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Mixed Messages, Mixed Outcomes: Exposure to Direct-to-Consumer Advertising for Statin Drugs is Associated with More Frequent Visits to Fast Food Restaurants and Exercise

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Abstract

This study examines whether exposure to direct to consumer advertisements (DTCA) for statin drugs is associated with non-pharmaceutical behaviors to prevent cardiovascular disease (CVD). We focus on the relationship between statin drug DTCA exposure and the frequency of (a) visits to fast food restaurants and (b) exercise. We combine data on the televised broadcast availability of statin drug DTCAs in large media markets in the United States with 18 waves of the Simmons National Consumer Survey (n = 120,229) from 2001 to 2009. We find that statin drug DTCA exposure is associated, in a dose-response pattern, with modest increases in the frequency of exercise and large increases in the frequency of fast food restaurant visits. The relationship between statin DTCA exposure and fast food restaurant visits were largely consistent in direction but differed in magnitude between those without a previous diagnosis of high cholesterol and those treating high cholesterol with a statin. We conclude with a discussion of the implications of these results for future research on pharmaceutical DTCA and population health.

Direct to consumer advertising (DTCA) of pharmaceutical products accelerated dramatically with a 1997 change in the Food and Drug Administration's (FDA) regulatory policy and is now the third-largest class of televised (TV) product advertising in the United States (Nielsen, 2014). Pharmaceutical DTCA is a unique class of product advertising because viewers must visit a health professional in order to gain a prescription and thus purchase the drug. Proponents of pharmaceutical DTCA argue that they educate the population about health risks, encourage people to visit healthcare providers, promote relevant diagnostic tests, and increase the likelihood of appropriate treatment (Holmer, 2002; Liu & Gupta,

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2011). While the validity of these claims has been subject to considerable study and debate (Mintzes, 2012; Frosch, Grande, Tarn, & Kravitz, 2010), pharmaceutical DTCA are undeniably a unique and disproportionately large source of health-related information for Americans—the average American is exposed to approximately 16 hours of DTCAs each year, compared to only 15 minutes a year spent with a primary care physician (Brownfield, Berhardt, Phan, Williams, & Parker, 2004).

While the obvious goal of pharmaceutical DTCA is to promote the sale and use of specific pharmaceutical products (Pharmaceutical Research and Manufacturers of America (PhRMA), 2008), many DTCAs also contain information about health behaviors that do not require a prescription. Clinical practice guidelines for many health conditions, including high cholesterol among those without history of a cardiac event, recommend that patients engage in lifestyle changes (e.g., a low-fat diet and regular exercise) before moving to a prescription drug (National Cholesterol Education Program (NCEP), 2002). Pharmaceutical self-regulatory codes likewise suggest that DTCA should include information about the availability of non-pharmaceutical treatment options (PhRMA, 2008). While less than a third of DTCAs in general offer information about behavioral alternatives to medication (Frosch et al., 2010; Macias, Pashupati, & Lewis, 2007; Wilkes, Bell, & Kravitz, 2000), DTCAs for statin drugs, prescribed to treat high cholesterol and reduce the risk of cardiac events, frequently reference the efficacy (and, in many cases, the inefficacy) of diet and exercise for reducing cholesterol (Byrne, Niederdeppe, Avery, & Cantor, 2013). Statin DTCAs are also the largest class of pharmaceutical DTCA (Donohue, Cevasco, & Rosenthal, 2007; Mintzes, 2012; Niederdeppe, Byrne, Avery, & Cantor, 2013). In light of the sheer volume of statin DTCA exposure, these ads represent a major source of exposure to information about the role of diet and exercise in health promotion. Relatively little is known about the role of DTCA in promoting or undermining non-pharmaceutical and non-clinical health behaviors. The current study addresses this gap by testing the relationship between estimated exposure to DTCA for statin drugs and both diet and exercise behavior, among both those diagnosed with high cholesterol and those without such a diagnosis.

Direct to Consumer Advertising (DTCA) of Statin Drugs

The 1997 changes in regulations of DTCA were particularly relevant to the market for statin drugs designed to treat high cholesterol and reduce risk of cardiovascular disease (CVD), the leading mortality risk facing the American public (Minino, Murphy, Xu, & Kochanek, 2011). Drugs focused on chronic conditions where there is a large potential population of untreated consumers tend to have high levels of DTCA (Iizuka, 2004; de Frutos, Ornaghi, & Siotis, 2013). Recent estimates indicate that over 85 million Americans suffer from some form of CVD, many of whom remain undiagnosed (Holmer, 1999; Mozaffarian, Benjamin, Go, Arnett, Blaha, Cushman et al., 2015). One of the major risk factors for CVD is elevated levels of low density lipoprotein cholesterol (LDL) in the blood. In contrast, high density lipoprotein cholesterol (HDL) is protective and elevated levels of HDL have positive benefits in terms of CVD. Statin drugs have been shown, in a large number of well-designed clinical trials, to lower LDL by up to 60 percent, raise HDL, and lower the total amount of serum cholesterol (National Cholesterol Education Program (NCEP), 2002). Statin drugs can also prevent serious cardiac events among those without a history of CVD (NCEP, 2002),

although there is still debate about whether or not a statin should be added to lifestyle change efforts (eating a low-fat diet and regular exercise) for primary prevention of CVD among those with few risk factors (Blaha, Nasir, & Blumenthal, 2012; Redberg & Katz, 2012; Taylor, Ward, Moore, Burke, Davey Smith, Casas et al., 2013).

There is clear and voluminous evidence that pharmaceutical DTCA increases both patient demand for pharmaceutical products and prescribing volume (Frosch et al., 2010; Mintzes, 2012). Statin DTCA exposure, in particular, is associated with increased rates of high cholesterol diagnosis and statin drug use (Niederdeppe et al., 2013). Researchers have raised concerns, however, about the extent to which pharmaceutical DTCA leads to over-diagnosis and over-prescribing (Frosch et al., 2010; Mintzes, 2012). In the case of statin DTCA, Niederdeppe et al. (2013) found that DTCA exposure effects on cholesterol diagnosis and statin drug use were most pronounced among respondents at comparably low risk for cardiac events. These concerns have led some to suggest that DTCA may have negative consequences for population health by changing public perceptions of when symptoms or health conditions should be treated medically, rather than through lifestyle changes (Bolton, Reed, Volpp, & Armstrong, 2008).

