

The Role of Social Science in Prescription Drug Promotion

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Renaissance Downtown Hotel | Washington, DC**

OPDP Research Team

- Kathryn Aikin, Ph.D. (Team Lead)
- Kevin Betts, Ph.D.
- Amie O'Donoghue, Ph.D.
- Helen Sullivan, Ph.D., M.P.H.

OPDP's Mission

- Protect the public health by ensuring that prescription drug information is truthful, balanced, and accurately communicated
- Guard against false and misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs

How Social Science Can Inform Approach to Problems



- Help identify goals
- Identify barriers to achieving goals
 - Cognitive barriers (capacity, motivation, attention)
 - Behavioral barriers (time, opportunity)
 - Others (literacy)
- Identify potential solutions
- Test and verify effectiveness of solutions

Role of Research Team

- Apply social science/communication principles to:
 - Surveillance and compliance activities
 - Advice to industry/academia/within FDA
 - Guidance and policy development
 - Research

Focus Areas of Social Science Research

- Advertising Features
 - Content
 - Format
- Target Population(s)
- Research Quality



Additional Information About OPDP Research

- OPDP Research Website
- Completed projects
 - Link to publication
- Research in progress
 - Link to 60day FRN, 30day FRN
- <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm>



Research Studies

Study of Comparative Price Information in DTC and Professional Print Ads - Background

- Millions in the U.S. use Rx drugs to maintain health.
- Monetary cost can be a salient factor.
- Direct-to-consumer (DTC) advertising sponsors can include price-comparison information in advertising.

Background *(continued)*

- Prescription drug advertisements must be truthful and non-misleading with respect to side effects, contraindications, and effectiveness.
- Price comparisons may misleadingly imply superiority or equivalence of drug efficacy or safety when not warranted.
- Potential remedy: ***a context statement***
 - For example, disclosure noting that products may or may not be equally effective or safe and that products may or may not differ in afforded savings.

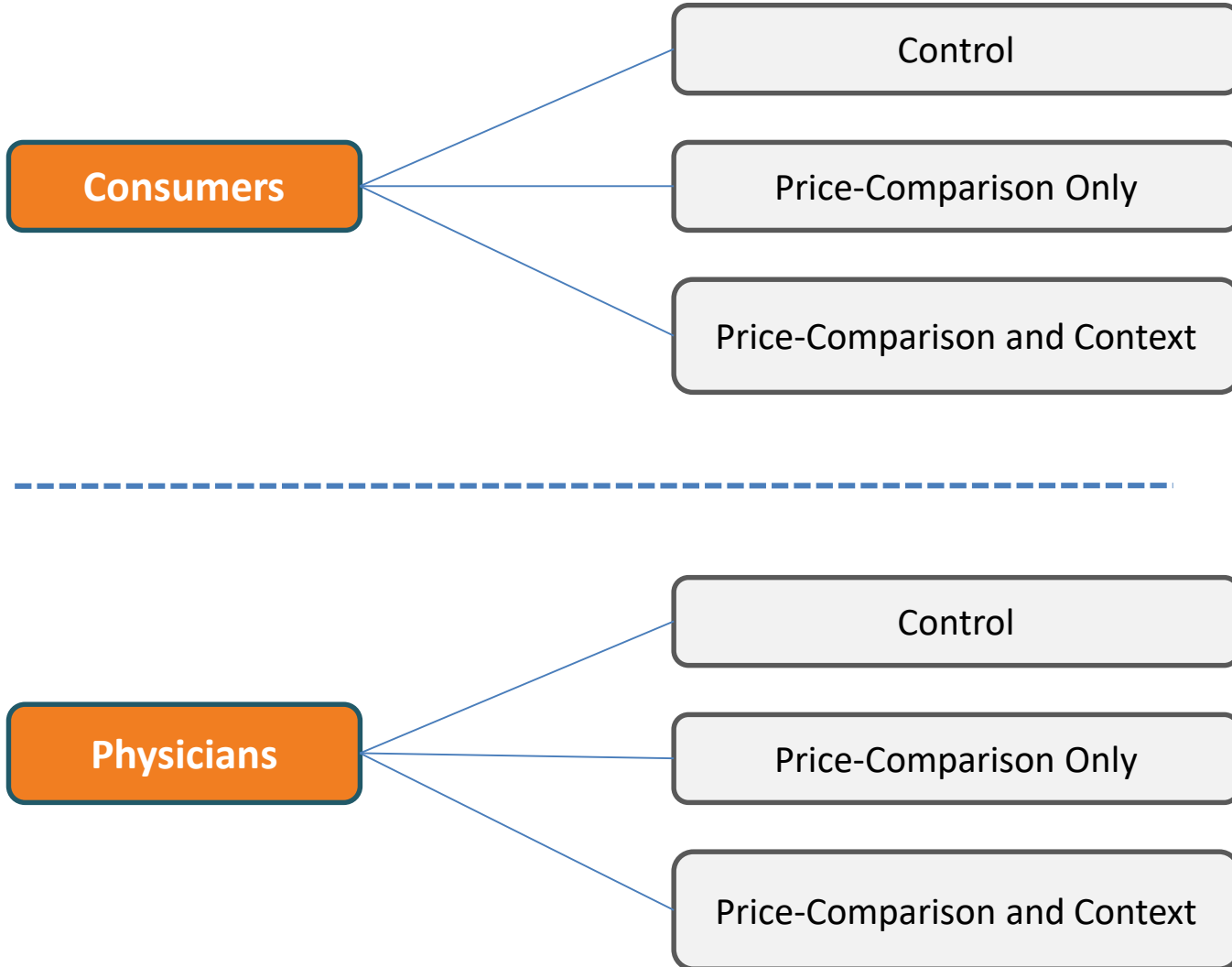
Purpose of Study

- Investigate impact of providing
 - Price-comparison information
 - Context statement on perceptions of advertised Rx drug
- Population
 - Adults diagnosed with diabetes
 - Physicians who treat diabetic patients
 - *Primary care physicians (PCPs) and endocrinologists*

