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IN WHOM WE TRUST:
THE ROLE OF CERTIFICATION AGENCIES IN ONLINE DRUG MARKETS

Roger Bate
Ginger Zhe Jin
Aparna Mathur

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ABSTRACT

This study assesses the role that certification agencies play in online drug markets, by conducting an audit study on the supply side and a consumer survey on the demand end of the transaction.

In the audit study, we focus on five popular brand-name prescription drugs and acquire drug samples from three types of online pharmacies: tier 1 pharmacies are US-based and certified by the National Association of Boards of Pharmacy (NABP) or LegitScript.com, tier 2 are not certified by NABP or LegitScript but have certification from PharmacyChecker.com or the Canadian International Pharmacy Association (CIPA), tier 3 are not certified by any of the four certification agencies. Most tier 2 and tier 3 websites are foreign. Using Raman spectrometry test, we find no failure of authenticity in tier 1 or tier 2, the only failures are Viagra from non-certified websites in tier 3. Within certified websites, tier 1 websites on average charge 51% more than tier 2 sites in final price for the same drug and dosage except for Viagra. On Viagra, tier 1 and tier 2 websites show no difference in drug safety and price, but if one aims to get authentic Viagra, certified websites are both safer and no more expensive than non-certified websites in tier 3.

These findings confirm the FDA warning against rogue websites but suggest that a blanket warning against any foreign website may deny consumers substantial price savings from certified tier 2 websites. Our online survey shows that, despite the FDA warning, 61.54% of respondents do purchase drugs online and mostly from foreign websites, citing cost saving as the leading reason. Many online shoppers are cautious in their choice of website, by checking with certification agencies, using personal referrals, and sticking to one primary website.

Roger Bate
American Enterprise Institute
1150 Seventeenth Street, NW
Washington DC 20036
rbate@aei.org

Aparna Mathur
American Enterprise Institute
1150 Seventeenth Street, N.W.
Washington, DC 20036
amathur@aei.org

Ginger Zhe Jin
University of Maryland
Department of Economics
3105 Tydings Hall
College Park, MD 20742-7211
and NBER
jin@econ.umd.edu

I. Introduction

Economists have demonstrated that a market will function poorly if buyers have less information about product quality than sellers do (Akerlof 1970 and the follow-up literature). This asymmetric information problem could be addressed in many ways. A government based solution could involve policymakers educating consumers about the presence of poor-quality products, recommending high-quality sellers directly, or even prohibiting some sellers from entering the market. A market based solution could instead involve a third-party certification agency setting up a quality standard, certifying that a seller (or his products) has satisfied the standard, and disseminating such information to final consumers. While many studies have examined regulation and certification separately, it is unclear how a market operates if both public and private sectors attempt to address the information problem but they are not fully consistent with each other. We tackle this question in a special market – the online market for prescription drugs.

Despite its large market size, prescription medication is a latecomer in e-commerce. A review by IMS health shows that, prescription drug sales in the US had grown from \$135 billion in 2001 to \$307 billion in 2010, but prescriptions serviced through mail, the closest proxy to online sale, accounted for only 6.6 percent of sales in 2010.¹ Consistently, a report issued by Forrester Research in 2007 shows that only six percent of prescription drug consumers purchased prescription drugs on the Internet in the past year.² Asking a similar question in 2008, Deloitte Center for Health Solutions finds that 21 percent of prescription drug users reported buying drugs online or through the mail in the previous 12 months and this number increased to 30 percent in 2009.³ The upward trend of online drugs sales is confirmed in our own survey in 2012, which shows that 61.54% of respondents admitted to purchase drugs online, mostly by month or once per year.

¹ IMS Institute, April 2011. “The Use of Medicines in the United States: Review of 2010. Accessed at http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_UseOfMed_report1_.pdf on March 20, 2012.

² Forrester Research report “Who Buys Drugs Online? Most Consumers Still Buy Offline And Ignore Drug Advertisements” by Carlton A. Doty, Carrie Johnson, Jacqueline Lyons and Brendan McGowan, June 12, 2007, http://www.forrester.com/rb/Research/who_buys_drugs_online/q/id/41582/t/2.

³ Deloitte Center for Health Solutions (2009) 2009 Survey of Health Care Consumers: Key Findings, Strategic Implications. Accessed at http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_chs_2009SurveyHealthConsumers_March2009.pdf on March 20, 2012.

From consumers' point of view, the online purchase of prescription drugs presents an intriguing tradeoff between convenience, cost savings and quality concerns. Given the high and rising price of prescription drugs⁴, it is tempting to resort to the Internet. According to GAO (2001), which collected cash-paying price of 17 prescription drugs across various pharmacies, internet pharmacies offer on average 15% discount from retail stores, but these internet prices are 9.7% higher than the discount card programs that are typically run by large pharmacy benefit management (PBM) companies and only available to their members. If we restrict the GAO sample to brand name drugs only, the price of online pharmacies is very similar to that of discount card programs, both approximately 12.5% lower than the average bricks and mortar price.⁵

The above data were for the US only. There are no solid data on the potential savings from foreign online pharmacies, although politicians have claimed that US drug prices are 30 percent higher than in other industrial nations.⁶ The potential larger savings from foreign sources have motivated consumers to cross the US-Canada border for prescription drugs, and more recently, order prescription drugs directly from online pharmacies allegedly based in Canada. By 2003, anecdotal evidence suggested that about one million Americans were purchasing medication online annually.⁷

Arguably, the biggest concern of online purchase is safety. To attract consumers that seek cost savings, privacy and convenience on the Internet, rogue websites peddle fake or real medication without requiring a prescription. Some rogue websites also aim to steal consumer credit card information for identity theft.

Both US governments and private certification agencies attempt to address the safety concern of online pharmacies, but the two approaches are not fully consistent. On the public side, any online pharmacy operating within the US must comply with federal and state regulations, and any personal importation of prescription drugs is technically illegal. However, small

⁴ GAO (2011) shows that retail price of 100 commonly used prescription medications⁴ increased at an average annual rate of 6.6 percent from 2006 to 2010. The annual price rise is particularly high in brand-name drugs (8.3%) as compared to generic drugs (-2.6%). The pain of high price is real and substantial: According to the Commonwealth Fund, 48 million Americans did not fill a prescription due to cost in 2010, up 66% since 2001 (<http://www.commonwealthfund.org/Surveys/2011/Mar/2010-Biennial-Health-Insurance-Survey.aspx>).

⁵ These numbers are computed by the authors based on tables presented in GAO (2001).

⁶ US News & World Report, July 28, 2011, "How to Cut Your Drug Costs" accessed at <http://money.usnews.com/money/blogs/the-best-life/2011/07/28/how-to-cut-your-drug-costs> on February 28, 2012.

⁷ Orlando Sentinel, May 2, 2012. "It's Illegal, but desperate Americans are buying drugs online from Canada" Accessed at: http://articles.orlandosentinel.com/2010-05-02/news/os-drugs-canada-online-20100502_1_doughnut-hole-canadian-online-pharmacy-drugs_on_March_20, 2012.

amounts of importation (no more than 90 day supply for personal use) are rarely enforced. Rather, the Food and Drug Administration (FDA) publicizes anecdotes of unsafe pharmaceuticals on the Internet and warns consumers against rogue websites (which could be domestic or foreign).⁸ FDA also advises consumers to avoid any foreign website and only make online purchase from the US websites certified by the National Association of Boards of Pharmacy (NABP).

Interestingly, NABP is not the only organization that certifies drug-selling websites. As detailed in Section 2, at least three other agencies (all private) compete in the certification service and they differ in certification standard, coverage, business model, and even final certification outcomes. How do websites vary in price and safety by their certification status? Do NABP-certified websites enjoy higher price because they are endorsed by the FDA guidelines? How dangerous are non-NABP-certified websites, even if they are certified by another certification agency? What kinds of consumers buy prescription drugs online? Do they follow the FDA guidance and shy away from foreign websites? Are they aware of certification agencies and use them to determine where to shop?

To shed light on these questions, we collect two distinctive datasets: one is a sample of best-selling brand-name prescription drugs, purchased from various types of websites. After conducting an authenticity test, we correlate drug price and authenticity to drug type and the website's certification status. The second dataset is a survey of 2,522 consumers who purchase prescription medication for either self or family members. Within this sample, we report summary statistics on who buys prescription drugs online plus how and why they choose to do so. Contrary to the FDA advice, 73.58% of our online shoppers admit to purchases from foreign

⁸ In numerous actions, the FDA has confiscated parcels at Customs and discovered various problems with foreign online pharmacies: first, drugs that are claimed to be of Canadian origin could come from 27 different countries ("FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries" December 16, 2005, accessed at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108534.htm> on February 29, 2012). Second, some parcels have counterfeit or substandard drugs which contain no active ingredients, or the wrong active ingredients or incorrect amounts of the active ingredients and could generate serious health problems if consumed by human beings ("The Possible Dangers of Buying Medicines over the Internet", updated January 26, 2011, accessed at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm> on February 29, 2012); third, even if the drugs are authentic, they may not be adequately labeled in English to help assure safe and effective use. Even the belief of cost savings can be misleading: FDA's examination of foreign mail shipments finds that about 45 percent of imported products are already available in the US as an FDA-approved generic drug and about half of these generic drugs can be obtained from national pharmacy chains at the relatively low cost of \$4 each (FDA announcement "FDA Finds Consumers Continue to Buy Potentially Risky Drugs Over the Internet", July 2, 2007, accessed at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108946.htm> on February 29, 2012).

websites only and an overwhelming majority (92.53%) cites cost savings to be one of the reasons for buying from foreign websites. Given these data, we believe the online drug market has grown to be a tremendous source of prescription medications and our paper is the first in economics to understand the supply of and demand for retail drugs on the Internet.