Meta-analyses show that regular exercise raises HDL, decreases LDL, and lowers overall cholesterol levels (Kelly, 2010). Diet can have a significant effect on HDL and LDL levels (Bruckert & Rosenbaum, 2011). Others have studied the impact of combining diet and exercise and have found these combinations to significantly improve lipid profiles (Varady & Jones, 2005). Healthy diet and exercise are also linked to improved cardiovascular health and reduced cancer risk beyond their impact on cholesterol levels (World Health Organization (WHO), 2004). Clinical practice guidelines recommend that physicians encourage lifestyle changes (low-fat diet and increased exercise) prior to prescribing statin drugs for many patients, and in conjunction with the use of statin drugs once they are prescribed (NCEP, 2002). As noted earlier, industry self-regulatory codes also recommend that DTCAs include information about non-pharmaceutical treatment options when available (PhRMA, 2008). Each of these factors underscores the need to assess the impact of statin DTCA on these behaviors.

Consistent with PhRMA recommendations, statin DTCAs do contain a wealth of messages, albeit not always consistent, about the role of diet and exercise in CVD prevention (Byrne et al., 2013). Byrne and colleagues (2013) analyzed the content of TV statin DTCA that appeared on U.S. airwaves between 1999 and 2007 and found that statin DTCAs contain mixed messages about the efficacy of diet and exercise in reducing LDL cholesterol and risk of CVD. On the one hand, almost three out of four TV statin DTCA appearances (71.1 percent) mentioned the efficacy of diet in reducing cholesterol or CVD risk and nearly half (45.1 percent) described the efficacy of regular exercise in achieving these outcomes. Nearly one-fifth (19.0 percent) showed images of low-fat food and more than half (51.4 percent) depicted characters engaging in physical activity. On the other hand, a majority also raised questions about the efficacy of diet (77.6 percent) or exercise (66.6 percent) in reducing cholesterol (often using phrases like, “when diet and exercise aren’t enough”¹), and almost a quarter (23.6 percent) showed images of high-fat foods. Furthermore, the vast majority of ads that offered messages about the efficacy of diet or exercise at some point in the ad also

included messages that undermined these claims by suggesting that diet (in 94.6 percent of ads with diet efficacy messages) and exercise (in 96.7 percent of ads with exercise efficacy messages) may not work.

Evidence on the Impact of DTCA on Non-Pharmaceutical Prevention Behaviors

The accumulated evidence from observational, experimental, and content analytic studies does not lend itself to clear predictions about whether the impact of statin DTCA on diet and exercise behavior is likely to be universally positive (health-promoting) or negative (health-undermining). A few DTCA effect studies do show evidence for positive impact on non-clinical and non-pharmaceutical health behaviors. For example, Avery, Kenkel, Lillard, and Mathios (2007) combined data on magazine ad appearances for pharmaceutical smoking cessation DTCAs with individual-level data from the 1995 to 2004 Simmons National Consumer Surveys (NCS), finding that increased exposure to smoking cessation DTCAs increased the likelihood of smokers' quit attempts and sustained succession. These effects were observed regardless of whether or not a pharmaceutical aid was used. Yang (2012) used similar methods (magazine DTCA ad appearances) and data (the 2000-2004 NCS) to assess the impact of magazine ad appearances for cholesterol, hypertension, diabetes, and obesity DTCAs on diet and exercise behaviors, concluding that exposure to cholesterol ads was associated with increased likelihood of regular exercise, increased exercise frequency, and dieting to lose weight.

Conversely, several studies suggest that pharmaceutical DTCA exposure may reduce the likelihood that people engage in health-promoting, non-pharmaceutical behaviors. In the same analysis described above, Yang (2012) also found evidence that diabetes DTCA exposure was associated with reduced exercise and diet control behaviors. Klausner, Kim, and Kent (2002) surveyed men attending sexually transmitted disease (STD) clinics in San Francisco in 2001 and concluded that greater exposure to DTCA for retroviral drugs among HIV-positive men was associated with increased engagement in unsafe sex practices among this group. Iizuka and Jin (2007) merged data on media market-level DTCA ad expenditures for cholesterol, hypertension, diabetes, and obesity, with individual-level data from the 1997 to 2001 National Health Interview Surveys (NHIS), finding that greater levels of DTCA exposure were associated with reduced likelihood of engaging in moderate exercise. Bolton, Cohen, and Bloom (2006) conducted a series of randomized experiments where they exposed smokers (and non-smokers) to DTCAs for pharmaceutical smoking cessation products, showing that DTCA exposure increased intentions to smoke in the future among those who already engaged in the behavior. Finally, Bolton et al. (2008) reported on a similar experiment (Experiment 1 from the study) showing that exposure to a statin drug DTCA that emphasized the efficacy of the drug in reducing cholesterol levels led to lower intentions to eat foods low in cholesterol.

¹It is noteworthy that many of these diet and exercise inefficacy messages used the term “when diet and exercise aren't enough” rather than “if,” subtly suggesting that the inefficacy of these behaviors are a given rather than probabilistic.

On the whole, the accumulated evidence for pharmaceutical DTCA effects on lifestyle behaviors is quite mixed, although on balance they suggest the potential for negative outcomes (with five papers showing adverse effects using multiple methods versus two papers showing favorable effects using observational methods). Among these studies, only two examined the impact of cholesterol-related DTCAs, finding positive effects on the frequency of exercise (Yang, 2012) but negative effects on intentions to eat a low cholesterol diet (Bolton et al., 2008).

Plausible Theoretical Explanations for Effects Based on the Content of Statin DTCA

As described earlier, content analyses of statin DTCA suggest that these ads contain verbal and visual content that could both promote or undermine non-pharmaceutical prevention behaviors. On the one hand, by depicting characters engaging in physical activity or showing healthy low-fat foods, statin drug DTCAs could promote healthy dietary behavior and increased exercise among viewers via modeling healthy behavior (as would be consistent with social cognitive theory; see Bandura, 1986) or serving as a cue to action by reminding individuals about the connection between healthy food and heart health (as would be consistent with the health belief model; see Rosenstock, 1974). Far more TV statin DTCA appearances depict exercise (over half) than low-fat food options (less than one in five), suggesting that modeling effects of statin DTCA could explain previous favorable effects on exercise behavior (Byrne et al., 2013).