Main Research Questions

- **RQ1:** What is the impact of price-comparison information and context statements on prescription drug perceptions in prescription drug advertising?
- **RQ2:** Do people notice price comparison and context information in prescription drug ads?
- **RQ3:** Does adding contextual information correct the impression that the products are interchangeable?

Design



Ad Manipulations

Hypothetical Diabetic Neuropathy Product

Consumers

Control	“Using Veridan could save you money.”
Price-Comparison Only	“If you take Lyrica, switching to Veridan could save you up to \$560.00 a year.”
Price-Comparison and Context	“The price savings presented may not reflect the actual savings by consumers or third-party payers. The products in this price comparison may or may not be equally effective or safe.”

Physicians

Control	“Prescribing Veridan to treat diabetic peripheral neuropathy could save your patients money.”
Price-Comparison Only	“If you currently prescribe Lyrica to treat diabetic peripheral neuropathy, switching your patients to Veridan could save them up to \$560.00 a year.”
Price-Comparison and Context	“The price savings presented may not reflect the actual savings by consumers or third-party payers. The products in this price comparison may or may not be equally effective or safe.”

Sample Consumer Stimuli

FDA

Price-Comparison and Context (Page 1)

Page 2 (All Ads)

You might be willing to pay a high price to treat your diabetes-related nerve pain—but why should you?

If you take Lyrica, switching to Veridan[™] could save you up to \$560.00 a year*.

Veridan is a prescription medicine used for the treatment of diabetes-related nerve pain (neuropathy). Taken once a day, it works by interfering with chemical processes in the brain that cause you to feel pain, providing significant relief.

The STING

If you use Lyrica, you are paying more than you should to treat your diabetes-related nerve pain.

The RELIEF

Veridan is an FDA-approved treatment for your diabetes-related nerve pain, and it costs \$560.00 less per year. Discuss Veridan with your doctor. Don't let the treatment cost you more this year.

*The price savings presented may not reflect the actual savings by consumers or third-party payers. The products in this price comparison may or may not be equally effective or safe.



Verifiable relief.

Verifiable savings.

Veridan[™]
verdexetine tablets 150 mg

Important Risk Information

Do not take Veridan if you are also using a monoamine oxidase inhibitor (MAOI), as a life-threatening drug interaction could occur.

Tell your doctor if you are nursing, pregnant, or plan to become pregnant during your course of treatment. Veridan may harm a developing fetus. It can also pass into breast milk and may harm your baby.

Stop taking Veridan and call your doctor right away if you have any signs of a serious allergic reaction such as swelling of your face, mouth, lips, gums, tongue, throat, or neck, or if you have any trouble breathing.

You may have thoughts of suicide when you first start taking Veridan, especially if you are 24 years of age or younger. Tell your doctor if your symptoms of depression or suicidal thoughts increase during the first several weeks of treatment, or whenever your dose is changed.

Also tell your doctor if you have any of the following conditions, as they may require a dose adjustment or special tests:

- High blood pressure
- High cholesterol
- Liver disease
- Kidney disease
- Eye disease
- Seizures or epilepsy

Common side effects include blurred vision, headache, high blood pressure, dizziness, sleepiness or insomnia, diarrhea, confusion, tiredness, indigestion, sweating, and nausea.

Please see important information about Veridan on next page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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www.Veridan.com

Important Information

Veridan[™] (VER-ih-dan)
verdexetine tablets 150 mg

What is Veridan?

Veridan is a prescription medicine that is one of a class of prescription antidepressants called serotonin and norepinephrine reuptake inhibitors (SNRIs). This medication is used to treat neuropathic pain associated with diabetic nerve pain (neuropathy).

Who is Veridan for?

Veridan is available only by prescription for:

- People who suffer from diabetes-related nerve pain.
- Adults 18 or over.

Who should NOT take Veridan?

- People who are using a monoamine oxidase inhibitor (MAOI), as a life-threatening drug interaction could occur.
- Women who are pregnant or may become pregnant. Veridan may harm a developing fetus. If you become pregnant, stop taking Veridan and call your doctor right away.
- Women who are nursing. Veridan can pass into breast milk and may harm your baby.

Talk to your doctor

Before you start taking Veridan, tell your doctor:

- About all of your prescription and over-the-counter medications as well as vitamins and herbal supplements.
- If you have a history of:
 - High blood pressure
 - High cholesterol
 - Liver disease
 - Kidney disease
 - Eye disease
 - Seizures or epilepsy

Possible serious side effects of Veridan

- **Suicidal thoughts.** Veridan is an antidepressant. You may have thoughts of suicide when you first start taking it, especially if you are 24 years of age or younger. Tell your doctor if your symptoms of depression or suicidal thoughts increase during the first several weeks of treatment, or whenever your dose is changed.
- **Allergic reactions.** Stop taking Veridan and call your doctor right away if you have any signs of a serious allergic reaction such as swelling of your face, mouth, lips, gums, tongue, throat, or neck, or if you have any trouble breathing.

