**OCP Labeling Project**

**Alternative Presentations of Clinical Pharmacology in Approved Drug Labeling:**

**Effect on Comprehension, Memory, and Action**

**Test Instrument**

*[****Notes to reviewers in italics, within square brackets.]***

***[Instrument based on methods developed and tested in the Medical Cognition Lab at Duke.]***

**Brief Overview**

This study is offered by the FDA Center for Drug Evaluation and Research’s Office of Clinical Pharmacology in collaboration with the Medical Cognition Laboratory at Duke University. You will see some information about a prescription drug, then answer some questions about it. The drug is hypothetical, developed for this study, but the information is the same type provided in all FDA-approved labeling (“prescribing information”). The purpose of the study is to determine effective ways to display drug information in approved labeling.

**Drug-X: General Information**

You will see information about “Drug-X.” Your job is to read the information as you would in everyday practice. To get a quick overview of Drug-X, we’ll start with the Table of Contents and Highlights sections of the labeling. You will have \_\_\_ minutes to look at this information. If you finish before time is up, click “NEXT.”

**Drug-X: More Detailed Information**

Now you will see some more detailed information about Drug-X. Again, read this as you would in everyday practice. We will ask you some questions about it later. You will have \_\_\_ minutes to look at this information. If you finish before time is up, click “NEXT.”

**Questions**

Now you will see some questions about Drug-X, your experience in reading the information and your evaluation of it. Click the NEXT button to start the questions and when you finish each page.

**Reading about Drug-X**

You had some time to read the Table of Contents and Highlights sections of the labeling. Was it about: \_\_\_enough time \_\_\_too little \_\_\_too much

Later you had some time to read the more detailed information.

Was it about \_\_\_enough time \_\_\_too little \_\_\_too much

The more detailed information came from one section of the labeling. What section was it? If you are not sure, it is OK to guess. If you don’t know, enter a question mark (?).

Name of section: \_\_\_\_\_\_\_\_\_\_

Enter a number for each question below:

 --About what % of the detailed section did you read completely?\_\_\_\_

 --About what % did you just skim?\_\_\_

 --About what % did you not read at all?\_\_\_

**Your Evaluation**

Please answer all remaining questions for the detailed information you saw, the section on pharmacokinetics (PK).

Overall, how easy/hard was it to understand the information about PK?

 \_\_\_ver easy \_\_\_easy \_\_\_moderate \_\_\_hard \_\_\_very hard

Overall, how easy/hard would it be to remember this information?

 \_\_\_ver easy \_\_\_easy \_\_\_moderate \_\_\_hard \_\_\_very hard

How confident are you -- that you know enough to consider Drug-X as a possible treatment for patients, based on what you read (before you consult other parts of the labeling)?

 \_\_very confident \_\_confident \_\_somewhat confident \_\_unconfident \_\_very unconfident

**Drug-X: PK Content**

Now we will ask you questions about PK information you just read. Try to answer each question as quickly and accurately as you can. Base your answers on the information provided in this study. If you are not sure about an answer, it is all right to guess. If you have no idea, enter a question mark (?); don’t worry about this – if you don’t know, that just tells us that the information could be more clear. So just do the best that you can.

We do not expect you to answer all of the questions correctly. We just want to know how effective the labeling is and what “take-home” messages it emphasizes. So do not worry if you are uncertain or don’t know – just give your best guess.

**Labeling Sections**

The PK information is divided into major sections.

--About how many sections are there? You do NOT have to say what they are, just

 estimate about how many there are. If you are not sure, make your best guess – a

 ballpark number. Enter a number:\_\_\_\_

--What are the names of the major sections? If you are not sure, it is OK to guess. If you have

 no idea, enter “?” Put a comma after each section name. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

--Now you will see topic names, one at a time. For each, decide whether it was – or was not –

 a section in the PK information. If you think it was a major section in the labeling, click YES;

 if you think it was not, click NO. If you are not sure, make a guess anyway.

 \_\_\_elimination \_\_\_drug interactions

 \_\_\_distribution \_\_\_pharmacodynamics

 \_\_\_absorption \_\_\_contraindications

 [***Note: these items are presented in independent random order for each participant.]***

**General PK Information**

**Drugoxide exposure**

Given a single dose of Drug-X, what is the approximate drugoxide exposure:

--for Cmax (mcg/mL)

 \_\_\_1-2 \_\_\_2-3 \_\_\_3-4 \_\_\_5-6 \_\_\_6-7

--for AUC (mcg\*h/mL)

 \_\_\_0-25 \_\_\_26-50 \_\_\_51-75 \_\_\_76-100

Given steady state sampling, what is the approximate Drugoxide exposure:

--for Cmax (mcg/mL)

 \_\_\_1-2 \_\_\_2-3 \_\_\_3-4 \_\_\_5-6 \_\_\_6-7

--for AUC (mcg\*h/mL)

 \_\_\_0-25 \_\_\_26-50 \_\_\_51-75 \_\_\_76-100

**Dose Proportionality**

Steady-state drugoxide AUC increases proportionally with doses of about what amount over the recommended dosage?

 \_\_\_>25 mg \_\_\_>50 mg \_\_\_>75 mg \_\_\_>100 mg

**Absorption**

What is the general duration of Drug-X half-life? \_\_\_short \_\_\_medium \_\_\_long

What is the time to peak plasma concentrations after fasting at least 8 hours? \_\_\_\_\_

What is the general range for this value: \_\_\_narrow \_\_\_moderate \_\_\_wide

Which range for this value is correct? \_\_\_2-6 hours \_\_\_2-10 hours \_\_\_2-23 hours

How many metabolites does Drug-X have?

