription drug costs. To prevent this outcome, the regulations for plans participating in Part D require coverage of at least one drug in every therapeutic category and require risk adjustments to be applied to reimbursement rates so that the risks of higher than anticipated drug expenditures are limited.[13-15] Furthermore, antidepressants were included in a special category of

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drugs for which all chemical entities had to be covered.[16] Despite these protections, concerns remained that plans had too much flexibility in benefit design, allowing plan designers to make the plans appear less attractive to individuals with mental illness in order to avoid high-cost enrollees. Although the plans might meet formulary requirements, in order to steer higher- cost beneficiaries away, they might offer coverage only for less frequently prescribed formulations or might erect other administrative barriers such as step therapy and prior authorization requirements.[13]

Past research has consistently documented distinct differences between the elderly and nonelderly disabled Medicare populations.[17-19] The disabled are heavy medication users and tend to use more psychotropic medications than the elderly.[18] Historically, nonelderly disabled, who are more likely to have low income and poor health status, have encountered significantly more access problems and cost-related barriers to care than the elderly.[18] Therefore, it is possible that, even with the expansion of drug coverage, the nonelderly disabled seeking treatment for depression would still have difficulty navigating the new insurance system and gaining access to antidepressant medications. We know that a large proportion (approximately 50%, compared with about 27% among the elderly) of the disabled population likely had drug coverage under Medicaid prior to Part D because they are dually eligible for Medicare and Medicaid. Since state Medicaid drug insurance policies vary in benefit generosity, it's possible that some of these beneficiaries may not experience an improvement in access to medicines after Part D implementation because of new utilization management policies that may be in place. For example, some state Medicaid programs don't require any copayments, so the addition of a $3 copayment requirement for filling a prescription among the dual nonelderly disabled may reduce the likelihood that a dually eligible beneficiary will get access to that medication. Previous

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research has found that copayments as low as $0.50 are associated with an immediate drop in medication utilization.[20] Depending on their prior experience in Medicaid, the dually eligible beneficiaries may not experience improved access to medications after Part D went into effect.

Recent research found that cost-related medication nonadherence (CRN) is much higher among those who report symptoms of depression, compared to those reporting no symptoms. [8,21] Further, after Part D implementation, CRN for Medicare beneficiaries remained unchanged for those also reporting symptoms of depression, whereas CRN decreased substantially among those reporting no symptoms. Another study found that among Medicare beneficiaries reporting any type of nonadherence, antidepressants were among the most frequently unfilled prescription drugs.[22]

In this study, we examine self-reported prevalence of treatment and treatment intensity with antidepressant medications among elderly and nonelderly disabled beneficiaries before and after Part D implementation. We also evaluate a subset of beneficiaries reporting depressive symptoms. We use time series models to estimate the impact of Part D on these outcomes while accounting for pre-existing trends.

Methods

Data and study population

Using the Medicare Current Beneficiary Survey (MCBS) from 2001 to 2007, we identified annual cohorts of Medicare enrollees in the Cost and Use data files. The MCBS is a nationally representative survey that selects beneficiaries from Medicare enrollment records according to a multi-stage sampling plan. The Cost and Use sample has a 3-year rotating design, with approximately one third of the sample panel replenished each year. Survey data include a wide range of self-reported outcomes including demographics, health status and chronic illness,

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health insurance, health services utilization, prescription drug fills, and payment amounts from all sources. For our main study population we included only community-dwelling individuals who were enrolled in Medicare Parts A and B for 12 months in each calendar year of participation.

For our supplemental analysis, we identified a subgroup of respondents who reported beneficiaries with depressive symptoms. To identify this group we used two questions in the MCBS that address specific criteria in the Diagnostic and Statistical Manual of Mental Disorders:[23] sadness and anhedonia, which have been established as strong indicators of depression.[24] Based on previously published methods,[8,21] respondents were assigned to "depressive" status during a given study year if they answered "all of the time" or "most of the time" to the survey question, "In the past 12 months, how much of the time did you feel sad, blue, or depressed?," or "Yes" to the item, "In the past 12 months, have you had two weeks or more when you lost interest or pleasure in things you usually enjoyed?".

Study variables

We have two outcome measures: total prevalence of antidepressant treatment (percentage of the population with any antidepressant fill in a year) and intensity of treatment (mean number of antidepressant fills among the population that received any fills in a year). Demographic characteristics we describe for the elderly and nonelderly disabled subgroups were gender, race, education, and number of comorbidities. Although the MCBS began to include Part D event data (claims) in the 2006 Cost and Use file in addition to self-reported prescription drug events, we included only self-reported drug events in all sample years, so as to measure outcomes consistently over time. Spending on medications was converted to 2007 US dollars using the consumer price index.[25] Recognizing that nonelderly disabled and elderly Medicare beneficiaries

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represent quite distinct populations in terms of healthcare utilization and various demographic and clinical characteristics,[26] including prevalence of depression,[10] we stratified our analyses accordingly.

Statistical Analyses

We examined demographic and health characteristics of the MCBS population, nonelderly and elderly, overall and with depressive symptoms, in all study years.[27,28] We calculated the survey-weighted annual prevalence of antidepressant treatment and mean treatment intensity for each study cohort. Annual cross-sectional survey-weights supplied by the MCBS were applied in all analyses.

