How Do Restrictions on Advertising A ect Consumer Search?

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Abstract

Advertising is often criticized for presenting only partial or selective information about products. This criticism is particularly pronounced for health products, where large asymmetries in information may exist between consumers and rms. This paper explores how government restrictions designed to prevent selective advertising a ect the types of information to which consumers are exposed. We exploit a natural experiment in the form of an FDA crackdown that prevented pharmaceutical companies from using selectively chosen information in their Internet search ads. Since companies could not adequately document side-e ects within the advertising space allowed, they removed their ads. Our results suggest that, after the ads were removed, consumers were more likely to seek information from websites based on user-generated content or websites that focused on medical treatments not regulated by the FDA, such as Canadian pharmacies and sites promoting herbal remedies.

1 Introduction

When designing ads, companies select which information to provide to consumers. Selective information may be undesirable if large asymmetries exist between consumers and rms regarding a product's quality or risks. To protect consumers against ads with misleading or

brand name searches, but some evidence of complementarities between paid search ads and

The ambiguity in policy changed on March 26, 2009 when the FDA issued letters of warning to 14 major pharmaceutical companies, regarding their Internet ads that accompanied keyword searches on Google and other search engines. The FDA indicated in its press release that its concerns were motivated by the severity of the potential side-e ects associated with these drugs. It stated that the ads were misleading because they did not include information on the risks or side-e ects associated with a drug. These warnings were one of the rst major actions by the FDA to crackdown on Internet promotions. The companies that received letters were Biogen, Sano -Aventis SA, Johnson & Johnson, GlaxoSmithKline PLC, Forest Laboratories Inc., Cephalon Inc., Bayer AG, Novartis AG, Merck & Co., Eli Lilly & Co., P zer, Roche Holding AG, Genentech Inc. (now acquired by Roche), and Boehringer Ingelheim Pharmaceuticals Inc. Nineteen of the 48 drugs cited in the letters carry a black box, which is the FDA's strongest warning on possible side-e ects.[2]

A typical FDA letter resembled the one sent to Ho mann-La Roche, regarding its drugs Boniva, Pegasys, and Xeloda. We quote the full text of the letter in the Appendix to this article. The letter cited ads that had the message, \XELODA Information www.xeloda.com Learn About An Oral Chemotherapy Treatment For Colon Cancer." The FDA criticized these ads, saying \By omitting the most serious and frequently occurring risks associated with the drugs promoted in the links above, the sponsored links misleadingly suggest that Boniva, Pegasys and Xeloda are safer than has been demonstrated." Even though the ad included a link to the website for the drug, which did contain the relevant risk information, the FDA said the link was \insu cient to mitigate the misleading omission of risk information from these promotional materials." The FDA gave the company until April 9, 2009 to prove compliance.

paid search advertising had not yet evolved.

[2]FDA Warns Drug Firms Over Internet Ads, Wall Street Journal, April 4, 2009.

3 Data

We obtain data on search advertising and consumer online behavior from comScore's Search Planner database.[3] This database reports the average click behavior of consumers following a keyword search on any of the three major search engines. For each keyword search, comScore reports the monthly aggregate number of clicks received by a website either through a \paid" link or a \non-paid" link.

When a user conducts a keyword search for a pharmaceutical product, the search engine returns a list of results containing links to several di erent websites. Some of the links are from advertised sources (\paid links") while others are from non-advertised sources (\unpaid links"). For instance, Figure 1 depicts the search results from a query on the keyword of the drug \Levitra" using the Google search engine. The search engine displays a list of paid links in the sponsored results section (at the top and to the right) of the search results page as well as a separate list of non-paid links within the body of the main search results. Advertisers bid for the paid links, which are text ads that appear in response to consumers' keyword searches. When a user clicks on the paid link, the advertiser must pay the search engine. A website can sometimes appear in both the sponsored and main results page. For instance, in Figure 1, the product website for Levitra (www.levitra.com) appears both as a paid link in the sponsored results section and also as a non-paid link within the main search results. Note that the FDA warning targeted the paid links or search ads by pharmaceutical companies. In addition to pharmaceutical companies, many di erent types of advertisers place ads on keywords containing a pharmaceutical brand name or medical condition. For instance, most

[3]ComScore tracks the online activity of a panel of more than 2 million users based in the US and subsequently aggregates their search patterns to the search-term level for resale to commercial clients. ComScore recruits its panel members through a liate programs and partnering with third party application providers.

ads for the keyword \Levitra" are either for online pharmacies (often Canadian) such as northwestpharmacy.com or kwikmed.com, or for alternative natural remedies for erectile dysfunction like zernerx.com. These sites are able to advertise because no legal restriction exists on bidding for a pharmaceutical brand name.[4]

Since a vast set of combinations of search terms and websites exist, comScore imposes some selection criteria for inclusion into its database. ComScore only collects data on speci c phrases that arise from queries by at least two di erent panel members. Under its minimum reporting standards, comScore does not record the number of clicks for websites that receive clicks from fewer than three unique users but instead reports them simply as having been visited at least once. We assume that such websites receive two clicks.[5]

3.1 Types of Keywords

We collect information on keyword searches for medical conditions and symptoms associated with the targeted products. We identify the top two medical condition and symptom phrases that were used by consumers to navigate to a pharmaceutical website in February 2009, where such data was available. The medical conditions include terms such as \breast cancer" and \hypertension." These keyword terms align closely with the medical conditions mentioned in the FDA warning letters. Table A-2 contains a list of the 61 keywords for the corresponding medical conditions within our sample. Some overlap of medical conditions occurs among the targeted drugs.[6]

To provide a baseline for any change in health-related searches, we also collect data on keyword searches on medical devices. For example, if a patient has \erectile dysfunction," they may search for a drug like \Viagra," or they may search for a treatment based on a

[4] In *Merck & Co. v. Mediplan Health Consulting, 2006 WL 800756 (SDNY Mar. 30, 2006)*, the court dismissed Merck's claims of infringement on the grounds that Mediplan's search advertising on keywords such as \Zocor" did not represent a use of a trademark in commerce.

