

Focus Group Report on Consumer Perceptions of Prescription Drug Communications

Submitted to:



U.S. Food and Drug Administration

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Chapter I: Introduction

Background

To effectively inform consumers about newly identified risks of medical products, the U.S. Food and Drug Administration (FDA) must understand how consumers think about both the risks and benefits of medical products. To this end, FDA conducted focus groups in the Spring of 2010 as formative research to provide critical information needed about target audiences. Findings from this initial set of focus groups provided insight into the needs, decision-making processes, and misperceptions of prescription drug users and caregivers.

FDA used the 2010 focus group findings in its development of draft messages to provide consumers with the better context they need in which to place new risk information more completely. Among the many findings from the 2010 focus groups that FDA addressed in its messages were the following:

- Confidence in brand name prescription drugs is higher because they are perceived as being stronger and more effective than generic drugs.
- A fear of potential side effects is the single greatest deterrent from filling and taking prescription drugs.
- The perceived threshold for drug effectiveness appears to be lower than the perceived threshold for drug safety.
- A lack of research was identified as the main reason for newly discovered risks.
- FDA is often perceived as rushing the approval process in response to manufacturer pressure to quickly get drugs on the market.
- Caregivers are more willing to take risks with their own health than with their children's health.
- Profit margins are perceived as outweighing safety concerns.
- FDA's role in testing and approving prescription drugs is unclear.

FDA drafted a series of 18 messages related to these findings. This report summarizes a second set of focus groups conducted in the Fall of 2011 used to test FDA's messages. The objective of this qualitative research is to assess whether FDA's messages fill in the gaps in consumer perceptions, whether they lend credibility to the FDA as a source of risk and benefit information, and whether they are useful for decision-making purposes (especially for newly emerging risks). This report includes findings from participants' reactions to the messages.

Study Design and Methodology

FDA contracted with Olchak Market Research (OMR) and ICF Macro to conduct a series of focus groups to collect public input as it assessed the potential effectiveness of its messages in successfully communicating with intended audiences. Focus group methodology was chosen for this project as a research technique offering exploratory, formative, and information-rich data.

Focus group discussions are a flexible tool for exploring respondent awareness, behavior, concerns, beliefs, experiences, motivation, operating practices, and intentions related to a particular topic and sub-issues. Focus groups are particularly useful for generating an in-depth understanding of issues, because a skilled moderator can amplify individual responses through group comments or individual feedback. In addition, a skilled moderator can follow up or probe certain tangents or views that were unanticipated in the design of the moderator's guide, often yielding new information or additional nuances of existing information. Despite its many advantages, focus group methodology is not without limitations. Findings from focus group discussions are not quantitative, nor can they be generalized to the target population as a whole.

ICF Macro conducted a series of 12 focus groups in September and October 2011. Each focus group included up to nine participants and lasted approximately 90 minutes. A professional moderator led the group discussions, and FDA staff observed each group. The groups were internally homogenous with respect to education and recent experience with prescription drugs. To gather feedback from a mix of participants with different backgrounds, FDA conducted the focus groups in two different geographical locations: Greenbelt, MD and San Antonio, TX. At each of the two locations, the focus groups were segmented by education: Lower education (less than one year of college) and Higher education (one or more years of college credit). The education groups were further segmented by prescription drug use in the last six months: Chronic users, Intermittent users, and Parent/Caregivers. The segmentation of the 2011 focus groups was consistent with the segmentation of the 2010 focus groups.¹

Recruitment. Olchak Market Research (OMR) recruited participants. The contractor and FDA collaborated to produce a Participant Screener (see Appendix A) to recruit individuals from diverse backgrounds. The final screener ensured that the following criteria were met:

- **Prescription Drug Use:** Within the last six months, individuals must have used prescription drugs either on a chronic or intermittent basis, or cared for someone using prescription drugs, as defined below.
 - *Chronic users:* Those who have taken at least one prescription drug on a regular basis (daily, weekly, or monthly) in the last six months.
 - *Intermittent users:* Those who have taken a prescription drug occasionally or on an “as needed” basis in the last six months. Examples given for the purpose of self-classification included taking an antibiotic for a few days up to a few weeks for an infection, or taking a painkiller as needed for migraines or following a minor injury or surgery.
 - *Parents/Caregivers:* Those who have the primary responsibility of caring for a child in their immediate family who is less than 16 years old and is a chronic or intermittent user (as defined above) of a prescription drug.

¹ Although the segmentation of groups was consistent across studies, the criteria used to define education levels in 2011 were slightly different from the criteria used in 2010. To ease recruitment difficulties, participants in 2011 with “some college credit, but less than 1 year” were included in “Lower education” groups rather than “Higher education” groups.

- **Age:** Individuals recruited for the chronic users groups were age 35 or older. Participants in the intermittent groups and parents/caregivers groups were age 21 or older.
- **Language skills:** All participants must have been able to read, understand, and speak English.
- **Work Experience:** Individuals were excluded if they, or someone from their immediate family, worked for any of the following agencies/industries: an advertising agency; a market research firm; a pharmaceutical company; a physician's office, hospital, clinic, or pharmacy; FDA; the National Institutes of Health; the Department of Health and Human Services; or a state health department.
- **Recent Focus Group Participation:** Individuals were excluded if they had participated in another focus group within the past six months.

During the screening process, the recruiter asked participants about their highest level of education completed to segment groups by lower and higher education. The recruiter also collected data on participants' gender and race/ethnicity to ensure a diverse mix of participants within each group.

- **Education:** "Lower education" groups included participants who completed less than high school, high school/received a GED, technical/vocational school, or less than one year of college. "Higher education" groups included participants who completed at least one year of college, an Associate's degree, a Bachelor's degree, or a Master's degree or higher.
- **Gender:** Each group consisted of no less than three members of each gender. Participants were advised during the screening process that these were mixed gender groups.
- **Race/ethnicity:** Each group was a diverse mix of races and ethnicities. The groups reflected the demographics of the surrounding areas. Overall, there was roughly an even split between Hispanic, Non-Hispanic White, and Non-Hispanic Black participants.

Structured telephone interviews were conducted to recruit participants for the study. Two weeks prior to the planned focus group dates, recruiters began placing outgoing telephone calls to recruit individuals. If the potential recruit was not qualified, the recruiter screened other household members for qualification. The recruiter invited individuals who fit the screening criteria to attend the appropriate group and informed them that they would receive \$75 for their participation. As is standard practice in commercial market research, and as has been approved by OMB in the past, this incentive was offered at a regionally appropriate market rate as remuneration. Qualified participants received the incentive at the focus group facility.

A few days before the focus groups took place, participants received flyers that briefly described the purpose of the discussion/interview and stated the date, time, and location, as well as directions to the research facility. As mentioned earlier, six focus groups were conducted in Maryland and six groups were conducted in Texas. Table 1 shows how the focus groups were segmented.

Table 1: Schedule of Focus Groups

Date	Time	Education Level	Medication Use
Greenbelt, MD			
September 12, 2011	6:00 PM–7:30 PM	Lower Education	Chronic Users
September 12, 2011	8:00 PM–9:30 PM	Higher Education	Chronic Users
September 14, 2011	6:00 PM–7:30 PM	Lower Education	Intermittent users
September 14, 2011	8:00 PM–9:30 PM	Higher Education	Intermittent users
September 15, 2011	6:00 PM–7:30 PM	Lower Education	Parent/Caregivers
September 15, 2011	8:00 PM–9:30 PM	Higher Education	Parent/Caregivers
San Antonio, TX			
October 25, 2011	6:00 PM–7:30 PM	Lower Education	Chronic Users
October 25, 2011	8:00 PM–9:30 PM	Higher Education	Chronic Users
October 26, 2011	6:00 PM–7:30 PM	Lower Education	Intermittent Users
October 26, 2011	8:00 PM–9:30 PM	Higher Education	Intermittent Users
October 27, 2011	6:00 PM–7:30 PM	Lower Education	Parent/Caregivers
October 27, 2011	8:00 PM–9:30 PM	Higher Education	Parent/Caregivers

Participant Demographics. Overall, there were 99 focus group participants. Forty-eight people participated in Maryland and 51 participated in Texas. This included 34 chronic users, 34 intermittent users, and 31 caregivers.

Roughly an even mix of women (55%) and men (45%) participated in the groups. Participants ranged in age from 22 to 80 years old, with an average age of 44. About half of the total participants were determined to be in into lower education groups (47%) and about half of the participants were determined to be in into higher education groups (53%).

Across all 12 groups, there was roughly an even mix of Non-Hispanic White (37%), Hispanic (34%), and Non-Hispanic Black (27%) participants. Participants were intentionally recruited to reflect the demographic characteristics of the general population in each location; this resulted in a large proportion of Non-Hispanic Black participants in Maryland and a large proportion of Hispanic participants in Texas. In Maryland, 50% of participants were Non-Hispanic Black, 48% were Non-Hispanic White and 2% (one person) was another race. In contrast, in Texas, 67% were Hispanic, 27% were Non-Hispanic White, and 6% were Non-Hispanic Black. Table 2 presents participants’ demographic information collected during the telephone screening process.

Table 2: Participant Demographics, by Location

Screening Items	Greenbelt, MD		San Antonio, TX		Total	
	N = 48	49%	N = 51	51%	N = 99	100%
Group						
Chronic Users	17	35%	17	33%	34	34%
Intermittent Users	18	38%	16	31%	34	34%
Parent/Caregivers	13	27%	18	35%	31	31%
Total	48	100%	51	100%	99	100%
Gender						
Male	21	44%	24	47%	45	45%
Female	27	56%	27	53%	54	55%
Total	48	100%	51	100%	99	100%
Age						
Average	48.2		40.1		43.6	
Range	22–80 years		23–71 years		22–80 years	
Race/Ethnicity						
Non-Hispanic White	23	48%	14	27%	37	37%
Hispanic	0		34	67%	34	34%
Non-Hispanic Black	24	50%	3	6%	27	27%
Other Minority	1	2%	0		1	1%
Total	48	100%	51	100%	99	100%
Education						
Lower Education	22	46%	25	49%	47	47%
Higher Education	26	54%	26	51%	52	53%
Total	48	100%	51	100%	99	100%
Breakdown by Education Level						
Lower Education						
Less than high school	1	2%	0		1	1%
High school/GED	13	27%	13	25%	26	26%
Technical/vocational school	3	6%	5	10%	8	8%
Less than 1 year of college	5	10%	7	14%	12	12%
Higher Education						
Some college	2	4%	6	12%	8	8%
Associate's degree	2	4%	4	8%	6	6%
Bachelor's degree	11	23%	11	21%	22	22%
Master's degree or higher	11	23%	5	10%	16	16%
Total	48	100%	51	100%	99	100%

*Due to rounding, totals may not add up to 100%

Protection of Human Subjects. ICF Macro's Institutional Review Board (IRB) reviews all research involving human subjects and ensures that such research complies with all Federal regulations. The ICF Macro Office of Human Research Participant Protections' review board approved the proposed procedures and techniques for this research study. Additionally, FDA's IRB (Research Involving Human Subject Committee) determined the study to be in the category of exempt research.

Eligible participants were given an informed consent form when they arrived at the focus group facility (see Appendix B). The form explained the purpose of the project and affirmed participants' willingness to participate. The informed consent statement also informed individuals that their participation was voluntary, that the 90-minute discussion would be recorded and observed by FDA staff, and that their participation and everything said during the discussion would stay private to the extent permitted by law. The moderator also reviewed the content of the informed consent before proceeding with the discussion.

Participants were identified only by first name throughout the recruitment and sign-in processes and during the focus group discussion. Any personal information about participants obtained during recruitment and or focus groups discussion (e.g., age, number of children, and prescription drug use habits) are associated only with the participant's first name and with no other personally identifying information (i.e., phone number, address). No personally identifiable information, including names, was used in the findings from this research.

Conduct of the Focus Groups. Before each focus group began, the moderator talked in person with FDA observers, to review the list of attendees and determine if any potential participants should be eliminated from the group.

All discussions were led by a moderator with extensive experience in focus group research. Moderators used a structured moderator's guide (see Appendix C). According to standard focus group methodology, the moderator's guide began with general topics before delving into more specific topics.

The moderator's guide included the following sections:

- Welcome/ground rules
- General discussion of prescription drugs
- Generic drugs versus brand name drugs
- Side effects
- Research needed for drug review
- Discussing decisions with healthcare providers
- Understanding FDA's role

Each focus group discussion lasted approximately 90 minutes. The moderator began each section of the discussion by asking participants a few general questions about issues related to prescription drugs. The moderator then presented a number of statements about prescription drugs and asked the participants for their own thoughts and reactions. Participants were informed that the statements could be something they might read or hear in a news report or consumer update that would go along with more detailed information about a specific drug.

After the discussion, but before dismissing the participants, the moderator briefly left the discussion and asked FDA observers whether there were any additional questions to be asked of the group participants. Upon completion of the group, participants were thanked for their time and received a \$75 stipend for their participation.

Transcripts and Report Writing. The focus groups were audio- and video-recorded. The discussions were also documented in detailed, word-for-word transcripts. These transcripts were used as a basis for the report of findings. The textual data in the transcripts were reviewed and coded, and the major themes/findings were identified. Supporting comments illustrate these themes in the participants' own words. Consistent with the qualitative nature of this analysis, no attempt was made to quantify the number of comments made on any theme. Where appropriate, findings indicate differences by education level, prescription drug use, and gender. There were no observed differences by focus group location.

Findings for each tested message are summarized in the following chapters. These findings are presented as participants' own words, not as formal recommendations by ICF Macro for FDA to edit, use, or not use the messages in its future communications. See Appendix D for FDA's independently written conclusions based on the findings of this report.

Chapter II: Reactions to Messages about Generic and Brand Name Prescription Drugs

A key finding from the previous study conducted in 2010 was that many participants had more confidence in brand name prescription drugs. In particular, these participants seemed to believe that brand name drugs were stronger and more effective than generic drugs. This perception was reinforced by the lower cost of generic drugs. Few participants were able to explain differences between brand name and generic drugs other than cost. Many participants attributed the higher cost of brand name drugs to the recouping of marketing expenses rather than research and development.

In this current study, the moderator began the discussion by asking participants about their understanding of the differences between generic and brand name drugs. Participants echoed many of the same sentiments and confusion expressed in the previous study, focusing on the difference in cost and questioning whether brand name and generic drugs have the same ingredients and effectiveness.

I think some people still like to get the brand name, though, because you can, like I don't know, something you trust and you always know them. Female, Intermittent, Higher Education, San Antonio, TX

I really can't figure it out...I understand research and development is expensive. I understand that advertising and all that is expensive. But I don't see where the huge difference is between the same drug being \$800 and \$50. And I just, I've always wondered, "What is the difference?" Male, Chronic, Higher Education, San Antonio, TX

I think it's because the pharmaceutical companies want to maximize profits. When you have a generic drug that's widely available you're going to get competition. They have a monopoly when they have the patent on it. So they use their monopolistic powers to extract profits. Male, Intermittent, Higher Education, Greenbelt, MD

And then, when you have the generics, once the patent expires or they open it up to copy the formula, then you get...maybe not as good a quality control. So I generally think of a brand name drug as one that underwent more scrutiny than did the generic. Male, Chronic, Higher Education, Greenbelt, MD

I think sometimes they're a weaker drug, a weaker form of the drug that they're giving you. Male, Chronic, Lower Education, San Antonio, TX

I know in the brand names, like say for pain pills, that the generics don't work as good, they don't last as long as the [brand name] – it's just from an experience. Female, Intermittent, Lower Education, San Antonio, TX

The generic is more basic. It does the same function without the glamour of the packaging; I guess you could say, of what a brand name would require. Male, Chronic, Higher Education, Greenbelt, MD

After a brief discussion of the differences between generic and brand name drugs, the moderator showed participants three statements related to the topic. The sequence in which the statements were presented to participants was balanced to limit order effects. The moderator informed participants that the statements could be something they might read or hear in a news report or consumer update that would go along with more detailed information about a specific drug. The moderator then asked participants for their reactions to, and suggestions for, revising each statement. For all statements shown during the focus groups, the moderator encouraged participants to consider the following set of questions in framing their responses:

- What does this mean to you?
- Does it make sense to you?
- How clear or confusing is it?
- Would you rephrase it?
- How believable is it?
- How does it compare to what your health care provider may have told you?
- Are you surprised by it?

The remaining sections of this chapter summarize participants' feedback on each individual message.

MESSAGE 1—A GENERIC DRUG INCLUDES THE SAME ACTIVE INGREDIENT THAT MAKES A BRAND NAME DRUG WORK. YOUR DOCTOR OR PHARMACIST CAN TALK WITH YOU ABOUT OTHER DIFFERENCES.

In general, participants seemed to understand the statement. Many participants felt that the statement was accurate and to the point. Several participants also said that the statement confirmed what had been told to them by their health care provider, pharmacist, or others in the health care field.

It's telling me that the active ingredient is the same between the name brand and generic, and there might be slightly other components added to the generic that makes a difference. Male, Chronic, Lower Education, Greenbelt, MD

That it pretty much has the same effect as a premium drug, because I've had a pharmacist tell me that. Female, Chronic, Higher Education, Greenbelt, MD

My mother was a nurse, so she would tell me about these things. Male, Intermittent, Higher Education, San Antonio, TX

Some participants said the statement seemed contradictory. These participants commented that while the first sentence in the statement stressed that generic and brand name drugs have the same ingredients, the second sentence suggested that there were differences between the two drugs. As a result, some of these participants became skeptical of the statement.

Well, they're saying it has the same active ingredient, so why would you have to talk to a doctor or pharmacist to find the difference, the other differences? If they have the exact same ingredients, it contradicts what it's actually saying. Female, Chronic, Lower Education, San Antonio, TX

Well, we [are] talking same and then differences. So I'm now confused because if they're using the same ingredients, then why are we talking about the differences? Female, Parent/Caregiver, Higher Education, Greenbelt, MD

My impression of that is [that it is] deceptive. If you have to ask your doctor, why can't they just tell you outright what the difference is? Female, Intermittent, Higher Education, Greenbelt, MD

It also raises the question of, "Oh, there is a difference and are they going to bring that up to me or is that something that I have got to remember and ask?" Female, Intermittent, Lower Education, San Antonio, TX

It is disturbing because it says talk with your doctor about other differences when it has not pointed out any differences, it has pointed out the similarity. There's a conflict there. Female, Intermittent, Higher Education, San Antonio, TX

Several participants questioned whether generic drugs had the same amount or percentage of the active ingredient.

To read that, it makes it sound like you have the same active ingredient, but not as much, and the rest of its placebo. [If] it has the same active ingredient then why do you need a generic? Female, Chronic, Lower Education, San Antonio, TX

Are they putting less? It's the same active ingredients, but how much? Male, Intermittent, Lower Education, San Antonio, TX

What percentage is the active ingredient? 80% and then the other difference is 20? I mean how does it break down? [The word] "includes" doesn't mean that it equals. It just means that it's some of it in there. Female, Chronic, Lower Education, Greenbelt, MD

Most of the revisions participants offered pertained to the second sentence in the statement. A few suggested dropping the second sentence. Several participants recommended replacing “other differences” with “possible differences.” A few others suggested more specific changes.

