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How Direct-to-Consumer Advertising for Prescription Drugs Affects Consumers' Welfare

A Natural Experiment Tests The Impact of FDA Legislation

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ABSTRACT

In August 1997, the FDA allowed brand specific advertising on TV. A simultaneous rise in Direct to Consumer Advertising (DTCA) spending and prescription drug sales has resulted in a heated debate among pharmaceutical firms, medical practitioners, in the US Congress, and the popular press. One side claims that DTCA creates demand for the advertised brand; the other claims that DTCA increases consumer knowledge. The current study sheds light on the debate with a comparison of consumer welfare before and after the 1997 policy change, using a structural econometric model. The results suggest that DTCA seems to be increasing consumer welfare.

Key words: Direct to Consumer Advertising; Pharmaceutical Markets; Consumer Welfare; Structural Econometric Modeling; Aggregate Mixed Logit Choice Models

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1. Introduction

The pharmaceutical industry is a heavily advertised industry, with spending in 2012 of roughly 27 billion Dollars (Pew Health, 2013). Pharmaceutical firms use a number of promotional tools, such as visits by sales persons to physicians' offices (commonly known as detailing), product sampling, journal advertising, and direct to consumer advertising (DTCA).

There has long been a debate about both the effectiveness and consequences of these promotional tools. Whereas proponents argue that they help physicians learn about the drug and keep up with medical information (Frosch et al., 2010), detractors argue that physicians do not find most of these tools useful (Reast et al., 2008). These latter also suggest that such promotions increase the costs of drugs, in turn preventing a wider population from enjoying the benefits of new drugs. As a result, various governmental agencies have started closely monitoring how much pharmaceutical firms spend on these tools (for example, the United States government, concerned that marketing practices by pharmaceutical firms are behind increases in drug prices, has issued a warning to limit some of these practices (US Governmental Accountability Office, 2006)). DTCA, in particular, is the object of much heated debate and considerable scrutiny. The key reason for this is probably that DTCA is the only marketing tool that aims to reach and influence patients directly, unlike the others that have traditionally been aimed at physicians.

With DTCA, pharmaceutical firms are now able to exert a pull strategy on end consumers, in effect making patients consult their doctors about the advertised prescription drugs (Gonul et al., 2000). In effect, successful DTCA changes the nature of the relationship between the players in the market for pharmaceuticals (drug companies, physicians, and patients). Much of the controversy around DTCA is centered on the type of patients that DTCA entices. A few studies (for example, Holmer, 1999; Roth, 2003) suggest that DTCA provides valuable information to consumers that they may not otherwise have received, or have received too late. This motivates undiagnosed patients to seek additional information from sources such as physicians and pharmacists (Calfee, 2002; The National Consumers League, 2003).

On the other hand, one study suggests that DTCA influences current patients who have been already diagnosed and are currently being treated, and does not motivate the undiagnosed to meet with their physicians and to seek out medication for the disease (Frosch et al., 2010). Further, Reast et al., 2008 also argue that DTCA overstates benefits and does not adequately represent the risks associated with the drugs. Medical professionals on this side of the debate say DTCA leads to the creation of demand for specific brand names and possibly generates pressure on physicians to write prescriptions for expensive brands (Hollon, 1999; Mehta and Purvis, 2003), or worse leads patients to self-diagnose themselves into a therapeutic condition. Politicians like Representative Jerrold Nadler (New York) sums up the public's concern by saying that "You should not be diagnosed by some pitchman on TV who doesn't know you whatsoever" (*New York Times* 2009).

If there is one common theme in the debate around DTCA, it is that various stakeholders differ in their assessment of whether consumers are better or worse off because of DTCA. Somewhat surprisingly, there exists no rigorous empirical examination of this issue. The current study attempts to fill this gap by examining the impact of DTCA in a leading therapeutic category. A change in policy by the FDA provides a natural experiment that lets us isolate the impact of DTCA. Briefly, prior to 1997 a "brief summary" of side effects and contraindications etc. was required to be part of any DTCA. The "brief summary" entailed a lot of information and was therefore prohibitively costly for anything but print advertising. In 1997 this requirement was relaxed to replace "brief summary" with "adequate provision", making it possible to have DTCA on TV.

Following prior literature (Brynjolfsson et al. 2003; Petrin 2002; Trajtenberg 1989), a standard measure of consumer welfare is used to examine whether consumers are better or worse off as a result of DTCA. We use the notion of compensating variation, that captures the dollar amount by which a consumer needs to be compensated to maintain the same utility level after a policy change as she had before the policy change (Hicks 1942). Consumer choice is used to infer utility gained from the good, and the measure is based on the assumption that the utility a consumer derives from a "good" before and after is

based on certain underlying preferences that do not change due to the policy. Note that a weakness of this approach is that the welfare change so measured cannot account for changes in life styles or consumer preferences.

Using a dataset for HMG-CoA reductase inhibitors (“Statins”), our data consist of information on sales, detailing and DTCA in the US Statin market. Statins are the standard drug class for the treatment of hyperlipidemia. This particular therapeutic category was chosen because it had the third highest overall category sales (\$29B worldwide sales in 2012) and is one of the more heavily advertised therapeutic categories.

