# The "Black Box" of Strategy: Competitive Responses to and Performance from Adverse Events[1]

JEFFREY T. MACHER
McDonough School of Business
Georgetown University
Washington, DC 20057
jtm4@georgetown.edu

and

JAMES B. WADE
Goizueta Business School
Emory University
Atlanta, GA 30322
jbwade@emory.edu

**Abstract**: In many markets and industries, firms face adverse regulatory events to their normal business operations. These events can be represent any change to market or industry status quo, and can trigger strategic and competitive responses by firms and shape subsequent performance. Understanding and examining competitive responses to adverse regulatory events is important, given the effects on customers, regulators, the firm itself and its rivals. In this paper, we examine the performance effects of an adverse regulatory event (a black box warning) on the competitive responses of pharmaceutical firms and their proximate and distant rivals via sales visit and promotion strategies. Black box warnings are medication-related safety warnings that appear on the package insert of prescription drug products that indicate major drug-related risks based on post-market surveillance. Sales visit and promotion strategies are the efforts by pharmaceutical firms' sales representatives to market or otherwise promote their pharmaceutical drugs directly to doctors. We utilize a combination of publicly-available FDA data on black box warnings, and proprietary-level data on pharmaceutical firm sales visit and promotion strategies and prescriptions (Rx) written by primary care physicians (PCPs). We posit that (1) firms act strategically by changing their sales visit and promotion strategies when they or their rivals are faced with black box warnings; and (2) black box warnings and firms' responses have direct consequences on performance. Using a variety of econometric models, we find strong overall support for our hypotheses.

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# 1 INTRODUCTION

In many markets and industries, firms face adverse events to their normal business operations. These events can be defined broadly to represent any change to the market or industry status quo, including but not limited to detrimental demand or supply shifts, unfavorable regulatory rulings, or unexpected societal interventions. Not surprisingly, adverse events can trigger strategic and competitive responses by firms and effect subsequent performance, depending on the magnitude and distribution of the adverse event across the population of firms in the market or industry. To be sure, some firms are made worse-off from adverse events, while other firms may benefit. Despite these somewhat obvious performance consequences associated with adverse events, past examinations of this phenomenon through a strategy lens have been rather banal—partly because of the difficulties associated with identifying exogenous adverse events (i.e., an ideal natural experiment) and partly because of the data requirements (i.e., possessing sufficient data both pre- and post-adverse adverse event).

We nevertheless suggest that a comprehensive understanding of adverse events is important for several reasons. First, customers must be effectively communicated to during adverse events, and this requires that firms have appropriate strategies in place in dealing with such shocks. Second, regulators are often the impetus behind adverse events and can demand more from the firms that they regulate, in terms of safety studies, customer support, etc. Third, other firms might benefit from the adverse events of their rivals by altering their own strategic and competitive approaches, and subsequently, improve their performance effectively by stealing market share. The strategic and competitive interaction among firms therefore requires that adverse event-affected firms alter their own strategic approaches to combat rivals to minimize any undesired performance outcomes.

In this paper, we examine the strategic approaches and performance effects of an adverse regulatory event—a black box warning—on the competitive responses of pharmaceutical firms and their proximate and distant rivals via sales visit and promotion strategies. Black box warnings (a.k.a. “boxed warnings”) are medication-related safety warnings instituted by the Food and Drug Administration (FDA) that appear on the package insert of prescription drug products that indicate—based on post-market surveillance—major drug-related risks. A black box warning (BBW) includes restrictions for use and warns of adverse drug reactions or interactions. Sales visit and promotion strategies are the efforts by pharmaceutical firms’ sales representatives (or reps) to market or otherwise promote their drug products directly to doctors—most typically in doctors’ offices. We posit (1) that firms act strategically by changing their sales visit and promotion strategies—in terms of frequency and approach—when they or

their rivals are faced with black box warnings; and (2) that black box warnings and firms' strategic and competitive responses to these warnings have direct consequences on subsequent performance.

We utilize a combination of publicly-available FDA data on black box warnings, proprietary-level data on the sales visit and promotion strategies of pharmaceutical firms and their product families, and proprietary-level data on the prescription (Rx) writing behavior of thousands of "high prescribing" primary care physicians (PCPs) to test these predictions. A variety of econometric models appropriate for time-series panel data are implemented, and suggest that the results obtained are both as expected and somewhat provocative. We first find that adverse events trigger strategic and competitive responses across the population of firms. These responses differ, however, depending on the pharmaceutical firm and on whether the focal product family faces a black box warning or not. Some affected pharmaceutical firms significantly increase sales visit and promotion activities for BBW-affected product families, while other firms significantly decrease sales visit and promotion activities for BBW-unaffected product families. We also find that the magnitude and rapidity of these strategic and competitive responses affect subsequent performance. Greater sales visit and promotion activity by adverse event-affected firms reduces their marketplace stature and prescription market share over the entire sample window. But these strategic and competitive responses provide only temporary (and declining) benefits post-adverse event. We also find that changes in marketplace stature and prescription market share are most strongly affected by the competitive actions of "proximate" rivals (i.e., firms in the same product class) versus "distant" rivals (i.e., firms in different product classes). Increased competitive actions by pharmaceutical firms in other product classes have little to no effect on performance pre-black box warning. Increased strategic and competitive responses by pharmaceutical firms in other product classes becomes much more effective post-black box warming, however, allowing these firms to substantially increase their performance. The last finding is somewhat counterintuitive. First, economic and strategic theory generally postulates that firms target their direct (or proximate) rivals, in terms of price setting, quantity setting, new product development, marketing, etc. Reacting to events that affect more distant rivals is generally expected to yield limited benefits. In our context, however, adverse event-unaffected firms are made "better off" by taking vigorous competitive actions toward more distant adverse event-affected firms after the adverse event. In short, adverse events may create situations whereby firms and their distant rivals move from limited competitive interaction to greater competitive overlap.

The rest of this paper is organized as follows. The next section provides a review of the strategy literature that examines competitive responses and competitive interaction. It then develops hypotheses from this review. The following section sets the empirical context by highlighting the setting, describing the data, defining the variables and providing sample statistics. The next section discusses the empirical

approaches, econometric results and robustness tests. The final section discusses the main findings, highlights the managerial and policy implications, and identifies potential limitations. A final conclusion is then provided.

## 2 HYPOTHESES DEVELOPMENT

Regulatory decisions or actions often negatively impact one set of firms, while simultaneously have little or no effects on different sets of firms. For instance, decisions by the U.S. Department of Homeland Security's (DHS) Citizenship and Immigration Services to cap the number of H-1B visas disproportionally affect U.S. high technology firms in their abilities to hire foreign-born engineers. Evolving federal and state environmental regulations over 1994-2006 have significantly contributed to the demise of small hog farms, in comparison to their larger brethren (Nene, Azzam, & Schoengold, 2010). The Patient Protection Affordable Healthcare Act (so-called Obamacare) is expected to disproportionately affect businesses with 50 employees or fewer, given its health insurance mandates and potential fines and/or taxes associated with non-compliance. In our context, FDA decisions regarding the extent of medication-related safety warnings in labeling information across different drug classes are expected to create heterogeneous outcomes and effects.

Regulatory decisions or actions obviously impact status-quo business operation and subsequent performance, and not surprisingly, draw immediate managerial attention not only from affected firms but also from unaffected firms. Given the impact of regulatory decisions and actions will differ between affected firms and unaffected firms, understanding competitive actions and responses between these types of firms become increasingly important. In particular, questions around the rapidity (or delay), magnitude and complexity of competitive action and response become paramount. The competitive dynamics stream of strategy research examines head-to-head rivalry and competitive interaction between and among participants (Grimm & Smith, 1997). This research stream generally emphasizes the competitive interaction that exists among "sets" of firms at multiple and distinct levels of analysis (Ferrier, 2001), but most often examines competitive action-response dyads. It is argued that the action-response dyad is where actual competitive engagement among firms occurs (Chen & MacMillan, 1992), depending upon the characteristics of and expected payoffs from competitive actions and responses (Chen, Smith, & Grimm, 1992).

Competitive actions and responses most typically refer to activities that are "directed, specific and observable competitive moves initiated by a firm to enhance its competitive position" (Ferrier, Smith, & Grimm, 1999: 859), and are often categorized into particular actions (e.g., pricing, marketing, new product, capacity). Using this categorization approach, this research stream demonstrates a causal link

between competitive actions and responses and subsequent performance by aggregating the characteristics, repertoire and frequency of actions and responses over a finite time period (Ferrier et al., 1999; Young, Smith, & Grimm, 1996). The majority of this research stream suggests that the more competitive actions, the more varied these competitive actions, and the more rapid the competitive actions that firms undertake, the better their subsequent performance. A variant of this research stream instead suggests that rather than rapid competitive response, delayed response (Boyd & Bresser, 2008) or non-response (Chen & MacMillan, 1992) to competitive actions are superior (e.g., performance-improving) approaches.

While this research stream has made theoretical strides in detailing the offensive and defensive actions by firms and examining head-to-head rivalry important to creating and sustaining competitive advantage, empirical tests have arguably lagged. One major challenge in studying competitive interaction is objectively identifying competitive actions and responses (Chen & MacMillan, 1992). Notable difficulties include delineating a "market" into a well-defined boundary, accurately identifying competitors within that boundary, and possessing adequate and detailed information on firms' actions and responses over a sufficiently long time horizon. Much of the literature in the competitive dynamics stream relies on structured content analysis approaches that categorize news headlines of selected firms from various publication sources over a finite time window into competitive action and response events (Ferrier et al., 1999; Ferrier, 2001). While structured content analysis has proven beneficial for examining strategic and competitive interaction, it also poses some concerns, including ex-post rationalization, insufficient rigor and/or accuracy, lack of completeness or comprehensiveness, among others. We elaborate on some of these concerns, as well as how our own approach differs and overcomes some of these concerns further below.

### 2.1 Strategic Responses and Adverse Regulatory Events

Regulatory decisions or actions that create adverse events for firms not surprisingly affect status-quo business operation, especially for affected firms. Adverse event-affected firms have strong incentives to respond immediately, as delay might potentially open windows of opportunity for unaffected rivals (Dutton & Jackson, 1987). The behavioral theory of the firm (Cyert & March, 1963) suggests in general that firm threats initiate problemistic search to alleviate or eliminate any impact (Greve, 2003). A rich body of literature, moreover, subscribes to speed and aggression as sources of advantage (Brown & Eisenhardt, 1998), especially in competitive interactions among firms (D'Aveni, 1994; Porter, 1985). Speed prevents the building of barriers that might be difficult to overcome, while aggression signals commitment to defending market positions. As mentioned, the competitive dynamics literature largely prescribes to the argument that rapid and aggressive actions are most effective in limiting changes to the

status quo via competitive attacks (Smith, Grimm, Chen, & Gannon, 1989; Smith, Grimm, Gannon, & Chen, 1991). One possibility then is that adverse event-affected firms actively increase strategic activities that aid in either maintaining status quo or minimizing expected losses. At the same time, however, adverse event-unaffected firms play in the same competitive space as affected firms and recognize the potential changes in marketplace and competitive dynamics that might obtain. These firms also likely have strong incentives to response rapidly to adverse events, given the windows of opportunity presented and performance gains possible.

It might be the case that adverse-event affected firms instead benefit from delayed competitive response. Rapid competitive responses, while reducing the risks of appearing lethargic, also increase the risks of hasty and ill-devised approaches or investments (Boyd & Bresser, 2008). A more delayed competitive responses allows for resolution of any market, technological or regulatory uncertainties, and provides additional information useful in crafting more thoughtful and potentially more effective responses (Shamsie, Phelps, & Kuperman, 2004). Compelling empirical support in favor of rapid responses, moreover, is indeed lacking (Ferrier et al., 1999; Smith, Grimm, & Gannon, 1992), with some research suggesting a negative relationship between speed of response and performance exists (Lee, Smith, & Grimm, 2000). The competitive actions of unaffected rivals nevertheless suggest that these firms still have greater leeway in navigating the new competitive realities present. Given these unaffected rival firms are likely to respond, given the marketplace realities, some type of response by affected focal firms is more likely.

