

# **Exploring Implications of the Nonprescription Drug Safe Use Regulatory Expansion (NSURE) Initiative on Reimbursement and Access**

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**Engelberg Center for Health Care Reform  
The Brookings Institution • Washington, DC  
November 4, 2013**

# Nicotine Replacement Therapy: Case Study of OTC Switch Benefits

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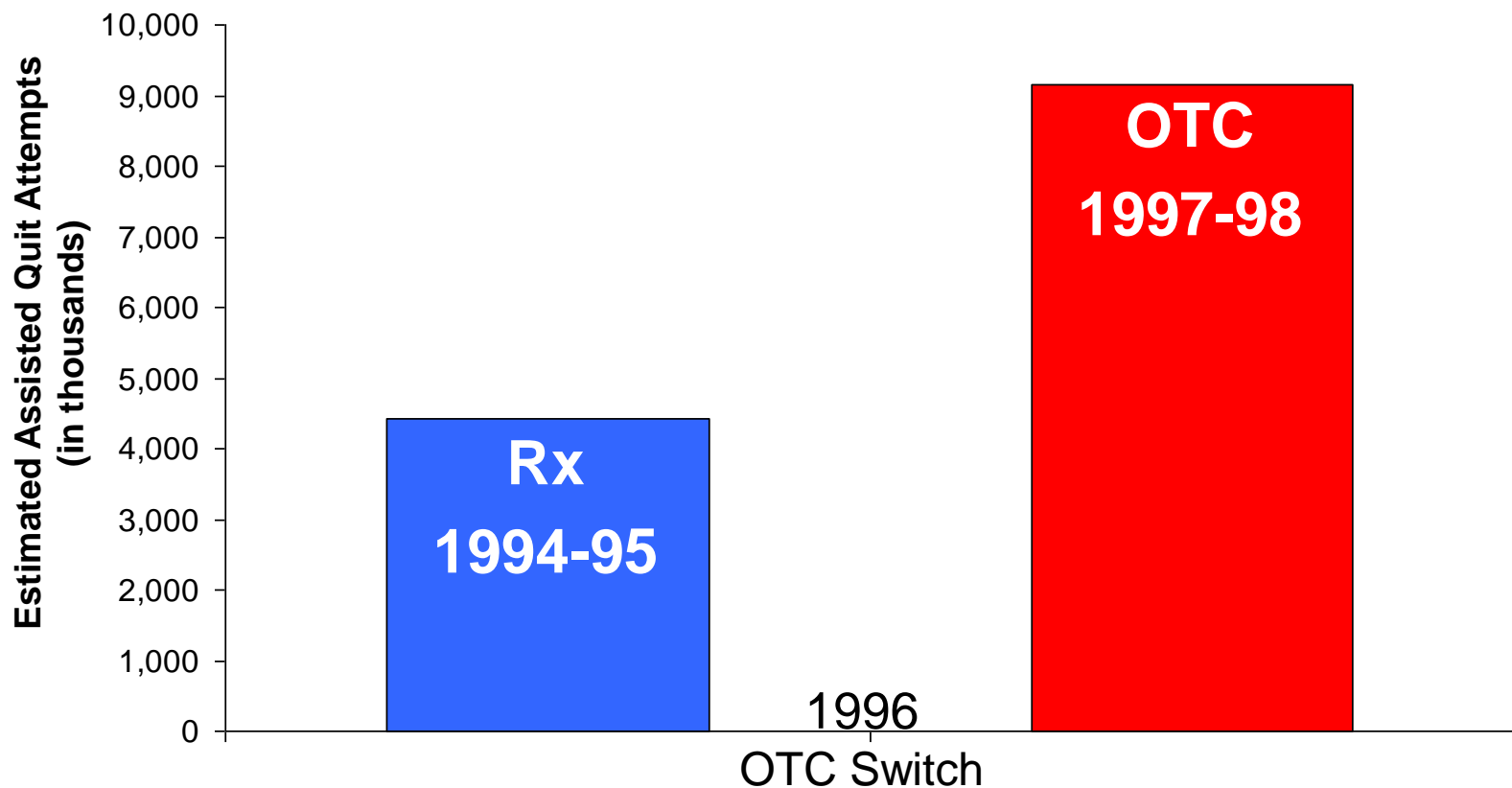
Saul Shiffman, PhD  
University of Pittsburgh  
PinneyAssociates  
Consultant to GlaxoSmithKline

