



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 30, 2006

John Mack
Pharma Marketing News
Po box 760
Newtown, PA 18940

In reply to: 2006-14998

Dear Mr. Mack:

This is in response to your request for records from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act.

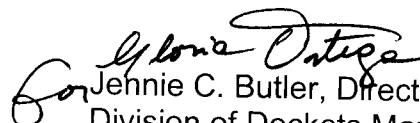
Enclosed are the records you requested: Consumer-Directed Promotion of Regulated Medical Products; Part 15 Public Hearing Docket Number 2005N-0354, EMC 590.

You will receive an invoice from the Freedom of Information Staff. The charges listed below may not reflect the final charges for this request. Please do not send payment until you receive an invoice.

Reproduction \$ 2.60 Certification \$ _____ CD-ROM \$ _____ Total \$ 2.60

If you have any questions, please contact Ms. Michelle Bigesby at 301-827-6857.

Sincerely yours,


Jhennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

Enclosure(s)

Pharma Marketing News

www.pharmamarketingnews.com

PO Box 760, Newtown, PA 18940 • 215-504-4164

September 18, 2006

Food and Drug Administration
Office of Management Programs
Division of Freedom of Information (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

06-14998
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FDA DFOI (HFI-35)

To whom it may concern:

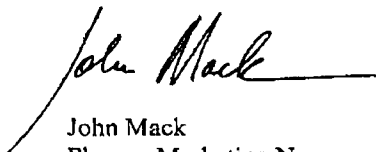
This is a FOIA request for a copy of the following document that was submitted to the FDA on July 19, 2006 by CommonHealth:

Docket No. 2005N-0354; Consumer-Directed Promotion of Regulated Medical Products; Part 15 Public Hearing; EMC 590 CommonHealth Vol #: 12

I am making this request a news media representative. I am the publisher and editor of *Pharma marketing News* (www.pharmamarketingnews.com). As such, I hope that there will be no duplication charge for the first 100 pages and a charge of \$0.10 per page over 100 pages as indicated on your web site.

I eagerly look forward to your response to this matter.

Sincerely,



John Mack
Pharma Marketing News
PO Box 760
Newtown, PA 18940
215-504-4164

Via Fax: (301) 443-1726 and postal mail

HFA305

DIVISION OF FOI	
REQUESTER TYPE:	22
REQUESTER CATEGORY:	22

docdispatchserv[1]

From: Moncavage, Melissa M
Sent: Monday, July 24, 2006 3:19 PM
To: Butler, Jennie C
Cc: Aikin, Kathryn J; Moncavage, Melissa M
Subject: FW: DTC impact on physician-patient communication

Attachments: CommonHealth DTC Study 7 11 06.ppt

Hi, Jennie.

Rose Cunningham suggested I send this DTC docket submission directly to you. This submission is for the docket created for our Public Meeting last November. (2005N-0354) Please let me know if you need anything else. Melissa

Melissa Moncavage, MPH
Leader, DTC Review Group
Division of Drug Marketing, Advertising, and Communications
Center for Drug Evaluation and Research, FDA

phone: 301-796-1200
fax: 301-796-9877

From: Bradley Davidson [mailto:bdavidson@CommonHealth.com]
Sent: Tuesday, July 11, 2006 9:21 PM
To: Aikin, Kathryn J; Moncavage, Melissa M
Cc: Matt Giegerich; Joe Gattuso; Kamp, John
Subject: DTC impact on physician-patient communication

Dear Kit and Melissa,

On behalf of CommonHealth, I am submitting the following deck for inclusion in the FDA docket regarding the impact of DTC advertising on physician-patient communication. Please let me know if there is a more formal process for including this data in the docket. This should be considered the definitive version of the data and previous drafts should be discarded.

I want to thank both of you for meeting with John Kamp and I back in February, and for your feedback and comments at that time. As we stated then, if you have any further questions, please do not hesitate to contact myself or Joe at jgattuso@commonhealth.com. Also as we discussed at that time, we as an organization would be very happy to discuss further with you any of the issues that are currently being evaluated by the FDA regarding DTC and its impact on communication in particular and health care in general.