The empirical strategy was to construct a structural econometric discrete choice model of demand pre- and post- policy change (Chintagunta, Bonfrer and Song 2002). An attractive feature of the discrete choice model is its ability to compute consumer welfare explicitly (Chintagunta, Dube and Singh 2003). Therefore, a mixed-logit aggregate demand model that allows for a flexible substitution pattern between the various drugs in the therapeutic category was developed, while accounting for the endogeneity of prices of drugs (Berry, Levinson and Pakes (henceforth BLP) 1995); Villas-Boas and Winer, 1999). Based on parameters of the structural econometric demand system, computation of the change in consumers’ welfare due to the introduction of DTCA was carried out (Chintagunta, Dube and Singh 2003).

The results of the research study indicate that consumer welfare increases as a result of the FDA’s relaxation of the DTCA rule. The study also finds that DTCA has a significant impact on both overall category sales and individual drug choice. However, detailing has a larger impact on overall category sales in the earlier part of the category life cycle, and also plays a larger role than DTCA on individual drug choice. The results offer implications for lawmakers, policy officials and managers of pharmaceutical firms.

The remainder of the paper is organized as follows. In the next section, the relevant literature is reviewed. In §3, the data are discussed and various institutional details related to the Statin market are provided. §4, provides the model formulation and estimation procedure. In §5, the results are discussed

and §6 concludes.

2. Context and Relevant Literature

Context. Prior to 1997, as per the Kefauver Harris Amendment of 1962, FDA permitted DTCA by pharmaceutical firms if the firms offered a “brief summary (FDA 1)” of side effects, contraindications and effectiveness (Iizuka, 2004). The US department of Health and Human Services acknowledged that, “providing this (brief summary) amount of information in television and radio advertising was difficult, because of time and space constraints” (HHS News, US Department of Health, 1997). As a result, the requirement enabled firms to pursue DTCA efforts mainly through print media as providing the brief summary in television advertising was prohibitively costly.

In 1997, FDA relaxed this requirement and allowed drug specific DTCA in which firms could mention the drug’s name and the condition for which it was to be used. More importantly, the advertisements were now required to carry an "adequate provision" statement instead of providing a “brief summary” statement. Broadcast advertisements could meet the "adequate provision" requirement by giving a number of sources for finding a drug's prescribing information. Such sources could include a healthcare provider (for example, a doctor), a toll-free telephone number, the current issue of a magazine that contains a print advertisement or a web site address (for more details on the timeline of the regulation, see Iizuka, 2004). After this policy change, DTCA as a percentage of total pharmaceutical promotion grew from 8.6% in 1996 to 16% in 2000. DTC advertising increased 28% annually between 1996 and 2001 (Kaiser report, 2003). During the same time interval total prescription drugs sales almost doubled to \$208 billion (NDC Health, 2003). An NIHCM (2001) study found that the 50 most heavily advertised drugs accounted for 48% of the rise in sales of all prescription drugs in 1999-2000.

Related Literature. While the majority of the early literature in the area of pharmaceutical sales promotion has focused on the effect of detailing (not surprisingly, given the emphasis on understanding physicians’

prescription behavior), there is now a nascent literature examining the demand-side effects of DTCA.

Recent work based on surveys has established that DTCA motivates patients to visit their physicians and to talk about their condition and symptoms (Wilkes et al., 2002). Rosenthal (2003) uses aggregate data of sales from six therapeutic classes and demonstrates that DTCA has a positive and significant effect on overall demand, but does not affect the market share within the particular class. Iizuka and Jiin (2005) also use data from pre- and post- the FDA regulation change and find that increased DTCA is associated with increased doctor visits. Donohue and Berndt (2004) and Narayanan, Desiraju and Chintagunta (2004) compare the effectiveness of detailing meetings and DTCA on drug choice. Both studies find that detailing has a greater effect than DTCA on drug choice. The latter study also finds evidence of complementary effects of detailing and DTCA efforts on drug choice. It is worth noting that the effects of DTCA on category sales vis-à-vis individual drug market share are mixed. Iizuka and Jin (2005) find that DTCA by a drug helps category expansion and not necessarily the market share of the drug, while Narayanan, Desiraju and Chintagunta (2004) find that DTCA has a positive impact on both category sales and individual market share.

Another set of studies is concerned with the effects of DTCA on patients' compliance. For example, Bowman, Heilman, and Seetharaman (2004) report that advertising has a varied response on patients' compliance. Wosinska (2005) finds similar results and suggests spillover effects of DTCA, in that compliance with a brand may increase when other competing brands advertise more heavily. This is consistent with the DTCA proponents' claim that advertising by any brand of drug motivates consumers to visit their physicians to talk about their condition and also helps in reminding them about the benefits of the drug, thereby affecting their compliance. Although the extant studies help understand the various demand effects of DTCA, no study has quantified the effects of DTCA on consumer welfare.

Consumer Welfare. The concept of consumer welfare has long been an established way to measure how well off a consumer is. Various studies have explicitly empirically tested this across multiple industries. For example, Trajtenberg (1989) computes the welfare change due to use of computer tomography, and

Brynjolfsson et al. (2003) compute the change in consumer welfare due to increased product variety in online book stores. The change in consumer welfare is one of the key considerations of the US Federal Trade Commission (FTC) when it evaluates mergers (Werder and Froeb, 1994). Studies on linking changes in consumer welfare to discrete policy shifts have also been undertaken. Lusk et al. (2010) study the effect of food labels and bans (on cloning in beef production and methyl mercury in fish) on consumer welfare. Dubois et al. (2014) quantify the welfare impacts of banning advertising in the potato chip market. We should point out that in this research we do not claim to test whether DTCA is informative or not (e.g., Morgan et al. 2003). Further, this research does not test if life style choices or other non-drug interventions would benefit a consumer (we would like to thank an anonymous reviewer for our drawing attention to this distinction).

