OTC vs. Prescription Drugs

Summary

- OTC drugs have a greater market share than prescription drugs in the rest of the world as compared to the US
- Consumers and government pressure on pricing will continue to help accelerate the Rx-to-OTC transition in the US
- The Rx-to-OTC transition will probably be limited to the traditional markets such as allergy/cold, analgesics, anti-infectives, gastrointestinal, and smoking cessation for now
- There is widespread support for OTC usage among physicians for fever, cold/cough and minor ailments of that nature; beyond that, the physicians do have some reservations

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OTC and Prescription Drugs

Introduction

For a medicine to be granted OTC status, it must have a wide safety margin and be effective, and must bear understandable labeling to ensure proper use. More than 700 OTC products on the market today use ingredients or dosages available only by prescription less than 30 years ago. Rx-to-OTC switch refers to the transfer of proven prescription drugs (Rx) to non-prescription, over-the-counter (OTC) status. Rx-to-OTC switch is a data-driven, scientifically rigorous, and highly regulated process that allows consumers to have OTC access to a growing range of medicines

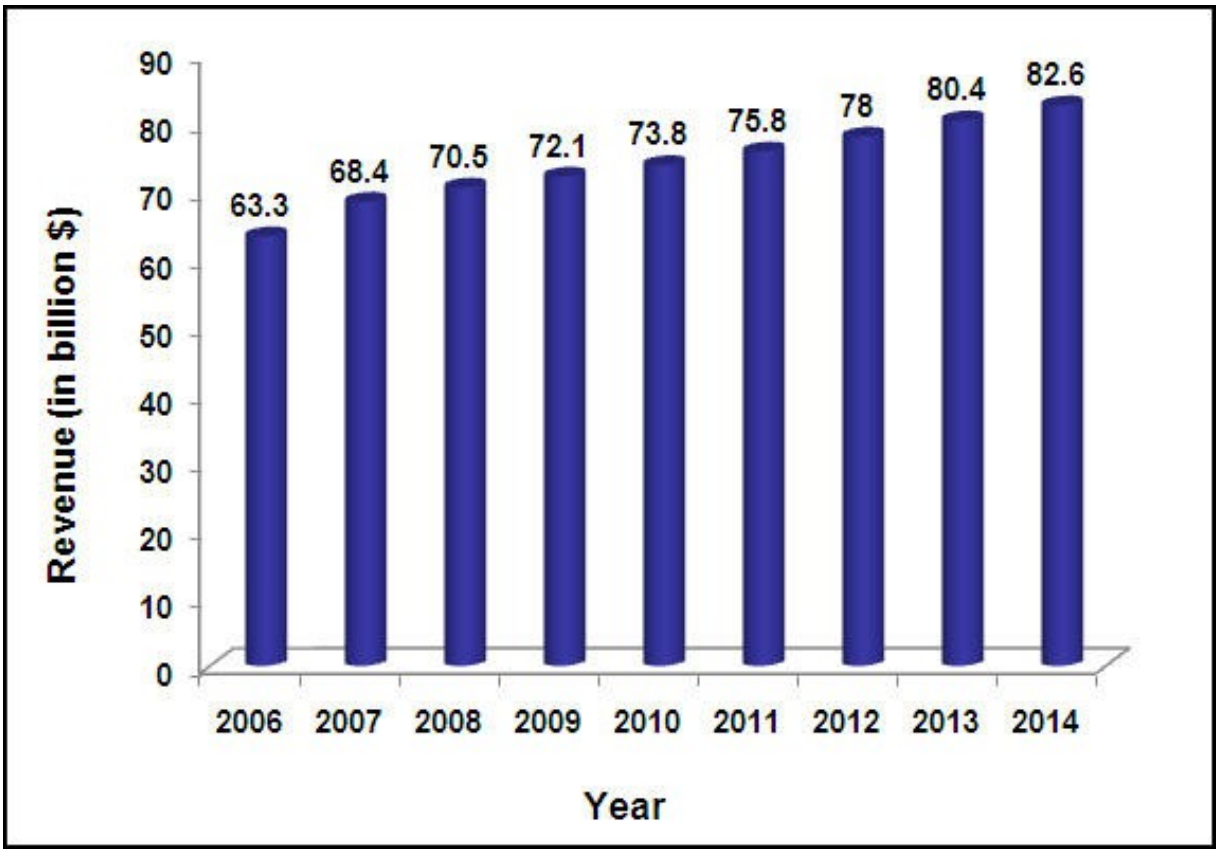
OTC Players

Supplier	Segments of Major Participation					
	Allergy/Cold	Analgesics	Anti-infectives	Gastrointestinal	Smoking Cessation	Othe
Bayer Consumer	☑	☑				
Boehringer Ingelheim				☑		
GlaxoSmithKline Consumer	☑			☑	☑	
McNeil Consumer/ McNeil-PPC	☑	☑	☑	☑		
J&J/Merck Consumer Products				☑		
Novartis Consumer	☑		☑		☑	
Procter & Gamble Co.	☑			☑		
Schering-Plough	☑		☑	☑		
Wyeth Consumer	☑	☑		☑		