On the other hand, by suggesting that diet and exercise may be ineffective at reducing LDL cholesterol or CVD risk or showing images of unhealthy high-fat foods, statin drug DTCAs may reduce the likelihood of a person engaging in healthy dietary behavior or exercise by changing beliefs that these behaviors will lead to favorable outcomes (as would be consistent with the integrated model of behavior prediction; see Fishbein & Azjen, 2009) or stimulating cravings for unhealthy food among viewers (as would be consistent with cue reactivity theory; see Carter & Tiffany, 1999). More than three of four TV statin DTCA appearances raised questions about the efficacy of diet in reducing cholesterol levels, a rate more frequent than content questioning the efficacy of exercise in achieving this goal (Byrne et al., 2013).

The direction and magnitude of these effects might differ depending on whether or not an individual has been diagnosed with high cholesterol and, if so, whether or not s/he is using a statin drug to treat it. Previous research on the effects of statin DTCA has not addressed this question. The theory of risk compensation suggests that when there is an increase in “safety,” consumers often compensate by decreasing other risk-avoiding behavior related to this risk (Peltzman, 1975). In the case of statin therapy it is possible that the (perceived or actual) effectiveness of statin drugs in reducing measured amounts of cholesterol in the blood could decrease the demand for other behaviors that impact cholesterol levels—particularly diet and exercise. In this case, exposure to statin drug advertising would lead to a greater probability of using statins (as previously demonstrated by Niederdeppe et al., 2013), which in turn, could decrease the likelihood of dietary change or regular exercise. Moreover, exposure to statin drug advertising could induce a physician visit in which one

finds out that they have lower than expected cholesterol levels. This too, could lower the demand for dietary restrictions or exercise.

Research Questions

In light of reasons to predict statin drug DTCA effects in both directions (promoting or undermining healthy diet and exercise), we offer the following research questions (RQs):

RQ1: Is exposure to TV statin drug DTCAs associated with dietary behavior?

RQ2: Do associations between TV statin drug DTCA exposure and dietary behavior differ by cholesterol (high cholesterol diagnosis or not) or treatment status (statin use or not)?

RQ3: Is exposure to TV statin drug DTCAs associated with exercise behavior?

RQ4: Do associations between TV statin drug DTCA exposure and exercise differ by cholesterol (high cholesterol diagnosis or not) or treatment status (statin use or not)?

To address these questions, we merged data on the TV broadcast availability of statin drug DTCAs with the largest national consumer survey in the U.S. (the Simmons NCS) from 2001 to 2009. This design offers a more rigorous test of these questions than previous studies because of the focus on TV advertising exposure (which far exceeds print advertising exposure; see Byrne et al., 2013), the ability to measure and account for cumulative exposure to multiple statin DTCAs over time (in contrast to single-exposures that characterize the randomized experiments published by Bolton et al., 2006 and Bolton et al., 2008), observations over an extended time period (nine years, from 2001-2009), and the sample size (a sample size of over 100,000 overall) and resulting statistical power to stratify the sample by both cholesterol status and treatment status. We focus on one class of dietary behavior (the number of visits to fast food restaurants in the past 30 days) and a single measure of exercise (frequency of exercise in the past week) based on available measures of diet and physical activity in the NCS. While our focus on fast food visits and exercise frequency obviously does not capture the full breadth of dietary and active behaviors, there is strong evidence that more frequent fast-food consumption is a major predictor of greater overall fat intake (Moore, Diez Roux, Nettleton, Jacobs, & Franco, 2009; Paeratakul, Ferdinand, Champagne, Ryan, & Bray, 2003), and regular exercise is linked to an overall reduction of CVD risk (Thompson, Buchner, Piña, Balady, Williams, Marcus et al., 2003).

Methods

Individual-level Survey Data Overview

The source of individual-level data was the Simmons National Consumer Survey (NCS), a national, repeated, cross-sectional survey of the continental United States. Each wave of the survey was composed of an independently drawn multi-stage stratified probability sample. Households were randomly cluster-sampled from substrata within one of five primary strata (three of which are designed to oversample Hispanics). The substrata were constructed such that higher income respondents are overrepresented in the final sample, arising from the fact that the NCS is primarily directed toward use by marketers. Our analysis used data from 18

NCS waves administered between 2001 and 2009, the most recent data available to the research team.

The NCS measured a large number of demographic characteristics that included age, race, gender, education, household income, census region of residence, marital status, employment characteristics, health insurance status, the number of adults in the respondent's household, and the number of children in the respondent's household. The NCS also contained extensive measures on consumer behavior, including frequency of visits to fast food restaurants and regularity of exercise. In addition, the NCS collected information about ailments the respondent reported suffering from in the past year (including high cholesterol), the severity of those ailments, whether the respondent treated those ailments with a prescription drug, and if so, which drug they used. Finally, the NCS included detailed information on the extent and intensity of respondents' TV viewership, including the TV programs they regularly watched on broadcast networks; the cable channels they watched and when they watched them in the past five weekdays and the past weekend; and the times which they watched any broadcast TV in the past five weekdays and the past weekend. The TV viewership information that NCS collected on respondents did not cover Spanish-language cable TV or Spanish-language broadcast TV programs in the United States. Consequently, we omitted individuals who reported Spanish as being the language they use at home or who reported watching mainly Spanish language TV.

The full NCS sample across all 18 waves collected between 2001 and 2009 encompassed 208,133 respondents. We excluded 49,664 (23.9 percent) of these respondents from the analytic sample in the current study because they did not live in an identified media DMA, while we excluded another 38,240 (18.7 percent) because they reported a preference for reading/watching television in Spanish. The final analytic sample thus contained a total of 120,229 respondents.