It might also be the case that adverse-event affected firms instead benefit from no competitive response. Such a shift in strategic approach might be warranted if competitive responses are visible and call further attention to the adverse event or to those affected firms. If such cases, greater (or any) attention might further damage affected firm reputations and competitive standings. In short, deferment might be the best (i.e., least performance detrimental) alternative. There is support in the literature that stigma easily spreads by association (Mehta & Farina, 1988; Pontikes, Giacomo, & Rao, 2010). Further identification could potentially harm firm reputation and ultimately damage key stakeholder relationships (Devers, Dewett, Mishina, & Belsito, 2009). Because stigma diffuses widely, any negative effects could spill over and reduce stakeholders' perceptions of the overall firm and/or other products that are not part of the adverse regulatory event (Pontikes et al., 2010). In this instance, affected firms might seek to disassociate or decouple themselves from the adverse event by sharply reducing any and all strategic actions or responses. Under such a scenario, however, unaffected rival firms are even more likely to respond to the adverse event via increased competitive response. In short, while "silence is golden" for

affected firms, it might prove detrimental as unaffected firms take increased competitive responses to improve their competitive standing.

Under all response scenarios, we therefore expect affected focal firms to change or alter their competitive approaches. This argument is based in part on these firms being the most directly affected by the adverse event, and based in part on the competitive responses of their unaffected rivals. We therefore expect that responding to the threats posed by adverse regulatory events and countering the potential competitive responses taken by unaffected rivals will dominate for affected firms. While both types of firms are expected to respond to an adverse event by altering their strategic and competitive approaches, we expect the responses of adverse event-affected firms to be larger in magnitude than adverse event-unaffected firms. In short, cognitive and decision-making burdens are placed on affected firms to sense, predict and react to the series of competitive actions carried out by unaffected rival firms (Ferrier, 2001). The following set of hypotheses is therefore examined:

*H1: Adverse regulatory events trigger strategic responses by affected focal firms and unaffected rival firms.*

*H2: The strategic responses of adverse event-affected focal firms are larger in magnitude than the strategic responses of adverse event-unaffected rival firms.*

## 2.2 Strategic Responses and Performance

A general argument from the competitive dynamics stream is that aggressive competitive behavior is directly related to improved performance. The majority of this literature suggests that firms that increase competitive actions and more quickly respond to competitive challenges experience better performance (Lee et al., 2000). Prior research has documented more aggressive (i.e., attacking) firms experience higher profitability (Young et al., 1996) and market share gains (Ferrier et al., 1999). The dynamic interchange among rivals in the context of offensive and defensive moves and "punch-counterpunch" interactions suggests that competitive aggressiveness might allow firms to overwhelm or deter their rivals. Competitive aggressiveness approaches are broadly defined, and include attack volume (i.e., the number of competitive actions), attack duration (i.e., the timeframe of competitive actions) and attack complexity (i.e., the range of competitive actions). And empirical research supports the arguments that the number of competitive actions (D'Aveni, 1994), the timing of competitive actions (Boyd & Bresser, 2008), and the repertoire of competitive actions (Miller & Chen, 1996) each result in performance benefits.

The competitive dynamics performance arguments above have generally been made outside of any regulatory decisions or actions. But regulatory decisions and actions that create adverse events

suggest that the performance implications from competitive aggression might be different among the population of firms. In particular, affected firms are likely to experience greater difficulties than unaffected firms in navigating the market and competitive landscapes. In short, adverse regulatory events at least initially damage key stakeholder relationships for affected firms. Despite the best efforts of these firms in terms of competitive actions and responses, their marketplace standing obviously takes a hit immediately following any adverse event, which has performance implications. While these firms might be able to overcome any associated organizational stigma (Devers et al., 2009) via any one of the above competitive aggressiveness approaches, their abilities to do so are governed by the competitive actions and responses of their unaffected rivals.

Unaffected rival firms are likely to perceive an adverse event directly affecting their competitors as opportunities to improve marketplace standing and subsequently steal market share. Indeed, past research suggests that when competitors perceive opportunities they are more likely to undertake competitive actions (Dutton & Jackson, 1987). We therefore suspect that unaffected rival firms will increasingly undertake "go on the offensive" initiatives. Unaffected rival firms are therefore likely to respond to any adverse event by increasing the volume, duration and complexity of competitive actions. Increased competitive aggressiveness by unaffected firms allows them to point out the deficiencies of affected firms' product and service offerings, while proffering their own as more viable alternatives.

Given the discussion above, we therefore suggest that affected focal firms can at best reduce the expected and subsequent performance losses that obtain via strategic and competitive responses, in comparison to unaffected rival firms. While we fully expect affected focal firms and unaffected rival firms to respond in kind to an adverse event, the combined effects of adverse events and unaffected firms' strategic and competitive actions suggest that affected focal firms will suffer performance losses, despite their own strategic and competitive actions. The following set of hypotheses is therefore examined:

*H3:* *The strategic responses of affected focal firms and unaffected rival firms following an adverse event have a direct effect on performance.*

*H4:* *The strategic responses of affected focal firms following an adverse event have a smaller direct effect on performance than the strategic responses of unaffected rival firms.*

## 3 EMPIRICAL SETTING

Diabetes is a disease related to the amount of glucose in the bloodstream, and is classified as either Type-1 or Type-2. Type-1 diabetes is an immune disorder where the body destroys insulin-producing beta cells in the pancreas. In short, the body makes too little or no insulin. Because the body cannot produce enough insulin, glucose builds-up in the blood and subsequently damages internal organ systems. Type-1

diabetics must therefore take insulin—normally via insulin injections—as well as manage their diets and partake in exercise. Type-1 diabetes accounts for between five and ten percent of all diabetes cases. Because Type-1 diabetes most commonly afflicts children, it is often referred to as insulin-dependent or juvenile-onset diabetes. Type-2 diabetes is a disease in which the body does not produce enough insulin or the cells ignore the insulin produced. In short, the body cannot use the insulin it makes. Type-2 diabetes also causes glucose build-up in the bloodstream which damages internal organ systems. Type-2 diabetics must also manage their diets and partake in exercise, as well as take oral anti-diabetic medication. Type-2 diabetes accounts for between 90-95 percent of all diabetes cases. Because Type-2 diabetes most commonly afflicts older and heavier individuals, it is commonly referred to as adult-onset diabetes.

Given increased economic development, growing populations, more sedentary lifestyles and subsequent rises in obesity levels, diabetes—Type-2 in particular—is growing at exponential rates. More than 370 million people globally are currently afflicted with this disease, and this number is expected to exceed 550 million by 2030. Managing this disease—including but not limited to lifestyle modifications related to diet control and physical activity—is paramount for global healthcare providers over the next several decades, given the implications for public health, life expectancy and healthcare costs. The "diabetes management" market (i.e., diabetes drugs and devices) was nearly $51 billion in global revenue in 2011 and is expected to exceed $98 billion in 2018—a CAGR of nearly ten percent (Research, 2012). Diabetes management is classified into three broad categories: (1) monitoring devices (e.g., monitors, test strips, meters); (2) delivery devices (e.g., pumps, syringes); and (3) oral diabetes drugs.

We narrow our examination in this paper to the Type-2 diabetes market, for anti-diabetic drugs, and within the United States. Type-2 diabetes is most frequently treated with anti-diabetic drug products administered orally (i.e., tablets, capsules, pills, etc.). As diabetes drug products generally require prescriptions (i.e., relatively limited over the counter (OTC) availability), individuals afflicted with this disease must meet with their doctors—most commonly primary care physicians (PCPs) in an office setting—to devise treatment regimens. It is in the office setting that pharmaceutical firms compete for the "attention" of PCPs. Pharmaceutical firm sales representatives (reps) make regular and repeated visits to PCP offices—providing literature, information, samples, etc.—to promote their own firms' drug products, to educate PCPs of the merits of these drug products, and ideally, to convince PCPs to write prescriptions for these drug products over other firms' available drug products.

Given the size and growth potential of the oral diabetes drug product market, several pharmaceutical firms compete in this space—not only by offering equivalent (i.e., direct substitutes) drug products, but also by offering drug products with different "mechanisms of action" (i.e., less direct

substitutes). [2] There are several different Type-2 diabetes treatment regimens (or agents), each of which attempt to control blood glucose levels using different pharmacokinetic approaches. These approaches include blocking glucose production by the liver, increasing insulin secretion by the pancreas, increasing glucose uptake into the skeletal muscle, limiting carbohydrate absorption in the small intestine, among others.[3] We refer to these different "mechanisms of action" as product classes in our empirical analyses below.

It is precisely because of the different mechanisms of action available in the oral diabetes market that allow for this examination. In May 2007, the United States Food and Drug Administration (FDA) required that Glaxo Smith Klein (GSK) and Takeda add black box warnings to their respective oral anti-diabetes drugs—Avandia and Actos—both of which are classified as Thiazolidinediones (TZDs). The black box warning received by GSK and Takeda resulted from a May 2007 *New England Journal of Medicine* post-market surveillance study on the safety risks related to Avandia, and in particular, its negative side effects associated with increased cardiac risk.[4]

Black box warnings (BBWs) are medication-related safety warnings that appear on the package insert of prescription drug products that indicate—based on post-market surveillance—major drug-related risks. A BBW often include restrictions for use and warn of adverse drug reactions or interactions associated with the drug product's use. The package insert is a primary source of consumer information, and provides a template for safe and rational use by consumers based primarily on pre-clinical trials. Because drug safety is often subject to changes based on post-market surveillance, however, package inserts are revised as necessary based on new data related to safety (e.g., side effects, drug reactions or interactions), restrictions for use, or distribution (Generali & Paxton, 2011). BBWs are considered the strongest alert that FDA requires for pharmaceutical drug products. Since 2005, around 14 percent of safety labeling changes are related to black box warning additions or modifications (Generali & Paxton, 2011).

We examine the strategic reactions and approaches of pharmaceutical firms that received BBWs in comparison to the strategic reactions and approaches of pharmaceutical firms that did not over the May 2007 timeframe. We do so by examining particular oral diabetes product families, or drug products within

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[2] "Mechanism of action" refers the pharmacokinetic (e.g., chemical, biological, and physiological) properties of particular drug products.

[3] Biguanides (e.g., Glucophage) inhibit glucose production by the liver. Sulfonylureas (e.g., Amaryl, Glucotrol, Diabeta, Micronase) and meglitinides (e.g., Prandin, Starlix) increase insulin secretion by pancreatic beta cells. Thiazolidinediones (TZDs) (e.g., Actos, Avandia) increase glucose uptake by the skeletal muscle. Alpha-glucosidase inhibitors (e.g., Precose, Glyset) inhibit carbohydrate breakdown in the stomach and small intestine.

[4] The stock market's reaction to this news was not surprisingly negative for both companies. For instance, Glaxo Smith Klein's market capitalization fell by more than $14 Billion in two days.

a common platform.[5] As most of our data extend from JAN 2004 to DEC 2010, we are able to examine the pre- and post-BBW strategies and competitive reactions of BBW-affected and BBW-unaffected product families. Moreover, we are able to examine whether changes in PCPs' intent to prescribe particular product families or changes in PCPs' actual prescriptions written result from BBWs or from changes in product family sales visit and promotional strategies and competitive reactions.

### 3.1 Data

Data used in the empirical analyses come from two principle sources. Black box warnings are taken from annual study guides that tracks all BBWs issued by the FDA. These data record whether a pharmaceutical drug product received a black box warning, and if so the exact dates when this warning occurred, was modified or was rescinded.

Pharmaceutical firm sales visit and promotion data, PCP sales visit quality data, and PCP prescription writing data were obtained from ImpactRx, a market research and consulting firm based in Mount Laurel, New Jersey. These data were shared with the authors via confidentiality and non-disclosure agreements. ImpactRx outfits thousands of "high prescribing" primary care physicians with smart devices (e.g., PDAs, iPhones, etc.). PCPs use these smart devices to record each pharmaceutical rep sales visit that they participate in and each treatment (i.e., new or renewal prescription) that they write on a continuous but random basis at least two days per week. On recording days, PCPs log information electronically related to each sales visit, including the date, length of time; participation level (i.e., one- or two-way); visual aid use (e.g., paper, electronic, clinical studies); drug samples or meals offered; quality of the sales visit; among other factors. Two other variables recorded are the number of drug products detailed and the order of drug products discussed during the sales visit. These variables allow for the examination of whether pharmaceutical firms' detailing strategies—in terms of frequency and/or approach—change post-adverse event. On recording days, PCPs also log information electronically on each prescription written, including which drug product, whether it is a new or renewal prescription, patient demographics (e.g., age, gender, race), among others. We describe the specific measures in more detail immediately below.

ImpactRx closely monitors, inspects and analyzes these data to ensure accuracy and validity. PCPs whose data appear to be inaccurately recorded are dropped from the sample. Through its proprietary methodology, ImpactRx captures more than one million sales visits and three million prescriptions written annually from more than 2,000 PCPs. While we possess these proprietary data across all primary

[5] Pharmaceutical product families represent groups of products derived from a common pharmaceutical product platform. In the oral anti-diabetes market, several combination drugs that mix common diabetes medications exist. Most commonly, these combination drugs use one branded drug and one or more generic drugs.

care markets, we refine our data and analysis to the diabetes market and to the major pharmaceutical firms that compete in this market. This approach nevertheless results in more than 400,000 unique pharmaceutical rep sales visits and more than 1.3 million prescriptions written by PCPs over the sample timeframe.