The rest of the paper is organized as follows: Section 2 discusses government regulations and private certification services for online drug sales. Section 3 reviews the literature and testable predictions. Section 4 describes the sample, methodology, and results from our audit sample. Section 5 summarizes the consumer survey. Discussion and conclusion are offered in Section 6.

II. Government Regulation and Private Certification Services

By online pharmacies, we mean website-based entities that sell the same types of pharmaceutical products one historically has only been able to purchase with a doctor's prescription from brick and mortar pharmacies.

To be clear, the safety problem of online pharmacies is not driven by *lack* of regulation. Rather, Clifton (2003) argues that online pharmacies are subject to "an inefficient patchwork of state and federal regulations that are unable to offer uniform and adequate consumer protection." At the local level, state governments have the authority to license and regulate online pharmacies, but laws vary greatly from one state to another regarding online dispensing and prescribing. At the federal level, regulation of online pharmacies could involve the FDA, the Federal Trade Commission, the Department of Justice, the Drug Enforcement Agency, and the Federal Bureau of Investigation.

To overcome differential regulations across states, the National Association of Boards of Pharmacy (NABP), a national organization that represents all the states' boards of pharmacy, initiated the Verified Internet Pharmacy Practice Sites (VIPPS) in 1999. The VIPPS program accredits US-based online pharmacies that comply with laws in both the state of their business operation and the states that they ship medications to. As of February 29, 2012, VIPPS has accredited 30 online pharmacies. Twelve of them are run by large PBM companies and open to members only. The other open-to-all VIPPS-accredited pharmacies include national chain pharmacies (such as cvs.com and walgreens.com) and large online-only pharmacies (such as drugstore.com).

Another certification agency is LegitScript.com, founded by John Horton who was a White House aide on drug policy issues from 2002 to 2007. Like the NABP's VIPPS program, LegitScript only approves US-based websites for online drug sales. As of March 5, 2012, the home page of LegitScript announces that they monitor 228,419 Internet pharmacies among which 40,233 are active. Within active websites, LegitScript finds 221 legitimate (0.5%), 1,082 potentially legitimate (2.7%) and 38,929 not legitimate (96.8%). Their certification criteria includes valid license with local US jurisdictions, valid registration with the US Drug Enforcement Administration (DEA) if dispensing controlled substances, valid contract information, valid domain name registration, requiring valid prescription, only dispensing FDA approved drugs, and protecting user privacy according to the HIPAA Privacy Rule (45 CFR 164). NABP praises the work of LegitScript⁹ and endorses the use of LegitScript by domain name registrars to assist in identifying illegally operating websites.¹⁰

It is unclear why most of NABP-approved websites are approved by LegitScript, but the majority of LegitScript approved websites are not approved by NABP. One possible explanation is that NABP requires interested websites to apply and pay verification fees while LegitScript's approval is free and does not require website application. In May 2012, one of us compared these two lists of approved websites with consumer clicks data recorded by ComScore from September 2008 to September 2011. The comparison shows that most NABP-unapproved-but-LegitScript-approved websites do not receive significant amount of clicks in ComScore's Internet search data. In contrast, many NABP-and-LegitScript-approved websites that are accessible to everyone have retail stores in the US and thus are well covered in ComScore data.

By definition, both NABP and LegitScript.com do not approve non-US pharmacies, on the grounds that importing prescription drugs is technically illegal. However, personal importation is almost always overlooked by the FDA, if the amount is small (no more than 90 days supply for personal use) and the medication is not a controlled substance.¹¹ The FDA also advises consumers to avoid foreign websites and only buy prescription medication from the NABP-approved US websites that require prescription from a licensed health care professional.

This FDA guideline intends to protect American consumers from the risk of unsafe drugs on foreign websites; it also helps define consumer attitudes to foreign websites. If some foreign

⁹ NABP news "NABP Applauds LegitScript and KnujOn for Spotlighting Exploitation of Internet Ad Programs by Rogue Internet Drug Outlets", August 18, 2009, accessed as www.nabp.net on September 19, 2012.

¹⁰ http://www.legitscript.com/download/DNR-letter_10Feb2011.pdf.

¹¹ FDA "Travelers Alert" updated on June 30, 2012, accessed at <http://www.fda.gov/ForIndustry/ImportProgram/ucm173743.htm> on February 29, 2012.

websites sell safe prescription drugs with substantial price discount but American consumers are guided to buy from US websites only, the FDA could potentially discourage price competition between US and foreign pharmacies and therefore reduce drug affordability within the US.

The danger of reducing price competition depends on whether consumers can distinguish trustworthy websites from the vast pool of foreign websites. Like all markets where consumers desire information on unobservable product quality, consumer demand fosters private certification services for foreign pharmacies, even if importation is technically illegal. For example, the Canadian International Pharmacy Association (CIPA), a trade association of Canadian pharmacies, has provided a list of certified Canadian websites that comply with Canadian laws. From American consumers' point of view, one shortcoming of CIPA is that it only certifies websites that are officially registered in Canada.

Another private certification agency, PharmacyChecker.com, casts a wider net over US, Canada, UK, Israel, and other countries. Started in 2003, PharmacyChecker verifies that any approved website has a valid pharmacy license from its local pharmacy board, requires a prescription for US purchase if the FDA requires prescription on the medication, protects consumer information, encrypts financial and personal information, and presents valid mailing address and phone number for contact information. As of March 9, 2012, PharmacyChecker has approved 73 foreign websites and 51 US websites.

Like NABP, PharmacyChecker requires websites to voluntarily apply and pay a certification fee. This probably explains why the number of approved US websites is less in PharmacyChecker than in LegitScript. PharmacyChecker also charges fees for an approved website to be listed on PharmacyChecker.com beyond a short period of initial approval. Consequently, those listed on PharmacyChecker's Pharmacy Ratings page is only a selected list of PharmacyChecker-approved websites. Since PharmacyChecker is unwilling to share their complete list of approvals, we are not able to conduct a full comparison between approvals by PharmacyChecker and those by NABP, LegitScript or CIPA. Of the 37 websites listed on the Pharmacy Ratings page of PharmacyChecker.com¹², we find that only three of them are labeled US in the "country" column, all the others are either listed under one foreign country, or a number of foreign countries plus US. This list is incompletely overlapped with the list of approval from NABP, LegitScript and CIPA. Finally, of the four certification agencies,

¹² Accessed on August 14, 2012 at <http://www.pharmacychecker.com/onlinepharmacyratings.asp>.

PharmacyChecker is the only one that provides head-to-head drug price comparison across online pharmacies.

To summarize, FDA advises consumers to avoid foreign websites and only purchase from NABP-approved websites. However, there are at least four certification agencies that verify the credentials and business practices of online pharmacies, some upon voluntary application (with fees) from online pharmacies. By definition, NABP and LegitScript.com only approve US websites, CIPA only approves Canada-based websites, and PharmacyChecker.com covers websites operating in US, Canada and other countries. By this design, it is not surprising that the lists of verified US websites overlap between NABP and LegitScript, and the lists of verified foreign websites overlap between CIPA and PharmacyChecker. In the audit study, we will group NABP-or-LegitScript-certified websites as tier 1, websites with CIPA-or-PharmacyChecker certification but not NABP-or-LegitScript certification as tier 2, and websites with no certification from any of the four certification agencies as tier 3.

III. Literature Review and Testable Predictions

Third-party certification is a typical solution to the information asymmetry of buyers and sellers regarding product quality. According to Milgrom (1981) and Grossman (1981), if a third-party certifier provides certification services free of charge, firms of every quality level have an incentive to disclose their true product quality because consumers will interpret non-disclosure as the lowest quality. When disclosure cost is positive, the disclosure equilibrium can be categorized by a quality cutoff such that all qualities above the cutoff disclose and all qualities below the cutoff do not disclose (Jovanovic 1982). These theories generate two predictions in our context:

Prediction 1: Drugs sold by certified websites (tier 1 and tier 2) are more likely to be authentic than drugs sold by non-certified websites (tier 3).

Prediction 2: Conditional on the same drug type, certified websites (tier 1 and tier 2) should sell the drug at a higher price than non-certified websites (tier 3).

These predictions are derived under the assumptions that consumers are willing to pay for higher quality, third-party certifier(s) always disclose quality information fully and truthfully, and all consumers know all certification outcomes without cost. These assumptions do not automatically hold in reality. Researchers have shown that a for-profit certifier may have

incentive to disclose minimum information in order to attract more business (Lizzeri 1999), a certifier facing conflict of interest may disclose biased information (Michaely and Womack 1999 on financial analyst, Waguespack and Sorenson 2010 on movie classification), and competition or reputation does not necessarily guarantee full and truthful disclosure of a certifier (Becker and Milbourn 2008, Hubbard 2002).

When consumers are concerned about certifier trustworthiness, they may view government as a certifier of certifiers. As stated above, FDA advises US consumers to avoid any foreign website and only purchase from NABP-certified website inside the US. If the FDA is the main source of information for a typical US consumer, it implies that NABP is more trustworthy than other certifiers, especially those that certify foreign websites. Since both NABP and LegitScript certify US websites only, NABP endorses the use of LegitScript by domain name registrars, and six of the eight tier 1 websites in our data are certified by both, this implies:

Alternative prediction 1: Following FDA advice, tier 1 websites should have better quality and higher price than tier 2 and tier 3 websites.