Table 1 provides descriptive information from this analytic sample. Compared to the 2010 U.S. Census (U.S. Census, 2010), the study sample was older, more educated, wealthier, and a higher percent were White. About 56 percent were female; 21.7 percent were between age 45-54, with 8.7 percent above age 75; 85 percent of respondents were white, and 11 percent Hispanic; 35 percent had a college or graduate degree; 64 percent were married; approximately 50 percent worked full time; and, over 50 percent of households had incomes above \$75,000 per year. In terms of media use, sample respondents reported watching an average of 38 hours of television per week (comparable to Nielsen reported averages for adults; Hinckley, 2012). We estimate that 85 percent of the sample had health insurance, a rate comparable to the U.S. general population (87 percent as of 2013, according to the Kaiser Family Foundation, 2015).²

²Respondents reported in the NCS whether or not they had medical/hospital insurance at the time of surveying. For those leaving the question unanswered, but who provided household income information meeting some criteria for their household size/age, we assigned Medicaid/Medicare as their primary insurance. Any respondent who reported an income range with a midpoint below the weighted average poverty threshold for their household size in 2010 were assigned as their insurance Medicaid. Those not reporting health insurance but over age 65 were assigned Medicare as their insurance. About 80.1% of respondents reported that they have health insurance. After recoding those eligible for Medicare and Medicaid as having health insurance, that number went up to 85.1%.

Independent Variable: Estimated Exposure to TV Statin DTCA

We estimated individual-level exposure to TV statin drug DTCA by linking an individual's self-reported TV viewership patterns to data on advertisements to which the individual was likely to be exposed based on their geographic location (media market) and reported media behavior. This corresponds to statin drug DTCAs which aired on cable channels in their media market at the times that the respondent reported watching those channels, on the network TV programs in their media market which the respondent reported watching, and on broadcast networks in their media market at the times the respondent reported watching broadcast TV that are not accounted for by the programs he or she reported watching.

The data on TV statin drug DTCA broadcast patterns came from Kantar/TNS Media Intelligence and contained information on every ad appearance for a product in this category in the continental United States. The TV advertisement data provided information on the exact time and program during which an advertisement aired. We used data on advertisements that aired between 2000 and 2009 (to merge volume of potential exposure in the previous year with 2001 to 2009 survey data) on national broadcast networks, cable channels, and spot markets identified by Designated Marketing Areas (DMAs). In 2001, the TNS data covered the largest 75 DMAs; from 2002 to 2009, the TNS data covered the largest 100 DMAs. Ads used for estimating exposure measures include those which aired within a 365-day period ending with the first day on which the respondent's survey wave was fielded.

To identify which advertisements a respondent was likely to have seen, we relied on several NCS questions. Each respondent in the survey was asked about whether they watched episodes from a list of approximately 300 broadcast programs, depending on their survey wave. They were also asked about whether they watched specific cable TV networks during narrowly defined time slots of the day in the past week, and whether they watched broadcast TV during specific time slots of the day in the past week. We considered an individual potentially exposed to an advertisement if the ad aired during broadcast programs they reported watching on TV or aired in time slots and on specific cable networks they reported watching regularly.

The measure of potential advertising exposure employed here underestimates actual exposure since we rely on respondents reporting programs they view from a list that is extensive, but not exhaustive. Consequently, to adjust for the fact that this method would underestimate broadcast ad exposure, we also matched time slots in which respondents reported watching broadcast TV (in which no program they reported viewing airs). We summed the number of ads appearing on broadcast TV in that time slot, weighted by the number of networks the respondent could have been watching in that time slot. As a reliability check we estimate that our algorithm matches about 84 percent of all statin drug DTCAs to the programs on which they aired—only 16 percent of ads were in programs that were not identified in the NCS data. Similarly, 85 percent of cable advertisements were matched to the time slots on which they aired in the Simmons Survey. Shows airing from 1 a.m. to 6 a.m. on cable TV time were not covered by our data.

Table 1 shows that we estimate that the average respondent was potentially exposed to 143.5 TV statin DTCA's in the past year ($SD = 139.6$). Levels of estimated exposure varied substantially by year. Figure 1 graphs the number of ads appearing on television per year from the TNS data, and our estimated mean number of ads exposed to by year. These data track closely, offering evidence for the validity of our exposure measure. The drop off in advertising during the later years (2008-2009) is indicative of the economic recession occurring at that time where pharmaceutical firms cut back on advertising. This pattern is also consistent with other published data on DTCA trends (e.g., Kornfield, Alexander, Qato, Kim, Hirsch, & Emery, 2015).

We divided TV statin DTCA exposure into sextiles for the multivariable analysis in order to capture any non-linearity in the pattern of association with diet and exercise behavior. The first sextile (sextile 1) ranged from 0 to 21.8 ads; sextile 2 ranged from >21.8 to 60.0 ads; sextile 3 ranged from >60.0 to 106.8 ads; sextile 4 ranged from >106.8 to 166.0 ads; sextile 5 ranged from >166.0 to 259.5 ads; and sextile 6 ranged from >259.5 to 2,068.6 ads.

Dependent Variables: Frequency of Fast Food Restaurant Visits and Exercise

We gauged the frequency of fast food visits using a series of questions that asked about the frequency with which respondents reported visiting over 60 different fast food restaurants. The stem question read as follows: "Mark the number of times visited in the last 30 days: [list of 60+ restaurants]." We gauged the frequency of exercise using two items. First, respondents were asked, "Have you engaged in a regular exercise program in the last 12 months where you exercised strenuously, either at home or elsewhere?" Respondents who answered "yes" were then asked, "How many times a week do you exercise?" On average, respondents reported visiting fast food restaurants approximately 16 times in the past 30 days and exercising approximately 1.8 times in the past week. These levels are generally consistent with other national estimates—in 2012, about half of Americans reported eating at fast food restaurants at least weekly and almost a quarter reported visiting several times a week in 2012 (Dugan, 2013), and while half of Americans reported exercising three or more days a week in 2013 (Sharpe, 2014), more than 20% report engaging in no exercise at all (Physical Activity Council, 2016).

Moderating Variables: Cholesterol Status and Statin Use

Approximately 18 percent of sample respondents reported suffering from high cholesterol in the past 12 months, 4 percent suffering from heart disease, and 20 percent from hypertension. The sample percent reporting a high cholesterol rate is significantly lower than the incidence of high cholesterol in the general U.S. population reported from other sources (25 percent from 1999-2002; 27.7 percent from 2003-2006; and 27.6 percent from 2009-2012 according to the National Center for Health Statistics (NCHS), 2014). Figure 2 shows the number of respondents suffering from high cholesterol by year; the upward trend in reported percentages tracks closely with national high cholesterol incident trends reported elsewhere (NCHS, 2014).