The above-mentioned FDA BBW data are linked to the sales visit and promotion data and treatment data using available information on the brand and manufacturer of the drug products. We aggregate the combined data to calendar weeks over our sample window (e.g., weekly aggregated observations from JAN 2004 through DEC 2010). As described in more detail below, our dependent and independent variables are generally aggregated to—but in some cases averaged across—calendar weeks.

## 3.2 Measures

### 3.2.1 Dependent Variables

Given the hypotheses examined, several dependent variables are examined. Our first set of dependent variables capture weekly counts of sales visit and promotion strategies made by pharmaceutical firm sales representatives. We aggregate the number of sales visits made and the number of particular sales promotion strategies taken by pharmaceutical sales reps in a calendar week by product family, with the requirement that at least one diabetes product family is discussed during the sales visit.[6] These measures capture not only PCP "visits" made in a calendar week—e.g., total sales visits and unique PCP sales visits (i.e., count of unique PCPs visited)—but also the promotional strategies taken in a calendar week—e.g., single versus multiple drug details, samples or meals provided, use of visual aids, etc.

Our second dependent variable represents PCPs' "intent to prescribe" particular product families. Over the JAN 2005 to DEC 2010 period—but only for a subset (roughly 25 percent) of sales visits—ImpactRx randomly surveys PCPs to collect "sales visit quality" information, including whether the sales rep was believable, provided important or new information, was knowledgeable about the information presented, and made effective use of PCPs' time. Most germane to our study, PCPs are surveyed regarding their "intent to prescribe" a particular product family. Surveyed PCPs answer in particular the question of whether "[a]s a result of my interaction with the representative my prescribing of the drug discussed will increase or decrease," using a seven-point Likert scale. We aggregate and average these measures across PCPs by product family and by calendar week. *Rx Intent* represents the weekly average of PCPs' intent to prescribe a product family, and ranges from zero (significant intent to decrease) to seven (significant intent to increase).

[6] Between one and four drug products might be discussed during a pharmaceutical rep sales visit, which suggests that up to four distinct diabetes drug products are discussed.

Our third set of dependent variables represents weekly counts and market shares of different types of written prescriptions, disaggregated by product family. Over our entire sample, ImpactRx collects information from PCPs on the number of new and renewal (and total) written prescriptions. We aggregate these data to the calendar week for each product family. *New Rx* represents the weekly number of new diabetes written prescriptions by product family, while *Renewal Rx* represents the weekly number of renewal diabetes written prescriptions by product family. *Total Rx* represents the simple summation of new and renewal diabetes written prescriptions. Instead of examining the number of written prescriptions, product family market share measures are also examined. *New Rx Share* and *Renewal Rx Share* represent the weekly market share held by each product family using, respectively, new written prescriptions and renewal written prescriptions. *Total Rx Share* represents the weekly market share held by each product family using the weekly summation of new and renewal written prescriptions. Table 1 provides further description of the dependent variables used in our empirical analyses.

### 3.2.2 Independent Variables

We use several independent variables to capture pharmaceutical rep sales visits and promotion strategies. Comprehensive information exists on each sales visit, including the date, time and location of the sales visit; the number and sequence of drug products discussed; the minutes spent discussing each drug product; whether any visual aids were used; whether any samples or meals were provided; among other factors. Several count variables are therefore created by calendar week and at different levels of aggregation. Weekly aggregated measures are constructed by focal product family (*OF*) and by focal product class (*OC* – an aggregation of other product families with equivalent mechanisms of action). Equivalent measures are also constructed by rival product families (*RF*) and by rival product classes (*RC* – an aggregation of other product families with different mechanisms of action than the focal product class). We describe these variables in more detail immediately below.

Measures are created that represent the weekly number of pharmaceutical rep sales visits made by the focal product family and focal product class. Equivalent measures are created to capture the weekly number of pharmaceutical rep sales visits made by rival product families and rival product classes. Measures are also created that represent the weekly number of unique doctor visits made by pharmaceutical sales reps during the calendar week. This variable examines whether pharmaceutical firms take broad or narrow strategic approaches to sales visits. The data are aggregated weekly to the product family and product class categories, and by focal and rival classifications.

Pharmaceutical firms use a variety of strategic and promotional approaches in their sales visits, including detailing single or multiple drug products, using visual aids, providing meals or samples, engaging in one- or two-way communication, among others. In terms of strategic approaches,

pharmaceutical reps discuss up to four distinct drug products during the sales visits. The drug products discussed might target the same disease—and thus represent direct substitutes—or might fall across multiple disease groups and/or therapeutic areas. Our data provide the number of drug products discussed (i.e., details) for each sales visit and the number of minutes spent on each drug product. We capture the total number of details made in a calendar week at the focal product family and focal product class. Equivalent measures capture the weekly number of details made by rival product families and rival product classes. These measures are highly correlated with their respective sales visit measures.

We create several variables that disaggregate the sales visit information into fine-grained categories. Variables that represent the number of single-detail sales visits (i.e., sales visits where only a single [diabetes] drug is discussed), multi-detail sales visits (i.e., sales visits where more than one drug [and at least one diabetes drug] is discussed), multi-detail single-diabetes sales visits (i.e., sales visits where more than one drug [and at most one diabetes drug] is discussed), and multi-detail multi-diabetes sales visits (i.e., sales visits where more than one drug [and at least two diabetes drugs] is discussed) are created. Variables are created that capture the number of minutes spent detailing each drug during each pharmaceutical rep sales visit. We create weekly totals and weekly sales visit averages of minutes detailing diabetes product families, non-diabetes product families, and in total. Variables are created that capture whether visual aids were utilized during the sales visits, either in paper form, in electronic form, or in clinical study form. We again create weekly totals of sales visits where no visual aids, paper visual aids, electronic visual aids and clinical study visual aids are utilized. Variables are created that capture whether meals or samples were provided during the sales visit. Pharmaceutical firms often use meals *ex-ante* to gain access to PCPs, and use samples *ex-post* to leave favorable impressions with PCPs. We create weekly totals of sales visits where meals and samples are provided. Most of the independent variables exist by product family and product class categories, and by focal and rival classifications.

Several indicator variables are used to control for unobserved factors that vary either across product families or across time. Product family indicator variables are used to control for potential group, class or firm differences. Time indicator variables are used for each sample week (JAN 2004-DEC 2010, inclusive) and for specific calendar months (JAN-DEC) to control for potential temporal differences. Indicator variables also denote product families that do and do not receive a BBW and the calendar time that the BBW occurred. The BBW indicator variables are interacted with a variety of independent variables in several empirical estimations. Table 1 provides further description of the independent variables used in the empirical estimations. The descriptions provided are general, but are meant to apply across the product family and product class categories and across the focal and rival classifications.

--- Insert Table 1 here ---

### 3.3 Summary Statistics[7]

Table 2 provides descriptive statistics of the dependent and independent variables, separated by product family and product class categories and by rival product family and rival product class classifications. The average diabetes product family has roughly five percent market share, the average pharmaceutical firm has around eight percent market share, and the average product class has about ten percent market share. Substantial heterogeneity exists in new and total written prescriptions counts and market share. Renewal written prescriptions (the difference between total and new written prescriptions) represent the largest portion of overall written prescriptions. Pharmaceutical firms take different sales and promotion strategies, as substantial heterogeneity exists across unique doctor visits; sales visits; promotion approaches (e.g., single- versus multi-details; provision of meals, visual aids and samples); and emphasis and approach (i.e., diabetes- versus non-diabetes-focused details and minutes spent).

Table 3 provides descriptive statistics of the dependent and independent variables, separated by BBW-affected and BBW-unaffected product families and by pre-BBW and post-BBW time. The average BBW-affected product family not surprisingly sees declines in prescription intent and written prescriptions counts and market share from pre-treatment to post-treatment, while the opposite is true for the average BBW-unaffected product family. Different sales visit and promotion strategies are also observed, between BBW-affected and BBW-unaffected product families and across treatment time. While illustrative, these descriptive statistics empirical support and refute our hypotheses.

--- Insert Tables 2 and 3 here ---

## 4 EMPIRICAL RESULTS

### 4.1 Econometric Methods

Given the set of questions addressed, they hypotheses examined and the dependent variables used, several econometric models are employed in the empirical analyses. The first set of dependent variables captures pharmaceutical firms' strategic approaches and competitive reactions to the issuance of black box warnings. As we compare a treatment group (BBW-affected product families) to a control group (BBW-unaffected product families), we utilize "difference-in-difference" estimation. The second dependent variable captures PCPs' average intent to prescribe particular product families. We utilize fixed-effects linear regression models, as they are appropriate for cross-sectional time-series data.[8] Our third set of dependent variables captures the counts of new written prescriptions by PCPs across product families per

[7] The Table 2 and 3 descriptive statistics are based on weekly averages of 25 diabetes product families across 16 pharmaceutical firms and over the JAN 2005 to DEC 2010 time period (364 distinct calendar weeks).

[8] The Stata command xtreg (with robust standard errors) is utilized for the linear regression model estimations.

calendar week. Given the nature of these data, we employ fixed-effects Poisson model regression estimation.[9] The majority of the independent variables enter into the estimations in natural log form.

### 4.2 Promotion Strategy Approach Results

We take a difference-in-differences (DiD) empirical approach to assess the impact of a BBW on the sales visit and promotion strategies of BBW-affected product families in comparison to BBW-unaffected product families. The DiD approach "differences out" fixed differences between treatment group and control group product families. Post-treatment changes in sales visit and promotion strategies by BBW-unaffected product families are used as a counterfactual for what would have happened to BBW-affected product families.

Gertler et al. (2011) indicate that the DiD approach is one of the most widely used statistical methodologies in social sciences. The DiD approach fortunately does not require that the treatment and control groups are the same, which is not the case in our empirical setting. Nor does the DiD approach require random assignment of treatment across groups, which is the case in our empirical setting as the treatment is exogenously assigned by the FDA to particular product families based upon mechanism of action.[10] We use a standard DiD specification to estimate the impact of the black box warnings on several sales visit and promotion strategy variables:

$$Y_{it} = \alpha_i + \beta_1 \cdot BBWPF_i + \beta_2 \cdot BBWT_t + \beta_3 \cdot BBWPF_i \bullet BBWT_t + \gamma_t + \varepsilon_{it}$$

where $Y_{it}$ represents the set of sales visit and promotion strategy approach variables, $BBWPF_i$ is an indicator variable equal to one if the product family (or families) received a BBW and zero otherwise, $BBWT_t$ is an indicator variable equal to one for all dates post-BBW and zero otherwise, and $BBWPF_i \bullet BBWT_t$ is the interaction of the indicator variables. This specification takes advantage of the panel nature of the data by introducing a full set of fixed effects. In particular, $\alpha_i$ represents product family fixed effects and accounts for unobserved heterogeneity across these categories and $\gamma_t$ represents time fixed effects and accounts for unobserved heterogeneity across both individual year-weeks and calendar months. With product family and time fixed effects included in the specifications, the *BBWPF* and *BBWT* indicator variables are both absorbed. We vary slightly from the standard DiD specification by creating interaction terms for each product family affected by a black box warning in our estimations below.

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[9] The Stata command xtpqml—a wrapper for the xtpoisson command that provides robust standard errors—is used for the Poisson model regressions estimations.

[10] Most BBWs are applied to all members of a given product class ("class-wide fashion."), which is defined on the basis of mechanism of action (Panagiotou, Papanikolaou, Ntzani, & Ioannidis, 2011) .

Table 4 provides the DiD results, using a variety of sales visit and promotion strategy variables. Each model includes product family, individual year-week and calendar month fixed effects, as well as robust standard errors adjusted for clustering (by product family). Results are shown for each variable using a single treatment group (i.e., a single interaction term for all BBW-affected product families) and using disaggregated treatment groups (i.e., separate interaction terms for each BBW-affected product family). The *BBW* variables represent the interaction between treatment group (i.e., BBW-affected product family or families) and treatment time (i.e., post- BBW dates).