Thank you, again, for your feedback as we prepared this document.

Best,

Brad

docdispatchserv[1]

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DTC Advertising's Influence on Physician-Patient Communication: Results of Observational Linguistic Analysis



Contents

- Current beliefs about DTC
- Summary of study results
- Detailed study findings
 - Methodology
 - Sample
 - Analysis
- Conclusions and implications
- Appendix

DTC Impact*

- Consumers are highly aware of DTC
 - Conditions, brands—primarily from TV
- Public health benefits
 - DTC results in diagnosis of previously undiagnosed conditions
 - Consumers are reminded to take/refill Rx's—potentially more likely to be compliant when Rx is requested
- DTC drives patients to physician's office
 - 1 out of 3 patients claim DTC prompted visit

*Presented to DDMAC 12/05

Source: Prevention Magazine Survey; Kaiser Permanente Study; Pfizer P.R.; Pfizer/Rx Remedy Study.

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Concerns About DTC Impact on Physician-Patient Interactions

- DTC leads to inappropriate patient requests for medications
- DTC negatively influences risk-benefit discussions
 - Physicians are not providing adequate "risk-benefit" discussions of requested Rx medications
 - Patients are over-exposed to medication benefits and under-exposed to potential risks

Source: Gilbody S, Wilson P, Watt I. Benefits and harms of direct to consumer advertising: a systematic review. *Qual Saf Health Care*. 2005 August; 14(4):246-50.

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Concerns About DTC Impact: Reported Patient-Initiated Rx Requests

- In general, belief that patients are led by DTC to ask for Rx medications that are dangerous or inappropriate
- Example: survey of reported COX-2s prescribing behavior:
 - “Suggests that DTC advertising leads to inappropriate prescribing with costly medications”
 - However, “some patients for whom the drugs are truly appropriate may benefit from DTC advertising”

Sources: Robinson et al. Direct-to-Consumer Pharmaceutical Advertising: Physician and Public Opinion and Potential Effects on the Physician-Patient Relationship. *Arch Int Med* 164(4). Feb 23 2004. 427-431
Spence et al. Direct-to-Consumer Advertising of COX-2 Inhibitors: Effect on Appropriateness of Treatment. *Medical Care Research and Review*. Vol. 62 No. 5, (October 2005)

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Concerns About DTC Impact: Risk-Benefit Presentation

- Concern that DTC is not “fair” in risk-benefit presentation, which may undermine physician presentation of risk-benefit analysis
 - “The risks are usually discussed toward the end of the advertisement and discussed in a rapid-fire manner. The terms often are in medical speak and not layman’s terms”
- Of note:
 - New PhRMA Principles have increased the emphasis on risk in DTC advertising created since August 2005

Source: Stein G. Direct-to-Consumer Promotion of Regulated Medical Products. FDA Public Meeting. November 1, 2005

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Summary of Study Results

Patient Rx Requests are Not Driven by DTC

- In 440 visits analyzed, patient-initiated Rx requests are minimal
 - Patients rarely request Rx medications by name or category
 - Of these requests, only one patient asks for an Rx by name (Zyrtec), and this patient had been prescribed this medication previously
 - All other requests either ask for “something new”, OR ask about possible risks of medications patients are currently on (in response to a physician mention of the medication)
- DTC is rarely referenced by patients, and never as “I saw/heard this ad and want this Rx”

DTC Does Not Influence Balance of Risk/Benefit

- In 291 visits in which select categories of medication were discussed by name, risk-benefit presentation by physicians is minimal, for both brands with heavy and minimal DTC spends
- DTC spend does not appear to increase amount of benefit presentation by physician in relation to risk presentations
 - In categories with high DTC spend (cholesterol, allergy), “risk-benefit” discussion is more common than in hypertension (with a negligible DTC spend)
- In no instance were patients engaged in a discussion about their opinion of their own “risk-benefit” (“These are the risks and benefits—what do you want to do?”)

