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**SCREENER FOR HEALTHCARE PROFESSIONAL FOCUS GROUPS AND IN-DEPTH INTERVIEWS**

INTRODUCTION

Hello, my name is [Moderator’s Name], and I am calling from the research firm, Lightspeed Health, for a study sponsored by the U.S. Food and Drug Administration. FDA is sponsoring a series of online [focus groups/interviews] to obtain insight about healthcare professionals’ experiences and opinions communicating with patients about a specific type of drug. Each [focus group/interview] will be led by a qualified researcher [FOR FOCUS GROUPS ONLY: and will include about five to eight participants who will be asked to share their thoughts]. The [focus groups/interviews] will be held online via screen-sharing and will last about 90 minutes. Those who participate will receive an incentive as a thank you for taking part in the study.

May I ask you a few questions to see if you are eligible to participate in the study?

Yes	[ ]	<b>[CONTINUE]</b>
No	[ ]	<b>[THANK AND TERMINATE]</b>

Great! Before we begin, you should know that there are no wrong answers to the questions I’m going to ask you. If an answer leads to me ending the call, it just means that you weren’t eligible to participate based on the requirements for this specific study.

[Termination Language]

Thank you for your time. Unfortunately, you are not eligible to participate at this time.

**SECTION 1: SCREENER & DEMOGRAPHIC QUESTIONS**

- In the past five years up to today, have you or a member of your immediate family worked for any of the following types of organizations?  
**[Recruiter: READ LIST AND RECORD]**

A pharmaceutical company	[ ]	<b>&gt; TERMINATE IF YES TO</b>
A research firm or department	[ ]	

U.S. Food and Drug Administration (FDA)	[ ]	<b>ANY</b>
National Institutes of Health (NIH)	[ ]	
Centers for Medicare and Medicaid Services (CMS)	[ ]	
Centers for Disease Control and Prevention (CDC)	[ ]	
U.S. Department of Health and Human Services	[ ]	

2. When, if ever, was the last time you participated in a research study, such as an interview or a group discussion? [Recruiter: **DO NOT READ LIST**]

Within the past three months	[ ]	> <b>TERMINATE</b>
Over three months ago	[ ]	> <b>CONTINUE</b>
Never	[ ]	> <b>CONTINUE</b>

3. Which of the following best describes your occupation? [Recruiter: **READ LIST**]

Physician (MD, DO)	[ ]	> <b>CONTINUE</b>
Pharmacist	[ ]	> <b>CONTINUE</b>
Nurse practitioner	[ ]	>
Physician assistant	[ ]	> <b>CONTINUE</b>
Other healthcare professional [Specify ____]	[ ]	> <b>TERMINATE</b>

4. Are you currently practicing medicine [Recruiter: replace “practicing medicine” with “dispensing medicine” if Q3=Pharmacist] in the USA?

Yes [What is the zip code of your primary practice location (i.e., where you see the most patients)? ____]	[ ]	> <b>CONTINUE</b>
No	[ ]	> <b>TERMINATE</b>

**[Recruiter: IF Q3=Pharmacist AND Q4=Yes, SKIP TO Q7]**

Physician, Nurse Practitioner, and Physician Assistant Only Questions:

5. In what medical specialty do you currently practice?

Rheumatology	[ ]	> <b>CONTINUE</b>
Oncology	[ ]	>

Hematology	[ ]	CONTINUE
		>
Hematology/Oncology	[ ]	CONTINUE
Dermatology	[ ]	> CONTINUE
Nephrology	[ ]	>
Gastroenterology	[ ]	>
Other	[ ]	> <b>TERMINATE</b>

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

Community hospital	[ ]	> <b>SKIP TO Q8</b>
Academic hospital	[ ]	> <b>SKIP TO Q8</b>
Outpatient clinic	[ ]	> <b>SKIP TO Q8</b>
Private/group practice	[ ]	> <b>SKIP TO Q8</b>
Other outpatient setting (e.g., infusion center, dialysis clinic)	[ ]	> <b>SKIP TO Q8</b>
Other [Specify ____] {RECORD}	[ ]	> <b>SKIP TO Q8</b>

Pharmacist Only Question:

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

Community hospital	[ ]	> <b>CONTINUE</b>
Academic hospital	[ ]	> <b>CONTINUE</b>
Community pharmacy/chain drug store	[ ]	> <b>CONTINUE</b>
Outpatient clinic	[ ]	> <b>CONTINUE</b>
Other outpatient setting (e.g., infusion center, dialysis clinic)	[ ]	> <b>CONTINUE</b>
Other [Specify ____] [RECORD]	[ ]	> <b>CONTINUE</b>

All Audience Questions:

8. How long have you been practicing?

_____ years [RECORD]	[ ]	> <b>CONTINUE</b>
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**[Recruiter: PLEASE AIM TO RECRUIT A MIX OF YEARS OF PRACTICE ACROSS ALL [GROUPS/INTERVIEWS].**

9. In an average year, what percentage of your work time is spent 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.

50% or more	<input type="checkbox"/>	> <b>CONTINUE</b>
Less than 50%	<input type="checkbox"/>	> <b>TERMINATE</b>

In this study, we will focus on biological products other than vaccines. Biological products are medications derived from a living organism, such as humans, animals, micro-organisms or yeast. Examples of the types of FDA-approved biological products we'll discuss in the [focus groups/interviews] include Humira, Enbrel, Remicade, Rituxin, Herceptin, Neulasta, and Neupogen.

10. When was the last time you prescribed [Recruiter: replace “prescribed” with “dispensed” if Q3=Pharmacist] a biological product to a patient?

