

**Healthcare Professional Survey of Prescription Drug Promotion II
[Main Survey]**

INFORMED CONSENT FORM

[Consent Screen 1]

[DISPLAY]

The Food and Drug Administration is conducting this study to understand health care providers' attitudes regarding pharmaceutical promotion as it relates to public health. Your responses, and those of your colleagues nationwide, will provide valuable insight into matters affecting the medical community. This survey will take between 15-20 minutes to complete and your responses will be kept confidential.

This research is authorized by Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)). Confidentiality is protected by 5 U.S.C. 552(a) and (b) and 21 CFR part 20.

OMB Control #0910-xxxx. Expires xx/xx/20xx.

[Consent Screen 2]

[DISPLAY]

This survey is being conducted by Westat, an independent social science research firm, on behalf of the U.S. Department of Health and Human Services. Westat is working with WebMD to conduct this survey but is not affiliated with WebMD in any way. If you have questions about this survey, please contact the project director, Dr. Simani Price, at 301-610-5536. She can be reached between 9 AM and 5 PM Eastern Time Monday to Friday.

Privacy and Confidentiality

This survey will ask you for some general demographic information (for example, age, gender, race/ethnicity). However, no personal information, such as your name, will be collected. Your identity will not be linked to your responses. We will be very careful to only let people working on the study see your responses, which will not be linked back to any personal information that can be used to identify you. Your information will be kept private to the extent allowed by law.

Possible Risks or Discomforts

There are no anticipated risks to participating in the survey. However, you can skip any questions you do not wish to answer and continue with the survey. While we will be very careful to let only members of the research team see your information, there is a small risk that others might find out what you say, despite all our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

Benefits

Your responses are very important because they will help researchers understand how people make decisions about medications. There is no direct benefit to you for your participation.

Incentive

In appreciation for your time, you will receive \$(50/60) for completing this survey.

Rights as a Participant

If you have any questions about your rights as a participant, you may wish to contact Westat Human Subjects Protections office at 1-888-920-7631. You may also contact RIHSC at 301-796-9605 or RIHSC@fda.hhs.gov. RIHSC is an institutional review board (IRB), a group of people who are responsible for ensuring that the rights of participants in research are protected.

[Consent Screen 3]

Consent1. If you have read the previous screens and agree to participate, please click the **Yes button. If not, click the **No** button.**

- Yes, I agree to participate. [CONTINUE WITH NEXT SECTION]
- No, I do not agree to participate. [GO TO NEXT QUESTION]

Consent2. Are you sure you don't want to participate? Your opinions are important to us. Please select the **Yes button to continue this survey. Select the **No** button to exit.**

- Yes, I agree to participate. [CONTINUE WITH NEXT SECTION]
- No, I do not agree to participate. [END SURVEY]

[DISPLAY]

INTRODUCTION

Thank you for participating in this survey. The questions ask about your experiences with professionally-directed pharmaceutical marketing materials or activities prepared or conducted by drug companies intended to promote the use of the companies' drugs. It also asks about other information sources for learning about prescription drugs. Please answer honestly and give us your best guess on answers you do not know.

[PROFESSIONAL MATERIALS AND ACTIVITIES]

Q1. How often do you read professional medical journals?

1. More than once a week
2. About once a week
3. About once a month
4. A few times a year
5. Once a year or less
6. Never [GO TO Q2]

Q1a. When you read through journals, how often do you notice pharmaceutical promotions?

1. Every time
2. Most of the time
3. Some of the time
4. Rarely
5. Never [GO TO Q2]

Q1b. When you notice a prescription drug advertisement **for a new product**, how closely do you usually read it?

1. Read it thoroughly
2. Read certain parts thoroughly
3. Skim it
4. Glance at it
5. Don't read it at all

Q1c. When you notice a prescription drug advertisement **related to your practice**, how closely do you usually read it?

1. Read it thoroughly
2. Read certain parts thoroughly
3. Skim it
4. Glance at it

5. Don't read it at all

Q2. How often do you visit commercial prescription drug websites (e.g., "name of drug.com")?

1. More than once a week
2. About once a week
3. About once a month
4. A few times a year
5. Once a year or less
6. Never

Q2a. When you visit a prescription drug website, how closely do you usually read it?