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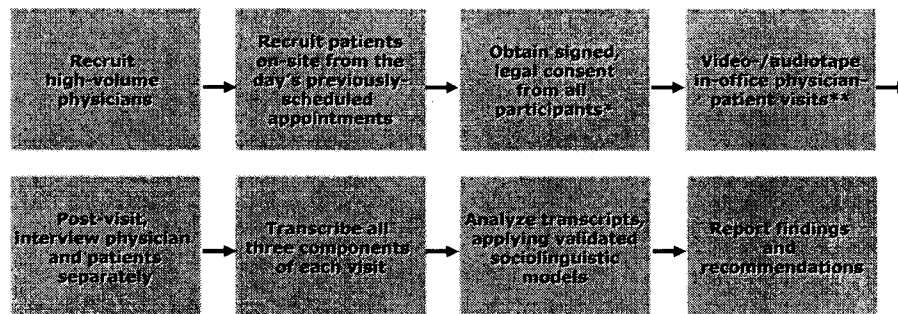
Detailed Study Findings

Reality-Based Research

- Research fielded by MBS/Vox, a CommonHealth unit focused on analysis of actual physician-patient interactions
- Multi-disciplinary team with experts in medical linguistics and related social sciences, professional and patient promotion, education and clinical practice
- 5+ years' experience in 27 therapeutic categories—largest known library of recorded visits

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In-Office Linguistic Methodology



Completed over 45 studies in 27 therapeutic categories—
Nearly 2,000 hours of *actual* physician-patient visits

* All studies are HIPAA compliant; since 2005, all studies are IRB approved

** All visit participants are recorded and interviewed including parents and patients where appropriate

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Categories Studied to Date

- Acne
- Allergy
- Alzheimer's Disease
- Anticoagulation
- Antiplatelet
- Asthma
- BPH
- Contraception
- COPD
- Dental Care
- Depression
- Type II Diabetes
- Hepatitis C
- Hormone Replacement Therapy
- Hypercholesterolemia
- Hypertension
- Irritable Bowel Syndrome
- Migraine
- Multiple Sclerosis
- Obesity
- Oncology
- Onychomycosis
- Osteoporosis
- Pain/Arthritis
- Pediatric Vaccines
- Vision Care
- Women's Health

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Data Analysis

Uses validated sociolinguistic techniques to determine and quantify:

- Allocation of topics by time, speaker and sequence
- Symptoms leading to diagnosis and/or treatment choice
- Language that "encourages" or "discourages" discussion
- Risks and benefits of treatment options
- Specific language to describe brands
- How physician, parent/patient emotion influences visit outcome
- Degree of alignment (re: diagnosis, prognosis, goals of therapy, severity of condition, etc.) between physician and patient
- Language used to set expectations and encourage compliance
- How DTC, Internet and other consumer media influence the visit

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Specifics of Sample

- Represents 10 different in-office studies, conducted 2001-2005, selected for likelihood of discussion of target Rx medications
- 440 individual patients
- 172 healthcare providers
 - 164 physicians
 - 82 PCPs, 8 Pediatricians, 13 OB/Gyns, 13 Pulminologists, 21 Cardiologists, 9 Endocrinologists, 12 Allergists, and 6 Rheumatologists
 - 8 "Allied Health Providers" (Nurses, PAs)
- Geographically dispersed across US within each study
 - Typically 3-5 locations per each of the 10 studies

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Sample Composition

- Three therapeutic categories chosen to test impact of DTC on physician-patient conversation, with comparison across categories possible:

	Overall DTC spend 2001-2005	Type of condition
Allergy	High (~\$2.6 billion)	Symptomatic, "lifestyle"
Cholesterol	High (~1.6 billion)	Asymptomatic, CV
Hypertension	Low (~\$0.118 billion)	Asymptomatic, CV

Source: TNS Media Intelligence Copyright 2006. Magazine Publishers of America Inc.