A standard measure for welfare in such contexts is the Hicksian, or compensating variation (Hicks 1942; Chintagunta, Dube and Singh 2003). The idea is to capture the amount of change, in monetary terms that is necessary to compensate the consumer for the change in price after the policy change, to keep them at the same level of utility (in our case, the introduction of DTCA is the policy change). Formally, if there are two budgets a consumer faces, with initial price and income (p_1, m_1) and post- policy change price and income (p_2, m_2) then a measure of welfare change is the difference in indirect utility, $v_1(p_1, m_1) - v_2(p_1, m_1)$. If this utility difference is positive, then the policy change is worth doing, from a consumer's point of view (Petrin 2001). The method requires specification of the parametric form of demand followed by estimation of the parameters of the utility function (please see section 4 and the technical appendix for more details). We would like to emphasize that the Hicksian measure of consumer welfare is driven by the share/choice of a good and does not capture the role of other life style changes on consumer welfare.

3. Data

The proposed model is ideally tested on drugs that have substantial sales, market aggressively, and have existed both before and after the policy change. The choice of drugs used in this study is based on these criteria. The data set spans a period from January 1992 to December 2001, and consists of four branded

cholesterol reducing drugs (Statins) in the U.S.A., that were all launched before the policy change in 1997. These were the only four products in the market during that time. In 2011 almost 20 million Americans were taking some form of Statin (Reuters, 2012), which are considered the first line of treatment for most patients with high cholesterol. The total Statin market in 2009 was \$27 billion.

The four drugs in our data set are Mevacor (Lovastatin, 1987), Pravachol (Pravastatin, 1991), Zocor (Simvastatin, 1991) and Lipitor (Atorvastatin, 1996), in order of first approval to market (brand name followed by the chemical name and the year of approval). Lipitor, with sales of \$6.1 billion (IMS, 2003) was the largest selling drug (across all drugs, not just Statins) and was destined to become the world's first \$10 billion drug (Business Week online, 2002). Zocor, at \$4.2 billion sales was the second largest selling drug, and Pravachol had achieved the \$1 billion mark in 2002. Lipitor's sales grew by 39% in 1999-2000, Zocor's by 22.2% and Pravachol's by 16%. Indeed, by 2012 Lipitor was the world's largest selling drug, at \$12.5B, indicating the importance of this category.

These drugs not only have large sales but also spend heavily on DTCA. In 2000, Zocor with a DTCA expenditure of \$91.2 million was the fifth largest DTCA spender, followed by Pravachol in 12th place with \$62 million and Lipitor in 15th place with \$58.2 million (Kaiser, 2002). Each brand had positive sales and undertook detailing before 1997. After the change in FDA policy Pravachol, Zocor and Lipitor started DTCA, from January 1998, while continuing with detailing. Mevacor did not use DTCA and reduced its detailing over time (Mevacor was due to lose its patent protection in December 2001 and may have reduced its detailing because of this). It is very important to note that during the study time period, all the four brands were on patent, and faced no competition from generics (henceforth, we use the terms brand and drug interchangeably).

The data were sourced from IMS Health USA, a leading company in healthcare. IMS Health USA uses its National Prescription Audit (NPA) to gather these data. NPA measures demand for prescription drugs, in the retail setting and hospitals and captures what is ultimately dispensed to consumers. From the universe of retail, standard mail service, specialty mail service and long-term care pharmacies, IMS selects

a representative sample stratified by geographic location. The pharmacy universe is comprised of more than three billion prescriptions from retail, mail service, and long-term care pharmacies. From this IMS collects data on new and refilled prescriptions for every day of the month. IMS's The National Sales Perspectives™ (NSP) measures sales at actual transaction prices (IMS Health via CDSE). IMS health also measures total promotional spend (detailing and DTCA) using its Integrated Promotional Services™ (IPS) from office-based and hospital-based physicians(IMS Health via CDSE).

The data variables used in this paper are i) monthly sales to retailers and monthly sales to hospitals in USD for the four brands (at the dosage level, e.g., Mevacor 20 mg, packet of 90 tablets); ii) monthly unit sales to retailers, and monthly unit sales to hospitals; iii) monthly detailing expenditure; iv) monthly DTCA expenditure in USD.

3.1 Operationalization of Variables

Sales and Price. Monthly data on volume sales (units) at the dosage packet level were used. One issue here is that the equivalent dosages of different products may differ, e.g., a 20 mg daily dosage of Mevacor is equivalent to a 10 mg daily dosage of Lipitor. To account for this, the daily equivalent dosage, available from the *Physicians Desk Reference*, was used to calculate sales of equivalent doses and price per dose of each of these products.

The therapy length for cardiovascular drugs is a month. Since the data are monthly, the volume sales at the brand level in units of *daily* equivalent dosage were summed to a *monthly* level. Calculation of price per unit dosage was done using the daily equivalent dosage from which average price per dose at the brand level was calculated. Prices were deflated to 1984 prices using the Consumer Price Index. Category level prices were obtained by weighting the brand prices by their shares.