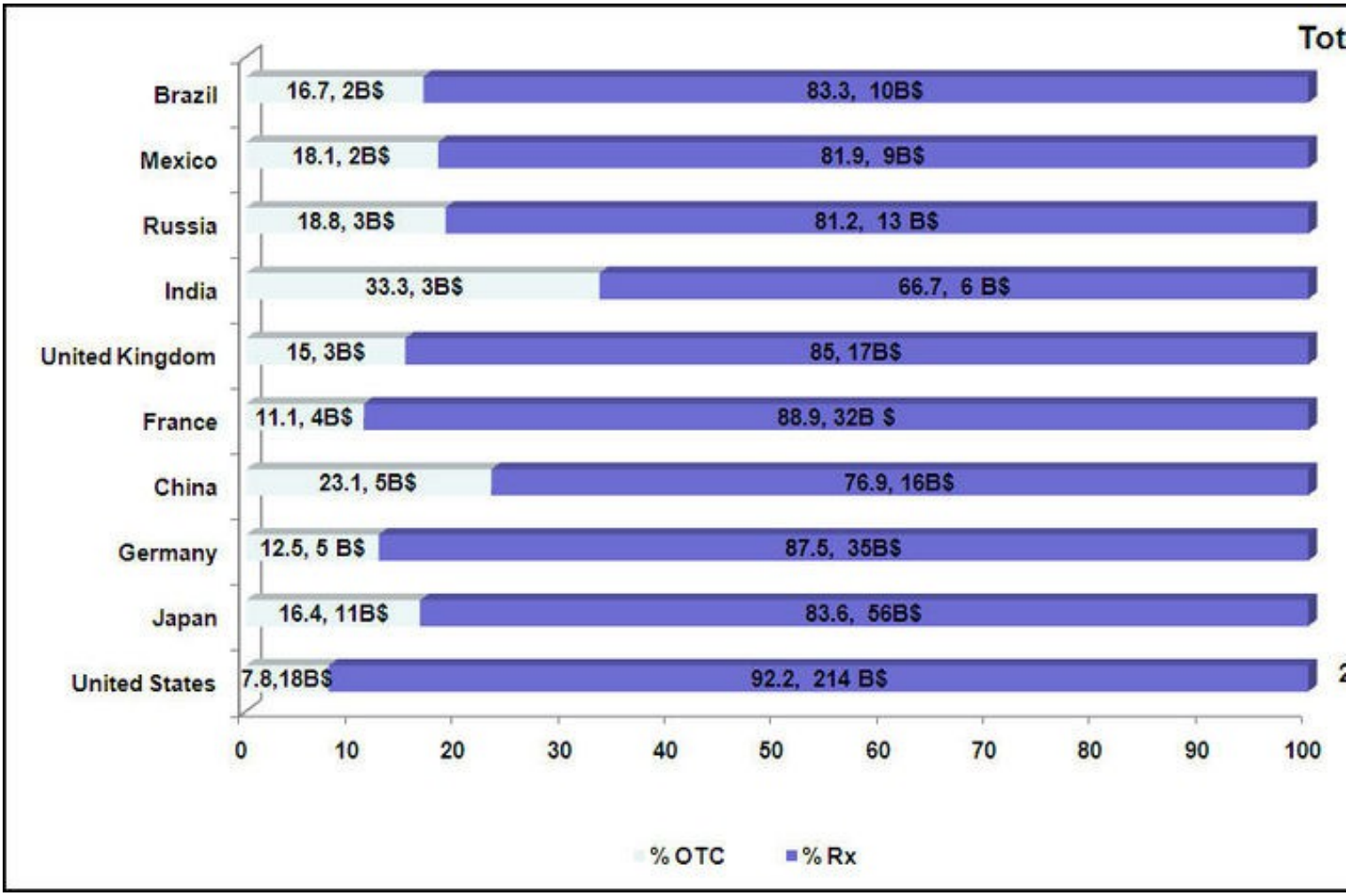


OTC Market

The compound annual growth rate (CAGR) of OTC market from 2005-2009 was 3.3%. The CAGR from 2009-2014 is expected to be 2.7%.



OTC vs. Rx Market



Rx-to-OTC Switch

There are two ways in which drugs are commonly switched as approved by FDA in US:

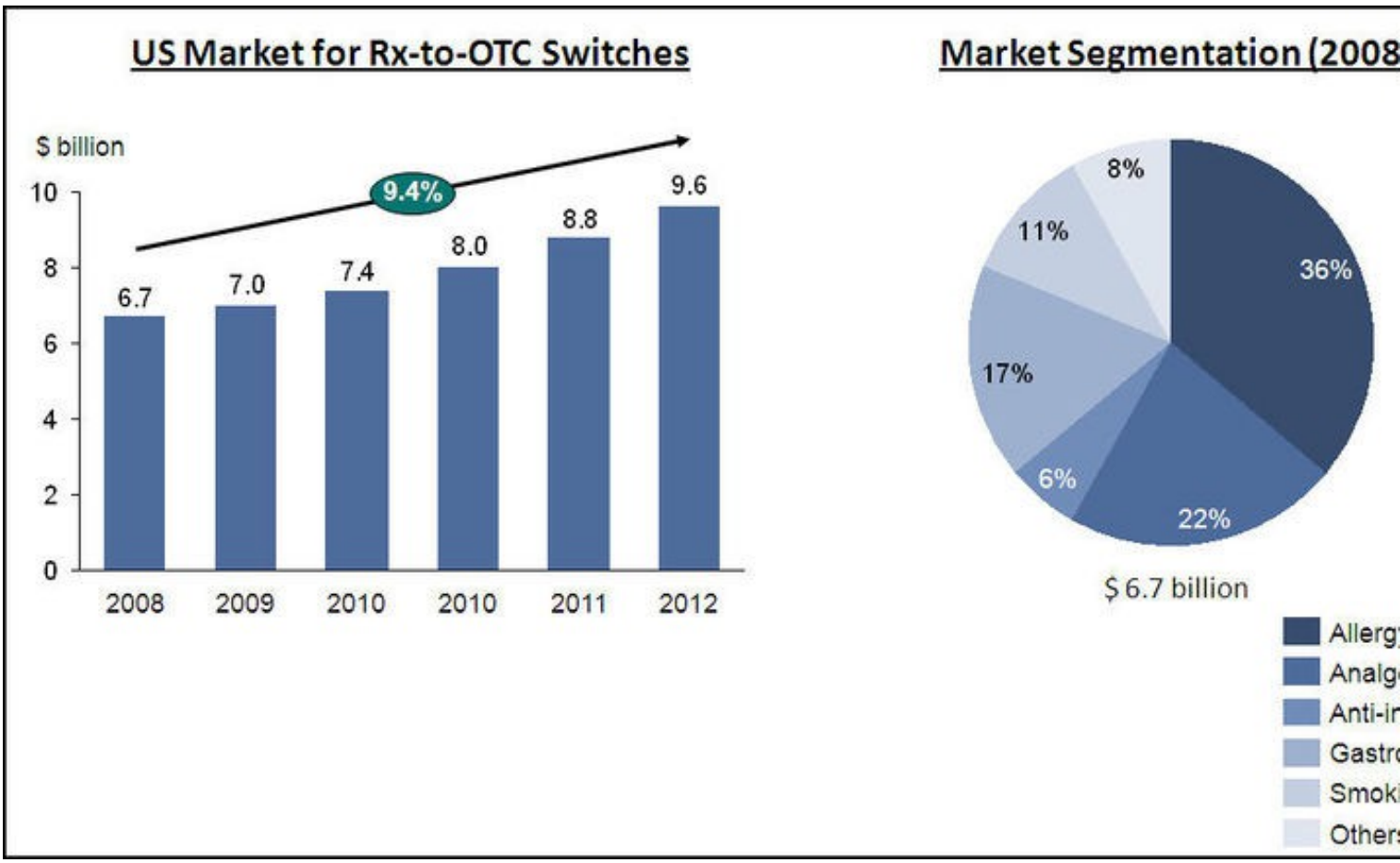
- The OTC Drug Review

1. Began in 1972
2. Ongoing assessment of the safety and effectiveness of all nonprescription drugs
3. Panels of non-government experts review active ingredients in marketed OTC drug products to determine whether they can be classified as safe and effective
4. About 40 former prescription-only drug ingredients have been switched by this process

- New drug application (NDA) process

1. Manufacturers submit data to the FDA showing the drug is appropriate for self-administration.
2. The submission includes studies showing that the product's labeling can be read, understood, and followed by the consumer without the guidance of a health care provider
3. Some drugs are approved initially as OTC drugs, but most are first approved for prescription use and later switched to OTC

Market Overview



Sales Data for Selected Rx-to-OTC Switches, USA

S.No	Switched Drug	Manufacturer/Marketer	Drug Category	Switch Year	First 12-Month Sales (in millions)
1	Aleve	Bayer Consumer Care	Analgesic	1994	$110
2	Alli	GlaxoSmithKline Consumer Healthcare	Weight Loss Aid	2007	$80
3	Claritin	Schering-Plough Healthcare	Allergy	2002	$380
4	MiraLax	Schering-Plough Healthcare	Gastrointestinal	2006	$40
5	Nicoderm CQ	GlaxoSmithKline Consumer Healthcare	Smoking Cessation	1996	$160
6	Nicorette	GlaxoSmithKline Consumer Healthcare	Smoking Cessation	1996	$195
7	Pepcid AC	Johnson & Johnson - Merck Consumer Pharmaceuticals Co.	Gastrointestinal	1995	$200