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Intra-Sample Comparisons

- Sample will allow for comparison between impact of “type of condition” and “overall DTC spend”
- Allergy and cholesterol categories are very different types of conditions but both had large DTC spend between 2001-2005
 - Similarities in patterns of discourse may reflect impact of DTC on physician-patient communication
- Cholesterol and hypertension categories are similar types of conditions but have very different DTC spends overall between 2001-2005
 - Similarities in patterns of discourse may reflect underlying importance of the nature of the condition treated, regardless of DTC spend

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Sample for Analysis

- Initial search for target Rx mentions in 440 physician-patient visits (recorded 2001-2005) in primary care setting
- Yielded 291 visits in which selected allergy, cholesterol, and hypertension Rx medications were discussed by name, representing conversations in these three distinct therapeutic categories:*
- 112 visits with at least 1 mention of an Allergy Rx
- 157 visits with at least 1 mention of a Cholesterol Rx
- 113 visits with at least 1 mention of a Hypertension Rx

* Note: Visits may contain discussions of Rx medications from more than one category

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Allergy Medications Reviewed

With DTC spend (in millions), 2001-2005*

- Astelin (\$ 00.7)
- Allegra/ Allegra-D (\$601.2)
- Clarinex (\$284.1)
- Claritin/ Claritin-D (\$ 79.3)
- Flonase (\$470.7)
- Nasacort AQ (\$ 41.3)
- Nasonex (\$190.9)
- Rhinocort Aqua (\$ 40.9)
- Singulair (\$441.8)
- Zyrtec (\$373.9)

*Note: "DTC spend" refers to any DTC advertising that mentions the Rx by name; DTC spend data from TNS Media Intelligence Copyright 2006. Magazine Publishers of America Inc.

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Cholesterol Medications Reviewed

With DTC spend (in millions), 2001-2005*

- Crestor (\$354.8)
- Lescol (\$ 0.6)
- Lipitor (\$446.8)
- Niaspan (\$ 1.0)
- Pravachol (\$131.1)
- Welchol (\$ 14.6)
- Vytorin (\$206.5)
- Zetia (\$ 1.2)
- Zocor (\$402.6)

Without DTC spend, 2001-2005*

- Mevacor
- Niacin
- Tricor

*Note: "DTC spend" refers to any DTC advertising that mentions the Rx by name; DTC spend data from TNS Media Intelligence Copyright 2006. Magazine Publishers of America Inc.

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Hypertension Medications Reviewed

With DTC spend (in millions), 2001-2005*

- Altace (\$46.4)
- Coreg (\$17.9)

*Note: "DTC spend" refers to any DTC advertising that mentions the Rx by name; DTC spend data from TNS Media Intelligence Copyright 2006. Magazine Publishers of America Inc.

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Hypertension Medications Reviewed

Without DTC spend, 2001-2005*

- Accupril
- Atacand
- Avapro
- Cardizem
- Catapres
- Cozaar
- Diovan
- DynaCirc
- Hyzaar
- Inderal
- Lasix
- Lopressor
- Lotensin
- Lotrel
- Minipress
- Monopril
- Norvasc
- Prinivil
- Procardia XL
- Tiazac
- Toprol-XL
- Zestril

*Note: "DTC spend" refers to any DTC advertising that mentions the Rx by name; DTC spend data from TNS Media Intelligence Copyright 2006. Magazine Publishers of America Inc.