Never	[ ]	> <b>TERMINATE</b>
Within the past 6 months	[ ]	> <b>CONTINUE</b> (To be considered first-tier recent)
More than 6 months up to 1 year	[ ]	> <b>CONTINUE</b> (To be considered first-tier recent)
More than 1 year but less than 2 years	[ ]	> <b>CONTINUE</b> (to be considered second-tier recent)
More than 2 years ago [How long? _____]	[ ]	> <b>CONTINUE</b>
Don't Know	[ ]	> <b>TERMINATE</b>

To be asked only of respondents who indicate they have recent/within the last year (first 2 categories in Q10) experience prescribing biologics:

11. To about how many different patients have you prescribed [Recruiter: replace “prescribed” with “dispensed” if Q3=Pharmacist] biological products **in the past year**?

<b>None</b>	[ ]	> <b>CONTINUE</b> (see note below)
Fewer than 1 per month	[ ]	> <b>CONTINUE</b>
1 to 3 patients per month	[ ]	> <b>CONTINUE</b>
3 to 5 patients per month	[ ]	> <b>CONTINUE</b>
More than 5 patients per month	[ ]	> <b>CONTINUE</b>
Don't Know	[ ]	> <b>CONTINUE</b>

[Recruiter: Initially, only participants with **recent** experience prescribing or dispensing biologics should be scheduled for [focus groups/interviews], i.e. those that answered Q10 with timeframes of “within the past 6 months” or “more than 6 months up to 1 year”; these participants should be scheduled immediately for [focus group/interview] participation. However, do not immediately terminate participants who indicate it has been longer than 1 year. Ask these participants the

rest of the screening questions and use script at end of screener: “Thank you for your time today. We will follow up with you soon if you are eligible for the study.”]

12. How many **different types of biological products** have you prescribed [Recruiter: replace prescribed with dispensed if Q3=Pharmacist]?

..... [Recruiter: **RECORD A NUMBER**] [ ] > **CONTINUE**

13. Have you ever prescribed [Recruiter: replace “prescribed” with “dispensed” if Q3=Pharmacist] a specific type of biological product called a biosimilar? The FDA-approved biosimilars currently on the market are Renflexis, Inflectra, and Zarxio,

Yes	[ ]	> <b>CONTINUE</b>
No	[ ]	
Don't Know	[ ]	

I have a few more questions to ensure that we speak to a variety of people.

14. What is your gender? [Recruiter: **DO NOT READ LIST**]

Female	[ ]	> <b>CONTINUE</b>
Male	[ ]	
	[ ]	

[Recruiter: **PLEASE AIM TO RECRUIT A MIX OF GENDER [FOR EACH GROUP/FOR THE INTERVIEWS]**]

15. Are you Hispanic or Latino?

Yes	[ ]	> <b>CONTINUE</b>
No	[ ]	

16. Which of the following best describes your race? You may choose one or more categories as they apply. [Recruiter: **READ AND RECORD ALL THAT APPLY**]

White	[ ]	> <b>CONTINUE</b>
Black or African American	[ ]	
Asian	[ ]	
American Indian or Alaska Native	[ ]	
Native Hawaiian or Other Pacific Islander	[ ]	
	[ ]	

[Recruiter: **PLEASE AIM TO RECRUIT A MIX OF RACE/ETHNICITIES FOR EACH GROUP, and ACROSS THE INTERVIEWS. ANYONE WHO SELECTS MORE THAN ONE RACIAL CATEGORY SHOULD BE CONSIDERED OF MIXED RACE, AND BE COUNTED AS SUCH FOR THE PURPOSES OF DIVERSITY.**]

17. What is your age?

..... [RECORD NUMBER] ..... [ ] > CONTINUE

**[Recruiter: IF PARTICIPANT HAS PRESCRIBED A BIOLOGIC BUT NOT IN PAST YEAR, THANK FOR TIME AND INDICATE YOU MAY FOLLOW UP LATER TO SCHEDULE WITH THEM]**

Thank you for your time today. We will follow up with you soon if you are eligible for the study.

**[Recruiter: SECTION 3: SCRIPT FOR INVITATION TO PARTICIPATE IN [FOCUS GROUP/INTERVIEW]**

We would like to invite you to participate in [a focus group/an interview]. The [focus group/interview] will take place online, and we will be asking about your experiences and opinions about communicating with patients about biologic drugs and will get your feedback on some educational materials about them. The [focus group/interview] will be audio and video recorded.

The [focus group/interview] will last approximately 90 minutes, and you will receive [AMOUNT per amounts stated in the protocol memo] in appreciation of your time.

Your opinions are very important to us.

18. Are you interested in participating in this study?

Yes ..... [ ] > CONTINUE  
No ..... [ ] > **TERMINATE**

19. The focus group will take place on DATE at TIME online. Will you be available to participate at this time?

Yes ..... [ ] > CONTINUE  
No ..... [ ] > **HOLD IN CASE SCHEDULE CHANGES**

We have interview slots available at the following dates and times [READ LIST]. Will you be available to participate at any of these times?

Yes [SCHEDULE FOR SELECTED SLOT] ..... [ ] > CONTINUE  
No ..... [ ] > **HOLD IN CASE SCHEDULE CHANGES**



We will send you a confirmation email with instructions for the [group/interview].  
Could you please confirm your name, email address and phone number?

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

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

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

Your participation in this study is very important. If for some reason you will not be able to attend, please let us know right away so we can find someone to take your spot. You can call us anytime at [PHONE #], and if we are not here, please leave a message and we will return your call.