[5] Our main results are robust to assuming such websites receive only one click.

[6] The drugs Bystolic, Diovan, and Exforge treat hypertension. Avandmet, Avandia, and Januvia treat diabetes.

medical device such as a \penile implant." Similarly, a patient who has \heart disease" could search for one of the drugs in our sample or for a \home blood pressure monitor." We collect this data because our identi cation strategy relies on changes in search outcomes correlated with the change in FDA enforcement and not with another contemporaneous change in health-related searches.

3.2

such as nativeremedies.com. Although homeopathic remedies are regulated by the FDA, they do not have to undergo the same testing and review by the FDA before being sold as pharmaceutical products do. These manufacturers are not subject to the same fair-balance requirements in advertising as pharmaceutical products.

The third group of non-regulated websites o ers advice about the consumption of marijuana, such as weedsthatplease.com. At the time, thirteen states approved the use of marijuana for medical purposes, but the FDA had not approved a medical use for marijuana.

Then, we identify sites as \user-generated content" (UGC) if their URLs contained the words \community," \groups," \answers," or \forum." We also include websites that allowed users to pose questions, which are then answered by other community members, such as \Yahoo! Answers." This categorization de nes a set of websites where information is provided by members of the public rather than by veri ed or o cial sources. Given the FDA's emphasis in its letters on ensuring that information was complete and balanced, such websites do not necessarily ful ll this role. However, we do emphasize that the role of user-generated in content and its helpfulness in spreading accurate information is subject of academic inquiry and debate (Moorhead et al., 2013).

For the remaining websites, we use the su x of their URL to divide them into two additional categories: \non-pro t" and \commercial." We identify websites as \non-pro t" if the website address contained a su x of .ORG, .EDU, or .GOV, and we identify websites as \commercial" if they did not contain either of these su xes. The motivation behind classifying \non-pro t" sites is to delineate a set of websites that are more likely to provide impartial, balanced, and educational information because of their governmental or non-pro t status.

The commercial websites include websites, such as www.webmd.com, that speci cally provide medical content and may be supported by revenues from advertising. This category also includes more general sources of information that may feature health-related news or

products, such as associatedcontent.com, as well as the websites of pharmaceutical products and manufacturers that were not targeted by the FDA.

The final category of websites in our data is search websites. This category captures the behavior of consumers who were dissatisfied with the search results and returned to the search engine to perform a different search. We refer to this behavior as terminating that search and treat it as the "outside" option in our empirical specifications. Given the way comScore data is constructed, we do not observe details on people who completely stop searching after seeing a set of search results. This occurs because the comScore data are focused on searches and online navigation rather than termination.

To summarize, the categories of websites described above are mutually exclusive and exhaustive of the sites we observe in our sample. The categories include pharmaceutical, non-regulated, user-generated content, non-profit, and commercial. The outside option is terminating the current keyword search by performing a different keyword search.[8]

3.3 Final Sample

Our final sample contains the number of total, paid, and non-paid clicks received by each website for keyword searches at the monthly and search engine level. The data span the period from February 2009 to June 2009. Our data captures online behavior on the three major search engines | Google, Live (Bing) and Yahoo!. As an example of an observation within our sample, we observe the total number of total, paid and non-paid clicks received by www.levitra.com from users who conducted a keyword search containing "Levitra" from Google during June 2009.

The initial dataset on medical conditions and symptoms includes 13,016 combinations of keyword and websites subsequently visited by consumers, totalling 52,064 observations over four months. Some overlap of websites occurs across search terms; for example, webmd.com

[8] For our sample of medical devices, we do not observe any paid or non-paid clicks to the targeted pharmaceutical companies, which is not surprising given that a search for a device is unlikely to lead to a visit to a pharmaceutical company.

ad purchasing; 12 and 14% of these websites display paid ads in March and April 2009.

Though the majority of search ads was removed, some pharmaceutical companies continued displaying their ads, but with dramatically changed text. For example, Eli Lilly tried to circumvent the fair balance requirements by removing any mention of treatment in its ads. An ad for the drug Cialis might provide a link to the o cial website and text that merely states, \O cial Site. Free Trial Voucher."[10] Therefore, the prohibition of selectively informative ads by the FDA captures both the removal of actual ads by pharmaceutical companies and the removal of informative content within ads by pharmaceutical companies. We later use this variation in compliance to compare outcomes from the policy shift in Table 6.

3 also presents click behavior in 2008 when no such shift in policy enforcement occurred. As expected, little change in behavior occurs across the different website categories in 2008.

Initially, we examine searches of medical conditions and symptoms in our data. We investigate how each website's share of clicks changed in response to the FDA enforcement. Note that we examine the proportion of clicks because this relative measure is not sensitive to the level or absolute number of searches. For every search term j on search engine k in month t, we compute the proportion of clicks received by website i as the number of clicks received by website i divided by the total number of clicks received by all websites for search term j on search engine k in month t.