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Analysis: Patient-Initiated Rx Discussions and DTC Mentions

Analysis: Patient Initiated Rx Discussions

- Review of all target Rx medication mentions, in all visits
- Count who first introduces Rx into conversation by name—index of “indirect requests” by patients

Category	MD:Patient Rx initiation	Total Mentions, MD:PT
Allergy	2.5:1 MD:Patient	143:58
Cholesterol	4.3:1 MD:Patient	202:47
Hypertension	4.4:1 MD:Patient	110:25

- Implication: Disease category, not DTC spend, influences how frequently patients initiate discussion of specific Rx medication

Note: Nurse (20) and Visit Companion (17) Rx initiations are negligible in these visits

Analysis: DTC References in Visits—Rules

- Included: Direct DTC mentions (DTC clearly referenced)
 - Examples:
 - 'I saw it advertised'
 - 'You see it on TV a lot'
- Included: Ambiguous DTC mentions—source could be DTC, but could also be another source (e.g., radio program on NPR; magazine article...)—cast a very
 - Examples:
 - 'Have you heard about (drug name)?'
 - 'I heard something on the radio'
 - 'I was reading about that'

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Analysis of General DTC References

- Analyzed all 440 visits
- References of DTC for any Rx medication (including, e.g., Rx medications for diabetes, depression, etc.):
 - Direct DTC references occurred in 16 visits (3.7%)
 - Ambiguous references occurred in 25 visits* (5.7%)

* 2 visits had both direct and ambiguous references to DTC

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Analysis of DTC References for Allergy, Cholesterol, Hypertension Medications

- Analyzed relevant discussions from 291 visits in which an allergy, cholesterol, or hypertension medication was discussed, for DTC references relating to brands/category:
 - Cholesterol: 9 references (including "statins") in 157 visits
 - 3 direct, 2 by MD and 1 by patients (1.9% of visits)
 - 6 ambiguous, 4 by MD and 2 by patients
 - Allergy: 6 references (including "nasal sprays") in 112 visits
 - 4 direct, 2 by MD and 2 by patients (3.6% of visits)
 - 2 ambiguous, by MD
 - Hypertension: 2 references (including "diuretics") in 113 visits
 - 1 direct, by patient (1% of visits)
 - 1 ambiguous, by Nurse Practitioner

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Analysis of DTC References About Allergy, Cholesterol, Hypertension Medications

- Majority of DTC references, direct or indirect, come from physicians and other health care providers
 - 4 of 8 direct references from MD or Allied Health Provider
 - 7 of 9 ambiguous references from MD
- Direct correlation between DTC spend and number of references to DTC in conversation
 - Hypertension Rx's had no direct branded DTC references whatsoever, which is not surprising given the relative lack of DTC in this category—the only DTC reference is to "diuretics" in general, by a patient
- No instance observed of patient using DTC to request Rx medication

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Direct DTC Mentions—Example from Cholesterol

- Patient: And then the next time I came in—but that was a couple of—
- Doctor: That was a while ago. Here's—here's what we need to do, okay? There's one main class of cholesterol medicine called the statins, okay? That's what Lipitor is in. Lipitor—**all the ones you see on TV are in this category**. Lipitor, Zocor, you've seen on TV; Pravachol, I don't think is on TV, isn't that ridiculous that that's how I discuss things? (Laughs)
- Patient: When you watch Lifetime, that's all they show—
- Doctor: I know, that and, like, hemorrhoid commercials. (Laughs)
- Patient: And tampons.
- Doctor: (Laughs) Yeah. Exactly. These are all statins. You got muscle aches from the Lipitor.

—37-Year-Old Male with a PCP

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Patient Requests for Medication

- Overall, patients requested Rx medications (by name or otherwise) in 2.7% of visits (8/291)
- In the six cases where patients request a medication, that request is fulfilled
- In the two cases where a patient raises a concern about a medication, that patient got a new Rx (1) or told to stop the medication in question (1)
- In NO CASE did a patient reference a DTC ad directly as the motivation for the request (see following slide)

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Patient Requests for Medication

<u>Asks for...</u>	<u>Brand</u>	<u>Outcome</u>
"Something other than..."	Claritin	Gets Zyrtec
"Something other than..."	Allegra-D	Gets "plain" Allegra
"That new one..."	Crestor	Gets Crestor
"That new thing..."	Crestor	Gets Crestor
"A prescription for..."	Allegra	Gets Allegra
"The Zyrtec I've used before..."	Zyrtec	Gets Zyrtec
<u>Asks about...</u>		
"Bad news I've heard about..."	Crestor	Gets Zocor
"Bad news I've heard about..."	Zocor	Told to stop Zocor