To estimate changes after Part D for each outcome and beneficiary group, we constructed time-series regression models based on the pre-Part D data (2001-2005). Each model established a baseline intercept and trend and allowed us to calculate the expected value of outcomes in 2007, had Medicare Part D not been implemented. Using parametric bootstrapping techniques,[3] we then conducted 10,000 simulations per model to construct 95% confidence intervals around the predicted value. We compared these predicted values to observed values from the 2007 survey data to determine whether the transition to Part D had an impact on outcomes. Our primary analysis focused on 2007, because 2006 was a transitional year. We also modeled 2006 expected outcomes in a sensitivity analysis. We controlled for changes in education over the study period of the different yearly cohorts by deriving and applying standardized weights from stratum-level characteristics of the population in 2007.

We used SAS software, version 9.3 (SAS institute, Inc., Cary, North Carolina), to conduct these analyses. This study was approved by the Human Subjects Committee of Harvard Pilgrim Health Care.

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Results

Demographic characteristics of the study population for a selection of study years in 2001, 2003, 2005, and 2007 are presented in Table 3.1. Population characteristics were fairly stable over time; even though the educational attainment rose over the years, our statistical models accounted for these gradual shifts. Rates of self-reported depression were remarkably stable, although with a slight downward trend. Self-reported symptoms of depression were associated with disability status and higher burden of comorbid illness. For example, among the elderly in 2007, 53% of individuals reported 3 or more non-psychiatric chronic conditions, but among the subgroup with depressive symptoms, 67% reported 3 or more.

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Table. 3.1 Demographic and Health Characteristics of Community-dwelling Medicare Beneficiaries, 2001, 2003, 2005, and 2007.

	2001		2003		2005		2007	
	% (95% Confidence Interval)							
Study Population								
Under 65, overall	1,341	(100%)	1,344	(100%)	1,347	(100%)	1,383	(100%)
Depressive symptoms[1]	557	(42%)	553	(41%)	550	(41%)	553	(40%)
65 or older, overall	7,712	(100%)	7,634	(100%)	7,328	(100%)	7,401	(100%)
Depressive symptoms	1,185	(15%)	989	(13%)	873	(12%)	870	(12%)
Sex (female)								
Under 65, overall	45.6%	(43.0-48.2)	45.9%	(42.8-49.0)	48.0%	(44.8-51.2)	49.4%	(45.8-53.0)
Depressive symptoms	49.7%	(44.9-54.5)	50.1%	(45.5-54.7)	52.0%	(47.3-56.7)	52.0%	(46.6-57.4)
65 or older, overall	59.9%	(58.8-60.9)	58.5%	(57.4-59.5)	58.2%	(57.1-59.4)	57.4%	(56.1-58.8)
Depressive symptoms	65.7%	(63.0-68.3)	63.4%	(60.7-66.1)	65.0%	(61.6-68.4)	64.7%	(61.3-68.1)
Race								
Under 65, overall								
White	76.2%	(73.0-79.4)	71.4%	(67.0-75.9)	74.5%	(70.0-79.0)	72.7%	(68.9-76.5)
Other	23.8%	(20.6-27.0)	28.6%	(24.1-33.0)	25.5%	(21.0-30.0)	27.3%	(23.5-31.1)
Depressive symptoms								
White	79.3%	(75.7-82.9)	73.1%	(67.1-79.1)	77.4%	(71.4-83.4)	75.7%	(71.4-80.0)
Other	20.7%	(17.1-24.3)	26.9%	(20.9-32.9)	22.6%	(16.6-28.6)	24.3%	(20.0-28.6)
65 or older, overall								
White	87.8%	(86.6-80.1)	87.4%	(11.3-13.9)	87.2%	(85.6-88.8)	87.7%	(86.2-89.1)
Other	12.2%	(10.9-13.4)	87.4%	(86.1-88.7)	12.8%	(11.2-14.4)	12.3%	(10.9-13.8)
Depressive symptoms								
White	86.4%	(83.9-88.9)	86.3%	(83.5-89.1)	86.3%	(83.6-89.1)	85.8%	(83.0-88.5)
Other	13.6%	(11.1-16.1)	13.7%	(10.9-16.5)	13.7%	(10.9-16.4)	14.2%	(11.5-17.0)

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Table 3.1 (continued). Demographic and Health Characteristics of Community-dwelling Medicare Beneficiaries, 2001, 2003, 2005, and 2007.

	2001	2003	2005	2007
	% (95% Confidence Interval)			
Education				
Under 65, overall				
No high school diploma	36.3% (33.4-39.1)	33.6% (30.8-36.4)	30.5% (28.0-33.1)	29.0% (26.4-31.7)
High school diploma or higher	63.7% (60.9-66.6)	66.4% (63.6-69.2)	69.5% (66.9-72.0)	71.0% (68.3-73.6)
Depressive symptoms				
No high school diploma	34.2% (29.8-38.6)	32.7% (28.5-37.0)	32.6% (28.5-36.7)	29.4% (25.2-33.6)
High school diploma or higher	65.8% (61.4-70.2)	67.3% (63.0-71.5)	67.4% (63.3-71.5)	70.6% (66.4-74.8)
65 or older, overall				
No high school diploma	31.5% (29.7-33.2)	29.3% (27.8-30.8)	27.2% (25.6-28.8)	25.6% (24.0-27.3)
High school diploma or higher	68.5% (66.7-70.3)	70.7% (69.2-72.2)	72.8% (71.2-74.4)	74.4% (72.7-76.0)
Depressive symptoms				
No high school diploma	41.2% (38.3-44.1)	39.6% (36.0-43.2)	41.7% (37.7-45.7)	36.0% (32.6-39.4)
High school diploma or higher	58.8% (55.9-61.7)	60.4% (56.8-64.0)	58.3% (54.3-62.3)	64.0% (60.6-67.4)
Comorbidities[2]				
Under 65, overall				
0-2	41.1% (37.2-45.1)	39.0% (35.7-42.3)	37.0% (33.6-40.4)	36.2% (32.8-39.7)
3+	58.8% (54.8-63.0)	61.0% (57.7-64.3)	62.8% (59.4-66.2)	62.8% (59.8-65.9)
Depressive symptoms				
0-2	30.9% (25.7-36.0)	30.5% (26.3-34.7)	25.2% (21.3-29.0)	29.7% (24.4-35.0)
3+	69.1% (64.0-74.3)	69.5% (65.3-73.7)	74.4% (70.5-78.4)	70.2% (64.9-75.5)
65 or older, overall				
0-2	49.1% (47.6-50.6)	47.6% (46.3-48.9)	46.2% (44.9-47.4)	44.7% (43.2-46.2)
3+	50.8% (49.2-52.3)	52.4% 51.0-53.7)	53.5% (52.2-54.8)	54.8% (53.3-56.3)
Depressive symptoms				
0-2	33.0% (30.1-36.0)	28.7% (25.5-31.9)	30.2% (26.7-33.7)	27.1% (24.1-30.0)
3+	67.0% (64.0-69.9)	71.3% (68.1-74.5)	69.4% (66.0-72.9)	72.6% (70.0-75.5)