# Background to Switch

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- Smoking kills 50% of continuing smokers; largest preventable cause of death in US
- Nicotine Replacement Therapy doubles quit rates
- When Rx...
  - NRT used in 7% of quit efforts
  - 5% of those prescribed NRT got adequate counseling
- Prescription status was a barrier to care
- BUT...
  - Nicotine is an addictive drug (FDA was asserting jurisdiction)
  - Concern that treatment required behavioral counseling

# OTC Switch Increased Utilization of NRT by 150%



**MMWR**

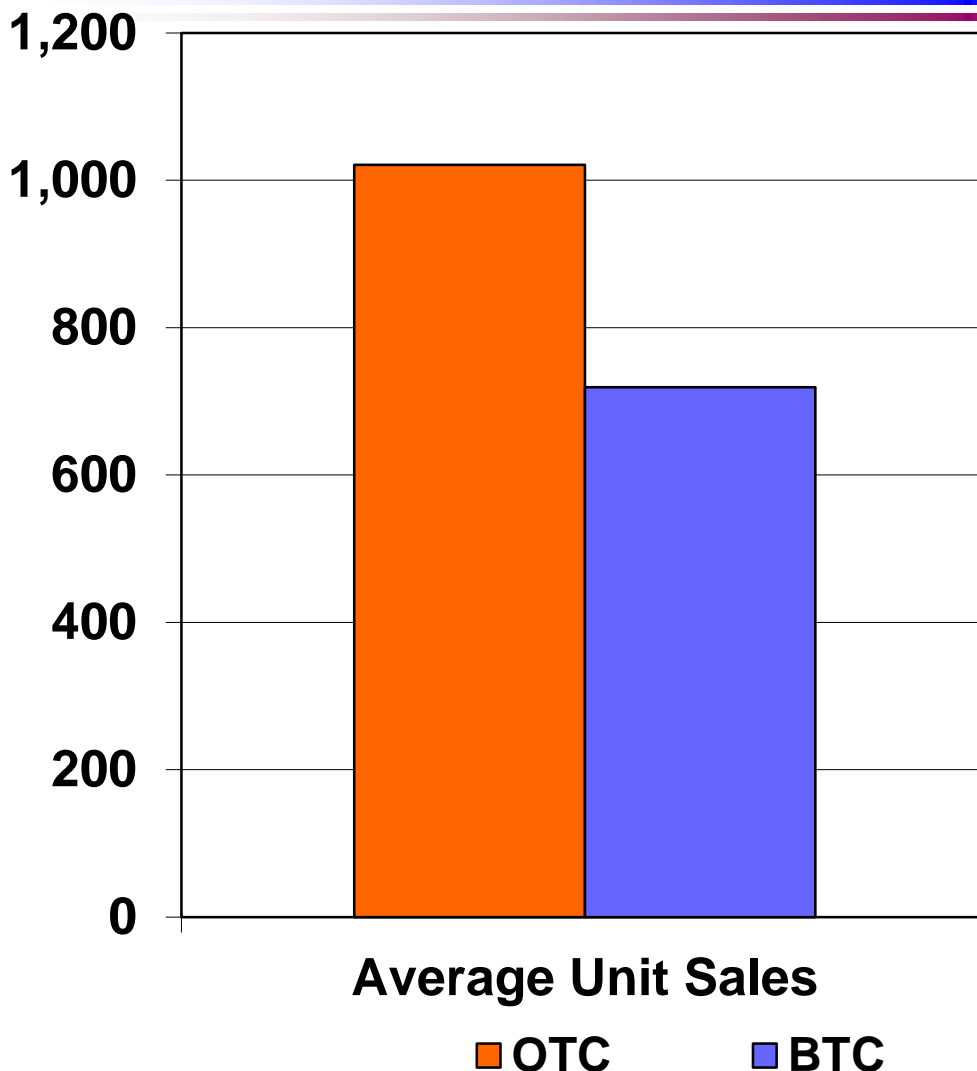
# Impact of OTC Switch of NRT

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- Switch studies showed OTC=Rx efficacy
- ~ 200,000 quitters / yr (Lawrence, Shiffman),  
each gaining 4.4 years of life (Lawrence)
- ~ \$2,000,000,000/year social benefit (very conservative) (Keeler)

# BTC Placement Limits Consumer Access

NRT Experience – Major National U.S. Retailer



- Some retail outlets put NRT BTC to limit theft
