

OMB Control NO. 0910-0497  
Expiration Date: 10/31/2020

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0497 and the expiration date is 10/31/2020. The time required to complete this information collection is estimated to average 5 minutes per response, including the time for reviewing instructions and completing and reviewing the collection of information.

## PLLR FOCUS GROUP ELIGIBILITY SCREENER

### Segment 1: Ob/Gyn

Thank you for your interest in participating in our focus group to get feedback on prescription labeling for pregnant women. These focus groups are being conducted on behalf of the U.S. Food and Drug Administration, in partnership with [the American College of Obstetricians and Gynecologists/Society for Maternal Fetal Medicine]. The 75-minute focus groups will be held online. If you are eligible and participate in a focus group you will receive \$300 as a token of our appreciation.

In order to determine if you are eligible to participate in the focus group, please answer the questions below. These questions should take you no more than 5 minutes to answer.

1. Are you an Ob/Gyn and currently taking care of patients?

1. Yes

2. No

**INELIGIBLE**

2. In an average year, what percentage of your work time do you spend on patient care? *Patient care activities include examining patients, performing diagnostic tests, prescribing or dispensing medications, reviewing patient records, and other activities directly connected to treatment. Non-patient care activities include teaching, research, and administration.*

1. Less than 25%

2. 26% - 50%

3. 51% - 75%

4. 76% - 100%

3. Do you have prescribing authority in the United States?

1. Yes

2. No

**INELIGIBLE**

4. How many years have you been in practice? [RECRUIT A MIX]

1. 0 - 10 years [Recruit at least 5]

2. 11 - 20 years

3. 21+ years [Recruit no more than 12]

5. How many pregnant patients do you see per month?

1. 0 - 2

**INELIGIBLE**

2. 3 - 4

**INELIGIBLE**

3. 5 - 9

4. 10 - 14

5. 15 +

6. In which medical setting do you practice most often?

1. Private practice office

2. Ambulatory care clinic of hospital/medical center

3. Institutional setting/clinic (e.g., correctional, nursing home)

4. Clinic that is part of a Health Maintenance Organization

5. Community health center

6. Academic or teaching hospital

7. Public health clinic

8. Other type of clinic

(specify) \_\_\_\_\_

7. What is the zip code of the location of your primary practice setting?

\_\_\_\_\_

8. How would you describe this area? [RECRUIT A MIX]

1. Urban (city)
2. Suburban (outside of a big city)
3. Rural (far from any large city)

9. Are you or your partner currently pregnant?

1. Yes
2. No

10. Are you currently employed by any of the following?

- |                                |                   |
|--------------------------------|-------------------|
| 1. A federal government agency | <b>INELIGIBLE</b> |
| 2. A pharmaceutical company    | <b>INELIGIBLE</b> |
| 3. A marketing research firm   | <b>INELIGIBLE</b> |
| 4. None of the above           |                   |

11. When was the last time you participated in a research study, such as an interview or a focus group discussion?

- |                                |                   |
|--------------------------------|-------------------|
| 1. Less than 6 months ago      | <b>INELIGIBLE</b> |
| 2. Between 6 and 12 months ago |                   |
| 3. 12 months ago or more       |                   |
| 4. Never                       |                   |
| 5. Refused                     | <b>INELIGIBLE</b> |
| 6. Don't know                  | <b>INELIGIBLE</b> |

12. What is your gender?

1. Female

2. Male

13. How old are you? \_\_\_\_\_ years

14. Are you of Hispanic, Latino, or Spanish origin?

1. Yes

2. No

15. What is your race? (Select one or more)

1. American Indian or Alaskan Native

2. Asian/Asian American

3. Black or African American

4. Native Hawaiian or Other Pacific Islander

5. White

16. Do you currently have daily high-speed internet access for personal use?  
(DSL or faster for computers/tablets and /or 4G data connection for tablets)

1. Yes

2. No

**INELIGIBLE**

17. The focus groups will be audio recorded. Are you willing to be audio recorded during the group?

1. Yes

2. No

**INELIGIBLE**

18. In general, what days would you prefer to participate in a 75-minute focus group? (Select all that apply)

1. Monday

2. Tuesday

3. Wednesday

4. Thursday

5. Friday

19. In general, what time of day works better for you to participate in a 75-minute focus group? *(Select all that apply)*

1. Early mornings (before 9am)
2. Mornings (9am to noon)
3. Afternoons (noon to 5pm)
4. Evenings (after 5pm)

Thank you for answering our questions. Based on your answers, you may be chosen to participate in the focus group. If you are selected to participate, a member of our research team will contact you within the next week to schedule you for an available session.

Please provide your name, email address, and phone number so that we can contact you if you are selected to participate in a focus group. Be assured that your contact information will be kept private and will only be used for the purpose of contacting you about this focus group.

