

**Dairy Farmers' Decision-Making to Avoid Drug Tissue Residue in Dairy Cows
Solicitation # 1078187**

**Mental Models Interview Protocol
(Final Version, After Pre-test)**

Invitation to Participate:

Hello Mr./Ms. XXXXX, this is <name>. I'm a researcher with Decision Partners. We are working with veterinarians at the U.S. Food and Drug Administration to learn from dairy farmers how they make medical treatment decisions for their dairy herd. This valuable input will help FDA communicate more useful information to dairy farmers on issues related to treatment.

As part of this project, we're inviting dairy farmers like you to participate in a phone interview. The interview will be kept strictly confidential. It will take about 45 minutes and can be scheduled at a time that is convenient for you. We will provide a \$50 honorarium in appreciation for your time. Would you be willing to participate in a phone interview?

If asked how we got their name: Our collaborators at FDA worked with their state government partners and other veterinarians to identify lists of dairy farmers.

If no: Thank you for your time and consideration. Is there a particular reason why you do not want to, or are not able to participate at this time?

If yes: Thank you.

Screening Questions

I'd like to ask you a few questions to make sure you meet the criteria for our research project.

S1 Screen for eligible dairy farming operation - matching operation name on the list

S2 Screen for appropriate interviewee - person who has responsibility for overseeing medical treatment of dairy herd. This will likely be the dairy herdsman for a large operation or an owner if a small operation. For a large operation, it will not likely be the owner.

S3 Farming operation zip code

Thank you, I'd like to schedule an interview with you. When would be a good time for us to schedule an interview? Or, we can conduct the interview now, if you are free.

Introduction

(State this paragraph only if calling back) Hello, this is <name> with Decision Partners. I'm calling back for our scheduled interview as part of the project we are conducting with veterinarians at the U.S. Food and Drug Administration. Thank you for agreeing to participate. Your input today will provide valuable insight that will help FDA communicate more useful information to dairy farmers on issues related to medical treatment of dairy cows.

Our conversation today will be very open-ended. I have a list of questions to help guide our discussion, but please feel free to raise anything that comes to mind as we go along. In this kind of interview, there are no right or wrong answers. All of your comments are important to us. You can also choose to not answer a question at any time, for any reason.

I also want to assure you that this interview is strictly confidential to the Decision Partners' research team. The people we are working with at FDA do not know who we are interviewing. We will not share any information with the FDA that could be used to identify you or your farming operation, and we will not identify you as the source of any comments in our report. Our report will consolidate all of the responses from everyone we interview.

Having said that, I would like your permission to record our conversation to ensure that my notes are complete. Your responses will be kept confidential and you will not be able to be identified through the recording. May we proceed on that basis? *(Confirm with Interviewee on the recording that consent is granted and proceed appropriately. If consent is not given, take detailed handwritten notes.)*

Interview Opening

Our discussion will take place in three parts. First we'll talk briefly about your farming operation and your role on the farm. Next, we'll discuss the decisions you make about treating or culling your dairy cows. Finally, we will discuss the information that might be useful to you when treating and culling dairy cattle.

Interviewer Note: *This interview may touch upon topics that are very sensitive to the Interviewee. If the Interviewee seems to be uncomfortable with any question during the interview, remind him or her as needed:*

- *Your participation in this research and the information you provide is confidential to the Decision Partners' research team. We will not share any information with FDA that could be used to identify you or your farming operation.*
- *In this kind of an interview, there are no right or wrong answers. All of your comments are important to us. We want to know your thoughts and perspectives on treating dairy cattle.*
- *I can turn the tape off and take handwritten notes if that would make you more comfortable.*
- *For whatever reason, if you are uncomfortable with a question, you don't have to answer it.*

Part 1: Dairy farm operations

First, let's begin by talking generally about your dairy farm and your role on the farm.

1. Please briefly describe your dairy farming operations.
 - *If not mentioned:* What is the average number of cows you milk?
 - How many years has the dairy farm been in operation?
 - About how many workers do you have on your dairy farm?
 - Where and how do you sell your milk, e.g. through a Co-op?
2. Can you briefly describe your key roles on the dairy farm?

- *If not mentioned:* What about any roles specifically related to medical treatment of dairy cows?
- Can you briefly describe your background with dairy farming?
- Have you had any specific training on how to medically treat dairy cows? *If so:* Please describe.

3. In general, how would you describe the key goals for your farm overall?

- What are the biggest challenges you're encountering today in trying to achieve your goals? *{Probe beyond milk price.}*

Part 2a: Treatment - Making Treatment Decisions

Our conversation today will focus on how you and your staff make decisions regarding the medical treatment of your dairy herd.