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Analysis: Risk-Benefit Presentation

Risk-Benefit Discussions Analysis

- Review of all target Rx medication mentions, in all visits
 - Code for “risk” or “benefit” presentation
- Analyze between categories
 - Determine if nature of condition or DTC spend influence patterns of risk-benefit presentation
- Analyze within categories
 - Determine if Rx brands with DTC spend have different risk-benefit presentation than Rx brands with no DTC spend

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“Risk-Benefit” Rules Applied

- Risk: Any potential negative consequence of an Rx medication
 - Statement: “It [Allegra] can make you drowsy” (1 risk)
 - Question: “Claritin-D ever cause any symptoms for you? Any palpitations, or kind of get you wired or, uh...any chest discomfort from that?” (4 risks)
- Benefit: Any potential positive consequence of an Rx medication
 - Statement: “And we’re going to add a pill called Zetia which will lower your cholesterol.” (1 benefit)
 - Statement: “But, in any event, I think Crestor’s safe.” (1 benefit)

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“Risk-Benefit” Rules Applied

- Focused on semantics of words spoken
- Not included:
 - Implied benefits (e.g., that by prescribing a medication an MD is implying a future, but unspoken, benefit)
 - Implied risks (e.g., by comparing two Rx medications, “*Brand x is safer than brand y*”, implication is that both brands are to some degree unsafe)
 - Conversations about:
 - Dosing
 - Samples
 - Cost
 - Formulary or insurance coverage

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Typical Physician Benefit Presentation

- Benefit presentation by physician is usually minimal
- Typically involve statements of fact or anticipated results
- Patients rarely ask questions about these statements

*DOCTOR: Pravachol and the-Niaspan is 500 mg twice a day.
And, um, you know, the Pravachol is to lower your bad cholesterol mainly and the Niaspan raises your good cholesterol mainly.*

PATIENT: Uh-huh.

Primary Care Physician

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Typical Physician Risk Presentation

- Risk presentation by physician is usually minimal
- Typically involve statements or directions to contact physician in case of potential future consequences
- Patients rarely ask questions about these statements

DOCTOR: And what you can do is just let us know if you're feeling any different. Um, if you're having any muscle pain or if you feel different after taking the medication. You've been on Zocor, so.

PATIENT: Yeah, just 20!

Primary Care Physician

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Minimal Risk/Benefit Discussion

- Over half of visits in which a medication was discussed had no risk or benefit discussion for that medication
 - Allergy 43% of visits; Cholesterol 41% of visits; Hypertension 29% of visits
- The majority of medication mentions do NOT have an associated risk or benefit
 - Cholesterol 26% of medication mentions; Allergy 16%; Hypertension 13%
- All categories show more benefits being presented than risks; allergy medications show the highest ratio, hypertension the lowest
 - Allergy medication "risks" typically involved drowsiness or discomfort
 - Cholesterol and hypertension "risks" typically involved liver functions, neuralgias, or other signs of serious side-effects

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Impact of DTC on Physician Risk/Benefit Presentation

- DTC spend does not appear to influence the presentation of risk/benefit in CV conditions; allergy, with a lower consequence of risks, has a higher risk-benefit

	Risk	Benefit
Allergy*	17%	83%
Cholesterol, with DTC	27%	73%
Cholesterol, without DTC	24%	76%
Hypertension, with and without DTC**	26%	73%

*All Allergy medications analyzed had DTC between 2001-2005

** Individually, "Hypertension with DTC" and "Hypertension without DTC" did not have a sufficient number of risk-benefit statements for statistical comparison, however both "with" and "without" categories mirror the overall finding directionally.