1. Read it thoroughly
2. Read certain parts thoroughly
3. Skim it
4. Glance at it
5. Don't read it at all

Q3. How often do you visit medical reference websites (e.g., Epocrates, Prescribers' Digital Reference [PDR], UpToDate, or Clinical Key) to get information about prescription drugs?

1. More than once a week
2. About once a week
3. About once a month
4. A few times a year
5. Once a year or less
6. Never **[GO TO Q4]**

Q3a. When you visit these reference websites, how often do you notice prescription drug promotions?

1. Every time
2. Most of the time
3. Some of the time.
4. Rarely
5. Never **[GO TO Q4]**

Q3b. When you notice a prescription drug promotion on a reference website, how closely do you usually read it?

1. Read it thoroughly
2. Read certain parts thoroughly
3. Skim it
4. Glance at it

5. Don't read it at all

Q4. When you watch television, how often do you notice ads for prescription drugs?

1. Every time
2. Most of the time
3. Some of the time
4. Rarely
5. Never
6. I do not watch TV

Q5. Does your practice allow visits from pharmaceutical sales representatives?

1. Yes
2. No [GO TO Q6]

Q5a. How often do pharmaceutical sales representatives bring promotional materials to your practice?

1. More than once a week
2. About once a week
3. About once a month
4. A few times a year
5. Once a year or less

Q5b. In the last six months, which of the following have pharmaceutical sales representatives brought to your practice? [Check all that apply.]

1. Drug samples
2. Food or beverages for staff
3. Posters/diagrams for exam rooms
4. Three-dimensional displays of organs/systems
5. Sales aids or electronic visual aids containing product information
6. Brochures for patients or healthcare providers
7. Personal use items (e.g., pens, fidget spinners, sunglass cleaner wipes)
8. Coupons/patient discount cards
9. Other, please specify _____

Q6. Approximately, how many pharmaceutical sponsored dinner meetings with medical experts do you attend each year? ___ [DROP DOWN: '0-20,' '>20']

Q7. In the last 24 months, approximately how many professional conferences have you attended? ___ [DROP DOWN: '0-25', '>25'] [IF ZERO, GO TO Q8)

Q7a. How often do you visit the exhibit hall during professional conferences?

1. Every time
2. Most of the time

3. Some of the time
4. Rarely
5. Never [GO TO Q7c]
6. The conferences I attend do not have exhibit halls [GO TO Q7c]

Q7b. What are your goals for visiting the exhibit hall? [Check all that apply.]

1. Learn about new treatments and technologies
2. Ask specific questions about treatments and technologies
3. Pass time between sessions
4. To pick up giveaways
5. To interact with colleagues or exhibitors
6. To attend mini-presentations
7. For free meals or snacks

Q7c. How often do you attend sessions sponsored by pharmaceutical companies at professional conferences?

1. Every time
2. Most of the time
3. Some of the time
4. Rarely
5. Never

[RANDOMIZE PRESENTATION ORDER OF Q8 AND Q8a]

Q8. How influential are the following information sources to you in informing decisions about prescription drugs?

	Very influential	Somewhat influential	Slightly influential	Not at all influential
a. Journal advertisements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Sales aids with product information from pharmaceutical sales representatives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Commercial drug websites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Sponsored conference sessions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Direct-to-consumer advertising (e.g., television advertisements)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Dinner talks sponsored by pharmaceutical companies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Key experts in the field presenting at conferences	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Colleagues/peers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Online communities of healthcare providers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Q8a. How influential are the following information sources to your colleagues in informing decisions about prescription drugs?

	Very influential	Somewhat influential	Slightly influential	Not at all influential
a. Journal advertisements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Sales aids with product information from pharmaceutical sales representatives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Commercial drug websites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Sponsored conference sessions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Direct-to-consumer advertising (e.g., television advertisements)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Dinner talks sponsored by pharmaceutical companies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Key experts in the field presenting at conferences	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Colleagues/peers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Online communities of healthcare providers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[RANDOMIZE PRESENTATION ORDER OF Q9 AND Q9a]

Q9. Have you done any of the following activities during the last 24 months?

	Yes	No
a. Given a talk or conference presentation on behalf of a pharmaceutical company	<input type="checkbox"/>	<input type="checkbox"/>
b. Served as a consultant for a pharmaceutical company	<input type="checkbox"/>	<input type="checkbox"/>
c. Participated as an investigator in a clinical trial or other research study funded by a pharmaceutical company	<input type="checkbox"/>	<input type="checkbox"/>

Q9a. Are you aware of any colleagues who have done any of the following activities during the last 24 months?

