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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: "GUIDANCE FOR INDUSTRY: LABELING OF COMBINED ORAL  
CONTRACEPTIVES" [Docket No. 2000D-1350]**

Dear Sir or Madam:

I appreciate the opportunity to provide comments on the FDA's (2<sup>nd</sup>) Draft Guidance for Industry on Oral Contraceptives [*Federal Register: March 5, 2004 (Volume 69, Number 44, pp 10457-10458)*] with regard to Section III: Patient Labeling.

To begin, I would like to say how very gratified my collaborators (Kay Armstrong and Beth Stearman) and I were to see how much shorter and simpler this second draft of the patient labeling is than the July 2000 version, and how dramatically simplified it is from what is currently in oral contraceptive (OC) pill packs. The re-organization, which places pill-taking instructions at the front, before instead of after of safety issues, will make those instructions easier to find.

We strongly recommend that the field tested labeling we submitted in February 2001 replace the (2<sup>nd</sup>) Draft Guidance document text, insofar as possible and re-ordered to put pill-taking instructions before safety issues, as mentioned above. However, we recognize that this total replacement may not be possible. If not possible, we suggest that the patient labeling in the (2<sup>nd</sup>) Draft Guidance document be modified as shown in Appendix 1 and formatted in the manner discussed in Appendix 2, Comments.

Following are the components of this Comments package:

*Appendix 1* is the FDA's (2<sup>nd</sup>) Draft Guidance with redlined suggested changes based on field testing in 2000-2001 of patient labeling originally submitted by Family Health International (McCann and Potter) in 1997.

*Appendix 2* contains additional comments and recommendations regarding the language and presentation of the information in the patient labeling.

**00D-1350**

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*Appendix 3* is the actual field tested draft patient labeling referred to in Appendix 2 and submitted to the FDA in February 2001. At that time, we recommended that this field tested version *replace* Section III. of the FDA's (1<sup>st</sup>) Draft Guidance document.

Regarding, most specifically, the instructions for what to do when pills are missed, we would like to point out that on April 14, 2004, the World Health Organization drafted revised instructions for missed pills, based in part on the instructions we developed in our field testing. We understand that Dr. Herbert Peterson may be sending WHO's draft revisions to you. Or you may contact Sarah Johnson at WHO for further information, at [johnsons@who.int](mailto:johnsons@who.int) . We believe that WHO's decision to simplify their instructions strongly supports adopting the field tested instructions contained in Appendix 3 of these Comments.

*Appendix 4* is an article on that field testing process that was published in the March/April 2004 issue of the *Journal of Obstetric, Gynecological and Neonatal Nursing* (Vol. 33:198-208) by the authors of the field tested labeling revisions and this submission. That article, "Improving patient educational literature: An Understandable Patient Package Insert for the Pill", reviews the literature on health literacy and OC use instructions, describes the methods we used in our own field testing of the PPI and the results of that field testing. (Note: The sections of the article most relevant to our Comments are in bold.)

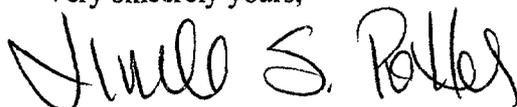
Finally, *Appendix 5* is the list of experts on oral contraceptives, health literacy and health education who reviewed drafts of the field tested version of the labeling for accuracy and presentation at least once during the course of the project.

The signatory author of these Comments on the FDA's (2<sup>nd</sup>) Draft Guidance for Industry is Dr. Linda Potter. Also contributing were Beth Stearman, Kay Armstrong and Margaret McCann.

Please contact Linda Potter at (609) 716-6365 or [lspotter@att.net](mailto:lspotter@att.net) if you have any questions regarding this submission.

We hope you will consider these comments and recommendations as you make your final decisions about the content of the revised Guidance. Thank you very much.

Very sincerely yours,



Linda S. Potter, Dr.P.H.  
Project Director  
President, Family Health Research

cc: Lesley-Anne Furlong, MD, Medical Officer, DRUDP/CDER/FDA  
Margaret Kober, DRUDP/CDER/FDA  
Dorothy Mann, Executive Director, Family Planning Council

**APPENDIX 1. FDA's DRAFT GUIDANCE TEXT, SECTION III. PATIENT LABELING,  
WITH RECOMMENDATIONS FOR MODIFICATIONS.**

[COMMENT 1: ALSO PLEASE SEE APPENDIX 2 AND 3  
APPENDIX 2. Comments for other suggested changes in format and wording.  
APPENDIX 3. Field tested version of Section III of draft Guidance.]

[COMMENT 2: We strongly replacing this version with the field tested version in Appendix 3, revising any text that reflects new evidence and adding the FDA's italicized text below. However, we believe that the modifications we have made (redlined) to the FDA's draft text below and those included in Appendix 2 would be sufficient if that is not possible.]

### **Guide for Using (*OC name*)**

#### **WARNING TO WOMEN WHO SMOKE**

Do not use (*OC name*) if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious side effects from birth control pills, including death from heart attack, blood clots, or stroke. The risk increases with age and the number of cigarettes you smoke.

Birth control pills help to lower the chances of becoming pregnant. They do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

#### **WHAT IS (*OC NAME*)?**

(*OC name*) is a birth control pill. It contains two hormones, an estrogen called (*name of estrogen*), and a progestin called (*name of progestin*).

#### **HOW WELL DOES (*OC NAME*) WORK?**

Your chance of getting pregnant depends on how well you follow the directions for taking your birth control pills. The more carefully you follow the directions, the less chance you have of getting pregnant.

In clinical studies, about (*insert whole number here*) out of 100 women got pregnant during the first year that they used (*insert OC name here*).

## Appendix 1, p2

The following table shows how the birth control pill compares with some other methods of birth control. The numbers are estimates of the number of women out of 100 women who become pregnant in 1 year of use.<sup>1</sup>

[COMMENT 3: The table on effectiveness rates combines use effectiveness rates for some methods with typical rates for others. It should include only typical rates or clearly differentiate between the two.]

### HOW DO I TAKE (OC NAME)?

*Consider the instructions given to women during clinical trials when crafting the text for this section. To minimize errors, all OC instructions should be similar, but some differences are inevitable because of the diversity of OCs.*

*To improve clarity, place the instructions for only one brand and regimen in the patient label for a given birth control pill. For example, package only 21-day pill instructions with 21-day pills, and only 28-day pill instructions with 28-day pills.*

*Insert illustration of pill pack, direction in which pills are taken, and other labeling that might make the directions clearer, such as which pills are active and which are inactive.*

*The sample answers below apply to an imaginary birth control pill named Brand X, a 28-day pack with 21 active pills. In the Brand X clinical trials, women were told to start the first pack on day 1 of their menstrual periods. Brand X instructions do not include Sunday Start instructions because Sunday Start was not studied in the clinical trials.*

~~If you have regular periods, take the first pill of the first pack on the first day of your period. If you are not having regular periods, talk with your health care provider about when to start your birth control pill.~~

**[COMMENT 4: WE suggest replacing this section with the “Quick Start” method as follows]**

Decide with your doctor or clinic staff when to start your first pack of Pills.

- You can begin taking the Pill any time but it is usually easier to pick a specific day. For example, the first Sunday after your period starts or the first day of your menstrual period.
- Use condoms until you have taken (color) active pills for 7 days in a row unless you start on the first day of your period.
- If you’ve had a miscarriage or an abortion, talk to your doctor or clinic staff about when you can start taking the Pill.

Take one pill about the same time every day. ~~Faking a pill every day must become a habit.~~

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<sup>1</sup> The estimates for drugs and devices come from clinical trial data reviewed by the Food and Drug Administration. The IUDs include the levonorgestrel IUD and the copper IUD. The estimates for sterilization and spermicides come from the medical literature.

## Appendix 1, p3

When you finish a pill pack, start the next pack on the following day so you are always taking one pill a day, whether or not you are having your period. You are more likely to get pregnant if you start the next pack late or miss any pills.

Look at the picture of your pill pack. There are 21 active (*insert color here*) pills that ~~contain~~ have hormones and 7 inactive (*insert color here*) “reminder” pills that do not ~~contain~~ have hormones. You are most likely to have your period during the time you are taking the ~~inactive~~ reminder pills.