The classical prediction on a monotone relationship between price and quality can also be violated. For example, if some consumers are unaware of quality certification or have difficulty interpreting the meaning of non-certified products, fly-by-night sellers could take advantage of uninformed or misinformed consumers by pretending to be high quality. To the extent that some gullible consumers associate higher price with better quality, non-verified sellers could even charge higher price than verified sellers and flee after the transaction. In the online drug market, although multiple agencies provide certification services, not all certifiers provide a complete list of their approved websites on the Internet – some require extra fees to list an approved website explicitly on the main page of the certification agency. Moreover, approval across different certifiers overlaps incompletely, and only one of the four certifiers – PharmacyChecker – provides a head-to-head price comparison across approved online pharmacies. These information frictions may frustrate consumer search and allow high-price-low-quality to survive in some parts of the market.

Even if all consumers are rational and search cost is minimal, US and foreign websites may sell the same drug at different prices for reasons unrelated to drug quality. To our best knowledge, US government does not regulate the listing price of brand name drugs in retail pharmacies, although Medicaid program limits Medicaid reimbursement price relative to market price (Duggan and Scott Morton 2006), and some states mandate generic substitution if a generic

is available. In comparison, Canada, European countries and many developing countries, cap prices for prescription drugs and the price cap is often lower than those charged in the freer US market.

Not only does price regulation affect retail price directly, different price regulations (and local demand) also motivate a brand-name drug manufacturer to charge different wholesale prices for websites in different countries. Apparently, manufacturer's ability to price discriminate depends on the ease of arbitrage across countries. While criminalizing prescription drug importation is one way to protect drug safety in the US, it also adds difficulty to arbitrage retail price difference across countries. This could yield two potential outcomes: first, significant price difference persists between US and non-US countries; second, only those consumers who are more price sensitive and incur less (psychological) cost in illegal importation choose to buy from foreign websites.¹³

Price discrimination may occur within a country as well. In our sample, all but one drug (Viagra) are covered under insurance plans. Therefore, the actual cost of the drug to the buyer would vary across buyers depending upon their insurance status. Whether lack of drug insurance is the leading reason for online drug purchase is an important question to be examined in our consumer survey.

The above discussion can be summarized into:

Alternative prediction 2: Conditional on the same drug type, US websites (mostly tier 1) may charge higher price than foreign websites (mostly tier 2 and tier 3) due to differences in price regulation, local demand, and wholesale cost, but such a price differential is not necessarily driven by drug quality.

While no academic study has evaluated price and quality by the certification status of online pharmacies, our study builds on a small literature of drug safety. For example, public health researchers, as well as the World Health Organization (WHO), have examined the extent of counterfeit and substandard drugs, mostly in less developed countries, on drugs targeting infectious diseases such as malaria, and focusing on drug safety only (WHO 2011, USP and USAID 2009, Bate et al. 2009, Bate et al. 2008). Bate and Hess (2010) tabulate drug safety and

¹³ One may argue that foreign websites could specify different prices for US and local customers; hence their US price need not be subject to local demand or local regulations. Unfortunately, we do not have any first-hand experience on this, but some websites do post price online for all potential consumers around the world and this could limit their ability to price discriminate against US customers.

price data based on a fraction of the sample used in this paper, but their sample is too small to warrant rigorous statistical tests of price by types of websites. In another study conducted by us (Bate, Jin and Mathur 2011), we demonstrate that the probability of counterfeit and substandard drugs varies by drug safety regulations in the country of purchase but neither retail price nor the subjective assessment of the quality of the pharmacy store constitutes a clear signal of actual drug quality. That study focuses on bricks and mortar pharmacies only in 17 mid-income and developing countries.

In other industries, several empirical studies have examined how price and quality vary by certification status (e.g. Wimmer and Chezum 2003 on horses, Dewan and Hsu 2004 on collectible stamps, Jin and Kato 2007 on online sales of baseball cards), some even look at the inconsistency between different certifiers (e.g. Canter and Packer 1997 on bond ratings). To our best knowledge, none of these studies include governmental endorsement on a particular certification agency or address a conflict between government advice and market information. The special setting of online pharmacies allows us to extend the general literature on quality certification in this regard.

IV. Audit Study

Our audit study consists of three steps: we first purchased five best-selling prescription drugs from three types of online pharmacies, and then compared the purchased sample to the authentic version of the drug via a Raman spectrometry test. After that, we analyze test result and price across pharmacy type.

IV.1 Data and Methodology

To identify drugs that American consumers are most likely to purchase on the Internet, we consulted several sources including lists of the most-popular online drug searches from licit website pharmacies and IMS's list of the top 10 products "most often prescribed" in the United States in 2007.¹⁴ The five drugs selected for purchase were (in order of selection priority):

- Lipitor® 10mg (atorvastatin calcium) a synthetic lipid-lowering agent to reduce cholesterol, manufactured by Pfizer;

¹⁴ The Wall Street Journal Online/Harris Interactive Health-Care Poll (2004) Six Million People Have Bought Prescription Drugs Online; Most Are satisfied. The Wall Street Journal Online 3(6).

- Viagra® 100mg (sildenafil citrate) an oral therapy for erectile dysfunction, manufactured by Pfizer;
- Celebrex® 200mg (celecoxib) a nonsteroidal anti-inflammatory drug for treatment of arthritis, manufactured by Pfizer;
- Nexium® 40mg (esomeprazole magnesium) a proton pump inhibitor for treatment of Gastroesophageal Reflux Disease, manufactured by AstraZeneca Pharmaceuticals LP; and
- Zoloft® 100mg (sertraline HCl) a selective serotonin reuptake inhibitor for treatment of depression, manufactured by Pfizer.

The dosages chosen were the most popular among identified websites and after consultation with Joseph Moody, MD, the physician advising this study. With the approval of his state health board, Dr. Moody provided prescriptions for the drugs. During the procurement process, we always instructed website pharmacies to provide brand-name drugs, and did not procure from websites where only generic versions were available. Once the most popular dosages were identified, reference standards were established for the chosen handheld Raman spectrometer. The spectrometer created a detailed spectral “fingerprint” for each reference standard, which was then compared against spectral readings from drugs procured over the Internet.

To create the reference standards, genuine samples provided via prescription by a national pharmacy chain (West Lafayette, Indiana, US) were analyzed using the Raman spectrometer and cross-checked against a second lot from a separate national pharmacy chain store to verify consistency and determine method robustness. In cases where slight lot-to-lot variation was present (as in the case for Lipitor coating thickness), a reference spectrum from both lots was included in the Raman spectroscopic method. In all cases, the two lots of drugs matched well and it was deemed that they were representative samples of authentic products.

Drugs were ordered in two rounds, first in January and February 2009, and then in November 2011. We identified online pharmacies using Google and Yahoo! search criteria and the list of approved and not recommended websites provided by certification agencies, as well as examination of spam emails sent to the authors and those caught in the spam filters of their organizations. While every reasonable effort was made to procure drugs from each website, this was not always possible. The lead author attempted to procure drugs from websites experiencing problems three times before moving on to the next website.

In total, we made 372 drug orders from 79 websites, of which 8 are US-based and verified by NABP and/or LegitScript (tier 1), 22 are not approved by NABP and LegitScript, but verified by either PharmacyChecker or CIPA (tier 2), and the remaining 49 are not certified by any of the four agencies (tier 3). Six of the eight tier-1 websites are certified by NABP and LegitScript, covering both large retail chains and online-only drug stores. The only two that are certified by LegitScript but not by NABP are both national retail chains in the US. Given the similarity of NABP and LegitScript certification, we group NABP- or LegitScript-certified websites as tier 1.

For Tier 3, clearly, the 49 websites we sampled are not likely to be representative of the thousands of illegal websites that allegedly exist. The sites from which drugs were procured were identified using key words of drug names and since there was not a list available to randomly select from, we simply procured in the order that we came across web entities until the project budget was used up. In other words this was biased towards the most popular sites, or perhaps those sites that paid most for their sites to be viewed in search engines. We have no evidence that this would bias the subject in regards to quality.

Tier 2 faces a similar problem. Since both PharmacyChecker and CIPA provide a “selected” list of their members on the website, it is difficult to make random draws from the whole population of tier 2 websites. Rather, we randomly choose a sub-sample from the list posted on PharmacyChecker.com, and for the websites that we encounter in the process of selecting tier-3 websites, we check their certification status with PharmacyChecker and CIPA.¹⁵ If they turn out to be certified by either (and not certified by NABP or LegitScript) at time of purchase, they are labeled tier 2. Four tier 2 websites were certified by PharmacyChecker at the time of purchase, but cancelled their PharmacyChecker membership recently.¹⁶ We still count them as tier 2. Within our 22 tier 2 websites, 12 are certified by both PharmacyChecker and CIPA, 10 are certified by PharmacyChecker only, and 0 are certified by CIPA only.

Most websites in tiers 2 and 3 are straightforwardly foreign. The only exceptions are two tier 2 websites and one tier 3 website, who leave a US mail address in their “contact us” web

¹⁵ Checking with CIPA involves entering the website name in the name-check box on cipa.com. PharmacyChecker does not offer such an interactive checking process on its own website, so checking with PharmacyChecker involves email exchange with Gabriel Levitt, the Vice President of PharmacyChecker.