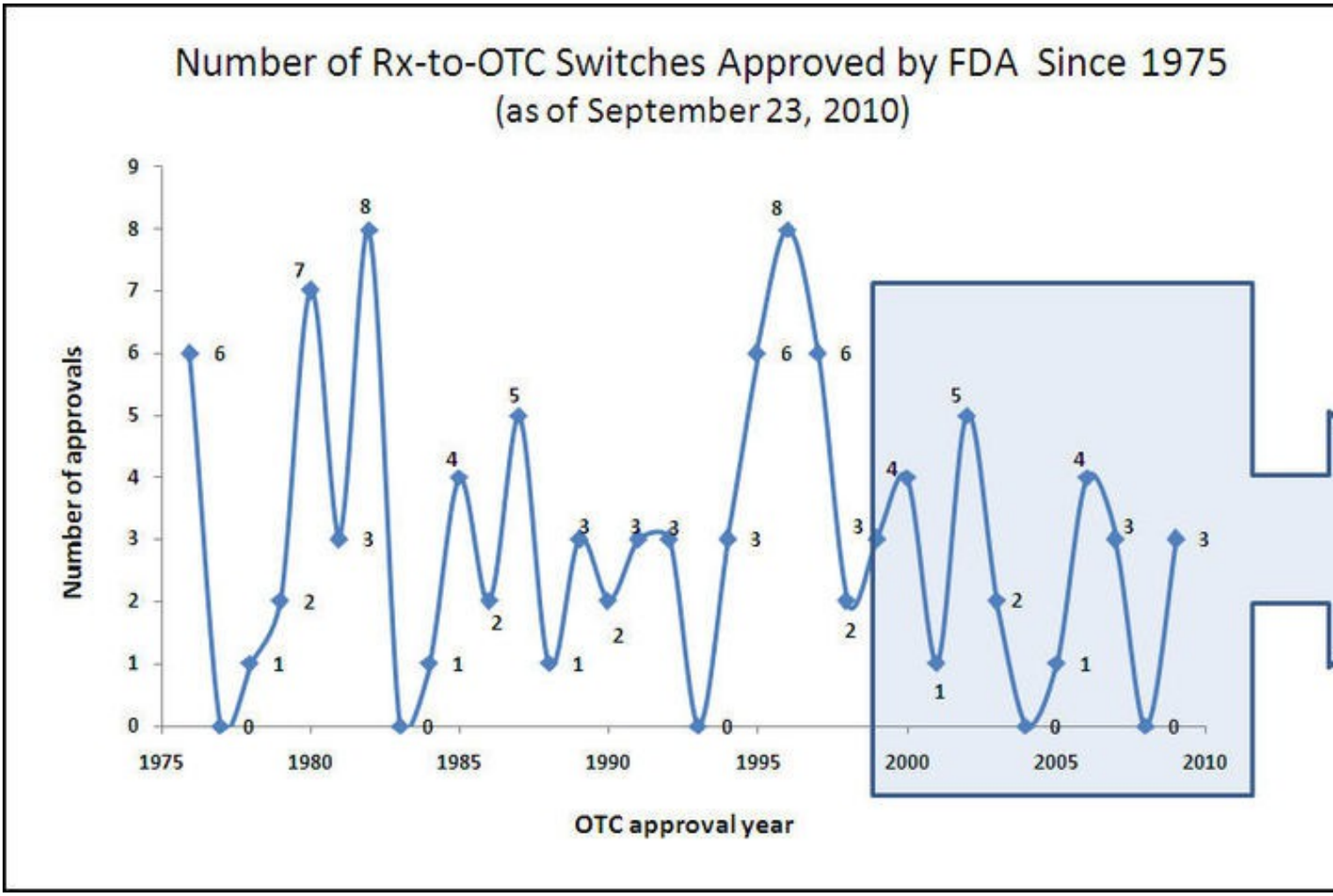
8	Prilosec OTC	Procter & Gamble	Gastrointestinal	2003	$130
9	Rogaine	McNeil Consumer Healthcare	Hair Loss	1996	$180
10	Zantac 75	Boehringer Ingelheim Consumer Healthcare Products	Gastrointestinal	1995	$140

Factors Affecting Rx-to-OTC Switch

Consumers: In the current scenario, consumers are looking to cut their health care costs
Government: US government is proactively finding ways to make health care more affordable
Companies: Companies are constantly evaluating various options to keep the consumer product segments profitable

Trends in Rx-to-OTC Switch

New OTC Switch Approvals



Rx-to-OTC Switches Since 2000

S.NO.	INGREDIENT	PRODUCT CATEGORY	DATE OF OTC APPROVAL	PRODUCT EXAMPLES	COMPANY
1	ibuprofen (NDA)**	migraine	25/02/2000	Motrin Migraine Pain	McNeil Consumer Healthcare
2	docosanol (NDA)*	cold sore/fever blister	25/07/2000	Abreva Cream	Avanir Pharmaceuticals
3	famotidine, calcium carbonate, magnesium hydroxide (NDA)*	heartburn, acid indigestion	17/10/2000	Pepcid Complete	J&J/Merck
4	butenafine hydrochloride (NDA)	athlete?s foot, jock itch, ringworm	7/12/2001	Lotrimin Ultra	Schering-Plough

5	ibuprofen, pseudoephedrine HCl, suspension for pediatric use (NDA)*	analgesic/decongestant	18/04/2002	Children?s Advil Cold	Wyeth
6	guaifenesin extended-release tablet (NDA)	expectorant	12/7/2002	Mucinex	Adams Respiratory Therapeutics
7	nicotine polacrilex troche/lozenge (NDA)*	smoking cessation	31/10/2002	Commit	GlaxoSmithKline
8	loratadine (NDA)	antihistamine	27/11/2002	Claritin Tablets, Claritin RediTabs, Claritin Syrup	Schering-Plough
9	loratadine, pseudoephededrine sulfate (NDA)	antihistamine/ decongestant	27/11/2002	Claritin-D 12 Hour Extended Release Tablets,	Schering-Plough
10	omeprazole magnesium	acid reducer to treat frequent heartburn	20/06/2003	Prilosec OTC	Procter & Gamble
11	loratadine (NDA)**	hives relief	15/11/2003	Claritin hives relief	Schering-Plough
	diphenhydramine citrate & ibuprofen (NDA)*; diphenhydramine HCl & ibuprofen potassium (NDA)*	analgesic sleep-aid	21/12/2005	Advil PM	Wyeth
12	ecamsule (combined with avobenzone and octocrylene (NDA)*	sunscreen	21/07/2006	Anthelios SX	L?Oreal
13	levonorgestrel (NDA)	contraceptive	24/08/2006	Plan B	Duramed
	polyethylene glycol 3350 (NDA)	laxative	6/10/2006	MiraLAX	Schering-Plough
14	ketotifen (NDA)	antihistamine eye drops	19/10/2006	Zaditor	Novartis
15	orlistat (NDA)	weight loss aid	7/2/2007	alli	GlaxoSmithKline
16	cetirizine HCl & pseudoephedrine HCl (NDA)	antihistamine/ decongestant	9/11/2007	Zyrtec-D	McNeil
17	cetirizine HCl (NDA)	antihistamine, hives relief	16/11/2007	Zyrtec	McNeil
18	lansoprazole (NDA)	acid reducer to treat frequent heartburn	18/05/2009	Prevacid 24 HR	Novartis
19	levonorgestrel (NDA)	contraceptive	10/7/2009	Plan B One Step	Duramed
20	omeprazole and sodium bicarbonate (NDA)	acid reducer to treat frequent heartburn	1/12/2009	Zegerid OTC	Schering-Plough

Blue highlighted drugs are patent-protected
Purple highlighted drugs are under FDA exclusivity period

Rx-to-OTC Switches before patent expiry

S.NO.	PRODUCT EXAMPLES	COMPANY	DATE OF OTC APPROVAL	PATENT EXPIRY	FDA EXCLUSIVITY	PATENT NUMBER
1	Abreva Cream	Avanir Pharmaceuticals	**25/07/2000**	**28/04/2014**	--	4,874,794
2	Pepcid Complete	J&J/Merck	**17/10/2000**	**15/10/2000**	--	4,283,408
3	Mucinex	Adams Respiratory Therapeutics	**12/7/2002**	**28/04/2020**	--	6,372,252
4	Commit	GlaxoSmithKline	**31/10/2002**	**21/08/2010**	--	5,110,605
5	Prilosec OTC	Procter & Gamble	**20/06/2003**	**15/11/2019**	--	5690960, 5753265, 5817338, 5900424, 6403616, 6428810
6	Claritin hives relief	Schering-Plough	**15/11/2003**	**19/06/2002**	--	4,282,233
7	Anthelios SX	L?Oreal	**21/07/2006**	**24/12/2013**	--	5,587,150
8	Plan B	Duramed	**24/08/2006**	--	**24/08/2009**	--
9	MiraLAX	Schering-Plough	**6/10/2006**	--	**6/10/2009**	--
10	alli	GlaxoSmithKline	**7/2/2007**	**6/1/2018**	**7/2/2010**	6004996

11	Zyrtec-D	McNeil	**9/11/2007**	**10/6/2022**	--	6469009, 6489329, 7014867, 7226614
12	Zyrtec	McNeil	**16/11/2007**	**2/7/2018**	--	6455533
13	Prevacid 24 HR	Novartis	**18/05/2009**	**--**	**18/05/2012**	--
14	Plan B One Step	Duramed	**10/7/2009**	**--**	**10/7/2012**	--
15	Zegerid OTC	Schering-Plough	**1/12/2009**	**15/07/2016**	--	6489346, 6645988, 6699885, 7399772

Blue highlighted drugs are patent-protected
Purple highlighted drugs are under FDA exclusivity period

Trend Analysis

- 11 out of 22 recent drugs (50%) which switched from Rx to OTC were patent protected
- 4 out of 22 recent drugs (18.2%) which switched from Rx to OTC were under FDA exclusivity period
- 13 out of 22 recent drugs (59%) were switched from Rx to OTC before their patent or FDA exclusivity expiry. Two drugs switched after the expiry of patents
- 6 out of these 13 drugs made a switch more than 10 years before expiry
- 5 out of these 13 drugs made a switch between 3 to 10 years before expiry

Potential Drugs for Rx-to-OTC Switch

S.NO	DRUG	PATENT EXPIRY DATE	EXPECTED SWITCH YEAR	US PATENT NUMBERS
1	Allegra	14/3/2017	2012	5578610, 6037353, 6187791, 6399632, 7138524
2	Clarinex	1/12/2018	>2013	6514520, 7211582, 7214683, 7214684
3	Crestor	17/6/2022	>2014	6858618, 6316460, 7030152, RE37314
4	Lescol	12/6/2012	>2014	5356896, 5354772,
5	Lipitor	8/1/2017	>2014	5969156, 4681893, 5273995, 5686104, 5969156, 6126971, RE40667
6	Pravachol	22/10/2014	>2014	5622985
7	TriCor	21/2/2023	>2014	7276249, 5145684, 6277405, 6375986 , 6652881, 7037529, 7041319, 7320802
8	Vytorin	25/4/2017	>2014	RE37721, 5846966,
9	Zetia	25/7/2022	>2014	7030106, 5846966, 7612058, RE37721
10	AcipHex	8/5/2013	2013	5045552
11	Nexium	25/11/2018	>2014	7411070, 5690960, 5714504, 5877192, 5900424, 6147103, 6166213, 6191148, 6369085, 6428810, 6875872
12	Protonix	30/3/2025	2010	7553498, 4758579, 7544370, 7550153
13	Zofran	7/12/2026	>2014	7544370, 4758579, 7550153, 7553498
14	Propecia	5/11/2013	2011	5571817, 5547957, 5886184
15	Imitrex	10/3/2014	>2010	5554639, 5307953, 5705520
16	Actonel	10/12/2018	>2014	6165513, 5583122, 6096342
17	Boniva	2/9/2014	>2014	5662918, 4927814
18	Fosamax	17/1/2019	>2014	6225294, 5462932, 5994329, 6015801
19	Evista	10/3/2017	>2014	6894064, 6797719, 6458811, 5393763, 5457117, 5478847, 5811120, 5972383, 6906086, RE38968, RE39049, RE39050
20	Detrol	11/5/2020	>2014	5382600, 6630162, 6770295, 6911217
21	Ditropan	22/11/2015	>2014	5674895, 5840754, 1 5912268, 6262115, 6919092
22	Cialis	26/4/2020	>2014	7182958, 5859006, 6140329, 6821975, 6943166
23	Levitra	31/10/2018	>2014	6362178, 7696206
24	Viagra	22/10/2019	>2014	6469012, 5250534

Physician Preferences and Insights: US Market Survey

Rx vs. OTC Survey

Objectives of the survey

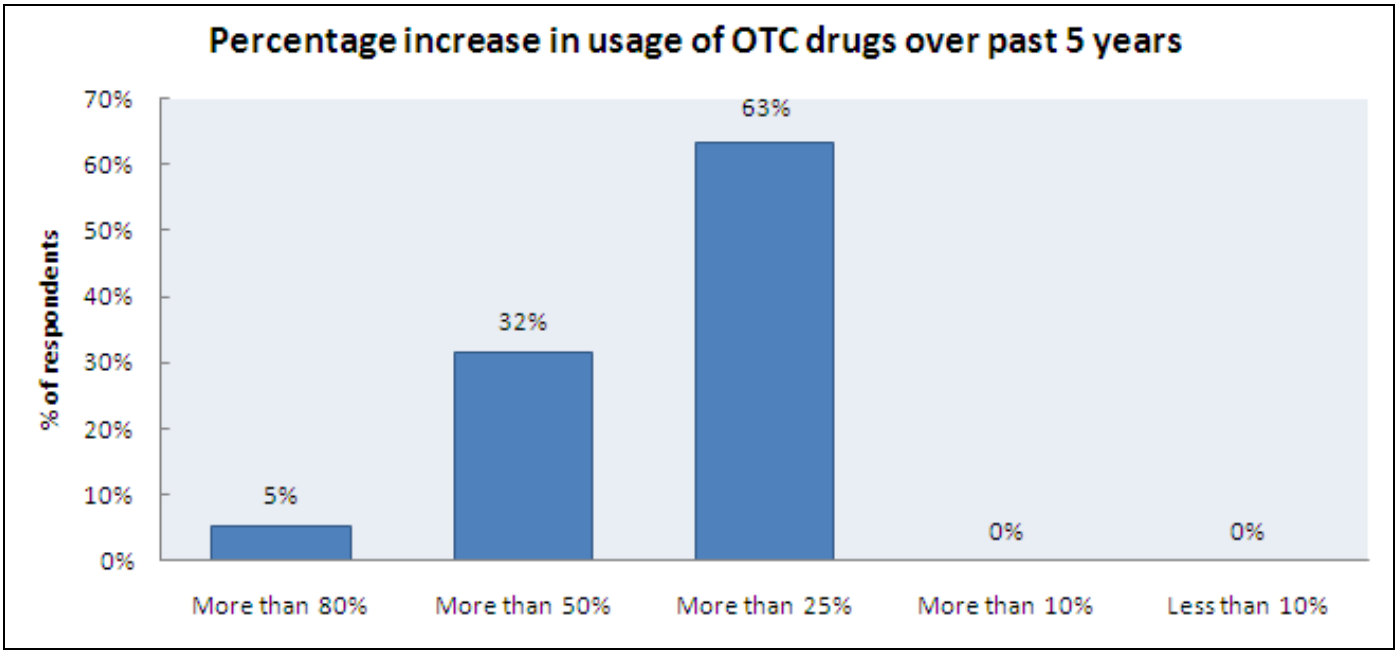
- General information on OTC market and usage
- Attitude of physicians towards OTC drugs as compared to Rx drugs
- Effectiveness of marketing campaigns