Common side effects of Veridan

- Blurred vision
- Headache
- High blood pressure
- Dizziness
- Sleepiness or insomnia
- Diarrhea
- Confusion
- Tiredness
- Indigestion
- Sweating
- Nausea

How should I take Veridan?

- Take Veridan exactly as prescribed by your doctor.
- Take Veridan around the same time every day, with or without food.
- Do not break the tablet.
- If you miss a dose, take it as soon as you remember unless it has been more than 12 hours since your missed dose. Then take the next dose at your regular time.
- Do NOT change your doses or stop taking Veridan without talking to your doctor.

Need more information?

- Talk to your doctor or health care provider.
- Talk to your pharmacist.
- Call 1-866-Veridan.

Veridan[™]

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

www.Veridan.com

Study Phases

PHASE ONE

Cognitive Interviews

Test draft of survey for readability and comprehension, refine stimuli.

PHASE TWO

Pretest Study

Test the final draft of the survey and stimuli and conduct sub-study on incentives (physician sample).

PHASE THREE

Main Experimental Study

Test effect of price comparisons and context on comprehension and perceived drug risk and efficacy.

Main Study

- Purpose

- Assess extent to which disclosure of cost-comparison information limitations affect understanding of risks/benefits of prescription drug for diabetic neuropathy.

- Procedure



Main Study: Methods

- Survey length
 - Median length: 16 minutes
- Respondents
 - Consumers w/ diabetes ($n = 1,490$); 30% RR
 - Physicians w/ diabetic patients ($n = 1,438$); 14% RR
 - *Sample source*: Research Now online consumer and health care provider research panels

Main Study:

Key Measures by Research Question

RQ1: What is the impact of price-comparison information and context statements on prescription drug perceptions in prescription drug advertising?

Risk and Benefit Recall (open ended) and Recognition

Risk and Efficacy Perceptions (7 items)

Intentions (5 items)

RQ2: Do people notice price-comparison and context information in prescription drug ads?

Perceived Importance and Accuracy of Price and Context Statements (4 items)

Context Statement Comprehension (open ended)

RQ3: Does adding contextual information correct the impression that the products are interchangeable?

Intended Uncertainty about Risks and Efficacy

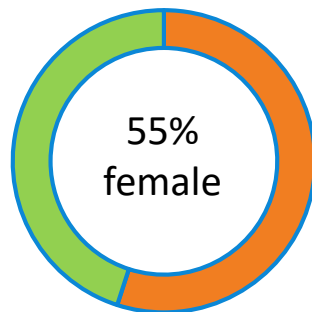
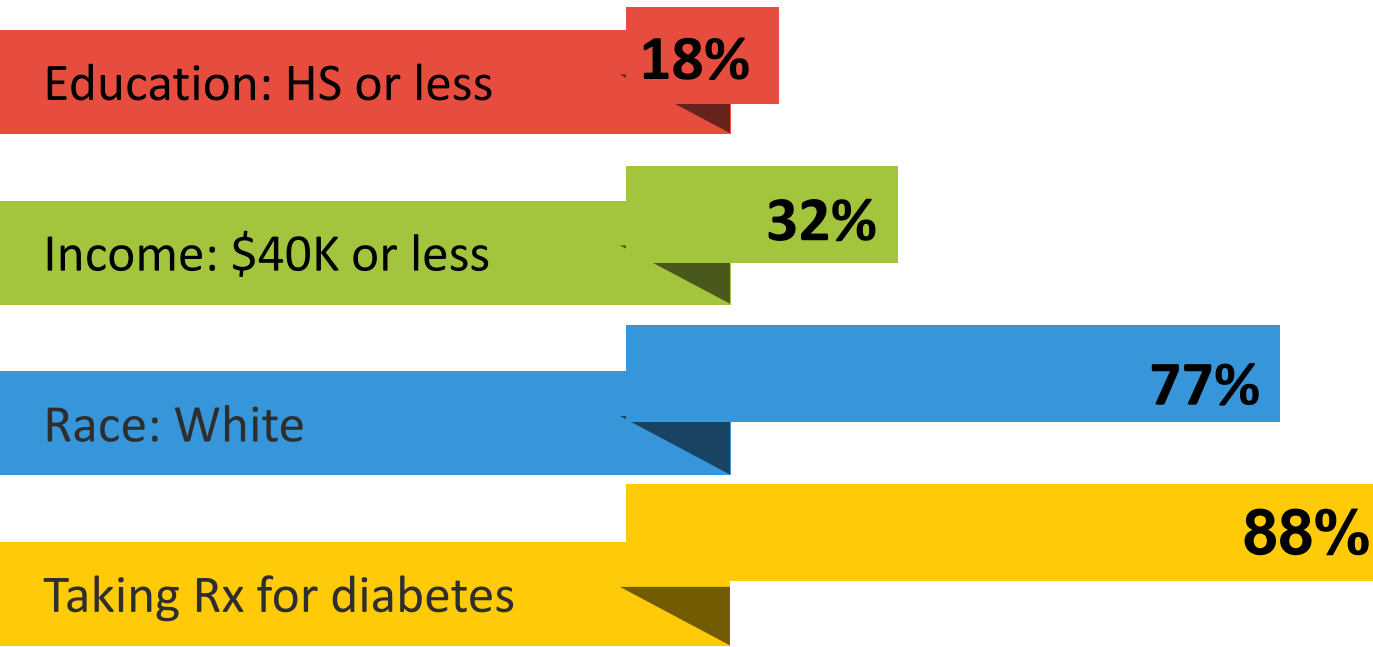
Interchangeability Inferences