Name: \_\_\_\_\_

Email: \_\_\_\_\_

Phone: \_\_\_\_\_

**THANK AND TERMINATE:** Thank you for answering these questions. Unfortunately, based on your responses, you are not eligible for this study.

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### Segment 2: Family Medicine

Thank you for your interest in participating in our focus group to get feedback on prescription labeling for pregnant women. These focus groups are being conducted on behalf of the U.S. Food and Drug Administration, in partnership with the American Academy of Family Physicians. The 75-minute focus groups will be held online. If you are eligible and participate in a focus group you will receive \$300 as a token of our appreciation.

In order to determine if you are eligible to participate in the focus group, please answer the questions below. These questions should take you no more than 5 minutes to answer.

1. Are you a physician currently taking care of patients?

1. Yes

2. No

**INELIGIBLE**

2. In an average year, what percentage of your work time do you spend on patient care? *Patient care activities include examining patients, performing diagnostic tests, prescribing or dispensing medications, reviewing patient records, and other activities directly connected to treatment. Non-patient care activities include teaching, research, and administration.*

1. Less than 25%

2. 26% - 50%
3. 51% - 75%
4. 76% - 100%

3. Do you have prescribing authority in the United States?

1. Yes
2. No

**INELIGIBLE**

4. How many years have you been in practice? [RECRUIT A MIX]

1. 0 - 10 years [Recruit at least 5]
2. 11 - 20 years
3. 21+ years [Recruit no more than 12]

5. Do you currently treat any pregnant patients?

1. Yes
2. No

**INELIGIBLE**

6. How many pregnant patients do you see per month? [RECRUIT A MIX]

1. 0 - 2
2. 3 - 4
3. 5 - 9
4. 10 - 14
5. 15 +

**INELIGIBLE**

7. In which medical setting do you practice most often?

1. Private practice office
2. Hospital emergency department
3. Ambulatory care clinic of hospital/medical center
4. Institutional setting/clinic (e.g., correctional, nursing home)

5. Urgent care clinic
6. Clinic that is part of a Health Maintenance Organization
7. Community health center
8. Academic or teaching hospital
9. Public health clinic
10. Other type of clinic  
(specify) \_\_\_\_\_

8. What is the zip code of the location of your primary practice setting?

\_\_\_\_\_

9. How would you describe this area? [RECRUIT A MIX]

1. Urban (city)
2. Suburban (outside of a big city)
3. Rural (far from any large city)

10. Are you or your partner currently pregnant?

1. Yes
2. No

11. Are you currently employed by any of the following?

1. A federal government agency **INELIGIBLE**
2. A pharmaceutical company **INELIGIBLE**
3. A marketing research firm **INELIGIBLE**
4. None of the above

12. When was the last time you participated in a research study, such as an interview or a focus group discussion?

1. Less than 6 months ago **INELIGIBLE**

2. Between 6 and 12 months ago

3. 12 months ago or more

4. Never

5. Refused **INELIGIBLE**

6. Don't know **INELIGIBLE**

13. What is your gender?

1. Female

2. Male

14. How old are you? \_\_\_\_\_ years

15. Are you of Hispanic, Latino, or Spanish origin?

1. Yes

2. No

16. What is your race? *(Select one or more)*

1. American Indian or Alaskan Native

2. Asian/Asian American

3. Black or African American

4. Native Hawaiian or Other Pacific Islander

5. White

17. Do you currently have daily high-speed internet access for personal use?  
*(DSL or faster for computers/tablets and /or 4G data connection for tablets)*

1. Yes

2. No **INELIGIBLE**

18. The focus groups will be audio recorded. Are you willing to be audio recorded during the group?

1. Yes

2. No

**INELIGIBLE**

19. In general, what days would you prefer to participate in a 75-minute focus group? *(Select all that apply)*

1. Monday

2. Tuesday

3. Wednesday

4. Thursday

5. Friday

20. In general, what time of day works better for you to participate in a 75-minute focus group? *(Select all that apply)*

1. Early mornings (before 9am)

2. Mornings (9am to noon)

3. Afternoons (noon to 5pm)

4. Evenings (after 5pm)

Thank you for answering our questions. Based on your answers, you may be chosen to participate in the focus group. If you are selected to participate, a member of our research team will contact you within the next week to schedule you for an available session.

Please provide your name, email address, and phone number so that we can contact you if you are selected to participate in a focus group. Be assured that your contact information will be kept private and will only be used for the purpose of contacting you about this focus group.

Name: \_\_\_\_\_

Email: \_\_\_\_\_

Phone: \_\_\_\_\_

**THANK AND TERMINATE:** Thank you for answering these questions.  
Unfortunately, based on your responses, you are not eligible for this study.