We use the following specification to estimate how the FDA prohibition on selectively informative advertising affected consumer searches. We run the regression for the proportion of clicks:

$$\begin{aligned} Propclicks_{ijkt} &= {}_1 Pharma_i \quad PostFDA_t \\ &+ {}_2 Nonregulated_i \quad PostFDA_t \\ &+ {}_3 Nonprofit_i \quad PostFDA_t \\ &+ {}_4 UGC_i \quad PostFDA_t \\ &+ {}_5 Commercial_i \quad PostFDA_t \\ &+ {}_i + {}_j + {}_k + !_t + {}_{ijkt} \end{aligned} \tag{1}$$

where *Pharma* is an indicator variable equal to 1 if the website is owned by one of the targeted pharmaceutical companies. *NonRegulated* is an indicator variable equal to 1 if the website directs consumers to products that are not regulated by the FDA; *UGC* is an indicator variable equal to 1 if the website is composed of user-generated content; *Nonprofit* is an indicator variable equal to 1 if the website is a non-profit site with an address that contains a suffix of .ORG, .EDU, or .GOV; *Commercial* is an indicator equal to 1 if the

website is a regular commercial website. The variable *PostFDA* is an indicator variable equal to 1 if the month occurs after March 2009, when the FDA issued the letters. Since *PostFDA*

the period after the FDA enforcement letters. This suggests that our results on navigation shifting from pharmaceutical websites to other alternative categories is not likely driven by seasonal di erences in medical searches. Table 5 runs a regression similar to Table 4 for medical device keywords. The results con rm that we do not observe changes in the alternative categories.

4.1 Robustness Checks

We also perform numerous robustness checks in Table 6. The majority of these speci cations check that our decision to exclude or include certain observations does not drive our results.

Our results remain consistent throughout these alternative speci cations. Columns (1) and (2) of Table 6 shows robustness to the exclusion of visits to either the most visited or least visited 5% of websites. This is reassuring evidence that the tail of the distribution is not driving our results.[13] Columns (3) and (4) of Table 6 provide some reassuring evidence that the change we observe for pharmaceutical websites was indeed driven by the policy. We distinguish between pharmaceutical sites who completely complied with the FDA warning by removing their ads and those who only partially complied and still had a few ads after the change. As expected, the e ect of the shift in FDA enforcement was greater and statistically signi cant for those websites that completely complied with the policy by removing all ads; the enforcement had no statistically signi cant e ect for websites that did not comply with the policy by removing all ads. Column (5) performs a robustness check where we do not distinguish between the di erent search engines at the observation level. In other words, an observation is a keyword-website combination rather than a combination by keyword, search

other means after the change in FDA enforcement. However, as shown by Figure 6, total visits to pharmaceutical websites had a sizeable and persistent decrease.

not regulated by the FDA.

5 Implications and Conclusion

5.1 Implications

To understand the implications of our findings that regulating selectively provided information may lead consumers to seek non-regulated websites, it is useful to calibrate whether the non-regulated websites provided similar, better, or worse information than the regulated websites. To assess this, we implemented a survey where we asked survey participants how they viewed the reliability of a website.[16] For each non-regulated website, we asked participants to respond on a Likert scale of 1 (entirely disagree) to 7 (entirely agree) regarding several statements of whether the website feels reliable, trustworthy, could damage my well-being, or could improve my health.

Figure 9 presents the ratings for non-regulated website in a variety of dimensions. The figure indicates that participants did not feel strongly that the unregulated websites were particularly reliable, helpful, or able to improve their well-being. At the same time, participants did not view the websites as a serious threat to their health. The overall takeaway is that participants did not view unregulated websites as particularly helpful or impactful to improving their health.

5.2 Conclusion

An obvious critique of advertising is that ads provide one-sided information and that such one-sidedness may be harmful if consumers are relatively ill-informed about the risks or quality of a product, as often is in the case of the health and financial sectors. In response to concerns that companies may provide selective information in their ads, regulators have imposed restrictions on the type and amount of information disclosed within advertisements. By examining a recent change in FDA policy enforcement in March 2009, we study how

[16] We used Amazon Mechanical Turk to perform this survey.

prohibiting ads with selectively-chosen information a ects consumer behavior. Our paper asks whether consumers respond by seeking information from other alternative sources and whether these sources provide more reliable or balanced information.

We nd that restricting pharmaceutical advertising does not necessarily lead consumers to seek more balanced sources of information. The major bene ciaries of the restrictions appear to be channels not regulated by the FDA, such as Canadian pharmacies and purveyors of alternative homeopathic remedies. We also nd some evidence that a sizable number of consumers may increasingly rely on non-veri ed information from the public in the form of user-generated content. We emphasize that this is not necessarily harmful, as some papers have shown the usefulness of user-generated content sites for consumers seeking health information (McNab, 2009; Moorhead et al., 2013). However, others have also documented that user-generated sites can be used for misinformation (Chiou and Tucker, 2018). Recent research looking at the Zika pandemic found on balance that there was more misleading rather than helpful information (Sharma et al., 2017) on such websites.

Our results have direct public policy implications for the regulation of advertising. They suggest that imposing regulation on advertising by \unreliable" sources of information may not necessarily improve consumers' information set, since users may seek more unveri ed information through non-advertised channels. Furthermore, our results suggest that expanding

regulatory changes and how these responses may change our findings. We have been told that eventually Google was able to format its ads in such a way that satisfied the FDA, and ads were consequently restored. In the long-run, the incentives of a platform may mitigate the effects of regulation. Third, the fact that we have aggregate data rather than individual-level data means we cannot track how subsequent actions (beyond the first website visited) of each individual evolved in response to the change in FDA enforcement. Fourth, a new literature (Lewis and Reiley, 2014; Lewis and Rao, 2016) emphasizes the difficulty of measuring the small effects of advertising on actual sales. It thus remains a question the extent to which changes in advertising ultimately affected customer behavior, especially given the relatively small proportion of clicks directed to the pharmaceutical company websites. Finally, it is possible that net benefits might occur if people assume that advertising provides regulated information whereas unadvertised sources do not. Notwithstanding these limitations, we believe that our results shed light on the some potential pitfalls and complexities associated with the regulation of online advertising.

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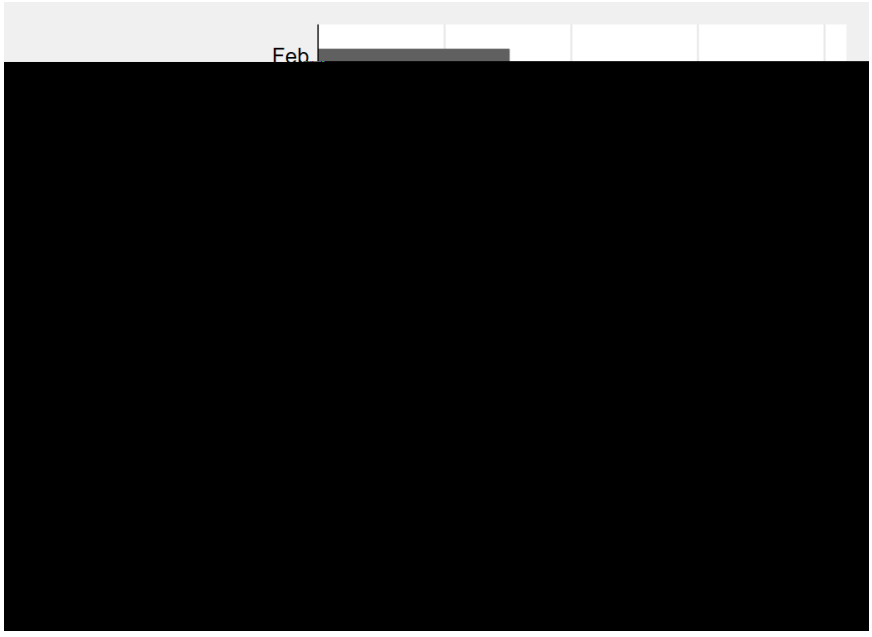
Figure 2: By Website Type: How the fraction of search ads changed

Notes: This gure compares the 4-month period in 2009 when there was a change in FDA enforcement policy with the same 4-month period in 2008 when there was not. It shows the number of search ads by di erent types of websites. These search ads were associated with keyword searches containing the brand name or associated medical condition and symptoms of the pharmaceutical products targeted by the FDA.

Figure 3: By Website Type: How the proportion of clicks changed for medical conditions and symptoms.

Notes: This gure compares the 4-month period in 2009 when there was a change in FDA enforcement policy with the same 4-month period in 2008 when there was not. The clicks are for keyword searches on medical conditions and symptoms.

Figure 4: By Website Type: How the proportion of clicks changed for medical devices.

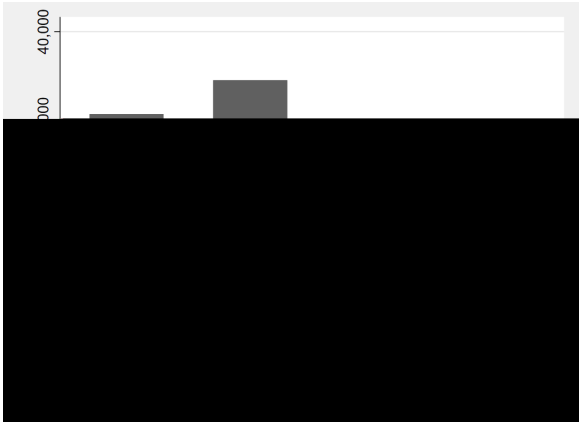


Notes: This gure compares the 4-month period in 2009 for keyword searches on medical devices, which was not covered by the FDA regulation.

Figure 5: No systematic change in o ine spending on advertising occurred during change in FDA enforcement policy

Notes: This gure shows data on pharmaceutical advertising in a variety of o ine channels over the period studied in this paper.

Figure 6: How the Number of Visits to Pharmaceutical Websites Changed in 2009.



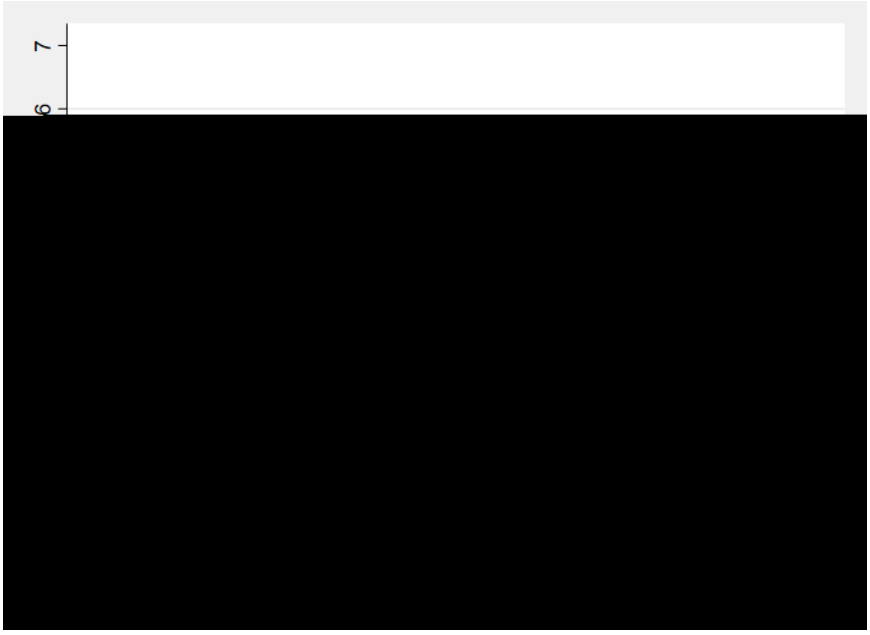
Notes: This gure shows the average of total tra c to pharmaceutical websites in our sample. This covers

Figure 7: How Sources of Incoming Tra c to Pharmaceutical Websites Changed in 2009.

Notes: This gure graphs the total number of unique visitors (in thousands) incoming to pharmaceutical websites from search tra c vs. other tra c. This covers the time period two months before and after the FDA policy change in April.

Figure 8: How the Variety of Search Terms to Pharmaceutical Websites Changed in 2009.

Figure 9: Average ratings of quality for non-regulated websites.



Notes: Participants' ratings of quality of non-regulated websites on a scale of 1 (entirely disagree) to 7 (entirely agree). The gure reports the average ratings with con dence intervals.

Table 1: Summary statistics

	Mean	Std Dev	Min	Max	Observations
Total Clicks	1541.6	6541.7	2	305233	52064
Non-Paid Clicks	1421.5	6398.6	2	299024	52064
Paid Clicks	120.3	1071.4	2	53543	52064
PostFDA	0.50	0.50	0	1	52064
Pharma Website	0.012	0.11	0	1	52064
Non-Regulated Website	0.011	0.10	0	1	52064
UGC Website	0.021	0.14	0	1	52064
Non-Commercial Website	0.23	0.42	0	1	52064
Commercial Website	0.68	0.47	0	1	52064
Terminate	0.031	0.17	0	1	52064
Observations	52064				

Notes: Each observation represents a website and keyword combination from a given search engine during a particular month. The data includes searches on the three main search engines (Google, Yahoo!, and Live) and spans the periods from February 2009 to June 2009. The variable Post-FDA indicates the period after the FDA ruling. The types of websites in our sample include pharmaceutical, non-regulated, UGC, non-pro t, and commercial. The data includes information on click behavior from keyword searches that contained the associated medical conditions and symptoms for the pharmaceutical products targeted by the FDA.

Table 2: Summary statistics: Site Level

	Mean	Std Dev	Min	Max	Observations
Total Clicks	6106.3	54736.9	2	2304408	13144
Non-Paid Clicks	5630.5	54162.8	2	2292944	13144
Paid Clicks	476.5	4430.7	2	227421	13144
Pharma Website	0.013	0.11	0	1	13144
Non-Regulated Website	0.015	0.12	0	1	13144
UGC Website	0.0070	0.083	0	1	13144
Non-Commercial Website	0.23	0.42	0	1	13144
Commercial Website	0.73	0.44	0	1	13144
Terminate	0.0049	0.070	0	1	13144
Observations	13144				

Notes: Each obser(7e[)55(atioh)-373represencsingbleebsitefrometoy2009.:Thleri(abr(7te)-74(Pc)28ost-4)]TJ 0 -11.951 Td [FI
andThldataincluioClicb1ehac
ywcearactsebnitions
ebFDc

Table 4: Restrictions on selectively informative advertising change search behavior for paid vs. non-paid clicks

			(1)	(2)
PostFDA	Pharma-Owned Website	Paid	-0.0743	-0.0743
			(0.0141)	(0.0141)
PostFDA	Non-Regulated Website	Paid	-0.00105	-0.00105
			(0.00776)	(0.00776)
PostFDA	Non-Pro t Website	Paid	-0.00794	-0.00794
			(0.00463)	(0.00463)
PostFDA	UGC Website	Paid	-0.00750	-0.00750
			(0.00481)	(0.00481)
PostFDA	Commercial Website	Paid	-0.00801	-0.00801
			(0.00457)	(0.00457)
PostFDA	Pharma-Owned Website		0.00248	0.00248
			(0.00196)	(0.00196)
PostFDA	Non-Regulated Website		0.00507	
			p p	

Table 5: Placebo Check: Medical Devices

		(1)	(2)
PostFDA	Device-Owned Website Paid		-0.0561
			(0.0869)
PostFDA	Non-Regulated Website Paid		-0.0154
			(0.0165)
PostFDA	Non-Pro t Website Paid		-0.0299
			(0.0432)
PostFDA	UGC Website Paid		-0.0145
			(0.0579)
PostFDA	Commercial Website Paid		-0.0463
			(0.0364)
PostFDA	Device-Owned Website	0.128	0.0813
		(0.0693)	(0.0619)
PostFDA	Non-Regulated Website	0.00915	0.0100
		(0.0118)	(0.0115)
PostFDA	Non-Pro t Website	-0.00375	0.0120
		(0.0382)	(0.0373)
PostFDA	UGC Website	-0.0440	-0.0323
		(0.0300)	(0.0309)
PostFDA	Commercial Website	0.00363	0.0226
		(0.0295)	(0.0267)
Search Engine Fixed E ects		Yes	Yes
Website Fixed E ects		Yes	Yes
Keyword Fixed E ects		Yes	Yes
Month Fixed E ects		Yes	Yes