Source: Medicare Current Beneficiary Survey Cost and Use data 2001, 2003, 2005, and 2007.

Note: All percentages estimated based on MCBS survey weights.

[1]Self report of symptoms of depression based on response to two MCBS survey questions described in Methods section
[2]Morbidity categories included cardiac disease, hypertension, cerebrovascular disease, lung disease, cancer, diabetes mellitus, arthritis, psychiatric disorder or depression, dementia, and other neurological conditions.

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Changes in Antidepressant Treatment among Elderly Beneficiaries

Figure 3.1a displays annual prevalence of antidepressant treatment for elderly Medicare beneficiaries overall and for the subgroup reporting depressive symptoms. The rate of treatment for depression among the entire elderly population increased from 11.2% to 13.9% during the baseline period (2001-2005) and reached 14.8% in 2007. The average number of antidepressant fills per year among elderly beneficiaries treated for depression increased from 5.9 in 2001 to 6.4 in 2005 (Figure 3.1b). By 2007, average treatment intensity had reached 7.1. Among the subset of elderly with depressive symptoms, treatment prevalence increased from 25.8% to 29.5% during the baseline and then increased to 36.0% in 2007. The treatment intensity for this beneficiary group increased from 5.7 fills in 2001 to 7.0 fills in 2005, and then increased to 7.8 fills in 2007.

Table 3.2 displays estimated changes in outcomes for elderly beneficiaries after Part D based on our time-series modeling of the five baseline years and bootstrapped estimates of predicted values in 2007. Among the elderly overall, which was the largest of our study cohorts, we found no significant change in the prevalence of treatment attributable to Part D. However, the relative difference in predicted versus observed number of fills among the treated in 2007 was 11.9% (95% CI: 6.8-17.6%). Among the elderly with depressive symptoms, both treatment prevalence and treatment intensity were significantly higher in 2007 than predicted based on baseline data (relative differences of 11.8% (95% CI: 1.4-25.0%) and 7.2% (95% CI: 1.4-13.9%), respectively).

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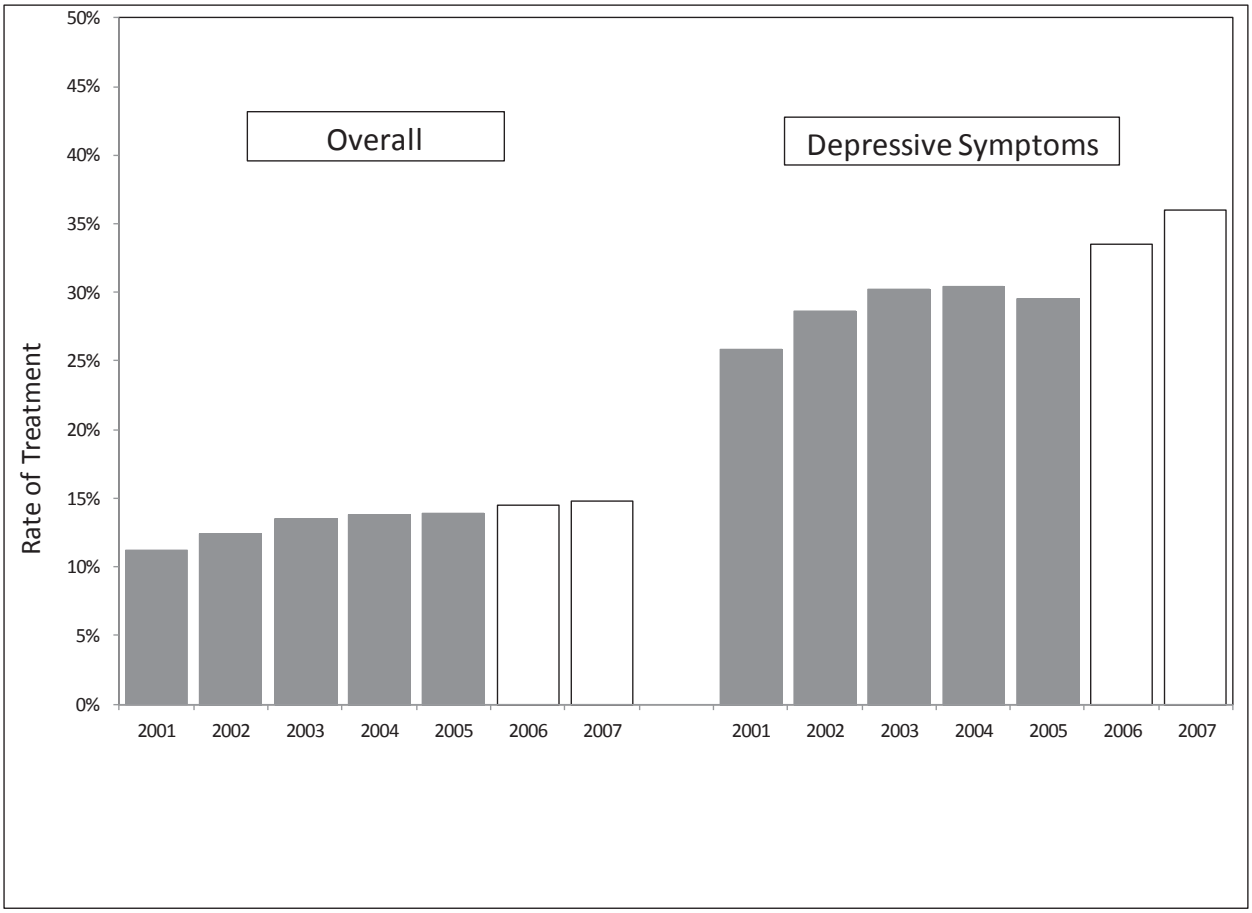
Figure 3.1a. Rate of Antidepressant Treatment Among Elderly Medicare Beneficiaries and the Subgroup Reporting Depressive Symptoms