- Analyzed consumer purchase of NRT at matched OTC vs BTC retail outlets within a national chain
- Average 30% reduction in utilization when NRT shelved BTC instead of OTC

Source: Major U.S. national retailer, GSK NRT sales, 52 wks. ending July 31, 2007

# Other Concerns Managed via Conditions of Approval

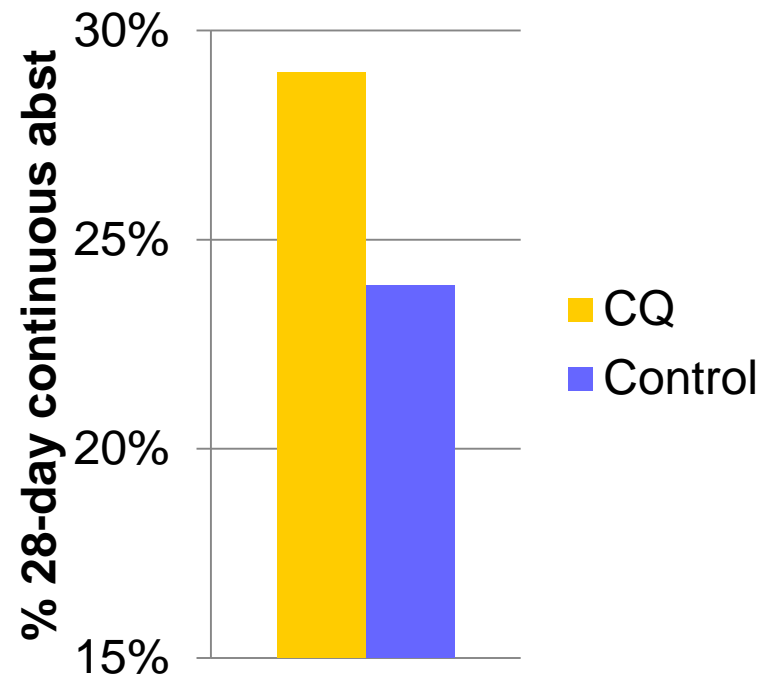
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- FDA & sponsor agreed on conditions of approval
  - Age limit with verification
  - Surveillance
  - Offer of smoking cessation program
- Result
  - No problematic use/abuse by youth (Shiffman)
  - 10,000,000 MD recommendations/yr for OTC NRT (Shiffman)
  - The *Committed Quitters* program

# Supplementing OTC Medication with Behavioral Program: GSK's *Committed Quitters*

- CQ= tailored online program
- In-market RCT
- CQ vs untailored website

## Smoking Cessation Rates (ITT)



Understanding Your Dependency - Microsoft Internet Explorer

You are enrolled under B5PRIN05TEEN (Bruce Springsteen).