	Yes	No
a. Given a talk or conference presentation on behalf of a pharmaceutical company	<input type="checkbox"/>	<input type="checkbox"/>
b. Served as a consultant for a pharmaceutical company	<input type="checkbox"/>	<input type="checkbox"/>
c. Participated as an investigator in a clinical trial or other research study funded by a pharmaceutical company	<input type="checkbox"/>	<input type="checkbox"/>

Q10. In the last year, how often have you interacted with pharmaceutical companies online (e.g., speaking with a sales representative via Skype, viewing a product presentation on a website)?

1. More than once a week
2. About once a week
3. About once a month
4. A few times a year
5. Once a year or less
6. Never

Q11. Do you use online sites to interact with other healthcare professional colleagues?

1. Yes
2. No **[GO TO Q12]**

Q11a. How often do you use these sites for the following activities:

	Always	Often	Sometimes	Rarely	Never
a. Posting information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Responding to others' posts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Moderating discussions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Reading posts and information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Browsing the site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Q11b. Do you participate in these sites to:

	Yes	No
a. Seek colleague opinions	<input type="checkbox"/>	<input type="checkbox"/>
b. Provide advice to others	<input type="checkbox"/>	<input type="checkbox"/>
c. Experience camaraderie	<input type="checkbox"/>	<input type="checkbox"/>
d. To post or read about patient issues	<input type="checkbox"/>	<input type="checkbox"/>
e. To post or read about healthcare insurance provider issues	<input type="checkbox"/>	<input type="checkbox"/>
f. To post or read about office management issues	<input type="checkbox"/>	<input type="checkbox"/>
g. To post or read about issues with pharmaceutical representatives	<input type="checkbox"/>	<input type="checkbox"/>

[CLINICAL TRIAL KNOWLEDGE AND TRAINING]

The next few questions are about clinical trial information.

Q12. What types of clinical trial information would you like to see in professional promotional materials? [Check all that apply.]

1. Sample (e.g., population inclusion/exclusion criteria, number enrolled and dropouts, etc.)

2. Study design (e.g., blinded or not, cohort study, length of trial, etc.)
3. Number of trials conducted
4. Summary of results
5. Statistical findings
6. Subgroup analyses
7. None [GO TO Q15]

Q13. In general, how much information about the clinical trial *methodology* (e.g., sample, study design, etc.) should be included in professional promotional materials?

1. All information
2. A moderate amount
3. A minimal amount
4. None

Q14. In general, how much information about the clinical trial *outcome* should be included in professional promotional materials?

1. All information
2. A moderate amount
3. A minimal amount
4. None

Q15. How comfortable are you interpreting clinical trial *methodology* (e.g., sample, study design, etc.) information?

1. Very
2. Somewhat
3. A little
4. Not at all

Q16. How comfortable are you interpreting clinical trial *outcomes* information?

1. Very
2. Somewhat
3. A little
4. Not at all

Q17. How often do you consider clinical trial data when deciding which drugs to prescribe to your patients?

1. Every time
2. Most of the time
3. Some of the time

4. Rarely
5. Never

Q18. How much formal training have you had regarding clinical trial *methodology* (e.g., sample, study design, etc.)?

1. A lot
2. A moderate amount
3. A minimal amount
4. None

[FDA APPROVAL OF PRESCRIPTION DRUGS]

The next few questions ask about FDA approval and prescription drugs. FDA knows that the approval process for pharmaceutical products is quite complex and that it sometimes uses terminology unfamiliar to many medical professionals. The following questions ask about your familiarity with certain terms. Please answer using your own words and based on your existing knowledge. We ask that you do not consult other sources before answering. It is important for FDA to understand if terms are unclear or confusing so it can improve the language it uses for medical professionals. Please note that FDA does not regulate the practice of medicine and nothing in this questionnaire should be interpreted in such a way.

Q19. Can you describe your understanding of what FDA approval of prescription drugs means?

Q20. Please check the statement that best describes your understanding of how FDA regulates prescription drug promotion.

1. FDA does not monitor promotional activities once a prescription drug is approved.
2. FDA reviews all promotional materials before they are released.
3. FDA regulates prescription drug promotion, but does not generally require review before release.
4. I'm not sure how FDA regulates prescription drug promotion.