Comparative Risk (4 items) and Comparative Efficacy (3 items)

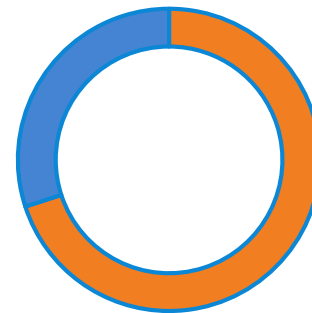
Main Study: Analysis Plan

- Two Samples Analyzed
 - Whole sample
 - Confirmed exposure subgroup
- Analysis
 - Descriptive statistics
 - Hypothesis testing
 - ANOVA, regressions and chi-square tests

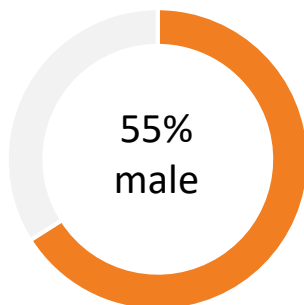
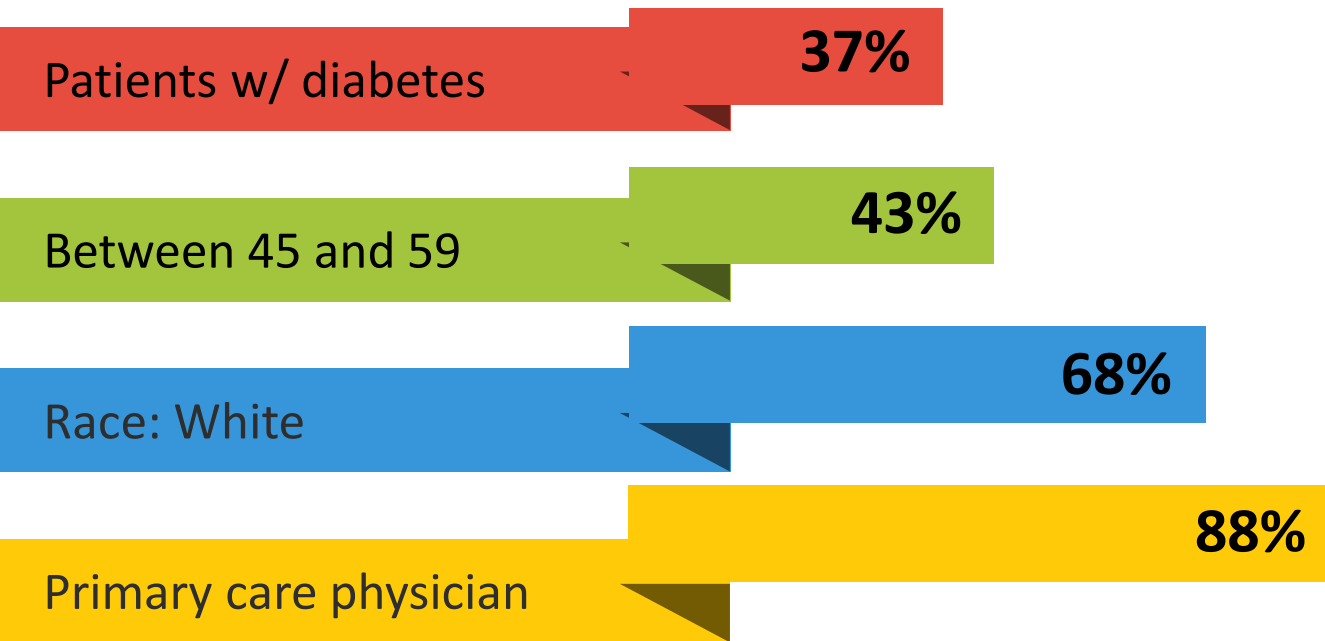
Consumer Characteristics