Detailing and DTCA. As mentioned earlier, pharmaceutical firms also undertake direct marketing to physicians. The principal form of this is detailing, wherein a sales representative goes to the physician's office and talks to him/her, aided by graphs, charts, videos etc., often citing results from scientific research

(Parsons and Vanden Abeele, 1981). Pharmaceutical firms spent \$4.7B in 2001 on detailing in the U.S. (IMS health), making it the single largest expenditure by pharmaceutical firms (Wittink 2002). We have data on detailing and DTCA at the monthly level. All the four brands in the dataset had undertaken detailing for the span of data. Although FDA's guidelines were issued in August 1997, the Statin brands studied here did not start DTCA until January 1998. Data on DTC advertisements span from January 1998 through December 2001. Mevacor had no DTCA spending at any time.

Market Share. The estimation of our econometric models involves a specification of the market share of each drug. In order to account for customers not currently using Statins (and thus allowing for possibility of category expansion) it is imperative to get an estimate of the total market for such drugs is required. Data from the National Institute of Health's (NIH) National Cholesterol Education Program (NCEP) suggest that about 12.7 million people in the US required lipid lowering drugs at the time (Sempos et. al., 1993). This number was the total possible number of patients, and when combined with the equivalent dosage and therapy length allowed calculation of the total market. Note, that this total market includes all those that are on Statins, those on other cholesterol reducing drugs, and those that do not take any cholesterol reducing drugs. Each brand's market share in each month was calculated based on this total market.

3.2. Descriptive Statistics

Descriptive statistics for the variables of interest are given in Table 1. The table shows the mean dosage units, price, detailing and DTCA expenditures for the four drugs pre- and post-DTCA. Figures 1 to 4 presents how the mean dosage units, price, detailing expenditures and DTCA expenditures vary over time for the four drugs under analysis.

Table 1: Descriptive Statistics

Drug	Mean Sales (\$M)	Mean Price (\$)	Mean Detailing (\$M)	Mean DTCA
-------------	-----------------------------	----------------------------	---------------------------------	------------------

	(\$M)							
	1992- 1997	1998- 2001	1992- 1997	1998- 2001	1992- 1997	1998- 2001	1992- 1997	1998- 2001
Lipitor	27.07	188.30	108.30	91.16	4.83	5.97	--	3.62
Zocor	44.40	186.65	99.31	88.67	2.34	3.93	--	5.27
Pravachol	19.94	57.07	116.63	125.92	2.53	3.16	--	3.52
Mevacor	70.02	16.68	76.31	81.64	1.58	0.07	--	0.00

Figure 1: Volume Sales

Figure 2: Price

Figure 3: Detailing

Figure 4: DTC Advertising

4. Model Formulation

Similar to any form of advertising, DTCA can have two different effects: a) it can expand the category, b) it can change the market share of individual drugs within the category. Two sets of models are required to capture these separate effects: a category level model to capture category growth and a brand level discrete choice model to understand individual drug choice (Narayanan et al. 2004).

One complication is the need to account for the possible carryover effects of detailing and DTCA over time. Following prior literature, accounting for such effects is done through a Nerlove-Arrow exponential decay goodwill model (Nerlove and Arrow, 1962; Narayanan et al., 2004). Previous studies also show that promotional efforts such as detailing and advertising have diminishing returns due to wear-out (Manchanda et al., 2000; Malaviya et al., 1999). Wear-out is incorporated in the model by using a square root term. The relevant equations indicating carryover and wear-out can be found in the technical appendix (T1 and T2).

4.1 Category Level Model

Sales of a product category are a function of category level prices and category level marketing variables. Thus, category sales at time t ($CategorySales_t$) are a function of category prices ($CategoryPrice_t$), category detailing stock ($CatDetailStock_t$), category DTCA advertising stock ($CategoryDTCTock_t$), and time trend variables that account for category growth over a period of time. These include the linear and quadratic time trend variables (time and time squared respectively). The equations for the category expansion model for the two regimes (Pre-1997 no DTCA; post- 1997 with DTCA) are given by:

[Pre-1997: No DTCA]

$$\ln(CategorySales_t) = \alpha_0 + \alpha_1 CategoryPrice_t + \alpha_2 CategoryDetailingStock_t + \alpha_3 Time + \alpha_4 Time^2 + \varepsilon_t \quad (1)$$

[Post-1997: With DTCA]

$$\ln(\text{CategorySales}_t) = \alpha_0' + \alpha_1' \text{CategoryPrice}_t + \alpha_2' \text{CategoryDetailingStock}_t + \alpha_3' \text{CategoryDTCAStock}_t + \alpha_4' \text{Time} + \alpha_5' \text{Time}^2 + \varepsilon_t' \quad (2)$$

In the above equations, the category sales, CategorySales_t is the sum of sales for all (four) brands at time t , and is given by:

$$\text{CategorySales}_t = \sum_{j=1}^4 \text{Sales}_{jt} \quad (3)$$

where Sales_{jt} is the sales of brand j at time t . For CategoryPrice_t , $\text{CategoryDetailingStock}_t$ and $\text{CategoryDTCAStock}_t$ the weighted mean of prices, the sum of brand specific detailing stock, and the sum of brand specific DTCA stock are used (the weights are the shares of the individual brands). Time represents the time in months since Mevacor was introduced. This was the first brand to be introduced and this operationalization is meant to capture both the linear and nonlinear effects of time on category diffusion since the introduction of the first drug in the category.