4. What are the most common conditions that you are currently treating in your dairy herd?

5. How are decisions regarding the treatment of those conditions typically made on your farm? *If not mentioned:*

- Who typically makes these decisions? Who is ultimately responsible?
- Who typically carries out the decisions? *If someone other than the interviewee:* What is this person's general background?
- *If not mentioned:* Do you follow any standard practices or operating procedures? *If yes:* Could you please briefly describe them?
- *If not mentioned:* Does a veterinarian have a role in treating dairy cows on your farm? *If yes:* Could you please describe his or her role?

6. About how many cows are culled on your farm in a year?

- *If they have difficulty with this question:* I'm just looking for a round figure. Or, if you prefer, the approximate percentage of your herd that is culled in a year.
- Who makes these decisions and how are they made?
- What's the number one reason an animal is culled on your farm?
- How do you sell your cows for meat? *(If an example is needed:* Do you sell directly to the meat packer or in some other way? Why?

To focus our discussion, I'd like you to walk me through a typical case you recently faced with a cow that you treated but eventually culled and sold for meat because she didn't respond to treatment.

7. Can you briefly describe the situation? What was her condition?

- What were your primary goals for treating this cow?

8. Which drug did you use to treat this cow and why? *Be sensitive to overlap with Question 5. Tie follow up questions back to responses given in Question 5.* What were the key things you took into account when making your decision?

- How did you determine the medical dose? What dose was given? *{Listen for compliance with label or regulations - probe into more detail}.*
- How was the drug given? Why? *This is also called route of administration and examples include intravenous, intramuscular, and oral. When asked why, listen for compliance with label or regulations - probe into more detail.*
- Who gave the drug? *If someone other than the interviewee:* How was this decision communicated?
- Was a veterinarian involved in any way in this specific case? Why (or why not)? How?
- *If not mentioned:* Did you decide to use the drug in some way other than what is described in the drug's label? Why?

9. *If not mentioned:* Did you consider not treating this cow? Why?

- What were your other alternatives? What were the pros and cons of these options?

10. What did you do next to manage this cow's treatment? *Be sensitive to overlap with Question 5. Tie follow up questions back to responses given in Question 5.*

- *If not mentioned:* Was she marked or specially-identified in any way? Why (or why not)? How? How long?
- *If not mentioned:* Was she separated from the herd? Why (or why not)? How? How long?
- Was her treatment documented in any way? *If yes:* How? Who was responsible for documenting the treatment?

11. How long after treatment did you decide to cull the cow?

- How was the cow culled? *For example, did you sell her? Did you have her euthanized? Why?*
 - *If the cow was sold:* How long after her treatment did she leave the farm?

12. If your cow had responded to treatment, and if you had decided not to cull, how would you have determined when to return her to milking production?

13. Are there other situations where you have treated a cow even though you knew she would likely not be returned to production?

- Can you give me an example?
- Why would you treat the cow in this case?
- Would you handle this cow's treatment any differently than you described in your earlier example? How? Why?

Part 2b: Treatment - Avoiding violative (above tolerance) drug tissue residues

Thank you. Now I'd like to turn our discussion to the topic of drug residues in dairy cows sold into the meat supply *for beef*.

14a. What first comes to mind when you think about drug tissue residues?

- What about avoiding drug tissue residues in dairy cows that are culled?
- Do any questions come to mind when you think about avoiding drug tissue residues?

So that we are on the same page in our discussion, by avoiding drug tissue residues, we mean making sure, through treatment and management practices, that the meat from dairy cows slaughtered and added to the meat supply does not contain levels of medical drugs that are higher than allowed by government regulations.

14b. Do any questions come to mind when you hear this definition?

Note: If they ask if this means "meat withholding", say: Meat withholding may be considered one management practice to avoid tissue residues.

15. How important would you say it is to avoid drug tissue residues in dairy cows that are culled? Would you say it is: very important, somewhat important, or not important? Why?

16. How, if at all, can drug tissue residues be avoided?

Listen for: consulting a veterinarian, choosing the right treatment, administering it the right way (following the label directions), maintaining treatment records, testing. Probe into these topics - why is that important?

- Anything else?
- Of the things that you've mentioned, what is the most effective? Why?

17. How familiar are you with any rules and regulations regarding drug tissue residues? Would you say you are: very familiar, somewhat familiar, or not familiar?

- How did you learn about these rules and regulations?
- Who puts out these rules and regulations? *If government is mentioned:* which government agency? *If an association is mentioned:* which association?
- Can you describe a typical rule or regulation?
- How do these regulations compare to those designed to avoid residues in milk?