### WHAT SHOULD I DO IF I MISS ANY BIRTH CONTROL PILLS?

*As noted in the preceding question, consider the instructions given to women during clinical trials when crafting the text for this section. Below is the redlined FDA text followed by the text field tested by the Family Planning Council.*

**[COMMENT 5: We strongly recommend replacing the instructions for pill-taking contained in the draft Guidance with the following field tested version.]**

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#### What should I do if I miss any Pills?

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If you miss one of the [color(s)] active pills:

- Take the missed pill as soon as you remember.
- Take the next pill at the regular time. This means you may take two pills in one day.
- Keep taking one pill each day, as usual.
- You do not need to use condoms to prevent pregnancy if you miss just one pill.

If you miss two or more of the [color(s)] active pills in a row, or if you start your next pill pack two or more days late:

- Take one pill now.
- Don't try to make up the other [color(s)] pills you missed. Throw them out.
- Keep taking one [color(s)] active Pill every day until they are gone
- Use condoms or do not have sex until you have been back on the [color(s)] active pills for 7 days in a row.
- Go straight to the next pack after you finish the [color] active pills. You do not need to take the 7 [color] reminder pills.

If you missed two or more [color(s)] of the active pills, and then had sex without using condoms in the next 7 days:

- Call your doctor or clinic as soon as possible.
- They can prescribe Emergency Contraceptive Pills (ECPs), sometimes called “EC” or “Morning After Pills”.

## Appendix 1, p4

If you forget to take any of the 7 [color] reminder pills:

- Throw out the [color] reminder pills that you missed.
- Keep taking one [color] reminder pill every day until it is time to start a new pill pack.
- You do not need to use condoms to prevent pregnancy if you missed only the reminder pills.

## WHO SHOULD NOT TAKE (OC NAME)?

Birth control pills are safe for most women. ~~However,~~ But taking birth control pills can cause serious health problems, especially for women with certain conditions.

### [COMMENT 6: We suggest dividing this list as follows]

Do not take (*name of OC*) if you have ever had:

- Breast cancer or any cancer that is sensitive to hormones
- Blood clots in your arms, legs, or lungs
- A stroke
- A heart attack or chest pains

Do not take (*name of OC*) if you now have:

- Liver disease, including liver tumors
- Unexplained bleeding from your vagina
- Certain heart problems ~~valve problems or heart rhythm abnormalities that can cause blood clots to form in the heart~~
- An inherited problem ~~with your blood that makes it your blood~~ clot more than normal
- High blood pressure that medicine can't control
- Diabetes with kidney, eye, or blood vessel damage
- Severe migraine headaches

Also, do not take birth control pills if you:

- Smoke and are over 35 years old
- Know you ~~Are~~ pregnant
- Are allergic to anything in (*OC*) (COMMENT: Add examples?)

*If applicable, the following statement is inserted here: The risks for serious blood clots may be greater with desogestrel-containing pills such as (name of OC) than with certain other birth control pills.*

If you have ever had jaundice ~~(yellowing of the skin or eyes)~~ birth control pills may not be a good choice for you. ~~caused by pregnancy, also called cholestasis of pregnancy.~~

## Appendix 1, p5

### WHAT ELSE SHOULD I KNOW ABOUT TAKING (OC NAME)?

Do not skip any pills, even if you do not have sex often.

If you miss a period, you could be pregnant. However, some women miss periods or have light periods while they are on birth control pills, even when they are not pregnant. Contact your ~~health-care provider~~doctor or clinic for advice if you:

- Think you are pregnant
- Miss 1 period and have not taken your birth control pills according to directions
- Miss 2 periods

Birth control pills should not be taken during pregnancy. However, birth control pills taken by accident during pregnancy do not seem to cause birth defects. *If the OC contains a new progestin or estrogen, note that fact and summarize what is known about pregnancy risk here. If any component of the drug product is associated with birth defects, add a statement about the types of defects, estimated frequency, the associated doses, and the gestational age of exposure, if known.*

~~You should consider another birth control method if~~ if you are breast-feeding, consider using another method because birth control pills may decrease the amount and quality of your milk. A small amount of the pill's hormones are passed on to your baby in your milk.

**[COMMENT 7: Move to end of list.]** If you need laboratory tests, tell your ~~health-care provider~~doctor or clinic that you are taking birth control pills. Birth control pills may affect some blood tests.

Tell your ~~health-care provider~~doctor or clinic about all medicines and herbal products that you take. Some medicines and herbal products may make birth control pills less effective. Some examples are rifampin, medicines used for epilepsy (such as barbiturates, topiramate, carbamazepine, and phenytoin), phenylbutazone, certain medicines used to treat HIV or AIDS, certain antibiotics, and the herbal product St. John's Wort. Consider using another birth control method when you take medicines that may make birth control pills less effective.

If you have vomiting or diarrhea, your birth control pills may not work as well. Use another birth control method, like condoms, until you check with your ~~health-care provider~~doctor or clinic.

## Appendix 1, p6

### WHAT ARE COMMON SIDE EFFECTS OF BIRTH CONTROL PILLS?

The most common side effects of birth control pills are:

- Nausea
- Breast tenderness
- Headache
- Bleeding between menstrual periods

These side effects are usually mild and may disappear with time.

Less common side effects are:

- ~~Bloating~~ Swelling or fluid retention.
- Darkening of the skin, especially on the face. ~~This problem may be related to the darkening of the skin that sometimes happens during pregnancy.~~
- High blood sugar, especially in women who already have diabetes.
- High triglycerides (high fat levels in the blood).
- Depression, especially if you have had depression in the past. ~~Call your health care provider immediately if you have any thoughts of harming yourself.~~
- ~~Weight changes.~~ Gaining or losing weight.

This is not a complete list of possible side effects. Talk to your ~~health care provider~~ doctor or clinic if you develop any side effects that concern you.

No serious problems have been reported from a birth control pill overdose, even when they have been taken accidentally ~~taken by children.~~

### WHAT ARE THE MOST SERIOUS RISKS OF TAKING BIRTH CONTROL PILLS?

Like pregnancy, birth control pills increase the ~~risk~~ change of getting of serious blood clots. These blood clots can occur in the legs (thrombophlebitis), lungs (pulmonary embolus), eyes (blindness), heart (heart attack), brain (stroke).

**[COMMENT 8: Place all of these in a single paragraph so not unduly alarming.]**

It is possible to die from a problem caused by a blood clot, such as a heart attack or a stroke.

A few women who take birth control pills may get:

- ☐ ~~Rare cancerous or noncancerous liver tumors~~ Liver problems
- Gallbladder problems
- High blood pressure [Make this the first of the three listed since most common.]

## Appendix 1, p7

Call your ~~health care provider~~doctor or clinic right away if you have:

- ~~Persistent~~ Pain in the calf (lower leg) that does not go away.
- Sudden shortness of breath
- Sudden blindness or trouble seeing, ~~partial or complete~~
- Severe pain in your chest
- Sudden, severe headache
- Weakness or numbness in an arm or leg, or trouble speaking
- Yellowing of the skin or eyeballs

### DO BIRTH CONTROL PILLS CAUSE CANCER?

Birth control pills do not seem to cause breast cancer. However, if you have breast cancer now, or have had it in the past, do not use birth control pills because some breast cancers are sensitive to hormones.

Women who use birth control pills may have a slightly higher chance of getting cervical cancer. However, this may be due to other reasons such as having more sexual partners.

### WHAT IF I WANT TO BECOME PREGNANT?

Consider a visit with your ~~health care provider~~doctor or clinic for a ~~pre-pregnancy~~ checkup before you stop taking the pill. Your ~~health care provider~~doctor or clinic may advise you to wait for your first regular period before you try to become pregnant. A daily dose of the vitamin called folic acid is recommended for all women who are planning a pregnancy (ADD:) to prevent birth defects.

### ARE THERE OTHER ~~BENEFITS~~ ADVANTAGES OF THE BIRTH CONTROL PILL?

[COMMENT 9: We suggest moving this section up to follow “How well does the pill work?”]

[COMMENT 10: We also suggest using the more complete list of advantages listed in Appendix 3.]

Your periods may be more comfortable:

- they may be more regular
- they may be shorter
- you may have less bleeding
- you may have less cramps or pain.

## Appendix 1, p8

### There is less chance of having:

- a pregnancy outside of the uterus/womb (ectopic pregnancy)
- a lump in the ovary (ovarian cyst)
- not enough iron in the blood (anemia).

### While you are on the pill and for many years after you stop taking it, there is less chance of getting :

- cancer in the ovaries (ovarian cancer)
- lumps in the breast that are not cancer (benign breast tumors)
- cancer of the uterus (endometrial cancer).

### ALSO...

- taking the Pill keeps bones strong (helps prevent osteoporosis).
- taking the Pill may help prevent pimples (acne).

### GENERAL ADVICE ABOUT *(OC NAME)*

Your ~~health care provider~~ doctor or clinic prescribed *(OC name)* for you. Please do not share *(OC name)* with anyone else. Keep *(OC name)* out of the reach of children.

Birth control pills are sometimes prescribed for reasons other than those listed in your Guide. If you have concerns or questions, ask your ~~health care provider~~ doctor or clinic. You may also ask your ~~health care provider~~ doctor or clinic for a more detailed label written for medical professionals.

*List the name and place of business of the manufacturer, packer, or distributor of OC here.*

*Write the date of the most recent revision of the Guide here.*

## **APPENDIX 2. ADDITIONAL COMMENTS ON PRESENTATION AND CONTENT**

The following comments are organized according to the sections of the field tested labeling proposed by the authors in February 2001 and contained in *Appendix 3*.

### **1. Format**

The following comments on format are written in the format we recommend be used by manufacturers in their Patient Labeling. This kind of format has been documented repeatedly to be the easiest to read and understand and the numbering makes specific information easier to find.

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### **1. Comments**

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#### **1.1 Format**

- Place headings in boxes, numbered and in bold.
  - Number each major sub-heading as a sub-set of heading number to make it easy to find a specific piece of information.
  - Use bullets for lists of items under sub-headings.
  - Use bold for all numbered headings and sub-headings.
  - Use serif or sans serif typeface for all headings and subheadings.
  - Use serif type, not in bold, for bullets.
  - Use upper/lower case throughout.
  - *At minimum*, use 10pt. font.
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### **2. Wording**

- We found in field testing that many of the respondents did not know what is a “health care provider.” We strongly suggest changing “health care provider” to “doctor or clinic” throughout—for the patients’ benefit. [See *Appendix 4* for rationale for these changes—Ross *et al* article, paras.3-4 of Results, p.202, which discusses respondents’ preferences as elicited during field testing.]
- Please change “birth control pill” to “the pill” or “the Pill” except where essential, beginning with the section on “Who should not take...” since readers know that the Pill is for birth control.

## Appendix 2, p2

### 3. Content

The following items are numbered according to the field tested patient labeling text in *Appendix 3*, as submitted to the FDA in February 2001. Again, these comments do not deal with the scientific basis of the content but only the text itself.

- Section 4. What are some advantages to taking the Pill?  
This section of the labeling we submitted in February 2001 lists many more advantages (benefits) to using the pill than are included in the 2004 FDA proposed guidance. We hope you will add these.
- Section 5. Who should not take the Pill?  
The format submitted in February 2001 was found in field testing to be more user-friendly.
- Section 11. What should I do if I miss any pills?  
The content, format and wording of this section are as field tested and submitted in February 2001. They are brief, clear and easy to understand. Most importantly, they differentiate only between one and two or more missed pills and require back-up protection only when two or more pills are missed.

The simplified instructions included in the text of *Appendix 3 (Field tested text for Guidance document)* not only increase the protection provided by oral contraceptives but make the instructions easier to understand and use than differentiating between 1, 2 and 3 or more missed pills. See Appendix 3 for the authors' article on field testing process and outcomes. [Ross, Beth Stearman, Linda S. Potter, and Kay A. Armstrong. Improving patient educational literature: an understandable patient package insert for "the Pill." *J Obstet Gynecol Nurs* 33:198-208; 2004.]

On April 14, 2004, WHO drafted very similar instructions for pill-taking, based in large part on the content and wording of these recommendations. Please contact Sarah Johnson at WHO if you would like a copy of WHO's draft missed pill instructions ([johnsons@who.int](mailto:johnsons@who.int))

We suggest adding "to prevent pregnancy" after "Use condoms..." because many women should still use condoms for STI prevention.

- Section 12. "Important Reminders"  
These "Important Reminders" are especially useful for quick reference and include important information on Emergency Contraception.
- Section 13. Emergency Contraceptive Pills.  
[Could be deleted, per FDA, if the following information is included in Section 12 or elsewhere: If you have unprotected sex for any reason, including broken condoms or missed pills, call your doctor or clinic as soon as possible about getting Emergency Contraceptive Pills ("EC" or "Morning After Pills").

**Appendix 2, p3**

- Section 14. What if I miss my monthly period?  
Most important is 14.2, which could be added to Section 12. Important Reminders.
  
- Section 15. What if I want to stop taking the pill or change to another kind of birth control? Not included in FDA Guidance. Stopping one method without immediately beginning another is one of the leading causes of pregnancy (see Appendix 3 article.) Might possibly state: “If you want to stop taking the pill or change to another kind of birth control, inform your doctor or clinic about your plans and continue taking the pills until you finish the complete pack.”

**APPENDIX 3. Original field tested Patient Labeling as submitted to the FDA in February 2001.**

**Information for the Patient**  
(for Combined Oral Contraceptives)

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**1. About Birth Control Pills (“the Pill”)**

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- This pamphlet is about the “combined” birth control pills (“the Pill”). The combined Pill has two hormones to prevent pregnancy—estrogen and progestin.
- This pamphlet has important information about [NAME] and how to take the Pill safely and effectively.
- Please read all of this pamphlet before you start taking your first pack of Pills. Check it again any time you have a question.
- **Talk to your doctor or clinic staff:**
  - if you have any questions about anything this pamphlet says.
  - if you are worried about taking the Pill for any reason.

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**2. How does the Pill work?**

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**The Pill can prevent pregnancy in 3 ways:**

1. The Pill keeps the egg (ovum) from leaving the ovary (ovulation).
2. It can make it hard for the sperm to get to the egg (fertilization).
3. The Pill can make it harder for the egg to attach to the uterus/womb (implantation).

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**3. How well does the Pill work?**

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**3.1 The Pill prevents pregnancy best:**

- if you never miss a pill
- if you miss 2 or more [color(s)] active Pills in a row, use condoms until you’ve been back on the [color(s)] Pills for 7 days in a row.

**3.2 If you take one birth control pill every day, it prevents pregnancy very well.**

Less than 1 out of every 1000 women (less than 0.1%) who take the Pill every day will get pregnant in their first year on the Pill.

3.3 Your chance of getting pregnant goes up every time you miss more than one pill.

3.4 This list shows how well different methods prevent pregnancy, in typical use. The only birth control methods that work better than the Pill are Norplant, the IUD, Depo-Provera (“the shot”) and Lunelle (“the 1-month shot”).

<i>Works best</i>	<i>Method</i>	<i>Chance of getting pregnant in the first year of use</i>
↓          ↓	Norplant	1%
	IUD	1%
	Depo-Provera (“the shot”)	1%
	Lunelle (the 1-month shot”)	*
	<b>“The Pill”</b>	<b>5%</b>
	Male Condom	14%
	Diaphragm	20%
	Female Condom	21%
	Not having sex for long periods of time (periodic abstinence)	25%
	Not having sex at certain times of the month (“calendar method” or natural family planning)	25%
<i>Works Least</i>	Not using any kind of birth control	85%

*Adapted from Contraceptive Technology, 1998*

\* How well Lunelle works in typical use is not yet known.

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#### **4. What are some advantages of taking the Pill?**

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4.1 Your periods may be more comfortable:

- they may be more regular
- they may be shorter
- you may have less bleeding
- you may have less cramps or pain.

4.2 There is less chance of having:

- a pregnancy outside of the uterus/womb (ectopic pregnancy)
- a lump in the ovary (ovarian cyst)
- not enough iron in the blood (anemia).

4.3 While you are on the Pill and for many years after you stop taking it, there is less chance of getting :

- cancer in the ovaries (ovarian cancer)
- lumps in the breast that are not cancer (benign breast tumors)
- cancer of the uterus (endometrial cancer).

#### 4.4 **ALSO...**

- taking the Pill keeps bones strong (helps prevent osteoporosis).
- taking the Pill may help prevent pimples (acne).

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### **5. Who should not take the Pill?**

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**The Pill is very safe. But if you have any of the medical problems listed below, it is very important to talk to your doctor or clinic staff.**

#### 5.1 **You should not take the Pill if you:**

- are more than 35 years old *and* you smoke
- are already pregnant or you think you might be pregnant
- have just had major surgery that keeps you in bed for a long time
- are allergic to anything in the Pills.

#### 5.2 **You should not take the Pill if you now have:**

- very high blood pressure (severe, uncontrolled hypertension)
- breast cancer
- very high blood sugar (severe diabetes) if the blood vessels are not normal
- any kind of liver disease.

#### 5.3 **You should not take the Pill if you've ever had:**

- very bad headaches that also make it hard for you to see clearly
- a heart attack or a stroke
- blood clots in your lungs (pulmonary embolism)
- blood clots in your eyes or your legs (thrombosis)
- breast cancer.

#### 5.4 **If your doctor or clinic staff thinks the following problems are not too serious, it is still safe to take the Pill if you have:**

- high blood pressure (hypertension) and you take medicine for it
- high blood sugar (diabetes) if your blood vessels are normal
- bad headaches (such as migraines) if they don't change your vision
- bleeding from your vagina that is not your menstrual period.

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### **6. Can the Pill cause medical problems?**

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Most healthy women do not get medical problems because they take the Pill. However, there is a small chance that the Pill can increase the chance of having:

- 6.1 **Heart attack or stroke [only] if you also have:**
- very high blood pressure (severe hypertension)
  - high cholesterol
  - high blood sugar (diabetes).
  - These problems only last as long as you are on the Pill.
  - Most important: If you smoke and you are over 35 years old, you are much more likely to have a heart attack or a stroke.
- 6.2 **Blood clots in the veins**
- 6.3 **Breast cancer**
- The chance getting breast cancer is low but the chance of finding it is a little higher while on the Pill.
  - Any effect the Pill might have on breast cancer goes down after stopping the Pill.
- 6.4 **Cancer of the cervix**
- Cervical cancer is very rare. It is not known yet whether the Pill has any effect on cancer of the cervix (the opening to the uterus).
- 6.5 **Gall bladder disease**
- If you already have gall bladder disease, the Pill could make the problem worse.
- 6.6 **Liver cancer**
- The Pill can increase the chance of getting liver cancer. Liver cancer is very rare.

\*\*\*\*\***WARNING SIGNS**\*\*\*\*\*

Call your doctor or clinic as soon as possible if you get:

- a very bad headache that also makes it hard for you to see clearly
- a very bad pain in your chest, your stomach (abdomen) or your legs.

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## 7. What side effects can I get from the Pill?

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- 7.1 **You may get one or more side effects while taking the Pill.**
- These side effects are almost never dangerous, but if they worry you, check with your doctor or clinic.
  - Keep taking the Pill until you can talk to your doctor or clinic staff.

## 7.2 **Bleeding Side Effects**

- You may have some spotting or light bleeding between periods, especially after you miss any Pills.

## 7.3 **Other Side Effects**

It is not always clear whether the Pill causes these side effects. Many of them go away in the first 3 months.

- The most common side effects are:
  - nausea or upset stomach
  - headaches
  - tender or sore breasts.
- Less common side effects are:
  - vomiting
  - mood changes
  - weight gain
  - less interest in sex
  - dizziness
  - brown spots on the face (melasma)
  - vaginal yeast infection
  - swelling (fluid retention)
  - dry eyes.

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## **8. Can I take the Pill with other medicines?**

---

### 8.1 **If you are taking other medicines, tell your doctor or clinic staff.**

- Taking antibiotics while on the Pill does not make it easier to get pregnant.
- A few medicines can make the Pill less effective, especially certain medicines for seizures (epilepsy), and tuberculosis (TB).
- Any time you get a prescription from another doctor's office or clinic, tell them that you are taking the Pill. The Pill can make some medicines less effective.

### 8.2 **If you have lab tests for any reason, be sure to say that you are taking birth control pills.** The hormones in the Pill can change the results of some lab tests.

---

## **9. STDs (Sexually Transmitted Diseases)**

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### 9.1 **The birth control pill does not protect against HIV (the virus that causes AIDS) or any other STD.**

### 9.2 **Use a condom every time you have sex if there is any chance you could get HIV (the AIDS virus) or any other STD.**

---

## 10. What should I do when I start taking “the Pill”?

---

[DELETE 10.1 Check your Pill pack. Is it a 28-day pack or a 21-day pack of Pills?]

10.2 Check this picture of the Pill pack to see:

- which Pill to take first
- what direction to take the Pills in
- the week numbers and Pill colors.

*[MANUFACTURER: INSERT PILL PACK PICTURE HERE]*

10.3 Decide with your doctor or clinic staff when to start your first pack of Pills.

- You can begin taking the Pill any time but it is usually easier to pick a specific day. For example:
  - the first Sunday after your period starts
  - or the first day of your menstrual period.
- Use condoms until you have taken [color(s)] active Pills for 7 days in a row unless you start on the first day of your period.

10.4 If you’ve had a miscarriage or an abortion, talk to your doctor or clinic staff about when you can start taking the Pill.

10.5 Take one Pill every day until the pack is empty.

- Take that Pill at the same time every day.
- Do not skip taking any Pills:
  - even if you have some spotting of blood between your periods
  - if you have other side effects, such as nausea or an upset stomach.

10.6 Your chance of getting pregnant goes up every time you miss more than one Pill.

- Get your next pack of Pills before you need them so you can start every pack on time.
- Keep condoms in case you do start a Pill pack late or you miss two or more Pills in a row.

---

## 11. What should I do if I miss any Pills?

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11.1 If you miss one of the[color(s)] active Pills:

- Take the missed Pill as soon as you remember.
- Take the next Pill at the regular time. This means you may take two Pills in one day.

- Keep taking one Pill each day, as usual.
- You do not need to use condoms to prevent pregnancy if you miss just one Pill.

**11.2 If you miss two or more of the [color(s)] active Pills in a row, or if you start your next Pill pack two or more days late:**

- Take one pill now.
- Don't try to make up the other [color(s)] Pills you missed. Throw them out.
- Keep taking one [color(s)] active Pill every day until they are gone
- Use condoms or do not have sex until you have been back on the [color(s)] active Pills for 7 days in a row.
- Go straight to the next pack after you finish the [color] active Pills. You do not need to take the 7 [color] reminder Pills.

**11.3 If you missed two or more [color(s)] of the active Pills, and then had sex without using condoms in the next 7 days:**

- Call your doctor or clinic as soon as possible.
- They can prescribe Emergency Contraceptive Pills (ECPs), sometimes called Morning After Pills. *[See Section 13 below.]*

**11.4 If you forget to take any of the 7 [color] reminder Pills:**

- Throw out the [color] reminder pills that you missed.
- Keep taking one [color] reminder Pill every day until it is time to start a new Pill pack.
- You do not need to use condoms to prevent pregnancy if you missed only the reminder Pills.

**[DELETE:** 11.5 If you are using a 21-day pack, you will not be taking any Pills during the 4<sup>th</sup> week.]

**11.6 If you have very bad vomiting for two days in a row, and the vomiting is in the first 3 hours after taking your Pill:**

- Call your doctor or clinic for advice.
- Use a condom if you have sex during the next 7 days.