Back Continue

Fields marked with \*\*\* must be completed

- \* How soon after you wake up  
☐ Within 5 minutes  
☐ 6-30 minutes  
☐ 31-60 minutes  
☐ More than 60 minutes
- \* Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, in a library)?  
☐ Yes  
☐ No
- \* Which cigarette would you most like to quit?  
☐ The first of the day  
☐ Any other cigarette
- \* How many cigarettes do you smoke per day?  
☐ 10 or fewer  
☐ 11-20  
☐ 21-30  
☐ 31 or more
- \* Do you smoke more frequently than during the rest of the day?  
☐ Yes  
☐ No

What is *NiQuitin* CQ?

Committed Quitters Stop Smoking Plan - Printer Friendly Version

Stop smoking it's worth it!

You are enrolled under BRY701 (bry701.smith701).

Back Continue

In the first few days the craving for cigarettes is still strong. Your body is accustomed to nicotine and needs to adjust. However, you will experience many positive changes—regardless of your age. Giving up smoking is the right decision.

In the first few days: Nervousness, headache, difficulty in sleeping.

After 1 month: The craving for cigarettes become less frequent.

Benefits of Quitting Smoking

Immediately  
The air around you is no longer dangerous to children and other adults.

8 hours after quitting:  
Carbon monoxide level in the blood drops to normal

2 weeks to 3 months after quitting:  
Circulation improves  
Lung function increases by up to 30%

1 to 9 months after quitting:  
Coughing, sinus congestion, fatigue, shortness of breath decrease  
Cilia (tiny hair-like structures in the lungs) regenerate

Strecher, Shiffman & West, 2005



# Summary

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- OTC switches can have large public health benefits
- Conditions of approval can
  - Help manage concerns, promote safe use
  - Limit access, utilization, benefit
  - Enhance benefit

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# Increasing Access to Effective Drugs

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# Some Assumptions

- We have a shortage of Primary Care Physicians
- This shortage can only increase
- Physicians should spend time with Complex Cases
- Any drug safely used for 25 years should be a switch candidate

# Rx to OTC Candidates

- \* Not abuseable
- \* Patient can determine treatment success
- \* No lab work/monitoring required
- \* Sufficient Patient Experience

# Possible Categories

- Antifungals
- Antidiabetics
- Oral Contraceptives
- Cough and Cold
- Asthma/COPD
- Antismoking
- Antihypertension
- Muscle relaxants
- Topical steroids

# The Oral Contraceptives

- Safely used since 1960 (53 years)
- Lower doses today
- Low cost generics
- Likely many sellers
- Enormous savings
- Caution label: age, emboli, smoker

# Contraceptive Market

Total in 2018                      \$23.3 billion

Oral Contraceptives   10.7 million women (17.3%)

Most available as generics



# OCs OTC

Yes – Amer. Coll. Of OB and Gyn

Yes – Many other countries

# Savings in 2001

Nearly \$13 billion

For 2013, nearly \$22 billion

# Go Figure

Morning after pill – OTC  
Oral Contraceptives– Rx

# Thank you

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# Utilization effects of Rx-OTC switches and implications for future switches

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Summary of a paper authored by Stomberg, Philipson, Albaugh, and Sood