A Appendix

Table A-1: Full listing of drugs, FDA approved use, product webpage, and brand keywords within data sample

Drug	FDA-approved use	Webpage	Brand Keyword
Avandamet	Avandamet is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus when treatment with dual rosiglitazone and metformin therapy is appropriate. The PI includes important limitations to use, such that Avandamet should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, the co-administration of Avandamet and insulin is not recommended, and the use of Avandamet with nitrates is also not recommended.	AVANDAMET.COM	avandamet
Avandia	Avandia is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Avandia should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, the co-administration of Avandia and insulin is not recommended, and the use of Avandia with nitrates is also not recommended.	AVANDIA.COM	avandia
Avastin	Avastin is indicated, among other things, in combination with intravenous 5- uorouracil-based chemotherapy for rst- or second-line treatment of patients with metastatic carcinoma of the colon or rectum.	AVASTIN.COM	avastin
Avodart	Avodart is indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention (AUR), and reduce the risk of the need for BPH-related surgery.	AVODART.COM	avodart
Boniva	Boniva is indicated for the treatment and prevention of osteoporosis in postmenopausal women. Boniva increases bone mineral density (BMD) and reduces the incidence of vertebral fractures.	BONIVA.COM	boniva
Bystolic	Bystolic is indicated for the treatment of hypertension. Bystolic may be used alone or in combination with other antihypertensive agents.	BYSTOLIC.COM	bystolic
Caduet	Caduet (amlodipine and atorvastatin) is indicated in patients for whom treatment with both amlodipine and atorvastatin is appropriate. The Indications and Usage section provides a detailed description of the indications for each of the drug's two active ingredients.	CADUET.COM	caduet, no-vasc
Campral	Campral is indicated for the maintenance of abstinence from alcohol in patients with alcohol		

Table A-1 { continued from previous page

Drug	FDA-approved use	Webpage	Brand Keyword
Exforge	Exforge is indicated for the treatment of hypertension. Exforge may be used in patients whose blood pressure is not adequately controlled on either [amlodipine or valsartan as] monotherapy. Exforge may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals. The choice of Exforge as initial therapy for hypertension should be based on an assessment of potential bene ts and risks including whether the patient is likely to tolerate the lowest dose of Exforge	EXFORGE.COM	exforge
Femara	Femara is indicated for the adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. Femara is indicated for the extended adjuvant treatment of early breast cancer in postmenopausal women who have received 5 years of adjuvant tamoxifen therapy. Femara is indicated for rst-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. Femara is also indicated for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy. The Indications and Usage section of the PI includes important limitations for Femara's use in the adjuvant setting, including that the e ectiveness of Femara in early breast cancer is based on an analysis of disease-free survival in patients treated for a median of 24 months and followed for a median of 26 months and follow-up analyses will determine long-term outcomes for both safety and e cacy. This section also includes important limitations for Femara's use in the extended adjuvant setting, including that the e ectiveness of Femara in extended adjuvant treatment of early breast cancer is based on an analysis of disease-free survival in patients treated for a median of 24 months and further data will be required to determine long-term outcome.	FEMARA.COM	femara
Flomax	Flomax is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Flomax is not indicated for the treatment of hypertension.		

Table A-1 { continued from previous page

Drug	FDA-approved use	Webpage	Brand Keyword
Herceptin	Herceptin is indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; with docetaxel and carboplatin; as a single agent following multi-modality anthracycline based therapy. Herceptin is also indicated in combination with paclitaxel for rst-line treatment of HER2-overexpressing metastatic breast cancer, or as a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.	HERCEPTIN.COM	
Januvia	Januvia is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The PI includes important limitations of use, such that Januvia should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be e ective in these settings, and that Januvia has not been studied in combination with insulin.	JANUVIA.COM	januvia
Levitra	Levitra is indicated for the treatment of erectile dysfunction.	LEVITRA.COM	levitra
Lexapro	Lexapro is indicated, among other things, for the acute and maintenance treatment of major depressive disorder (MDD) in adults and in adolescents 12 to 17 years of age.	LEXAPRO.COM	lexapro
Lyrica	Lyrica is indicated, among other things, for: . . . Management of neuropathic pain associated with diabetic peripheral neuropathy; . . . Adjunctive therapy for adult patients with partial onset seizures [and] . . . Management of bromyalgia.	LYRICA.COM	lyrica
Mirapex	Mirapex is indicated, among other things, for the treatment of moderate-to-severe primary Restless Legs Syndrome (RLS).	MIRAPEX.COM	mirapex
Mirena	Mirena is indicated for intrauterine contraception for up to 5 years. Thereafter, if continued contraception is desired, the system should be replaced. Mirena is recommended for women who have had at least one child.	MIRENA-US.COM	mirena
Namenda	Namenda is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.	NAMENDA.COM	namenda
Plavix	For patients with a history of recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease, PLAVIX has been shown to reduce the rate of a combined endpoint of new ischemic stroke (fatal or not), new MI (fatal or not), and other vascular death.	PLAVIX.COM	plavix
Propecia	PROPECIA is indicated for the treatment of male pattern hair loss (androgenetic alopecia) in MEN ONLY. Safety and e cacy were demonstrated in men between 18 to 41 years of age with mild to moderate hair loss of the vertex and anterior mid-scalp area. E cacy in bitemporal recession has not been established. PROPECIA is not indicated in women . . . [or] children . . . "	PROPECIA.COM	propecia
Rituxan	Rituxan is indicated for the treatment of non-Hodgkin's Lymphoma (NHL) patients with: Relapsed or refractory, low-grade or follicular, CD-20-positive, B-cell, NHL as a single agent; Previously untreated follicular, CD-20-positive, B-cell NHL in combination with CVP chemotherapy; Non-progressing (including stable disease), low-grade, CD-20-positive, B-cell NHL, as a single agent, after rst-line CVP chemotherapy; Previously untreated di use large B-cell, CD20-positive, NHL in combination with CHOP or other anthracycline-based chemotherapy regimens. Rituxan in combination with methotrexate is also indicated to reduce signs and symptoms and to slow the progression of structural damage in adult patients with moderately-to-severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.	RITUXAN.COM	rituxan
Singulair	Singulair is indicated, among other things, for the relief of symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older, and perennial allergic rhinitis in adults and pediatric patients 6 months of age and older).	SINGULAIR.COM	singulair
Spiriva	Spiriva is indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.	SPIRIVA.COM	spiriva