Approximately 14 percent of sample respondents reported taking a statin drug in the past 12 months. The incidence of statin use in sample is significantly lower than the general U.S.

adult population overall (18 percent for males age 45-64, 29 percent for males 65-74, and 25 percent for males 75+; 15 percent for females 45-64, 29 percent for females 65-74, and 27 percent for females 75+) (Wehrwein, 2011). In terms of general health, 12 percent of respondents reported suffering from one severe ailment in the past 12 months, 7.5 percent from two to four severe ailments, and 1.2 percent from five or more severe ailments. 17 percent of the sample reported smoking (slightly lower than national estimates of 23.9 percent in 2005; Jamal, Homa, O'Connor, Babb, Caraballo, Singh et al., 2015), and smokers smoked approximately 15.9 cigarettes per day.

Analytic Approach

To test whether exposure to TV statin drug DTCA impacts the number of times a respondent visited a fast food restaurant in the past 30 days or exercised in the past 7 days, we regressed these two dependent variables on TV statin drug DTCA exposure, controlling for the very large set of demographic, behavioral, and medical control variables shown in Table 1. Specifically, all models included controls (using dummy variable coding unless otherwise specified) for gender, age, number of severe ailments suffered in the last year, having coronary heart disease, having hypertension, race, Hispanic, census region, education, employment, income, number of people in the household, number of children in the household, employment status, weekly work hours, survey wave, a list of over 1,000 TV programs viewed 75% of the time or more, hours of TV watched in the last 7 days (linear), and number of cigarettes smoked per day (linear and set to zero for non-smokers). To examine whether the pattern of association differs by cholesterol status and statin use, we stratified models by these factors (Tables 2 and 3) and formally tested for differences in coefficients using interaction terms (described in the results but not shown in tables). We also estimated models interacting exposure with gender and race to test for differences in ad exposure coefficients by these factors (not shown in tables).

Results

Frequency of Fast Food Restaurant Visits in the Past 30 Days

Research Question 1 asked whether exposure to TV statin drug DTCAs was associated with dietary behavior, measured here as the frequency of visits to fast food restaurants. Table 2 reports results of the regression estimating the impact of exposure to TV statin drug DTCA on reported number of visits to fast food restaurants in the past 30 days, stratified by those not diagnosed with high cholesterol ($N = 96,946$), those diagnosed but not taking a statin ($N = 5,356$), and those diagnosed and taking a statin ($N = 16,005$).

Among those not diagnosed with high cholesterol, there was a positive and significant association between exposure to TV statin drug DTCA on the frequency of visiting fast food restaurants. The magnitude of this association increased monotonically with each sextile of exposure. For example, the impact of exposure to the number of statin ads in the 6th sextile (259-2068 ads) compared to the first sextile (0-22 ads) was to increase the number of visits to fast food restaurants visited in the past 30 days by 4.4 visits. We observed a similarly positive and monotonically increasing pattern of associations among those diagnosed with high cholesterol and taking a statin, but those associations did not achieve statistical

significance at lower levels of exposure. In the smaller sample of those diagnosed with high cholesterol but not taking a statin, we again observed positive and monotonically increasing associations, with coefficients being statistically significant only at higher sextiles of exposure.

Research Question 2 asked whether associations between TV statin drug DTCA exposure and dietary behavior differed by cholesterol (high cholesterol diagnosis or not) or treatment status (statin use or not). Multivariable models using the entire sample but featuring interaction terms between sextiles of exposure and both cholesterol and statin drug status (not shown in tables) showed that the statin DTCA exposure coefficients were significantly smaller ($p < .05$) among those taking a statin relative to those not diagnosed with high cholesterol.

In a supplementary exploratory analysis, we ran a similar OLS regression model on the full sample of respondents in which we interacted exposure with gender and race (not shown in tables). An examination of the pattern of associations between TV statin drug DTCA exposure and frequency of visits to fast food restaurants in the past 30 days in the model with gender interactions revealed that the coefficients for each ad exposure sextile tended to be weaker for females than for males. However, these differences were only significant at higher levels of exposure, and in each case the overall association was still consistent with increased frequency of fast food restaurant visits with higher levels of exposure. We did not observe differences in the pattern of association between statin ad exposure sextile and fast food restaurant visits by race or ethnicity relative to white non-Hispanics, with one exception: Hispanics and respondents identifying as another race had stronger associations between statin ad exposure and fast food restaurant visits than non-Hispanic white respondents at the highest sextile of exposure.

Frequency of Exercise in the Past Seven Days

Research Question 3 asked whether exposure to TV statin drug DTCA was associated with exercise frequency. Table 3 reports results of the regression estimating the pattern of associations between exposure to TV statin drug DTCA and the number of times a respondent reported exercising in the past seven days. We again stratified models by those not diagnosed with high cholesterol ($N = 95,832$), those diagnosed but not taking a statin ($N = 5,308$), and those diagnosed and taking a statin ($N = 15,850$). Results indicate that, among those not diagnosed with high cholesterol, there are small but positive, statistically significant and monotonically increasing associations between each sextile of ad exposure and the frequency of exercise. For example, the model predicts that respondents seeing the highest volume of statin ads (in the 6th sextile, 259-2068 ads) compared to the first sextile (0-22 ads) exercised 0.27 days more frequently in the past seven days. We see similarly positive and generally monotonically increasing patterns of association among those diagnosed with high cholesterol and taking a statin drug, although those associations were not statistically significant at lower levels of exposure. In the smaller sample of those diagnosed with high cholesterol but not taking a statin, coefficients did not increase monotonically with higher levels of exposure and were not statistically significantly different from zero.

Research Question 4 asked whether associations between TV statin drug DTCA exposure and exercise behavior differed by cholesterol (high cholesterol diagnosis or not) or treatment status (statin use or not). Subsequent models (not shown in tables) using the entire sample but featuring interaction terms between sextiles of exposure and cholesterol and statin drug status showed that the statin DTCA exposure coefficients were statistically equivalent ($p < .05$) regardless of cholesterol or statin drug status.

We ran a similar analysis on the full sample of respondents (unstratified by cholesterol status) in which we interacted exposure with gender and race (not shown in tables). Results show positive, significant, and monotonically increasing patterns of association between exposure and the frequency of exercise in the past seven days, but no significant differences by gender. We observed larger and statistically significant associations between exposure and frequency of exercise at higher levels of exposure for Black respondents relative to non-Hispanics White respondents, but no consistent and statistically significant differences for statin DTCA exposure coefficients for other racial or ethnic groups relative to non-Hispanic whites.