70%
60+

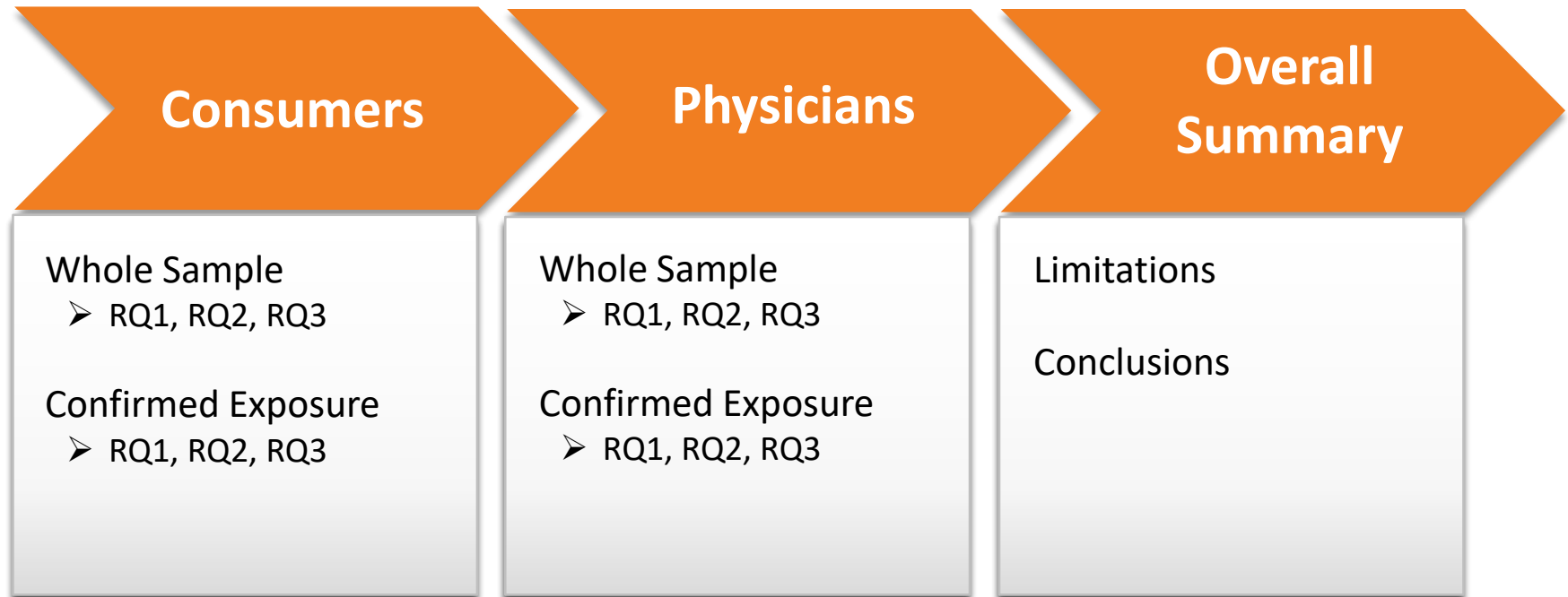


Physician Characteristics



Results Overview

Results grouped by research question





Consumer Results

Do Consumers Notice and Understand Price-Comparison and Context Information in Prescription Drug Ads?

You might be willing to pay a high price to treat your diabetes-related nerve pain—but why should you?

If you take Lyrica, switching to Veridan could save you up to \$560.00 a year.*

Veridan is a prescription medicine used for the treatment of diabetes-related nerve pain (neuropathy). Taken once a day, it works by interfering with chemical processes in the brain that cause you to feel pain, providing significant relief.



Verifiable relief.

The STING

If you use Lyrica, you are paying more than you should to treat your diabetes-related nerve pain.

The RELIEF

Veridan is an FDA-approved treatment for your diabetes-related nerve pain, and it can save you up to \$560.00 per year. Discuss Veridan with your doctor to see if it's right for you and how much the treatment cost you may save.

*The price savings presented may not be realized by consumers or third-party payers. The comparison may or may not be equally applicable to all patients.

Verifiable savings.

A majority of participants assigned to the context condition (59%) **did not** remember seeing this context statement.

Do Consumers Notice and Understand Price-Comparison and Context Information in Prescription Drug Ads?



Outcome	Findings
Perceived Importance: Price Statement Context Statement	<ul style="list-style-type: none">• Price statement: <i>NS</i>• Context statement: Higher in PC-only and PC-context conditions than control
Perceived Accuracy: Price Statement	<ul style="list-style-type: none">• Price statement: <i>NS</i>
Context Statement Comprehension (open ended)	<ul style="list-style-type: none">• 64% provided correct interpretation.• Of those, 39% mentioned all elements of the context statement

Does Adding Contextual Information Correct the Impression that the Products Are Interchangeable?

Outcome	Findings
Interchangeability Inferences (Aside from price, Veridan and Lyrica are interchangeable)	<i>NS</i>
Intended Uncertainty about Risks and Efficacy (Ad contained insufficient information to know whether Veridan and Lyrica are interchangeable)	<i>NS</i>
Comparative Risk (4 items)	<i>NS</i>
Comparative Efficacy (3 items)	<i>NS</i>

What Is the Impact of Price-Comparison Information and Context Statements on Prescription Drug Perceptions in Prescription Drug Advertising?



Outcome	Findings
Benefit Recall	<ul style="list-style-type: none">Control participants recalled <i>fewer</i> benefits than PC-only and PC-context participants.
Benefit Recognition	<ul style="list-style-type: none">Control participants correctly recognized <i>more</i> real and bogus benefit claims than PC-only and PC-context participants.
Risk Recall	NS
Risk Recognition	NS
Risk Perceptions (4 items)	NS
Efficacy Perceptions (3 items)	NS
Intention	NS