¹⁶ In February 2010, Google has stopped using PharmacyChecker as the certification agency for online pharmacies listed in Google search results and switched to contract with LegitScript in April 2010. In August 2011, Google and the US Department of Justice settled for the investigation of Google advertising for illegal pharmacies, with Google paying 500 million for the settlement.

page. However, the country of operation as claimed on the web page is not necessarily consistent with the country of drug manufacturing, repackaging or delivery. Such inconsistency is prevalent in some tier 2 and many tier 3 websites. Even one tier 1 website, which is also a well-known retail chain with outlets in both US and Canada, delivered us drugs that appear to be manufactured or repackaged in non-US countries. For this reason, most of our empirical analysis focuses on the tier distinction by certification status rather than differences in the country of website operation, drug manufacturing, drug packaging, and mail delivery. At the end of this section, we examine whether the country of drug source as shown on the delivered drug package helps to explain price variations in our sample¹⁷.

Conditional on being able to make an order online, some orders did not lead to a successful delivery of the ordered drug. In round 1, two tier 1 pharmacies returned prescriptions; three tier 3 websites would not accept payment; in round 2, one tier 3 website refused payment. In total, we were able to pay for 372 orders, 365 of which were successfully delivered and 331 can be linked to a website identity. The remaining 34 drugs were shipped in a discreet package that did not provide enough information for us to identify the sending website. Thirty-two of the 34 discreet deliveries are Viagra, the other two are Zoloft. Although we cannot pin down the exact delivering website, we are sure that these discreet deliveries (and all of the 7 undelivered orders) are all from tier 3 websites because all the tier 1 and tier 2 orders are accounted for. If we assume that every website delivers all orders in one package (in order to save shipping cost), after all this was the case in all identifiable website deliveries, we can identify 2 of the 38 unaccounted tier-3 websites as no-delivery at all. The remaining 36 unaccounted tier-3 websites deliver either nothing or discreet package(s). The 331 delivered drug samples with clear website identity are linked to 41 websites, of which 8 are tier 1, 22 are tier 2 and 11 are tier 3.

We attempt to assess all delivered drug samples, using Raman spectrometry.¹⁸ Numerous studies have demonstrated that Raman spectrometry is a quick, reliable and cost-effective way for non-specialists to differentiate between genuine and counterfeit drugs (de Veij et al. 2007; Witkowski 2005; Gryniiewicz et al. 2007; Bugay and Brush 2010). To ascertain the nature, and not just the spectra, of all compounds in a given drug, including impurities and degradation products as well as active ingredients, high-performance liquid chromatography (HPLC),

17 The internal AEI ethical review conducted for the early part of this project in 2009 concluded that no websites would be named.

18 The lead author did the testing after being trained by a spectroscopist from the company that owns the spectrometer platform. In addition to the company's assistance, all testing was completed in the observation of a professional outside our research team.

considered the current gold standard analytical method in drug analysis, would be required¹⁹. HPLC requires sophisticated sample preparation that is expensive and time consuming and requires trained chemists for analysis and interpretation of results. Given that the aim of this study was to authenticate a finished product (rather than its individual components), comparison with a known HPLC standard was unnecessary.

We used a handheld Raman spectrometer, the TruScan by Thermofisher (formerly Ahura Scientific of Wilmington, MA), on loan for the duration of the study. One necessity, and potential limitation, of spectrometers is that they require exact reference standards, obtained by scanning each separate brand with the same formulation for calibration. This means that a drug substituted for the branded version would record likely as a failure (since the excipients – colors and binding agents -could be different, yielding different spectra, between two equally effective drugs). For this reason, generic substitutes were not sought from websites for this study. While a pass identifies a good quality drug, a “failure” does not mean that a given drug is necessarily of low quality. The spectrometer recorded a “failure” if a sampled drug was spectroscopically inconsistent with the reference standard; under this metric, both FDA-approved bioequivalent generics of the chosen drugs and different types of formulations that innovator companies (Pfizer and Astra Zeneca) produce for different markets may fail the test. Such versions must contain the same quantities of active ingredient but they often contain different excipients in different concentrations. The spectrum created by the spectrometer is for the total sample formulation, not only the active ingredient.

For this reason, a limited number of the drug samples were not testable. For example, although innovator products were ordered, some innovator formulations, sold outside of US were different from those sold in US. Additionally some generics were substituted for innovator products. If the package states “generic” explicitly or is clearly in a form that is different from our authentic reference (say capsule versus tablet), we label them as non-testable. Whenever we are not sure, we put the drug up for test. In total, we test 328 of the 365 delivered samples.

Prices were calculated as “stand-alone” orders; that is, shipping expenses were not amortized across the entire five-drug order. Prices of tier 1 online pharmacies were compared with five bricks and mortar US-based pharmacies but there was no significant difference in price – not surprising since some of these pharmacies have bricks and mortar operations. For the 34

¹⁹ Indeed, for a truly thorough analysis myriad techniques including dissolution analysis, and tandem mass spectrometry, would be required to monitor all types of problems.

discreet deliveries, the delivering package often spelled out price and drug type, but not the exact identity of the website. Although price and other information make it possible to infer many website names, we cannot be 100% sure. To be conservative, we leave them as discreet in the raw data.

All prices are presented as price per pill including shipping and handling. Prices from the first round are kept nominal, while prices from the second round are deflated to February 2009 according to the Consumer Price Index for all urban consumers published by the US Department of Labor.²⁰

IV.2 Data Summary

Table 1 summarizes pharmacy characteristics (as of February 2012) by tier for the 41 websites from which we have received at least one drug sample. Not surprisingly, all tier 1 websites – by definition US-based and verified by either NABP or LegitScript – remain valid in February 2012, all requiring and checking prescription, all denying discreet shipping, with an average \$0.625 shipping cost per standard package (most with free shipping) and 10.625 days in shipping time. About half of them require an online questionnaire. Half of tier 1 pharmacies are national chains in the US with bricks and mortar retail stores throughout the country, one of them even has retail stores in Canada.

In contrast, 8 of the 11 tier 3 websites – by definition non-verified and mostly foreign – do not exist as of February 2012, and two of the three remaining ones require an online questionnaire. Two of the remaining tier 3 websites offer “discreet shipping” (although we were able to identify the source of these sites sending drugs), and one of them does not require prescription. While the count of tier 3 websites (with identifiable delivery) is very small, it confirms the casual impression that many non-verified foreign websites are likely fly-by-night sellers, trying to lure customers by privacy and often without requiring a prescription. The same impression is further confirmed by the facts that 7 of our tier-3 orders were not delivered and many (up to 38) of our tier-3 websites delivered products in a discreet package with no clear information for their website identity.

Tier 2 websites are somewhere in between. Two of the 22 tier 2 websites were no longer existing in February 2012. Among the remaining 20 websites, 75% of them require an online

²⁰ Historical CPI table for all urban consumers as of February 17, 2012 accessed at <ftp://ftp.bls.gov/pub/special.requests/cpi/cpiiai.txt> on March 13, 2012.

questionnaire and only two (10%) offer discreet shipping. Eighteen (or 90%) of them have clear prescription requirement (and check methods) on the web page, the other two (both US-based) offer internet prescribing of specific medications using an online (and free) diagnostic consultation and claim this practice is licensed by the local licensing authority.²¹ On average, tier 2 and tier 3 websites charge higher shipping cost than tier 1, not surprising given that most of them ship from foreign countries.

Table 2 lists the number of samples obtained by drug type and pharmacy tier. Conditional on delivery, we have 105 samples for Viagra and between 62 and 71 samples for each other drug. Viagra is a lifestyle drug and is offered in more tier 3 websites, which is consistent with the fact that tier 3 websites are more likely to offer discreet shipping without prescription. Of the total 365 drug samples, 216 are from round 1 and 149 are from round 2.

As shown in the bottom of Table 2, all of the Celebrex and Lipitor samples were testable, but 12 Nexium samples (some Nexium sold outside US is in tablet form whereas it is capsule form in US), 11 Viagra (all generic substitutes) and 14 Zoloft (6 were generic substitutes, 8 were Zoloft in different formulations) were not testable. Conditional on being testable, Celebrex, Lipitor, Nexium and Zoloft all had a 100 percent success rate: there were no detectable failures, and the spectrometry test revealed the spectra to be identical to that of the reference drugs. In the case of Viagra, 8 out of a total of 94 testable samples were recorded as failures.

Dividing up the results by tier, we see that tier 1 websites are most likely to deliver testable samples (97.44%), followed by tier 2 (90.77%) and tier 3 (81.52%). All the 8 failures for Viagra came essentially from tier 3 pharmacies but only one of these failures can be linked to a particular website because the other seven are all discreet delivery with no website information on the mail package. Within the eight failures for Viagra, all of them have China as the source of drug packaging but it is not always clear where the drug was manufactured and where it was shipped from. In one case, the drug was undoubtedly mailed from China (the bank account for this rogue site was in Panama); in another two samples the postal marks were from Austria and India. This is consistent with the FDA finding that orders on online foreign pharmacies could come from many countries even if they appear Canada-based.²²

²¹ When we purchased from tier 2 websites, every one of them required prescription.

²²“FDA Operation Reveals Many Drugs Promoted as ‘Canadian’ Products Really Originate From Other Countries” accessed at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108534.htm> on February 29, 2012.

Above all, failure of delivery and failure of authenticity test from some tier 3 websites support quality differential between certified and non-certified websites as stated in *Prediction 1*. However, the 100% pass rate for both tier 1 and tier 2 websites does not support the perceived better quality of tier 1 as implied by the FDA advice in *Alternative Prediction 1*.