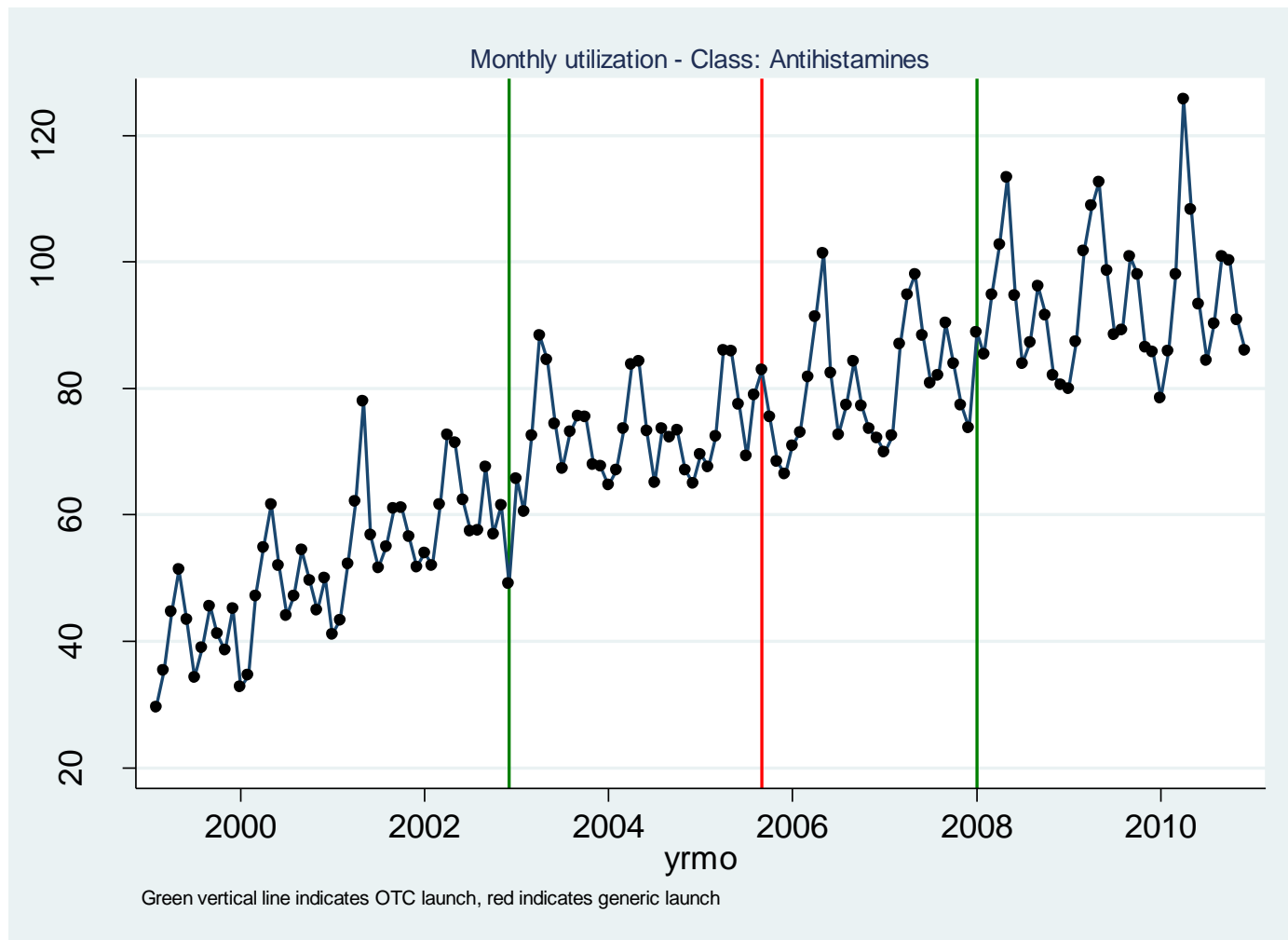
**Presented by**  
**Christopher Stomberg, Ph.D., Partner – Bates White, LLC**  
November 4, 2013