Table 4 reveals several interesting results. The aggregate treatment group is generally statistically insignificant across all estimations. When the treatment group is disaggregated by product family, however, markedly different results obtain. In terms of sales visits and relative to BBW-unaffected product families, the Actos (Takeda) product family significantly increases sales visits ($p<0.01$) and single-detail sales visits ($p<0.01$) and decreases slightly multi-detail sales visits ($p<0.01$). At the same time, the Avandia (GSK) product family decreases substantially sales visits ($p<0.01$), single-detail sales visits ($p<0.01$), multi-detail sales visits ($p<0.01$) and unique doctor visits ($p<0.01$). In short, the two adverse event-affected product families implement vastly different sales visit strategies post-BBW. In terms of promotional strategies, the Actos product family provides more samples ($p<0.01$), meals ($p<0.01$), electronic visual aids ($p<0.01$) and clinical study visual aids ($p<0.01$), relative to product families not receiving a black box warning. At the same time, the Avandia product family provides less samples ($p<0.01$), meals ($p<0.01$), paper visual aids ($p<0.01$) and clinical study visual aids ($p<0.01$), relative to BBW-unaffected product families. Again, the BBW-affected product families take vastly different sales and promotional approach strategies post-BBW, relative to each other and relative to adverse event-unaffected pharmaceutical firms.

Consistent with hypothesis H1, the strategic and competitive approaches of affected and unaffected product families substantially differ following the issuance of a black box warning. The Actos product family increases its sales visit and promotion activity, while the Avandia product family decreases its activity. This finding provides only moderate support for hypothesis H2. An interesting and important question then is why these two product families (or pharmaceutical firms) undertook completely opposite strategies when confronted with an adverse regulatory event. We offer some explanation as to why this might have occurred in the final section.

--- Insert Table 4 here ---

### 4.3 Intent to Prescribe Results

We first implement a difference-in-differences (DiD) model to assess the impact of BBWs on PCPs' intent to prescribe affected product families versus unaffected product families:

$$Y_{it} = \alpha_i + \beta_1 \cdot BBWPF_i + \beta_2 \cdot BBWT_t + \beta_3 \cdot BBWPF_i \square BBWT_t + \gamma_t + \varepsilon_{it}$$

where $Y_{it}$ represents PCPs' average weekly intent to prescribe and the other variables are defined as described above. We next implement fixed effect linear regression models to assess the impact of sales visit and promotion strategies on PCPs' intent to prescribe, accounting for BBW-affected versus BBW-unaffected firms via interaction terms:

$$Y_{it} = \alpha_i + \beta_0 + \beta_1 \cdot OF_{it} + \beta_2 \cdot OC_{it} + \beta_3 \cdot RC_{it} + \beta_3 \cdot OF_{it} \cdot BBWT_t + \beta_4 \cdot OF_{it} \cdot BBWT_t \cdot BBWPF_i + \gamma_t + \varepsilon_{it}$$

where $Y_{it}$ represents PCPs' average weekly intent to prescribe, $OF_{it}$, $OC_{it}$ and $RC_{it}$ represent, respectively, measures of own-product family, own-class and rival-class sales visit and promotion strategies. The first interaction term captures the post-BBW effect of own product family sales visit and promotion strategies on average intent to prescribe, while the second interaction term captures the effect of post-BBW own product family sales visits and promotion strategies for treatment-affected product families on average intent to prescribe.

In both empirical approaches, we again take advantage of the panel nature of the data and introduce a full set of fixed effects. We also use separate product family treatment interaction terms in some estimations. Table 4 provides the DiD and fixed effects linear regression results using the weekly average of PCPs' intent to prescribe as the dependent variable. Each model in Table 4 includes product family, individual year-week and calendar month fixed effects, with robust standard errors adjusted for clustering (by product family). In the DiD estimation, results are provided using a single treatment group (i.e., a single interaction for all BBW-affected product families) and disaggregated treatment groups (i.e., separate interactions for each BBW-affected product family). In the fixed effect linear regression models, results are provided using aggregate product family and disaggregated product family interaction terms.

The first column of Table 5 provides the DiD regression results. The aggregate product family treatment group is statistically insignificant. When separate product family treatment groups are included, however, the Avandia product family treatment is negative and statistically significant ($p < 0.01$) while the Actos product family treatment is also negative but not statistically significant. These results suggest that the Avandia product family took a substantial hit in terms of PCPs' intent to prescribe post-BBW.

The second through eighth columns of Table 5 provide the fixed effect linear regression results. Given columns three through eight of Table 5 are variants of column two (sales visits), we focus our

discussion on column two to ease explication. The results indicate own product family sales visit decrease PCPs' intent to prescribe ($p$<0.01)—a somewhat surprising result. Own class (i.e., other product families with equivalent mechanisms of action) sales visits similarly decrease PCPs' intent to prescribe ($p$<0.05)—a more expected result. Finally, the effect of rival class (i.e., other product families with different mechanisms of action) sales visits on intent to prescribe is statistically insignificant. The effect of the interaction terms on PCPs' intent to prescribe is interesting, although interpretation difficulties increase given the two- and three-way interactions present. In any event, the effect of own product family sales visits post-BBW is positive and moderately statistically significant ($p$<0.10), suggesting all product families benefit from increased sales visits in terms of PCPs intent to prescribe. However, BBW-affected product families are made worse off post-BBW in terms of PCPs intent to prescribe from increased sales visits. The effect of own product family sales visits for these product families post-treatment is negative and statistically significant ($p$<0.05). The results further indicate that the Avandia product family is most affected in comparison to the Actos product family in terms of PCPs' intent to prescribe.

Taken together, these results do not support hypothesis H3 but provide support for hypothesis H4. Increased sales visit and promotion activity following a black box warning benefits BBW-unaffected firms in terms of intent to prescribe, while harms BBW-affected firms. We recognize that PCPs' intent to prescribe is not the same thing as PCPs' actual written prescriptions, and therefore turn to just such an analysis.

--- Insert Table 5 here ---

### 4.4 New Written Prescription Results

We take an identical empirical approach to examining actual prescriptions written by PCPs, in comparison to PCPs' prescription intent. We first implement a difference-in-differences (DiD) model to assess the impact of BBWs on PCPs' new written prescriptions:

$$Y_{it} = \alpha_i + \beta_1 \cdot BBWPF_i + \beta_2 \cdot BBWT_t + \beta_3 \cdot BBWPF_i \square BBWT_t + \gamma_t + \varepsilon_{it}$$

where $Y_{it}$ represents weekly counts of new written prescriptions and the other variables are defined as described above. We next implement fixed effect negative binomial regression models to assess the impact of sales visit and promotional approach strategies on PCPs' new written prescriptions, accounting for BBW-affected versus BBW-unaffected firms via interaction terms:

$$Y_{it} = \alpha_i + \beta_0 + \beta_1 \cdot OF_{it} + \beta_2 \cdot OC_{it} + \beta_3 \cdot RC_{it} + \beta_3 \cdot OF_{it} \cdot BBWT_t + \beta_4 \cdot OF_{it} \cdot BBWT_t \cdot BBWPF_i + \gamma_t + \varepsilon_{it}$$

where $Y_{it}$ represents weekly counts of new written prescriptions and the other variables are defined as described above.

Table 6 uses counts of new written prescriptions by product family as the dependent variable, given these types of prescriptions are considered to represent the most accurate measure of growth potential. New written prescriptions take into account new patient starts, existing patient add-on therapies (e.g., combination drugs), and existing patient switches (i.e., substitute or replacement therapies). We also utilize the market share of new written prescriptions and the number of total written prescriptions (new and renewal) as other dependent variables to determine whether any changes to the base case estimation results obtain and to demonstrate empirical robustness.

The first column of Table 6 provides the DiD regression results. The aggregate product family treatment group is again statistically insignificant. But when separate product family treatment groups are included, the Avandia product family treatment is negative and statistically significant ($p < 0.01$) and the Actos product family treatment is negative but not statistically significant. These results suggest that the Avandia product family saw large and significant reductions in new written prescriptions post-BBW across the PCPs in our sample.

The second through eighth columns of Table 6 provide the fixed effect negative binomial regression results. We again focus our discussion on column two (overall sales visits) to ease explication. The results indicate own product family sales visit increase new written prescriptions ($p < 0.01$), while own class sales visits decrease new written prescriptions for the focal product family ($p < 0.05$)—both of which are as expected. The effect of rival class sales visits on new written prescription counts is statistically insignificant across all models.

Consistent with hypothesis 2a and 2b, the net effect of own product family sales visits post-BBW is positive and statistically significant ($p<0.05$), suggesting BBW-unaffected product families benefit from increased sales visits on new written prescriptions post-BBW. BBW-affected product families do not share in these benefits, however, as the negative coefficient for the BBW-affected families effectively cancels out the positive effect of own family sales visits post-BBW. While the effectiveness of sales visits for BBW-affected product families do not decline following a BBW warning—as expected from hypothesis 2—they do much more poorly than other BBW-affected firms. The effect of own product family sales visits for these BBW-affected product families post-BBW is negative and moderately statistically significant ($p<0.10$). The results also indicate that the effect of own product family sales visits post-BBW is negative and statistically significant ($p<0.01$) for the Actos product family and negative and statistically significant ($p<0.01$) for the Avandia product family. This negative effect is substantially larger, however, for the Avandia product family in comparison to the Actos product family.

The Table 6 results overall do not proffer support for hypothesis H3 but do so for hypothesis H4. Increased sales visit and promotion activity following a black box warning benefits BBW-unaffected

firms in terms of new written prescriptions, while this same activity is generally harmful for BBW-affected firms. We discuss possible reasons why the effects are different for Avandia and Actos in the final section.

--- Insert Table 6 here ---

### 4.5 Economic Significance

The two- and three-way interactions create interpretation difficulties of the empirical results. We create several figures to better illustrate some of the main empirical findings. We utilize the Table 6 results using new written prescriptions as the dependent variable and sales visits (as well as the product family and time BBW interactions) as the independent variable. Figure 1 plots the multiplicative effect of sales visits on new written prescriptions, disaggregated by BBW-affected and BBW-unaffected product families and pre-BBW and post-BBW time. This figure clearly indicates that—relative to pre-BBW product family sales visits—BBW-unaffected product family sales visits substantially increase new written prescriptions post-BBW, while BBW-affected product family visits substantially decrease new written prescriptions post-BBW. Figure 2 recasts Figure 1 by showing the percentage changes of these effects, but corroborates the same basic results.

Figure 3 disaggregates the BBW-affected firms into separate treatment groups, showing the effects of sales visits by the Actos product family and the Avandia product family on new written prescriptions. Relative to pre-BBW product family sales visits, BBW-unaffected product family sales visits substantially increase new written prescriptions via increased sales visits post-BBW. The Actos product family is able to maintain new written prescriptions via increased sales visits post-BBW, however, at roughly the same rate as pre-BBW product family sales visits. The Avandia product family suffers substantial new written prescription losses post-BBW via increased sales visits. Figure 4 recasts Figure 3 by showing the percentage changes of these effects.

--- Insert Figures 1-4 here ---

### 4.6 Robustness Tests

Table 7 presents several empirical robustness tests. The first four columns address concerns regarding the time window around the treatment event, as it can be argued that sales visit and/or promotion strategies or prescription intent and new written prescription outcomes become muted after a sufficient length of time post-BBW. As our data is inclusive over JAN 2004-DEC 2010, we rerun several analyses on subsamples that encompass plus-or-minus one year time windows around the BBW (occurring in MAY 2007). Column one uses a DiD approach and linear regression estimation using PCPs intent to prescribe, and

indicates BBW-affected product families take a substantial—albeit moderately statistically significant ($p$<0.10)—hit up to one year post-BBW. This negative effect is larger moreover for the Avandia product family ($p$<0.10). Column two uses a DiD approach and count model estimation on new written prescription counts, and indicates BBW-affected product families are no worse off than BBW-unaffected firms up to one year post-BBW. A disaggregation of BBW-affected product families does indicate the Actos product family increases new written prescription counts ($p$<0.01), while the Avandia product family decreases new written prescription counts ($p$<0.01) up to one year post-BBW. Column three uses linear regression estimation of PCPs' intent to prescribe, and indicates BBW-affected product families are made moderately worse off up to one year post-BBW via sales visits. These negative effects are most severe for the Avandia product family. Column four uses linear regression estimation of new written prescriptions, and indicates BBW-affected product families are made no worse than BBW-unaffected product families via pharmaceutical rep sales visits impact on new written prescriptions up to one year post-BBW. However, the disaggregation of BBW-affected product families indicates additional sales visits actually increase new written prescriptions for the Actos product family ($p$<0.01) and substantially decrease new written prescriptions for the Avandia product family ($p$<0.01).