Table 3 summarizes price distribution by drug type, pharmacy tier and drug authenticity conditional on testable samples. Celebrex, Lipitor and Zolofit are similar in several aspects: (1) on average, tier 1 is the most expensive, tier 2 is in the middle, and tier 3 is the cheapest, although some of the mean price differences are not statistically significant due to small samples; (2) even the minimum price from tier 1 is higher than the average price of tier 2 and tier 3; (3) there are wide price variations within the same tier, especially for tier 2 and tier 3. The price pattern of Nexium is similar to Celebrex, Lipitor and Zolofit except that its average price in tier 3 is slightly higher than tier 2.

It is worth noting that Lipitor started to face generic competition on November 30, 2011, which is right after our second round purchase. While Pfizer has engaged in aggressive pricing after November 2011²³, the price slash does not appear in our data. In fact, the average price of our Lipitor purchases is slight higher in the second round (\$2.139 per pill) than the first round (\$2.017) in real terms.

The pricing pattern of Viagra is different from the other four drugs. Unlike the other drugs, tier 2 Viagra is slightly more expensive than tier 1 on average (\$17.025 vs. \$16.465) and the average price of tier 3 Viagra is much higher than the other two tiers if the sample is authentic (\$19.166) but much cheaper than the other two tiers if the sample is not authentic (\$12.773). While these numbers are based on very small samples, they could be explained by Viagra's reputation as a lifestyle drug (Keith 2000, Catalano 2008). Potential users of Viagra may place value on privacy, non-prescription requirement, and discreet shipping, all of which are more prevalent among tier 3 websites. For privacy reasons, Viagra users may rely more on private internet search and have less reliable information on drug price and quality across various websites. There is also an active black market for Viagra (without prescription), which could motivate middlemen to arbitrage more on price across websites in different tiers.

IV.3 Regression results on testability and price

²³See more on Pfizer's pricing strategy at a 12/1/2012 Times article "Lipitor Already Cheaper after Patent Expiration" by Josh Sanburn accessed at <http://moneyland.time.com/2011/12/01/lipitor-patient-expiration-wont-mean-cheaper-generics-yet/> accessed on March 14, 2012.

The above summary statistics are based on detailed and sometimes very small sub-samples by drug type and pharmacy tier. To ensure statistical rigor, we regress the key outcomes (sample test-ability and price) on the dummies of tier 1 and tier 3 (tier 2 is the default), after controlling for a full set of drug type fixed effects (α_d) and a dummy of purchase round one. In particular, the specification is:

$$Y = \alpha_d + \beta_1 \cdot 1_{tier1} + \beta_2 \cdot 1_{tier3} + \gamma \cdot 1_{round1} + \varepsilon.$$

When Y is the dummy of whether a drug sample is testable, we run the specification by probit. We cannot run a probit estimation of whether a drug sample is authentic conditional on being testable because all the non-authentic drugs are Viagra. For price, we define Y as log of price (because of its skewed distribution) and run the specification by linear OLS. In probit and OLS, we cluster errors by drug type and allow them to be robust.²⁴

Table 4 reports regression results for the full sample, the sample of all drugs except Viagra, and the sample of Viagra only. Within three samples, we also report a price regression conditional on authentic drug samples only. Overall, regression results confirm the summary statistics presented above: except for Viagra, tier 1 websites are more likely to deliver testable drugs and conditional on being testable, drugs from tier 1 websites are more expensive than both tier 2 and tier 3 drugs.²⁵ Compared to tier 2, the average price hike of tier 1 is 39.6% higher in the full sample and 51% higher if we exclude Viagra. Surprisingly, drugs from tier 2 are priced similarly to tier 3, which is against the expectation of higher price for certified sellers (Prediction 2).

Because authenticity test does not fail except for Viagra, the comparison of full and authentic-only samples is most meaningful when we focus on Viagra only: the full testable sample shows no price difference across all three tiers, but conditional on authentic samples, prices from certified websites (both tier 1 and tier 2) are 10.64% lower than tier 3 on average. This number is insignificant from zero due to small sample. This suggests that it is *safer and no more expensive* to buy Viagra from certified websites if one has a prescription.

Above all, regressions suggest that purchasing from certified tier 2 websites could lead to substantial savings from certified US websites (tier 1) without compromising drug safety. In

²⁴ Robust and clustered errors are not possible in the sample of Viagra only.

²⁵ Column 1 of Table 4 includes 295 observations rather than 365 since it drops certain observations that perfectly predict the outcome variable.

fact, tier 2 websites demonstrate large price dispersion, if consumers are willing to search within certified tier 2 websites, the price savings can be even higher than what has been shown on average (51%). For Viagra, there is no statistical difference between tier 1 and tier 2 websites, both are safer and no more expensive than non-verified tier 3 websites.

The tier 1 versus tier 2 comparison is intriguing. Since the FDA endorses NABP certification and NABP endorses LegitScript, one may expect tier 1 drugs to enjoy higher price and higher quality than tier 2 (*Alternative Prediction 1*). The price difference is indeed substantial for non-Viagra drugs, but it cannot be explained by the uniform pass rate of all tier 1 and tier 2 testable samples. In an unreported table, we rerun the price regression for all deliveries and include a dummy of being testable on the right hand side. The coefficient of that dummy is positive and not different from zero. This suggests that the substantial price difference between tier 1 and tier 2 samples is not driven by their difference in testability, either.

One potential alternative explanation for the price difference is that most tier 2 websites have their drugs sourced from non-US countries and these countries have better price due to more consumer friendly price regulation, more price sensitive demand in their own domestic market, or more competition in price. We cannot distinguish these specific explanations, but we can correlate drug source with price. By drug source, we mean the country source of drug manufacturing or packaging as indicated on the delivered drug package. If the drug labels manufacturing and packaging countries differently, we define drug source as manufacturing country. To be consistent with above analysis, we will focus on testable drug samples only.

Table 5 displays count of testable samples by drug source and pharmacy tier. Of the total 328 testable samples, 68 are sourced from US, 116 from Canada, 90 from Europe (Italy/ Turkey/ UK/ Germany), and 37 from Asia and Pan-pacific regions (China/ India/ Israel/ Australia). Probably because of discreet shipping, 17 drug samples do not provide clear label of drug source. Across tiers, all but eight tier 1 samples are from US and all the ones with missing drug source are from tier 3.

Conditional on testable samples, we add drug source dummies (Europe, Asia/Pacific, Canada, missing) to the OLS regression of log price. We omit US and missing drug source because all US sourced drugs are in tier 1 and all drugs with missing source are in tier 3.²⁶ To

²⁶ Recall that not all tier 1 websites have drug source from US, this allows us to identify tier dummies separately from drug source dummies.

account for the fact that four of our tier 1 pharmacies have retail outlets and may price differently because of this, we also include a dummy of having retail stores in the regression.

Table 6 reports the regression results for all testable drugs, all testable and authentic drugs, all testable (and authentic) drugs without Viagra, and authentic Viagra only. To our surprise, on top of the significant effect of tier 1 on price, there are no price differences across Asia/pacific, Europe and Canada as compared to the default of US/missing. This is partly driven by Viagra: when we exclude Viagra, Europe is the only drug source category that correlates with significantly lower price. For Viagra only, the R-square of the price regression drops dramatically (to 10%), and no drug source categories indicate higher or lower price once we condition on authentic Viagra. This supports our conjecture that there is relatively complete price arbitrage on Viagra due to its popularity as a lifestyle drug. We also try the sample regression including both authentic and non-authentic Viagra: it does return several significant coefficients, but they are all driven by the 8 non-authentic Viagra samples of which one is from China and the other have missing drug source. We believe this result is not reliable thus do not report it in Table 6.

In short, data suggest that price variations in our sample are not driven by country of drug source. The only exception is relatively lower price from Europe for non-Viagra drugs. This is somewhat surprising, but likely driven by the small size of our sample. In particular, countries with potentially lower manufacturing cost – for example China and India – have very few observations in our sample and therefore we cannot distinguish them from other Asia/pacific countries statistically.

V. Summary of Consumer Survey

The above audit study raises a number of questions about online consumers: To what extent do consumers shop online? How many of them shop on foreign websites despite the FDA warning? What kind of people shop online? Is online purchase primarily driven by lack of drug insurance? To what extent do online shoppers realize the price and quality difference between US and foreign websites? Do certification agencies play any role in their search for drug websites?

To shed light on these questions, we administered an online survey in September 2012 with the help of RxRights, a coalition concerned about the price of US pharmaceuticals. RxRights sends out a newsletter to individuals who have signed up to receive information. We surveyed this list, survey emails were sent to approximately 20,000 recipients, of which 2907

(14.5%) responded. This response rate is higher than most online surveys, which are often in the 3 to 5 per cent range. This high response rate may demonstrate considerable interest in the topic from respondents.

Our first survey question is “Which one of the following statements best describes you? (A) I purchase prescription medications for myself; (B) I purchase prescription medications for a family member; (C) Both, I purchase these for myself and a family member; (D) None of the above applies to me, My family does not purchase prescription medications.”²⁷ If a respondent answers D to this question, the survey is over and he/she is not counted in our data set. By this design, all our 2907 respondents are prescription drug consumers, which is arguably the most relevant population for potential online drug purchase. Conditional on providing valid answer to age, sex and family income (age and income in brackets), we focus on the final sample of 2522 respondents.