Instead of saying other differences, maybe possible differences, that maybe not all drugs have a big difference or any difference at all. Male, Parent/Caregiver, Lower Education, San Antonio, TX

I might change that to say possible differences because not every drug is going to be different. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

Or it should be more specific, [Your doctor or pharmacist] could talk with you about the other ingredients and how they may differ or something along those lines. Female, Intermittent, Higher Education, San Antonio, TX

If I were to revise it where it says your doctor or pharmacist, I would probably say, “Your doctor or pharmacist can talk to you about other medicine, other types of medicine that will do the same function versus the differences.” Female, Intermittent, Higher Education, Greenbelt, MD

You might want to add some websites to that [statement]. So, just not the pharmacist or the doctor, but, you know, “If you want further information, you can go to this [website].” Female, Chronic, Higher Education, San Antonio, TX

MESSAGE 2: A DRUG’S COST DOES NOT REFLECT HOW WELL IT WORKS. BRAND NAME DRUGS COST MORE TO PAY FOR DRUG RESEARCH AND DEVELOPMENT. GENERIC DRUGS COST LESS BECAUSE THEY USE EXISTING RESEARCH.

Although participants had some concerns about the statement, many indicated that it was clear, straightforward, and informative. The intended effect of the message could be seen as a few participants asked themselves why they would pay more for a brand name drug.

It’s explaining the fact that brand names cost more and that doesn’t necessarily mean it’s going to work any better or worse than the lower cost. That’s what I’m getting out of that. Male, Chronic, Lower Education, Greenbelt, MD

Well, it is a good statement because we know the fact that generic drugs are available as brand name and they are cheaper, but I never knew why. Female, Parent/Caregiver, Lower Education, San Antonio, TX

It’s an informative statement, but it is something that I didn’t know. So it’s good information to know. Female, Parent/Caregiver, Lower Education, San Antonio, TX

It makes you kind of wonder...if that brand name has a generic already out there, why do they need to pay—why do you need to pay the extra cost for a brand name, if a generic is out there that's so much cheaper? Female, Chronic, Lower Education, San Antonio, TX

I think the confusing part of it is when you say the cost doesn't reflect how well the drug works. That makes everyone stop and say, well, you know, if it doesn't reflect how well the drug works, then why does one cost so much more than the other one?... People generally, genuinely think, “well, if I'm paying more for it, it's better,” and that's not necessarily the truth. Male, Chronic, Higher Education, San Antonio, TX

Participants questioned whether producers of generic drugs only relied on existing research. A few participants went as far as to question whether this would be considered good professional practice given the need to stay on top of and contribute to new developments regarding prescription drugs.

There's been a lot of new drugs that have come up. To say that they use existing research is kind of weird to me. Female, Parent/Caregiver, High Education, San Antonio, TX

That last sentence is very like suspicious because they're not doing the research. They're doing the duplicating of the name brand. Female, Intermittent, Lower Education, Greenbelt, MD

I think generic drug companies still have to use their own bit of research too because just from prior experience I would assume that research and development is great and everything, but what about improving upon research and development?...Like do they get rid of the mistakes that were made in the development of the brand name? Female, Intermittent, Lower Education, San Antonio, TX

It tells me that the generic drug, they rely on paperwork...but on the brand name, they have research. That kind of throws me off a little bit. Male, Parent/Caregiver, Higher Education, San Antonio, TX

Most of the concerns participants had with the statement pertained to the last two sentences. It was difficult for participants to accept that brand name drugs cost more than generic drugs solely because of research and development. These participants also attributed the higher cost of brand name drugs to marketing, advertising, and market power.

I would add to that statement “marketing, research and development” because marketing is such a large component of the drugs, of a brand...It's comparable to the R&D cost. Male, Intermittent, Higher Education, Greenbelt, MD

That second sentence is not exactly accurate. Brand names do millions of dollars of advertising. It's not just for the development of the drug. They spend a lot of money, and they get big profits. Female, Intermittent, Lower Education, Greenbelt, MD

I don't know if I really believe the part that brand name drugs cost more to pay for drug research and development. Oftentimes brand name drugs cost more because they can charge more. Male, Parent/Caregiver, Higher Education, San Antonio, TX

A few participants also questioned the purpose of each sentence. They indicated that sentences seemed out of place and did not add much value to the overall statement. As a result, they suggested removing sentences.

Take out the part about how well it works, because the other two sentences have nothing to do with it except efficacy. Because all you're talking about here is why a brand name costs more than a generic, but the first sentence leads you to believe that it's going to talk about which one is more effective than the other, or that they're equally effective, and it doesn't say anything about that. Male, Chronic, Higher Education, Greenbelt, MD

I would just say, "A drug's cost does not reflect how well they work. Generic drugs cost less because they use existing research." I think that gets the point across better than trying to explain why prescription brand name costs more. Female, Chronic, Higher Education, San Antonio, TX

MESSAGE 3—GENERIC DRUGS ARE AS SAFE AND WORK AS WELL AS BRAND NAME DRUGS. ALL DRUGS MEET FDA'S HIGH STANDARDS – FROM QUALITY AND PERFORMANCE TO MANUFACTURING AND LABELING.

Participants generally agreed that the statement was clear and easy to understand. Most participants said that the statement communicated that generic and brand name drugs meet the same standards of quality.

Well, I was just thinking that it's just basically telling me that both generic and brand name are both tested by the FDA the same way, and they both meet those standards. Male, Chronic, Lower Education, Greenbelt, MD

It means that it is just as good as the name brand, they go through the same testing, the FDA, so one is not better than the other. Male, Parent/Caregiver, Lower Education, San Antonio, TX

It says it right at the beginning, "generic drugs are safe and work as well as brand name drugs and the FDA." It is passing the quality performance, so it is believable. It's not confusing. Male, Parent/Caregiver, Lower Education, San Antonio, TX

Although participants said that the statement was clear and easy to understand, several thought that this statement was not believable.

Instead of saying why is the generic brand cheaper, let's ask the question if the performance is the same and the quantity is the same and the reaction or the results is the same, why isn't the price the same? Male, Intermittent, Lower Education, Greenbelt, MD

But the FDA cannot test all the drugs all the time. We keep hearing it that they haven't been proved. Female, Chronic, Lower Education, Greenbelt, MD

If they stretch on this one, what else are they stretching about? Maybe some of the ingredients they put in the drugs? So you have to be very careful what words you use, and it looks like they're saying that it's as [good] and works as well as brand name drugs, and I don't believe that can be proven. Female, Chronic, Lower Education, Greenbelt, MD

One term some participants had concerns about was “FDA’s high standards.” These participants said that it was not clear what standards were being referenced and that these should be spelled out.

I don't know what FDA's standards are. First of all, do they have standards in quality, performance, manufacturing, labeling? Do they have all those kind of standards? And if they do, what defines “high” standards? Female, Parent/Caregiver, Higher Education, Greenbelt, MD

You know – then again what is FDA's standards? I mean they put stuff out on the market for you to buy and then they have recalls. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

I don't think that it clearly states or quantifies what are all the standards. If it's within the parameters of quality and performance, manufacturing and labeling, that's one thing, but if there are other high standards the FDA requires of these drugs and it's not mentioned in that statement following the high standards, then I'm not so sure if I'm getting the clear picture. Male, Chronic, Higher Education, Greenbelt, MD

A few participants suggested that seeing “FDA” in the statement provided a sense of comfort by informing them that the standards are established by a recognizable government agency.

I think maybe they put the FDA [in] because it kind of pops from the statement and people will see that and they automatically will be like – okay, FDA high standards, we are good to go. Female, Parent/Caregiver, Lower Education, San Antonio, TX

I think it makes people feel better...I think just seeing the FDA and then I feel better. So if you read nothing more of the statement and you see the FDA and then you go okay, that is fine, that's good. Male, Parent/Caregiver, Lower Education, San Antonio, TX

Participants were particularly concerned with the first sentence in the statement. They suggested that the word “safe” cannot be easily defined and questioned how a generic drug is determined to be as safe as a brand name drug, since there are so many factors to consider. For this reason, they also questioned the validity of stating that generic drugs work “as well as” brand name drugs.

I don't like the word “safe.” I mean it's such a vague word...What do you mean safe? They don't produce the same number of side effects? The same severity of side effects? Female, Parent/Caregiver, Higher Education, Greenbelt, MD

Wouldn't it also kind of depend...on what other drugs, prescriptions you're taking in conjunction with it. Female, Intermittent, Higher Education, Greenbelt, MD

I would say that that first sentence is misleading because they don't know. So unless they can provide evidence, they're on a slippery slope that I will say that that's not being truthful, because they don't know that. Female, Chronic, Lower Education, Greenbelt, MD

Participants provided specific suggestions on how the statement could be revised. These participants attempted to offer ways in which the statement could be revised to make it more believable.

You might say instead of all drugs meet [FDA's high standards], say “the FDA ensures that these drugs meet all of their standards.” And that way, it shows that they're taking responsibility rather than the drugs taking the responsibility. Male, Chronic, Higher Education, Greenbelt, MD

I don't really like the word “work”. I would rather say it is effective. Male, Intermittent, Higher Education, San Antonio, TX

I don't know how true this would be, but if it said all drugs must meet FDA's high standards. The addition of the word “must” or some definitive statement like that would make me feel more comfortable. Male, Chronic, Higher Education, Greenbelt, MD

It should say all drugs are required to meet the same high standards of quality. Male, Intermittent, Higher Education, Greenbelt, MD

I would rephrase that as, “generic drugs are as safe and work almost as well as brand name drugs.” Male, Chronic, Lower Education, San Antonio, TX

I have just a problem with that word “all.” I think that “all” should be taken out. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

Chapter III: Reactions to Messages about Prescription Drug Side Effects

Another key finding from the previous study conducted in 2010 was that fear of potential side effects is the single greatest deterrent from filling and taking prescription drugs. Hearing about potential side effects through advertisements strongly discouraged participants from considering taking a particular drug. If participants actually fill a prescription, the long list of side effects on the package insert sometimes serves as a deterrent to taking the prescription.

Findings from the 2010 study also indicated that the perceived threshold for drug effectiveness appears to be lower than the perceived threshold for drug safety. Participants suggested that success rates do not necessarily have to be high in order for a drug to be considered effective, but suggested a much higher threshold (ranging from 70% to 99%) for determining whether a drug is safe.

In this current study, the moderator transitioned into the topic of side effects by asking participants to provide their general sense of how prescription drug ads make them feel about taking a particular medication. Specifically, participants were asked to describe their reactions to reading or hearing the side effect information. Similar to the 2010 groups, many participants were concerned about taking the medication after seeing or hearing about the potential side effects. In some cases, this information deterred them from taking the medication.

[It makes you] scared and not want to take it, because in a lot of cases, the side effects are worse than the drug itself. Your nose bleeds, your tongue swells. Male, Intermittent, Lower Education, Greenbelt, MD

Leery, especially when there's five pages about it in a magazine and three of the pages are about the ingredients and possible side effects. Female, Intermittent, Higher Education, Greenbelt, MD

When I read some of the side effects, sometimes it scares me. So I don't take the medication unless I really, really have to. The last two instances where I was prescribed drugs by a doctor and I read over the things, [I decided], "I'm not taking this stuff," and I did not take it. Male, Intermittent, Higher Education, Greenbelt, MD

To manage their reactions, some participants said that they choose not to read or listen to the information on potential side effects.

I throw the side effect thing away. I do not read it. Female, Chronic, Lower Education, Greenbelt, MD

I'd rather not look [at the side effects] until something doesn't feel right. Female, Chronic, Lower Education, San Antonio, TX

There were also a few participants, however, that stated that the ads were appropriate and that presenting the potential side effects was helpful in deciding whether to take the drug. The ads also provide participants with information that they could use to identify a side effect that they may be experiencing.

Personally, I am very happy that they put all of that on there because as consumers we shouldn't just buy into only one side of the coin. We should know and be reminded. I think it is really good to have that stuff out there. Female, Intermittent, Higher Education, San Antonio, TX

I like the fact that they tell you when they do those commercials what the side effects are. So that's nice that I could go in and say, "I saw this commercial for Imitrex and would this work for me?" and it actually ended up working for me. The doctor would have never known. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

It makes me be aware of how I'm feeling and if something that I read is on there I can call the doctor and say I'm having this side effect, and they can tell you whether you should stop and try something different. I like to be aware of what's going on. Female, Chronic, Lower Education, Greenbelt, MD

Some participants in the parent/caregiver groups expressed that they look closely at the medication their children take and have strong feelings about being aware of the side effects. This information helps them monitor their children's reaction to the medication and helps them determine whether they are going to give their child the medication.

When it's the kids, then I take more time and I look at all the side effects. And if there is a side effect, then I am going to, probably more so, call the doctor. So I am more aware of the side effects for the children. Male, Parent/Caregiver, Lower Education, San Antonio, TX

My daughter, she was prescribed medication and I read the side effects and I didn't give her the medication. Female, Parent/Caregiver, Higher Education, San Antonio, TX

The remaining sections of this chapter summarize participants' feedback on messages about prescription drug side effects. To generate feedback on the messages, the moderator again asked participants to frame their responses using the same set of questions noted in Chapter Two.

MESSAGE 4—DON'T LET INFORMATION ABOUT SIDE EFFECTS SCARE YOU AWAY FROM USING A PRESCRIPTION DRUG. INSTEAD, ASK YOUR DOCTOR IF THE DRUG'S BENEFIT TO YOUR HEALTH IS MORE IMPORTANT THAN THE POSSIBLE SIDE EFFECTS.

Most participants were critical of this message and disliked its negative tone and connotation. Participants were most concerned with the word “scare.” This word discouraged them from wanting to take a prescription drug at all.

If you have that first sentence up there, “Don't let the side effects scare you away,” well, that, gives you cause to pause, “Do I really want to do this?” Female, Chronic, Lower Education, San Antonio, TX

I think the “scare” word kind of to me says, “Wow, how bad are they thinking it's going to be?” Female, Chronic, Higher Education, Greenbelt, MD

I don't like [the word “scare”] because, “don't let information about side effects scare you away.” Oh My God, what are the side effects that they would have to state that? Female, Parent/Caregiver, Lower Education, Greenbelt, MD

I think “don't let it scare you,” how it is worded, it makes you automatically scared. Female, Intermittent, Lower Education, San Antonio, TX

Participants also disliked the word “don't” because they said it communicates a negative command and comes off as overly aggressive and condescending.

I find [“don't”] kind of a little too aggressive or something. [In the second sentence] they're giving a command too, “ask.” But it's a positive command. It's not a negative command. I don't like the tone of [“don't”]. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I don't like beginning with a command that's a negative command. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

To me it sounds like they are talking to a child. Male, Intermittent, Higher Education, San Antonio, TX

I like the last part. Instead “ask your doctor,” you know. Not the first part. That sounds like kindergarten. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

A few participants suggested the word “don't” minimizes their sense of empowerment. They indicated that the statement does not acknowledge prescription drug use decisions as being personal and relying on more than a doctor's advice.

I think that it's one of those things where you still have to decide for yourself because what may be your doctor's idea of what is more important is probably different than your own. Female, Intermittent, Lower Education, San Antonio, TX

I like that being phrased [“if you have concerns”] rather than this telling me how to think. That puts the ball back in my court and it is my decision. Female, Intermittent, Higher Education, San Antonio, TX

Other participants indicated the statement was too vague and may not apply to all situations. A few participants suggested that not everyone is scared by side effect information, while others said the statement gives the impression that drug benefits generally outweigh side effects.

I think the statement’s very ambiguous. Male, Chronic, Higher Education, Greenbelt, MD

I mean that doesn’t apply to every one of us. Male, Chronic, Higher Education, Greenbelt, MD

The first sentence assumes that side effects are going to scare everybody. So I think if I rewrote it, I would say something about, “If you’re concerned about side effects, consult your doctor, and weigh the benefits of the drug against potential side effects.” Male, Chronic, Higher Education, San Antonio, TX

It sounds like, to me, that they’re saying you should take the drugs, regardless of the side effects, if it’s going to help you. I can’t take a drug that’s supposed to help me, but is making me sick at the same time. I don’t see how that’s helping me. Female, Chronic, Higher Education, Greenbelt, MD

While some participants thought the statement was accurate in recommending talking to your doctor, a few raised suspicions about the motive behind the statement.

When I see that statement, the first thing I think about is how much my physician [is] in the drug company’s pocket and what are they trying to push, because oftentimes I look at doctors like drug dealers, especially when it comes to some of the [drugs]. Male, Intermittent, Higher Education, Greenbelt, MD

To me it looks like they are minimizing the side effects. Male, Intermittent, Lower Education, San Antonio, TX

If I saw it on a medicine – that looks pushy. Because they want to push it on you. In high school or junior high when they offer you drugs, they are trying to push it on you. Male, Intermittent, Lower Education, San Antonio, TX

Because most participants liked the second part of the message, a common suggestion was to simply get rid of the first sentence to avoid the negative tone and connotation.

I think the first sentence should just be omitted completely, yes. Male, Intermittent, Higher Education, San Antonio, TX

It should just be rephrased – “Talk to your doctor about the benefits of this drug to see if the health benefits are more important than the possible side effects.” That’s all it needs to say. Female, Intermittent, Higher Education, San Antonio, TX

The whole first sentence would be a throw-off. If you read that, you wouldn't even get to the second sentence. Male, Parent/Caregiver, Higher Education, San Antonio, TX

Other participants suggested keeping the first sentence, but softening its tone to convey the message in a more positive way.

I think from what most of us have said... the second statement was pretty okay. For the first statement that word "scare," I think if they could just rephrase it. Female, Intermittent, Higher Education, Greenbelt, MD

I would change it. I would say, "There may be side effects for using prescription drugs. Ask your doctor of the benefits to your health." Something like that. Male, Intermittent, Higher Education, Greenbelt, MD

Possible side effects shouldn't prevent you from taking any prescription drug. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I would probably rephrase it. I would say, "Always read the information about side effects. If you're scared about taking a prescription drug, consult your doctor about the benefits to your health." Male, Chronic, Higher Education, San Antonio, TX

MESSAGE 5—NO DRUG IS 100% SAFE – IF IT HAS A GOOD EFFECT, THERE'S AT LEAST A CHANCE OF AN UNWANTED BAD EFFECT.

Participants had mixed responses to this message. Some participants felt the message was informative and useful.

To me it's a good statement. I like where it had no drug is 100% safe for everyone. This statement just makes people aware that you should just talk with your doctor about the possible side effects, or your pharmacist. It just makes you aware. Some people may not know that drugs aren't 100% safe. So I think if you say that, it's simple enough that the average person of any intelligence can get it. Female, Intermittent, Higher Education, Greenbelt, MD

I think it's a very true statement. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I would actually find that [statement] very useful to me because if I'm just the average consumer who doesn't know much or have a good relationship with my doctor maybe I need someone to educate me. Female, Intermittent, Higher Education, Greenbelt, MD

Personally I think that more information like this needs to be available in our face because we are a society that there is a pill for everything. Female, Intermittent, Higher Education, San Antonio, TX

Other participants thought the message was too simplistic and not worth communicating to consumers.

It doesn't seem like it is written professionally, like a kid in high school wrote it. Male, Parent/Caregiver, Lower Education, San Antonio, TX

It's like you're insulting me or being condescending. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I wouldn't even use that statement. I think most people understand that there's some risk involved. Female, Chronic, Lower Education, Greenbelt, MD

Get rid of it. Male, Intermittent, Lower Education, Greenbelt, MD

The message also generated discussion among participants about what was being conveyed, which caused some to raise suspicion about the underlying intent of the message.

They pretty much have a 50/50 chance. Male, Parent/Caregiver, Lower Education, Greenbelt, MD

Almost guaranteeing like for each action there is an opposite equal negative reaction. Male, Parent/Caregiver, Lower Education, San Antonio, TX

You know a headache might be an unwanted side effect, but does that mean it's not a safe drug? When I think of safety, I'm thinking about something that's going to make my health worse or kill me. Male, Chronic, Higher Education, Greenbelt, MD

Some participants said that the message was negative and invoked fear while others questioned the truthfulness of the statement. A few also indicated that they did not understand the message.

It's kind of scary. No drug is 100% safe. Why are you telling me that it's not safe if I need to take this drug? Male, Parent/Caregiver, Higher Education, San Antonio, TX

Negative. It's kind of gloomy, you know? Female, Chronic, Lower Education, Greenbelt, MD

It almost sounds negative. Male, Parent/Caregiver, Higher Education, San Antonio, TX

But everybody's different, so, I think it contradicts each other. If it's safe and it has a good effect, then why would there be a bad effect? Female, Chronic, Lower Education, San Antonio, TX

I don't know; I don't understand it. Male, Intermittent, Lower Education, San Antonio, TX

Some participants offered ideas to improve the message. Most suggestions related to changing the phrase “unwanted bad effect.” A few participants also suggested dropping the word “if.”

I don't know if there are any bad effects that are wanted, so I don't know why they would put “unwanted.” Female, Parent/Caregiver, Lower Education, San Antonio, TX

Any unwanted effect is bad. They've got them mixed up. They should have put the unwanted effect first. Male, Intermittent, Lower Education, Greenbelt, MD

No drug is 100% without side effects. Male, Chronic, Higher Education, Greenbelt, MD

I think they should replace one word with unwanted side effect, instead of unwanted bad effect. Female, Intermittent, Lower Education, Greenbelt, MD

I wouldn't put “if” because then they're saying it's like you're taking a chance. Male, Chronic, Lower Education, San Antonio, TX

If it has a good effect? If? Female, Parent/Caregiver, Higher Education, Greenbelt, MD

MESSAGE 6—LIKE EVERYTHING YOU PUT IN YOUR BODY, PRESCRIPTION DRUGS HAVE RISKS. MANY ARE MINOR AND UNLIKELY TO HAPPEN, BUT SOME CAN BE MORE SERIOUS. YOUR DOCTOR CAN HELP YOU DECIDE WHICH RISKS ARE WORTH TAKING.

Overall, participants thought the message was clear and many felt that it was believable.

I think it's just a very safe kind of statement. Obviously they have to be overly cautious for legal reasons. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

It is giving you a head's up. This is the chance you are taking. Then you know it can be either minor or very dangerous. It is really up to you, the chance you are taking. No one is forcing you to take it. Female, Intermittent, Lower Education, San Antonio, TX

I think it is common knowledge. [If] you are taking a prescription, there are going to be side effects or risks. It just depends on how you take the word risk and how you take the side effects. They are saying the same thing. There may be some issues that you may have after you take this medicine, talk to your doctor. Just common sense. Female, Parent/Caregiver, Lower Education, San Antonio, TX

I think that's pretty true, pretty accurate. Male, Chronic, Lower Education, Greenbelt, MD

It's clear and it makes sense. Female, Chronic, Lower Education, San Antonio, TX

Some participants challenged the first sentence, questioning the validity of the statement.

I don't agree with the first statement. Everything that you put in your body is not a risk. Female, Intermittent, Higher Education, Greenbelt, MD

I don't like the wording, "Like everything you put in your body." Male, Chronic, Higher Education, San Antonio, TX

I wouldn't say like most things, because not everything you put in your body has risks. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

Other participants took issue with the last sentence. These participants questioned whether the kind of discussion described with one's healthcare provider is feasible, due to limited access to the provider and participants' relationship with the provider. These participants also felt that only they can ultimately decide whether to take a prescription drug.

[What] if there's not a relationship there [with your doctor]? There are some people that don't take those pre-measurements ahead of time to research certain things, to discuss certain things with their doctor. Female, Intermittent, Higher Education, Greenbelt, MD

I think that last statement makes you wonder if your doctor can help you. You decide which risks are worth taking and if there are adverse side effects. Even your doctor says, "Oh yeah, you can still take it," are you really going to still take it knowing that there is a really big chance that it could happen to you? Male, Parent/Caregiver, Lower Education, San Antonio, TX

You know, most people are going to say it's not very believable because they've got questions in the back of their heads and they're saying, "Can I trust my doctor, to go ask him, is this fair?" Male, Chronic, Higher Education, San Antonio, TX

I believe it only if I know that my doctor is qualified to make that decision. Female, Chronic, Lower Education, Greenbelt, MD

I've got a problem with the last sentence. It's not with the risk. My doctor's not going to help me decide anything. I want him to quantify the risk. You know, I would say your doctor can help you understand the seriousness of the risk. I'll decide if it's over my personal risk threshold. Male, Chronic, Higher Education, Greenbelt, MD

Participants provided a few suggestions for revising the message, primarily focusing on the last sentence and avoiding the phrase "risks worth taking."

Your doctor can help you decide what is best for you. Male, Intermittent, Lower Education, Greenbelt, MD

I can see the last sentence saying something more along the lines of, "if the benefits for you outweigh the risks." Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I think if you take the word “risk” out, I think you would feel better. Maybe, your doctor can help you with possible side effects. Male, Parent/Caregiver, Lower Education, San Antonio, TX

The last sentence, you might reword it a little differently, “Your doctor can help you decide possible risks,” or something like that. Male, Intermittent, Higher Education, San Antonio, TX

I would say, “your doctor and healthcare providers.” I think many people have nurses that visit them. Home healthcare nurses have more time with the patients. Male, Chronic, Higher Education, San Antonio, TX

Chapter IV: Reactions to Messages about Drug Review and Newly Discovered Risks

In 2010, participants identified a lack of research as the main reason for newly discovered risks pertaining to prescription drugs. Participants indicated that new risks are discovered because of a lack of thorough testing. Participants suggested that drugs are not tested on enough people or on the right people. In discussing why new risks of prescription drugs are discovered, participants suggested that FDA rushes the approval process in response to manufacturer pressure to quickly get drugs on the market.

To gather feedback from current study participants on this topic, the moderator asked them to share their understanding of how drugs are researched, reviewed, and approved. Many participants felt they understood how drugs were researched, and were able to describe the basic steps involved.

[Researching drugs means] to test to get the right dosage and determine what side effects there are before they even ever put it out in the general population. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

I was actually in a research study one time and I had to go in for a certain amount of time and they monitored me, took blood. It turned out I actually had the placebo, but it basically showed me that's how they do a lot of research. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

You get a drug that they've given preliminary approval; it's given out to a small group. They check it out. Actually, guinea pigs, if you want to call them that. And they come back with results. It could be over a month, six months, a year. Then they increase the group and the demographics, increase everything about it. Then it goes to the larger scale. It looks like three or four different scales. And then they get all the reviews. Male, Chronic, Higher Education, San Antonio, TX

Participants were also asked how much and what kind of research is needed for the FDA to approve a drug, and also how many people they thought were involved in the research. Some believed that the FDA tests drugs on animals before experimenting with them on humans. Participants' answers to how many people are involved in drug testing varied, ranging from hundreds to thousands. Most participants believed drug research took several years.

I would think they do animal trials before human. Male, Intermittent, Higher Education, San Antonio, TX

Animal tested and a lot of people—like a certain number of people throughout a certain amount of time. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

Maybe in different ages, different ethnic backgrounds. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

In order to get a good idea of how each person's body is going to react, it has to be a pretty big number. Female, Intermittent, Lower Education, San Antonio, TX

Statisticians come up with what's a statistically significant number, and my guess would be five to ten thousand people. My understanding is it takes several years to get it through, so you're going to test it on a fairly good number of people. I'm not sure the system has enough checks and balances to make it foolproof, though. Male, Chronic, Higher Education, Greenbelt, MD

There are probably not thousands. Probably close to a couple hundred. Male, Parent/Caregiver, Higher Education, San Antonio, TX

Studies over several years. I don't know what the timeframe would be, but it would have to be some timeframe involved. Male, Parent/Caregiver, Higher Education, San Antonio, TX

It takes years because they have to pass the first phase before they can move on to the second, third, fourth. Female, Intermittent, Lower Education, San Antonio, TX

Other participants said that they did not understand the drug review process, and were unsure if it was adequate. These responses were similar to sentiments expressed in the 2010 groups in which participants indicated that new risks are discovered because of a lack of thorough testing.

A lot of research, over and over again. I don't understand myself what it requires, [or] how much is required to stop the research. They have pages and pages of information, but who's going to determine okay, that is enough now? Female, Chronic, Lower Education, Greenbelt, MD

I have no understanding of it at all. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I would hope it is extensive, but I don't think so because there are drugs that are pulled from the market all the time. So I don't think there is enough research. Male, Parent/Caregiver, Lower Education, San Antonio, TX

After this initial discussion, participants were asked to look at three messages discussing FDA's role in research and drug review. The moderator asked participants to think about the same questions noted in Chapter Two when reading and responding to the messages.

MESSAGE 7—BY THE TIME YOU HEAR ABOUT A “NEW” DRUG, IT ISN’T NEW TO FDA. FDA BASES ITS DRUG APPROVAL DECISIONS ON YEARS OF RESEARCH, STARTING FROM DRUG MAKERS’ EARLY SAFETY TESTS IN ANIMALS TO LATER TESTS IN HUNDREDS OR THOUSANDS OF PATIENTS.

Overall, participants liked this message. They thought it was informative, reassuring, and well-written.

It is informative. Female, Intermittent, Higher Education, San Antonio, TX

It is reassuring to know that it’s not new; it’s just new in the market. Female, Intermittent, Higher Education, San Antonio, TX

That’s what we want to hear. Male, Parent/Caregiver, Higher Education, San Antonio, TX

It makes sense. It’s written very well. Female, Chronic, Lower Education, Greenbelt, MD

That is good information. Female, Intermittent, Lower Education, San Antonio, TX

It makes you feel comfortable knowing that they have years of research, safety tests on animals and later, tests in hundreds or thousands of patients. Male, Parent/Caregiver, Lower Education, San Antonio, TX

I like the top of that, it says, “By the time you hear about a ‘new’ drug, it’s not new to the FDA.” Female, Parent/Caregiver, Lower Education, Greenbelt, MD

It’s clear. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

Participants had mixed feelings on whether to include the information about testing on animals. Although many disagreed with the concept of drug testing on animals, some thought it would be reassuring to the public that it was tested on animals *before* humans.

I don’t think any of that drug testing is necessarily safe for the animals. Male, Intermittent, Higher Education, Greenbelt, MD

But why bother the animals in the first place? I mean it’s human beings that it’s meant for. Female, Intermittent, Lower Education, Greenbelt, MD

How safe it is for the animals? Male, Intermittent, Higher Education, Greenbelt, MD

It doesn’t bother me for the animals, but I think some people might be alarmed that they were safety tested on animals. [Do] you have to say that or not? Male, Intermittent, Higher Education, San Antonio, TX

I'm not like an animal activist or anything, matter of fact I don't like cats. But people really tend to react very strongly when things are tested. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

I think some people would be reassured that they are testing animals. I think they might think [that for] something to happen to an animal would be better than for something to happen to a human. It sounds bad, but somebody would rather have an animal get a side effect than a human later on. Male, Intermittent, Higher Education, San Antonio, TX

A few participants took issue and/or questioned the phrase, “years of research.” They believed it was too vague. These participants wanted to know specifically how many years of research are devoted to a drug.

“Years of research,” is that three years or, you know, 15 years? The other day I saw something on TV about lawyers, about Haldol, [and it said], “If you took Haldol and your kids had side effects, call us and we’ll help you sue them.” If they’ve got a huge class action lawsuit about all these people, where was the FDA and all this testing safety if there are so many problems with it? Male, Chronic, Higher Education, Greenbelt, MD

So the [word] “years” is very vague. Is it five years or 15 years? Male, Chronic, Higher Education, Greenbelt, MD

Some participants also raised questions about the phrase, “tests in hundreds or thousands of patients.” These participants wanted to know how many people are really used in drug research since the number range is wide.

I guess just the way it says hundreds or thousands of patients kind of makes me wonder if... or that there's not a real specific standard that they have. Female, Chronic, Higher Education, Greenbelt, MD

And then you put hundreds or thousands, that's a big difference. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

Was it hundreds or was it thousands? Female, Parent/Caregiver, Lower Education, Greenbelt, MD

My knee-jerk [reaction] is I look at it and go, “Okay. So was mine tested on hundreds or thousands?” I'd rather have the one that was tested on thousands. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I mean that could be anywhere from just 200 people to up above thousands, and I'm thinking, some drugs have probably not been researched that much. Female, Chronic, Lower Education, Greenbelt, MD

Only a few of the participants had suggestions on how to improve the message by shortening or clarifying the second sentence.

In the second long sentence here, I think that “FDA bases its drug approval decisions on years of research” is good enough. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

Based on years of the drug company’s research. Male, Intermittent, Higher Education, Greenbelt, MD

MESSAGE 8—DRUG APPROVALS ARE NEVER RUSHED. FDA’S DECISION TO APPROVE EACH NEW DRUG REQUIRES YEARS OF RESEARCH AND EVIDENCE OF SAFETY AND EFFECTIVENESS.

Participants’ reactions to the statement were consistent in that they liked the second sentence, indicating that it was clear, accurate, and believable. However, the first sentence raised a great deal of concern for participants, causing them to question the validity and believability of the overall message.

The bottom part is definitely believable but the top part – [if] they were “never rushed” and they were 100% approved and ready to go and safe and effective – we wouldn’t have recalls. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

I don’t believe it, because there’s a lot of politics behind when the FDA will release a drug, so I don’t think all those years that the drug is sitting there waiting to be released is because they’re still doing research and safety checks. I think it’s just a lot of politics behind it. Female, Chronic, Higher Education, Greenbelt, MD

As a consumer, I look at it and I’m bothered with the definitiveness of the first sentence. So I feel like someone is right now conditioning me for the message of the deliverer, whoever that may be. [The second sentence] doesn’t speak to process at all. But they are both believable. I really hope that’s true. Male, Intermittent, Lower Education, Greenbelt, MD

I think [the first sentence] sounds defensive and it makes you think, “Has there been some suspicion [of the FDA]?” Female, Parent/Caregiver, Higher Education, San Antonio, TX

Some participants felt that there should be more information included in this message because it was too vague. As a result, participants asked more questions about the process of drug approvals rather than being comforted by the information provided in the message.

That statement right there leaves me—the whole thing, especially the second sentence— to wonder whether or not the guideline is across the board. Is it the same for this drug as for this drug, that’s for all the drugs? You’re using the same rubric to come up with what is approved? It just leaves a question mark. Female, Chronic, Higher Education, Greenbelt, MD

I feel like it is dumbed down. Female, Intermittent, Higher Education, San Antonio, TX

I want it more specific. “Drug approvals are, go through this, this, this and this.” I am not going to accept that at this point. Female, Intermittent, Higher Education, San Antonio, TX

Well, I think that they approve drugs that are effective, but I don’t think that they test anywhere near as stringently for the effectiveness as they do for safety, because that’s not their priority. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

Overall, participants disliked the first sentence because they felt there were cases where the FDA rushed drug approvals, and also because they felt the FDA *should* sometimes rush drug approvals.

And it’s actually kind of depressing to know that if they are never rushed where there is urgency for something, what are they going to do? Have a magic drug and never release it because they want to go through their regulations? No, rush and get it out to people who need it. Female, Parent/Caregiver, Lower Education, San Antonio, TX

It sounds like never is never. There are always exceptions to their rule. Male, Intermittent, Higher Education, San Antonio, TX

There are just so many cases of rushing. That’s probably the reason we have all these class action lawsuits. The HPV virus, you know, penicillin. Male, Intermittent, Higher Education, Greenbelt, MD

I’ve read in the media where they were fast tracking certain drugs because they showed promise. So that voids that first statement. Male, Intermittent, Lower Education, San Antonio, TX

I wouldn’t say that they were “never rushed,” because if they were “never rushed,” then why do we have recalls? Female, Parent/Caregiver, Lower Education, Greenbelt, MD

Many participants, therefore, had suggestions for how to improve the message. They overwhelmingly suggested removing or changing the first sentence.

I think it would be a better statement if the first statement was deleted. Female, Chronic, Higher Education, San Antonio, TX

Again, I would say remove that first statement and just go with [the second sentence starting with] their decision. Female, Intermittent, Higher Education, Greenbelt, MD

I don't know why they'd even put that first sentence in there. I don't know that it has any added benefit to it. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

That first piece [of the message] would need to be rephrased. I rather would start this statement with "The FDA's decision to approve each new drug requires years of research and evidence of safety and effectiveness. The only time that drugs might be fast tracked would be because they show immediate results." But to start it off with "drug approvals are never rushed," that's not true. Female, Chronic, Higher Education, San Antonio, TX

Instead of the words "never rush," [I would say], "drug approvals go through the same rigorous process." "Rushed" gets back to the word "scared." When it says "never rushed" then it makes me suspicious. Female, Intermittent, Higher Education, Greenbelt, MD

MESSAGE 9—FDA DOES NOT SPEED DRUG APPROVALS TO HELP DRUG MAKERS. IN SPECIAL CASES, FDA SPEEDS THE APPROVAL PROCESS FOR PROMISING DRUGS THAT TREAT SERIOUS CONDITIONS. THIS IS TO BENEFIT PATIENTS WHO DESPERATELY NEED NEW THERAPIES THAT WORK.

In general, participants were suspicious of this message and felt that the first sentence contradicted the rest of the message. However, some participants thought the message made sense and many understood its intended purpose.

That says in special cases. It makes sense to me. Male, Intermittent, Lower Education, Greenbelt, MD

I think for terminal patients, it's the way I see that. If I have a sick family member and they only have a few months to live and there is this possible drug that is being researched right now, for terminal patients I could see them trying to speed it through because they are going to pass away without some help. Male, Intermittent, Higher Education, San Antonio, TX

It's factual based on what I've heard. I would think they would speed up the approvals for serious conditions if there are persons who desperately need therapies. Male, Chronic, Higher Education, Greenbelt, MD

When I think of that last sentence, I think about a lot of people who are having life threatening illnesses and especially the people that there is nothing [that] can help [them]. So these new drugs that they are speeding along, in those special cases, that would make sense. Male, Parent/Caregiver, Higher Education, San Antonio, TX

I think the FDA and the drug manufacturers work pretty close with each other, so, I could believe that. In special cases, the FDA speeds the approval process for promising drugs that treat serious conditions. I could believe that. Male, Chronic, Lower Education, San Antonio, TX

They don't speed them because the pharmaceutical companies are paying them. In cases that they do speed them, it's for patients or people who need the help. That is the way I am reading it. Female, Intermittent, Higher Education, San Antonio, TX

Other participants grappled with what the message was saying. Many participants had issues with specific parts of the message, especially the phrase “to help drug makers,” and the words “speed,” “special,” and “serious condition.”

“FDA does not speed drug approvals to help drug makers.” “To help?” – how would it help drug makers? Male, Chronic, Lower Education, San Antonio, TX

Why would we need that first sentence at all? Don't speed drug approvals to help drug makers? Are they being accused of that? Why would they even say that? Female, Chronic, Higher Education, Greenbelt, MD

“Speed” is: these people are very sick; they need it yesterday, so how quickly can you get that drug to them? One week, two weeks, a month? Female, Chronic, Higher Education, Greenbelt, MD

What is “serious condition?” To me it may be one thing and to another it may not be a “serious condition.” Male, Parent/Caregiver, Lower Education, San Antonio, TX

Who determines whether or not this case is “special” or that case is “special?” Male, Intermittent, Higher Education, San Antonio, TX

Many participants were critical of this message because they felt that the first sentence contradicted the second one.

The first sentence is clearly telling you [the FDA] does not speed approval to help drug makers. And in the second sentence it is saying in special cases the FDA speeds the approval. So that's two totally [different] sides of the spectrum right there. The first sentence is telling you that it does not do it and the second sentence is telling you that it does do it in special cases. Male, Parent/Caregiver, Lower Education, San Antonio, TX

It says it does not speed approval and then it says in special cases, we do. Female, Intermittent, Higher Education, San Antonio, TX

That would contradict – it says [FDA] does not speed the drug approvals then we do speed them. Female, Parent/Caregiver, Higher Education, San Antonio, TX

They're saying they don't do it, then another part of it they're saying that they do. So they're actually saying that they do it [speed drug approvals]. Male, Intermittent, Lower Education, Greenbelt, MD

Of those participants that did not like the statement, they felt that removing the first sentence would be helpful. Some thought providing an additional caveat to the first sentence would make it more believable.

I would leave it the same. Just take out the first sentence because they don't need to prove themselves to anybody by making that statement. Female, Chronic, Higher Education, San Antonio, TX

They left a word out, like usually or sometimes, because there are exceptions to everything. Female, Intermittent, Lower Education, Greenbelt, MD

In extreme circumstances, FDA speeds up the approval. Female, Intermittent, Lower Education, Greenbelt, MD

“In most cases, the FDA does not speed drug approvals to help drug makers,” and leave the rest. Male, Parent/Caregiver, Higher Education, San Antonio, TX

Speed the approval process for patients who just really need therapies that work. Female, Parent/Caregiver, Higher Education, San Antonio, TX

The second part should be reworded. Where it says, “In special cases they speed the approval process,” maybe, “they will administer a drug that's close to being approved for special needs,” because they're totally contradicting themselves in the very next sentence. Female, Chronic, Lower Education, San Antonio, TX

In the next part of the discussion, the moderator asked participants about newly discovered risks associated with prescription drugs. They were asked to provide feedback on how new risks are sometimes discovered for drugs that have been available for years. In the 2010 study, participants commonly suggested that FDA rushes the approval process in response to manufacturer pressure to quickly get drugs on the market. In the current study, participants were more likely to indicate that new risks are discovered as more people take a drug, especially in cases where drugs are used in combination with other drugs that were not tested together or when drugs are used to treat conditions for which they are not indicated.

Because you can't test every single person. Everybody is different. You can't always ensure that out of a thousand people, each one of those people is exactly like somebody else. Male, Parent/Caregiver, Lower Education, San Antonio, TX

Some drugs were created or meant for a certain symptom or condition. Through trial and error they find out that certain drugs will also work on other conditions. Male, Chronic, Higher Education, San Antonio, TX

Different variables. Say I am taking a certain medication, and then I end up taking another new medication that was approved, but different combinations that haven't been tested because that drug wasn't available at the time and your body reacted a certain way. Male, Chronic, Lower Education, San Antonio, TX

The longer they're out, the more people that are taking them and trying them out. There's going to be side effects and risks that develop with different people. Female, Chronic, Lower Education, Greenbelt, MD

Probably because it takes a while for the FDA to get wind of it. I mean, someone has to report it to the FDA. Female, Intermittent, Higher Education, Greenbelt, MD

Doctors may begin using it for a different type of illness that it wasn't originally intended for and that particular group may have side effects or adverse effects that weren't in that group that you originally planned to use the drug. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

Participants were then asked to imagine they were reading a news report about a newly discovered risk for a prescription drug that has been available for years. The report offers these statements about how the new risk was discovered. The next two sections summarize participants' feedback on each of these statements. Participants were again asked to think about the same questions noted in Chapter Two.

MESSAGE 10—NEW SCIENCE CAN REVEAL NEW RISKS OF APPROVED DRUGS.

Participants seemed to understand the message, but did not like the term “new science.” For those that liked the message, they thought it was believable, true, and important to convey to the public.

We've been conditioned to believe that in America, that science is good. But the fact is, as new advances in science come about, you get a new type of cancer or a new type of cancer can be detected. So I would say in response to that, it is a believable message. Male, Intermittent, Lower Education, Greenbelt, MD

There are scientists now that have learned stuff that they didn't know years ago. They're going into a development process and they're finding out that when they put certain things together, that this drug does do this and nobody tried that particular combination before or saw that side effect possibly, or that danger. Male, Chronic, Lower Education, Greenbelt, MD

It makes me feel better to know that they can go back and recheck [if] this [drug is] okay. I would like to know if there are new risks. Female, Intermittent, Lower Education, San Antonio, TX

That makes sense because before, diabetic people had to take out like this much blood to test their glucose, but now it's only one drop. That is new science. That makes sense to me. Male, Intermittent, Lower Education, San Antonio, TX

You've uncovered previously unknown risks. Male, Intermittent, Higher Education, Greenbelt, MD

We know it's true because you always hear about the recalls, about the drugs and tests found that this drug is bad for you after so many years. Male, Parent/Caregiver, Lower Education, San Antonio, TX

Nonetheless, some participants had trouble understanding what “new science” meant or questioned whether or not it was really “new science” that revealed risks.

What do they mean “new science?” Research done right from a drug taken 10 years ago? Does “new science” mean that we discovered that 50 people just have died within the 10 years after taking this drug? Male, Parent/Caregiver, Lower Education, San Antonio, TX

What do they mean by “new science?” Female, Intermittent, Lower Education, San Antonio, TX

The term “new science,” what does that really mean? Sometimes people have reactions just based on time. Female, Chronic, Lower Education, Greenbelt, MD

It begs the question “what is ‘new science?’” I think some people would understand, new testing, new procedures, new whatever. But I think that could be expanded upon, made a bit clearer. Male, Chronic, Higher Education, Greenbelt, MD

Several participants felt that this message more than other messages seemed to be a campaign for the FDA, or something they are trying to state to protect themselves.

I don't have any problems with it. It just seems as though the FDA is on a campaign to promote itself. That's what I'm gathering from all of this. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

It's almost like these are excuses for when something goes wrong. Something they're going to say after five people died from this. “But new science can reveal new risks of approved drugs, so you should be careful.” Male, Parent/Caregiver, Higher Education, Greenbelt, MD

I think they're trying to protect themselves. There must have been a whole lot of lawsuits. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

To me it reads like a flag. Why are they doing [research] on drugs that have already been approved? That should be done before they get approved. Female, Intermittent, Lower Education, San Antonio, TX

Like a shield for possible future legal ramifications. Just saying, “When we approved it, everything was cool, but there is just new technology that shows [us] what we could not have seen 10 years ago.” Female, Intermittent, Higher Education, San Antonio, TX

Participants provided suggestions to clarify their understanding of the term “new science” and to make the message more informative. A few participants also suggested adding the word “benefits” to the statement, because both new risks *and* benefits can be discovered.

Maybe new scientific methods and technology. Male, Chronic, Higher Education, Greenbelt, MD

I would say instead of “new science,” new understanding of... Female, Intermittent, Higher Education, Greenbelt, MD

I like advances in science and technology because it gives it a distinction that we’ve actually gone out and tested and we’ve got new equipment and we got new bells and whistles and we can find out more stuff. Male, Intermittent, Higher Education, Greenbelt, MD

I like the word “evolving” science. You’re going forward, new stuff coming in. Younger scientists, fresher people, fresher eyes. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

Maybe research instead of science? Male, Chronic, Lower Education, San Antonio, TX

I was thinking maybe like “scientific discoveries” or something like that, instead of the word “science.” Because it is talking about new risks and you discover new risks. Male, Parent/Caregiver, Higher Education, San Antonio, TX

As opposed to “new science,” ongoing studies, ongoing research, continued research. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

Put [in] that first statement, the new risks and benefits of approved drugs. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

If it can reveal new risks, why can’t it reveal the new benefits too? Female, Parent/Caregiver, Lower Education, Greenbelt, MD

MESSAGE 11—SCIENTIFIC KNOWLEDGE ABOUT DRUG RISKS AND BENEFITS INCREASES AS DRUGS ARE TAKEN BY MORE AND MORE PEOPLE.

Participants overall agreed with the message, and thought it was a clear and accurate statement.

We learn more as we have a larger and larger sample. Of course, at that point, people are already taking it, it's already been tested, but essentially, they're still part of a larger sample group, and the doctors, pharmaceutical companies and FDA, they're all still learning the more it's prescribed. Male, Chronic, Lower Education, Greenbelt, MD

The knowledge does increase as more and more people are taking it, because everybody is different. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

The more people you've got taking a medication, you increase your chances of finding out different reactions and things it might help that they didn't know before. Female, Intermittent, Higher Education, San Antonio, TX

It says to me that the more people that take it, they are going to discover new risks or new benefits because every person is different and every person has a different lifestyle, the way they eat or some people maybe take other drugs for like smoking or something, so their risks are going to be different. Female, Intermittent, Higher Education, San Antonio, TX

I agree with it. Because as people start taking the medications, you also have to think people are also taking other medications. I had a friend who had ADD and was on anti-depressants. So that might affect someone differently than someone just on an ADD medication. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

A few participants felt that the message stated the obvious and offended participants by presenting the idea in what they felt was a simplistic way.

But it's not terribly informative. It's the statement of the obvious. Male, Intermittent, Higher Education, Greenbelt, MD

They're trying to use very clear language and small words to the point where it feels condescending. I didn't realize it at first, but it's almost making it too simplistic. Like you don't really understand so I'm going to speak slowly... Female, Parent/Caregiver, Higher Education, Greenbelt, MD

Those who felt the statement could be improved offered some small wording changes.

I'm a consumer, so my knowledge as a consumer will increase, too. So knowledge in general, about drugs, increases. So instead of ["scientific knowledge"], just take out the word "scientific" because it's just "knowledge about drug risk and benefits increases as drugs are taken by more and more people." Female, Chronic, Higher Education, San Antonio, TX

I would still like the statement if it said, you know, “consumer knowledge about drug risks.” If it said consumer knowledge, I would still like the statement.
Female, Chronic, Higher Education, San Antonio, TX

Put “benefits” before “risks.” Female, Intermittent, Lower Education, San Antonio, TX

I would put it differently. I don't know how, but it just makes it sound like the only way to find those risks is for more and more people to take it first. I don't like that.
Male, Intermittent, Higher Education, San Antonio, TX

Maybe put that, “pros and cons.” [It's] pretty much the same thing, but it's a little bit lesser than risk and benefits. Male, Parent/Caregiver, Higher Education, San Antonio, TX

Chapter V: Reactions to Messages about Discussing Decisions with Healthcare Providers

Findings from the 2010 study showed that if participants experienced an adverse reaction to a prescription drug, depending on the severity of the reaction and their need for the prescription, they would likely stop taking the drug. In some cases, participants indicated that they would reach out to their doctor or pharmacist to obtain guidance on how to proceed, but most said they would stop the drug before contacting their healthcare professional. In the case of a newly discovered risk, participants said they would continue with the drug if they were not experiencing the actual condition. The likelihood that they would consult their healthcare professional depended upon the potential severity of the new risk.

In 2010, caregivers generally indicated that they were more willing to take risks with their own health than with their children's health. This perspective was especially evident when caregivers discussed how they would respond to a newly discovered risk of a prescription drug. If the decision was for their child, caregivers were more likely to call the child's doctor to discuss the risks and possible alternatives. Caregivers also said that they would usually fill their child's prescriptions but would consider not filling their own.

In this current study, the moderator asked participants if they ever felt they should stop taking a prescription drug without first talking to their doctor. Most participants said they had, at one point or another, stopped taking a prescription drug without consulting their doctor. As in the 2010 groups, several participants said they made the decision to stop a prescription drug after weighing the pros and cons for themselves.

I was taking cholesterol drugs, and I found myself forgetting things and didn't really discuss it with anybody. I was having to come up with a lot of money, and I started talking to somebody and she told me that she had taken cholesterol drugs and was finding that she was forgetting things, and she said and she quit and she became much clearer. At that point, I had stopped because I couldn't afford it anymore, and I found myself thinking clearer too. And so I stopped taking it and I didn't talk to my doctor about it. Female, Chronic, Lower Education, Greenbelt, MD

I was told that I had high blood pressure, and the medicine I was taking caused me to have headaches. So I said, "I'm not taking this stuff anymore." Male, Chronic, Higher Education, Greenbelt, MD

I think that if it [is] not life threatening, which it was in my case, I just stopped taking it. It's not like [my doctor] was going to care. The problem went away. If it was something life threatening, like cancer or dialysis that required a real approval, I wouldn't stop taking something. Male, Intermittent, Lower Education, San Antonio, TX

And as soon as I think I am feeling better, I stop [the drug] because I'm so afraid of side effects and what it's actually doing to my body. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

It was for my daughter, and within a week of her taking it, she just had hives. She just broke out and her face was swollen and puffy and her eyes were almost shut within five days of taking it. So there wasn't any question that I was not going to give it to her anymore. Female, Parent/Caregiver, Lower Education, San Antonio, TX

A few participants mentioned that they trusted their doctor and made sure that they consulted with him/her before they stopped a medication. These participants felt that they did not have the knowledge to make this decision on their own.

I have had a friend who was on an anti-depressant and it says, the doctor told her, "Do not stop taking it." Well, she stopped taking it and the lapse in the medication in her system made her crazy. And she went crazy and he said it's because you are supposed to taper off. So since I am not a physician, all I can do is just depend on the education of the physician to tell me what to do. Female, Parent/Caregiver, Lower Education, San Antonio, TX

I went to the doctor and they prescribed a new prescription and there again at that stage I didn't ask what are the side effects going to be. I felt this irritation and I didn't stop [taking the medicine] until I went back to the doctor and said "look it's causing this irritation," then they advised me to stop. But I wouldn't have known if the irritation was something that it was actually working and I just felt miserable or whether I should just stop altogether because it's not working. So I did end up going to the doctor and then once I described it they stopped it. Female, Intermittent, Higher Education, Greenbelt, MD

In the following part of the discussion, the moderator gathered feedback from participants to see if the messages encouraged consumers to discuss decisions with healthcare providers before stopping prescription drugs. Again, the moderator asked participants to frame their responses using the same questions noted in Chapter Two.

MESSAGE 12A—DON'T STOP TAKING A PRESCRIBED DRUG UNTIL YOU'VE CHECKED WITH YOUR DOCTOR. YOUR DOCTOR IS A TRAINED MEDICAL PROFESSIONAL WHO HAS SPENT YEARS LEARNING ABOUT BODIES AND KEEPING THEM HEALTHY— ARE YOU?

*Please note that this message was only tested in the Chronic groups in Greenbelt, MD.

This message was not well received by participants. They were especially turned off by the tone of the message, stating that it was very confrontational. In particular, they did not like the way the message ended with the question, “are you?” Participants stated that they were offended by the second sentence, in that it seemed condescending and disrespectful.

I don't think they should pose it as a question in that fashion. I wish they had used a different way of saying it rather than saying “are you?” It's too much attitude. You don't want to offend your audience. Female, Chronic, Higher Education, Greenbelt, MD

It sounds like there should be a gesture with it. You can just drop the “are you?” Male, Chronic, Higher Education, Greenbelt, MD

I think that second statement is too combative. Are they trying to get smart? It's got too much of an attitude. Female, Chronic, Lower Education, Greenbelt, MD

I would say the second sentence here sounds condescending. Male, Chronic, Higher Education, Greenbelt, MD

I would question the second statement. It has a little attitude. You [don't] need to tell us that, because even when they prescribe a pill to you, if [the doctor has] never had a patient that's taken that pill before, he may not necessarily know all about that particular pill. He looked up in the book what would work for your particular condition. Male, Chronic, Lower Education, Greenbelt, MD

After the first night of testing, FDA modified Message 12A to remove “are you” from the end of the second sentence because the overwhelming consensus was that it was too aggressive and condescending. Because Message 12A was only tested with two groups, there were few suggestions for improvement other than the criticism given to the “are you?” and the second sentence. One suggestion made was to change the first sentence to one that offers advice rather than presenting a command.

I think that if the FDA wants to put something out, it should be advice. One should consult a doctor if you think that there's a reason to stop taking your prescription medication. Don't come out with these statements of don't do this and don't do that. Male, Chronic, Higher Education, Greenbelt, MD

MESSAGE 12B— DON'T STOP TAKING A PRESCRIBED DRUG UNTIL YOU'VE CHECKED WITH YOUR DOCTOR. YOUR DOCTOR IS A TRAINED MEDICAL PROFESSIONAL WHO HAS SPENT YEARS LEARNING ABOUT BODIES AND KEEPING THEM HEALTHY.

*Please note that this message was only tested in the Intermittent and Parent/Caregiver groups in Greenbelt, MD.

After removing “are you?” from the statement, the moderator tested Message 12B with the remaining Greenbelt focus groups to see if participant feedback on the rest of the message was any different. Participants had mixed feelings about this message, with many indicating that the tone of the message was still condescending.

Why is it like they are talking to you like you're a child? Male, Intermittent, Lower Education, Greenbelt, MD

If it were a second grade class [that was receiving this message], it would be perfect. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

Participants felt that the first sentence was believable and important, but they still disliked the second sentence, saying that it was of little value to the overall message.

Is the second sentence supposed to justify the first sentence then? Or what's the intent of the second sentence? That's a statement, they've done that, but what's that got to do with taking a prescription drug or not? Male, Intermittent, Higher Education, Greenbelt, MD

I know a lot of my prescriptions now say, “Consult your doctor before [you] stop taking this.” Why do I need to know that he's a professional, been studying bodies, and doing what he needs to keep me healthy? Female, Parent/Caregiver, Lower Education, Greenbelt, MD

You don't have to tell them that they've been trained medically. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

Some also questioned whether the second statement was accurate, commenting that although a doctor has studied bodies he/she does not really know your body. Additionally, it is primarily the responsibility of the individual to keep their bodies healthy, and not their doctor.

I feel that I'm responsible for my health, and I should know when I'm healthy or not. My doctor is just helping me. It's a hand. Not completely 100%. I'm responsible for my health, not him. Male, Chronic, Lower Education, Greenbelt, MD

He spent all those years learning about bodies, but he hasn't studied my body, so he doesn't know what that medicine's going to do to my body. Female, Chronic, Higher Education, Greenbelt, MD

I understand you're a trained professional. You went to medical school, I see your degree. But it doesn't mean you know what's best for me. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

In spite of the concerns regarding the condescending tone of Message 12A and 12B, some participants liked what the statement was saying and thought it was a good reminder.

I really appreciate the first sentence because it's true. You could have some adverse reaction, so you really shouldn't stop taking a prescribed medicine until you have checked with the doctor. Female, Chronic, Higher Education, Greenbelt, MD

I agree with [the statement]. I would like to think that my doctor knows that it would be adverse to your health to just stop taking a drug, and I'm definitely going to listen to him, that you should not just stop it. Male, Chronic, Lower Education, Greenbelt, MD

So I think it's important, and I think it needs to be [gotten] across [to] anyone that is taking a prescription drug: they need to check with these trained professionals. Male, Intermittent, Lower Education, Greenbelt, MD

For the participants that disliked the message, they suggested removing the second sentence or made other recommendations on how to improve the wording.

The first sentence is okay. You don't need the rest. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I'd take the whole bottom sentence out. "Before stopping your prescription, please notify your doctor," is pretty much written on everything right now. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

I would get rid of that second sentence altogether. You assume that your doctor is a trained professional. You assume that he's gone through some kind of training. I would try to make it have a message that is to make sure that you check with your doctor for a prescribed drug. Just make it one clean statement. Male, Intermittent, Higher Education, Greenbelt, MD

If you wanted to stick with this, I would drop, "who has spent years learning." Male, Parent/Caregiver, Higher Education, Greenbelt, MD

I would probably restate it and say, "Your doctor is a trained medical professional and before considering stopping this medication, discuss the possibilities before discontinuing this medication, consult your physician." Female, Intermittent, Higher Education, Greenbelt, MD

Instead of "doctor" you could say "trained medical professional." If you want to leave it open to see a physician's assistant. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

MESSAGE 12C—DOCTORS AND NURSES SPEND YEARS LEARNING ABOUT BODIES AND KEEPING THEM HEALTHY. TALK TO A HEALTH CARE PROFESSIONAL BEFORE MAKING IMPORTANT DECISIONS ABOUT YOUR MEDICINES.

*Please note that this message was only tested in the San Antonio, TX groups.

Because the general consensus was that Messages 12A and 12B were condescending, FDA decided to test an alternate statement, Message 12C, with the remaining groups. In general, many participants agreed that the message was stating something that most people already know. Therefore, the feedback was that Message 12C was not a strong message that would catch their attention or persuade them to talk to their health care professionals about their prescription medications.

I think the first sentence is like yeah, I already know that. Female, Intermittent, Lower Education, San Antonio, TX

It doesn't tell me anything that I don't already know. Male, Intermittent, Higher Education, San Antonio, TX

I know that it is there, you have heard it a million times, so it's like something – oh okay, we already know what this is and then just go to the next sentence. Female, Intermittent, Lower Education, San Antonio, TX

I would [talk to a health care professional] anyway without having to read this. Male, Intermittent, Higher Education, San Antonio, TX

We know it. And we know they are professionally trained. Male, Parent/Caregiver, Higher Education, San Antonio, TX

A few participants thought the message would serve as a good reminder to people to talk to their doctor.

It is trying to set the light bulb off on top to trust that you can ask [doctors] and they are going to be honest with whatever concerns you may have over that medication. Some people need to read it because a lot of people don't want to ask and maybe need to read that so they can ask the question. Female, Intermittent, Lower Education, San Antonio, TX

Doctors and nurses know more about the human body than a regular person so if you need some guidance, talk to them. Male, Intermittent, Lower Education, San Antonio, TX

Most of the concerns participants had with this message was the first sentence. For them, this sentence comes across as condescending and implied that doctors and nurses are “smarter” than most people.

I think what's off-putting about the statement is that first part, “doctors and nurses spend years learning about bodies and keeping them healthy.” To me, it's saying we're smarter and we know everything more than you do. Male, Chronic, Higher Education, San Antonio, TX

It doesn't make sense—that first part. They don't need to educate us; we know doctors and nurses go to school, we know what they are for. Female, Parent/Caregiver, Lower Education, San Antonio, TX

It just sounds like second grade language to me. What is [with] the first part of the sentence anyway? Female, Intermittent, Higher Education, San Antonio, TX

It's already obvious doctors and nurses have gone to college and have spent years doing this training. I am not sure what else is going to be in the rest of the statement, so I probably wouldn't get past that. Male, Parent/Caregiver, Higher Education, San Antonio, TX

A few participants thought the first sentence should be removed while other participants suggested revising the message to be more personalized.

Get rid of the first sentence. Male, Intermittent, Higher Education, San Antonio, TX

I don't like the first sentence. Female, Parent/Caregiver, Higher Education, San Antonio, TX

I almost want to hear it say, “Healthcare professionals spend years and your neighbor spent five minutes on Google.” Make it a little confrontive. The first sentence is just whacked. Female, Intermittent, Higher Education, San Antonio, TX

Just [change] the part to, “Talk to your healthcare professional before making decisions about your medicines.” That makes sense. The other one is just too many words. Male, Parent/Caregiver, Higher Education, San Antonio, TX

If the statement said something like, “speak to your family, speak to your friends and speak to a healthcare professional about changing your medicines.” That would make more sense because it's not telling you, “Hey we know more than you. We went to school for this. You're not going to get it.” Female, Chronic, Higher Education, San Antonio, TX

I would probably reword it by saying like your doctor knows more about you. Your doctor obviously has a more intimate relationship with you because they know you so talking to that professional before making your decision is a good idea. Female, Intermittent, Lower Education, San Antonio, TX

MESSAGE 13—YOU WOULD CALL A DOCTOR BEFORE STOPPING YOUR CHILD'S PRESCRIPTION. DO THE SAME BEFORE STOPPING YOURS.

This message resonated with many participants, especially if they were parents. The mothers in particular commented that they could relate to this message. Most participants felt that the statement was accurate and would prompt them to respond as suggested or at least think about how they should respond.

It's an emotional message. It works. Male, Intermittent, Lower Education, Greenbelt, MD

You have to take care of yourself and love yourself as much as you love and take care of your child or children. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

It makes [you] think that you're more willing to take care of your child than yourself and that is a true statement. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

It makes more of an impact because you would definitely talk to your doctor before stopping a child's prescription, but not so much yours. I have. [The statement] puts it more into perspective for you. Female, Chronic, Lower Education, San Antonio, TX

Think about yourself like you do [your] children, because a lot of, I know, mothers do not think of themselves. They think of the child. Female, Intermittent, Lower Education, Greenbelt, MD

I think [it's] pretty believable. I know a lot of parents, including myself, that would call the doctor before stopping your child's prescription because that is your life right there. But for myself, I don't know. Female, Intermittent, Lower Education, San Antonio, TX

I'm not going to do anything that's going to harm my child. Yes, I'm going to call the doctor, but then it's telling me I should do the same for myself. I'm not going to harm my child, so it makes me feel guilty about harming myself. Female, Chronic, Higher Education, San Antonio, TX

A few parents even went so far as to say that the message sounded like a public service announcement that they might see in public places.

It wouldn't be bad on the side of a bus. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

Something you would see on a billboard. Male, Parent/Caregiver, Higher Education, San Antonio, TX

However, participants challenged the absolute nature of the statement, commenting that deciding whether to stop their child's prescription, or even their own, before they call their doctor would be determined by multiple factors. These included the relationship participants had with the doctor, the accessibility and responsiveness of the doctor, the level of severity of the reaction, and the purpose for taking the prescription.

I think it depends on the relationship with the doctor. Are they accessible, is the doctor immediately accessible? [That] would make a difference. Male, Chronic, Higher Education, San Antonio, TX

I don't like that, because if I gave my child a medicine and it gave her a bad reaction and I couldn't get a hold of the doctor, I'm not going to keep giving it to her. I would treat her then the same as I would treat myself. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

If it wasn't a serious reaction I wouldn't probably stop it, but if it was something like they were going into anaphylactic shock or they couldn't breathe, then I would stop it altogether. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

I think it also depends on the prescription. I mean, long-term prescription drugs are a little bit different than "you need to take this until you get better." Female, Intermittent, Lower Education, San Antonio, TX

Many participants said that they would stop their child's medication and decide on the next steps, which would likely include consulting with the doctor. These participants felt that they are ultimately responsible for the well-being of their child, not the doctor.

If you say that it's having an adverse effect on your child, you would stop giving the child the prescription then call the doctor. Female, Chronic, Higher Education, Greenbelt, MD

If the child is having adverse effects, you would stop the prescription. Why would you continue to give your child a prescription that is obviously making him or her worse? Female, Chronic, Lower Education, Greenbelt, MD

I really don't like the assumptions that it is making. I can think of possible scenarios going on through my head where I would stop a drug before I would call my doctor. I think that is ridiculous to assume that I would call the doctor before stopping a prescription, that I am not smart enough to see that the medicine is clearly causing a problem. That bothers me and I can't get past that. Female, Intermittent, Higher Education, San Antonio, TX

I'll decide what I'm going to do, don't tell me that. The other thing is there's an assumption made by whoever's sitting behind the glass there that you'll just pick up the phone. The doctor's not sitting there at a desk waiting for you to call. Leave a message, and two weeks later he might call you back. If I've got something going on, I'll try and get a hold of him, and as soon as I can, but I'm going to stop it first. Male, Chronic, Lower Education, Greenbelt, MD

It's your responsibility, not the doctor's. Male, Intermittent, Higher Education, Greenbelt, MD

It's taking [away] any control that we have as adults out of our hands or something, like we're mindless or something. Female, Chronic, Lower Education, Greenbelt, MD

In general, the Greenbelt participants who are chronic users of prescription drugs did not like that the message was giving them a command, and felt that the tone was disrespectful and/or condescending.

It's telling us what to do too much. It's almost like they're talking down to you. Female, Chronic, Higher Education, Greenbelt, MD

The second sentence is also a little bossy. Male, Chronic, Higher Education, Greenbelt, MD

That's a little forward. "Do the same before stopping yours." Why would they even infer that? Male, Chronic, Higher Education, Greenbelt, MD

Some participants felt that the message was too limited in that it seems to only target parents.

I just wanted to point out that some people don't have kids, so who is it they're trying to reach? Are they trying to reach everybody or just people with kids? Female, Chronic, Lower Education, Greenbelt, MD

And not everyone has children. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

I think this is for people that may have kids and for you thinking about your own self as well. Male, Chronic, Lower Education, Greenbelt, MD

Isn't the point is they want to reach a large audience, so why not use words in a more clever way that doesn't separate some people who don't have kids? Female, Chronic, Lower Education, Greenbelt, MD

I would just maybe put "loved one" or something in there like that. Male, Chronic, Lower Education, Greenbelt, MD

Participants offered some suggestions for revising the message. A few recommended not using the statement at all while others provided specific suggestions for rephrasing the message.

I don't know if there is a way to rephrase it. You can just get rid of it. Male, Intermittent, Higher Education, San Antonio, TX

Possibly jump ahead and just say, "If you have concerns or are considering stopping your medication," – or just say, "There could be consequences to stopping certain medications. If you have concerns, contact your doctor." Male, Intermittent, Higher Education, San Antonio, TX

It could say like, "some medications require a length of time for their effectiveness," so you are relating it to the timeframe. So, before you stop taking it, you should talk to your doctor. Maybe put in something about the timeframe that it might take. Male, Intermittent, Higher Education, San Antonio, TX

Everything is always, go to the doctor or call the doctor and, obviously, the doctor is the one who prescribes the medicine, but could you also go to a pharmacist? Couldn't you also check with a pharmacist if you had questions about a prescription? Male, Parent/Caregiver, Higher Education, Greenbelt, MD

MESSAGE 14—MEET JANE – MOTHER OF TWO. SHE VOLUNTEERS AT SCHOOL, DRIVES THE CARPOOL TO SOCCER PRACTICE, AND ALWAYS TALKS TO HER CHILDREN'S DOCTOR ABOUT THEIR HEALTH. BUT JANE WAS TOO BUSY TO TALK TO HER OWN DOCTOR ABOUT THE SIDE EFFECTS SHE EXPERIENCED FROM HER OWN MEDICINE. "I THOUGHT I KNEW ENOUGH AFTER READING ABOUT MY SYMPTOMS ONLINE, SO I QUIT TAKING MY PRESCRIPTION. THAT DECISION LANDED ME IN THE HOSPITAL." DON'T LET THIS HAPPEN TO YOU – TALK WITH YOUR DOCTOR BEFORE STOPPING YOUR PRESCRIPTIONS.

As with the previous statement, participants seemed to connect with this message, especially the female participants. The message seemed to accurately depict their life circumstances and the consequences of their actions.

I think they're trying to describe her as being a normal, responsible person. She's active in her community. I think the overall message is that she, like most people, you get busy with life, and look at the price that she paid for not being careful. So I think most people would think, "That could be me." Female, Chronic, Lower Education, Greenbelt, MD

I agree with it. I guess a statement like this makes it more personable so you see that there is someone just like you out there so it makes it feel like you need to speak to your doctor. Female, Intermittent, Lower Education, San Antonio, TX

And how many of us have a computer at home and research things? I mean, we all do it. The very first thing I do when I start taking a new medicine or have a new diagnosis or whatever, I am on the internet researching everything I can find out about it. Well, what if that information leads me to stopping my medicine because I didn't get the fully story? So this is an incredibly good story that would stick in my mind, the information. I really like that. Female, Intermittent, Higher Education, San Antonio, TX

That makes me think twice before stopping a medicine. Male, Intermittent, Lower Education, San Antonio, TX

They are trying to give you like a real life testimony that this happened to somebody so don't let it happen to you. This happened to a mom out there and she thought she would just go online and get something and look what happened to her. Male, Intermittent, Higher Education, San Antonio, TX

Participants resonated with the idea in the statement of prioritizing the needs of others over their own, which also includes how they approach their health. This sentiment was strongly conveyed by the caregivers.

As parents we don't think about ourselves. We can handle sleeping three hours a night or we can handle those things. But in reality when it comes to prescription drugs, we can't – they are serious. Female, Parent/Caregiver, Higher Education, San Antonio, TX

I mean, you do tell your kids to watch out for this, take this, take that, but then we always forget about ourselves. We always forget to take care of ourselves because we want to think of the other person first, which is our kids, our family, and our friends. We think of them. So when it comes down to us, we neglect ourselves. So that is true. Female, Intermittent, Lower Education, San Antonio, TX

I think we're all very busy in life and sometimes we pick and choose what we think is most important. Sometimes taking care of ourselves may not be your priority. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

Participants also liked the case study or story-like nature of the message.

To me, it sounds like a commercial, and it sounds effective. It's getting the point across, because it's clear. They want you to talk to the doctor before you stop a prescription. I think this is putting it in a more positive light, and showing a case study or whatever. I think I would be more apt to listen. Male, Chronic, Higher Education, Greenbelt, MD

If I hear an actual person telling their story more than what FDA [does] or anything like that. I guess with personal experience, like you see on commercials and stuff like that, you see the people talking about their personal experience—that's what really attracts me more. At least I know what they felt, what they went through and that catches me. Female, Intermittent, Lower Education, San Antonio, TX

There were mixed reactions, however, to the tone of the message. A few participants felt that the message was too forceful and did not like the use of the word, “don’t.”

I think it’s a little bit of a scare tactic. I do agree with the last statement. [But] not how they say “don’t,” like they’re pushing it on you. But I think you should always consult with your doctor before stopping your prescriptions. Female, Chronic, Higher Education, Greenbelt, MD

I just think that they’re trying too forcefully to get the point across with these commands. Male, Chronic, Higher Education, Greenbelt, MD

I liked this one all the way to the last sentence when they took a right turn and drove the bus off the cliff. Male, Chronic, Higher Education, Greenbelt, MD

As with the previous statement, some participants felt that the message seemed to be limited in that it targets a specific audience. In this case, it is the soccer mom.

A mother of two doesn’t have anything to do with my life at all and carpool and soccer practice. It doesn’t relate to me at all. Male, Intermittent, Higher Education, Greenbelt, MD

But what if you’re not female or a soccer mom and you don’t volunteer at school? By the time you got to the first sentence there are people who have tuned it out because they say, “That doesn’t apply to me.” Female, Parent/Caregiver, Higher Education, Greenbelt, MD

A common suggestion that participants provided was to use this message as a commercial or radio advertisement because of its length. Regarding the commercial, one recommendation was to include visuals while the story was told so that the viewer could have images they could connect with.

I think you need the visual, you know, soccer mom in the car running all over the place and in the hospital room. Male, Intermittent, Higher Education, Greenbelt, MD

I think it would be well-suited for maybe a radio-type campaign. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

This would be much better as a TV ad as opposed to a text ad. Male, Intermittent, Higher Education, Greenbelt, MD

Most of the other suggestions that participants provided focused on rephrasing the last sentence. One other recommendation was to create similar messages that would target other audiences.

It could probably be more direct that, if you stop taking a medication that you’re playing doctor. Female, Intermittent, Higher Education, Greenbelt, MD

So it gives you sort of an example, but that last sentence, it said don't let this happen to you, it would be something more encouraging. You know, it's important to talk to your doctor if you have concerns about your side effects. Male, Chronic, Higher Education, Greenbelt, MD

Well, maybe at the end, they just should say, you know, consult with your doctor before stopping your prescriptions. I mean, they're trying to do a little story here, but that's basically what I would do. Female, Chronic, Higher Education, Greenbelt, MD

Talk with your health professional before stopping your prescriptions, because not everybody maybe goes to a doctor. Female, Chronic, Higher Education, San Antonio, TX

It would be, "Meet Joe, the tough guy. He thought he knew everything about medicine." Female, Intermittent, Higher Education, Greenbelt, MD

Chapter VI: Reactions to Messages about FDA's Role

In this final discussion, the moderator asked participants about their perceptions of the relationship between the FDA and drug companies. The moderator asked participants about whose responsibility it is for making sure prescription drugs work and are safe, and whether the FDA and drug companies influence each other in any way.

Some of the responses shared by current participants were similar to those conveyed by the 2010 study participants. In both studies, participants expressed a sense of distrust regarding the safety and promotion of prescription drugs. Participants also questioned FDA's role in testing and approving prescription drugs. They had underlying concerns that the "business" of developing, approving, marketing and prescribing drugs was primarily about financial gain. However, this sentiment was expressed more strongly in the 2010 study groups.

Generally, current study participants had mixed feelings on what the FDA's role is in its relationship with the drug companies. Most participants viewed the FDA as overseeing drug manufacturers and acting in the best interest of public health. However, some participants questioned the relationship between the FDA and drug manufacturers, suggesting that both are financially motivated or that FDA is outmatched in its attempt to keep up with drug manufacturers.

The drug companies want to develop the drugs to do certain things amongst the people, and the FDA's job to me is to oversee all of that to make sure that those things are done well enough to take care of the people that they're designed for. Male, Chronic, Lower Education, Greenbelt, MD

Well, the drug companies have to prove that their medication does what they are claiming. And that has to be proved to the FDA. Female, Chronic, Lower Education, San Antonio, TX

[FDA is] independent, which is very good because they are non-biased to the drug companies and they are just out for the best for the consumer. So a lot of faith is put into them to keep us safe, almost more so than the drug makers because everyone looks at them as billion dollar industries. Female, Parent/Caregiver, Lower Education, San Antonio, TX

The FDA and the drug companies are both responsible for it, but I like to think at least that the FDA is just like the safety check or they are like, the drug police. Male, Parent/Caregiver, Higher Education, San Antonio, TX

It's about money. It's all about money. Male, Intermittent, Lower Education, Greenbelt, MD

Husband and wife. Well, they have their good days and they have their bad days. But they're still in bed together. Male, Chronic, Higher Education, Greenbelt, MD

Prescription drugs are a game and the FDA ... they're like a semi-pro outfit trying to keep up with the professionals. The pharmaceutical companies are completely outsized with what the FDA can keep up with in terms of their research and development capabilities, lobbying abilities, and budgets and money that they control. The FDA is only capable of taking on so much; it's really a David versus Goliath. Male, Intermittent, Higher Education, Greenbelt, MD

The remaining sections of this chapter summarize participants' feedback on four messages related to FDA's role. These statements differ from the previous messages in the report in that they are more like tagline messages or slogans. In addition to asking participants to frame their responses using the questions from Chapter 2, the moderator asked participants to think about whether the statements are consistent with how they think about the FDA as a source for health-related information.

MESSAGE 15—FDA. MAKING SCIENCE-BASED DECISIONS TO PROTECT YOUR HEALTH.

Overall, participants were mostly positive about this statement. Many liked the message and thought it was strong statement. They agreed that the statement made sense, was clear, and represented the FDA appropriately.

This one says they're using science-based fact. They're going and they're doing the research and they have a control study group and they have the non control, and, you know, that makes me feel good. Male, Chronic, Higher Education, San Antonio, TX

It comes across strong in saying it protects our health. That's their main focus. That's what the statement makes it seem like. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I like it because they are making a science-based decision to protect your health. Male, Intermittent, Lower Education, San Antonio, TX

It says that they're taking responsibility scientifically to make decisions that we hope [is to] protect our health. Just like some of us have sat here and said, nothing is going to be 100%, and I think the FDA with all best intentions is trying to focus [on] that. Male, Chronic, Lower Education, Greenbelt, MD

I think that it's clear. Female, Chronic, Lower Education, San Antonio, TX

I see like a guy in a lab coat. Male, Parent/Caregiver, Higher Education, San Antonio, TX

A great motto for the agency, I think. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

A few participants said they thought the message could be helpful for those who are unfamiliar with FDA.

A lot of people don't know the specifics of the FDA; they don't know the science aspect. They know, this is approved by the FDA. That's great, but how are they approving it? Female, Parent/Caregiver, Lower Education, Greenbelt, MD

They are letting you know because not everybody is as smart as everybody, so they are just trying to inform you. They are there to protect your health. Female, Intermittent, Lower Education, San Antonio, TX

However, a few participants questioned the believability of the message. Some said the message failed to acknowledge other factors on which FDA bases its decisions, the work performed by drug manufacturers, and consumers' role in protecting their own health.

Actually it makes it too narrow, because there should be laws. There are a whole lot of things that go into making a decision about your health besides science. Male, Intermittent, Higher Education, Greenbelt, MD

I don't think that all of the decisions they're making are based on science exclusively. They're a political entity. Male, Intermittent, Higher Education, Greenbelt, MD

I don't believe that. It is the drug makers that do that. FDA just approves them. Male, Intermittent, Lower Education, San Antonio, TX

It's not even informative. They are making decisions to protect us. It's like we have no input in there. We have no say-so. We have no access to that science-based information. Female, Parent/Caregiver, Lower Education, San Antonio, TX

I don't need the FDA protecting my health. I want them to say, "This particular prescription drug is safe" or "here are the side effects; we give it approval." I want them to ensure the safety of medications. So that protecting my health part is the one that rubs me wrong. Male, Chronic, Higher Education, Greenbelt, MD

A few participants also said the message seemed very commercial for a government agency.

It almost makes it commercialized, like a business sort of slogan. Male, Parent/Caregiver, Lower Education, San Antonio, TX

It looks like [the FDA is] trying too hard for a movie tagline kind of thing. Female, Intermittent, Higher Education, San Antonio, TX

Overall, the participants did not provide many recommendations on how to improve the statement. Those that did provide changes focused on improving the use of the word “science.”

I think science isn't perfect, so maybe, “making the best science-based decisions to protect your health.” Female, Parent/Caregiver, Higher Education, Greenbelt, MD

FDA. Using science to protect your health. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

MESSAGE 16—FDA KEEPS WATCH ON PRESCRIPTION DRUGS FOR YOUR SAFETY.

Participants liked the statement as a whole. For many participants, this statement made them feel safe and assured them that the FDA is monitoring drugs for their well-being. They also felt the statement correctly portrayed the FDA and was believable.

They are saying it is making sure the prescription is safe for you to take. They are watching over your health, making sure everything is okay before you take it. Female, Intermittent, Lower Education, San Antonio, TX

“Keeps watch” is I think positive in the sense that it's saying we don't just put it out there and forget about it. We're watching. We're monitoring it constantly. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I believe it, because it wouldn't have been released or approved in the first place. So if there's a prescription drug that's sold in America, it's already met the FDA's approval. Female, Chronic, Lower Education, Greenbelt, MD

That I could see on their website as a statement. Male, Parent/Caregiver, Higher Education, San Antonio, TX

It makes you feel all warm inside. Female, Intermittent, Lower Education, San Antonio, TX

I think it's a true statement. Female, Intermittent, Lower Education, Greenbelt, MD

That is believable. Male, Intermittent, Lower Education, San Antonio, TX

For others, the statement raised suspicion as to how or why the FDA would play this kind of role.

I actually feel a little suspicious about the FDA in this statement, that they have to keep watch on prescription drugs for our safety. If there was a question of safety, why release it? Female, Parent/Caregiver, Lower Education, San Antonio, TX

Who's watching the watchers? You don't hear of FDA being sued. It's the companies that made that medicine that got past FDA; they're the ones being sued, in trouble or in litigation. FDA, you don't hear no more about them after it gets passed. So I say who's watching them? Male, Intermittent, Lower Education, Greenbelt, MD

Is that before you're allowed to sell them? Or after [the drug companies are] selling them? Male, Chronic, Lower Education, San Antonio, TX

Although many participants liked the statement, some disliked the phrase “keeps watch.” They felt that the phrase implied that FDA played a passive role in drug monitoring.

This statement almost makes it seem like they're not as involved. One says just “keeps watch.” That kind of makes me skeptical. “Keeps watch?” Male, Parent/Caregiver, Higher Education, Greenbelt, MD

I think the statement's a little bit weak. “Keeps watch” seems very passive. Male, Chronic, Higher Education, Greenbelt, MD

What does “watch” mean? Male, Intermittent, Higher Education, San Antonio, TX

How much do they keep watch? And how do they keep watch? Female, Intermittent, Higher Education, Greenbelt, MD

There is no way they could keep an eye on every prescription. Male, Parent/Caregiver, Lower Education, San Antonio, TX

Some participants suggested ways to rephrase the statement to help the reader understand FDA's role in drug safety.

I would reword it to say something [like], “actively ensures that prescription drugs meet independently established safety standards.” Male, Chronic, Higher Education, Greenbelt, MD

I would just make it, “FDA keeps watch on drug safety.” Male, Intermittent, Higher Education, Greenbelt, MD

FDA approves prescription drugs for your safety. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

More like, “FDA working to keep prescriptions safe and effective.” Male, Parent/Caregiver, Higher Education, Greenbelt, MD

I think it would sound better: “FDA keeps monitoring prescription drugs for your safety.” Male, Intermittent, Lower Education, San Antonio, TX

I think “monitor” might be a more believable word. Because then they’re monitoring reports not watching. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

The FDA monitors prescriptions as like, as issues arise, like an under the radar kind of thing. Like if something happens, they are going to start keeping an eye on it. Male, Parent/Caregiver, Lower Education, San Antonio, TX

MESSAGE 17—IN THE COURT OF HEALTH, FDA WEIGHS THE EVIDENCE AND JUDGES IN YOUR FAVOR.

This statement invoked strong emotional reactions, where participants either really liked the statement or were completely turned off by it. The statement was problematic because many participants did not understand that the statement was a metaphor. For the few participants that did like the statement, they found it to be true and lighthearted, which they appreciated.

It’s just reiterating the fact that the FDA has the highest standards, and they are always going to put your best interests first. Male, Chronic, Lower Education, Greenbelt, MD

I do believe they weigh the evidence and they judge appropriately based on that. Female, Chronic, Lower Education, San Antonio, TX

I think it’s cute, I like [it]. It makes me smile. It’s a pun—“in the court of health.” Female, Parent/Caregiver, Lower Education, Greenbelt, MD

The subset of participants that did not understand what the statement meant had the most difficulty with the phrase “court of health.” This misunderstanding was especially prevalent in the lower education groups.

Where’s the court of health? Never heard of that before. Female, Chronic, Lower Education, San Antonio, TX

I don’t understand this one. Male, Chronic, Lower Education, San Antonio, TX

Where is the court of health? And if a drug is in your favor, they’re there for our safety and health anyway. It’s ridiculous. Male, Intermittent, Lower Education, Greenbelt, MD

“Judges in your favor,” I don’t know what that means. Female, Chronic, Lower Education, San Antonio, TX

However, even participants who understood the statement did not feel it described the FDA's role in an understandable or valuable way, especially to the lay person. A few of these participants felt that the statement should be more serious.

It might not be the best illustration. I mean [I] understand it, but I don't know if everyone would, because some people think quite literally, "what is the court of health?" Male, Chronic, Higher Education, Greenbelt, MD

I think it makes sense, but I think you are going to confuse a lot of people and they are not going to remember it. Female, Intermittent, Lower Education, San Antonio, TX

They're trying to make it catchy for a layperson I'm sure, but it seems as if they're being flippant to me. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

Too lighthearted. Female, Parent/Caregiver, Lower Education, San Antonio, TX

Corny. Female, Intermittent, Higher Education, San Antonio, TX

Many participants thought the statement should not be used at all. Several of these participants were of this opinion because the statement reminded them of lawsuits involving adverse events and drug recalls. A few others had some suggestions on how to improve the statement.

It's not a good statement. It makes you think of lawsuits. Male, Chronic, Higher Education, San Antonio, TX

People might think about some court cases that didn't speak highly of the whole process that the FDA uses. Female, Chronic, Lower Education, Greenbelt, MD

It weighs negatively on them because what it does is it makes me focus on all the litigation surrounding the FDA's decisions on recalls and everything else. So I would stay away from that one. Male, Intermittent, Higher Education, Greenbelt, MD

I think you should remove that statement altogether. Male, Chronic, Lower Education, Greenbelt, MD

I don't like that particular statement. Female, Chronic, Higher Education, San Antonio, TX

Take the "court of health" off. Female, Chronic, Higher Education, San Antonio, TX

It's not about judging in my favor. It's about judging the effectiveness of the drug against what are the standards for safety and effectiveness. Male, Chronic, Higher Education, Greenbelt, MD

Maybe when they say in the court of health, maybe the statement should say for purposes of your health. Female, Chronic, Higher Education, San Antonio, TX

MESSAGE 18—FDA. THE LAST WORD ON DRUG SAFETY.

In general, many participants had concerns with this statement. The majority of participants questioned the validity and believability of the statement. A few participants, however, stated this was a good, true statement.

I think it's a good slogan and is memorable. I think it is something they want ... maybe something you'd put at the end of a commercial or the end of something, and people would remember that. It just caught me, and it's funny, because it sounds so absolute like they really got it. Male, Chronic, Higher Education, Greenbelt, MD

I liked the FDA is the last word on drug safety, because it's something that I can remember, it's distinct, and it's positive. You can read whatever you want to into it, but it's a positive message and I think that's a good tagline. Male, Intermittent, Higher Education, Greenbelt, MD

It sounds good, the last word, the final – I feel assured by it, but it seems real bold. Male, Intermittent, Lower Education, San Antonio, TX

To the point. Female, Intermittent, Higher Education, San Antonio, TX

Reassuring. Male, Intermittent, Higher Education, San Antonio, TX

As with most of the other statements discussed in this chapter, many participants did not think this statement appropriately reflected the FDA's role in drug safety, and felt it was too strong of a statement.

I don't think their function is really to be the last word on drug safety. Male, Intermittent, Higher Education, Greenbelt, MD

I think they're taking too much ownership for the ability to know everything. Male, Parent/Caregiver, Higher Education, Greenbelt, MD

I think that they have some say on the last word of drug safety, but I think, again, that the drug manufacturers have a big influence on the FDA's last word on drug safety. Male, Chronic, Lower Education, San Antonio, TX

Too cocky. Female, Parent/Caregiver, Lower Education, San Antonio, TX

I just don't know if that's believable. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

[It is not believable] because they have too many recalls. Female, Parent/Caregiver, Lower Education, Greenbelt, MD

Some participants indicated the statement is untrue because they feel the consumer has the last word. A few also stated that, because there are always new developments pertaining to prescription drugs, no entity has the final word.

I think the last word on drug safety is the person that's taking that [drug]. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I think we are the last word on drug safety. We can make our own decision. Female, Chronic, Lower Education, Greenbelt, MD

It makes you discount it just because they can't be [true]. There is no final word. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

I don't think that is true because they are going to come out and say oh, new science has developed a new risk. Well, I thought it was the last word. Male, Intermittent, Lower Education, San Antonio, TX

Many participants had suggestions on how to improve the message's accuracy and/or believability.

I would take the word "safety" off and put "approval." Last word on drug approval, because FDA, even though they approve a drug, they still don't know how safe it is. Female, Chronic, Higher Education, Greenbelt, MD

You could be the best word, but it's not the "last" word. [I am] not saying anything's their fault. It's over time you find that there are things you didn't expect. Female, Parent/Caregiver, Higher Education, Greenbelt, MD

Change "the last word on drug safety" to "FDA. [The] first choice for drug safety." Male, Chronic, Higher Education, San Antonio, TX

I'd like to see something like "FDA. Working to make drugs safe," or "Working to build your trust in drug safety." Female, Chronic, Higher Education, San Antonio, TX

That would be better, "[FDA.] The seal of approval." Female, Intermittent, Lower Education, San Antonio, TX

**Appendix A:
Participant Screener**

Testing Messages to Improve Consumer Knowledge about Prescription Drug Risks and Benefits: Participant Screener

Recruiting Goals

- Six groups in each location. See table below for specifications at each location.
- Four groups will be with chronic users of prescriptions medications. Four groups will be with intermittent users of prescription medications who are not also chronic users. Four groups will be with parents or caretakers of children (infants to age 16). Caregivers who also indicate being personal users of prescription medications may be assigned to the respective group in which they are most needed (i.e., Chronic, Intermittent, or Caregiver).
- The groups will be segmented by level of education. Prepare the moderator for the possibility that they may not be able to cover the details of all the topics.
- The chronic users group will be with adults over 35 years old. The parents and caretakers group and the intermittent user group will be with adults age 21 and older.
- Each group will be a mix of men and women. There should be no fewer than 3 to 4 members of each gender (male, female) in each group. Participants will be advised during the screening process that these will be mixed gender groups.
- Each group will be a diverse mix of races and ethnicities. The groups should reflect the demographics of the surrounding areas. Overall, there should be an approximately even split between white and black non-Hispanic, and Hispanic participants.
- All participants must be able to read, understand, and speak English.
- Participants cannot have participated in a focus group or a similar study in the past **six months**. Participation in phone surveys is allowable.
- 12 recruits per group in order to get 8-10 to participate.
- **Participants will receive \$75 stipends.**
- Each focus group will last approximately 90 minutes and will be audio and videotaped.
- Participants do not have to answer any questions that they do not want to, but are encouraged to participate in the groups. The identity of the participants will remain private to the extent permitted by law.
- Food and Drug Administration staff will observe the groups.

Schedule

	Date & Time	Location	Education	Medication Use
Group I	Sept 12, 2011 6pm	Greenbelt, MD	Lower education	Chronic
Group II	Sept 12, 2011 8pm	Greenbelt, MD	Higher education	Chronic
Group III	Sept 14, 2011 6pm	Greenbelt, MD	Lower education	Intermittent
Group IV	Sept 14, 2011 8pm	Greenbelt, MD	Higher education	Intermittent
Group V	Sept 15, 2011 6pm	Greenbelt, MD	Lower education	Parent/Caregiver
Group VI	Sept 15, 2011 8pm	Greenbelt, MD	Higher education	Parent/Caregiver
Group VII	Oct 18, 2011 6pm	San Antonio, TX	Lower education	Chronic
Group VIII	Oct 18, 2011 8pm	San Antonio, TX	Higher education	Chronic
Group IX	Oct 19, 2011 6pm	San Antonio, TX	Lower education	Intermittent
Group X	Oct 19, 2011 8pm	San Antonio, TX	Higher education	Intermittent
Group XI	Oct 20, 2011 6pm	San Antonio, TX	Lower education	Parent/Caregiver
Group XII	Oct 20, 2011 8pm	San Antonio, TX	Higher education	Parent/Caregiver

Participant Screener for Adult Focus Groups

Hello, my name is _____ and I'm calling about a market research study in your area. We are recruiting for an upcoming focus group in which participants will be asked to share their thoughts and feelings about medicines.

Would you mind answering a few questions? All of the information you provide will remain private to the extent permitted by law.

Screening Questions

Q1. Have you taken any prescription drugs in the past 6 months, that is, since (month) 200x? We are talking about any prescription drugs. These could include, for example, antibiotics, prescription hormones of any sort, birth control pills, drugs to control diabetes, heart disease or mental health disorders, prescription pain relief drugs, etc.

- Yes → continue, Go to Q2
- No → Go to Q4

Q2. In the last six months, have you taken at least one prescription drug on a regular basis, such as daily, weekly, or monthly?

- Yes → assign to **Chronic user** group, Go to Q4
- No → continue, Go to Q3

Q3. In the last six months, have you taken a prescription drug occasionally or on an “as needed” basis? A few examples of this would be taking an antibiotic for a few days to a few weeks for an infection; or taking a painkiller as needed for migraines, or to control pain following a minor injury or surgery.

- Yes → assign to **Intermittent user** group, Go to Q4
- No → continue, Go to Q4

Q4. Do you have primary responsibility for caring for a child (who is less than 16 years old) as part of your immediate family?

- Yes → continue, Go to Q4a
- No → eliminate

Q4a. In the last 6 months, has that child taken at least one prescription drug on a regular basis, such as daily, weekly, or monthly?

- Yes → assign to **Caregiver** group, Go to Q5
- No → continue, Go to Q4b

Q4b. In the last 2 months, has that child taken at least one prescription drug occasionally or on an “as needed” basis? A few examples of this would be taking an antibiotic for a few days to a few weeks for an infection, or an allergy drug to treat an occasional reaction.

- Yes → assign to Caregiver group, Go to Q5
- No → eliminate

Q5. Do you or someone from your immediate family work or have worked or are retired from any of the following:

- Market Research Firm → eliminate [thank respondent politely]
- The Food and Drug Administration, → eliminate [thank respondent politely]
- The National Institutes of Health → eliminate [thank respondent politely]
- Pharmaceutical Company → eliminate [thank respondent politely]
- Physician office, hospital, clinic, or pharmacy → eliminate [thank respondent politely]
- The Department of Health and Human Services → eliminate [thank respondent politely]
- A State Health Department → eliminate [thank respondent politely]

Q6. Have you participated in a focus group within the past six months?

[Interviewer: participation in telephone surveys is allowable]

- Yes → eliminate [thank respondent politely]
- No → continue

Demographic Questions

Q7. Determine gender

- Male
- Female

Q8. How old are you? _____ years. (if under **21**, eliminate and thank politely)

Q9. What is the highest level of education that you have completed?

- Less than high school → lower education group
 - High school graduate or GED → lower education group
 - Technical/vocational school → lower education group
 - Some college credit, but less than 1 year → lower education group
-

- 1 or more years of college, no degree → higher education group
- Associate's degree (AA, AS) → higher education group
- Bachelor's degree (BA, AB, BS) → higher education group
- Master's, doctoral, or professional school degree (MA, MS, MEd, MEng, MBA, MSW, PhD, MD, JD, DVM, EdD) → higher education group

Q10. Are you of Hispanic, Latino, or Spanish origin?

- Yes
- No

Q11. What is your race? Please select one or more.

- White
- Black or African American
- American Indian or Alaska Native
- Asian
- Native Hawaiian or other Pacific Islander

We would like to invite you to participate in a focus group to discuss issues relating to medicines with 8 to 10 other participants. The focus group will take place on (Day), (Date), at [6:00 or 8:00 p.m.] at [site location]. The discussion will last approximately an hour and a half and will include both men and women. The group will be audio and video taped and observed by staff from the federal Food and Drug Administration. However, your participation and everything you say during the discussion will be private to the extent permitted by law. The FDA will not have your full names and will keep all tapes locked up until they are destroyed. You will receive **\$75** cash for your time. Additionally we will serve you [insert type of food served] before the group discussion will start. Will you be available to participate at this time?

- Yes → continue
- No → [Thank the person for his/her time]

I would like to send you a confirmation letter and directions to the focus group facility. Can you please tell me your mailing address (or fax number) and a phone number where you can be reached:

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____

Email: _____

Date of focus group: _____ Time: _____

We are only inviting a few people, so it is very important that you notify us as soon as possible if for some reason you are unable to attend. Please call [recruiter] at [telephone number] if this should happen. We look forward to seeing you on [date] at [time]. If you use reading glasses, please bring them with you to the focus group.

**Appendix B:
Informed Consent**

Informed Consent for Participation in the Food and Drug Administration Discussion Groups

ICF Macro is conducting discussion groups for the Department of Health and Human Services, to gather your thoughts and opinion on materials and messages developed to inform consumers about the risks and benefits associated with the use of prescription drugs. We have invited you to participate in a discussion with other consumers to share your knowledge and thoughts about this topic.

If you consent to participate in the discussion, here are some things you should know:

- Your participation is totally voluntary.
- Your name will not be used in any reports about this discussion group. We will be taking notes during the discussion about what was said, but we will not record who made the comments.
- The discussion will be audio- and video-taped so that when we write our report we can make sure we understand everything that was said.
- There will be observers from the Food and Drug Administration and ICF Macro in another room taking notes during this discussion.
- Anything discussed during the group will be confidential
- You will receive \$75 for participating in the group.
- You may discontinue participation at any time, either by leaving the discussion group or not answering a question, without penalty or loss of benefits.
- The discussion group will last approximately 90 minutes.
- Any questions you have about the discussion groups will be answered before we begin our discussion. Contact information is provided below for any questions that arise after the discussion.
- You will be provided with a copy of this form to take with you.

Contact information: If you have any concerns about your participation in this discussion group or have any further questions about the project, contact Ms. Edith Stevens at ICF Macro, telephone number (301) 572-0534.

Your signature below indicates that you understand the above and agree to participate in this group.

Print your name: _____ Date: _____

Signature: _____ Witness: _____

Appendix C: Moderator's Guide

Moderator's Guide

Consumer Perceptions of Prescription Drug Communications

Welcome and Introductions (2 minutes)

Good evening. My name is _____ and I will be your moderator for tonight's discussion about prescription drugs. I am employed by a management consulting firm located just outside of the District of Columbia. Right away, I want to let everyone know that I'm not a medical professional, and I am not an expert on the topic we will be discussing. I am a trained focus group moderator.

I want to hear your honest opinions about the topics we will discuss tonight. There are no right or wrong answers to the questions I'm going to ask. Please just relax and enjoy the discussion.

Please keep in mind that your participation in this discussion is completely voluntary. If for any reason you wish to leave the discussion, you may.

Ground Rules (3 minutes)

Before we begin, I'd like to review some ground rules for today's discussion. Ground rules are our guidelines for operating so that we can complete our task in a manner that is respectful of everyone and provides all of you with the opportunity to express your thoughts safely and confidentially.

- Everyone's participation is important.
- Please speak one at a time and avoid side conversations.
- Again, there are no right or wrong answers.
- Please use your first names only during the discussion.
- It's okay to be critical. I want to hear your views and opinions about whether you like or dislike something you see or hear.
- This session will be audio and video taped. This allows us to capture everything that is being said today, and we will include the information in a report to our client.
- All of your answers will be confidential, so feel free to say exactly what is on your mind. Nothing will be attributed to any particular person in our report.
- If anyone needs to use the restroom, they are located [specify]. There is no need to stop the discussion.
- You may excuse yourself from the conversation at any time for any reason.
- Lastly, please turn off the ringers on your cell phones.

NOTE TO MODERATOR: Mention to participants that there are observers in the adjacent room.

ICE BREAKER (5 MIN)

Moderator: Let's go around the room and introduce ourselves. Please tell me your first name, how long you have lived in the area, and just a little bit about your household.

1. GENERAL DISCUSSION (5 MIN)

Tonight we're going to talk about prescription drugs or medicines (and we can use those terms interchangeably). As part of the discussion, I'll be sharing with you a number of statements about prescription drugs and asking for your thoughts and reactions. The statements I'll be sharing tonight aren't about specific drugs. Rather, the statements are about prescription drugs in general. They are statements you might read or hear in a news report or consumer update that would go along with more detailed information about a specific drug.

- So to get started, what does the term prescription drug mean to you? What are some examples of these types of drugs? ***[IF THEY HAVEN'T ALREADY MENTIONED IT, let them know that a prescription medicine is one that you can't get without a prescription from a prescribing healthcare provider.]***

2. GENERIC VS. BRAND NAME (20 MIN)

- What does the term generic drug mean to you? Can you name any examples?
- What does the term brand name drug mean to you? Can you name any examples?
- Are brand name prescription drugs and generic prescription drugs identical? **[IF NO, PROBE]:**
 - How do they differ?
 - Is there a difference in cost between generic prescription drugs and brand name prescription drugs? **[PROBE]** Why do you think that is?

IF THEY HAVEN'T ALREADY MENTIONED IT, let them know that a generic drug is an equivalent version of a brand name drug. This differs from cases where different brand name drugs can be used to treat the same condition. For example, some of you may have heard of the drug Ambien that can help people fall asleep. A doctor could also prescribe Zolpidem tartrate tablets—this is the drug's generic name. This is what we are talking about when we discuss generic and brand name drugs. We are not talking about how both Ambien and Lunesta, another name brand drug made of different ingredients, can be used to help people fall asleep.

Now let's take a look at some specific statements about generic and brand name drugs. We are going to repeat this pattern throughout tonight's discussion. After we talk about a topic for a few minutes, I'll share some related statements for us to discuss.

DISPLAY STATEMENTS one at a time using large foam-board posters. Read each statement aloud as it is displayed. Make statements available on printed paper to any participant who has trouble viewing the large poster. The sequence in which the statements are presented to participants should be determined before each focus group and balanced to limit order effects.

REMIND PARTICIPANTS: When reviewing the statements, please stay focused on the following sets of questions. Do not focus on the layout or design of the statement. Rather, focus on what the statement means to you and how would you respond to it.

DISPLAY PROBING QUESTIONS on a flip chart for participants to keep in mind as they view each statement. 1) What does this mean to you? 2) Does it make sense to you? 3) How clear or confusing is it? 4) Would you re-phrase it? 5) How believable is it? 6) How does it compare to what your health care provider may have told you? 7) Are you surprised by it?

- *A generic drug includes the same active ingredient that makes a brand name drug work. Your doctor or pharmacist can talk with you about other differences.*
- *A drug's cost does not reflect how well it works. Brand name drugs cost more to pay for drug research and development. Generic drugs cost less because they use existing research.*
- *Generic drugs are as safe and work as well as brand name drugs. All drugs meet FDA's high standards – from quality and performance to manufacturing and labeling.*

3. SIDE EFFECTS (25 MIN)

Next, let's talk more about brand name prescription drugs. Specifically, let's discuss the ads for brand name prescription drugs you see on television, in magazines, or online.

- How do those ads usually make you feel about taking the advertised drug?
 - **[PROBE]** How does hearing the side effect information make you feel about taking the advertised drug? ***[IF OVER-THE-COUNTER DRUGS ARE MENTIONED, remind them we are only talking about drugs that require a prescription from a doctor or other prescribing healthcare provider.]***
- Potential side effects are also in the written information you probably get with your prescription drugs. Think about the last time you got a new prescription filled for a drug you had never taken before.
 - Did reading about the potential side effects affect how you felt about taking the drug? **[If yes, PROBE]** How did it affect how you felt?

- Let's look at some statements now about prescription drug side effects. As you review these next set of statements, please remember to respond to the questions posted on the flip chart
 - *Don't let information about side effects scare you away from using a prescription drug. Instead, ask your doctor if the drug's benefit to your health is more important than the possible side effects.*
 - *No drug is 100% safe – if it has a good effect, there's at least a chance of an unwanted bad effect.*
 - *Like everything you put in your body, prescription drugs have risks. Many are minor and unlikely to happen, but some can be more serious. Your doctor can help you decide which risks are worth taking.*

4. RESEARCH NEEDED FOR DRUG REVIEW (20MIN)

Now let's talk about the research needed to support whether a prescription drug should be approved.

- What is your understanding of how drugs are researched, reviewed, and approved? **[PROBE]:** For example, who conducts the research? How much and what kind of research do you think is needed for FDA to determine whether a drug should be approved? How many people do you think are studied?

Now let's look at some more statements – this time about drug review. Again, please remember to focus on the questions listed on the flip chart.

- *By the time you hear about a “new” drug, it isn't new to FDA. FDA bases its drug approval decisions on years of research, starting from drug makers' early safety tests in animals to later tests in hundreds or thousands of patients.*
- *Drug approvals are never rushed. FDA's decision to approve each new drug requires years of research and evidence of safety and effectiveness.*
- *FDA does not speed drug approvals to help drug makers. In special cases, FDA speeds the approval process for promising drugs that treat serious conditions. This is to benefit patients who desperately need new therapies that work.*

Now we are going to talk about newly discovered risks associated with prescription drugs. How is it that new risks are sometimes discovered for drugs that have been available for years?

Again, I am going to show you another set of statements and get your thoughts and opinions. For these statements, imagine you are reading a news report about a newly discovered risk for a prescription drug that has been available for years. The report offers these statements about how the new risk was discovered. Please remember to stay focused on the set of questions listed on the flipchart.

- *New science can reveal new risks of approved drugs.*
- *Scientific knowledge about drug risks and benefits increases as drugs are taken by more and more people.*

5. DISCUSSING DECISIONS WITH HEALTHCARE PROVIDERS (20 MIN)

We've discussed a few cases in which you might want to talk with your doctor about prescription drugs and the ads you see on television, in magazines, or online.

- Can I see a show of hands--how many of you have ever felt you should stop taking a prescription drug without first talking to your doctor? [moderator count the number of raised hands]
- **[PROBE]:** Can 1 or 2 of you tell me about the situation and the decision you made?
- Again, let's take a look at some possible relevant statements around this issue. Please remember to stay focused on the set of questions listed on the flip chart.
 - *(A) Don't stop taking a prescribed drug until you've checked with your doctor. Your doctor is a trained medical professional who has spent years learning about bodies and keeping them healthy – are you?*
 - *(B) Don't stop taking a prescribed drug until you've checked with your doctor. Your doctor is a trained medical professional who has spent years learning about bodies and keeping them healthy.*
 - *(C) Doctors and nurses spend years learning about bodies and keeping them healthy. Talk to a health care professional before making important decisions about your medicines.*
 - *You would call a doctor before stopping your child's prescription. Do the same before stopping yours.*
 - *Meet Jane – mother of two. She volunteers at school, drives the carpool to soccer practice, and always talks to her children's doctor about their health. But Jane was too busy to talk to her own doctor about the side effects she experienced from her own medicine. "I thought I knew enough after reading about my symptoms online, so I quit taking my prescription. That decision landed me in the hospital." Don't let this happen to you – talk with your doctor before stopping your prescriptions.*

6. UNDERSTANDING FDA'S ROLE (25 MIN)

- What do you think is the relationship between FDA and drug companies? **[PROBE]:** In terms of making sure prescription drugs work and are safe, who is responsible for what? Do they influence each other in any way?
- Here are the last few statements that I'd like you to consider. These last statements are a bit different from the ones you've seen so far in that they are more like tagline messages or slogans.

- In addition to the questions listed on the flipchart, I'd like you to also consider a few other questions: **[Additional PROBES for this section]** Is it consistent with how you think about the FDA, or is it different? What, if anything, does the statement say to you about FDA as a source for health-related information?
 - *FDA. Making Science-Based Decisions to Protect Your Health.*
 - *FDA keeps watch on prescription drugs for your safety.*
 - *In the court of health, FDA weighs the evidence and judges in your favor.*
 - *FDA. The last word on drug safety.*

FALSE CLOSE (2 MIN)

Moderator will leave the room to check with observers for follow up questions.

ENDING:

Those are all the questions I have for you tonight. Are there any final thoughts about this topic that you want to share before we leave?

Thank you again for your help with these focus groups. Good night.

**Appendix D:
FDA Workgroup Conclusions**

Appendix D: FDA Workgroup Conclusions

This appendix provides an overview of FDA's 2011 focus group study of 18 communication messages related to prescription drugs. Included in this overview is FDA's interpretation of the general findings, as well its conclusions on how to refine each message. These conclusions are based on the report prepared by ICF Macro and FDA's own notes from observing each focus group session. Although included as an Appendix in ICF Macro's report, the following conclusions were written independently by FDA's Risk Communication Staff (Office of the Commissioner/Office of Planning), and coordinated with a workgroup consisting of representatives from all three medical product Centers.

FDA initiated this focus group study because it has been told by many concerned healthcare providers that their patients are learning about relevant product problems, and often taking inappropriate action (e.g., stopping critical medicines) even before their providers know about the issue and can institute their own communications with their patients. Focus groups conducted in 2010 supported this notion and provided insight into consumer attitudes toward filling and taking prescription drugs. From this formative research, FDA drafted messages to fill in the gaps in consumer perceptions about the use of generic drugs, the importance of discussing decisions with healthcare providers, and FDA's role in the drug review process. These messages are intended for use in future FDA communications, possibly in combination with one another, and likely accompanying more detailed information about specific products. These short, tagline messages aim to provide consumers with the context they may need to have a better understanding of more complicated risk benefit information, and therefore enable better prescription drug decisions.

General Findings

FDA conducted the 2011 focus groups to pretest 18 messages related to prescription drugs. For the most part, participants' comments were specific to each statement. However, a few themes emerged across the messages. These themes can be generally applied to future communications, either in development of new messages or when tested messages need to be adapted to fit the context of a broader communication.

- **Avoid condescending language:** Participants were quick to identify language that seemed condescending. They responded negatively to messages that started with the word "Don't," explaining that these statements sounded like commands. They found language such as "are you?" to be overly aggressive. Participants also indicated that a few messages were simplistic and written in such basic terms that they were not informative. For example, participants called for an explanation of the phrase "new science," explaining that this simplified term raised more questions than it was worth.
- **Be mindful of audiences' intelligence:** Participants voiced displeasure with messages that they perceived as insulting their intelligence. They commented that they did not need to have explained to them that doctors are highly trained medical professionals. Participants also said that some messages that asserted doctors' expertise or FDA's authority seemed to ignore consumers' ability to make rational decisions for themselves.

- **Avoid broad assumptions:** Participants pointed out that some messages made assumptions that aren't always necessarily true. For example, they indicated that side effect information may not “scare” all consumers. In fact, many participants said that seeing the word “scare” would in fact cause them to be scared in cases where they would otherwise not be overly concerned. Participants also suggested that many patients do not feel they have a good enough relationship with their healthcare provider to have in-depth discussions about prescription drugs.
- **Use stories to connect with audiences:** Participants’ most favorable reactions were to messages that they said elicited an emotional response. Participants said they found a testimonial-style message helpful and relatable. They particularly liked messages about taking care of their own health the way they would their children’s health.
- **Remember that less can sometimes be more:** Participants were often distracted by language that was not essential to the core message. For example, the mention of animal testing had participants debating whether the practice was ethical rather than focusing on the message that FDA thoroughly reviews new drugs. In a separate message, participants discussed the defensive tone of FDA stating it does not speed drug approvals to help drug makers rather than focusing on reason why FDA sometimes does speed approvals.

The following sections provide a brief summary of participants’ feedback on each message, as well as explanations for FDA’s refinement of each communication.

Messages about Generic and Brand Name Prescription Drugs

Message 1 was generally well received by focus group participants, but participants identified two areas of concern. Participants said they believed the statement that generic drugs include the same active ingredient as brand name drugs, but they questioned if the amount was the same. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Therefore, the word “amount” was added to the message. Participants also pointed out that “other differences” only makes sense if the statement names a difference, which it does not. For this reason, “other differences” was changed to “possible minor differences.”

MESSAGE 1 EDITS

*A GENERIC DRUG INCLUDES THE SAME **AMOUNT OF THE** ACTIVE INGREDIENT THAT MAKES A BRAND NAME DRUG WORK. YOUR DOCTOR OR PHARMACIST CAN TALK WITH YOU ABOUT ~~OTHER~~ **POSSIBLE MINOR DIFFERENCES**.*

Message 2 had many focus group participants questioning why they would ever pay more for brand name drugs. Although the message seemed generally effective in this regard, the second sentence served as a distraction to some participants who wanted to list other potential reasons for brand name drugs costing more. By deleting the second sentence and mentioning the word “development” later, the revised message places more emphasis on the reason for generic drugs costing less.

MESSAGE 2 EDITS

*A DRUG'S COST DOES NOT REFLECT HOW WELL IT WORKS. ~~BRAND NAME DRUGS COST MORE TO PAY FOR DRUG RESEARCH AND DEVELOPMENT. GENERIC DRUGS COST LESS BECAUSE THEY USE EXISTING RESEARCH~~ **THAT LED TO THE DEVELOPMENT OF BRAND NAME DRUGS.***

Most participants indicated that Message 3 was clear and understandable, but they still offered a few suggestions for improving the statement. Participants frequently used the word “effective” throughout the discussions, and suggested using it rather than the phrase “works as well.” They suggested dropping the word “all” from the second sentence, so the word “both” was inserted to reference generic and brand name drugs and to build a stronger link between the two sentences. Participants also suggested that inserting the word “must” would build their confidence in FDA’s enforcement of its standards.

Participants questioned the phrase “FDA’s high standards.” Although many participants were comforted by seeing FDA mentioned in the statement, several participants were unsure if the standards are truly high. Others wondered if the standards listed are all inclusive. To address the latter issue, commas were used to replace the words “from” and “to.”

MESSAGE 3 EDITS

*GENERIC DRUGS ARE AS SAFE AND ~~WORK AS WELL~~ **EFFECTIVE** AS BRAND NAME DRUGS. ~~ALL DRUGS BOTH MUST MEET FDA'S HIGH STANDARDS~~ **FROM FOR QUALITY, AND PERFORMANCE, TO MANUFACTURING, AND LABELING.***

Messages about Prescription Drug Side Effects

Participants identified a number of concerns with Message 4. This was the first of several messages that received criticism for having a negative and condescending tone because of the word “don’t.” Participants also suggested that the message assumes that all audience members are scared. For these reasons, the word “don’t” was replaced with “if.” Participants said the word “scare” raised a red flag and made them even more wary of prescription drugs than before seeing this message. For this reason, the word “concerned” replaced the word “scare.” The message’s ending was changed from “side effect” to “risks” to make the resulting single-sentence statement less repetitive.

MESSAGE 4 EDITS

~~DON'T LET INFORMATION~~ **IF YOU ARE CONCERNED ABOUT A PRESCRIPTION DRUG'S POSSIBLE SIDE EFFECTS SCARE YOU AWAY FROM USING A PRESCRIPTION DRUG. INSTEAD, ASK YOUR DOCTOR IF THE DRUG'S BENEFIT TO YOUR HEALTH IS MORE IMPORTANT THAN THE SIDE-EFFECT RISKS.**

Although some participants did not see much value in Message 5, others said more information like this needs to be available to consumers. Some participants focused heavily on the word “if,” interpreting the main message as being that prescription drugs are a gamble. Even more participants said that the phrase “unwanted bad effects” was nonsensical because bad effects are never wanted. Message 5 was edited to avoid both of these issues. In addition, a new third sentence was added to encourage consumers to talk with their doctor or pharmacist about their concerns with side effects.

MESSAGE 5 EDITS

~~NO DRUG IS 100% SAFE. -IF IT HAS A~~ **THE GOOD EFFECTS, THERE'S THAT PRESCRIPTION DRUGS CAN HAVE ON YOUR HEALTH COME WITH AT LEAST A CHANCE OF AN UNWANTED BAD SIDE EFFECTS. YOUR DOCTOR OR PHARMACIST CAN EXPLAIN THE LIKELIHOOD OF THESE SIDE EFFECTS TO YOU.**

Although some participants disagreed with the assertion that everything has risks, most agreed with the wording of Message 6. The phrase “risks are worth taking” made several participants uncomfortable in much the same way that the word “scare” caused a sense of alarm in Message 4. The phrase “what is best for you” was inserted in its place.

MESSAGE 6 EDITS

LIKE EVERYTHING YOU PUT IN YOUR BODY, PRESCRIPTION DRUGS HAVE RISKS. MANY ARE MINOR AND UNLIKELY TO HAPPEN, BUT SOME CAN BE MORE SERIOUS. YOUR DOCTOR CAN HELP YOU DECIDE WHICH RISKS ARE WORTH TAKING WHAT IS BEST FOR YOU.

Messages about Drug Review and Newly Discovered Risks

The second sentence of Message 7 seemed to distract participants from the overall purpose of the statement. Several participants pointed out the sensitivities around animal testing even if they themselves were not animal rights activists. Participants also indicated that they viewed the difference between testing in hundreds or thousands of patients as significant, which caused them to be concerned with how extensively their prescriptions had been tested.

With Message 8, many participants disagreed with the absolute nature of the first sentence. Some questioned the believability of the sentence and blamed the occurrence of drug recalls on rushed approvals. Others indicated that the sentence contradicted their knowledge of cases in which drug approvals can be fast-tracked.

Consistent with participants' recommendations to drop the second sentence of Message 7 and the first sentence of Message 8, the remaining sentences (which were not doubted or criticized) were combined to form a single message.

MESSAGE 7 AND MESSAGE 8 MERGER

~~BY THE TIME YOU HEAR ABOUT A "NEW" DRUG, IT ISN'T NEW TO THE FDA. FDA BASES ITS DRUG APPROVAL DECISIONS ON YEARS OF RESEARCH, STARTING FROM DRUG MAKERS' EARLY SAFETY TESTS IN ANIMALS TO LATER TESTS IN HUNDREDS OR THOUSANDS OF PATIENTS.~~

~~DRUG APPROVALS ARE NEVER RUSHED. FDA'S DECISION TO APPROVE EACH NEW DRUG REQUIRES YEARS OF RESEARCH AND EVIDENCE OF SAFETY AND EFFECTIVENESS.~~

Participants' primary criticism of Message 9 was a perceived contradiction of the first and second sentences. Although the first sentence includes the clause "to help drug makers," little attention was paid to it. Instead, participants took issue with exceptions made for special cases after having stated that "FDA does not speed drug approvals." For this reason, the word "sometimes" was inserted and the text rearranged to avoid this perceived contradiction. A few participants also questioned the meaning of "to help drug makers" or said that it seemed defensive for FDA to state this. Based on these comments, the phrase was deleted.

MESSAGE 9 EDITS

~~FDA DOES NOT *SOMETIMES* SPEED DRUG APPROVALS TO HELP DRUG MAKERS. IN SPECIAL CASES, FDA SPEEDS THE APPROVAL PROCESS FOR PROMISING DRUGS THAT TREAT SERIOUS CONDITIONS. THIS IS *ONLY DONE IN SPECIAL CASES* TO BENEFIT PATIENTS WHO DESPERATELY NEED NEW THERAPIES THAT WORK.~~

While many participants saw the value of Message 10, several struggled with the phrase "new science." Edits were made to elaborate on this concept, as well as to place an equal emphasis on the possibility of new benefits being discovered.

MESSAGE 10 EDITS

NEW ADVANCES IN SCIENCE AND TECHNOLOGY CAN REVEAL NEW RISKS AND BENEFITS OF APPROVED DRUGS.

Message 11 was generally well received, with only a few participants saying that it stated the obvious. No edits were made.

MESSAGE 11: NO CHANGE

SCIENTIFIC KNOWLEDGE ABOUT DRUG RISKS AND BENEFITS INCREASES AS DRUGS ARE TAKEN BY MORE AND MORE PEOPLE.

Messages about Discussing Decisions with Healthcare Providers

In this section of the focus groups, the intent was to test messages that delivered the basic message of “talk to your doctor” in a way that would grab consumers’ attention. The messages used emotional, and sometimes aggressive, tactics in their attempts to get the point across. The focus group findings showed that some of these tactics worked better than others.

Participants in the first night of testing were so offended by Message 12A’s phrase “are you?” that they ignored the rest of the message. For this reason, FDA removed the controversial phrase and tested Message 12B during the next two nights. Even with this change, participants focused on the condescending nature of the second sentence. As with Message 4, the word “don’t” was perceived as a command and participants consistently commented on the statement’s negative tone. Despite the harsh criticism that Message 12A/B received, several participants saw value in the reminder to discuss prescription drug decisions with a doctor. In an attempt to keep the core message, FDA deleted the second sentence and added entirely new language to the remaining sentence. These substantial changes call for further focus group testing of the revamped message.

MESSAGE 12A/B EDITS

~~DON'T BEFORE YOU STOP TAKING A PRESCRIBED DRUG, TALK TO YOUR DOCTOR ABOUT THE IMPACT ON YOUR HEALTH AND OTHER OPTIONS FOR TREATING YOUR CONDITION. UNTIL YOU'VE CHECKED WITH YOUR DOCTOR. YOUR DOCTOR IS A TRAINED MEDICAL PROFESSIONAL WHO HAS SPENT YEARS LEARNING ABOUT BODIES AND KEEPING THEM HEALTHY — ARE YOU?~~

Because participant feedback on Message 12A/B became repetitive in the Greenbelt, MD focus groups, a new statement, Message 12C, was tested in the San Antonio, TX focus groups. Although Message 12C was not perceived as being negative or commanding like Message 12A/B, participants said it was just as condescending. They indicated that the first sentence insulted their intelligence and made them feel inferior to doctors. Participants also said the message failed to grab their attention. For these reasons, new language was added to build upon the second half of Message 12C. Again, the extent of these changes calls for further focus group testing of the new message.

MESSAGE 12C EDITS

~~DOCTORS AND NURSES SPEND YEARS LEARNING ABOUT BODIES AND KEEPING THEM HEALTHY.~~
~~TALK~~ **YOU RESEARCHED A PRESCRIPTION DRUG ONLINE – GOOD. YOU TALKED WITH YOUR FRIENDS ABOUT THEIR EXPERIENCES – GREAT. YOU TALKED TO A HEALTH-CARE PROFESSIONAL DOCTOR BEFORE MAKING IMPORTANT DECISIONS ABOUT YOUR MEDICINES: – PERFECT!**

Message 13 struck an emotional chord, with a few participants saying that the message even sounded like a good public service announcement. Although the feedback on this message was largely positive, two areas of concern became evident. First, participants often disagreed with the use of the word “before.” Participants said they would more realistically stop their child’s prescription and then call a doctor, especially in the event of an adverse reaction or when a doctor was not accessible. For this reason, the word “before” was deleted to better account for these types of scenarios. Second, several participants suggested that the message was limited because it only applied to people with children. The phrase “loved one” was added so the message would apply to a broader audience.

MESSAGE 13 EDITS

YOU WOULD CALL A DOCTOR ~~BEFORE~~ ABOUT STOPPING YOUR CHILD'S A PRESCRIPTION FOR YOUR CHILD OR LOVED ONE. DO THE SAME ~~BEFORE STOPPING~~ IF YOU THINK YOU NEED TO STOP YOURS.

Of all the messages tested, Message 14 was one of participants’ favorites. At the end of each discussion, participants often cited Message 14 as the one they could relate to and remember most easily. Although the scenario presented did not apply to all participants (i.e., men without children), the general sense was that the testimonial-style statement was an effective way of delivering the message and targeting specific audiences. The only criticism of the message was with the last sentence. As with other messages, participants did not like the negative tone of the word “don’t” so the words “to prevent” were used in its place.

MESSAGE 14 EDITS

MEET JANE – MOTHER OF TWO. SHE VOLUNTEERS AT SCHOOL, DRIVES THE CARPOOL TO SOCCER PRACTICE, AND ALWAYS TALKS TO HER CHILDREN’S DOCTOR ABOUT THEIR HEALTH. BUT JANE WAS TOO BUSY TO TALK TO HER OWN DOCTOR ABOUT THE SIDE EFFECTS SHE EXPERIENCED FROM HER OWN MEDICINE. “I THOUGHT I KNEW ENOUGH AFTER READING ABOUT MY SYMPTOMS ONLINE, SO I QUIT TAKING MY PRESCRIPTION. THAT DECISION LANDED ME IN THE HOSPITAL.”
DON’T LET TO PREVENT THIS FROM HAPPENING TO YOU, —TAKE TIME TO TALK WITH YOUR DOCTOR BEFORE STOPPING YOUR PRESCRIPTIONS.

Messages about FDA’s Role

Participants were generally positive about Message 15, with several saying the slogan was clear and gave them a favorable impression of FDA. A few questioned the believability of FDA’s decisions being based solely on science, but no major themes emerged to justify editing the statement.

MESSAGE 15: NO CHANGE

FDA. MAKING SCIENCE-BASED DECISIONS TO PROTECT YOUR HEALTH.

The majority of participants found it reassuring to see in Message 16 that FDA keeps watch on prescription drugs. However, a few participants had the opposite reaction, questioning why FDA would need to keep watch on drugs if they already approved them. The main criticism of Message 16 was that the phrase “keeps watch” was too passive. Several participants suggested the word “monitors” as a better fit for the statement.

MESSAGE 16 EDITS

*FDA ~~KEEPS WATCH ON~~ **MONITORS** PRESCRIPTION DRUGS FOR YOUR SAFETY.*

Message 17 received the most negative feedback of all the messages tested. Some participants had trouble with the metaphor. Others did not like the light-hearted approach to the subject. Some participants also said the message reminded them of television ads for drug recall lawsuits. Based on this feedback, Message 17 is not recommended for use.

MESSAGE 17: DO NOT USE

~~*IN THE COURT OF HEALTH, FDA WEIGHS THE EVIDENCE AND JUDGES IN YOUR FAVOR.*~~

Although several participants liked Message 18, some found it hard to believe given reports of drug recalls. Others found the message to be dismissive of consumers' input, with many saying that patients are ultimately the ones who decide if prescription drugs are safe enough for them to take. To soften the definitiveness of the statement and better acknowledge patient's ability to make decisions for themselves, the word "official" was inserted to replace "last."

MESSAGE 18 EDITS

*FDA. THE ~~LAST~~ **OFFICIAL** WORD ON DRUG SAFETY.*

Conclusion

Findings from the 2011 focus group study helped FDA evaluate its 18 communication messages that aim to provide consumers with the balanced risk-benefit context they need to make prescription drug use decisions. The focus groups provided FDA with real consumer reactions that enabled the agency to refine the messages and improve its likelihood of successfully communicating with intended audiences. Below are the final versions of the messages that resulted from the focus group study. Each message is followed by a Flesch-Kincaid grade level, which is a measure of readability that indicates the years of education generally required to understand text.

- *A generic drug includes the same amount of the active ingredient that makes a brand name drug work. Your doctor or pharmacist can talk with you about possible minor differences. (Flesch-Kincaid: 8.3)*
- *A drug's cost does not reflect how well it works. Generic drugs cost less because they use existing research that led to the development of brand name drugs. (Flesch-Kincaid: 5.8)*
- *Generic drugs are as safe and effective as brand name drugs. Both must meet FDA's high standards for quality, performance, manufacturing, and labeling. (Flesch-Kincaid: 8.3)*
- *If you are concerned about a prescription drug's possible side effects, ask your doctor if the drug's benefit to your health is more important than the risks. (Flesch-Kincaid: 11.9)*
- *No drug is 100% safe. The good effects that prescription drugs can have on your health come with at least a chance of unwanted side effects. Your doctor or pharmacist can explain the likelihood of these side effects to you. (Flesch-Kincaid: 6.1)*

- *Like everything you put in your body, prescription drugs have risks. Many are minor and unlikely to happen, but some can be more serious. Your doctor can help you decide what is best for you. (Flesch-Kincaid: 5.8)*
- *By the time you hear about a “new” drug, it isn’t new to FDA. FDA’s decision to approve each new drug requires years of research and evidence of safety and effectiveness. (Flesch-Kincaid: 7.5)*
- *FDA sometimes speeds the approval process for promising drugs that treat serious conditions. This is only done in special cases to benefit patients who desperately need new therapies that work. (Flesch-Kincaid: 10.7)*
- *Advances in science and technology can reveal new risks and benefits of approved drugs. (Flesch-Kincaid: 8.4)*
- *Scientific knowledge about drug risks and benefits increases as drugs are taken by more and more people. (Flesch-Kincaid: 9.7)*
- *Before you stop taking a prescribed drug, talk to your doctor about the impact on your health and other options for treating your condition. (Flesch-Kincaid: 11.4)*
- *You researched a prescription drug online – Good. You talked with your friends about their experiences – Great. You talked to a doctor before making important decisions about your medicines – PERFECT! (Flesch-Kincaid: 7.3)*
- *You would call a doctor about stopping a prescription for your child or loved one. Do the same if you think you need to stop yours. (Flesch-Kincaid: 3.5)*
- *Meet Jane – mother of two. She volunteers at school, drives the carpool to soccer practice, and always talks to her children’s doctor about their health. But Jane was too busy to talk to her own doctor about the side effects she experienced from her own medicine. “I thought I knew enough after reading about my symptoms online, so I quit taking my prescription. That decision landed me in the hospital.” To prevent this from happening to you, take time to talk with your doctor before stopping your prescriptions. (Flesch-Kincaid: 7.2)*
- *FDA. Making Science-Based Decisions to Protect Your Health. (Flesch-Kincaid: 6.6)*
- *FDA monitors prescription drugs for your safety. (Flesch-Kincaid: 9.0)*
- *FDA. The official word on drug safety. (Flesch-Kincaid: 4.3)*