As the data include all types (new, renewal and total) of written prescriptions, as well as market share measures of written prescriptions, the next four columns examine whether changes in the results obtain using alternative dependent variables. Column five uses a DiD approach and count model estimation on total (new and renewal) written prescriptions, and indicates BBW-affected product families are not impacted more than BBW-unaffected product families in terms of total written prescription counts post-BBW. Disaggregating BBW-affected product families indicates that the Avandia product family incurs substantial losses in post-BBW total written prescription counts. Column six uses count model estimation on total written prescriptions, and indicates BBW-affected product families are negatively impacted in comparison to BBW-unaffected product families in terms of post-BBW total written prescription counts. The disaggregation of BBW-affected product families shows, moreover, that the Actos and Avandia product families lose substantial post-BBW total written prescription counts. Somewhat interesting in these results is the increase in post-BBW total written prescriptions, and the statistically insignificant effects of own firm, own class and rival sales visits on total written prescriptions. Column seven uses a DiD approach and linear regression estimation on new written prescription market share, and indicates BBW-affected product families are negatively impacted in post-BBW new written prescription market share. Disaggregating BBW-affected product families demonstrates that the Actos and Avandia product families both experience losses in post-BBW new written prescription market share. Finally, Column eight uses linear regression estimation on new written prescription market share, and indicates BBW-affected product families incur reductions in post-BBW new written prescription market

shares via increased sales visits. Disaggregating BBW-affected product families demonstrates that both the Actos and Avandia product families lose substantial post-BBW new written prescription market share via increased sales visits, with the effect much larger for the Avandia product family than the Actos product family.

--- Insert Table 7 here ---

# 5 EPILOGUE

## 5.1 Discussion

Our hypotheses suggest that primary care physicians who have prescribed more of the focal product family adversely affected by a black box warning respond by either sharply decreasing or increasing their sales representative attention via sales visit and promotion activity. Glaxo Smith Klein (GSK) substantially reduced its sales visit and promotion activity for the Avandia product family, while Takeda significantly increased its sales visit and promotion activity for the Actos product family. One possible reason for this difference is that despite both product families receiving black box warnings, the Avandia product family was the subject of a report published at nearly the same time in the *New England Journal of Medicine* that provided strong evidence that use of Avandia was linked to increased cardiac risks. Takeda may have increased its marketing for Actos in the belief that the greatest stigma would be attached to Avandia, and subsequently, GSK. For the most part, this belief was incorrect as the effectiveness of their sales visits did not increase after the black box warning except in the short term (less than one year) for new prescriptions. In general, these results suggest that the stigma associated with such an adverse event is difficult to reduce by increased sales visit and promotion activities. These results suggest that firms with stigmatized products should be wary of directly responding as it may make outcomes even worse.

Our hypotheses also suggests that when product families receive black box warnings, pharmaceutical firms often attempt to counter this negative event by increasing their own sales visit and promotion strategies. This approach may backfire, however, if unaffected rival product families simultaneously increase or alter their own sales visit and promotion strategies, for several reasons. First, sales visit and promotion activity by adverse-event affected product families increases the saliency of their own problems to PCPs, resulting in negative stigma. Second, the increased efforts by rivals' provide PCPs information on and persuasion toward potential alternatives to the adverse-event affected product families. Indeed, one of our strongest results is that promotional activities by firms that have not received black box warnings become much more effective. As a result, firms with drug products that have received black box warnings must not only be cautious in selecting their own sales visit and promotion strategies,

but also wary of rivals in how they alter their sales visit and promotion strategies. For affected pharmaceutical firms, black box warnings increase the potential for losing market share. For unaffected rival pharmaceutical firms, these black box warnings offer potentially valuable opportunities to gain market share. Consequently, black box warnings coupled with firm strategic actions and interactions create the potential to substantially reshape the competitive landscape.

## 5.2 Limitations

Several potential limitations are worth noting in the empirical setting, data and measurement constructs, and empirical approaches. We examine a single and somewhat idiosyncratic industry in pharmaceuticals. The pharmaceuticals industry is indeed unique and in several dimensions, including the emphatic use of sales reps to promote drug products to primary care physicians. While many other industries (e.g., book publishing, medical devices, etc.) also utilize sales reps to promote their products and services, the magnitude and extent of sales reps in pharmaceuticals is substantial. We also examine an industry that is uniquely and heavily regulated. While many other industries face regulatory oversight and review in their products both pre- and post-approval, the scrutiny faced by pharmaceuticals firms from the Food and Drug Administration (FDA) and other regulatory bodies is substantial. We further narrow our focus to a single therapeutic area within the pharmaceuticals industry in diabetes. While such a narrow focus potentially limits generalizability, it nevertheless allows for greater precision in our measures and a more direct link between these measures and firm performance differences. An obvious next step is to determine whether the same results obtain in other therapeutic areas. Another potential next step is to examine instances whereby BBWs affect a subset of product families within a product class as opposed to all product families within a product class. We leave both of these exercises to future research.

The sales visits and promotional strategy, sales visit quality, and prescription writing data used comes from a market research firm that outfits thousands of PCPs. While ImpactRx closely monitors, inspects and analyzes these data to ensure accuracy and validity, our empirical analysis is based on“high-prescribing” PCPs who write more prescriptions than the “average” PCP. While bias might be present, the ImpactRx PCPs are nevertheless the target market that most pharmaceutical firms would pursue in terms of sales rep visits and promotions.

Our independent variables represent calendar week counts or averages of different sales visit and promotion strategies. As these variables are generally highly correlated with each other, we implement separate empirical estimations to tease out their distinct performance effects. Potential alternative constructs might include cumulative (and/or discounted) measures, given sales visit and promotional

strategies might require recent and/or repetitive visits with PCPs to effect intent to prescribe and actual prescription writing behaviors.

While it is not surprising adverse events negatively impact affected product families' marketplace stature, subsequent new prescriptions written and resulting market shares, the effects of a BBW might extend beyond the focal product family and potentially impact pharmaceutical firms' entire drug product portfolios. In short, PCPs might be more "put off" by pharmaceutical firms that face a plethora of BBWs across their various product families, and consequently discipline these pharmaceutical firms through reduced prescription writing across these drug portfolios. We recognize and identify this potential as an interesting research question, but table it for future research.

We use difference-in-difference (DiD) estimation to examine differences between adverse event-affected product families (i.e., the treatment group) and adverse event-unaffected product families (i.e., the control group) and between pre-treatment and post-treatment. We use this estimation approach not only for sales visit and promotion strategies, but also PCP-related outcomes such as intent to prescribe and prescription writing. While DiD estimation controls for time-invariant differences between the treatment and comparison groups, it does not eliminate time-varying differences between treatment and comparison groups (Gertler et al., 2011). We assume that no time-varying differences exist between treatment and control groups, but recognize the inherent difficulties and potential frailties in such claims.

We used fixed effects linear regression and count model estimation to tease out the effect of sales visit and promotion strategies on PCPs' intent to prescribe and actual prescription writing behavior. To do this, several two- and three-way interactions are implemented to tease out differences between adverse event-affected and adverse event-unaffected product families and by pre-treatment and post-treatment time. We recognize the interpretation difficulties associated with multiple interactions across these models. While we also utilize figures to demonstrate the economic significance of these results, other approaches might be considered as more effective.

## 5.3 Conclusion

This paper utilizes a natural experiment in the pharmaceutical industry to examine the strategic responses of firms and their rivals, as well as the performance outcomes that subsequently obtain. The natural experiment is the issuance of a "black box warning" (BBW) to a subset of firms that compete in the oral diabetes market. Black box warnings are indications that affected firms' drug products have undesirable characteristics (e.g., safety, side effects, drug interactions) based on post-market surveillance studies.

We examine empirically the strategic and competitive responses of firms and their rivals using a combination of publicly-available FDA data on BBWs and proprietary-level data on the sales visit and

promotion strategies of pharmaceutical firms and prescription (Rx) writing behavior of primary care physicians (PCPs). We find that adverse-event affected pharmaceutical firms act strategically by altering their sales visit and promotion strategies—in terms of frequency and approach—in attempts to reduce any marketplace stature losses or written prescription market share losses. But we also find that adverse event-unaffected firms change their sales visit and promotion strategies when their rivals face adverse regulatory events, and that their subsequent promotional activities have stronger positive effects on marketplace stature and prescription writing following the black box warning. In short, BBW-affected firms take strategic actions to mitigate losses, while BBW-unaffected firms take similar strategic actions to reinforce their rivals' losses (and thereby gain by doing so).

We add to the competitive dynamics stream of strategy research, which emphasizes head-to-head rivalry and competitive interaction between and among marketplace participants (Grimm & Smith, 1997). While this research stream has demonstrated a causal link between competitive actions and responses and subsequent performance (Ferrier et al., 1999; Young et al., 1996), empirical tests have arguably lagged. A major challenge in studying competitive interaction is objectively identifying competitive actions and responses, including delineating a "market" into a rigid well-defined boundary, identifying competitors within that boundary, and detailing the actions and responses of competitors over a sufficiently long time horizon. Much of the competitive dynamics literature not surprisingly relies on a structured content analysis approach that categorizes news headlines of selected firms from various publication sources into "competitive action events" (Ferrier et al., 1999; Ferrier, 2001). Such an approach admittedly presents potential concerns, including ex-post rationalization, insufficient rigor and/or accuracy, or lack of completeness, among others. We are able to at least partially overcome some of these concerns through the natural experiment that occurs in the pharmaceutical industry and the detailed data on competitive actions and responses that we possess. We are also able to show how competitive actions and responses are affected by adverse regulatory events. In particular, we document how different types of firms react to regulatory decisions and actions in different ways and the effects that adverse regulatory events and competitive actions and responses have on subsequent performance.

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## Table 1 – Variable Definitions

| **DEPENDENT VARIABLES** | **DESCRIPTION** |
|---|---|
| *Rx Intent* | Average of intent to prescribe product family per week |
| *New Rx* | Count of product family new written prescriptions per week |
| *Total Rx* | Count of product family total (new and renewal) written prescriptions per week |
| *New Rx Share* | Market share of product family new written prescriptions per week |
| *Total Rx Share* | Market share of product family total (new and renewal) written prescriptions per week |
| **INDEPENDENT VARIABLES** | **DESCRIPTION** |
| *Doctor Visits* | Count of unique doctor visits made per week |
| *Sales Visits* | Count of sales visits made per week |
| *SD Sales Visits* | Count of single-detail sales visits (one diabetes drug detailed) per week |
| *MD Sales Visits* | Count of multi-detail sales visits (≥ one diabetes drug detailed) per week |
| *MD SD Sales Visits* | Count of multi-detail single-diabetes sales visits ((≥ one drug but only one diabetes drug detailed) per week |
| *MD MD Sales Visits* | Count of multi-detail multi-diabetes sales visits ((≥ one drug and ≥ one diabetes drug detailed) per week |
| *SV Minutes* | Count of total sales visit minutes per week |
| *DSV Minutes* | Count of diabetes sales visit minutes per week |
| *N-DSV Minutes* | Count of non-diabetes sales visit minutes per week |
| *AVG SV Minutes* | Average of sales visit minutes per week |
| *AVG DSV Minutes* | Average of diabetes sales visit minutes per week |
| *AVG N-DSV Minutes* | Average of non-diabetes sales visit minutes per week |
| *No Visual Aids* | Count of sales visits with no visual aids per week |
| *Paper Visual Aids* | Count of sales visits with paper visual aids per week |
| *Electronic Visual Aids* | Count of sales visits with electronic visual aids per week |
| *Clinical Study Visual Aids* | Count of sales visits with clinical study visual aids per week |
| *Meals* | Count of sales visits with meals provided per week |
| *Samples* | Count of sales visits with samples provided per week |
| *One-Way Participation* | Count of sales visits with one-way rep-PCP communication per week |
| *Two-Way Participation* | Count of sales visits with two-way rep-PCP communication per week |
| *BBW Family* | Indicator that the product family received a black box warning |
| *BBW Firm* | Indicator that the pharmaceutical firm received a black box warning |
| *BBW Time* | Indicator of the calendar week that the black box warning occurred |
| *Year-Week* | Indicator of the calendar year-week |
| *Family* | Indicator of the oral diabetes product family |
| *Firm* | Indicator of the pharmaceutical firm |