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## PLLR FOCUS GROUP ELIGIBILITY SCREENER

### Segment 3: Other specialty physicians

Thank you for your interest in participating in our focus group to get feedback on prescription labeling for pregnant women. These focus groups are being conducted on behalf of the U.S. Food and Drug Administration, in partnership with [the American Psychiatric Association/American Academy of Neurology/American College of Gastroenterology/American Gastroenterological Association/American College of Rheumatology ]. The 75-minute focus groups will be held online.

In order to determine if you are eligible to participate in the focus group, please answer the questions below. These questions should take you no more than 5 minutes to answer.

1. Are you a physician and currently treating patients?

1. Yes

2. No

**INELIGIBLE**

2. In an average year, what percentage of your work time do you spend on patient care? *Patient care activities include examining patients, performing diagnostic tests, prescribing or dispensing medications, reviewing patient records, and other activities directly connected to treatment. Non-patient care activities include teaching, research, and administration.*

1. Less than 25%

2. 26% - 50%

3. 51% - 75%

4. 76% - 100%

3. What is your medical specialty?

1. Gastroenterology
2. Neurology
3. Psychiatry
4. Rheumatology
5. Allergist
6. Other (specify): \_\_\_\_\_

4. Do you have prescribing authority in the United States?

1. Yes
2. No **INELIGIBLE**

5. How many years have you been in practice? [RECRUIT A MIX]

1. 0 - 10 years [Recruit at least 5]
2. 11 - 20 years
3. 21+ years [Recruit no more than 12]

6. Do you currently treat any pregnant patients?

1. Yes
2. No **INELIGIBLE**

7. How many pregnant patients do you see per month? [RECRUIT A MIX]

1. 0 - 2 **INELIGIBLE**
2. 3 - 4
3. 5 - 9
4. 10 - 14
5. 15 +

8. In which medical setting do you practice most often?

1. Private practice office

2. Hospital emergency department
3. Ambulatory care clinic of hospital/medical center
4. Institutional setting/clinic (e.g., correctional, nursing home)
5. Urgent care clinic
6. Clinic that is part of a Health Maintenance Organization
7. Community health center
8. Academic or teaching hospital
9. Public health clinic
10. Other type of clinic

(specify) \_\_\_\_\_

9. What is the zip code of the location of your primary practice setting?

\_\_\_\_\_

10. How would you describe this area? [RECRUIT A MIX]

1. Urban (city)
2. Suburban (outside of a big city)
3. Rural (far from any large city)

11. Are you or your partner currently pregnant?

1. Yes
2. No

3. Are you currently employed by any of the following?

4. A federal government agency **INELIGIBLE**
5. A pharmaceutical company **INELIGIBLE**
6. A marketing research firm **INELIGIBLE**
7. None of the above

12. When was the last time you participated in a research study, such as an interview or a focus group discussion?

1. Less than 6 months ago **INELIGIBLE**
2. Between 6 and 12 months ago
3. 12 months ago or more
4. Never
5. Refused **INELIGIBLE**
6. Don't know **INELIGIBLE**

13. What is your gender?

1. Female
2. Male

14. How old are you? \_\_\_\_\_ years

15. Are you of Hispanic, Latino, or Spanish origin?

1. Yes
2. No

16. What is your race? *(Select one or more)*

1. American Indian or Alaskan Native
2. Asian/Asian American
3. Black or African American
4. Native Hawaiian or Other Pacific Islander
5. White

17. Do you currently have daily high-speed internet access for personal use?  
*(DSL or faster for computers/tablets and /or 4G data connection for tablets)*

1. Yes
2. No

**INELIGIBLE**

18. The focus groups will be audio recorded. Are you willing to be audio recorded during the group?

1. Yes

2. No

**INELIGIBLE**

19. In general, what days would you prefer to participate in a 90 minute focus group? *(Select all that apply)*

1. Monday

2. Tuesday

3. Wednesday

4. Thursday

5. Friday

20. In general, what time of day works better for you to participate in a 90 minute focus group? *(Select all that apply)*

1. Early mornings (before 9am)

2. Mornings (9am to noon)

3. Afternoons (noon to 5pm)

4. Evenings (after 5pm)

Thank you for answering our questions. Based on your answers, you may be chosen to participate in the focus group. If you are selected to participate, a member of our research team will contact you within the next week to schedule you for an available session.

Please provide your name, email address, and phone number so that we can contact you if you are selected to participate in a focus group. Be assured that your contact information will be kept private and will only be used for the purpose of contacting you about this focus group.

Name: \_\_\_\_\_

Email: \_\_\_\_\_

Phone: \_\_\_\_\_

**THANK AND TERMINATE:** Thank you for answering these questions.  
Unfortunately, based on your responses, you are not eligible for this study.