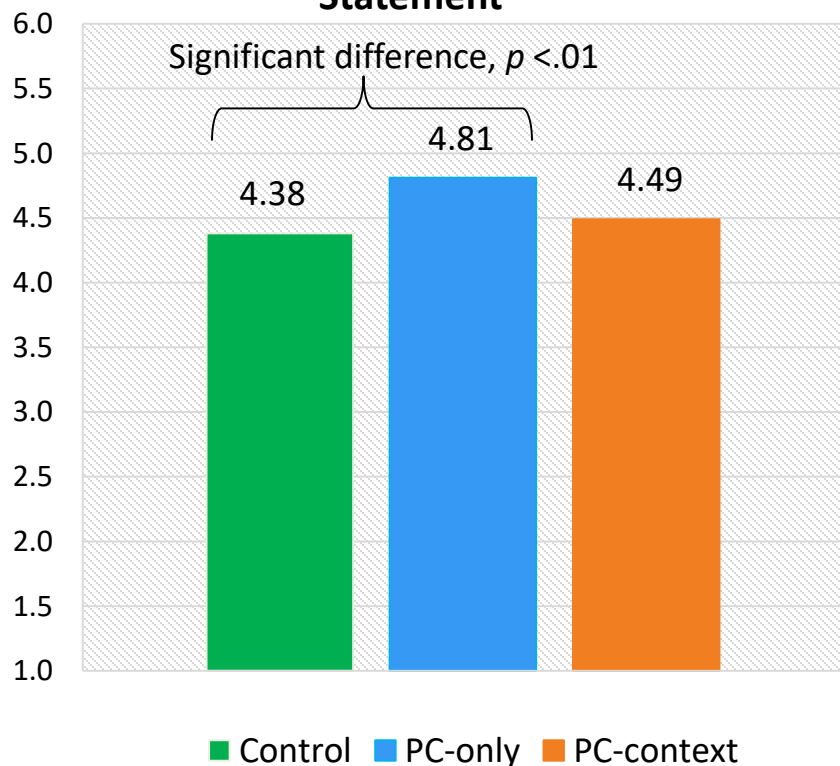
Consumer Confirmed Exposure Results

Do Consumers Notice and Understand Price-Comparison and Context Information in Prescription Drug Ads?

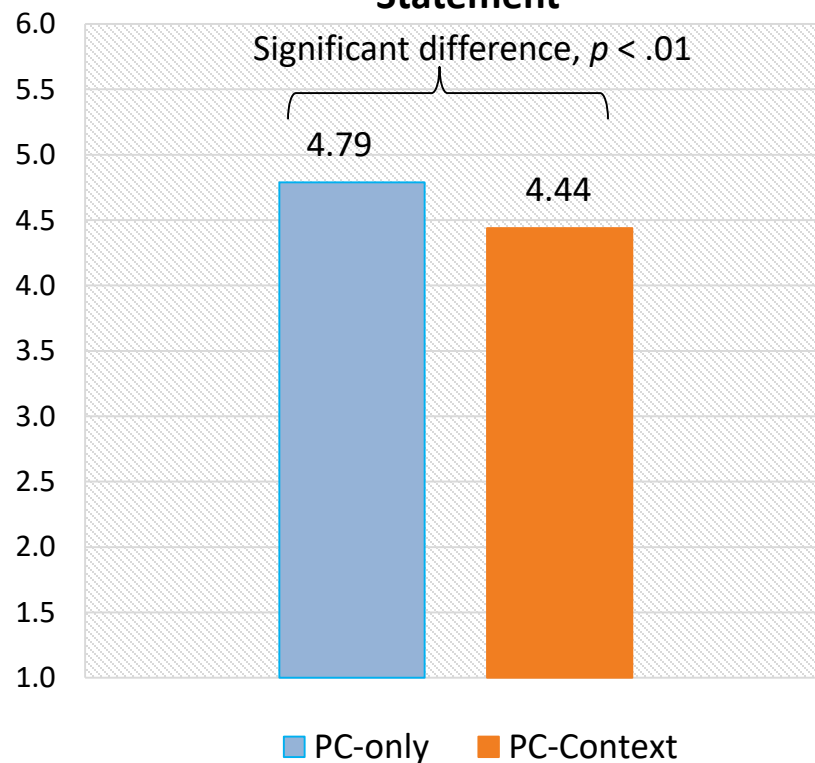


Context statement tempered accuracy and importance of price statement.