## Table 2 – Summary Statistics (Focal vs. Rival Product Families/Classes)

| | *FOCAL PRODUCT FAMILY* | | | | *FOCAL PRODUCT CLASS* | | | |
|---|---|---|---|---|---|---|---|---|
| | **MEAN** | **ST DEV** | **MIN** | **MAX** | **MEAN** | **ST DEV** | **MIN** | **MAX** |
| Rx Intent | 5.14 | 0.48 | 1.00 | 7.00 | 5.13 | 0.33 | 1.00 | 7.00 |
| New Rx | 26.02 | 37.23 | 0.00 | 228.00 | 55.16 | 43.04 | 0.00 | 179.00 |
| Total Rx | 167.69 | 238.32 | 0.00 | 1455.00 | 397.84 | 307.40 | 0.00 | 979.00 |
| New Rx Market Share | 0.05 | 0.07 | 0.00 | 0.35 | 0.10 | 0.07 | 0.00 | 0.25 |
| Total Rx Market Share | 0.05 | 0.06 | 0.00 | 0.35 | 0.11 | 0.08 | 0.00 | 0.26 |
| | | | | | | | | |
| Doctor Visits | 52.33 | 76.91 | 0.00 | 500.00 | 153.24 | 198.61 | 0.00 | 774.00 |
| Sales Visits | 44.20 | 68.86 | 0.00 | 519.00 | 126.29 | 164.95 | 0.00 | 640.00 |
| SD Sales Visits | 31.92 | 52.98 | 0.00 | 474.00 | 90.59 | 121.10 | 0.00 | 492.00 |
| MD Sales Visits | 12.28 | 18.97 | 0.00 | 127.00 | 35.70 | 46.04 | 0.00 | 180.00 |
| MD-SD Sales Visits | 5.99 | 12.97 | 0.00 | 93.00 | 11.17 | 16.07 | 0.00 | 93.00 |
| MD-MD Sales Visits | 6.29 | 10.03 | 0.00 | 66.00 | 24.53 | 34.76 | 0.00 | 135.00 |
| Meals | 8.55 | 14.65 | 0.00 | 158.00 | 25.89 | 35.92 | 0.00 | 154.00 |
| No Visual Aids | 16.97 | 26.75 | 0.00 | 178.00 | 47.91 | 63.66 | 0.00 | 273.00 |
| Electronic Visual Aids | 1.63 | 4.78 | 0.00 | 55.00 | 4.29 | 9.53 | 0.00 | 69.00 |
| Paper Visual Aids | 22.97 | 37.92 | 0.00 | 406.00 | 66.99 | 92.74 | 0.00 | 409.00 |
| Clinical Study Visual Aids | 4.31 | 8.84 | 0.00 | 174.00 | 11.90 | 17.25 | 0.00 | 174.00 |
| Samples | 31.90 | 57.68 | 0.00 | 385.00 | 94.87 | 140.20 | 0.00 | 536.00 |
| SV Minutes | 214.93 | 342.34 | 0.00 | 3201.00 | 633.47 | 844.01 | 0.00 | 3420.50 |
| DSV Minutes | 194.00 | 312.23 | 0.00 | 3073.33 | 592.69 | 801.29 | 0.00 | 3253.23 |
| N-DSV Minutes | 20.94 | 46.35 | 0.00 | 353.90 | 40.78 | 60.05 | 0.00 | 353.90 |
| AVG SV Minutes | 4.90 | 2.44 | 0.50 | 20.00 | 4.90 | 1.56 | 0.50 | 20.00 |
| AVG DSV Minutes | 4.43 | 2.39 | 0.10 | 20.00 | 4.45 | 1.52 | 0.20 | 20.00 |
| AVG N-DSV Minutes | 0.48 | 0.89 | 0.00 | 16.00 | 0.45 | 0.69 | 0.00 | 13.00 |
| One-Way Participation | 21.44 | 33.35 | 0.00 | 224.00 | 60.65 | 79.08 | 0.00 | 305.00 |
| Two-Way Participation | 22.76 | 35.98 | 0.00 | 334.00 | 65.64 | 86.38 | 0.00 | 364.00 |
| | *RIVAL PRODUCT FAMILIES* | | | | *RIVAL PRODUCT CLASSES* | | | |
| | **MEAN** | **ST DEV** | **MIN** | **MAX** | **MEAN** | **ST DEV** | **MIN** | **MAX** |
| Doctor Visits | 807.30 | 569.29 | 0.00 | 1914.00 | 654.06 | 485.88 | 0.00 | 1912.00 |
| Sales Visits | 801.35 | 564.70 | 0.00 | 1932.00 | 675.06 | 491.22 | 0.00 | 1930.00 |
| SD Sales Visits | 494.82 | 367.90 | 0.00 | 1348.00 | 404.23 | 314.34 | 0.00 | 1347.00 |
| MD Sales Visits | 306.53 | 209.74 | 0.00 | 711.00 | 270.83 | 189.24 | 0.00 | 711.00 |
| MD-SD Sales Visits | 201.87 | 141.47 | 0.00 | 503.00 | 190.70 | 134.93 | 0.00 | 503.00 |
| MD-MD Sales Visits | 104.66 | 76.26 | 0.00 | 280.00 | 80.12 | 64.64 | 0.00 | 280.00 |
| Meals | 166.47 | 128.13 | 0.00 | 447.00 | 140.58 | 112.11 | 0.00 | 446.00 |
| No Visual Aids | 309.17 | 220.54 | 0.00 | 732.00 | 261.26 | 191.93 | 0.00 | 731.00 |
| Electronic Visual Aids | 30.28 | 49.33 | 0.00 | 252.00 | 25.99 | 42.90 | 0.00 | 252.00 |
| Paper Visual Aids | 415.58 | 308.84 | 0.00 | 1086.00 | 348.59 | 267.63 | 0.00 | 1086.00 |
| Clinical Study Visual Aids | 76.86 | 65.22 | 0.00 | 333.00 | 64.96 | 57.37 | 0.00 | 332.00 |
| Samples | 596.14 | 553.06 | 0.00 | 1636.00 | 501.26 | 477.87 | 0.00 | 1636.00 |
| SV Minutes | 4101.14 | 2972.23 | 0.00 | 10564.00 | 3467.67 | 2595.87 | 0.00 | 10559.00 |
| DSV Minutes | 3377.31 | 2500.22 | 0.00 | 8789.73 | 2784.62 | 2152.54 | 0.00 | 8784.73 |
| N-DSV Minutes | 723.83 | 520.24 | 0.00 | 1814.83 | 683.05 | 495.15 | 0.00 | 1814.83 |
| AVG SV Minutes | 5.07 | 0.37 | 3.70 | 6.28 | 5.09 | 0.38 | 3.71 | 6.52 |
| AVG DSV Minutes | 4.14 | 0.42 | 2.77 | 5.37 | 4.04 | 0.43 | 2.70 | 5.87 |
| AVG N-DSV Minutes | 0.93 | 0.26 | 0.23 | 1.84 | 1.05 | 0.30 | 0.24 | 2.18 |
| One-Way Participation | 384.87 | 271.33 | 0.00 | 919.00 | 324.22 | 235.98 | 0.00 | 918.00 |
| Two-Way Participation | 416.48 | 294.90 | 0.00 | 1082.00 | 350.84 | 256.62 | 0.00 | 1080.00 |

## Table 3 – Summary Statistics (Treatment vs. Control Product Families)

| UNAFFECTED PRODUCT FAMILIES | *PRE-BLACK BOX WARNING* | | | | | *POST-BLACK BOX WARNING* | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **OBS** | **MEAN** | **ST DEV** | **MIN** | **MAX** | **OBS** | **MEAN** | **ST DEV** | **MIN** | **MAX** |
| Rx Intent | 1198 | 5.22 | 0.58 | 2.00 | 7.00 | 2248 | 5.12 | 0.46 | 1.00 | 7.00 |
| New Rx | 3334 | 19.39 | 31.33 | 0.00 | 213.00 | 3935 | 24.38 | 39.26 | 0.00 | 228.00 |
| Total Rx | 3334 | 135.21 | 208.72 | 0.00 | 1074.00 | 3935 | 153.13 | 255.50 | 0.00 | 1455.00 |
| New Rx SoM | 3334 | 0.04 | 0.06 | 0.00 | 0.35 | 3935 | 0.04 | 0.06 | 0.00 | 0.33 |
| Total Rx SoM | 3334 | 0.04 | 0.06 | 0.00 | 0.29 | 3935 | 0.04 | 0.07 | 0.00 | 0.35 |
| Doctor Visits | 3334 | 27.09 | 46.68 | 0.00 | 472.00 | 3935 | 49.73 | 74.79 | 0.00 | 390.00 |
| Sales Visits | 3334 | 21.20 | 40.07 | 0.00 | 519.00 | 3935 | 42.42 | 67.28 | 0.00 | 377.00 |
| SD Sales Visits | 3334 | 14.67 | 31.47 | 0.00 | 474.00 | 3935 | 31.90 | 53.95 | 0.00 | 348.00 |
| MD Sales Visits | 3334 | 6.53 | 10.88 | 0.00 | 105.00 | 3935 | 10.52 | 15.75 | 0.00 | 92.00 |
| MD-SD Sales Visits | 3334 | 2.76 | 6.57 | 0.00 | 68.00 | 3935 | 4.44 | 10.99 | 0.00 | 88.00 |
| MD-MD Sales Visits | 3334 | 3.77 | 7.43 | 0.00 | 66.00 | 3935 | 6.08 | 9.08 | 0.00 | 48.00 |
| Meals | 3334 | 4.53 | 10.71 | 0.00 | 161.00 | 3935 | 8.64 | 15.16 | 0.00 | 134.00 |
| No Visual Aids | 3334 | 8.22 | 13.91 | 0.00 | 126.00 | 3935 | 15.00 | 23.80 | 0.00 | 121.00 |
| Electronic Visual Aids | 3334 | 0.43 | 1.66 | 0.00 | 25.00 | 3935 | 2.46 | 6.30 | 0.00 | 57.00 |
| Paper Visual Aids | 3334 | 12.31 | 25.52 | 0.00 | 407.00 | 3935 | 21.19 | 36.55 | 0.00 | 284.00 |
| Clinical Study Visual Aids | 3334 | 1.91 | 4.88 | 0.00 | 104.00 | 3935 | 4.01 | 8.37 | 0.00 | 139.00 |
| Samples | 3334 | 11.32 | 31.69 | 0.00 | 383.00 | 3935 | 36.03 | 57.42 | 0.00 | 317.00 |
| SV Minutes | 3334 | 111.60 | 227.31 | 0.00 | 3248.50 | 3935 | 208.30 | 342.40 | 0.00 | 2714.50 |
| DSV Minutes | 3334 | 101.66 | 211.28 | 0.00 | 3096.03 | 3935 | 192.48 | 317.70 | 0.00 | 2714.50 |
| N-DSV Minutes | 3334 | 9.95 | 23.58 | 0.00 | 250.95 | 3935 | 15.82 | 40.62 | 0.00 | 348.15 |
| AVG SV Minutes | 2222 | 5.14 | 2.95 | 0.50 | 20.00 | 2645 | 4.89 | 2.35 | 0.50 | 20.00 |
| AVG DSV Minutes | 2222 | 4.56 | 2.85 | 0.40 | 20.00 | 2645 | 4.51 | 2.25 | 0.30 | 20.00 |
| AVG N-DSV Minutes | 2222 | 0.59 | 1.21 | 0.00 | 16.00 | 2645 | 0.39 | 0.92 | 0.00 | 16.00 |
| One-Way Participation | 3334 | 9.90 | 18.14 | 0.00 | 226.00 | 3935 | 20.61 | 32.45 | 0.00 | 177.00 |
| Two-Way Participation | 3334 | 11.31 | 22.26 | 0.00 | 293.00 | 3935 | 21.81 | 35.26 | 0.00 | 225.00 |
| **AFFECTED PRODUCT FAMILIES** | *PRE-BLACK BOX WARNING* | | | | | *POST-BLACK BOX WARNING* | | | | |
| | **OBS** | **MEAN** | **ST DEV** | **MIN** | **MAX** | **OBS** | **MEAN** | **ST DEV** | **MIN** | **MAX** |
| Rx Intent | 249 | 5.11 | 0.21 | 4.11 | 5.86 | 368 | 4.97 | 0.34 | 2.45 | 6.67 |
| New Rx | 354 | 72.80 | 17.69 | 30.00 | 179.00 | 374 | 46.85 | 33.94 | 1.00 | 160.00 |
| Total Rx | 354 | 415.84 | 60.25 | 231.00 | 566.00 | 374 | 303.84 | 187.96 | 13.00 | 598.00 |
| New Rx SoM | 354 | 0.14 | 0.03 | 0.04 | 0.23 | 374 | 0.08 | 0.05 | 0.00 | 0.20 |
| Total Rx SoM | 354 | 0.12 | 0.01 | 0.07 | 0.16 | 374 | 0.08 | 0.05 | 0.00 | 0.15 |
| Doctor Visits | 354 | 212.82 | 56.35 | 3.00 | 500.00 | 374 | 152.68 | 70.91 | 0.00 | 287.00 |
| Sales Visits | 354 | 179.91 | 51.10 | 2.00 | 508.00 | 374 | 138.66 | 74.88 | 0.00 | 287.00 |
| SD Sales Visits | 354 | 118.20 | 39.69 | 1.00 | 454.00 | 374 | 104.20 | 64.58 | 0.00 | 245.00 |
| MD Sales Visits | 354 | 61.71 | 25.17 | 0.00 | 120.00 | 374 | 34.46 | 16.01 | 0.00 | 81.00 |
| MD-SD Sales Visits | 354 | 38.74 | 19.34 | 0.00 | 84.00 | 374 | 19.47 | 15.87 | 0.00 | 64.00 |
| MD-MD Sales Visits | 354 | 22.97 | 15.53 | 0.00 | 67.00 | 374 | 14.99 | 13.38 | 0.00 | 53.00 |
| Meals | 354 | 28.17 | 11.69 | 0.00 | 75.00 | 374 | 24.69 | 15.21 | 0.00 | 63.00 |
| No Visual Aids | 354 | 77.28 | 21.76 | 0.00 | 182.00 | 374 | 58.44 | 35.52 | 0.00 | 144.00 |
| Electronic Visual Aids | 354 | 1.31 | 1.65 | 0.00 | 11.00 | 374 | 3.95 | 4.65 | 0.00 | 22.00 |
| Paper Visual Aids | 354 | 96.18 | 32.43 | 2.00 | 233.00 | 374 | 66.51 | 41.28 | 0.00 | 175.00 |
| Clinical Study Visual Aids | 354 | 17.57 | 14.71 | 1.00 | 167.00 | 374 | 16.37 | 12.29 | 0.00 | 98.00 |
| Samples | 354 | 77.69 | 88.12 | 0.00 | 326.00 | 374 | 127.51 | 69.52 | 0.00 | 270.00 |
| SV Minutes | 354 | 804.56 | 264.83 | 4.50 | 2356.50 | 374 | 645.29 | 357.25 | 0.00 | 1394.00 |
| DSV Minutes | 354 | 674.68 | 229.07 | 4.20 | 2216.53 | 374 | 577.21 | 358.18 | 0.00 | 1351.20 |
| N-DSV Minutes | 354 | 129.88 | 73.99 | 0.00 | 326.05 | 374 | 68.09 | 56.60 | 0.00 | 265.95 |
| AVG SV Minutes | 354 | 4.44 | 0.51 | 2.25 | 6.01 | 373 | 4.61 | 0.78 | 0.50 | 7.50 |
| AVG DSV Minutes | 354 | 3.73 | 0.53 | 2.10 | 5.65 | 373 | 3.96 | 0.72 | 0.50 | 5.80 |
| AVG N-DSV Minutes | 354 | 0.70 | 0.35 | 0.00 | 1.62 | 373 | 0.65 | 0.53 | 0.00 | 4.00 |
| One-Way Participation | 354 | 89.08 | 24.57 | 1.00 | 182.00 | 374 | 68.94 | 37.13 | 0.00 | 158.00 |
| Two-Way Participation | 354 | 90.83 | 28.76 | 1.00 | 326.00 | 374 | 69.72 | 38.98 | 0.00 | 157.00 |