Discussion

Summary of Findings

Statin DTCA contain mixed messages about the potential efficacy of diet and exercise in reducing cholesterol levels and risk of CVD. The current study shows that these mixed messages are associated with a mixed pattern of potential effects on non-pharmaceutical health behaviors.

On the one hand, increased exposure to statin DTCA was associated with a small but significant increase in the frequency of exercise in a dose-response pattern. Models predicted that respondents without a previous high cholesterol diagnosis with heavy statin DTCA exposure engaged in about one more day of exercise per month (0.27 days per week) than those non-diagnosed individuals with minimal levels of statin DTCA exposure. We observed a similar pattern of effects among those diagnosed with cholesterol and taking a statin drug, but no such pattern for those diagnosed with high cholesterol but not taking a statin.

On the other hand, increased exposure to statin DTCA was also associated with a sizeable increase in the frequency of fast food restaurant visits, also in a dose-response pattern. Models predicted that respondents without a previous high cholesterol diagnosis with heavy statin DTCA exposure went to fast food restaurants almost 4.5 more times per month than those non-diagnosed individuals with minimal levels of statin DTCA exposure. The pattern was more nearly identical among those diagnosed with high cholesterol but not taking a statin drug, and positive but somewhat attenuated among those diagnosed and treating high cholesterol with a statin.

Public Health Implications

On balance, combined with results from previous studies of pharmaceutical DTCA advertising effects on non-pharmaceutical behaviors, this set of findings raises concerns about the health-educating potential of statin DTCA, particularly for the population of

individuals who are not taking a prescription statin drug. While previous research indicates that DTCA in general promotes doctor-visits, screening test uptake, and prescription drug use (Frosch et al., 2010; Mintzes, 2012; Niederdeppe et al., 2013), these messages also appear to influence non-pharmaceutical and non-clinical health behaviors among the general population. While some of these potential effects were in a favorable direction (increased frequency of exercise), the magnitude of these associations was quite small (up to one day more of exercise per month) relative to their negative potential effects on health-damaging behavior (up to 4.5 fast food restaurant visits per month). In light of well-established strong associations between fast food restaurant visits and unhealthy diet from previous research (Moore et al., 2009; Paeratakul et al., 2003), this pattern of findings suggests that statin DTCA could be putting a large population of otherwise healthy people at risk.

One difference in the pattern of results by cholesterol status and statin use is worthy of mention and further study. While statin DTCA exposure was positively associated with increased fast food visits in all three samples (non-diagnosed, diagnosed but not taking a statin, diagnosed and taking a statin), the magnitude of these associations were smaller for those who have high cholesterol and are on statin drug therapy. These results suggest that being on statin therapy does not exacerbate any negative health consequences of statin DTCA exposure, a pattern of findings that is inconsistent with the theory of risk compensation (Peltzman, 1975).

A key question that emerges from these findings is why statin DTCA exposure is associated with a small but favorable (health-promoting) effect on exercise frequency but a larger and negative (health-undermining) effect on the frequency of fast food visits. First, we note that this pattern is consistent with the other two studies that have focused specifically on statin DTCA exposure, in which Yang (2012) found evidence of positive effects on the frequency of exercise (focusing on print statin DTCA) while Bolton et al. (2008) observed negative effects on intentions to eat a low cholesterol diet (using a single statin DTCA in a randomized experiment). The fact that the current study replicated this pattern of findings in an independent dataset which allowed us to gauge TV statin DTCA exposure (a much larger source of widespread exposure than print studied by Yang, 2012) and assess the impact of repeated exposure to these ads (relative to a single example as studied by Bolton et al., 2008) increases our confidence that this pattern of findings is real and robust to alternative research methods and sources of information.

The question remains, however, of why the same content may have a favorable impact on one lifestyle behavior (exercise) but an unfavorable impact on another (healthy diet). These data are not equipped to provide these answers, but we can offer a few speculative possibilities that stem from the content of the ads themselves. While a majority of statin DTCA raise questions about the efficacy of diet and exercise (more than two-thirds of these ads for each), statin DTCA are far more likely to depict characters engaging in physical activity (over 50 percent of ads) than they are to show images of low-fat food (19 percent; Byrne et al., 2013). If behavioral modeling (Bandura, 1986) is a mechanism through which DTCA influence health behaviors, one would expect greater positive effects on exercise given the increased frequency of these portrayals. Furthermore, almost a quarter of statin DTCA ads show unhealthy, high-fat foods (Byrne et al., 2013). If cue reactivity (Carter &

Tiffany, 1999) is another mechanism by which statin DTCA influence audiences, portrayal of these foods may be particularly influential, particularly among those for whom dietary restraint is most challenging. Also, more 75 percent of statin DTCA appearances raise questions about the efficacy of diet in reducing cholesterol levels, but fewer ads (although still a majority) question the value of exercise (Byrne et al., 2013). Differences in how statin DTCA describe expected outcomes of these behaviors could lead to differences in their effects via traditional belief change mechanisms (Fishbein & Ajzen, 2009).

As noted above, the current study was unable to test for these mechanisms. Future research using primary observational data (in which indicators of these mechanisms could be measured) or randomized experimental methods (in which the presence or absence of various message features could be systematically manipulated to test these mechanisms) seem warranted.

More broadly, the observed pattern of findings here, along with the larger literature on pharmaceutical DTCA effects on non-pharmaceutical behaviors, suggests that these ads are not uniformly favorable or unfavorable for public health – the content of the specific class of ads seems to matter. While this should come as no surprise to health communication scholars and practitioners, it does suggest that policy debates about the regulation of pharmaceutical DTCA could benefit from increased focus on how these ads engage with non-pharmaceutical options.

Study Limitations and Future Directions

The current study included a large number of control variables that include detailed socio-demographics, overall television viewing, and television program patterns and preferences, we relied on repeated cross-sectional survey data and thus cannot make definitive claims about the causal direction of relationships between statin DTCA exposure and diet and exercise behaviors.

The sample, while very large and diverse, is not a representative snapshot of the entire U.S. population. Notably, rates of high cholesterol and statin use in the NCS sample were lower than other national estimates of this conditions and behavior. These differences may stem from discrepancies between demographics of the sample and known distributions from the U.S. Census. Nevertheless, the fact that we controlled for a very large set of demographic variables in the analysis offsets concern about the potential for biased estimates of TV statin DTCA effects.

We conceptualized our measure of TV statin drug DTCA exposure as potential exposure because we do not know if respondents in the NCS sample actually saw an advertisement airing on a TV program they report watching regularly, as they could have been “surfing” channels. Furthermore, we assume that an individual's reported program viewership over the past week for daily programs or month for weekly programs reflects his/her viewership habits over the past year. Although our measure is to be viewed as potential TV statin drug DTCA exposure, it also has several advantages over aggregate national and market-level measures used in previous research, since those implicitly assume that all individuals in a particular market are exposed to the same level of advertising (see Niederdeppe, 2014, for a

discussion of methodological issues and tradeoffs in using media market-level ad availability in measuring exposure).

We are limited by the fact that we only measured one aspect of dietary behavior, frequency of fast food restaurant visits, which does not reflect the breadth of dietary choices that individuals make in their daily lives. We are also limited by our use of a single item to measure frequency of exercise behavior, which is likely subject to more measurement error than multi-item scales would have been. In addition, this measure was based on a two-part question – first whether or not respondents engaged in a regular exercise program in the last year in which they exercised *strenuously*, then asking about the frequency of exercise. Federal guidelines do recommend that Americans engage in vigorous physical activity for at least 20 minutes per day 3 or more days per week OR moderate physical activity for at least 30 minutes per day 5 or more days per week (Healthy People 2010). Nevertheless, it is possible that respondents who engage in regular, moderate (but not “strenuous” exercise could have been misclassified as not engaging in any exercise at all (since a “yes” response to the first item was required before the second, follow-up question). As noted earlier, we were also unable to test theoretical mechanisms through which statin DTCA exposure might influence diet and exercise behavior.

Our data and analytic strategy also has numerous strengths that offset these limitations, however. Self-reported ad recall measures would likely reflect personal interest and selective exposure, confounding exposure with issue involvement. By linking statin DTCA appearances to survey respondents' based on their reports of typical viewing patterns, study participants only had to indicate whether they regularly view a particular program on a network at a specified time. Our study also takes market-level variation and individual variation into account with our statistical controls, reducing the likelihood of unmeasured confounding. In addition, while our use of a single-item measure of exercise frequency and a single domain of dietary behavior (fast food restaurant visits) is a limitation, these items appeared alongside a wide variety of other measures gauging a large number of consumer topics so it is unlikely that respondents engaged in “hypothesis guessing” and offered socially desirable answers.

Finally, we expect that effects of statin DTCA on diet and exercise behavior would be incremental and cumulative, meaning that a randomized experiment (which would feature a limited number of exposures) could not adequately replicate the sheer volume of real-world statin DTCA exposure. Indeed, our average respondent was potentially exposed to over 140 statin DTCAs in the previous year (Table 1). At the same time, having now established relationships between statin DTCA exposure and these behaviors, there is a need to identify the cognitive pathways that lead to the behavioral responses we have observed here. Well-designed randomized experiments would be a valuable addition to this body of research.

Several important questions emerge from these findings: Does knowing that statins are effective at treating cholesterol absolve the audience from the fear or guilt of eating badly upon repeated messaging in DTCA that the dieting and exercise have dubious results? Among those not diagnosed, are all the images of delicious food stimulating appetite for variety foods at fast food restaurants? For exercise, do the recipients of DTCA messages

identify with the individuals depicted exercising in the ads—most of who look physically fit and healthy to begin with—or are the images in the ads causing them to disassociate with people who are “not like me” and therefore have only minimal effects in motivating physical activity? Randomized experiments that manipulate the presence or absence of specific ad features and assess their impact on a more comprehensive set of dietary and exercise behaviors would enable researchers to identify characteristics of statin DTCA that are particularly influential in shaping these behaviors.

Conclusions

Pharmaceutical DTCA are a major source of health-related information for Americans. We offer evidence that the largest class of these advertisements, statin DTCA, are consequential in shaping non-pharmaceutical behaviors, in one case for better (exercise frequency) and in another for worse (fast food restaurant visits). We see a similar pattern of response among those both suffering from high cholesterol and those without such a diagnosis, suggesting far-reaching potential for population health impact. This pattern of findings raises concerns about the health-educating potential of pharmaceutical DTCA and highlights the importance of future work to identify which aspects of these messages shape public response.

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Figure 1. Number of Statin DTCA that appeared on TV between 2000 and 2009 and Estimated Mean Statin DTCA Exposure in the Past 12 Months

Note. Data reported in this figure represent data points of mean exposure and number of ad airing in that year. Since the number of ads appearing in 2000 is used as the exposure window for respondent in 2001 (a 365-day look back), the reporting window for the figure is 2001-2010.

Figure 2. Percent of Sample Reporting Having High Cholesterol in the Past 12 Months and Estimated Mean Statin DTCA Exposure in the Past 12 Months

Note. Exposure data reported in this figure represent data points of mean exposure and number of ad airing in that year. Since the number of ads appearing in 2000 is used as the exposure window for respondent in 2001 (a 365-day look back), the reporting window for the figure is 2001-2010.

Table 1
Descriptive Statistics

Sample Characteristics		Mean/N	SD/Percent
Number of statin DTCAs exposed to in the last 12 months		M=143.5	SD=139.6
Number of fast food visits in the past 30 days		M=15.8	SD=16.2
Number of days exercised in the past 7 days		M=1.8	SD=1.9
Reported suffering from high cholesterol in the past 12 months		21,717	18.1%
Reported suffering from heart disease in the past 12 months		4,266	3.6%
Reported suffering from hypertension in the past 12 months		23,412	19.5%
Number of severe ailments reported suffering in the last 12 months			
	1	14,618	12.2%
	2-4	9,046	7.5%
	5 or More	1,443	1.2%
Reported taking a prescription statin drug in the last 12 months			
	Overall	16,263	13.5%
	Of males age 45-64	3,917	18.3%
	Of males age 65-74	1,984	29.2%
	Of males age 75+	1,130	25.4%
	Of females age 45-64	3,957	14.7%
	Of females age 65-74	2,477	29.5%
	Of females age 75+	1,597	26.7%
Gender	Male	52,922	44.0%
	Female	67,307	56.0%
Age	18-24	10,025	8.3%
	25-34	13,963	11.6%
	35-44	22,105	18.4%
	45-54	26,127	21.7%
	55-64	22,373	18.6%
	65-74	15,195	12.6%
	75+	10,441	8.7%
Race	White	102,272	85.1%
	Black	9,204	7.7%
	Asian	2,222	1.9%
	Other	6,531	5.4%
Ethnicity	Hispanic	12,777	10.6%
	Not Hispanic	107,452	89.4%
Education	Less than HS	10,289	8.6%
	High school	32,938	27.4%
	Some college	34,446	28.7%
	College graduate	22,094	18.4%