Perceived Importance of Price Statement



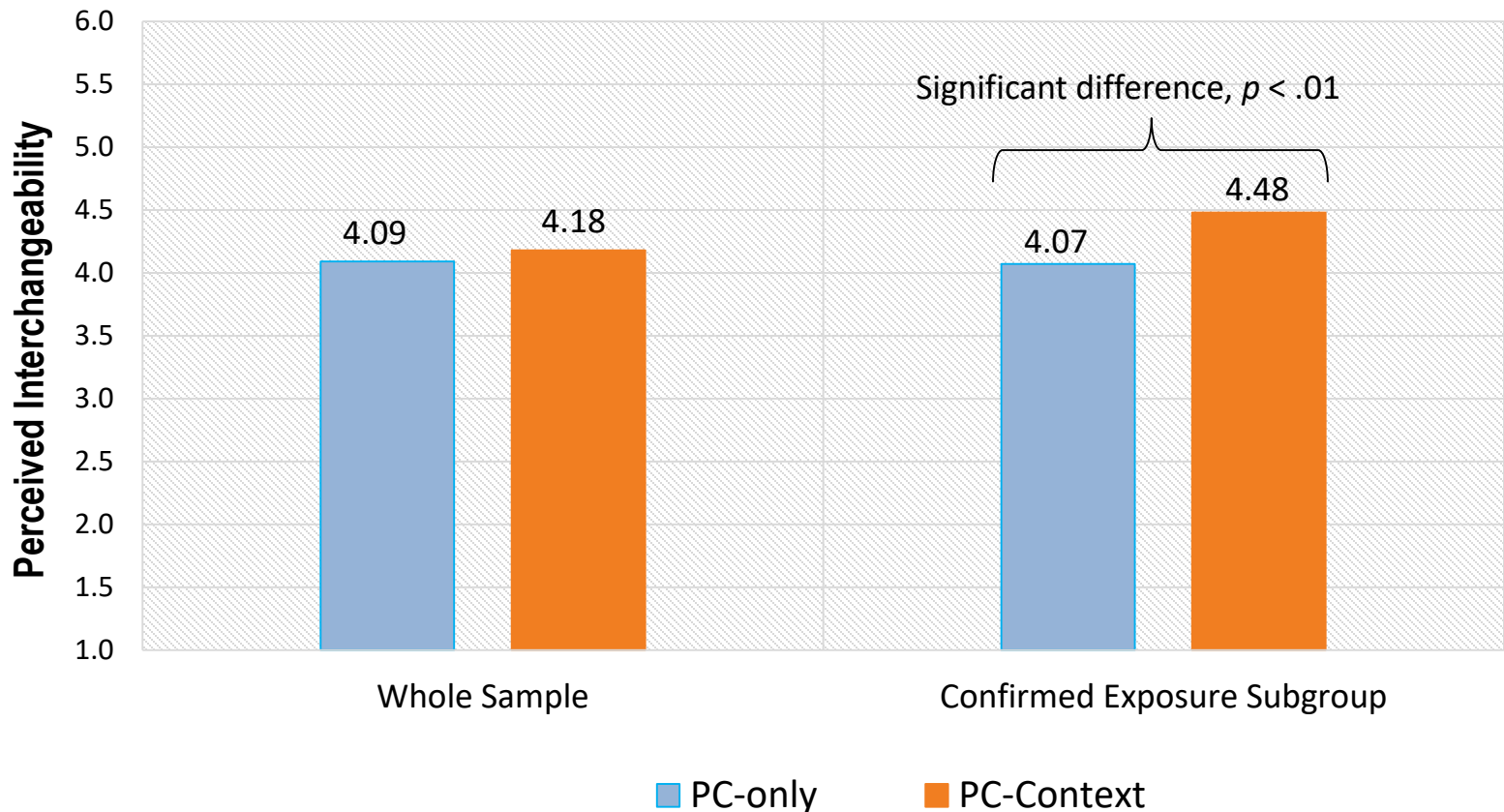
Perceived Accuracy of Price Statement



Intended Uncertainty about Risks and Efficacy



Consumers seeing context statement (compared to no context statement) were *more likely to agree* that there was insufficient information in the ad to know if Veridan and comparator were interchangeable.



Summary of Consumer Results

- Majority of consumers did not notice context statement.
- Effect of context statement on interchangeability perceptions was *NS* for whole sample, though some evidence of impact for confirmed exposure subgroup. Participants seeing price comparison more likely to mention cost savings as benefit than control.
 - Also more likely to say that bogus claim “Veridan works better than Lyrica” was in ad.

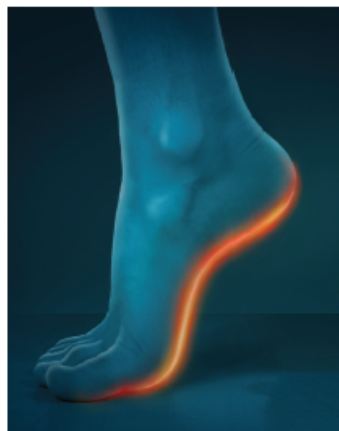


Physician Results

Do Physicians Notice and Understand Price-comparison and Context Information in Prescription Drug Ads?

The \$SMART Alternative for Treating Diabetic Peripheral Neuropathy

If you currently prescribe Lyrica to treat diabetic peripheral neuropathy, switching your patients to Veridan could save them up to \$560.00 a year.*



Verifiable relief.

Veridan is a prescription medicine used to treat diabetic peripheral neuropathy. Taken once a day, it works by interfering with chemical processes in the brain that cause sufferers to feel pain, providing significant relief.

The STING

If you prescribe Lyrica, your patients may be paying more than they should to treat their diabetic peripheral neuropathy.

The RELIEF

Veridan is an FDA-approved treatment for diabetic peripheral neuropathy, and it costs \$560.00 less per year. Treatment costs. Before you prescribe Lyrica, c

*The price savings presented may not reflect the savings realized by consumers or third-party payers. The product comparison are not known to have the same e

Verifiable savings.



*A majority of participants assigned to the context condition (55%) **did not** remember seeing this context statement.*

Do Physicians Notice and Understand Price-comparison and Context Information in Prescription Drug Ads?

Outcome	Findings
<p>Perceived Importance: Price Statement Context Statement</p>	<ul style="list-style-type: none"> • Price statement: <i>NS</i> • Context statement: Higher in PC-only and PC-context conditions than control
<p>Perceived Accuracy: Price Statement</p>	<ul style="list-style-type: none"> • Price statement: <i>NS</i>
<p>Context Statement Comprehension (open ended)</p>	<ul style="list-style-type: none"> • 79% provided correct interpretation. • Of those, 40% mentioned all elements of the context statement

Does Adding Contextual Information Correct the Impression that the Products Are Interchangeable?

Outcome	Findings
Interchangeability Inferences (Aside from price, Veridan and Lyrica are interchangeable)	<i>NS</i>
Intended Uncertainty about Risks and Efficacy (Ad contained insufficient information to know whether Veridan and Lyrica are interchangeable)	<i>NS</i>
Comparative Risk (4 items)	More PC-only participants than PC-context participants reported uncertainty
Comparative Efficacy (3 items)	More PC-only participants than PC-context participants reported uncertainty

What Is the Impact of Price-comparison Information and Context Statements on Prescription Drug Perceptions in Prescription Drug Advertising?



