



U.S. Food and Drug Administration

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FDLI's Conference on
Advertising and Promotion for the Pharmaceutical, Medical Device,
Biologics and Veterinary Medicine Industries

September 20-21, 2010
Washington, DC

DDMAC Research Update

Presented by

Helen Sullivan, Ph.D., M.P.H.

Division of Drug Marketing,
Advertising, and Communications

FDA



Research Team

Kathryn Aikin, Ph.D.

Amie O'Donoghue, Ph.D.

DDMAC, FDA

Jack Swasy, Ph.D.

Kogod School of Business,
American University

Clinical Efficacy Information in Professional Labeling and DTC Print Ads for Prescription Drugs

Clinical Efficacy Information Study

◆ Phase I

- ◆ Mental Models Research with physicians

◆ Phase II

- ◆ Consumer study

◆ Phase III

- ◆ Physician study

Phase I: Mental Models

Phase I: Mental Models

Research Questions

- ◆ How do physicians process and use clinical efficacy information?
- ◆ How do physicians make benefit-risk tradeoffs when making decisions about prescription drugs?
- ◆ How do physicians communicate with patients about drug effectiveness?

Phase I: Mental Models

Protocol

- ◆ Interviews with 44 physicians (general practitioners and rheumatologists)

Phase I: Mental Models

Two Representative Findings

- ◆ Defined drug effectiveness as the drug's ability to control the disease and relieve symptoms
- ◆ Thoughts about effectiveness differed for symptomatic vs. asymptomatic conditions:
 - Symptom relief, functionality and quality of life influence how the patient weighs benefits and risks.
 - Seeing, or not seeing, tangible benefits influences patient's compliance.

Phase II: Consumer Study

Phase II: Consumer Study

Research question:

Do consumers understand clinical efficacy information in print DTC ads?

Phase II: Consumer Study

Variables of interest:

- ◆ Type of Claim
- ◆ Placebo
- ◆ Framing

Phase II: Consumer Study

Type of Claim

- ◆ Treatment

 - i.e., reduces urinary frequency and urgency

- ◆ Prevention

 - i.e., reduces risk of bladder cancer

Claims differ on symptomatic/asymptomatic
and size of effect

Phase II: Consumer Study

Do people understand placebo?

- ◆ Will they be able to distinguish between high and low placebo rates,
- ◆ Or is it just a peripheral cue (more numbers = more scientific)?

Experience benefit with treatment	Experience benefit without treatment (high)	Experience benefit without treatment (low)
30 out of 100	20 out of 100	5 out of 100

Phase II: Consumer Study

Framing

◆ Single, Positive

- ◆ 30 out of 100 experienced a benefit on treatment

◆ Single, Negative

- ◆ 70 out of 100 did not experience a benefit on treatment

Phase II: Consumer Study

Framing

◆ Mixed

- ◆ 30 out of 100 experienced a benefit on treatment;
- ◆ 70 out of 100 did not experience a benefit on treatment

–commonly recommended, not well-studied

Phase II: Consumer Study

	Framing	
Placebo	Positive	Mixed
High	<ul style="list-style-type: none">•30/100 on treatment get benefit•20/100 with no treatment get benefit	<ul style="list-style-type: none">•30/100 on treatment get benefit; 70/100 do not•20/100 with no treatment get benefit; 80/100 do not
Low	<ul style="list-style-type: none">•30/100 on treatment get benefit•5/100 with no treatment get benefit	<ul style="list-style-type: none">•30/100 on treatment get benefit; 70/100 do not•5/100 with no treatment get benefit; 95/100 do not
None	<ul style="list-style-type: none">•30/100 on treatment get benefit	<ul style="list-style-type: none">•30/100 on treatment get benefit; 70/100 do not

Phase II: Consumer Study

Protocol

- ◆ Administered on Internet
- ◆ Each participant randomly assigned to view only one test ad

Phase II: Consumer Study

Study Sample

- ◆ Women diagnosed with/at risk for overactive bladder (OAB)
- ◆ Men diagnosed with/at risk for benign prostatic hyperplasia (BPH)

Phase II: Consumer Study

Key Dependent Variables

- ◆ Perceived efficacy
- ◆ Specific benefit accuracy
- ◆ Behavioral intention

Phase III: Physician Study

Phase III: Physician Study

Research questions:

How does consumer understanding (Phase II) correspond to physicians' assessments of the same drugs from the label?

How do physicians use prescription drug labels (prescribing information)?