---

## **12. Important reminders about missed pills**

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**12.1 Any time you miss 2 or more [color(s)] active Pills in a row, or you start a pack late:**

- Use condoms or do not have sex until you have been back on [color(s)] active Pills for 7 days in a row.
- If you do not use condoms after missing 2 or more Pills, call your doctor or clinic as soon as possible about getting ECPs (Emergency Contraceptive Pills) *[See Section 13 below]*

- 12.2 **Any time you are not sure what to do, or if you have any other questions, CALL your doctor or clinic.**

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### **13. Emergency Contraceptive Pills (“ECPs”)**

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- ECPs are sometimes called “Morning After Pills.”
- If you have sex without using a condom after you have missed 2 or more Pills in a row, ECPs can lower your chance of getting pregnant.
- ECPs work best if you take them as soon as possible, and within 3 days of having unprotected sex.
- ECPs do not work if you are already pregnant.
- ECPs are safe and easy to use.

---

### **14. What if I miss my monthly period?**

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14.1 **If you miss one period:**

- If you have taken your Pill every day or used condoms every time you had sex, you are probably not pregnant
- If you have not taken your Pill every day and have not used condoms every time you had sex, call your doctor or clinic for a pregnancy test.

14.2 **If you miss two periods in a row:**

- Call your doctor or clinic for a pregnancy test, even if you have taken your Pills every day or used condoms every time you had sex.

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### **15. What if I want to stop taking the Pill or change birth control methods?**

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15.1 **If you want to stop taking the Pill or change to another method:**

- Check with your doctor or clinic staff before you make any changes.
- If there is a chance that you will start taking the Pill again in the next few months, it is a good idea to keep taking the Pill every day.
- If you want to stop using birth control pills, to get pregnant, for example, waiting until you finish your pack will cause the least change in your monthly cycle.
- If you only want to change the kind of birth control pill you use, wait until you start your next pack to start the new Pills.

15.2 **If you change to the Pill from another method of birth control:**

- Keep using the other method until the day you want to start taking the Pill.
- Follow the instructions for “When to Start Your First Pack of Pills” [See section 10.3]

15.3 **If you change from the Pill to another method of birth control, wait until you finish your Pill pack to start the new method.**

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## 16. What if I want to get pregnant?

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**If you want to get pregnant, just stop taking the Pill.** (See section 15.1)

- Having been on the Pill does not make you less likely to get pregnant once you stop, but it may take a little longer.

---

## 17. Does the Pill cause birth defects?

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**The Pill does not cause birth defects.**

- Even if you are taking the Pill in the first 3 months you are pregnant (for example, before you know you are pregnant) your baby should be fine.
- If you find out that you are pregnant, stop taking the Pill.

---

## 18. What if I just had a baby?

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- **If you are not breast feeding, you can start the Pill after your baby is 3 weeks old.**
- **If you are breast feeding,**
  - Do not start taking the Pill until your baby is at least 6 weeks old.
  - It is safest to wait until you have finished breastfeeding to start taking the Pill. Use another birth control method instead.

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## 19. What if a child takes any of the Pills?

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**Taking birth control pills by mistake probably won't cause any problems, even in children, *but...***

- Call your child's doctor or clinic if you are worried.
- Keep all medicines where children cannot reach them.

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## **20. Where should I keep the Pills?**

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- Keep the Pills where you will remember to take them at the same time every day.
- Keep the Pills at room temperature.

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## **21. What if I have other questions?**

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- You can get information from [1-888-XXX-XXXX] or [WEBSITE].
- You can ask your doctor or clinic staff for the more detailed “Labeling for Healthcare Providers.”

**APPENDIX 4. TEXT OF ARTICLE DESCRIBING FIELD TESTING OF PATIENT LABELING FOR ORAL CONTRACEPTIVES.**

**Improving patient educational literature: an understandable patient package insert for “the Pill.”** Ross, Beth Stearman, Linda S. Potter, and Kay A. Armstrong. *Journal of Obstetric and Gynecological Nursing* 33:198-208; 2004.

[NOTE: Results that are especially relevant to our comments are in boldface.]

**ABSTRACT**

**Objective:** To develop a simpler, more understandable and accurate Patient Package Insert (PPI) for inclusion in all packs of oral contraceptives.

**Design:** The project involved field-testing using focus groups and semi-structured cognitive interviews with family planning patients, a self-administered survey of clinic staff, and written recommendations from oral contraceptive and readability experts.

**Setting:** Federally-funded reproductive health clinics in two urban hospitals and one suburban Planned Parenthood affiliate in southeastern Pennsylvania.

**Participants:** 24 focus group participants, 94 clinic patients, 18 clinic staff and 34 other experts on oral contraceptives and readability of health education materials.

**Results:** The revision and field-testing of the PPI reduced its length by one-third, its reading level from 10<sup>th</sup>-12<sup>th</sup> to 6<sup>th</sup>-grade, included lay as well as medical terminology and re-organized the information, thereby making it easier to find and easier to use. Clinic staff endorsed the simplified PPI for educating patients and training staff.

**Conclusion:** The revised PPI, as submitted to the FDA in February 2001, could increase patient knowledge of safe and effective Pill use and would be a valuable educational tool for providers of oral contraceptives.

**Keywords:** patient health education materials, patient package insert, contraceptive counseling, cognitive interviewing, health literacy, oral contraceptives, patient-provider interaction, readability, adherence

## **Improving Patient Educational Literature: An Understandable Patient Package Insert For “the Pill”**

American women take about 100 million cycles of oral contraceptives each year. Yet the tissue-paper leaflet inserted in each pack of Pills makes it difficult to read and understand the information they must have to use “the Pill” safely and effectively. Therefore, the purpose of the project was to translate the current oral contraceptive (OC) Patient Package Insert (PPI) into user-friendly language and format, while ensuring that it still met FDA standards. The simplified language would then be used to increase the consistency and clarity of information across OC brands and clinical guidelines; for training materials for nurses, physicians, and counselors; and for educational materials on the Pill. Three groups would be included in this process—family planning patients, clinic staff, and other experts. The specific objectives of the project were:

- To draft a short, simple and accurate patient package insert (PPI) for oral contraceptives;
- To field-test a series of PPI drafts with past, current and potential Pill users in order to assess their understanding of the information and to use their input to finalize a simplified PPI;
- To incorporate advice from contraceptive and readability experts as well as reproductive health clinic staff to ensure that the information in the revised PPI is sufficient and accurate to meet established standards for communicating medical information;
- To solicit feedback from clinic staff on ways to use the revised PPI; and
- To submit to the FDA the PPI culminating from this process, for inclusion in all packages of oral contraceptives.

### **Background**

Each year, more than 10 million women in the United States take oral contraceptives (the “Pill”) to prevent pregnancy; 300,000 of those women become pregnant each year during a month in which they have been taking the Pill (Abma, Chandra, Mosher, Peterson & Piccinino, 1997; Peterson, Oakley, Potter, & Darroch, 1998). Such a high failure rate could be avoided since the Pill, if taken correctly, is more than 99% effective in preventing pregnancy. Furthermore, at least half of the pill users discontinue the Pill within their first year due to fears, misunderstandings and side effects (Fu, Darroch, Haas & Ranjit, 1999; Rosenberg, Waugh & Burnhill, 1998). Too often these women do not immediately start using another method (Bressler, Casten & Armstrong, 1997). Others take the Pill inconsistently, without adequate backup protection after missing two or more Pills (Peterson et al., 1998; Potter, Oakley, de Leon-Wong & Cañamar, 1996; Rickert, Berenson, Williamson & Wiemann, 1999). One recent U.S. study found that only 16% of 371 women at a federally-funded family planning clinic could correctly state what they should do if they missed two pills, and less than half could spontaneously name any of the health risks or benefits of pill use (Davis, Williams, Potter & Green, unpublished).

The factors in safe and effective use of oral contraceptives are complex but understanding correct use, potential risks and side effects is essential. Several studies have found that written information reinforced by verbal counseling is the best way to increase patient understanding of oral contraceptive use (Felice, Feinstein, Fisher & Kaplan, 1999; Gazmararian, Parker & Baker, 1999; Little, Griffin, Kelly, Dickson & Sadler, 1998; Oakley, Potter, de Leon-Wong & Visness, 1997; Parker, Williams, Baker & Nurss, 1996; Smith & Whitfield, 1995) but counseling is not always available or may not be completely clear to the patient. Better written information alone cannot reduce the number of unplanned pregnancies or side effects, but safe and effective use of OCs does require having correct, consistent information that is easy to find and easy to understand, especially if the health care provider is not immediately reachable.