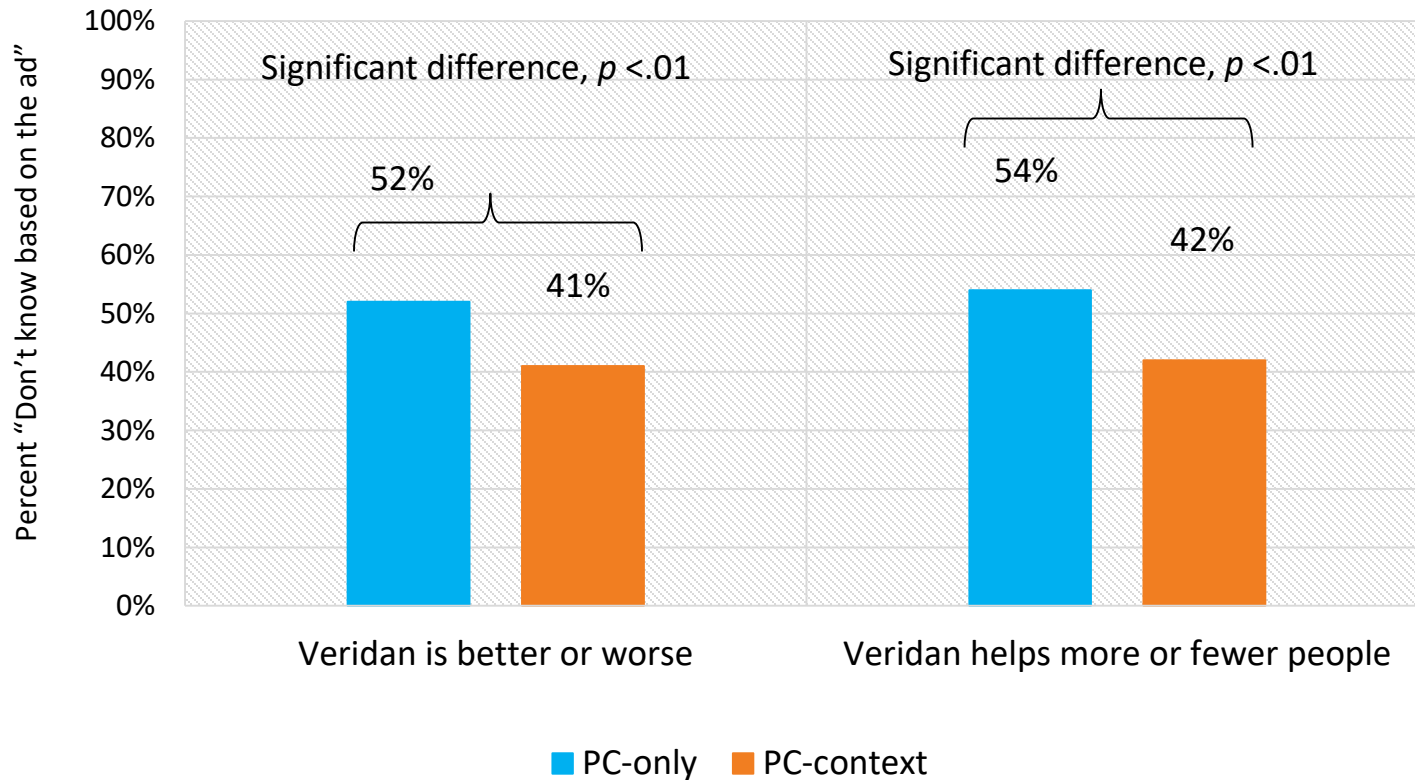
Outcome	Findings
Benefit Recall	<ul style="list-style-type: none">Control participants recalled significantly <i>fewer</i> benefits than participants in the PC-only condition, but not the PC-context condition.
Benefit Recognition	<ul style="list-style-type: none">NS
Risk Recall	<ul style="list-style-type: none">NS
Risk Recognition	<ul style="list-style-type: none">NS
Risk perceptions (4 items)	<ul style="list-style-type: none">PC-only participants reported <i>lower</i> perceived seriousness of side effects and overall severity of side effects than PC-context participants.
Efficacy perceptions (3 items)	<ul style="list-style-type: none">NS
Intention	<ul style="list-style-type: none">NS

Physician Confirmed Exposure Results

Physician Confirmed Exposure – Efficacy Uncertainty



% that **did not know** based on the ad whether Veridan is more or less efficacious than comparator



Summary of Physician Results



- Majority of physicians didn't notice context statement.
- Effect of context statement on interchangeability perceptions *NS*.
- Physicians seeing price comparison more likely to mention cost savings as a benefit than control.
- Context and uncertainty
 - More uncertainty regarding safety comparability in PC only group than PC-context group (counterintuitive)
 - Lower perceived likelihood and magnitude of Veridan's serious side effects (whole sample).
 - More uncertainty with comparative efficacy (confirmed exposure subgroup).

Discussion

- Despite prominence and placement, majority of consumers and physicians did not notice context statement.
- Context statement had limited effect on physicians' risk perceptions and did not have intended effect on uncertainty.
- When consumers *read and processed* the context statement, they demonstrated intended uncertainty about risks, efficacy, and savings.
- Although results support potential for developing comprehensible context statements to clarify price comparisons, consumer and physician attention may limit effectiveness.

Limitations

- Examined *short-term* ad effects.
- Single illness population.
- Sample excluded other health care professionals such as nurse practitioners and physician's assistants.
- Sampling limitations related to use of online panel.

Thank You!

- FDA Project Officers
 - Kathryn J. Aikin, PhD
 - Kevin R. Betts, PhD

- RTI International
 - Brian G. Southwell, PhD
 - Vanessa Boudewyns, PhD
 - Alex Stine, BS
 - Mihaela Johnson, PhD