Source: Medicare Current Beneficiary Survey Cost and Use data from 2001 to 2007.
Note: Estimates weighted to represent the national Medicare population.

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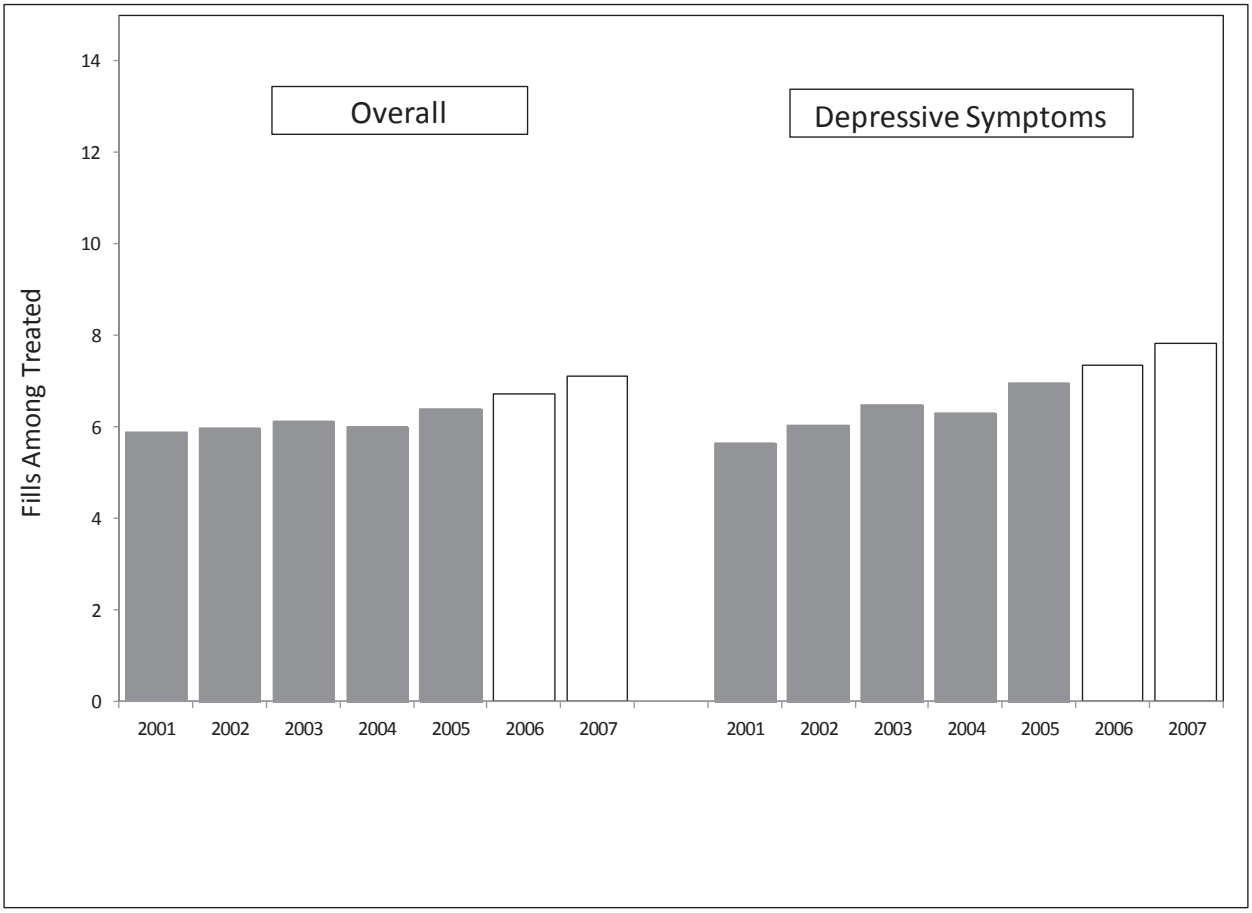
Figure 3.1b. Average antidepressant Drug Fills per Year Among the Treated Elderly Medicare Beneficiaries and the Subgroup Reporting Depressive Symptoms



Source: Medicare Current Beneficiary Survey Cost and Use data from 2001 to 2007.
Note: Estimates weighted to represent the national Medicare population.