 \_\_\_1 \_\_\_2 \_\_\_3 \_\_\_4

What is the active metabolite? \_\_\_M-1 \_\_\_M-2 \_\_\_M-3

**Effect of Food**

What were the effects of a low-fat meal? Choose one in each row:

 \_\_\_It increased drugoxide AUC \_\_\_It decreased drugoxide AUC

 \_\_\_It increased metabolite M-3 \_\_\_It decreased metabolite M-3

What were the effects of a high-fat meal? Choose one in each row:

 \_\_\_It increased Drugoxide AUC \_\_\_It decreased Drugoxide AUC

 \_\_\_It increased metabolite M-3 \_\_\_It decreased metabolite M-3

**Distribution**

About what % of drugoxide and its metabolite exhibit plasma protein binding?

 \_\_\_60-69% \_\_\_70-79% \_\_\_80-89% \_\_\_90-99%

**Elimination**

About how long does it take to eliminate drugoxide?

 \_\_\_10 hours \_\_\_20 hours \_\_\_30 hours \_\_\_40 hours

Is the range in this value

 \_\_\_narrow \_\_\_moderate \_\_\_wide

About how long does it take to eliminate the metabolite?

 \_\_\_10 hours \_\_\_20 hours \_\_\_30 hours \_\_\_40 hours

Is the range in this value

 \_\_\_narrow \_\_\_moderate \_\_\_wide

What are the primary metabolic pathways for each?

 Oxidation: \_\_\_\_\_\_

 Conjugation:\_\_\_\_\_

What is the primary route of elimination? \_\_\_liver \_\_\_kidneys

**Excretion in feces**

About what percent is excreted in feces?

 \_\_\_0-25% \_\_\_26-50% \_\_\_51-75% \_\_\_76%-100%

About what percent is drugoxide?

 \_\_\_0-25% \_\_\_26-50% \_\_\_51-75% \_\_\_76%-100%

About want percent is metabolite?

 \_\_\_0-25% \_\_\_26-50% \_\_\_51-75% \_\_\_76%-100%

**Excretion in urine**

About what percent is excreted in urine?

 \_\_\_0-25% \_\_\_26-50% \_\_\_51-75% \_\_\_76%-100%

About what percent is glucuronides?

 \_\_\_0-25% \_\_\_26-50% \_\_\_51-75% \_\_\_76%-100%

**Terms**

Some abbreviations were used in the labeling. Please define each term below. If you are not sure about an exact definition, give a general idea of what it is about. If you don’t know, enter “?”

Cmax:\_\_\_\_\_\_\_\_\_

AUC:\_\_\_\_\_\_\_\_

CV:\_\_\_\_\_\_\_\_\_\_\_

Tmax: \_\_\_\_\_\_\_\_\_\_

**Patient Scenarios**

Assume that the following patients all have the indication approved for Drug-X. For each, consider whether Dtug-X would be appropriate.

Patient A is already taking [Drug Y].

Would you be concerned about prescribing Drug-X for this patient? \_\_Yes \_\_\_No

If OK, what dose is appropriate: \_\_\_recommended dose \_\_\_higher dose \_\_\_lower dose

Patient B likes [food].

Would you be concerned about prescribing Drug-X for this patient? \_\_\_Yes \_\_\_No

If OK, what dose is appropriate: \_\_\_recommended dose \_\_\_higher dose \_\_\_lower dose

.

**Evaluate Alternative Displays**

Now you will see different ways to show PK information. They have the same information that you saw in this study. For each display, take a look at how the information is shown. Then answer the questions below.

**Display-1**

How easy/hard is it to understand the information in this display?

 \_\_\_very easy \_\_\_easy \_\_\_moderate \_\_\_hard \_\_\_very hard

How well do you like this display?

 \_\_\_like very much \_\_\_like \_\_\_neutral \_\_\_dislike \_\_\_dislike very much

**Display-2**

How easy/hard is it to understand the information in this display?

 \_\_\_very easy \_\_\_easy \_\_\_moderate \_\_\_hard \_\_\_very hard

How well do you like this display?

 \_\_\_like very much \_\_\_like \_\_\_neutral \_\_\_dislike \_\_\_dislike very much

**Compare Displays**

Here are both displays, side by side. They contain the same information but differ in their overall format. Please take a look, then answer the questions below.

How well do you like the display on the left?

 \_\_\_like very much \_\_\_like \_\_\_neutral \_\_\_dislike \_\_\_dislike very much

How well do you like the display on the right?

 \_\_\_like very much \_\_\_like \_\_\_neutral \_\_\_dislike \_\_\_dislike very much

Which do you prefer? \_\_\_left \_\_\_right \_\_no preference

**Comments**

If you have any comments about the displays or study, please write them here: \_\_\_\_\_\_\_\_\_\_\_\_

**Submit**

Please click NEXT to submit your responses.

**Explanation**

Thank you for participating in this study. Here is a brief overview.

This study examines different ways to show information about prescription drugs. Do some formats help health professionals understand, remember, and use the information in a more efficient and accurate manner?

Today, you read just one of the formats we are studying. On an random basis, participants see this format or a different version. We will compare the results for these formats, to help make prescription drug labeling easier to understand, remember, and use.