#### TABLE OF CONTENTS

#### CHAPTER ONE: EXECUTIVE SUMMARY

- Direct-to-consumer Testing and The Future of DTC Genetic Tests
- Existing Self-Test Markets
- DTC Genetic Tests
- Aggressive Regulatory Action
- Consumer Opinion
- Conclusions

#### CHAPTER TWO: INTRODUCTION

- Demographics
- Declining Doctor Visits
- Drop the Doctor But Keep the Pharmacist?
- Consumer Worries
  - Concern About Health and Healthcare Costs
  - o Baby Boomers More Concerned About Health
- Drug Stores
  - Competitive Positions of Key Players
  - o Increasing Space in the Drug Store For Tests
  - o Role of the Pharmacist in Conducting Some Tests?

#### CHAPTER THREE: EXISTING SELF-TEST MARKETS

- Highly Successful OTC Markets
  - o Glucose
  - Pregnancy/Fertility
- Moderately Successful OTC Test Markets
  - o Fecal Occult Blood
  - Cholesterol
- Implications

# CHAPTER FOUR: DIRECT-TO-CONSUMER GENETIC TESTING: PROMISE AND REALITY

## Background

- Criticisms of DTC Testing
  - o Scientific and Clinical Validity
  - False Advertising
  - o GAO Investigation
  - o Acu-Gen Biolab Lawsuit and Bankruptcy
- Regulatory Activity
  - o Pathway Genomics FDA Controversy
  - o 2011 FDA Warning Letters

- Regulatory Action Targeting Suppliers
- Actions in Response to FDA Letters
- DTC Testing Companies
  - DeCode Genetics
  - o 23andMe
  - o Genelex Corporation
  - Pathway Genomics
  - Navigenics
  - Lumigenix
  - o Medigenomix

### CHAPTER FIVE: CONSUMER OPINION

- Healthcare Out of the Home
- Consumer Worry Over Disease
  - Alzheimer's and Cancer Concerns
- How Confident Are Consumers in Self Test Results?
- Do Genetic Tests Increase Healthcare Usage?
- NIH-led study
- Would Consumers Take a Genetic Self-Test?
  - Loyola Study
  - o Kalorama Survey of Adults

#### **CHAPTER SIX: CONCLUSIONS**

#### LIST OF EXHIBITS

#### CHAPTER ONE: EXECUTIVE SUMMARY

- Figure 1-1: Have You Used A Self-Test?
- Figure 1-2: Kalorama Survey of Adults

#### **CHAPTER TWO: INTRODUCTION**

- Figure 2-1: US Population
- Figure 2-2: Doctor Visits, U.S. (millions of visits)
- Figure 2-3: Have You Visited a Healthcare Professional? (DO, FP, Internist, OBGY, Pharmacist)
- Figure 2-4: Concern About Healthcare Cost and Barriers
- Figure 2-5: How is Your Health? –AP Survey of Baby Boomers and Non-Boomers
- Figure 2-6: Health Gotten Better/Worse Last Five Years? –Baby Boomers and Non Baby Boomers
- Table -2-2: U.S. Drug Store Sales,, 2003–2013
- Table 2-3: Leading U.S. Drug Stores' Revenues and Market Share

#### CHAPTER THREE: EXISTING SELF-TEST MARKETS

- Figure 3-1: Glucose Testing, 2010-2015
- Figure 3-2: Pregnancy Testing, 2010-2015
- Figure 3-3: Fecal Occult Blood Testing, 2010-2015
- Figure 3-4: Cholesterol Testing, 2010-2015

## CHAPTER FIVE: CONSUMER OPINION

- Figure 5-1: Experian Simmons Survey: "Conditions I Don't Have But Feel I am at Risk For"
- Figure 5-2: Percent of Americans Concerned About Disease (Alzheimer's, Cancer, Stroke, Diabetes)
- Figure 5-3: Have You Used A Self-Test?
- Table 5-1: Kalorama Survey Results –Would You Take a Genetic Test?