## Table 4 – Sales Visit and Promotional Strategy Approach Results

| DEPENDENT VARIABLE | SALES VISITS | | SINGLE DETAIL SALES VISITS | | MULTI-DETAIL SALES VISITS | | UNIQUE DOCTOR VISITS | | SAMPLES PROV SALES VISITS | |
|---|---|---|---|---|---|---|---|---|---|---|
| | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) |
| BBW Treatment | -46.60 (48.74) | | -18.91 (31.26) | | -27.69 (17.59) | | -64.76 (48.43) | | 36.30 (42.43) | |
| BBW Treatment – Actos | | 18.86*** (4.85) | | 22.78*** (4.34) | | -3.92*** (1.32) | | 0.151 (5.279) | | 92.99*** (5.67) |
| BBW Treatment – Avandia | | -112.03*** (4.79) | | -60.56*** (4.29) | | -51.46*** (1.31) | | -129.62*** (5.21) | | -20.36*** (5.61) |
| Constant | 26.39*** (8.50) | 26.39*** (8.36) | 17.37** (6.31) | 17.37** (6.33) | 9.02*** (2.86) | 9.02*** (2.67) | 34.06*** (9091) | 34.06*** (9.63) | 4.04 (8.53) | 4.04 (8.51) |
| Year-Week FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Calendar Month FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Product Family FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| R-sq Within | 0.152 | 0.253 | 0.109 | 0.173 | 0.268 | 0.402 | 0.189 | 0.273 | 0.220 | 0.286 |
| R-sq Between | 0.305 | 0.059 | 0.202 | 0.002 | 0.465 | 0.343 | 0.327 | 0.133 | 0.474 | 0.228 |
| R-sq Overall | 0.012 | 0.002 | 0.000 | 0.020 | 0.03 | 0.009 | 0.020 | 0.001 | 0.212 | 0.231 |
| Observations | 7744 | 7744 | 7744 | 7744 | 7744 | 7744 | 7744 | 7744 | 7744 | 7744 |
| **DEPENDENT VARIABLE** | **MEALS PROV SALES VISITS** | | **NO VISUAL AID SALES VISITS** | | **PAPER VISUAL AID SALES VISITS** | | **ELEC VISUAL AID SALES VISITS** | | **CS VISUAL AID SALES VISITS** | |
| | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) |
| BBW Treatment | -3.96 (8.97) | | -20.66 (21.32) | | -30.48 (23.40) | | 1.83 (1.36) | | -1.61 (2.55) | |
| BBW Treatment – Actos | | 8.07*** (0.92) | | 8.07*** (1.76) | | 0.91 (2.36) | | 3.61*** (0.26) | | 1.70*** (0.52) |
| BBW Treatment – Avandia | | -15.99*** (0.91) | | -49.37*** (1.75) | | -61.84*** (2.34) | | 0.05 (0.35) | | -4.92*** (0.51) |
| Constant | 3.75** (1.71) | 3.75** (1.75) | 12.97*** (2.97) | 12.97*** (2.86) | 12.36*** (4.95) | 12.36** (4.91) | 0.61** (0.23) | 0.61** (0.23) | 1.38 (1.22) | 1.38** (1.21) |
| Year-Week FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Calendar Month FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Product Family FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| R-sq Within | 0.112 | 0.170 | 0.191 | 0.298 | 0.199 | 0.256 | 0.206 | 0.216 | 0.094 | 0.103 |
| R-sq Between | 0.076 | 0.000 | 0.447 | 0.090 | 0.291 | 0.104 | 0.101 | 0.080 | 0.188 | 0.021 |
| R-sq Overall | 0.011 | 0.032 | 0.009 | 0.003 | 0.000 | 0.005 | 0.137 | 0.146 | 0.020 | 0.027 |
| Observations | 7744 | 7744 | 7744 | 7744 | 7744 | 7744 | 7744 | 7744 | 7744 | 7744 |

## Table 5 – Intent to Prescribe Results

| DEPENDENT VARIABLE | INTENT TO PRESCRIBE | | INTENT TO PRESCRIBE | | INTENT TO PRESCRIBE | | INTENT TO PRESCRIBE | | INTENT TO PRESCRIBE | | INTENT TO PRESCRIBE | | INTENT TO PRESCRIBE | | INTENT TO PRESCRIBE | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| INDEPENDENT VARIABLE | | | SALES VISITS | | SINGLE DETAIL SALES VISITS | | MULTI DETAIL SALES VISITS | | MULTI DETAIL/ SINGLE DIABETES SALES VISITS | | MULTI DETAIL/ MULTI DIABETES SALES VISITS | | SAMPLES PROV SALES VISITS | | MEALS PROV SALES VISITS | |
| ESTIMATION | DiD – XTREG | | OLS – XTREG | | OLS – XTREG | | OLS – XTREG | | OLS – XTREG | | OLS – XTREG | | OLS – XTREG | | OLS – XTREG | |
| | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) |
| BBW – All Families | -0.067 (0.063) | | | | | | | | | | | | | | | |
| BBW – Actos Family | | -0.010 (0.047) | | | | | | | | | | | | | | |
| BBW – Avandia Family | | -0.124** (0.045) | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | |
| Own Family | | | -0.084*** (0.024) | -0.084*** (0.025) | -0.078*** (0.023) | -0.078*** (0.023) | -0.084** (0.031) | -0.084** (0.031) | -0.029 (0.029) | -0.033 (0.030) | -0.061 (0.041) | -0.057 (0.042) | -0.084** (0.031) | -0.084** (0.031) | -0.023 (0.032) | -0.021 (0.033) |
| Own Class | | | -0.026** (0.009) | -0.026*** (0.009) | -0.029** (0.007) | -0.028*** (0.007) | -0.016 (0.012) | -0.017 (0.012) | -0.051** (0.024) | -0.051** (0.024) | -0.075*** (0.022) | -0.083*** (0.026) | -0.016 (0.012) | -0.017 (0.012) | -0.040*** (0.013) | -0.041*** (0.014) |
| Rival Class | | | 0.051 (0.200) | 0.032 (0.198) | -0.004 (0.119) | -0.012 (0.115) | 0.047 (0.175) | 0.031 (0.174) | -0.197 (0.371) | -0.202 (0.374) | -0.213* (0.123) | -0.234* (0.128) | 0.047 (0.175) | 0.031 (0.174) | 0.049 (0.164) | 0.042 (0.163) |
| Own Family X BBW-Time | | | 0.037* (0.021) | 0.036* (0.020) | 0.024 (0.018) | 0.022 (0.018) | 0.048* (0.026) | 0.046* (0.026) | 0.003 (0.034) | 0.005 (0.034) | 0.049 (0.050) | 0.049 (0.051) | 0.048* (0.026) | 0.046* (0.026) | 0.006 (0.031) | 0.007 (0.031) |
| Own Family X BBW-Time X BBW–Affected PF | | | -0.022** (0.010) | | -0.019* (0.009) | | -0.017* (0.009) | | -0.017 (0.016) | | -0.027*** (0.008) | | -0.017* (0.009) | | -0.022** (0.008) | |
| Own Family X BBW Time X BBW– Actos PF | | | | -0.026 (0.016) | | -0.021 (0.014) | | -0.018 (0.014) | | -0.015 (0.028) | | -0.051** (0.021) | | -0.018 (0.014) | | -0.032** (0.015) |
| Own Family X BBW-Time X BBW–Avandia PF | | | | -0.056*** (0.017) | | -0.053** (0.016) | | -0.043** (0.016) | | -0.050 (0.032) | | -0.042** (0.018) | | -0.043** (0.016) | | -0.055*** (0.014) |
| Constant | 5.142*** (0.242) | 5.142*** (0.242) | 5.252*** (1.234) | 5.368*** (1.219) | 5.544*** (0.652) | 5.586*** (0.633) | 5.095*** (0.324) | 5.196*** (0.327) | 6.384*** (2.089) | 6.419*** (2.108) | 6.341*** (0.544) | 6.441*** (0.565) | 5.095*** (0.324) | 5.196*** (0.327) | 5.058*** (0.694) | 5.092*** (0.686) |
| | | | | | | | | | | | | | | | | |
| Year-Week FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Calendar Month FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Product Family FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| R-sq Within | 0.099 | 0.100 | 0.110 | 0.110 | 0.101 | 0.110 | 0.111 | 0.111 | 0.104 | 0.104 | 0.108 | 0.108 | 0.111 | 0.111 | 0.105 | 0.105 |
| R-sq Between | 0.001 | 0.000 | 0.062 | 0.058 | 0.045 | 0.044 | 0.031 | 0.028 | 0.063 | 0.053 | 0.098 | 0.112 | 0.031 | 0.028 | 0.092 | 0.094 |
| R-sq Overall | 0.099 | 0.104 | 0.086 | 0.090 | 0.086 | 0.090 | 0.102 | 0.106 | 0.010 | 0.101 | 0.085 | 0.079 | 0.102 | 0.106 | 0.084 | 0.084 |
| Observations | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 | 4063 |