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Risk-Benefit Statements by Patients

- Patients do not routinely ask about risks or benefits of Rx medications
 - They DO report on what has "worked" or "not worked", or side effects they have suffered
- In 12 of 291 visits, there were only 10 patient mentions of a risk, and 3 patient mentions of a benefit
 - 4 "risk statements" were made about allergy medications
 - 6 "risk statements" were made about Rx cholesterol medications, and 3 "benefit statements" about cholesterol medications (but only one branded medication, "Niaspan": the other mentions are "statins" and "niacin")

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Conclusion and Implications

Conclusion

- Overall, physician-patient dialogue about Rx medications is minimal, regardless of DTC spend
 - Physicians recommend Rx medications
 - Patients ask few questions relating to those recommendations
- DTC does not appear to drive specific patient requests for Rx medications
 - It is possible that DTC “primes” patients to be receptive when physicians introduce Rx medications into the discourse, however
- DTC does not appear to increase amount of “benefit talk” in relation to “risk talk”
 - Overall, risk-benefit discussions are minimal in all categories, and almost never occur in the context of an engaged “risk-benefit” discussion

If not in the Dialogue...Where?

- Hypothesis: DTC impact on physician:
 - Conscious awareness—medication and/or condition is top-of-mind for physician
 - Unconscious awareness—physician has been exposed to advertising and internalizes messages
 - Discussions outside the scope of the physician-patient dialogue—e.g., conversations with other physicians, nurse, allied health professional, etc.

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If not in the Dialogue...Where?

- Hypothesis: DTC impact on patient:
 - Remove stigma/raise awareness or willingness to discuss conditions (ED, migraine...)
 - Conscious awareness—patient can recall advertising
 - Medication awareness may have prompted visit, with no ensuing dialogue (i.e. car advertising)
 - Post Rx, leads to acceptance/compliance or discontinuation
 - Pre/Post visit, numerous non-physician behaviors
 - Discussions with family/friends
 - Internet searches
 - Chat room visits
 - 800 # calls
 - Unconscious awareness
 - While ad/medication are forgotten, ad surfaced a dormant concern that arises during visit

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Appendix: Study Methodology

Study Methodology—Physician Recruitment

- In this methodology, physicians and patients are research subjects
- Physicians were recruited for 10 different studies—data reviewed in this analysis is aggregate of all data from those studies
- 9,856 community-based physicians were sent letters via Federal Express inviting them to participate in a study of “physician-patient communication”
- Focus of study was never revealed to physicians, patients, or the researchers conducting the fieldwork, to minimize “Hawthorne effect”
 - Physicians were not part of “research panel”
 - Participating physicians responded to invitation and were screened via telephone for appropriate demographics and practice profile (volume; community-based; years in practice; etc.)
 - Allied Health Professionals, if part of study, were not recruited directly, but were enrolled on the day of research through the practice itself

Study Methodology—Patient Recruitment

- On previously scheduled days, a field researcher was sent to physicians' offices, and patients were recruited by the office staff to take part in a study of "physician-patient communication"
 - Office staff were instructed to recruit patients that had scheduled appointments and who were "likely to have a discussion about" the category in question
 - All research participants were compensated for their participation
- None of the participants (physicians, patients, field researchers) was aware of the specific focus of the study

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Study Methodology—Recording the Visit

- After obtaining informed written consent from all parties who would appear on the recording (physician, allied health professionals, patient, and visit companion, if any), the office visit was video- and audio-taped
 - the field researcher did not observe the visit
- To protect their privacy, participants were given the option to cover the camera lens (while maintaining audio recording) during any portion of the visit in which they might be undressed
- Immediately following visit, patient and healthcare provider participated individually in video- and audio-taped follow-up interviews
 - These short post-visit interviews revealed the relative match or mismatch of participants' perceptions regarding issues discussed in the visit
- Interview questions were designed to uncover what participants meant to convey (primarily on the part of the provider) and what they understood (primarily on the part of the patient)
 - Field researchers did not share information about physician's or patient's responses during interviews

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