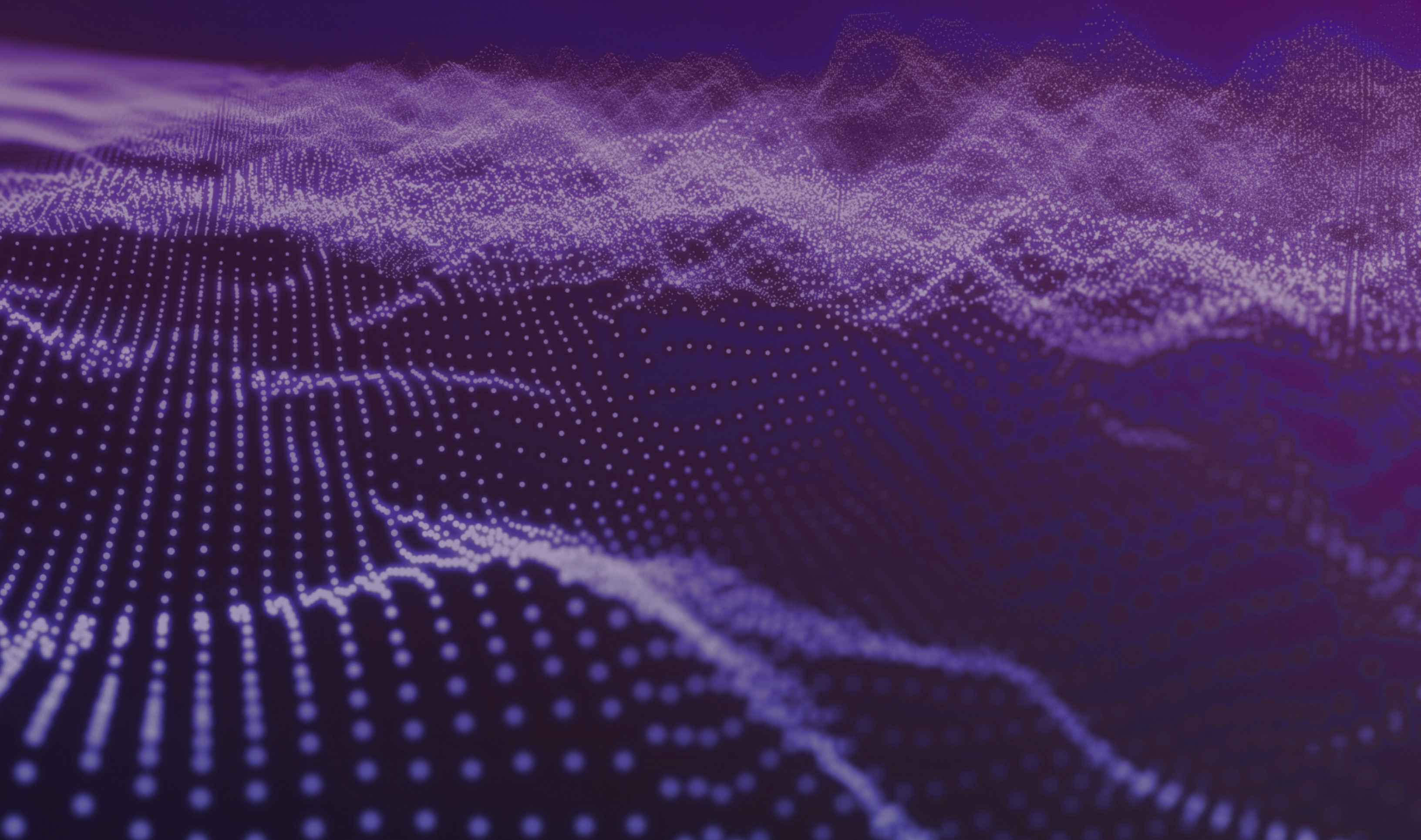
REAGAN-UDALL
FOUNDATION
FOR THE FDA

Improving Patient & Provider Engagement About Medication Information

Summary Report

October 2025

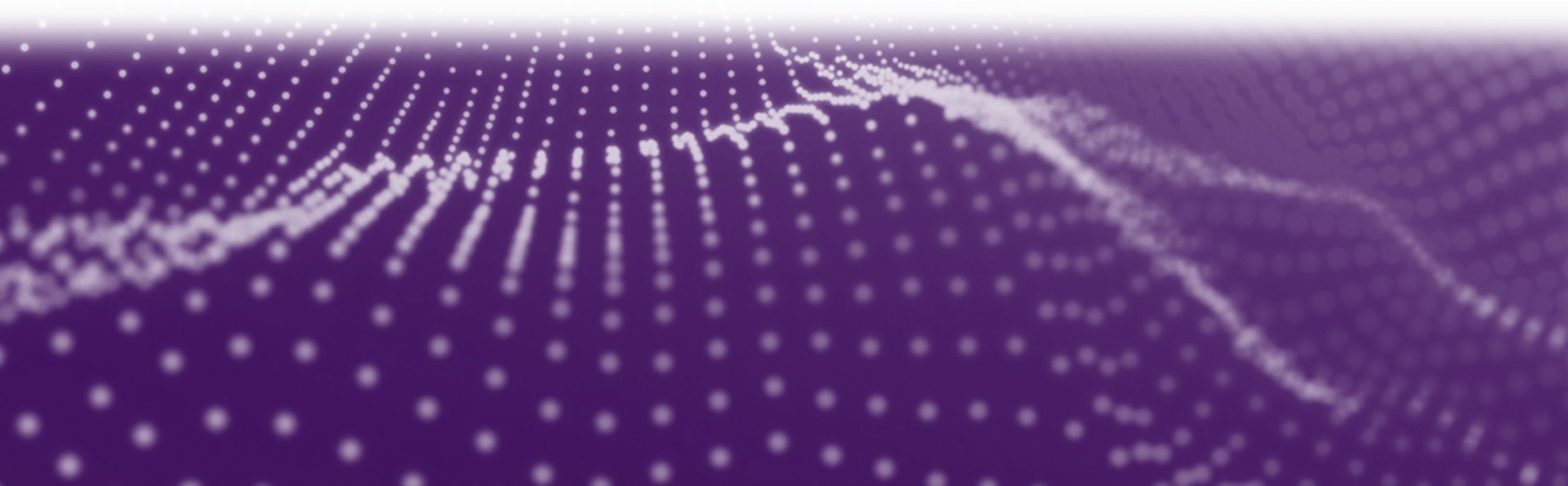


About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA (the Foundation) is an independent 501(c)(3) created by Congress to advance the mission of the FDA to modernize product development, accelerate innovation, and enhance product safety. The Foundation works to advance regulatory science, support development and dissemination of reliable information, and facilitate engagement and information exchange.

This project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of $76,344 in federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.

Contents



Introduction

Between the time a patient leaves their healthcare provider's office and the time they take their prescribed medication, a cascade of communication breakdowns can lead to medication errors, risky interactions, or nonadherence.

As part of the U.S. Food and Drug Administration's (FDA's) commitment to providing patients with the necessary information to take their prescription medications safely and effectively, the Reagan-Udall Foundation for the FDA (Foundation), in collaboration with the Agency's Office of Clinical Pharmacology (OCP) Strategic Plan Working Group, implemented and completed a patient engagement project to better understand how patients comprehend, react to, and use product information. This work is reflective of the Center for Drug Evaluation and Research (CDER) and Office of Translational Sciences (OTS) initiative and commitment to patient-centric engagement and the OCP Strategic Plan Working Group's intention to better understand the pharmacotherapeutic needs of patients, caregivers, and healthcare providers (HCPs).

The Foundation conducted qualitative research to learn how patients with chronic illnesses use and understand information about how to take their medications, specifically, any written materials that accompany their prescription drugs. Through data collected in patient and healthcare provider listening sessions and focus groups, combined with results from a national poll, the Foundation explored what information patients look for, the resources they use, and the concerns they may have about their prescription medications. The findings presented in this project summary are intended to inform the FDA's efforts to transform patient labeling with more effective and cohesive instructions about how to safely and effectively take prescription medications, a change that has potential to positively affect medication adherence, resulting in better health outcomes.