4.2 Brand Level Model

The brand level demand model captures a physicians' discrete choice of a particular drug, conditional on choosing to prescribe from the category. In other words, an “outside alternative” is explicitly modeled, which could mean prescribing some other drug or no drugs at all. Taking a random-utility approach, the utility U_{ijt} derived by individual i , for brand j at time t as follows is: $U_{ijt} = V_{ijt} + \varepsilon_{ijt}$ where V_{ijt} and ε_{ijt} are the deterministic and random components of utility respectively. V_{ijt} can be expressed as follows for the two regimes:

[Pre-1997: No DTCA]

$$U_{ijt} = \beta_{0ij} + \beta_{1i} \text{price}_{jt} + \beta_{2i} \text{DetailingStock}_{jt} + \xi_{jt} + \varepsilon_{ijt} \quad (4)$$

[Post-1997: With DTCA]

$$U_{ijt} = \beta_{0ij} + \beta_{1i} \text{price}_{jt} + \beta_{2i} \text{DetailingStock}_{jt} + \beta_{3i} \text{DTCAStock}_{jt} + \xi_{jt} + \varepsilon_{ijt} \quad (5)$$

where, $\text{DetailingStock}_{jt}$, DTCAStock_{jt} and price_{jt} capture the detailing stock, DTCA stock and price of the drug j at time t , respectively. In the above two equations, β_{1i} represents the price-sensitivity, β_{2i} and β_{3i} capture the response to detailing stock and DTCA stock respectively, and β_{0ij} represents the preference for the particular brand j (i.e., “brand constants”). ε_{ijt} represents the usual error term. Many product characteristics are unobserved by the econometrician but known to the manufacturer. Such unobserved characteristics may be correlated with price and not accounting for these correlations could lead to biased estimates of the price parameter (BLP 1995). Accounting for such effects in this formulation is done by using the unobserved ξ_{jt} term.

For the sake of brevity, we use the same notation for the parameters across the two regimes. All the parameters are allowed to change pre and post policy change. Following prior literature, in the brand choice model formulation an assumption is made that the decision making entity is the physician-patient pair, and the choice is made by this pair (see e.g., Narayanan et. al, 2005). While admittedly a simplification, note that while DTCA is targeted towards patients, prescriptions are written by physicians with inputs from the patients. It is during such discussions that the effect of DTCA on brand choice would manifest itself.

The decision maker can choose a product from among the brands under consideration, or choose the outside option. Let the utility from the outside option be given by

$$U_{i0t} = \alpha_{i0} + \varepsilon_{i0t} \quad (6)$$

Normalizing ε_{i0t} to 0 identifies the mean preferences of other brands. The standard assumption that ε_{ijt} and ε_{i0t} are i.i.d. and from an extreme value distribution is made.

4.3 Measuring Change in Consumer Welfare

A structural demand model is ideally suited for calculating changes in consumer welfare because it allows for the computation of consumer welfare explicitly (Chintagunta et al., 2003). The focus of this study is on computing the change in consumer welfare due to DTCA. The welfare change is calculated using Equation (7) (Levinsohn and Petrin, 2003; details are provided in the technical appendix). This measure of consumer welfare is based on changes in demand side utility parameters.

$$\Delta CS_i = \frac{\ln \left[\sum_{j=0}^J \exp(V_{ij}^{\text{Post-DTCA}}) \right]}{\beta_{li}^{\text{Post-DTCA}}} - \frac{\ln \left[\sum_{j=0}^J \exp(V_{ij}^{\text{Pre-DTCA}}) \right]}{\beta_{li}^{\text{Pre-DTCA}}} \quad (7)$$

5. Estimation

The data is split into two subsets. The first subset covers 1992-1997 and corresponds to equations (3) and (6) for category level and brand level estimation respectively. In this regime the four brands, Mevacor, Zocor, Pravachol, and Lipitor competed on price and detailing. The next subset comprises of the same four brands Mevacor, Zocor, Pravachol and Lipitor, competing on price, detailing, and DTCA between 1998 and 2001, and corresponds to equation (2) and (5) for category level and brand level estimations.

Demand parameters are estimated for each of these subsets of data for both the category level and within category brand level models. The utility equations account for consumer heterogeneity in sensitivity to price, detailing and DTCA. A logit demand model that does not account for unobserved heterogeneity suffers from the IIA property, wherein cross-elasticities of demand are always in the ratio of the shares of the brands (Nevo, 2001). To handle this problem and to facilitate a reasonable substitution pattern across the brands, a random coefficient logit model is estimated, with price, detailing and DTCA parameters assumed to be normally distributed across the population. Product characteristics unobserved by the econometrician may be correlated with price, giving rise to the problem of endogeneity. This is accounted for using three sets of instruments (please see the technical appendix).

As is now standard in the literature, an estimation approach which essentially tries to match the predicted and observed market shares is used. Specifically, a contraction mapping technique (BLP, 1995) is employed, from which a GMM objective function is minimized to recover the parameters (Nevo, 2001).

The carryover parameters δ_{Det} and δ_{Dtc} are estimated using a simpler model, because these cannot be estimated within the larger model and need to be fixed (Narayanan et al. 2004). The carryover parameter values thus estimated are 0.85 and 0.72 for detailing and DTCA respectively. Further details on the estimation are provided in the technical appendix.