The leaflet (“patient package insert” or PPI) included in each of the 100 million pill packs distributed each year is the only source of information most women have in hand that explains the Pill’s risks and benefits and what to do when they have missed two or more pills in a row. Yet specific points of information in those inserts can be difficult to find, and difficult to read and understand once found. Some of the information varies from manufacturer to manufacturer and the text of most PPIs is written at

a 10<sup>th</sup> to 12<sup>th</sup> grade reading level (Williams-Deane & Potter, 1992). This is well above the 8<sup>th</sup> grade reading level of the average person in the U.S. (Kirsch, Jungblut, Jenkins & Kolstad, 1993) and a 6<sup>th</sup> grade reading level is usually recommended for health education materials (Doak, Doak & Root, 1996). Even educational materials produced by family planning clinics for their own patients, with the goal of creating more culturally sensitive and easily understood information, often include unfamiliar medical terminology and are at a reading level above that of many of those most at risk for unwanted pregnancies. Cognitive interviewing techniques are the best way to uncover misperceptions about the meaning of health information and medical terminology, such as that in the PPI (Carbone, Campbell & Honess-Morreale, 2002; Sutherland et al., 2001; Willis, Royston & Bercini, 1991). Both the “think-aloud”(also known as “talk back”) method and verbal probing can be used to determine how a statement or question is interpreted and to obtain wording that makes it easier to understand. The think-aloud method consists of asking the respondent to tell the interviewer how they interpret the statement or how they might explain it to a friend. This combined with verbal probing about their responses, provides essential information for simplifying medical instructions and health education materials.

Based on the findings of Williams-Deane & Potter (1992) and Potter & Krieger (1991) and concerns of family planning providers, the U.S. Food and Drug Administration (FDA) in 1992 recommended to oral contraceptive manufacturers revisions that would standardize, shorten and simplify the wording of the section of the PPI that provides instructions about when to start the first pack of pills and what to do when pills are missed (USFDA, 1992). Those revised instructions are now included in all U.S. manufactured patient package inserts and in most clinical textbooks in the U.S.

In July of 2000, the FDA released draft guidelines for revising the “Professional Labeling” (the guidance for health care providers) to reflect new evidence regarding the safe and effective use of the Pill, including further simplified instructions for use (USFDA, 2000). Health professionals and oral contraceptive manufacturers were given the opportunity to comment on the draft guidance with the expectation that their comments would be taken into account by the FDA in preparing the final version of the guidance for the Professional Labeling, which was expected to be published in 2002.

This project represented the next step in preparing a simplified package insert for patients based on the updated professional labeling. The Family Planning Council obtained funding to revise and field-test such a PPI. The most qualified people to set the standards are those current and potential Pill users to whom it is directed, and especially those likely to have problems reading or understanding the information in the PPI, as well as the professionals who provide oral contraceptives to these women.

## **Methods**

### ***Study Design***

The project had three phases. *Phase I* included two focus groups, one with adults and one with adolescents, and group discussions with staff at the three participating family planning clinics. The aim of this first phase was to explore their reactions to the current PPI and then incorporate their feedback into a revised version. *Phase II* involved semi-structured interviews with clinic patients using a cognitive “think aloud” response strategy to obtain feedback on sequential revisions of the PPI until the entire PPI was easy to read and understand. This phase also included review by the contraceptive and readability experts to insure that each round of revisions continued to meet accepted standards for accuracy and ease of understanding. The project investigators then finalized the PPI. *Phase III* was a self-administered survey for clinic staff to obtain information about their past use of the existing Patient Package Insert and their suggestions for how the simplified PPI could be incorporated into staff training and clinical practice. (Figure 1 illustrates the project flow).

### ***Setting and Recruitment***

Three federally-funded Title X family planning clinics affiliated with the Family Planning Council in southeastern Pennsylvania agreed to participate in the project. The clinics were selected because of their diverse settings (a large inner city hospital, a small urban hospital, and a suburban Planned Parenthood

affiliate) and their willingness to support staff and patient participation in the project. Informed consent procedures and all data collection instruments were reviewed and approved by the institutional review boards associated with the participating clinics. By consenting to participate in the project, adolescent and adult family planning patients agreed to spend additional time at their clinic visit to provide feedback associated with the PPI.

*Family Planning Staff.* Clinic staff, including nurses, counselors, and physicians, were then invited to an initial meeting at each of the three sites for a group discussion about the PPI and to establish the interviewing procedures for each clinic. The only criterion for eligibility to participate in the clinician survey was that they had responsibility for counseling patients on family planning issues.

*Family Planning Patients.* Convenience samples of adult patients from an urban hospital clinic and high school students from a suburban Planned Parenthood clinic program were invited to participate in the two focus groups in Phase I. All participants signed informed consent forms and completed a short anonymous questionnaire about their demographic characteristics and reproductive history. They provided refreshments and given \$10 for their time.

Recruitment for the individual patient interviews (Phase II) was conducted by project staff during regular clinic hours. Patients were approached by project staff while waiting for their appointments at each of the three participating clinics. They were eligible to participate if they were between the ages of 15 and 45, regardless of whether they had used oral contraceptives or not; and if they were not sterilized or known to be infertile, and not using an IUD.

Ninety-four interested patients signed a consent form indicating that they understood they would be asked to read and comment on selected sections of the package insert, in order to help make it easier for others to read and understand, and that the information they provided would be confidential. Participants completed the informed consent and background forms prior to beginning the interview and received \$20 for their time.

*Experts.* Advice on content and presentation of the information was also sought from external experts on oral contraceptives, contraceptive labeling, and health literacy and communication, and from the two pharmaceutical companies manufacturing oral contraceptives that helped fund this project. These expert reviewers were selected to reflect diverse backgrounds by the project team who knew of their work on these issues, as evidenced by their publications and presentations, or who were recommended by other experts.

### ***Procedures***

Project start-up activities began in May 1999, and field-testing and PPI revisions took eight months. The final product was submitted to the FDA in February 2001.

First, the focus group discussion guide, semi-structured patient interview form, sections of the PPI to be tested as well as the informed consent and background forms were prepared. The project team met with staff from the three clinics and discussed the project and their current use of the PPI. Three interviewers were trained by the project team on how to introduce the project, obtain informed consent, select sections of the draft PPI for questioning, and use the cognitive interviewing technique to conduct the approximately 45-minute interviews. And, finally, the national experts were contacted to confirm their willingness to review at least one draft of the PPI.

The PPI sections chosen for field-testing were selected because they were essential to safe and effective use (risks, side effects, when to start, what to do when Pills are missed). Specific issues such as failure rates, side effects, and what to do when Pills are missed had previously been shown to be difficult for Pill users to understand, and are of such concern to Pill users that they can lead to irregular use and discontinuation (Potter & Krieger, 1991; Williams-Deane & Potter, 1992).

## **Data Collection**

**Phase I:** Two focus groups, one with 12 adult hospital family planning clinic patients, and the other with 12 members of a Planned Parenthood teen group, along with the initial staff discussions, provided an opportunity to explore general opinions about the current PPI and how they would like to see it improved. Participants in the focus groups were given copies of inserts currently included in Pill packs and asked first to comment on the format and layout. They were then asked if they understood specific medical terms used in each section of the PPI and to provide suggestions for alternative wording. Examples of the types of topics probed in these focus group sessions were “How clear are these medical terms about possible risks of taking the pill?” (e.g., benign, circulatory disease) and “What do the following words mean to you?” (e.g., active pill, estimated risk). Focus groups were audiotaped.

**Phase II:** *The individual interviews* were most often conducted in private examining rooms or offices while the patients waited for their clinic appointments. Clinic staff members occasionally made adjustments in the patient flow to accommodate these interviews.