Continued on next page

Table A-1 { continued from previous page

Drug	FDA-approved use	Webpage	Brand Keyword
Xeloda	Xeloda is indicated, among other things, as a single agent for adjuvant treatment in patients with Dukes' C colon cancer who have undergone complete resection of the primary tumor when treatment with uoropyrimidine therapy alone is preferred. Xeloda was non-inferior to 5- ourouracil and leucovorin (5-FU/LV) for disease-free survival and while neither Xeloda nor combination therapy increases overall survival, combination therapy has been shown to improve disease-free survival compared to 5-FU/LV. Xeloda is also indicated as rst-line treatment of patients with metastatic colorectal carcinoma when treatment with uoropyrimidine therapy alone is preferred. Combination chemotherapy demonstrated a survival bene t compared to 5-FU/LV alone, however, a survival bene t over 5-FU/LV has not been demonstrated with Xeloda monotherapy.	XELODA.COM	xeloda
Yaz	YAZ is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive. YAZ is also indicated for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who choose to use an oral contraceptive as their method of contraception. The e ectiveness of YAZ for PMDD when used for more than three menstrual cycles has not been evaluated. YAZ has not been evaluated for the treatment of premenstrual syndrome (PMS). YAZ is also indicated for the treatment of moderate acne vulgaris in women at least 14 years of age, who have no known contraindications to oral contraceptive therapy, and have achieved menarche. YAZ should be used for the treatment of acne only if the patient desires an oral contraceptive for birth control.	YAZ-US.COM	yaz

Table A-2: Medical condition keywords within data sample

Medical Condition Keywords	
aids	erection
alcoholism	bromyalgia
allergies	hair loss
alopecia	hay fever
alzheimer	headaches
anxiety	heart attack

A-1 Sample Warning Letter from FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service Food and Drug Administration Silver Spring, MD 20993

TRANSMITTED BY FACSIMILE

Margaret J. Jack Director, DRA Ho mann-La Roche Inc., Bldg 1/2 340 Kingsland Street Nutley, NJ 07110 RE: NDA #21-455, 21-858 BONIVA (ibandronate sodium) Tablets BLA #103964 PEGASYS (peginterferon alfa-2a) for Injection NDA #20-896 XELODA (capecitabine) Tablets MACMIS ID #17318

Dear Ms. Jack:

As part of its monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed Ho mann-La Roche Inc.'s (Ho mann-La Roche) sponsored links on Internet search engines (e.g., Google.com) for the following products: BONIVA (ibandronate sodium) Tablets (Boniva), PEGASYS (peginterferon alfa-2a) for Injection (Pegasys), and XELODA (capecitabine) Tablets (Xeloda). The sponsored links are misleading because they make repre-

when treatment with uoropyrimidine therapy alone is preferred. Xeloda was non-inferior to 5- ourouracil and leucovorin (5-FU/LV) for disease-free survival and while neither Xeloda nor combination therapy increases overall survival, combination therapy has been shown to improve disease-free survival compared to 5-FU/LV. Xeloda is also indicated as rst-line treatment of patients with metastatic colorectal carcinoma when treatment with uoropyrimidine therapy alone is preferred. Combination chemotherapy demonstrated a survival bene t compared to 5-FU/LV alone, however, a survival bene t over 5-FU/LV has not been demonstrated with Xeloda monotherapy Xeloda is associated with a number of risks, as re ected in the Boxed Warning, Contraindications, Warnings, Precautions, and Adverse Reactions sections of its PI. Omission of Risk Information

Promotional materials, other than reminder pieces, which include the name of the drug product but do not include indications or other representations or suggestions relative to the drug product (see 21 CFR 200.200, 201.100(f), 202.1(e)(2)(i)), are required to disclose risk and other information about the drug. Such materials are misleading if they fail to reveal facts that are material in light of the representations made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials. The sponsored links present the following claims:

> Free Trial O er www.Boniva.com BONIVA (ibandronate sodium). Learn About Postmenopausal Osteoporosis.
>
> PEGASYS O cial Site www.PEGASYS.com Learn About PEGASYS & Hepatitis C Register For The E-Mail Newsletter.
>
> XELODA Information www.xeloda.com Learn About An Oral Chemotherapy Treatment For Colon Cancer.