## Overview of paper

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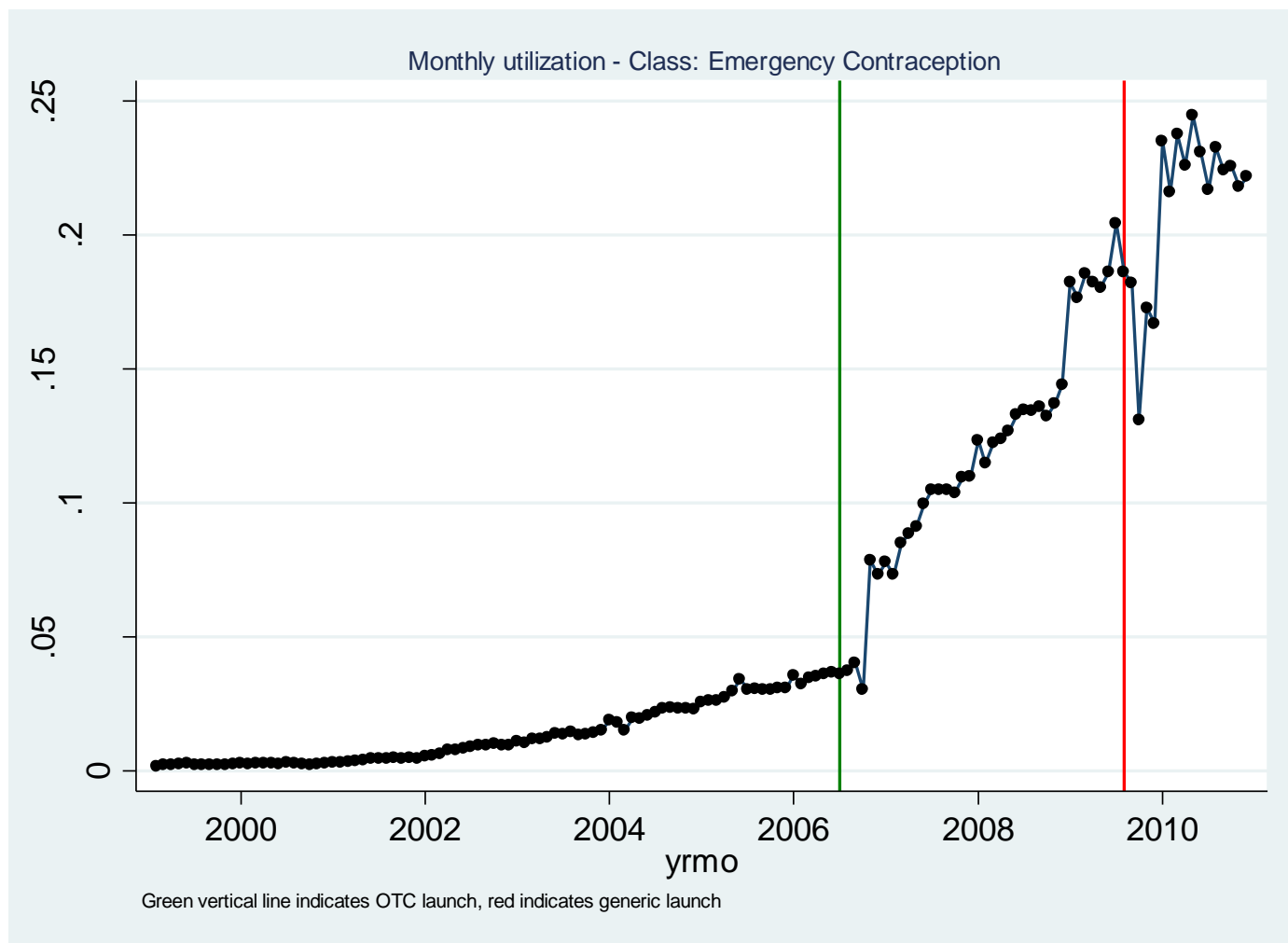
- Review data from 9 drug classes
  - 4 classes and 6 molecules experience switches
  - Remaining classes experience other important events such as generic entry
- Model effects of OTC switch on utilization
  - Class: aggregate effect of switch including within-class substitution
  - Molecule: identify potential role of in-class switching in results
  - Method: interrupted time series, multiple alternative specifications
- Results
  - Average post-switch growth in class between 25% and 42% depending on method of estimation
  - The magnitude of the utilization effect varies significantly across switching classes from less than 10% to over 140%
- Discussion
  - A brief review of classes with a potential to switch suggests significant potential benefits in light of our empirical results
- Download the paper: [online version](#)