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Table 3.2. Estimated changes in annual treatment rates and number of antidepressant[1] fills after Part D implementation among elderly community-dwelling Medicare beneficiaries, overall and for subgroup reporting depression symptoms

Outcome Measures	Observed Value[2]		Predicted Value[3] Mean (95% Confidence Interval)		Absolute difference between Observed and Predicted Mean (95% Confidence Interval)		Relative difference between Observed and Predicted Mean (95% Confidence Interval)
	2006	2007	2006	2007	2006	2007	2007
Overall population aged 65+							
Proportion receiving any antidepressant drug treatment in year	14.5%	14.8%	14.9% (13.8-%16.1%)	15.6% (14.4%-16.7%	-0.4% (-1.5%-0.07%)	-0.8% (-1.9%-0.3%)	-5.2% (-11.6%-2.4%)
Total antidepressant fills in year among those receiving treatment	6.7	7.1	6.3 (6.0-6.6)	6.3 (6.0-6.7)	**0.45 (0.13-0.76)**	**0.76 (0.45-1.06)**	**11.9% (6.8%-17.6%)**
Persons aged 65+ reporting depressive symptoms							
Proportion receiving any antidepressant drug treatment in year	33.5%	36.0%	31.4% (27.9%-35.0%)	32.2% (28.8-%35.5%	2.2% (-1.5%-5.6%)	**3.8% (0.5%-7.2%)**	**11.8% (1.4%-25.0%)**
Total antidepressant fills in year among those receiving treatment	7.4	7.8	7.0 (6.6-7.5)	7.3 (6.9-7.7)	0.34 (-0.1-0.8)	**0.53 (0.1-1.0)**	**7.2% (1.4%-13.9%)**

Note: Number of observations: overall elderly community-dwellers ranged from 7,276 to 7,712 survey respondents per year; treated elderly, 850 to 1,099, elderly with depressive symptoms, 870 to 1,185, treated elderly with depressive symptoms, 252 to 330.
Source: Medicare Current Beneficiary Survey data from 2001 to 2007
[1]The antidepressant medications did not include medications that are frequently used for indications other than depression, such as smoking cessation.
[2]Estimated based on MCBS survey weights
[3]Predicted using autoregressive models based on 2000 to 2005 historical trends. Confidence intervals were constructed by creating 10,000 simulated outcomes using the bootstrap method.

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Changes in Antidepressant Treatment among Nonelderly Disabled Beneficiaries

Figure 3.2a shows the prevalence of antidepressant treatment for the subgroup of nonelderly disabled beneficiaries overall and for the subgroup reporting symptoms of depression. Treatment prevalence was just over 30% between 2001 and 2003, then increased from 32.0% to 36.2% in 2004, and remained stable thereafter. Antidepressant treatment intensity (Figure 3.2b) was fairly stable during the baseline among the disabled overall (8.7 fills per year in 2001 and 8.8 in 2005), and then it increased to 10.2 fills by 2007. Among the subgroup with symptoms, treatment prevalence increased from 43.8% to 55.2% during the baseline period, apparently including an uptick between 2003 and 2004 similar to the increase in treatment prevalence among all the nonelderly disabled. After Part D was in effect, however, there was a notable decrease in prevalence to 49.9% among those with symptoms.

Table 3.3 displays estimated changes in outcomes for nonelderly disabled beneficiaries after Part D based on our time-series modeling of the five baseline years and bootstrapped estimates of predicted values in 2007. Because of the discontinuities (annual relative change of 10% or more) in the baseline trends for treatment prevalence among the two disabled groups, the linear regression models should be interpreted with caution because we analyzed the series based on an assumption of a linear trend. For the disabled overall, the time series and bootstrap approach predicts a significant relative decrease of 9.1% in treatment prevalence after Part D was in effect (95% CI: -14.8--2.4). However, the relative difference in predicted versus observed number of fills among the treated in 2007 was 11.1% (95% CI: 5.8 - 17.0%). Among the disabled reporting depressive symptoms, the relative difference between the predicted results from our statistical model and the observed data indicate a 17.9% relative decrease in antidepressant treatment prevalence (95% CI -24.1- -10.5). No significant change in treatment

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intensity was detected for this subgroup in 2007 using our statistical modeling approach (relative difference -3.2%; 95% CI: -11.8 - 7.4%).