6. Results

The category demand model parameters estimates are reported in Table 2 and the brand choice model parameter estimates in Table 3. For ease of discussion, the results have been tabulated such that the results for the pre- and post- DTCA are together in each table.

The category level estimates in Table 2 indicate that DTCA has a positive and significant effect on total category sales. The price parameters are negative and significant in both the pre- and post- DTCA regimes. The detailing response parameters are positive and significant in both the pre- and post- DTCA regimes. The response to detailing decreased post-DTCA; however, the difference in the detailing responses from pre- and post- DTCA regimes is not statistically significant. The category constant is higher in the post- DTCA regime indicating category expansion post policy change. The main takeaway from the model is that DTCA has a significant positive effect on category growth. This result is in conformity with some of the earlier studies that suggest DTCA helps new patients to seek treatment for their therapeutic condition. Interestingly, detailing which was highly significant in the early years of the category seems to play a somewhat lesser role in the latter period, possibility due to Statins being a mature category by 1998.

Table 2: Category Level Parameters

	Pre-DTCA (1992-1997)		Post-DTCA (1998-2001)	
	Parameter	Standard Errors	Parameter	Standard Errors
Constant	20.21 ***	0.99	23.57 ***	2.36
Price	-0.02 **	0.01	-0.05 ***	0.02
Detailing	1.711E-05 ***	5.02E-06	1.48E-05	4.07E-05
DTCA			2.22E-05 **	1.05E-05
Time	0.00	ns	0.09	ns
Time sq.	0.00	ns	-0.00	ns

*** Significant at 99%, ** Significant at 95%, * Significant at 90%,

The brand choice model estimates in Table 3 show that in the pre-DTCA regime the price parameter is both in the right direction and significant. The detailing parameter is positive and significant. The brand constants are generally in the proportion of the market shares of the competing brands during the pre-DTCA regime. For example, Mevacor with the largest average share has the highest brand constant while Pravachol with the lowest average share has the smallest brand constant.

In the post-DTCA regime, results show that price, detailing, and DTCA are all significant and in the right direction. In other words, detailing and DTCA affect not only category growth, but also aid in brand switching. Note that although the effect of detailing is greater than that of DTCA, there is no statistically significant difference between the two. The brand constants are generally proportional to the market shares of the brands. Note that the intercepts for all the four brands are negative in both the pre and post DTCA regime because the intrinsic preferences for the bands are normalized with respect to the outside good. There seems to be no significant unobserved heterogeneity on the four brands, price, detailing and DTCA.

In comparing the estimates across the two regimes, the first finding is that consumers' price sensitivity decreases post-DTCA. Implications of this are discussed in the next section. The effect of detailing also decreased post-DTCA. The intrinsic preferences for the four brands post-DTCA are

significantly higher as compared to the preferences from the pre-DTCA regime. This is in line with the earlier finding that DTCA helps in category growth.

Table 3: Brand Level Parameters

	Pre-DTCA (1992-1997)		Post-DTCA (1998-2001)	
	Parameter	Standard Errors	Parameter	Standard Errors
Lipitor Intercept	-8.79 ***	0.78	-4.09 **	1.83
Zocor Intercept	-9.47 ***	3.13	-3.86 **	1.71
Pravachol Intercept	-10.34 ***	3.52	-3.97 *	2.20
Mevacor Intercept	-8.76 ***	2.65	-4.87 ***	1.06
Price	-0.04 **	0.02	-0.02 **	0.01
Detailing	5.29E-04 *	2.81E-04	1.12E-04 *	6.00E-05
DTCA			4.78E-05 **	2.34E-05
*** Significant at 99%, ** Significant at 95%, * Significant at 90%, Note: Heterogeneity parameters were not found to be significant.				

The focal variable, change in consumer welfare, was calculated by inserting the demand side parameters from the pre- and post- DTCA regime into equation (7). This captures the dollar amount that consumers would need to be compensated to keep their level of utility the same as before the change (McFadden 1999). In this context, consumer welfare increases in the post- DTCA regime by \$9,408.14.

7. Discussion and Conclusion

The change in policy of allowing DTCA by pharmaceutical firms for prescription drugs has generated a lot of debate. The debate has focused mainly on whether DTCA increases the footfall of potential patients into doctors' offices leading to earlier diagnosis and better treatment of patients, or whether it simply makes patients desire a specific brand.

This study focuses on empirically testing for changes in consumers' welfare after DTCA was allowed. The findings suggest that in the case of Statins consumer welfare increased by \$9408.18 after DTCA was allowed. The results also suggest that DTCA led to category expansion as well as enhanced sales of each brand.

Of course, given each medical condition is different, DTCA in another category of drugs may or may not have a similar category expansion or consumer welfare enhancing effect. This study, being the first to empirically test the change in welfare after the policy change, can help in the analysis of future policy changes on DTCA.