18. Do you think these regulations on drug tissue residues in culled dairy cattle are: very appropriate, somewhat appropriate, or not appropriate? Please explain. *Listen for: Too burdensome, not effective, unfair. Probe for more details.*

- How could they be improved?

19. How well would you say these rules and regulations are followed on your farm? Would you say: very well, somewhat well, or not very well? Please explain your rating.

- Is there anything that is done particularly well on the farm?
- What are the key challenges and barriers to carrying out the rules and regulations on your farm? *Listen for: lack of time, lack of familiarity with rules and regulations, worker issues. Probe for more details.*
- What could be done to improve how these rules and regulations are followed on your farm?

20. If the cow in your earlier example had drug tissue residues above the limit allowed by the regulations, how likely is it that it would be detected as being in violation? Would you say: very likely, somewhat likely, or not likely? Please explain your rating.

- How would the violation be detected?
- What would happen next? What actions might be taken and by whom?
- What is the worst thing that could happen to a dairy farmer if a violation was detected? How likely would this be?

21. *If not mentioned:* What would you say is the number 1 cause of drug tissue residue violations in dairy cattle?

22. Would you say that the actions taken against dairy farmers who have a violation are: very effective, somewhat effective, or not effective at increasing the compliance of dairy farmers? Please explain your rating.

- How could they be improved to be more effective?

23. Have you ever had a cow for which a violation was detected? *If yes:*

- Can you describe what happened?
- Is there anything that is done differently on your farm now because of this?

Part 3: Communications

Thank you. Finally, I'd like to ask your thoughts on the types and sources of information that can help dairy farmers when treating and culling dairy cattle.

24. Where do you or your staff get most of your information about treating your dairy cattle? Why do you use these sources? *{If label is mentioned ask question 26}.*

- Where would you first go to learn more about avoiding drug tissue residues in your dairy cows?

25. How often would you say you or your staff consult drug labels when treating your cows? Would you say very often, somewhat often, not very often or never? Please explain your answer. *If they say never, move to last bullet.*

- *(Skip if "never")* When do you most often go to the drug label?
- *(Skip if "never")* Where do you get the drug label information?
- *(Skip if "never")* What information do you generally use on the drug label? Why?
- *(Skip if "never")* Would you say this information is very useful, somewhat useful, or not useful? Why?
- *Ask for all:* How could the drug label be improved to be more useful?

26. I'd like you to think through a list of sources that farmers may go to, and I'll ask you to rate how useful each of these sources are to you. *{Follow up for explanation on "very useful" or "not useful", if time permits, and if not already discussed.}*

- Your veterinarian? Would you say: very useful, somewhat useful, or not useful to you?
- Other dairy farmers? Ask same rating for each.
- A dairy co-operative representative?
- Dairy management handbooks of any kind? Which one(s)?
- Any training or certification courses? *Ask follow-up:* How likely would you be to participate in a training course specifically on avoiding milk and drug tissue residues? Would you be very likely, somewhat likely or not likely?
- Dairy or farm trade journals?

- Drug distributors or manufacturer's representatives?
 - Any sources on the Internet? Which sources?

27. Are there any barriers that limit you and your staff's ability to find and use the information you need to help you make decisions about how to treat or when to cull your dairy cows? Please explain.

- What could be done to help you and your staff, better find and use the information you need?

Closing

You've been very helpful and I appreciate the time you've taken to speak with me today. We are almost finished.

28. Is there anything else that came to mind while we were talking that you would like me to include in our research?

29. If you could offer one piece of advice to FDA regarding how they could help farmers avoid drug tissue residues, what would that be?

Demographic Questions

30. What is your age? Are you in your 20s, 30s, 40s, 50s, or 60 and above?

31. What is the highest level of education that you have completed? Below high school, high school graduate, some college or university, associate or technical education, college or university graduate, post-graduate education.

32. Record gender.

Thank you, again, for the time you've taken to share your knowledge and experience on this issue. Your thoughts and ideas will be very valuable to our team in learning about how dairy farmers, like you, make decisions, and about the best ways to communicate with them.

Turn off recording equipment. As I mentioned at the beginning of our conversation, we will send you a \$50 honorarium in appreciation for your time. May I have the address where you would like us to send the check?

If you have any questions about this research, you can get in touch with Sara Eggert at Decision Partners at (877) 588-9106 (*or take their number and say that we will have someone contact them*). You may also contact Martine Hartogensis at FDA at (240) 453-6833 for more information.