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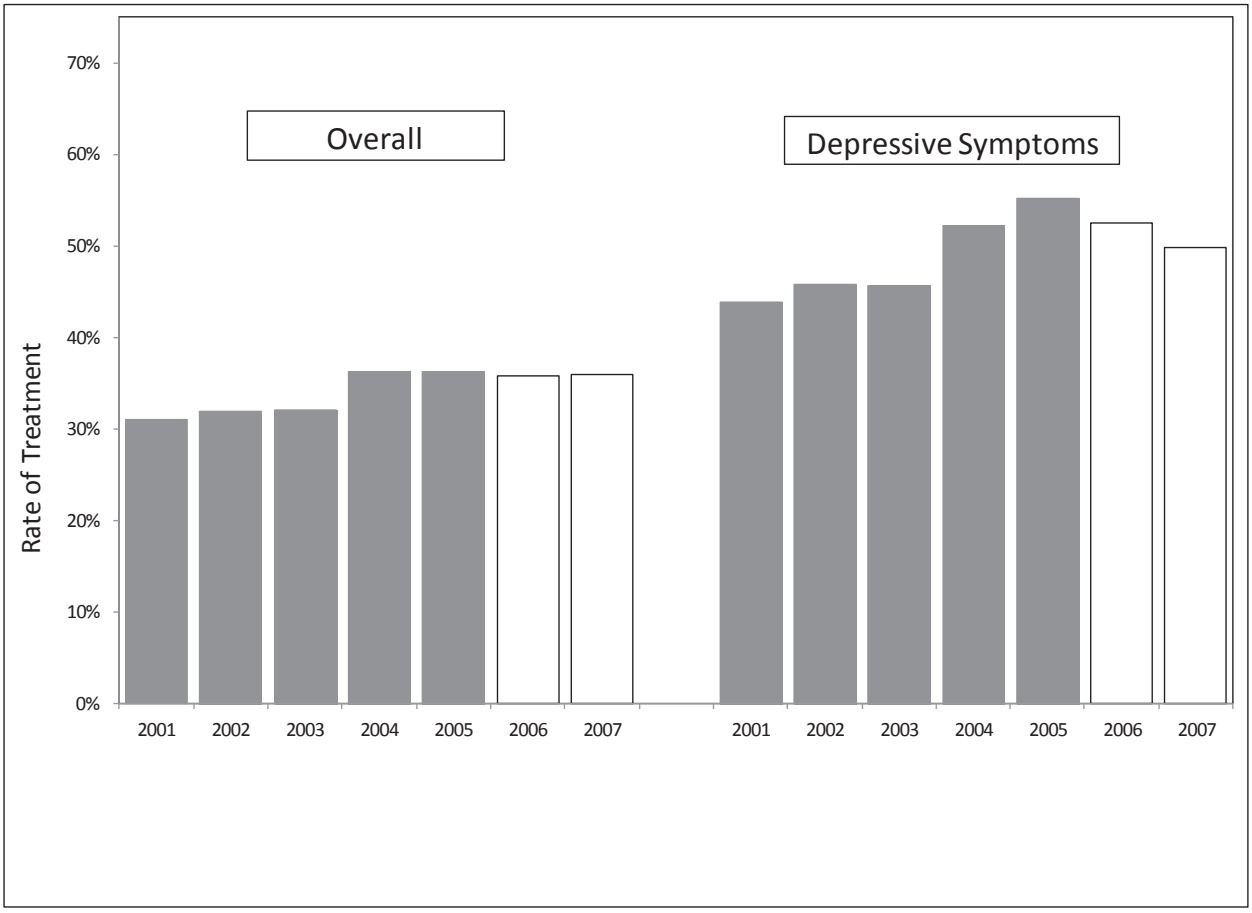
Figure 3.2a. Rate of Antidepressant Treatment Among Disabled (under age 65) Medicare Beneficiaries and the Subgroup Reporting Depressive Symptoms



Source: Medicare Current Beneficiary Survey Cost and Use data from 2001 to 2007.
Note: Estimates weighted to represent the national Medicare population.

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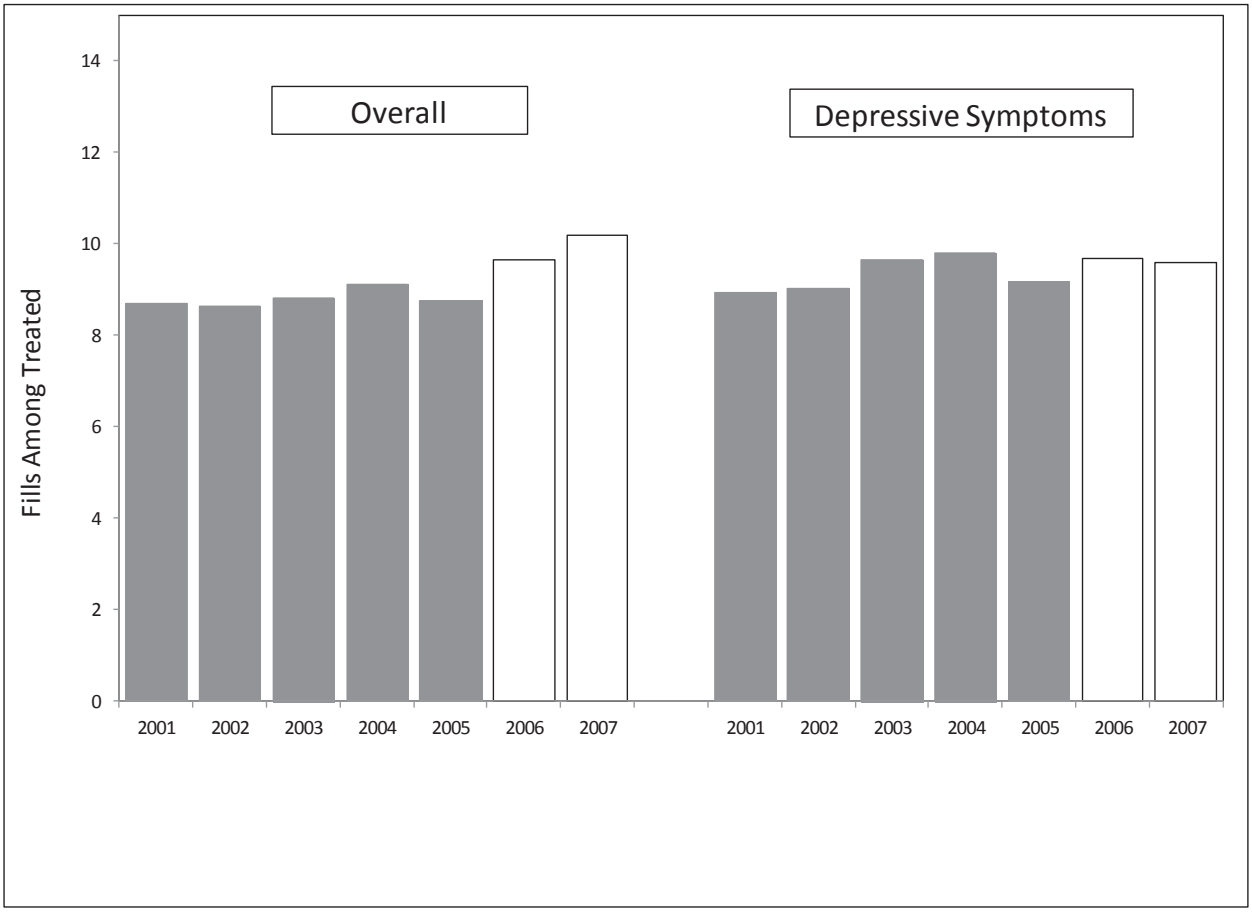
Figure 3.2b. Average antidepressant Drug Fills per Year Among the Treated Disabled Medicare Beneficiaries and the Subgroup Reporting Depressive Symptoms