# Figure 1: Antihistamine class

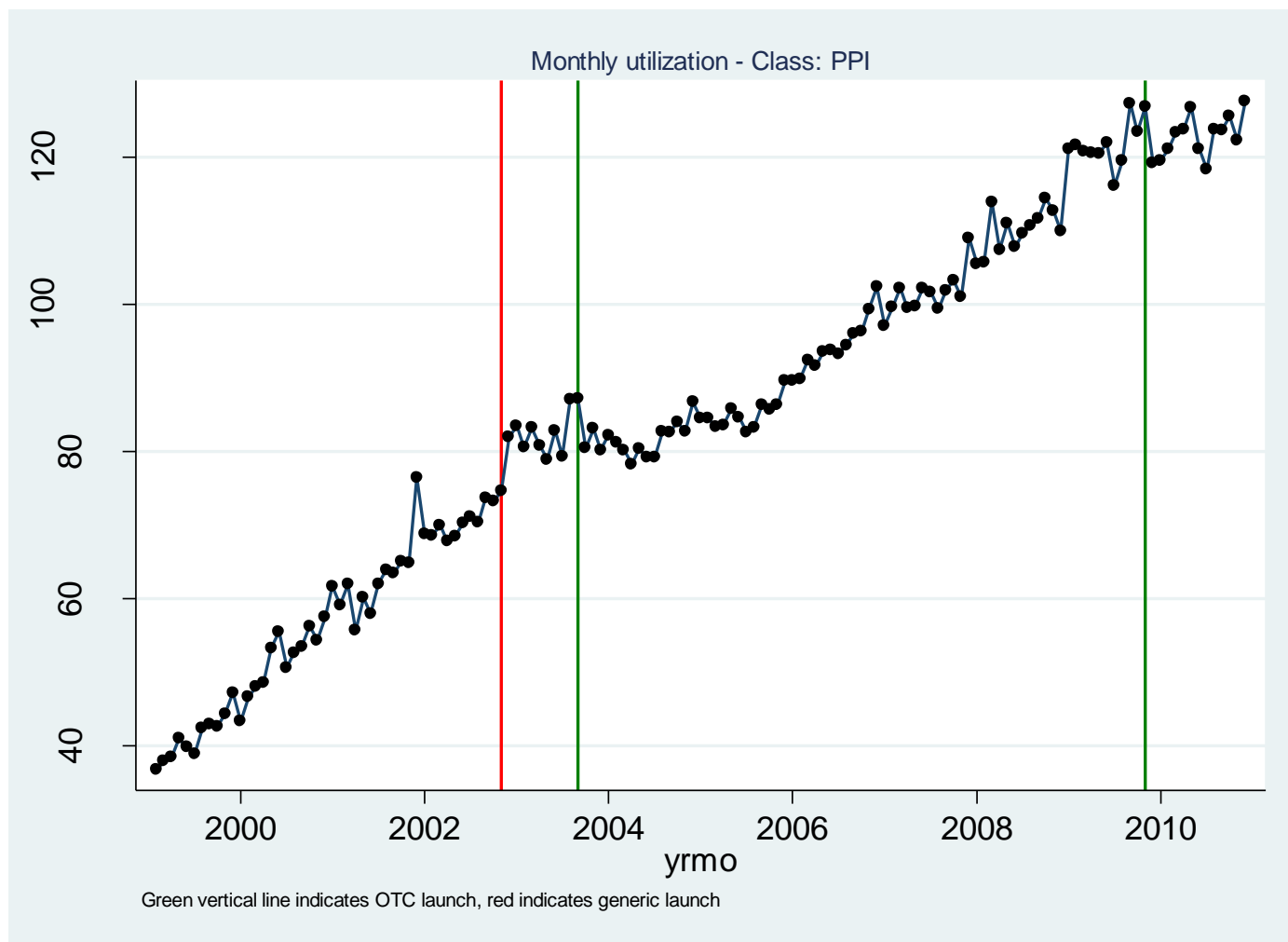




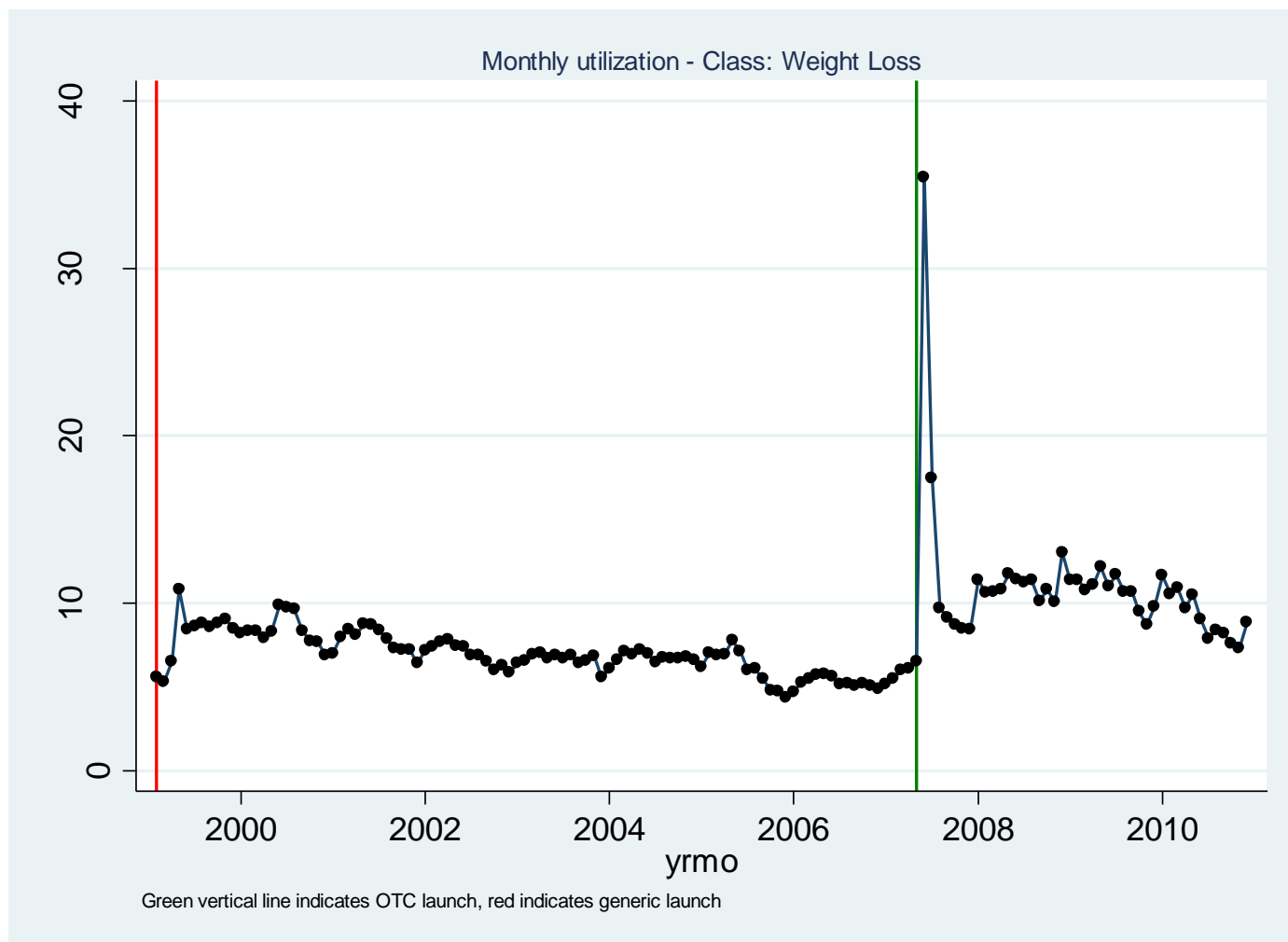
## Figure 2: Emergency contraception class



## Figure 3: Proton pump inhibitor (PPI) class



## Figure 4: Weight loss class



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