Sample Characteristics		Mean/N	SD/Percent
	More than college graduate	20,462	17.0%
Employment status	Full-time	59,517	49.5%
	Part-time	15,476	12.9%
	Retired	24,372	20.3%
	Temporarily unemployed	4,988	4.2%
	Disabled	4,023	3.4%
	Student	1,749	1.5%
	Homemaker	9,169	7.6%
	Never employed	935	0.8%
Weekly work hours	1-14	4,506	3.8%
	15-29	8,794	7.3%
	30-39	9,732	8.1%
	40	18,735	15.6%
	41-50	19,141	15.9%
	51 or More	7,467	6.2%
Student status	Full-time student	4,496	3.7%
	Part-time student	2,762	2.3%
Marital status	Married	77,399	64.4%
	Divorced	11,450	9.5%
	Separated	1,839	1.5%
	Widowed	7,959	6.6%
	Single	21,582	18.0%
Household income	Less than \$25,000	12,014	10.0%
	\$25,000 - \$49,999	23,061	19.2%
	\$50,000 - \$59,999	23,160	19.3%
	\$75,000 - \$99,999	18,007	15.0%
	\$100,000 - \$149,999	22,889	19.0%
	\$150,000 - \$249,999	14,701	12.2%
	\$250,000 or more	6,397	5.3%
Respondent has health insurance		102,295	85.1%
Number of children in the home		M=0.8	SD=1.2
Number of people in the home		M=3.0	SD=1.5
Region of residence	Midwest	28,684	23.9%
	West	25,566	21.3%
	Southeast	35,997	29.9%
	Northeast	29,982	24.9%
Cigarettes per day (smokers only)		M=15.9	SD=9.9
Identifies as a smoker		19,520	17.5%
Hours of TV viewed past 7 days		M=37.9	SD=31.1

Sample Characteristics		Mean/N	SD/Percent
Hours of TV viewed, top-coded		654	0.5%
Number of observations		120,229	100.0%

Table 2
Results from OLS Regression Models Estimating the Impact of Exposure to Statin DTCA
on the Number of Times Respondents Visited a Fast Food Restaurant in the Past 30 Days,
Stratified by High Cholesterol Diagnosis and Treatment Status

	Among Those Not Diagnosed with High Cholesterol B [SE]	Among Those Diagnosed but Not Taking Statin B [SE]	Among Those Diagnosed and Taking a Statin B [SE]
1st Sextile of Cholesterol Ad Exposure	Omitted Category	Omitted Category	Omitted Category
2nd Sextile of Cholesterol Ad Exposure	1.59 *** [0.16]	0.95 [0.87]	0.86 [0.50]
3rd Sextile of Cholesterol Ad Exposure	2.02 *** [0.17]	1.88 * [0.89]	0.91 [0.48]
4th Sextile of Cholesterol Ad Exposure	2.71 *** [0.19]	2.16 * [0.91]	1.26 ** [0.49]
5th Sextile of Cholesterol Ad Exposure	3.15 *** [0.22]	2.68 ** [1.03]	2.36 *** [0.53]
6th Sextile of Cholesterol Ad Exposure	4.40 *** [0.29]	4.30 ** [1.32]	3.41 *** [0.63]
Constant	10.53 *** [0.92]	18.07 ** [6.43]	9.03 [7.06]
Number of Observations	96,946	5,356	16,005

Notes: The first sextile of exposure is the omitted category. All models included controls (using dummy variable coding unless otherwise specified) for gender, age, number of severe ailments suffered in the last year, having coronary heart disease, having hypertension, race, Hispanic, census region, education, employment, income, number of people in the household, number of children in the household, employment status, weekly work hours, survey wave, a comprehensive list of over 1,000 TV programs viewed 75% of the time or more, hours of TV watched in the last 7 days (linear), and number of cigarettes smoked per day (linear and set to zero for non-smokers).

* denotes $p < 0.05$,

** $p < 0.01$,

*** $p < 0.001$.

Table 3
Results from OLS Regression Models Estimating the Impact of Exposure to Statin DTCA
on the Number of Days Respondents Exercised in the Past 7 Days, Stratified by High
Cholesterol Diagnosis and Treatment Status

	Among Those Not Diagnosed with High Cholesterol B [SE]	Among Those Diagnosed but Not Taking Statin B [SE]	Among Those Diagnosed and Taking a Statin B [SE]
1st Sextile of Cholesterol Ad Exposure	Omitted Category	Omitted Category	Omitted Category
2nd Sextile of Cholesterol Ad Exposure	0.09 *** [0.02]	0.01 [0.12]	0.09 [0.07]
3rd Sextile of Cholesterol Ad Exposure	0.10 *** [0.02]	0.06 [0.12]	0.04 [0.07]
4th Sextile of Cholesterol Ad Exposure	0.16 *** [0.02]	0.18 [0.12]	0.23 ** [0.07]
5th Sextile of Cholesterol Ad Exposure	0.21 *** [0.03]	0.09 [0.13]	0.28 *** [0.07]
6th Sextile of Cholesterol Ad Exposure	0.27 *** [0.03]	0.15 [0.16]	0.36 *** [0.09]
Constant	1.74 *** [0.10]	2.09 ** [0.65]	2.43 ** [0.89]
Number of Observations	95,832	5,308	15,850

Notes: The first sextile of exposure is the omitted category. All models included controls (using dummy variable coding unless otherwise specified) for gender, age, number of severe ailments suffered in the last year, having coronary heart disease, having hypertension, race, Hispanic, census region, education, employment, income, number of people in the household, number of children in the household, employment status, weekly work hours, survey wave, a comprehensive list of over 1,000 TV programs viewed 75% of the time or more, hours of TV watched in the last 7 days (linear), and number of cigarettes smoked per day (linear and set to zero for non-smokers).

* denotes $p < 0.05$,

** $p < 0.01$,

*** $p < 0.001$.