Source: Medicare Current Beneficiary Survey Cost and Use data from 2001 to 2007.
Note: Estimates weighted to represent the national Medicare population.

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Table 3.3. Estimated changes in annual treatment rates and number of antidepressant[1] fills after Part D implementation among nonelderly community-dwelling Medicare beneficiaries, overall and for subgroup reporting depression symptoms

Outcome Measures	Observed Value[2]		Predicted Value[3] Mean (95% Confidence Interval)		Absolute difference between Observed and Predicted Mean (95% Confidence Interval)		Relative difference between Observed and Predicted Mean (95% Confidence Interval)
	2006	2007	2006	2007	2006	2007	2007
Overall population aged under 65							
Proportion receiving any antidepressant drug treatment in year	36%	36%	38% (0.41-0.02)	39% (0.37-0.4)	-0.02 (-0.05-0.01)	**-0.04 (-0.06–0.01)**	**-9.1% (-14.8--2.4)**
Total antidepressant fills in year among those receiving treatment	9.7	10.2	9.1 (8.7-9.5)	9.2 (8.7-9.6)	**0.56 (0.17-0.95)**	**1.02 (0.56-1.49)**	**11.1% (5.8-17.0)**
Persons aged under 65 reporting depressive symptoms							
Proportion receiving any antidepressant drug treatment in year	53%	50%	58% (52.7-62.4)	61% (55.7-65.7)	**-5% (-9.8--0.2)**	**-11% (-15.9–5.9)**	**-17.9% (-24.1--10.5)**
Total antidepressant fills in year among those receiving treatment	9.7	9.6	9.8 (8.9-10.7)	9.9 (8.9-10.9)	-0.14 (-1.1-0.8)	-0.32 (-1.3-0.7)	-3.2% (-11.8-7.4)

Note: Number of observations: overall disabled community-dwellers ranged from 1,323 to 1,383 survey respondents per year; treated disabled, 460 to 568, disabled with depressive symptoms, 533 to 569, treated disabled with depressive symptoms, 300 to 331.
Source: Medicare Current Beneficiary Survey data from 2001 to 2007
[1]The antidepressant medications did not include medications that are frequently used for indications other than depression, such as smoking cessation.
[2]Estimated based on MCBS survey weights
[3]Predicted using autoregressive models based on 2000 to 2005 historical trends. Confidence intervals were constructed by creating 10,000 simulated outcomes using the bootstrap method.

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Discussion

Our analyses found no statistically significant change in the prevalence of antidepressant treatment attributable to Part D among elderly Medicare beneficiaries. However, elderly beneficiaries who did use an antidepressant medication were likely to receive more antidepressant prescription fills after Part D. This suggests that once they surmounted initial barriers to access (such as clinician prescribing and coverage restrictions), they received prescription drug treatment for a longer period after Part D. Among nonelderly disabled beneficiaries, our findings were similar. We did not observe any change in terms of the prevalence of treatment initiation among the disabled, but there was a significant increase in treatment intensity for those who were treated. These main findings raise several questions about the effectiveness of Part D in increasing access to medications for vulnerable populations. It is possible special protections around antidepressants under Part D were insufficient to ensure access to this drug class, and Part D plans erected excessively high barriers to treatment.

It is not possible to state precisely what prevalence of treatment might be termed the "appropriate" level for the population of Medicare beneficiaries. Nor is it possible, with the MCBS data, to know the extent to which treatment that was received was appropriate. However, we know from extensive research published elsewhere[29,30] that depression is seriously undertreated in the US, particularly among elderly and chronically ill populations. So we might expect that with a well-documented drug coverage expansion such as Part D, significant increases in use would occur. It may be that other factors, distinct from the changes in coverage, inhibited increases in use. For example, physicians, particularly those caring for older, sicker patients, may be prioritizing other conditions in the limited time available during visits. Patients are often reluctant to discuss stigmatized mental illnesses. A widely publicized FDA black box

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warning on SSRI medications in late 2004[31] is known to have led to the flattening or reversal of rising antidepressant use rates in other US populations.[32-34]

We focused our main analyses on the Medicare beneficiary population stratified by elderly versus nonelderly, regardless of depression status. To best ensure that these analyses were clinically relevant, we restricted our list of antidepressant agents to those medications that are usually used exclusively for the treatment of depression. We excluded medications such as bupropion and nortriptyline which are often prescribed for other purposes. In sensitivity analyses not shown here, we repeated all analyses using the broader list of antidepressant agents, and the results were nearly identical.