Phase III: Physician Study

- ◆ Shown highlights section of the prescribing information for a fictitious new drug, with hyperlinks to each section
- ◆ Asked to read through this prescribing information as if learning about new product
- ◆ Asked to read through again, focusing on efficacy

Phase III: Physician Study

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Imdicon safely and effectively. See full prescribing information for Imdicon.

IMDICON® (cholinamol) CAPSULES

Initial U.S. Approval: 2000

WARNING: LIFE-THREATENING HEMATOLOGICAL ADVERSE REACTIONS

See full prescribing information for complete boxed warning.

Monitor for hematological adverse reactions every 2 weeks for first 3 months of treatment (5.2). Discontinue Imdicon immediately if any of the following occur:

- Neutropenia/agranulocytosis (5.1)
- Thrombotic thrombocytopenic purpura (5.1)
- Aplastic anemia (5.1)

RECENT MAJOR CHANGES

Indications and Usage, Coronary Stenting (1.2) 2/200X
Dosage and Administration, Coronary Stenting (2.2) 2/200X

INDICATIONS AND USAGE

Imdicon is an adenosine diphosphate (ADP) antagonist platelet aggregation inhibitor indicated for:

- Reducing the risk of thrombotic stroke in patients who have experienced stroke precursors or who have had a completed thrombotic stroke (1.1)
- Reducing the incidence of subacute coronary stent thrombosis, when used with aspirin (1.2)

Important limitations:

- For stroke, Imdicon should be reserved for patients who are intolerant of or allergic to aspirin or who have failed aspirin therapy (1.1)

DOSAGE AND ADMINISTRATION

- Stroke: 50 mg once daily with food. (2.1)
- Coronary Stenting: 50 mg once daily with food, with antiplatelet doses of aspirin, for up to 30 days following stent implantation (2.2)

Discontinue in renally impaired patients if hemorrhagic or hematopoietic problems are encountered (2.3, 8.6, 12.3)

DOSAGE FORMS AND STRENGTHS

Capsules: 50 mg (3)

CONTRAINDICATIONS

- Hematopoietic disorders or a history of TTP or aplastic anemia (4)
- Hemostatic disorder or active bleeding (4)
- Severe hepatic impairment (4, 8.7)

WARNINGS AND PRECAUTIONS

- Neutropenia (2.4 % incidence; may occur suddenly; typically resolves within 1-2 weeks of discontinuation), thrombotic thrombocytopenic purpura (TTP), aplastic anemia, agranulocytosis, pancytopenia, leukemia, and thrombocytopenia can occur (5.1)
- Monitor for hematological adverse reactions every 2 weeks through the third month of treatment (5.2)

ADVERSE REACTIONS

Most common adverse reactions (incidence >2%) are diarrhea, nausea, dyspepsia, rash, gastrointestinal pain, neutropenia, and purpura (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact (manufacturer) at (phone # and Web address) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Anticoagulants: Discontinue prior to switching to Imdicon (5.3, 7.1)
- Phenytoin: Elevated phenytoin levels have been reported. Monitor levels. (7.2)

USE IN SPECIFIC POPULATIONS

- Hepatic impairment: Dose may need adjustment. Contraindicated in severe hepatic disease (4, 8.7, 12.3)
- Renal impairment: Dose may need adjustment (2.3, 8.6, 12.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 5/200X

Phase III: Physician Study

	Type of Claim	
	Treatment	Prevention
Overactive Bladder (OAB)	High Placebo	High Placebo
	Low Placebo	Low Placebo
Benign Prostatic Hyperplasia (BPH)	High Placebo	High Placebo
	Low Placebo	Low Placebo

Phase III: Physician Study

Protocol

- ◆ Administered on Internet
- ◆ Each participant randomly assigned to view only one label

Phase III: Physician Study

Study Sample

- ◆ General practitioners

Phase III: Physician Study

Key Dependent Variables

- ◆ Perceived efficacy
- ◆ Specific benefit accuracy

Phase III: Physician Study

Key Dependent Variables

- ◆ Perceived efficacy
- ◆ Specific benefit accuracy
- ◆ Sections read
- ◆ Time on each section
- ◆ Order of sections read

Clinical Efficacy Information Study

Timeline

◆ Phase I

- ◆ Completed

◆ Phases II & III

- ◆ 60-Day Federal Register notice closed;
submitting to OMB

Contact Information

◆ Helen.Sullivan@fda.hhs.gov

◆ DDMAC website:

[http://www.fda.gov/AboutFDA/CentersOffices/
CDER/ucm090142.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm)