

Table of Contents

INTRODUCTION	5
EXECUTIVE SUMMARY	7
Overview	7
Market Trends.....	7
Triggers for the Switch	7
Cost Analysis	8
Process of Switching	8
FDA NSURE Initiative.....	8
Switch Risks.....	9
Future Potential	9
MARKET ANALYSIS	10
Figure 1: Growth of the OTC Market	10
Figure 2: Forecasted Growth of the OTC Market.....	11
Importance of OTC Medications.....	11
Successful Rx-to-OTC Switches	11
Figure 3: Rx-to-OTC switches (1975-2014)	12
Table 1: Rx-to-OTC Switch Products	12
New Areas for Potential Switches.....	14
Market Drivers	14
Figure 4: Drivers for a Rx-to-OTC switch.....	15
Major Players	15
Table 2: Major Players in the Rx-to-OTC Switch Industry	16
Market Opportunity Analysis.....	16
Figure 5: Potential Opportunities	17
COST ANALYSIS.....	18
Details about the Cost Analysis.....	18
Deductible Silver – Kaiser Permanente Virginia Silver 1500/30/Dental	19
Cigna Health Insurance	19

CareFirst HealthyBlue Advantage	19
Humana Military TriCare Standard (E-4 Rank and below)	20
United Health Insurance (Medical Copay)	20
Results	20
Figure 6: Cost Difference between Branded Rx and OTC Drugs per Year	21
Table 3: Comparing the Most Recent Switches for Out-of Pocket Costs	22
REGULATORY LANDSCAPE	24
Acts and Amendments	24
The Switch Process – Steps Involved	24
Studies That Need to be Conducted	26
Figure 6: Label for a drug according to the OTC Drug Facts Label regulations	27
Table 4: Description of Study Procedures	29
Benefit-Risk Comparison	29
NSURE INITIATIVE	31
The NSURE Initiative	31
Conditions of Safe Use	31
FDA Public Hearings	32
Table 5: Clarifications by FDA for the Misconceptions Associated with NSURE	33
Next Steps	33
POTENTIAL SWITCH PRODUCT CATEGORIES	35
Acid Reflux	38
Table 6: Potential Switches in the Category of Acid Reflux	38
Vaginal Yeast Infections	39
Table 7: Potential Switches in the Category of Vaginal Yeast Infections	39
Allergy Nasal Sprays	41
Table 8: Potential Switches in the Category of Allergy Nasal Sprays	41
Overactive Bladder/Incontinence	43
Table 9: Potential Switches in the Category of Overactive Bladder/Incontinence	43
Tinea Pedis (Athlete’s Foot)	44
Table 10: Potential Switches in the Category of Tinea Pedis (Athlete’s Foot)	44
Analgesics, NSAIDs, and Pain Treatments	46
Table 11: Potential Switches in the Category of Analgesics, NSAIDs, and Pain Treatments	46

Antivirals	47
Table 12: Potential Switches in the Category of Antivirals	47
Migraine	50
Table 13: Potential Switches in the Category of Migraine.....	50
Erectile Dysfunction	53
Table 14: Potential Switches in the Category of Erectile Dysfunction.....	53
Smoking Cessation Aids	55
Table 15: Potential Switches in the Category of Smoking Cessation Aids	55
Cholesterol Reducing Drugs	56
Table 16: Potential Switches in the Category of Cholesterol Reducing Drugs.....	56
Osteoporosis Treatment	58
Table 17: Potential Switches in the Category of Osteoporosis Treatment.....	58
Sleep Aids.....	60
Table 18: Potential Switches in the Category of Sleep Aids.....	60
CONCLUSION.....	62
AVAILABLE RX-TO-OTC SWITCH PORTFOLIOS.....	63