In a further attempt to isolate treatment of true depression, we took advantage of clinical information available in the MCBS to conduct secondary analyses limited to persons reporting depressive symptoms. Using the MCBS measures of sadness and anhedonia represents a widely-validated[35] approach for identifying people with depression, and these measures appear strongly correlated with other characteristics known to be associated with depression and are stable over time. Our supplemental analyses evaluating changes after Part D among subgroups reporting these depressive symptoms offered a somewhat more complicated picture than our overall population analyses. Among the elderly, our findings suggested that patients reporting depressive symptoms were more likely than beneficiaries overall to experience an increase rate of treatment with antidepressants after Part D. By contrast, among the nonelderly disabled, those who reported depressive symptoms appeared to have experienced decreased prevalence of treatment and no change in treatment intensity after Part D. We note that the baseline data were somewhat unstable in this smaller group so we must interpret these changes with caution.

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Our findings are consistent with our previous work showing special vulnerability among nonelderly disabled and depressed Medicare beneficiaries who appeared to experience fewer or only delayed improvements in overall medication access after Part D when compared with the mainstream of beneficiaries.[3,8,21,36] Previous research among beneficiaries diagnosed with depression[11] found that prevalence of antidepressant use increased only among those enrolling in Part D who did not have drug coverage prior to Part D. We did not limit our analyses to persons entering Part D without prior drug coverage because self-selection into Part D (generally by sicker persons)[37,38] would invalidate any conclusions from such an analysis. Our population-wide analyses tend to dilute the effects of policies that affect only a portion of individuals (approximately 25% of beneficiaries gained drug coverage in 2006), but represent a valid and nationally representative longitudinal study, yielding appropriate estimates of actual changes.

There are several limitations in this study that merit mention. Identifying a subgroup of patients with depression is challenging. The MCBS includes linked claims data containing all diagnosis codes received through reimbursed health services, but we did not use these data to identify a depressed cohort, for two reasons. First, other research[39] has shown that depression is under-recorded in claims even when noticed in primary care, due in part to stigma or clinician uncertainty. In addition, the MCBS claims data are only available in the MCBS for beneficiaries in fee-for-service Medicare. In order to avoid selection biases that would result from increased beneficiary enrollment in managed care plans (Medicare Advantage), which cover prescription drugs, at the time of Part D implementation, we could not limit our study population to those in fee-for-services Medicare. By foregoing the linked claims data on the MCBS we could include the Medicare Advantage enrollees. Thus, we relied on the MCBS routine questions asking respondents about possible depressive symptoms rather than diagnosis codes to identify

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beneficiaries with depression. Sample size also presented a possible study limitation. Some subgroups were smaller (e.g., average N for depressed disabled was 554 respondents per year), leading to less stable outcome series. The timing of the interview questions about depressive symptoms (once each year in the fall) only partially corresponded with self-reported drug fills (prescriptions are filled throughout the year, reported in three interview sessions per year, and included in annual datasets without specific dates). Specifically, since the patient is asked to recall depressive symptoms in the prior 12 months when there is still time remaining in the current survey year, they may actually have experienced those symptoms in the prior year. Also, since there is no date associated with experiencing depressive symptoms, it is hard to know whether antidepressant use occurred before or after the report of symptoms. Moreover, symptoms may indicate lack of treatment or unsuccessful treatment, while lack of symptoms may indicate lack of depression or its successful treatment. Furthermore, we could not explain the apparent increase in antidepressant use among the nonelderly disabled between 2003 and 2004. We thoroughly examined rates and trends in the characteristics of this cohort, including geographic distribution and dual Medicaid enrollment, but found no evidence of change. We note that generic fluoxetine first came on the market in 2001,[40] but this did not coincide with the data anomaly. Finally, we lack data on individual Part D plan formularies and utilization management strategies that might shed light on possible problems of antidepressant access for beneficiaries. Previous research suggests that only a minority of plans use prior authorization for antidepressant medications, but the level of restrictiveness of the authorization procedures is not clear.[16]

Our evaluation found that both elderly and nonelderly Medicare beneficiaries experienced no change in the prevalence of antidepressant treatment after Part D. However, among those

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receiving antidepressants, the treatment intensity increased. Even though evidence suggests that prior authorization is not widely used in Part D plans,[16] other utilization management strategies, such as step therapy and quantity limits are both common for the top brand name drugs in Part D plans.[41] One study of employer insurance plans found that step therapy for antidepressant medications was associated with decreases in antidepressant days supplied and medication costs. However these reductions were accompanied by increases in mental health inpatient and emergency room utilization and costs that offset any savings.[42] These findings suggest that limitations on access to antidepressant medications may not result in reductions in overall spending on and use of depression-related health services. We found that although barriers to initial access may exist, once patients overcome those barriers they may be more likely to maintain their treatment after Part D was implemented. We conclude that Part D implementation did not effectively reduce barriers to initiating treatment for depression.

Further research investigating possible changes in utilization of other health services related to depression may also provide insight into shifts in care giving patterns in this population. An evaluation of the impacts of Part D on receipt of guideline concordant care would provide more understanding of our results and the impact of Part D on quality of treatment for patients with depression. Research that includes information about utilization management procedures will be important so that we can fully understand how Part D has changed access to specific medications. This knowledge will guide future policy safeguards meant to protect vulnerable subpopulations from unintended consequences of general policy changes.

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