Sample size of physicians	20
Primary medical specialty	General or Family Practice
Avg of visiting patients per month	466 patients
Avg of years of experience	20 years

Physician panel provisioned by: World One.

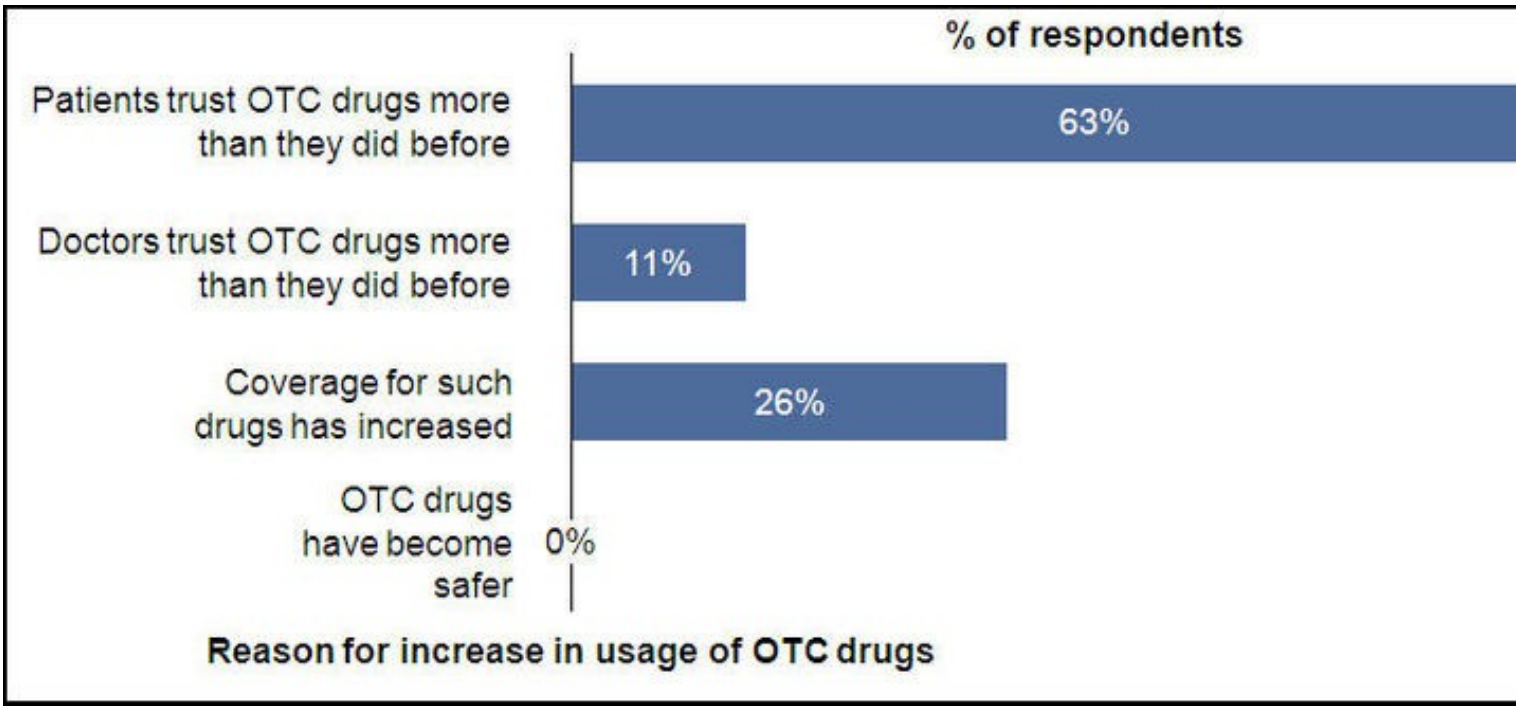
Increase in OTC Usage

- 95% of the respondents think that the usage of OTC drugs has increased in the past five years
- About 63% of them think that usage of OTC drugs has increased by more than 25% over the past 5 years



Reasons for Increased OTC Usage

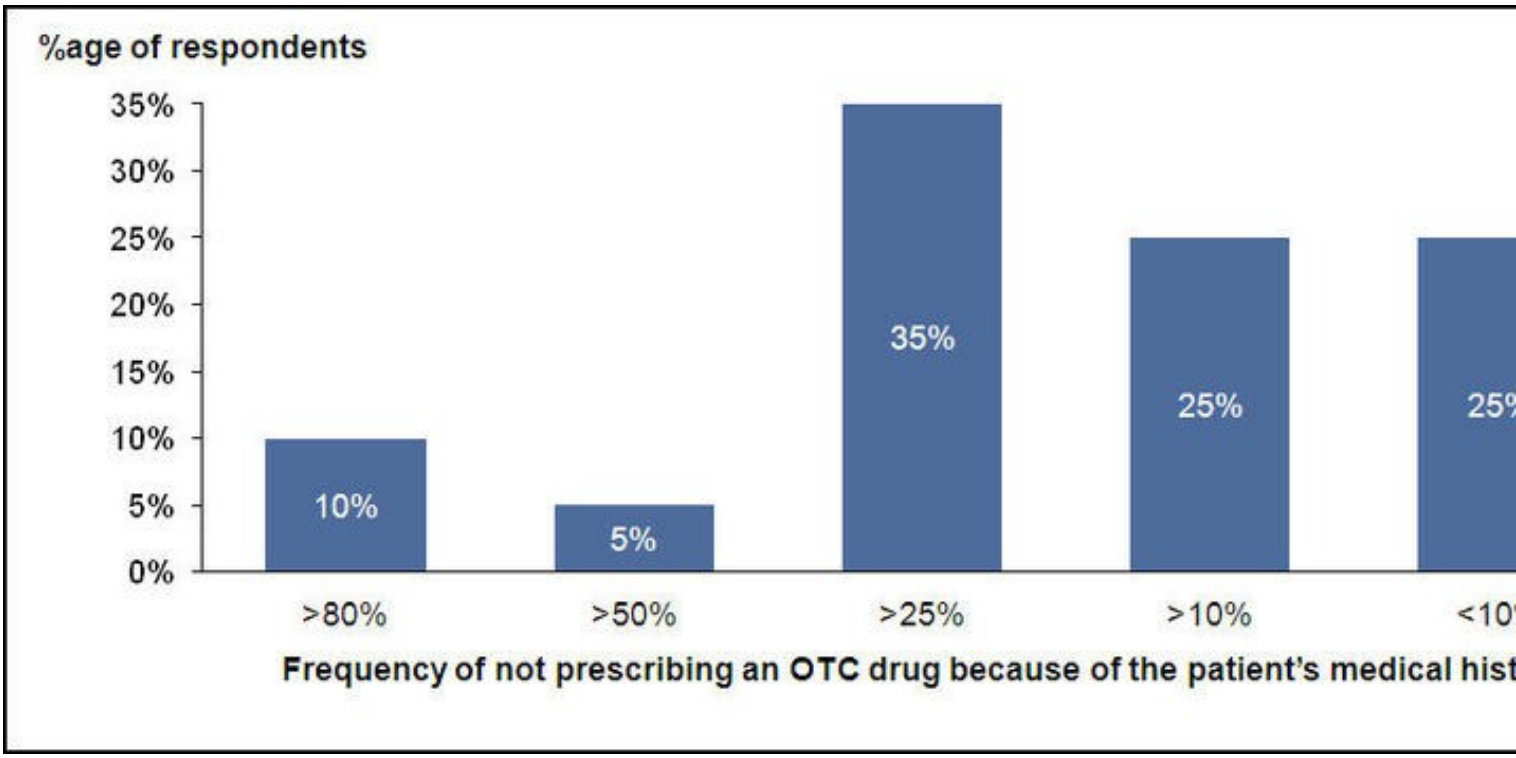
- Majority of the respondents feel that patients are trusting OTC drugs more than they used to do before and this, along with increased coverage to OTC drugs, triggered the increased usage of OTC drugs over the past five years



About 50% of the respondents think that more OTC drugs should be included under Medicare/insurance coverage.

OTC Usage and Medical History

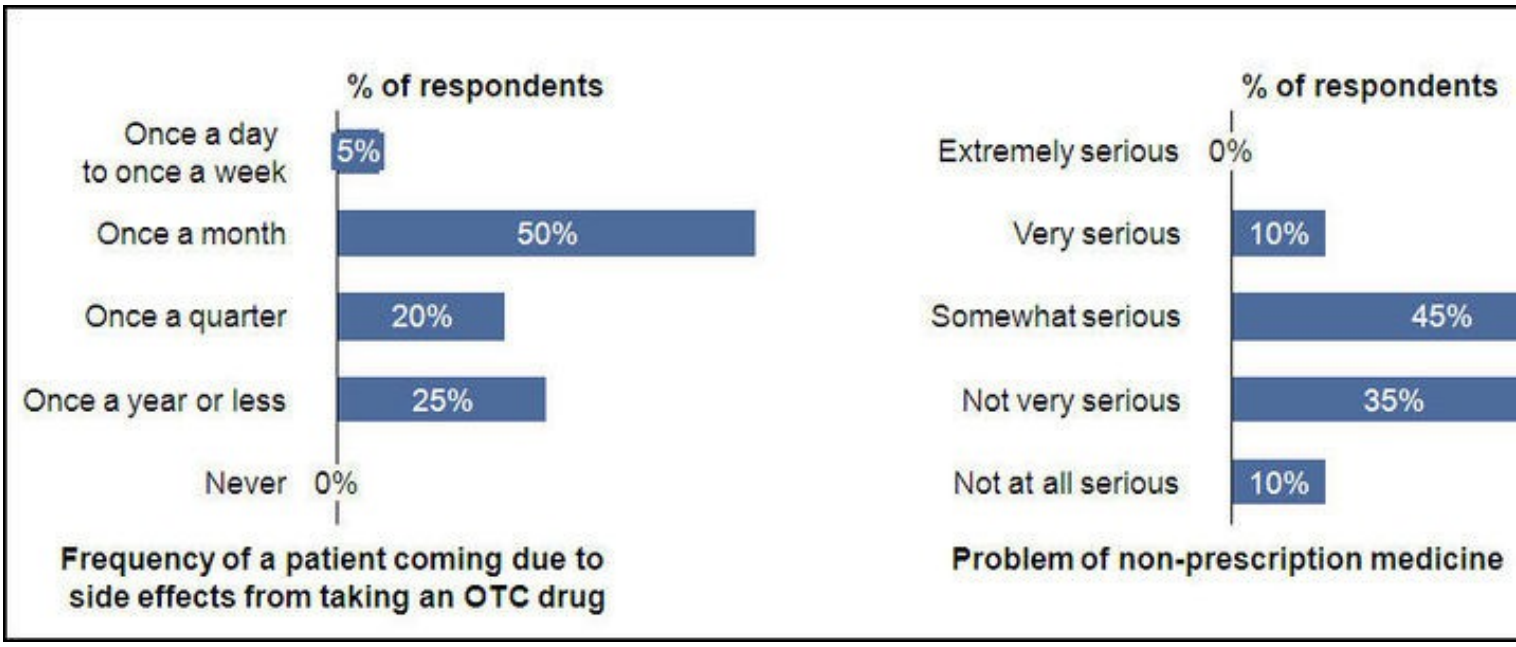
- Doctors generally check patient?s medical history for probable side effects and habits before prescribing OTC drugs



About 85% of the respondents think that the information on the labels of OTC drugs is sufficient.

OTC side effects

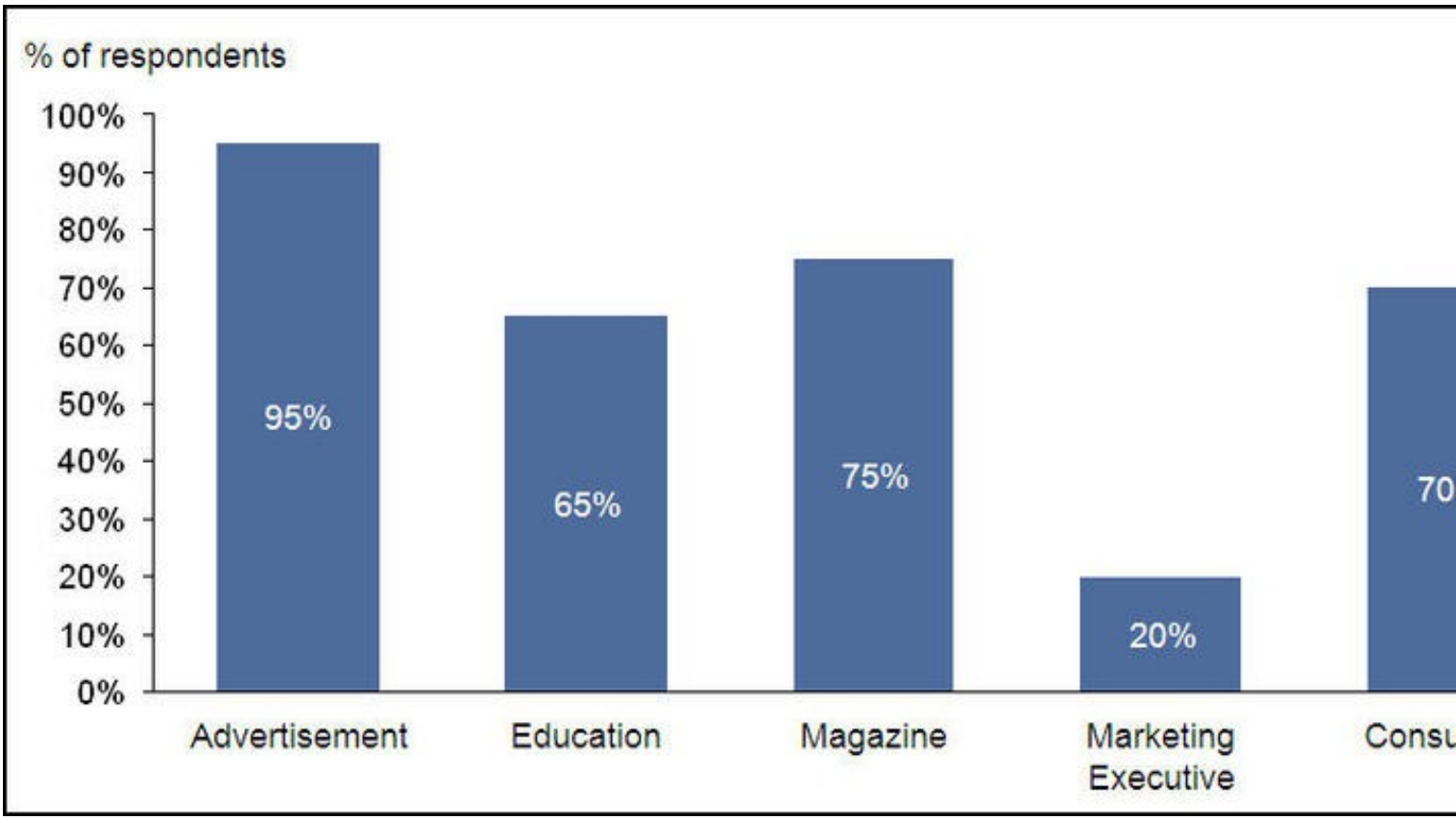
- The average no. of patients visiting each respondent in a month is 466 and about one patient among them would visit due to side effect from taking an OTC drug



About 45% of respondents think that the problem of non-prescription medicine today is somewhat serious.

Effectiveness of Marketing Campaigns

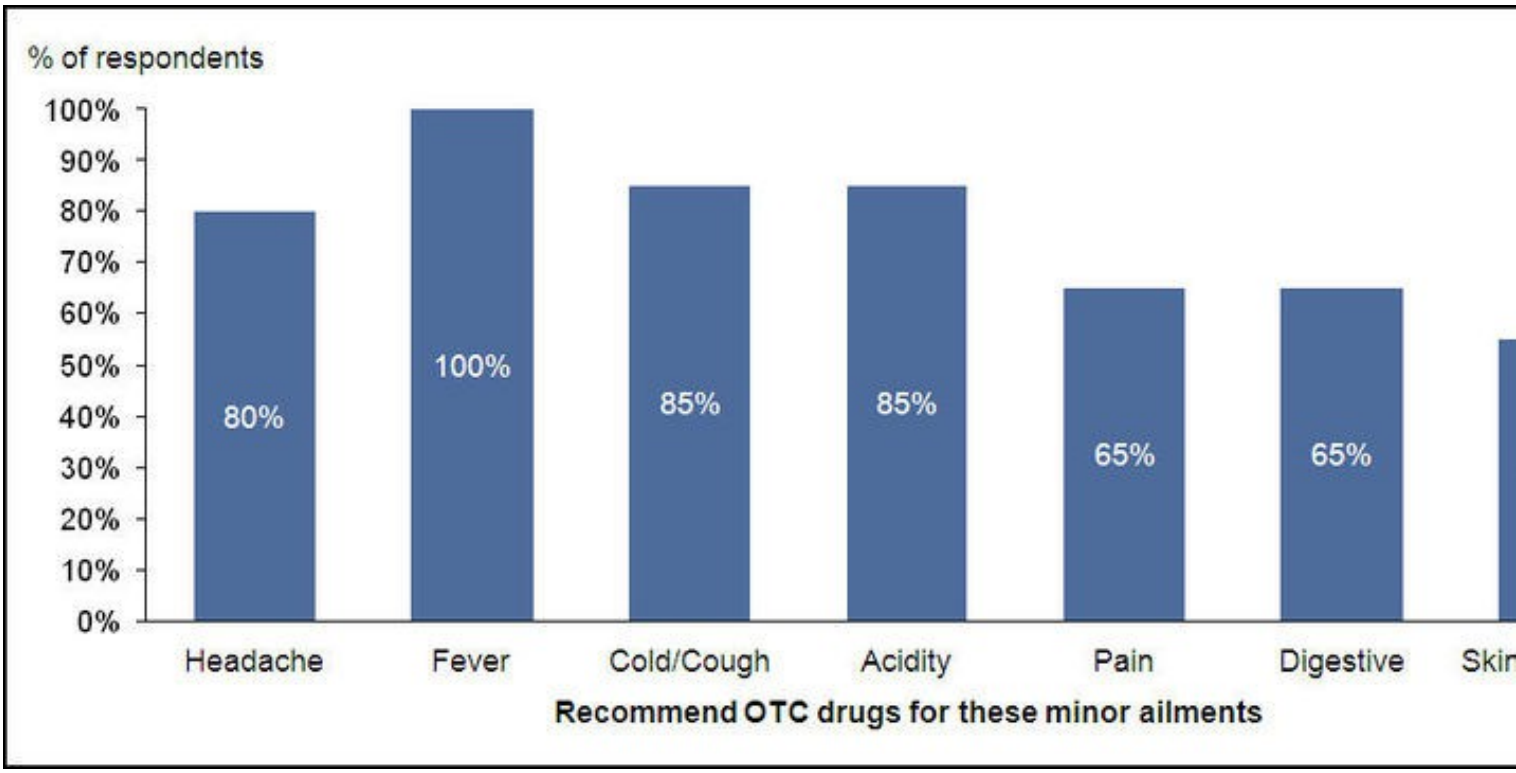
- Advertisement is the major source of information on OTC drugs for most of the respondents