The semi-structured patient interview format was based on procedures previously used by Potter and Krieger (1991) in testing Pill-taking instructions for the FDA and on the cognitive “think aloud” interviewing technique. The most complex and/or important sections in the PPI were initially identified by the project team and pasted onto 5 x 8 inch cards, one section per card, for a total of 26 cards. Approximately one-third (8-10) of the 26 cards were selected by the interviewer to be shown one at a time to each patient, aiming for an interview time of about 45 minutes. Thus, every card was not shown to every patient. After the patient looked at a card briefly, she was asked to read the excerpt aloud and describe “how you would explain this to a friend”. Probing questions were also utilized in order to elicit understanding of the information and suggestions for alternative language.

Individual items were modified as soon as problems became apparent or the patients proposed better alternatives. This usually occurred after two or three days of interviewing, when 15 to 20 interviews had been completed. At that point, the project team stopped testing the items that were found to be understandable and further revised the wording of the remaining items for the next group of interviews. The reading level of each revision of the PPI was tested using the MS Word version of the Flesch-Kincaid formula (Doak et al., 1996).

*Expert review:* Expert consultants were asked to review the PPI revisions at three points in the process: before interviews began, approximately half way through and after the interviews were completed. They provided written comments and suggestions to ensure that the medical information was accurate and thorough, and that the PPI met established standards for user-friendly format and readability. Of the 37 experts contacted, 34 provided comments and suggestions for the PPI revisions at least once. Suggestions were reviewed by two or more members of the project team and, where applicable, incorporated into the PPI prior to the next round of field-testing.

**Phase III:** After the final revisions were made by the project team, staff responsible for counseling family planning patients were asked to complete a self-administered survey to assess the utility of the revised PPI as an educational tool. The survey was pilot tested prior to distributing it to 29 clinic staff. The staff surveys obtained demographic information, history of oral contraceptive use, familiarity with the PPI, feedback on the content and format of the revised and final PPI, and exploration of the utility of the revised PPI with patients and staff. A self-addressed, stamped envelope was provided to return their completed survey. Eighteen clinic staff members returned completed surveys.

## Results

### *Phase I: Formative Feedback from Patients and Staff*

Suggestions from both focus groups for formatting the PPI included use of larger type, clearer headings and, ideally, color, to help women find the information they needed. When asked if they could find the section of the current PPI describing what to do if they missed two or more pills, participants were able to do so. However, when asked to locate the section on non-contraceptive benefits, which was at the end of the PPI, none could do so without assistance.

Because information about the use of oral contraceptives for emergency contraception (EC) was to be included in the revised PPI, patients were asked several related questions. A number of participants in both groups knew of ECs and what they were for; fewer teens recognized the term “morning-after” pills or knew that the full name was emergency contraceptive pills.

Because of the potential difficulty for some Pill users in reading and understanding the terms “health care professional” or “health care provider”, the focus group participants were asked if they understood specific medical terms used in each section of the PPI and to provide suggestions for alternative wording. They strongly preferred the terms “doctor or clinic,” some noting that they were not familiar with the more formal terms and that they were accustomed to being told to “call the clinic” when they had problems. Similarly, they preferred “patient” to “client.”

Focus group teens understood fewer medical terms than did the adults; adults offered more suggestions for alternative wording than did teens. A few examples of these suggestions included referring to such potential risks as cardiovascular disease as heart problems, fluid retention as swelling, malignant tumors as cancer, and benign as not cancer, or including both the medical and lay terms together. Adults also preferred the term “very serious” to the less familiar “severe.” “How fertile you are” was misinterpreted by some to mean “the time of the month you’re most likely to get pregnant,” instead of the physiological ability to conceive. Not one participant in either focus group knew that the cervix was the opening to the uterus.

Other comments from the focus groups included the desire for more thorough counseling, “especially when starting on the Pill”. As one focus group participant put it, “[just] reading the insert makes it seem harder than it is to take the Pill”.

Initial discussions with nursing and counseling staff about the current PPI reiterated the teen and adult focus group feedback regarding the complexity of the format and wording. Staff respondents especially wanted clearer instructions about side effects and medical complications.

After the focus groups and staff discussions were completed, the project team revised the draft PPI and sent it out for the first round of expert review before beginning the one-on-one field-testing.

### *Phase II: Multiple Revisions based on Patient Interviews and Expert Feedback.*

The 94 patients who agreed to be interviewed one-on-one ranged in age from 15 to 45, with more than two-thirds of them 20 years of age or older (see Table 1). About one in four of the patients had not yet completed 12 years of education and 38% were currently attending high school or college. The number of years of education ranged from 9 to 18. Most patients (93%) spoke only English at home (not shown) and 61% were working part or full time; the majority was African American (70%). Most patients (83%) had used oral contraceptives at some time and, of those, almost half were currently using the Pill (Ross, 2001).

Most patients were able to read the text on the cards aloud, said they understood the information and could explain the meaning in their own words, “as they would explain it to a friend.” Their comments were content analyzed by the project team.

Those patients who had never used the Pill generally had the most difficulty interpreting the information. Teens, never-users and those with less than a high school education had the most difficulty with medical terminology. Of the 28 sections of the PPI that were tested, the ones that proved most difficult to understand and explain “to a friend” were in four categories: 1) How well does the Pill work? 2) What are the Pill’s side effects? 3) How to take the Pill, and 4) What should I do if I miss any Pills?

Feedback related to the four categories and their related items are discussed below. Due to the open-ended nature of the interview and the methodology of randomly selecting a subset of cards for each interview, the number of individuals asked to discuss each category varied. In all four categories, more than half of the patients found the information in the revised PPI text to be clear and understandable. However, some patients pointed out numerous sections that were not clear.

### *1) How well does the Pill work?*

Two-thirds of the 75 patients who were asked understood at least the essence of Pill effectiveness, found the text understandable and when asked to read aloud, read the text clearly. Those with more than a 12<sup>th</sup> grade education had a greater level of understanding of the revised PPI text than did those with less education (14 of 18 patients vs. 34 out of 57 patients). **Overall, one out of three patients did not understand the meaning of “failure rate” or “average use” compared to “perfect use” of the Pill.** Women who had used the Pill were more likely to understand the concept of failure rate than those who had not used the Pill (39% vs. 8%). Patients with more education had more familiarity with other contraceptive methods than those patients with a 12<sup>th</sup> grade or less education (83% vs. 67%). Although the focus groups raised concerns about the term “fertile”, almost all patients (93%) interviewed in this phase understood “fertile” to be the physiological ability to conceive.

### *2) What are the Pill’s side effects?*

Side effects are an important factor for many women who discontinue the Pill. Most patients (73% of the 44 asked) understood the text on complications and side effects. **One in four patients had difficulty with the medical terminology; a greater proportion of patients under 20 had difficulty (5 out of 15) than adult patients (6 out of 29).** Further, a larger proportion of non-Pill users than Pill users had difficulty with the medical terminology. Adults and those who had used the Pill were more likely to comment specifically on their desire for further clarification on the frequency and duration of the side effects. In addition, four adult patients and five Pill users offered suggestions about clarifying the language related to explaining spotting or bleeding associated with Pill use.

### *3) How to take the Pill*

More than half (58%) of the 53 patients asked about general Pill-taking instructions understood the text. **However, many patients expressed concern about giving new Pill users too many choices for the pill start day, regardless of age, ever use of pill or level of education.** Currently, various manufacturers give the following options regarding starting the first pack: 1) Sunday, 2) the first day of the menstrual period, or 3) on any other day the woman chooses. Most patients who commented on this topic felt the choice of when to start should be decided with a clinician, and not left up to the patient alone. Three out of four patients understand the difference in the PPI instructions for using 28-day and 21-day packs that do not include the seven “reminder” placebo pills. Some of these patients specifically mentioned that they did not know 21-day packs were available. In addition, 15 women found the terminology used for hormonal and non-hormonal Pills confusing.