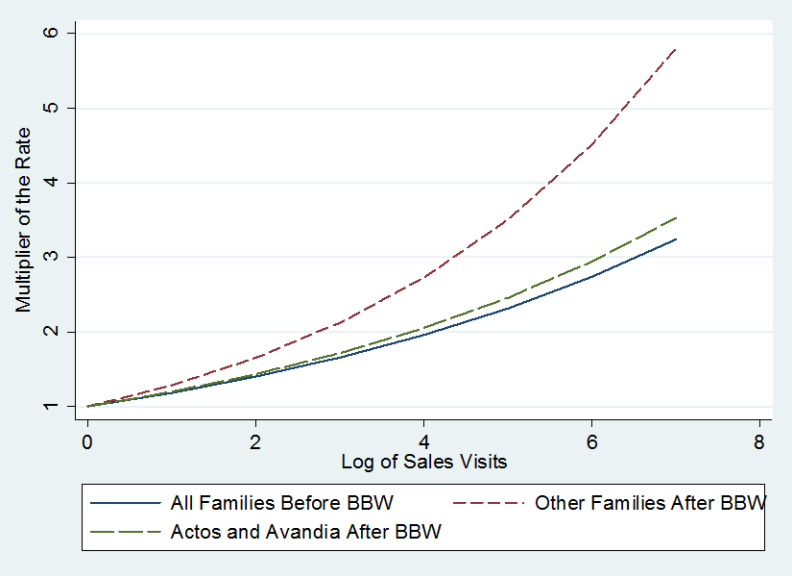
## Table 6 – New Written Prescription Results

| DEPENDENT VARIABLE | NEW Rx | | NEW Rx | | NEW Rx | | NEW Rx | | NEW Rx | | NEW Rx | | NEW Rx | | NEW Rx | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| INDEPENDENT VARIABLE | | | SALES VISITS | | SINGLE DETAIL SALES VISITS | | MULTI DETAIL SALES VISITS | | MULTI DETAIL/ SINGLE DIABETES SALES VISITS | | MULTI DETAIL/ MULTI DIABETES SALES VISITS | | SAMPLES PROV SALES VISITS | | MEALS PROV SALES VISITS | |
| ESTIMATION | DiD – XTPQML | | COUNT – XTPQML | | COUNT – XTPQML | | COUNT – XTPQML | | COUNT – XTPQML | | COUNT – XTPQML | | COUNT – XTPQML | | COUNT – XTPQML | |
| | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) |
| BBW – All Families | -0.544 (0.437) | | | | | | | | | | | | | | | |
| BBW – Actos Family | | -0.088 (0.083) | | | | | | | | | | | | | | |
| BBW – Avandia Family | | -1.586*** (0.083) | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | |
| Own Family | | | 0.168** (0.067) | 0.142*** (0.025) | 0.162*** (0.061) | 0.141** (0.056) | 0.147** (0.071) | 0.124* (0.064) | 0.096 (0.067) | 0.072 (0.062) | 0.157*** (0.051) | 0.143*** (0.052) | 0.184*** (0.026) | 0.165*** (0.027) | 0.192*** (0.047) | 0.175*** (0.045) |
| Own Class | | | -0.040** (0.017) | -0.026*** (0.009) | -0.041** (0.017) | -0.028* (0.016) | -0.035 (0.022) | -0.023 (0.020) | -0.033*** (0.010) | -0.022** (0.011) | -0.050 (0.035) | -0.011 (0.033) | -0.065*** (0.019) | -0.055*** (0.014) | -0.043** (0.198) | -0.029 (0.018) |
| Rival Class | | | -0.010 (0.012) | -0.008 (0.011) | -0.004 (0.013) | -0.002 (0.012) | 0.009 (0.013) | 0.007 (0.013) | 0.021 (0.013) | 0.019 (0.013) | 0.020 (0.017) | 0.015 (0.017) | -0.010 (0.010) | -0.005 (0.009) | 0.018 (0.015) | 0.018 (0.015) |
| Own Family X BBW-Time | | | 0.083** (0.038) | 0.074** (0.037) | 0.086** (0.043) | 0.071* (0.040) | 0.071* (0.043) | 0.078 (0.041) | 0.038 (0.044) | 0.049 (0.042) | 0.071 (0.051) | 0.041 (0.046) | 0.054 (0.041) | 0.045 (0.037) | 0.053 (0.044) | 0.041 (0.042) |
| Own Family X BBW-Time X BBW–Affected PF | | | -0.071* (0.038) | | -0.078* (0.042) | | -0.088 (0.055) | | -0.116** (0.057) | | -0.119** (0.051) | | -0.076** (0.039) | | -0.099 (0.057) | |
| Own Family X BBW Time X BBW– Actos PF | | | | -0.059*** (0.021) | | -0.061** (0.025) | | -0.069*** (0.022) | | -0.082*** (0.030) | | -0.075 (0.024) | | -0.069*** (0.018) | | -0.071*** (0.024) |
| Own Family X BBW-Time X BBW–Avandia PF | | | | -0.335*** (0.026) | | -0.366*** (0.029) | | -0.427*** (0.032) | | -0.472*** (0.029) | | -0.591*** (0.055) | | -0.346*** (0.019) | | -0.482*** (0.027) |
| | | | | | | | | | | | | | | | | |
| Year-Week FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Calendar Month FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Product Family FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Log-likelihood | -27473.5 | -25211.6 | -25642.1 | -24341.1 | -25789.6 | -25504.3 | -26132.9 | -24770.1 | -26759.9 | -25470.0 | -25779.1 | -25214.0 | -25183.1 | -23930.5 | -26039.0 | -24890.6 |
| Wald chi2 | 5310.4 | 8432.8 | 8675.6 | 10389.3 | 8408.6 | 10098.3 | 7817.4 | 9690.6 | 6670.0 | 8362.1 | 8537.9 | 9006.9 | 9699.0 | 11318.5 | 8008.1 | 9535.2 |
| Observations | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 |

## Table 7 – Robustness Results

| DEPENDENT VARIABLE | Rx INTENT | | NEW Rx | | Rx INTENT | | NEW Rx | | TOTAL Rx | | TOTAL Rx | | NEW Rx SoM | | NEW Rx SoM | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ROBUSTNESS TEST | ± 1 YEAR WINDOW | | ± 1 YEAR WINDOW | | ± 1 YEAR WINDOW | | ± 1 YEAR WINDOW | | DIFFERENT DV | | DIFFERENT DV | | DIFFERENT DV | | DIFFERENT DV | |
| ESTIMATION | DiD – XTREG | | DiD – XTPQML | | OLS - XTREG | | COUNT - XTPQML | | DiD – XTPQML | | COUNT – XTPQML | | DiD – XTREG | | OLS – XTREG | |
| | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) | β (se) |
| BBW – All Families | -0.191* (0.112) | | -0.248 (0.445) | | | | | | -0.440 (0.411) | | | | -0.064* (0.033) | | | |
| BBW – Actos Family | | -0.067 (0.061) | | 0.230*** (0.025) | | | | | | -0.003 (0.101) | | | | -0.019*** (0.003) | | |
| BBW – Avandia Family | | -0.318*** (0.062) | | -1.278*** (0.025) | | | | | | -1.314*** (0.101) | | | | -0.108*** (0.003) | | |
| | | | | | | | | | | | | | | | | |
| Own Family | | | | | -0.012 (0.142) | -0.021 (0.150) | 0.157** (0.076) | 0.413 (0.344) | | | 0.056 (0.052) | 0.036 (0.044) | | | 0.007** (0.002) | 0.006** (0.002) |
| Own Class | | | | | 0.023 (0.083) | 0.045 (0.084) | -0.075 (0.067) | 0.020 (0.026) | | | 0.001 (0.026) | 0.014 (0.024) | | | -0.001 (0.001) | -0.001 (0.001) |
| Rival Class | | | | | 0.371 (0.714) | 0.419 (0.718) | -0.002 (0.007) | -0.003 (0.007) | | | -0.015 (0.010) | -0.015 (0.010) | | | -0.000 (0.000) | -0.001 (0.000) |
| Own Family X BBW-Time | | | | | 0.013 (0.040) | 0.013 (0.041) | 0.011 (0.018) | 0.011 (0.015) | | | 0.165*** (0.034) | 0.154*** (0.037) | | | 0.002 (0.001) | 0.001 (0.001) |
| Own Family X BBW-Time X BBW–Affected PF | | | | | -0.025* (0.013) | | -0.025 (0.040) | | | | -0.082** (0.037) | | | | -0.007** (0.003) | |
| Own Family X BBW Time X BBW– Actos PF | | | | | | -0.020 (0.014) | | 0.039*** (0.008) | | | | -0.074*** (0.023) | | | | -0.005*** (0.001) |
| Own Family X BBW-Time X BBW–Avandia PF | | | | | | -0.082*** (0.022) | | -0.255*** (0.009) | | | | -0.326*** (0.023) | | | | -0.022*** (0.001) |
| Constant | 5.057*** (0.190) | 5.064*** (0.193) | | | 3.160 (3.882) | 2.895 (3.897) | | | | | | | 0.053*** (0.006) | 0.053*** (0.005) | 0.044*** (0.005) | 0.043*** (0.005) |
| Year-Week FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Calendar Month FE | N | N | N | N | N | N | N | N | Y | Y | Y | Y | Y | Y | Y | Y |
| Product Family FE | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Log-likelihood | | | -3448.4 | -3048.3 | | | -3398.1 | -3044.7 | -70701.4 | -59217.0 | -57660.8 | -51219.8 | | | | |
| Wald chi2 | | | 529.1 | 1202.8 | | | 622.0 | 1214.0 | 21236.0 | 40047.3 | 46245.9 | 56569.8 | | | | |
| R-sq Within | 0.075 | 0.078 | | | 0.102 | 0.132 | | | | | | | 0.297 | 0.414 | 0.346 | 0.419 |
| Observations | 762 | 762 | 1204 | 1204 | 762 | 762 | 1204 | 1204 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 | 7997 |

## FIGURE 1 – Multiplicative Effect of Sales Visits on New Rx (All Product Families)




## FIGURE 2 – Percentage Change Effect of Sales Visits on New Rx (All Product Families)

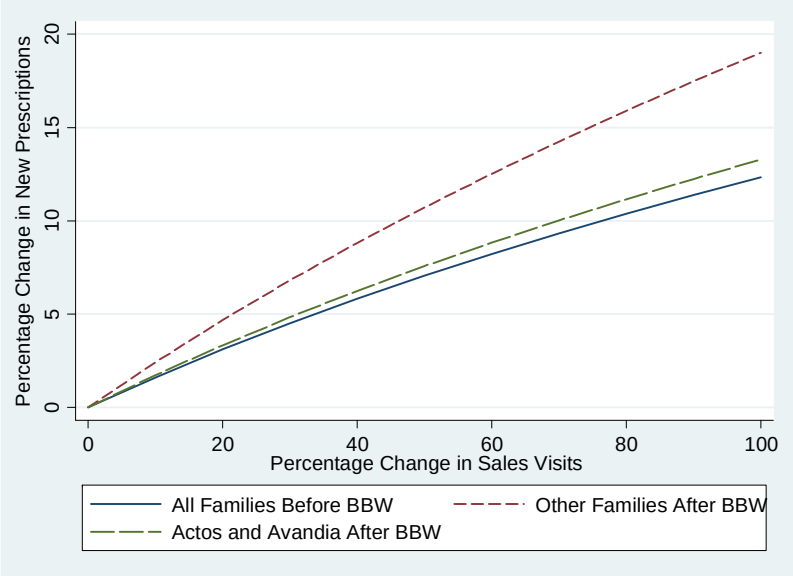


**FIGURE 3 – Multiplicative Effect of Sales Visits on New Rx (Actos and Avandia Families)**

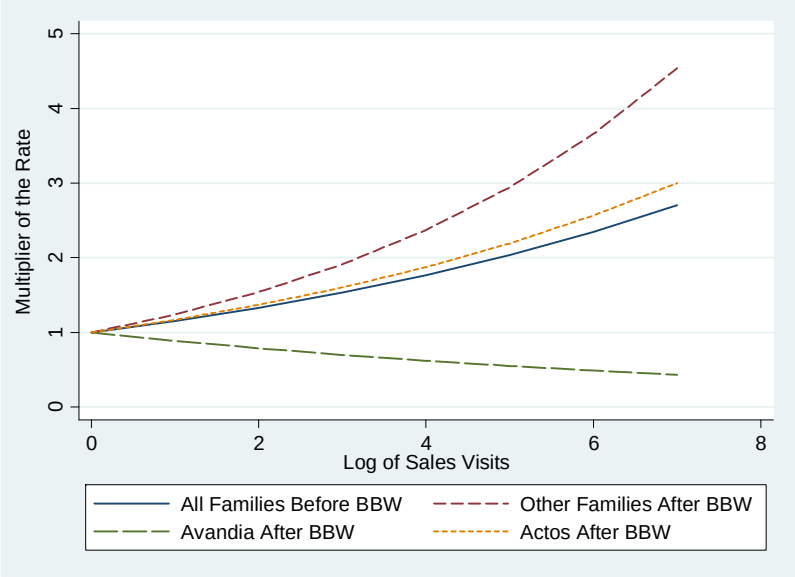



**FIGURE 4 – Percentage Change Effect of Sales Visits on New Rx (Actos and Avandia Families)**