These sponsored links make representations and/or suggestions about the e cacy of Boniva, Pegasys, and Xeloda, respectively, but fail to communicate any risk information. This omission of risk information is particularly concerning as two of the products, Pegasys and Xeloda, have Boxed Warnings. For promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any claims made about the drug.

By omitting the most serious and frequently occurring risks associated with the drugs promoted in the links above, the sponsored links misleadingly suggest that Boniva, Pegasys and Xeloda are safer than has been demonstrated. We note that these sponsored links contain a link to the products' websites. However, this is insu cient to mitigate the misleading omission of risk information from these promotional materials.

Inadequate Communication of Indication

The sponsored links for Pegasys and Xeloda provide very brief statements about what the drugs are for; however, these statements are incomplete and misleading, suggesting that the drugs are useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience.

Speci cally, the sponsored link for Pegasys misleadingly broadens the indication for Pegasys by implying that all patients with hepatitis C are candidates for Pegasys therapy (Learn About PEGASYS & Hepatitis C...), when this is not the case. Rather, Pegasys is only indicated (alone or in combination) for the treatment of

chronic hepatitis C virus infection in adults who have compensated liver disease and who have not been treated with interferon alpha previously.

Similarly, the sponsored link for Xeloda misleadingly broadens the indication for Xeloda by implying that the drug is approved to treat any type of colon cancer (Learn About An Oral Chemotherapy Treatment For Colon Cancer), when this is not the case. Rather, Xeloda's indication is limited to adjuvant treatment in patients with Duke's C colon cancer and as rst-line treatment for metastatic colorectal carcinoma. Furthermore, the sponsored link fails to communicate any of the limitations to either of these indications or the drug's limited proven survival bene ts.

Failure to Use Required Established Name

The sponsored links for Pegasys and Xeloda fail to present the full established name of the drugs being promoted, despite the requirement to do so. See 21 CFR 201.10(g)(1) & 202.1(b)(1).

Conclusions and Requested Action

For the reasons discussed aonv50349(the)-353(sp)-39(onsored)-353(linkd)-373(br16(and)-3B1(rrviv)5,and)-353(P)29(egasys)-316(and)8450

A-2 Further Detail on Data Sources

A-2.1 ComScore

The following contains excerpts from the comScore User Guide on the methodology and data collection.

Data capture and reporting are conducted in adherence to strict, industry-leading privacy protection policies. Data about user identity is stored in an encrypted, access-controlled database. Internet audience and behavior data is reported only in aggregate form.

Except for people in the calibration panel, comScore does not ask the people in its panel to identify themselves when they use the Internet. Instead, comScore infers who is at a computer at any point in time, using data that include biometric measurements (measurements of keystrokes and mouse clicks), the time of day that the computer is being used, and text strings in the data being accumulated (such as rst names in forms being posted). Consequently, comScore's panelists are not constantly reminded that their Internet use is being monitored and so the monitoring is much less likely to in uence their use of the Internet.

comScore calculates and applies weights to the data accumulated for panelists when aggregating the data to get the measurements it publishes. One purpose of these weights is to project measurements made across the Internet users in the Panel to the much larger number who are not. The other purpose is to eliminate the bias that published estimates would otherwise have because online recruitment yields disproportionately few or many people from some segments of Internet users (for example, too many intensive Internet users and too few Internet users from high income households). Panelists from a segment that is more poorly represented get

Web Search, and Yahoo! Web Search.

comScore Marketer utilizes comScore's Client Focus Dictionary with its categorized 6-level hierarchy but extends reporting to non-categorized media as well. A media domain is eligible to be reported based on visitation of at least 30 tracked machines during the time period.

Table A-3: Keywords for medical devices associated with medical conditions in data sample

Medical device keywords
air mask
allergy mattress covers
blood glucose meter
breast implants
compression stockings
coronary stent
distal protection device
dust covers
dust mask
feeding tube
glucose test
heart stent
humidi er
insulin pen
insulin pump
insulin syringes
insulin test
IV lines, PICC lines, central lines
lens implant
nebulizer
oxygen mask
penile implant
penile pump
pessary
rubber bulb ear syringe
spirometer
tissue expanders

Notes: This table lists the associated medical devices for the medical conditions within our sample.

Table A-4: Google Trends

	(1) All	(2) Conditions+Symptoms	(3) Pharma	(4) Device
PostFDA	-0.0103	0.00902	-0.0152	-0.0913
	(0.0400)	(0.0435)	(0.0964)	(0.0950)
Search Term Fixed E ects	Yes	Yes	No	No
Observations	532	308	160	64
R-Squared	0.0897	0.00296	0.000158	0.0147

Notes: Robust standard errors are clustered at the website level. *$p < 0.1$, **$p < 0.05$, ***$p < 0.01$. The regressions estimate the logarithm of search index for search terms before and after the FDA announcement. Column (1) includes all search terms used in this study. Column (2) includes search terms for conditions and symptoms. Column (3) includes pharmaceutical brand keywords. Column (4) contain search terms for medical devices. For regressions that pool di erent categories of search terms (e.g., conditions and symptoms), we include xed e ects for each category.