Q21. When prescribing a drug, how important is it to you that the drug is FDA-approved for that particular indication?

1. Very important
2. Somewhat important
3. A little important
4. Not at all important
5. It depends [GO TO Q21a]

Q21a. Please explain your answer.

Q22. How often do you prescribe a drug for a condition for which it is not approved?

1. Often
2. Sometimes
3. Rarely
4. Never [GO TO Q25]
5. Do not know

Q23. When you prescribe a drug for off-label use, how often do you record the reasons for prescribing the drug?

1. Always
2. Often
3. Sometimes
4. Rarely
5. Never

Q24. When you prescribe a drug for off-label use, how often do you explain to the patient that you are doing so?

1. Always
2. Often
3. Sometimes
4. Rarely
5. Never

Q25. In your own words, what is an accelerated approval drug?

Q25a. How comfortable are you prescribing an accelerated approval drug?

1. Very comfortable
2. Moderately comfortable
3. Somewhat comfortable
4. Not at all comfortable
5. I'm not sure what an accelerated approval drug is

Q26. “Scientific exchange” is a complex concept in FDA regulation of pharmaceutical products. In your own words, how would you explain “scientific exchange” to a colleague?

I am not sure what “scientific exchange is.”

Q27. Now we want to understand your perspective on “biosimilar.” In your own words, what is a “biosimilar”?

I am not sure what “biosimilar” is. [\[GO TO Q28\]](#)

Q27a. How comfortable are you prescribing “biosimilar” products?

1. Very comfortable
2. Moderately comfortable
3. Somewhat comfortable
4. Not at all comfortable
5. I am not sure what “biosimilar” is

Q28. Suppose Drug X is FDA approved for use A. Please mark your agreement with the following statement:

Drug X is safe and effective for use A.

1. Strongly agree
2. Somewhat agree
3. Somewhat disagree
4. Strongly disagree

Q29. Suppose Drug Y is FDA approved for use B and other products containing the same active ingredient are approved for uses B and C. However, Drug Y is not FDA approved for use C. Please mark your agreement with the following statement:

Drug Y is safe and effective for use C.

1. Strongly agree
2. Somewhat agree
3. Somewhat disagree
4. Strongly disagree

[OPIOID PRESCRIBING]

The next few questions are about the use of prescription drugs for chronic pain.

Q30. During the last three months, for about how many patients have you prescribed opioids for chronic pain?

1. None
2. 1-5
3. 6-10
4. 11-20
5. 21 or more
6. Don't know or not sure

Q30a. Is the number of patients you prescribed opioids for chronic pain in the last 3 months relative to 12 months ago:

1. The same
2. Less
3. More

Q31. During the last 12 months, have you read or attended an educational event that provided information about opioids from one of the following sources? (Check all that apply.)

1. Presentation at the hospital or conference (not pharmaceutical-sponsored)
2. Online presentations or webinars (not pharmaceutical-sponsored)
3. Pharmaceutical-sponsored dinner, workshop, or conference session
4. Read articles in medical journals
5. Read prescribing information (PI) or Risk Evaluation or Mitigation Strategy (REMS) materials
6. Read pharmaceutical promotional materials [GO TO Q31a AND Q31b]
7. Other, please specify _____
8. I haven't read or attended an event related to this topic during the last 12 months

Q31a. How often do these materials or events mention abuse potential?

1. Always
2. Often
3. Sometimes
4. Rarely

5. Never

Q31b. Promotional materials for opioid products provide an appropriate balance of benefits and risks.

1. Strongly agree
2. Somewhat agree
3. Neither agree nor disagree
4. Somewhat disagree
5. Strongly disagree

Q31c. In your opinion, what resources are most helpful to you as you work to ensure you are prescribing opioids in as safe and effective a manner as possible?

Q32. Which of the following statements best represents your opinion about abuse deterrent formulations (ADF)?

1. An ADF of a drug will have a lower addictive potential than a non-ADF of the same drug.
2. An ADF of a drug will have the same addictive potential as a non-ADF of the same drug.
3. An ADF of a drug will have a higher addictive potential than a non-ADF of the same drug.
4. I don't know.

Q32a. Which of the following do you believe are true about ADFs of opioids? For each question, please say whether you believe it is true, false, or not sure.