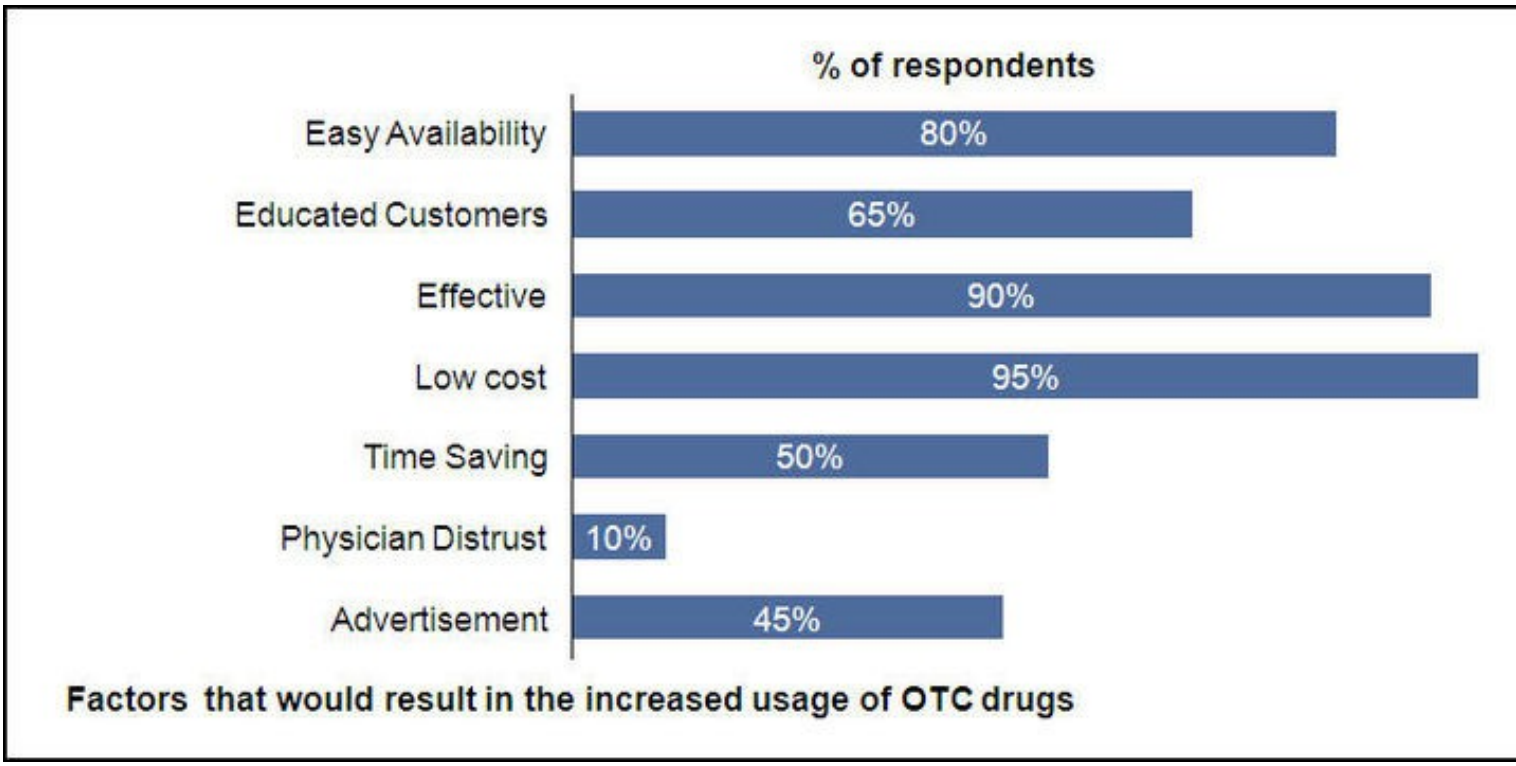
Only 30% of respondents replied in positive when asked about permitting marketing executives to market OTC products through them.

Physician attitude ? OTC vs. Rx

- 100% of the respondents would recommend an OTC drug for fever and about 85% of them would do so for other minor ailments like cold/cough and acidity



- About 95% of the respondents suggested low cost would be a major factor that would result in the increased usage of OTC drugs

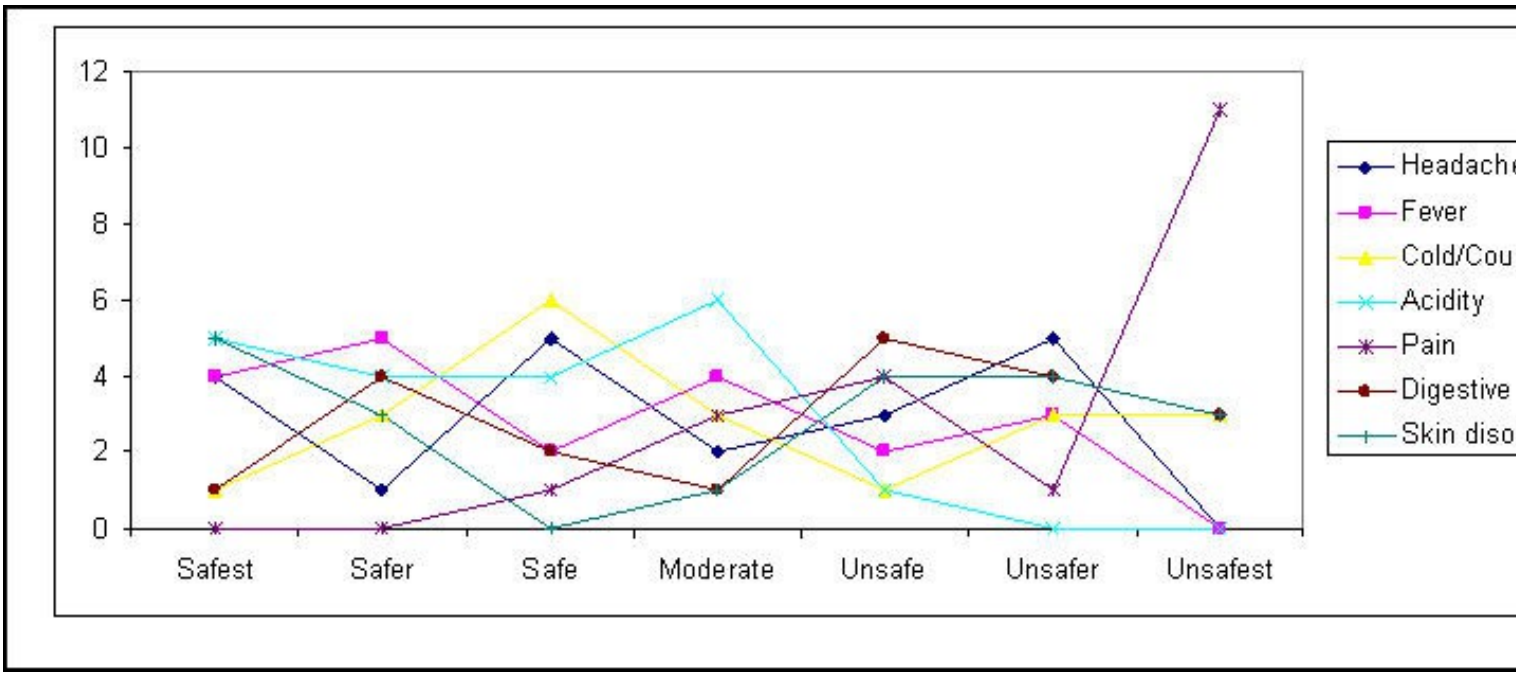


100% of the respondents feel it is important to prescribe a drug that minimizes patients' out-of-pocket costs, while choosing between equally effective and safe medications.

OTC Safety Perceptions

Physicians perceive OTC drugs to be:

- Very safe for fever, acidity, skin disorders
- Unsafe for pain
- Generally safe for headache, cold/cough and digestive disorders


12
10
8
6
4
2
0
Safest
Safer
Safe
Moderate
Unsafe
Unsafer
Unsafest
Headache
Fever
Cold/Cou
Acidity
Pain
Digestive
Skin diso