### *4) What should I do if I miss any Pills?*

**Knowing how to handle missed pills is essential to prevent unintended pregnancy, yet only 46 of the 73 patients (63%) who were asked said they understood this section.** Further, after reading the specific instructions for how to handle two or more missed Pills, 15 patients could not explain what to do in their own words. The instruction on when to use a backup method of contraception generated discussion, with 27 patients indicating that the instructions were not clear to them. **The first draft of the simplified PPI stated simply that condoms do not need to be used unless two or more Pills are missed.** Several patients were concerned that this advice would be interpreted to mean that condoms did not need to be used for STD prevention. While it is not the role of the oral contraceptive PPI to provide advice on how to prevent sexually transmitted

diseases, the final text of the PPI specified that “You do not need to use condoms *to prevent pregnancy* if you miss just one Pill or if you miss only the reminder Pills”.

Because a backup method of contraception is not needed if Pills are missed during the hormone-free week, knowing how to differentiate between the “hormonal” and “non-hormonal” Pills is important. However, 18 patients did not understand the terminology. Participants reported that “real” Pills and “sugar” Pills were the most commonly used terms, but most of those asked said they would be comfortable with the more specific “active” and “reminder” Pills, especially if the pills are color coded. Patients who had used the Pill and were age 20 or older raised more concerns with this section than adolescents and non-Pill users.

The expert reviewers confirmed that the PPI remained accurate and sufficiently thorough as it was being shortened and re-worded. Some of them also provided specific wording that they had found helpful in their own work and suggested re-arranging some sections for a more logical flow. None found factual errors but occasionally one or two experts suggested replacing previously deleted information on certain topics. For example, two experts recommended inserting more detailed information on liver disease as described in the professional labeling.

A rare disagreement between the experts and patients interviewed was that several of the medical reviewers preferred the terms “health care professional” and “client” whereas all of the patients preferred “doctor or clinic” and “patient” as noted above. In those two cases, the final PPI used the latter, simpler terms preferred by the patients themselves since none of the terms were inaccurate and our focus was on patient preference. (See Figure 2 for two examples of the differences between the original and final PPI.)

### ***Phase III: Clinical Use of Revised PPI***

After the final revisions were made by the project team based on both patient and expert feedback, 18 staff members (61% of those contacted) at the three participating clinics completed a self-administered survey. The job titles represented were counselor (44%), manager (17%), nurse/nurse practitioner (28%), and health/sex educator (11%). Sixty-one percent of the respondents had worked in family planning for more than eight years, and 61% were working full time. Half of the respondents had been in their current position less than two years.

All 18 staff respondents stated that they referred their patients to the current PPI only “some of the time” or “never”. The 11 staff respondents who said that they did not ever refer their patients to the current PPI, and the 16 who said they did not use it in counseling sessions, said this was primarily because of the formidable language and volume of information in the current PPI. In assessing the utility of the revised PPI as an educational tool for patients, half of the respondents said it was easy to read and understand and 22% said they would use it as a reference with patients. Regarding the revised PPI’s utility for themselves and other clinic staff, 44% said they would use it as a resource or refresher and 28% said they would use it as a tool to train new staff.

Although the length of the PPI has been reduced by one-third, three of the staff who participated in the final survey were concerned that it is still too long. However, all 18 felt that the revised PPI will be a valuable tool for patients and providers of reproductive health care since all sections, particularly the missed pills information, have been made clearer and thereby more useful to women seeking this information. Clinic staff had similar concerns to those of patients about the information on STD prevention. These concerns were addressed by specifying throughout the PPI that the condom use information relates only to pregnancy prevention since that is the purpose of the PPI.

## **Discussion**

The field-test and review process substantially shortened and simplified the oral contraceptive patient package insert without sacrificing accuracy. The length of the PPI was reduced by one-third, the language was reduced from a high school to sixth grade reading level, and so was understandable to a substantial majority of the women who participated in the revision process.

**This means that the information pill users have in hand with the revised PPI when they have questions or concerns can be a real resource for them. Secondly, this patient package insert can be a valuable tool for nurses, physicians, and counselors to use with their patients. Some information is too complex for some users, such as comparing failure rates of different contraceptive methods, but is required by the FDA.**

**Other information, such as what to do when two or more Pills are missed, can be (and was) simplified but is too important and too complicated to deal with only in writing, making it essential for health care professionals to reinforce and then verify that the patient understands the information. The patient package insert is best used as a resource to accompany counseling. In a larger context, this project also demonstrates that with help from consumers, health care providers and other experts, health education materials can be made easier to understand and easier to use.**

The methodology used to collect feedback on the patient package insert from the three groups (patients, clinic staff and other experts) provided rich information for revising the OC package insert. The project was designed to improve an educational tool for oral contraceptive users rather than as a formal research study to collect in-depth knowledge, attitudes, beliefs, and behaviors.

The open-ended nature of the interviews allowed for flexibility in using probing questions, while the interview guidelines and the training of the interviewers kept the discussion on topic. Different patients were asked to respond to different sections of the PPI. Using the “think aloud” or “talk back” method of cognitive interviewing was especially critical here. Repeatedly problematic or critical sections continued to be explored and modified throughout the process (especially those on the Pill-taking instructions and effectiveness of the method) while others were quickly found unnecessary to test further or needed only the addition of familiar wording to the medical terminology.

Some trends associated with age and experience using the Pill are apparent in these results. Adults and ‘ever users’ of the Pill voiced fewer problems than teens and those who had never used the Pill; however, the effect of education on whether concerns were raised is less clear. In some cases, it appears that those women with some college education had more problems with the wording since they raised more questions such as in the section describing side effects. However, this group also offered the most specific suggestions for how to clarify the items.

The same issue exists regarding variations in responses by age, education and ‘ever use’ of the Pill since the three categories interact. For example, ‘ever use’ of the Pill increased with age. About one in four of all participants had not yet completed 12 years of education; the percentage of those not completing 12 years of education was 54% of teens and 15% of adults. Most patients (83%) had used oral contraceptives at some time and of those, almost half were currently using the Pill with a slightly higher percentage of teens than adults currently using the Pill (42% compared to 36%).

It was clear from the patients’ thoughtful responses and suggestions, and from remarks several of them made, that they took pride in knowing that they were helping to make it easier for other women to understand complex information on the Pill. After completing the interview, one woman said “I made a difference!” and another felt that this project “would help a lot of people” and thanked the interviewers for “asking for our opinions”. Moreover, many staff at the three participating clinics demonstrated their commitment to improving the information their patients receive and to ensuring that these issues were addressed in the revised PPI through thoughtful review and consideration of how they would use the improved tool in their clinical practice. Although the number of completed clinician surveys was small, anticipated utility of the PPI for use with both patients and staff was positive in all cases.

Some limitations may reduce the generalizability of the findings to other populations. Patients from the three publicly-funded family planning clinics were a convenience sample. Although these patients reflect a population especially likely to benefit from simple, easily accessible information, they do not represent a cross-section of all U.S. Pill users. Further, the more confident and articulate patients were probably the most likely to participate and to voice their opinions and suggestions. Similarly, the expert reviewers were selected because they were known to the project team. Some experts were asked to provide feedback on several versions of the PPI while others only reviewed a few items. Full consensus was not reached on all items but patient feedback carried the most weight when opinions varied. The

project staff took responsibility for making final decisions regarding what information, wording and format to include in the PPI.

**A final limitation is that recommendations for revising the PPI were solicited only from English-speaking patients, staff and experts. Once finalized by the FDA, it is hoped that the PPI will be translated into other languages and field-tested in each language as soon as possible. The PPI will continue to need periodic revising, as new evidence on content and better ways to present the information are found.**

**The PPI that resulted from this project, as submitted to the FDA, is an important step in improving the quality of the information for using the Pill safely and effectively. Its ultimate success as an educational tool, however, will depend on how well it is received by other Pill users and providers, how widely it is used in developing other materials, and by how much more safely and effectively the Pill is used.**

As Wysocki (1998) pointed out, the quality of communication between health care provider and patient is the most important component of contraceptive education. Being able to use the simplified wording in the PPI can make it easier for reproductive health nurses and other professionals to know that the information they are providing to their patients is comprehensible. In addition, the field-testing process used to simplify the oral contraceptive package insert can serve as a model for testing and modifying other patient education materials.

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**APPENDIX 5: EXPERT REVIEWERS**

(reviewed field tested labeling in part or in whole, depending on area of specialty, in 2000-2001)

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