Having all signed up with RxRights, this population is probably more educated about the issues of price, access to medicines and drug quality than a typical US citizen. They may also be more concerned about the price of drugs and hence may be less insured or poorer than the average American (more details below). Geographically, our respondents spread all over the US, with only 2.82% living in a county that borders with Canada by land or by water (Figure 1).²⁸

Table 7 summarizes responses to the question “For each of the types of prescription medications shown below, from which of the following do you buy it? Please select all that apply below: (A) I do not buy this medication at all; (B) I buy it in person, at a walk-in pharmacy; (C) I buy it through a mail order pharmacy; (D) I buy it online, using the Internet. We ask this question separately for 10 popular drug categories plus a residual “other” category. About 61.54% of respondents admitted to purchase at least one category of the drugs online at some time in the past. In comparison, 58.21% have purchased at least one category in a walk-in pharmacy, 31.28% have purchased via mail order, and a majority of respondents (96.11%) have purchased prescription medications via online, walk-in or mail order. The online shopping percentage is higher than what is reported in previous surveys (Forrester Research 2007, Deloitte Center for Health Solutions 2009²⁹), probably because either online purchase has increased over

²⁷ The question does not specify a time frame for drug purchase. But later on, another question about purchase frequency on the Internet shows that most respondents buy every month or once a year.

²⁸ This figure is conditional on the respondents that provided valid answer in zipcode. Of the 2522 respondents in our final sample, 105 (4.16%) are missing in zipcode.

²⁹ Citations of these surveys are provided in footnotes 2 and 3.

time or as explained, our survey population is more prone to be concerned about drug price and hence may purchase online more than the general population.

Table 8 compares age, gender, family income, insurance status and health condition of online shoppers versus those that do not report any online purchase based on our Table-7 question. Shopping online or not, our respondents are mostly elderly or near-elderly. Those that shop online are slightly younger than offline shoppers, more likely to be male and slightly richer. Surprisingly, the majority of both groups of respondents have medical insurance although the percentage of being insured is lower among online shoppers as one would expect (88.45% vs. 81.83%). Similarly, most of the two groups have drug insurance, but as we expect online shoppers are less likely to have drug insurance (61.66%) than offline shoppers (74.64%). These numbers suggest that lack of any drug insurance cannot be the primary reason for shopping online. When asked whether the respondent or his/her family member takes prescription medication (occasionally or consistently) in a particular category, online shoppers are clearly more prone to take medication in almost every category. Similar patterns hold for their family members. This implies that online shoppers (and their family members) are either sicker or more willing to take medication given a particular health condition.

Conditional on shopping at least one category of prescription drugs online, Table 9 summarizes their answers to how and why they shop on the Internet. Most of them purchase online by month or by year, for chronic conditions. Regarding US- and foreign websites, 73.58% of our online shoppers purchase from foreign websites only, while 24.94% purchase from both US and foreign websites. Very few follow the FDA guideline to buy from US websites only. An overwhelming majority (92.53%) cite cost savings to be one of the reasons for buying from foreign websites, the other reasons including better service (12.45%), not available in the US (11.60%), easier to buy overseas (10.18%), not having insurance in the US (16.24%) and insurance not covering the drug (28.54%). Combined with the fact that 61.66% of our online shoppers have some form of drug insurance, we conclude that insurance coverage is one but not the most important reason for shopping on foreign websites. While the survey does not ask for the magnitude of cost savings from foreign websites, many respondents took time to mention (in text) the significant amount of saving they can obtain from foreign websites. A number of them mentioned the “donut hole” in the Medicare drug coverage and the consequently high price of uncovered prescription drugs as a reason for them to go for foreign websites.

Our survey also asks how one finds (or searches for) which website to purchase prescription drugs. Conditional on shopping online, 53.93% use Internet search, 41.11% check with a credentialing agency such as pharmacychecker.com, 22.62% use personal referrals, and only 12.95% look for the cheapest deal. Consistently, most online shoppers restrict themselves to one primary website, sometimes with supplements from other websites.

Table 10 reports two probit regression results, where the dependent variables are the dummy of whether a respondent purchases any category online (in Column 1) and the dummy of whether they use a credentialing agency if purchasing online (in Column 2). All regressions include the respondent's demographics, insurance status, drug-taking conditions, and state fixed effects on the right hand side. State information is derived from the respondent's self-reported zipcode of residence.

For buying online, the coefficient of age 50 to 59 (relative to 18-49) is positive while that of greater than 75 is negative, both with 90% confidence. This is probably because near-elderly people have demand for prescription drugs but they have not qualified for Medicare yet. Sex has no correlation with whether to buy online or not, but people with family income in 26-49k or 100k and up are more likely to shop online (as compared to family income in 0-25k). This is intuitive, as the former group (26-49k) may find drugs much more affordable on the Internet while the latter group (100k and up) may find online shopping more convenient. As expected, having drug insurance is negatively correlated with buying online, and self-taking medications, especially for blood pressure, cholesterol, diabetes, asthma and other drugs, is positively correlated with buying online. This confirms the fact that most respondents purchase online for chronic conditions and regularly (by month or once a year).

In comparison, almost nothing predicts significantly who checks with certification agencies when they buy online. The only exceptions are being male (positive), having any medical insurance (negative), and family members taking blood thinner drugs (negative). Given the percentage of using a certification agency is more than 40%, this suggests that certification agencies are useful to almost all types of consumers.

Overall, results from the consumer survey are consistent with our audit study. Consumers do buy from foreign websites despite the FDA warning, and mostly for substantial cost savings. At least 40% of them are aware of certification agencies and use them actively when they look for where to buy.

VI. Conclusion

This paper uses an audited sample and a consumer survey to study the intriguing market of online prescription drugs facing US customers. Compared with other online markets, the online drug market is unique in two aspects: On one hand, prescription drug sale is heavily regulated due to affordability and safety concerns, but US and international regulations are quite different. In theory, the difference in price regulation could invite online arbitrage across countries if trade were frictionless. On the other hand, the FDA advisory regarding online drug trade is somewhat inconsistent with market effort in quality certification. In the US, drug importation is technically illegal and the FDA advises consumers to only purchase from NABP-certified websites that operate in the US. In the mean time, a few private certification agencies strive to distinguish safe and unsafe websites although many of them are foreign.

Our data suggest that these non-FDA-endorsed certification agencies play an active role in both demand and supply of online drugs. From consumers' perspective, foreign websites offer significant cost savings than US websites, and these savings attract US customers despite the FDA warning. More importantly, many US consumers are cautious in their choice of foreign websites, by checking with certification agencies, using personal referrals, and sticking to a primary website. On the supply side, conditional on our testable drug samples, we find no failure of authenticity test as long as the drugs are from certified websites, whether FDA-endorsed or not. Admittedly, our audit sample is too small and of only five products to justify the overall drug safety on all verified tier 2 websites. And our survey sample is probably limited to those most concerned about drug prices and aware of possibilities for purchasing online. So the sample is not representative of the US population, but their experiences should hold for those who follow such practices, and hence the data are highly relevant. Indeed, both samples convey a consistent message that certification agencies deliver useful information for foreign websites and online consumers. It will be worthwhile to confirm this message in a larger and more representative sample of websites and consumers.

We suspect the FDA guideline against any foreign website is most likely based on FDA lack of jurisdiction and inability to oversee quality outside of US, rather than a careful assessment between drug safety and price savings. In the US, tens of millions of Americans go without prescribed medication due to cost each year. While the 55 million uninsured Americans (CBO 2012) will probably benefit most from the lower price of foreign online pharmacies, our

survey shows that the majority of online shoppers choose to purchase from foreign websites despite some drug insurance. Clearly, there is a greater danger when ordering from non-credentialed sites and a public policy imperative is to properly educate consumers about buying drugs online from domestic and foreign sources. The current illegal-but-no-enforcement approach on personal importation of prescription drugs does not stop consumers from buying drugs on foreign websites, but it does leave consumers in the gray area of searching for unofficial information on their own.

Another potential side effect of a blanket warning against foreign websites is limiting price competition between US and foreign websites. The recent settlement between Google and the US government regarding Google advertising illegal (foreign) pharmacies pushes Google to only list US-based pharmacies on its search results via a filter enforced by LegitScript.³⁰ Because LegitScript disqualifies any foreign website on the grounds that drug importation is technically illegal, this will add even more difficulties for US consumers to search and find legitimate foreign websites. According to economic theory, difficulty of arbitrage will strengthen a manufacturer's ability to price discriminate across different market segments, if the manufacturer has some market power. This implies that, the substantial cost savings from foreign websites on brand-name drugs could grow even larger over time and the door to these savings is closing, thanks to improved enforcement on the legality of drug importation. Whether this speculation is relevant in the real world is worth future study.

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Figure 1: # of survey respondents by county of residence

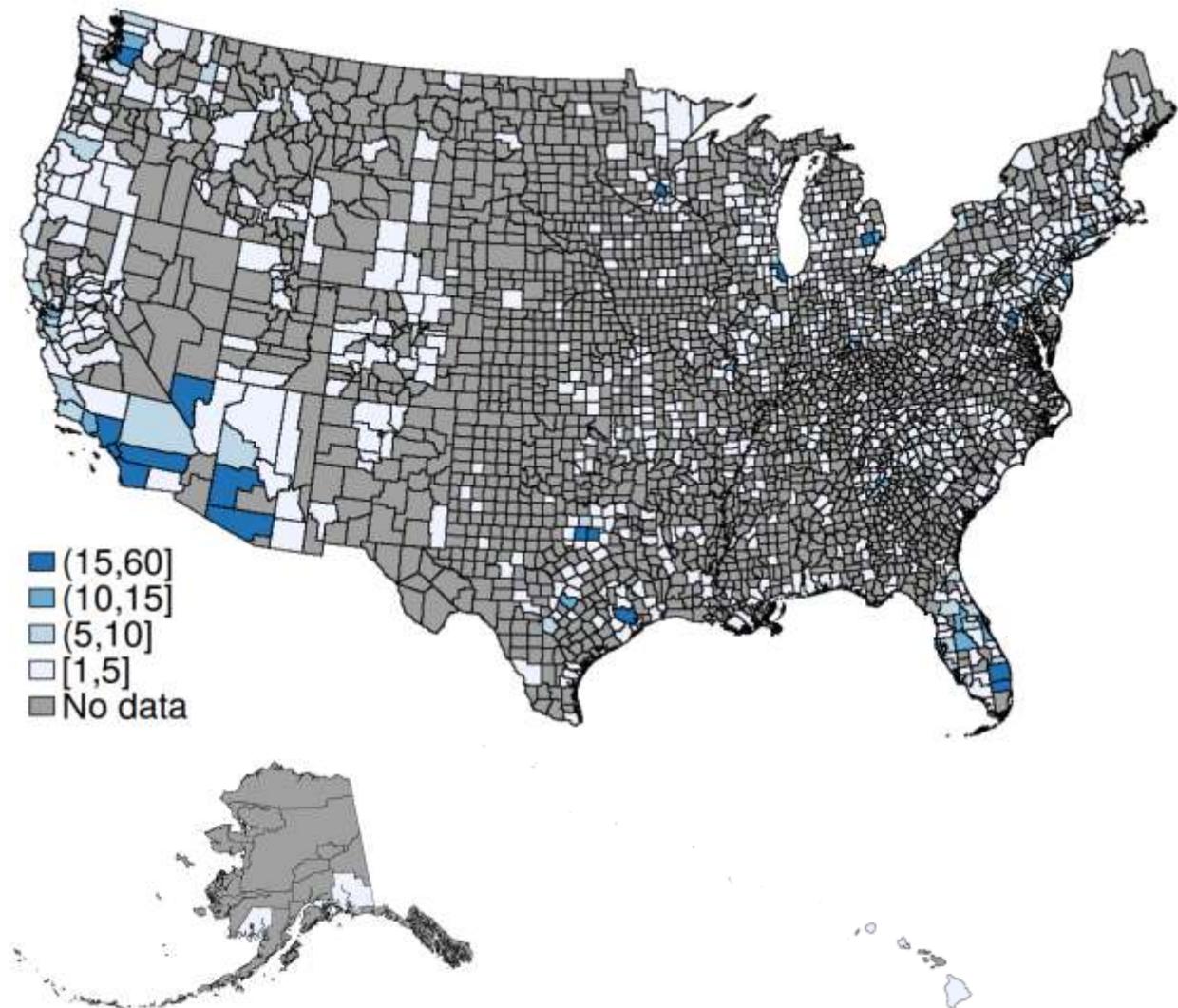


Table 1: Pharmacy characteristics as of February 2012

	Tier 1	Tier 2	Tier 3	Total
Total Count	8	22	11	41
Verified by	NABP (6) LegitScript.com (8)	PharmacyChecker.com (16) or CIPA (12), not by NABP nor by LegitScript.com	None of the four certification agencies	
Valid in February 2012?	100%	91.01%	27.28%	75.61%
Conditional on valid on February 2012				
Country of operation (as indicated on the web page)	US only	2 US, others Foreign	1 US, others Foreign	
Has retail store under the same pharmacy name	50%	0%	0%	9.76%
Require and check RX by email/mail/fax/doctor contact?	1	90% (the other 10% offers internet prescribing based on online consultation according to local licensing requirement)	66.67%	90.32%
Require online questionnaire?	50%	75%	66.67%	67.74%
Offer discreet delivery?	0%	10%	66.67%	12.90%
Shipping and handling cost per standard package	\$0.625	\$10.175	\$3.333	\$7.05
Average shipping time per standard package (days)	10.625	14.60	14.17	13.53

This table is conditional on the pharmacies from which we have received drug samples with clear website identity.

Table 2: Summary of drug samples by drug type and pharmacy tier

	Celebrex	Lipitor	Nexium	Viagra	Zoloft	Total
Count of all delivered drug samples						
Total	71	70	57	105	62	365
Tier 1	16	16	16	16	14	78
Tier 2	44	44	29	43	35	195
Tier 3	11	10	12	46	13	92
Round 1	37	37	35	68	39	216
Round 2	34	33	22	37	23	149
Count and percentage of all delivered drug samples that are testable						
Tier 1	16	16	16	16	12	76
	100%	100%	100%	100%	85.71%	97.44%
Tier 2	44	44	20	43	26	177
	100%	100%	68.97%	100%	74.29%	90.77%
Tier 3	11	10	9	35	10	75
	100%	100%	75%	76.09%	76.92%	81.52%
Total testable	71	70	45	94	48	328
	100%	100%	78.95%	89.52%	77.42%	89.86%
Count and percentage of authentic samples condition on being testable						
Tier 1	16	16	16	16	12	76
	100%	100%	100%	100%	100%	100%
Tier 2	44	44	20	43	26	177
	100%	100%	100%	100%	100%	100%
Tier 3	11	10	9	27	10	67
	100%	100%	100%	77.14%	100%	89.33%
Total authentic	71	70	45	86	48	320
	100%	100%	100%	91.49%	100%	97.56%

Table 3: Summary of price by drug type, pharmacy tier and sample authenticity conditional on testable samples only

Drug	Statistic	Tier 1, all authentic	Tier 2, all authentic	Tier 3, authentic only	Tier 3, non-authentic only
Celebrex	Mean (SD)	3.683 (0.487)	2.168 (0.523)	2.065 (0.637)	-
	Min.	2.579	1.247	1.482	-
	Max.	4.577	3.602	2.926	-
	N	16	44	11	
Lipitor	Mean (SD)	2.826 (0.266)	1.903 (0.441)	1.629 (0.463)	-
	Min.	2.289	0.938	1.032	-
	Max.	3.283	2.701	2.532	-
	N	16	44	10	-
Nexium	Mean (SD)	5.711 (0.687)	3.406 (1.204)	3.517 (1.883)	-
	Min.	4.662	1.341	1.369	-
	Max.	6.763	5.271	6.594	-
	N	16	20	9	-
Viagra	Mean (SD)	16.465 (2.639)	17.025 (4.750)	19.166 (5.845)	12.773 (2.819)
	Min.	12.953	11.612	12.381	9.895
	Max.	20.748	33.766	32.810	16.986
	N	16	43	27	8
Zoloft	Mean (SD)	3.647 (0.538)	2.248 (0.588)	2.203 (0.551)	-
	Min.	2.926	0.985	1.773	-
	Max.	4.605	3.311	3.555	-
	N	12	26	10	

Table 4: Regression Results on test-ability and price

	All	Conditional on being testable	
	(1) Testable?	(2) ln(price)	(3) ln(price) (authentic only)
Model	Probit Marginal effect	OLS Coefficient	OLS Coefficient
Full sample			
Tier 1	0.0029 (0.0013)	0.3959** (0.1169)	0.3965** (0.1166)
Tier 3	-0.0035 (0.0047)	-0.0105 (0.0403)	0.0130 (0.0628)
Round 1	-0.0126*** (0.0022)	-0.0082 (0.0228)	-0.0136 (0.0177)
Drug type FE	Yes	Yes	Yes
N	295	328	320
R2	0.309	0.9122	0.9118
All drugs except Viagra			
Tier 1	0.0008 (0.0001)	0.5102** (0.0386)	0.5102** (0.0386)
Tier 3	0.0002* (0.00003)	-0.0670 (0.0348)	-0.0670 (0.0348)
Round 1	-0.0035*** (0.0002)	-0.0324* (0.0133)	-0.0324* (0.0133)
Drug type FE	Yes	Yes	Yes
N	190	234	234
R2	0.3495	0.6090	0.6090
Viagra only			
Tier 1	-	-0.0153 (0.0546)	-0.0156 (0.0542)
Tier 3	-	0.0105 (0.0676)	0.1064 (0.0694)
Round 1	-	0.0380 (0.0572)	0.0078 (0.0559)
Drug type FE	-	No	No
N	-	94	86
R2	-	0.0077	0.0483

Number of observations in probit regressions is smaller because some variables predict whether a drug is testable perfectly and these observations are dropped out of the probit sample. For the probit result of testability on Viagra only, all the key variables (tier 1, tier 2 and round 1) are dropped out of the specification and only the constant is estimated. That's why we do not report the probit result for Viagra only. Standard errors in parentheses. *** p<0.01, ** p<0.05, * p<0.1. Probit and OLS have robust errors clustered by drug type for full sample and the sample without Viagra.

Table 5: Summary of drug source by pharmacy tier, testable drug samples only

Drug Source	Tier 1	Tier 2	Tier 3	Total
Missing	0	0	17	17
Australia	0	22	10	32
Canada	2	92	22	116
China	0	0	1	1
Germany	0	6	0	6
India	0	0	1	1
Israel	0	3	0	3
Italy	0	16	8	24
Turkey	4	21	15	40
UK	2	17	1	20
USA	68	0	0	68
Total	76	177	75	328

Table 6: Regression Results of Drug Price with Drug Source

	Ln(drug price)			
	All testable	All testable and authentic	All testable non-Viagra (all authentic)	All testable and authentic Viagra
Tier 1	0.3775*** (0.0606)	0.2645** (0.0848)	0.3512** (0.1007)	0.0455 (0.1027)
Tier 3	-0.0181 (0.0500)	-0.0047 (0.0848)	-0.0645 (0.0317)	0.1240 (0.0838)
Round 1	-0.0056 (0.0228)	-0.0151 (0.0150)	-0.0279 (0.0120)	0.0134 (0.0568)
Drug source: Asia/pacific	0.0622 (0.0900)	-0.0562 (0.0635)	-0.0744 (0.0871)	0.1174 (0.1103)
Drug source: Europe	-0.1151 (0.0935)	-0.2260** (0.0593)	-0.2594*** (0.0380)	-0.0314 (0.0975)
Drug source: Canada	-0.0164 (0.0985)	-0.1300 (0.0722)	-0.1605 (0.0877)	0.0869 (0.0963)
Has retail stores in US	-0.0206 (0.0257)	0.0029 (0.0216)	0.0051 (0.0284)	-0.0296 (0.0847)
Drug type fixed effects	Yes	Yes	Yes	No
N	328	320	234	86
R-squared	0.9158	0.9166	0.6325	0.1004

Standard errors in parentheses. *** p<0.01, ** p<0.05, * p<0.1. Errors are robust and clustered by drug type for all testable, all testable and authentic, and all testable non-Viagra samples.

Table 7: Extent of online purchase

Question: For each of the types of prescription medications shown below, from which of the following do you buy it? Please select all that apply below.				
A) I do not buy this medication at all.				
(B) I buy it in person, at a walk-in pharmacy.				
(C) I buy it through a mail order pharmacy.				
(D) I buy it online, using the Internet.				
	% buy online	% buy walk-in	% buy mail order	% buy any form
Blood pressure	18.40%	26.45%	15.58%	60.43%
Blood thinner	8.64%	9.60%	4.84%	23.08%
Acid reflux	9.67%	18.60%	6.62%	34.89%
Cholesterol	18.48%	17.68%	14.95%	51.11%
Diabetes	7.30%	8.49%	5.19%	20.98%
Pain	4.12%	28.98%	3.73%	36.84%
Immunodeficiency	1.03%	2.06%	0.67%	3.77%
Asthma/allergies	12.73%	14.47%	5.43%	32.63%
Psychoactive	6.30%	5.71%	2.89%	14.91%
Contraceptive	0.79%	1.07%	0.56%	2.42%
Other	31.40%	15.70%	12.37%	59.48%
Any of the above	61.54%	58.21%	31.28%	96.11%

Total number of respondents = 2522. All percentages are calculated by dividing the number of people answering yes to a particular question over 2522.

Table 8: Comparing online shoppers with offline-shoppers

	Not buy any RX online	buy any RX online
Average Age	66.36	64.68
% Age 18-29	0.52%	0.19%
% Age 30-39	1.13%	1.68%
% Age 40-49	4.33%	5.35%
% Age 50-59	13.51%	19.59%
% Age 60-65	21.03%	21.59%
% Age 66-69	18.35%	18.11%
% Age 70-75	22.37%	19.78%
% Age > 75	17.32%	13.53%
% male	55.77%	58.57%
Average family income imputed	50.95k	52.26k
% family income 0-25k	19.59%	17.14%
% family income 26-49k	25.26%	30.28%
% family income 50-75k	19.59%	17.53%
% family income 76-99k	9.48%	9.09%
% family income 100k+	7.53%	9.28%
County on US-Canada border	2.68%	2.90%
% have any medical insurance	88.45%	81.83%
% have any drug insurance	74.64%	61.66%
% have private insurance	18.04%	15.01%
% have employment insurance	18.14%	16.95%
% have Medicare insurance	41.44%	31.19%
% have veteran insurance	4.54%	2.58%
% have Medicare supplemental	30.52%	25.13%
% have other insurance	4.85%	3.09%
% Self taking medication in:		
Blood pressure	47.73%	55.15%
Blood thinner	18.76%	20.43%
Acid reflux	30.00%	32.86%
Cholesterol	42.37%	47.81%
Diabetes	15.05%	19.14%
Pain	35.05%	35.31%
Immunodeficiency	3.61%	2.90%
Asthma/allergies	27.84%	32.80%
Psychoactive	11.75%	11.79%
Contraceptive	1.44%	1.87%
Other	39.69%	47.23%
% Family member taking drug in:		
Blood pressure	32.58%	33.25%
Blood thinner	11.75%	11.53%
Acid reflux	22.37%	21.33%
Cholesterol	28.45%	28.16%
Diabetes	10.72%	10.82%
Pain	26.60%	23.90%
Immunodeficiency	3.20%	2.64%
Asthma/allergies	17.84%	17.72%
Psychoactive	9.18%	9.41%
Contraceptive	1.55%	2.19%
Other	33.92%	35.95%

All percentages are calculated by dividing the number of responding yes over total number of observations (2522). Average age and average family income are imputed by taking the mid-point of each bracket, conditional on non-missing. We assume average of 80 if age >75 and 120k if family income > 100k.

Table 9: Why and how to buy online?

Survey Questions	Conditional on buying any prescription medication as defined in Table 7
How frequently do you or your family member purchase prescription medications online?	
By week	0.39%
By month	28.35%
2-3 times a year	2.19%
Once a year	67.65%
Less than once a year	0.32%
Compared to brick and mortar (retail store) pharmacies, do your online pharmacy purchases typically cost:	
Less than purchases at the store	95.55%
same as / more than purchases at the store	2.64%
Are the medications that you or a family member purchase online for	
Temporary medical conditions	0.58%
Chronic conditions	86.53%
Both	12.05%
Do you or family member purchase from	
US-based online pharmacies	0.90%
Foreign/overseas online pharmacies	73.58%
Both	24.94%
What reasons below explain why you or a family member buys from overseas online pharmacies? Select all that apply.	
Not available in the US	11.60%
Can buy it without prescriptions overseas	2.96%
Cheaper overseas	92.53%
Easier to buy overseas	10.18%
I do not have insurance in the US	16.24%
My insurance does not cover this medication	28.54%
Better service overseas	12.45%
How do you or your family identify the online pharmacy from which to purchase? Select all that apply.	
Internet search	53.93%
Check with a credential agency like pharmacychecker.com	41.11%
Personal referral	22.62%
Respond to email/non-email ads	0.52%
Brands I recognize (like CVS, Walgreens or Walmart)	1.61%
Cheapest deal I can find	12.95%
Which one of the following best describes how you or your family member purchases from an online pharmacy?	
Always purchase from the same website	55.35%
Use a primary website, but supplement with other sites	10.70%
Consistently use several different websites	2.06%
Use a different website each time	0%
Register at the first visit and then fax in orders	24.61%
Shop for the cheapest	6.77%

Total number of respondents conditional on buying any prescription online = 1552. All percentages are calculated by dividing the number of people answering yes to a particular question over 1552.

Table 10: Probit Regression results from the consumer survey

	Buy any RX online			Check with certifier if buy online	
	Marginal effects		std. err.	Marginal effects	std. err.
Age 50 to 59	0.079	*	(0.043)	-0.067	(0.056)
Age 60 to 65	-0.017		(0.044)	0.014	(0.058)
Age 66 to 69	-0.019		(0.046)	-0.024	(0.059)
Age 70 to 75	-0.037		(0.046)	-0.043	(0.059)
Age > 75	-0.093	*	(0.049)	-0.030	(0.063)
Male	0.017		(0.022)	0.072	** (0.028)
Family income 26-49k	0.074	***	(0.025)	-0.044	(0.033)
Family income 50-75k	0.008		(0.029)	-0.043	(0.038)
Family income 76-99k	0.029		(0.037)	-0.014	(0.049)
Family income >=100k	0.081	**	(0.037)	-0.024	(0.050)
In a county that borders Canada	0.031		(0.065)	-0.020	(0.083)
Have any medical insurance	-0.019		(0.036)	-0.093	** (0.044)
Have any Rx drug insurance	-0.138	***	(0.026)	0.035	(0.035)
Self taking Rx drugs in:					
Blood pressure	0.058	**	(0.024)	0.040	(0.031)
Blood thinner	-0.003		(0.029)	-0.038	(0.036)
Acid reflux	0.034		(0.024)	-0.017	(0.031)
Cholesterol reducing	0.045	*	(0.025)	0.051	(0.031)
Diabetes	0.057	**	(0.028)	0.023	(0.036)
Pain relief	-0.027		(0.025)	-0.005	(0.032)
Immunodeficiency	-0.047		(0.063)	0.082	(0.087)
Asthma/Allergy	0.072	***	(0.023)	-0.011	(0.031)
Psychoactive	-0.024		(0.034)	0.006	(0.044)
Contraceptive	0.052		(0.078)	-0.116	(0.090)
Other	0.073	***	(0.021)	-0.011	(0.028)
Family member taking Rx drugs in:					
Blood pressure	0.009		(0.027)	-0.031	(0.035)
Blood thinner	0.013		(0.035)	-0.094	** (0.044)
Acid reflux	-0.009		(0.029)	0.019	(0.038)
Cholesterol reducing	-0.003		(0.029)	0.060	(0.038)
Diabetes	-0.006		(0.036)	0.012	(0.047)
Pain relief	-0.047		(0.029)	0.047	(0.039)
Immunodeficiency	-0.017		(0.067)	0.082	(0.095)
Asthma/Allergy	-0.031		(0.030)	0.043	(0.039)
Psychoactive	0.035		(0.037)	-0.030	(0.048)
Contraceptive	0.056		(0.076)	0.042	(0.094)
Other	0.018		(0.023)	0.020	(0.031)
Observations/Pseudo R2	2517 / 0.0635			1534 / 0.0459	

Robust standard errors. State fixed effects included. Default is age 18 to 49, female and family income under 25k. ***p<0.01, **p<0.05, *p<0.1.