The world of pharmaceutical marketing itself is changing. Traditionally blockbuster drugs, those with sales of \$1 billion, were driven by vast sales forces, and a share of voice driven commercial model (Rickwood, 2012). This seems to suggest that detailing and DTCA played a large role in the success of these blockbuster drugs. Today though, the definition of a blockbuster drug is changing. The previously mentioned billion-plus sellers were used predominantly in primary care settings and were targeted at chronic conditions. The new blockbuster model is focused more on specialty therapy. For example, in 2002, 70% of all traditionally defined blockbuster drugs were primary care products versus 44% in 2011 (Rickwood, 2012). Interestingly, markets for biologic and injectables, which have much smaller patient populations than small molecule drugs (traditional), are growing. These biologic and injectables are considered the products of the future and their share of market spending on promotions has been growing (Kornfiel et al, 2013). Further, DTCA via internet and electronic promotions, although small at the moment, is increasing (Stanton, 2011; Kornfiel et al., 2013). Given the findings of this study, it

would be interesting to examine the consumer welfare impact of a very targeted DTCA to these small populations. More generally, as advertising spending on paid digital media by the US healthcare and pharmaceutical industry keeps increasing (from \$1.18 billion in 2013 expected to be \$1.47 billion by 2017 (eMarketer, 2013) it may be worthwhile for practitioners to understand in what category of drugs such advertising enhances consumer welfare and where it does not. Marketing has been criticized for its focus on enhancing corporate rather than consumer welfare (Peltier et al., 2002). Hopefully more analysis of the kind this study has undertaken can help redress this imbalance of focus.

Being among the first, this study suffers from many limitations. First, it does not account for the welfare effects of life style changes and other non-drug interventions for a patient. Second, while it speaks to the change in consumers' welfare, it cannot shed any light on the change in producers' welfare. A future study empirically testing both components of social welfare would improve the understanding of policy decisions.

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Technical Appendix

We first write the equations used to estimate Detailing and DTCA stock. Then we write out the specification for the estimation of the demand parameters followed by equations used to calculate the change in consumer welfare.

T1: Specification of carryover and Wear-Out

Using a Nerlove-Arrow exponential decay goodwill model to capture carryover and a square root term to capture wear-out in marketing:

Brand j 's goodwill stock of detailing at time period t , $DetStock_{jt}$, is given by:

$$DetailingStock_{jt} = \delta_{Det} DetailingStock_{jt-1} + \sqrt{Detailing_{jt}} \quad (T1)$$

Where $Detailing_{jt}$ is brand j 's level of detailing at time at period t and δ_{Det} is the carryover coefficient of detailing. Similarly brand j 's goodwill stock of DTCA in period t , $DTCAStock_{jt}$, is given by:

$$DTCAStock_{jt} = \delta_{Dtca} DTCAStock_{jt-1} + \sqrt{DTCA_{jt}} \quad (T2)$$

Where $DTCA_{jt}$ is, brand j 's level of advertising at time t , an δ_{Dtca} is the carryover coefficient associated with DTCA.

Since we will refer to two particular equations from the body of paper in the next two sections, we rewrite them here for ease of exposition, retaining the numbering from the paper.

$$\begin{aligned} &[\text{Pre-1997: No DTCA}] \\ &U_{ijt} = \beta_{0ij} + \beta_{1i} price_{jt} + \beta_{2i} DetailingStock_{jt} + \xi_{jt} + \varepsilon_{ijt} \end{aligned} \quad (4)$$

$$\begin{aligned} &[\text{Post-1997: With DTCA}] \\ &U_{ijt} = \beta_{0ij} + \beta_{1i} price_{jt} + \beta_{2i} DetailingStock_{jt} + \beta_{3i} DTCAStock_{jt} + \xi_{jt} + \varepsilon_{ijt} \end{aligned} \quad (5)$$

T2: Estimation

We elaborate on the estimation technique for the two equations (4) and (5). The Berry, Levinson and Pakes ((henceforth BLP) 1995) estimation technique suggests that when accounting for both heterogeneity and endogeneity, the utility function be split into two parts, a mean utility term and an individual specific term. Following this technique, the parameters β_{1i} , β_{2i} , and β_{3i} are now written as

$$\begin{aligned}\beta_{1i} &= \bar{\beta}_1 + \sigma_i \zeta_{1i} \\ \beta_{2i} &= \bar{\beta}_2 + \sigma_i \zeta_{2i} \\ \beta_{3i} &= \bar{\beta}_3 + \sigma_i \zeta_{3i}\end{aligned}\tag{T3}$$

Thus utility for brand j , at time t , for individual i is now given by:

$$U_{ijt} = \delta_{jt} + v_{ijt} \tag{T4}$$

where δ_{jt} is the mean utility level of product j and is given by

$$\delta_{jt} = \beta_{0j} + \bar{\beta}_1 price_{jt} + \bar{\beta}_2 DetailingStock_{jt} + \bar{\beta}_3 DTCSStock_{jt} + \xi_{jt} \tag{T5}$$

The random component of the utility is v_{ijt} . Collecting the individual specific terms from equations (4) and (5) we get

$$v_{ijt} = \left[\sum_k X_{jkt} \sigma_k \zeta_{ikt} \right] + e_{ijt} \tag{T6}$$

where X_{jt} is a vector of $Price_{jt}$, $DetailingStock_{jt}$ and $DTCSStock_{jt}$. The distribution of ζ is assumed to be a multivariate normal Ω . Based on the mean utility δ_{jt} the probability of purchase of brand j at time t is:

$$P_{ijt}(\theta) = \frac{\exp(\beta_{0ij} + \bar{\beta}_{1i} price_{jt} + \bar{\beta}_{2i} DetailingStock_{jt} + \bar{\beta}_{3i} DTCA_{jt} + \xi_{jt})}{1 + \sum_k \exp(\beta_{0ik} + \bar{\beta}_{1i} price_{kt} + \bar{\beta}_{2i} DetailingStock_{kt} + \bar{\beta}_{3i} DTCA_{kt} + \xi_{kt})} \quad (T7)$$