	True	False	Not Sure
a. ADFs are the same as their non-ADF counterparts except that they cannot be abused.			
b. ADFs start to work more slowly than their non-ADF counterparts.			
c. ADFs use different mechanisms for preventing manipulation of opioid medications.			
d. ADFs have been proven to reduce the most common route of abuse.			

Q32b. In your opinion, in the last year has the content of promotional materials for opioid products contained more or less information on abuse potential?

- __More
 __Less

__No change

Q32c. In the last six months, do you recall seeing prescription drug promotion that included information about:

	Yes	No	Not Sure
i. Non-opioid analgesics			
ii. Medication-assisted treatment (MAT) for opioid deterrence			
iii. Opioid reversal agents			

[DEMOGRAPHICS]

[Q33-Q35 ARE ONLY TO BE ASKED OF PHYSICIAN RESPONDENTS; ALL OTHERS GO TO Q36]

Q33. Do you consider yourself a primary care physician?

1. Yes
2. No

Q34. Please indicate the type of degree you hold:

1. Doctor of Medicine (M.D.)
2. Doctor of Osteopathic Medicine (D.O.)

Q35. What year did you graduate from medical school? _____ [DROP DOWN RANGE DESCENDING: 2017 to 1935]

Q36. How many years have you been practicing?

1. Less than 5
2. 5 to 10
3. 11 to 15
4. 16 to 20
5. More than 20

Q37. During your last normal week of practice, how many patient visits did you have at all office locations? Number of patient visits ____

Q38. Approximately, how many prescriptions do you write in a typical week? ____

Q39. In the last year, how often have you prescribed a brand-name drug when an equivalent generic was available because the patient asked for the brand-name drug specifically?

1. Often
2. Sometimes
3. Rarely
4. Never

Q40. In which state is your practice based? **[DROP DOWN MENU OF STATES]**

Q41. How many physicians (including yourself) are associated with the practice you work in? (Please include all practice locations you work in.)

Q42. How many physicians' assistants and/or nurse practitioners (including yourself) are associated with the practice you work in? (Please include all practice locations you work in.)

Q43. Which of the following best describes the practice location you work in most often (i.e., where you spend the most hours per week)?

1. Private solo or group practice
2. Freestanding clinic/urgicenter (not part of a hospital outpatient department)
3. Non-Federal Government clinic (e.g., state, county, city, maternal and child health, etc.)
4. Federal Government operated clinic (e.g., Veterans Affairs, military, etc.) **[GO TO Q43a]**
5. Health maintenance organization or other prepaid practice (e.g., Kaiser Permanente)
6. Community Health Center (e.g., Federally Qualified Health Center (FQHC), federally funded clinics or "look alike" clinics)
7. Other, please specify _____

Q43a. Is the clinic you work for associated with one of the following?

1. Veterans Affairs
2. Indian Health Services
3. Bureau of Prisons
4. Other: _____

Thank you for participating in this survey. Your answers will help FDA ensure accurate and non-misleading promotion of prescription drugs.

[RECORD TIME TAKEN TO COMPLETE SURVEY]

[WEB PROBES FOR PRETEST]

We would like your feedback on the survey that you completed. This will help FDA improve the survey for future use with healthcare providers.

P1. Were you able to complete the survey in one session?

- Yes
- No

P2. Did you rely on other sources (e.g., Google, colleagues, etc.) to answer questions that you found difficult to answer?

- Yes, please explain: _____
- No

P3. Did you have any difficulty answering the following question?

How influential are the following information sources (journal advertisements, sales aids with product information from pharmaceutical sales representatives, commercial drug websites, sponsored conference sessions, direct to consumer advertising, dinner talks sponsored by pharmaceutical companies, key experts in the field presenting at conferences, colleagues/peers, online communities of healthcare providers) to your colleagues in informing decisions about prescription drugs?

- Yes, please explain: _____
- No

P4. Did you have difficulty selecting your answer from the choices provided (*all information, a moderate amount, a minimal amount, none*) for the following question?

In general, how much information about the clinical trial methodology (e.g., sample, study design, etc.) should be included in professional promotional materials?

- Yes, please explain: _____
- No

P5. Were there other questions that you had difficulty answering?

- Yes, please explain: _____
- No

Thank you for your feedback.