where θ represents the set of parameters. This is the usual multinomial logit model but with the added ξ_{jt} term (Chintagunta, 2001). Aggregation up to market shares of each brand is done starting with the utility of a brand j at time t for individual i . The predicted market share for brand j is given by:

$$S_{jt} = \int P_{jt}(\theta) f(\theta | \mu, \Omega) d\theta \quad (T8)$$

The random component terms are simulated from a standard normal distribution following which the predicted shares are derived. Contraction mapping (BLP, 1995) implies computing a value of the unobserved attribute of brand j at time t , ξ_{jt} , that makes the predicted brand shares close to the actual brand shares at time t . The parameters are estimated by interacting the ξ_{jt} term with instruments and using the Generalized Method of Moments (GMM).

T2.1 Instruments

Product characteristics unobserved by the econometrician may be correlated with price, giving rise to the problem of endogeneity. Three sets of instruments are used to control for endogeneity between price and unobserved variables. The first set of instruments used are hospital prices (IMS health). These are likely to be good instruments, because evidence suggests that although firms set hospital prices differently from retail prices, the two are correlated (Hurwitz and Caves, 1988). The second set of instruments for price are lagged own prices for each brand. A similar approach has been followed in the extant literature (for example, Chintagunta, 2000). A third set of instruments used is the “BLP instruments”, i.e., relevant characteristics of other products/brands. In particular, the average prices for all other brands (excluding the focal brand’s prices) are used as instruments.

Further, detailing and DTCA may also be correlated with unobserved product characteristics i.e., may be endogenous. Detailing and DTCA are instrumented using lagged detailing and lagged DTCA

respectively, as well as the relevant BLP instruments (i.e. the sum of detailing of other brands and sum of DTCA of other brands).

T.2.2 Carryover Parameters

Following past literature (Narayanan et. al., 2004, Wittink, 2002, Guadagni and Little, 1983) we use an aggregate logit model and a grid search method such that the parameters chosen had the highest R^2 values. These carryover coefficients are consistent with previous studies; for example, Narayanan et al. (2004) find carryover parameters of 0.86 and 0.75 for detailing and DTCA respectively in the anti-allergy category, while Berndt et al. (1997) find advertising carryover to be 0.85 in the anti-ulcer drug market. The carryover parameter values used in the model are 0.85 and 0.72 for detailing and DTCA respectively.

T3: Consumer Welfare

Equations (4) and (5) above are the indirect utilities before and after the policy change. To reiterate these are represented in general by

$$U_{ijt} = \delta_{jt} + v_{ijt} \quad (T4)$$

where the random component of utility is

$$v_{ijt} = \left[\sum_k X_{jkt} \sigma_k \zeta_{ikt} \right] + e_{ijt} \quad (T6)$$

It is these utilities that are used to calculate the change in consume welfare as shown below.

The compensating variation (CV) approach assumes that the marginal utility of income is constant across the two situations, i.e., utility is linear in income Assuming a constant marginal utility of income, the expected consumer surplus is given by (Train 2003; Small and Rosen, 1981):

$$CS_i = \frac{1}{\theta_i} \ln \left(\sum_j^J \exp(V_{ij}) \right) + C \quad (T9)$$

where the utility of consumer i net of the extreme value distribution is V_{ij} , and the marginal utility of consumption is θ_i , and C is an unknown indicating that absolute levels of utility cannot be measured (Train, 2003).

The change in welfare (Small and Rosen, 1981) for consumer i between the two policy conditions, before and after the change in FDA policy (denoted by pre-DTCA and post-DTCA respectively) is given by:

$$\Delta(CS_i) = \frac{1}{\theta_i} \left[\ln \left(\sum_j^J \exp(V_{ij}^{\text{Post-DTCA}}) \right) - \ln \left(\sum_j^J \exp(V_{ij}^{\text{Pre-DTCA}}) \right) \right] \quad (\text{T10})$$

Equation (T9) is derived assuming constant marginal utility of income; empirical evidence suggests that the estimates of changes in welfare are not substantially different when computed assuming constant marginal utility of income versus not (Herriges Kling, 1999).

The focus is on the change in consumer welfare after DTCA is allowed versus before. In order to measure this change, both, (4) and (5) are estimated to give us two sets of demand side parameters. Let the price response parameter before and after DTCA be denoted by $\beta_{li}^{\text{Pre-DTCA}}$ and $\beta_{li}^{\text{Post-DTCA}}$ respectively. Equation (T11) is used to estimate the change in consumer welfare. In calculating the change in welfare we use the absolute value of the price parameter value, β_{li} , since it is a negative number (Train, 2003).

$$\Delta CS_i = \frac{\ln \left[\sum_{j=0}^J \exp(V_{ij}^{\text{Post-DTCA}}) \right]}{\beta_{li}^{\text{Post-DTCA}}} - \frac{\ln \left[\sum_{j=0}^J \exp(V_{ij}^{\text{Pre-DTCA}}) \right]}{\beta_{li}^{\text{Pre-DTCA}}} \quad (\text{T11})$$

Equation (T11) is referred to as equation 7 in the body of the paper.