For the purpose of this report, sources of patient medication information provided on the FDA website *Patient Labeling Resources*[1] and in Appendix B will collectively be referred to as "medication information" and "medication information sheets."[2]

Purpose

This project supported efforts of OCP to increase and diversify its patient engagement by

- learning more about how patients understand medication information
- learning from healthcare providers about patient interactions (questions, concerns) related to medication information
- identifying improvements in patient communication about medication information

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[1] https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources

[2] Medication information sources may include patient package inserts, medication guides, instructions for use, and medication information sheets provided at the time of dispensing

Project activities explored real-world barriers to patient comprehension of prescription medication information and identified actionable strategies for improving understandability. The Foundation presents the information and opportunities in this report for consideration by the FDA as appropriate to its mission and authority.

Background

The FDA recognizes that effective patient engagement is vital to ensuring safety, efficacy, and patient adherence to taking medications and using biological products and medical devices. Understanding how patients interpret and use this information is a key factor to health outcomes, which are largely dependent upon correct medication administration.

Building on those learnings and recognizing that there is room to improve the format of FDA Patient Packet Insert, the OCP working group also wanted to better understand any visual elements on the prescription label that could present a barrier to patient understanding and comprehension. Areas of interest included patient reaction to type size, use of headings, and overall arrangement and presentation of the information.

From December 2024 to September 2025, the Foundation led a series of research activities with patients living with chronic illness and healthcare providers who commonly treat chronic conditions. These activities included listening sessions, focus groups, and polling.

Listening Sessions	facilitated discussions where individuals share their experiences, thoughts, and perceptions on a specific topic in a structured, open environment
Focus Groups	guided, moderated sessions with a small group of people to gather feedback and reactions as well as discuss a specific topic to obtain in-depth insights
Polling	a survey or inquiry into a topic, where a large sample of individuals is asked to respond to a series of questions

This sequential, mixed-methods approach, combining qualitative and quantitative data, allowed us to corroborate our project findings and supplement those learnings with more detail. Qualitative data was captured through the facilitated conversations during the listening session and focus groups and the quantitative data was obtained by the national poll responses, which were tracked and measured. This report highlights key learnings and findings that may improve patient understanding of prescription medication information.

Key Findings

Patients struggled to locate and interpret medication label information in three key areas: dosing, interactions, and side effects. Gaps in understanding in any of these three areas may pose serious risks to patient health and wellbeing.

Dosing. Although patients were confident about their understanding of dosing (i.e., dosing frequency and how the medication should be administered), healthcare providers perceived patient understanding of this information differently. Providers reported substantial patient confusion about dosing that can lead to medication errors.

Interactions. Patients felt that they could not find or did not have sufficient information about interactions with other medications, food, beverages, and/or supplements.

Side effects. Side effects were a major concern for patients, and failure to present the possibilities in proper perspective may lead to nonadherence and affect health outcomes.

More than half of the 30 participants in listening sessions and focus groups acknowledged they do not read all of the provided medication information (e.g., product label, FDA Patient Package Insert, pharmacy sheet) and some reported discarding them immediately upon receipt. In contrast, more than half of consumers polled (58%) said they typically read the medication information (FDA insert).

When first asked, patients reported high confidence in their ability to locate and understand medication information provided with their prescriptions. In fact, 78% of poll respondents reported that it was easy to find and understand important information in the medication information they received.

However, a significant gap existed between the level of understanding patients reported in the research activities (poll, listening sessions, and focus groups) and healthcare provider experiences and perceptions of patient understanding of the medication information that accompanied their prescription drugs (see Table 1).

In focus groups, for example, patients rated their understanding of medication information as high 4/5 (5 being greatest understanding) whereas providers rated their patients' understanding much lower (2.55/5). Provider concerns about the level of understanding were validated by patient performance in focus group exercises. When the facilitator asked patients to find and interpret specific medication information associated with their own medications (may have included pharmacy sheets, prescription inserts), many participants had difficulty and missed important details, particularly regarding interactions and side effects. Focus group participants explained that the visual format, length, complexity, and "medical jargon" made the medication information overwhelming.

Patients who took multiple medications struggled with how the medication information was formatted (e.g., a lack of headings, excessive length of medication information sheets). Patients also found it difficult to translate the information and integrate it into their routine.

Table 1. Overall Patient Understanding, Confidence, and Performance

Metric	Patients	Healthcare Providers
Self-rated understanding of prescription information	4 out of 5 on average*	Rated patients, on average, at 2.55 out of 5*
Dosing confidence level	Believed they followed dosing instructions well	Worried patients forget or misunderstand instructions
Exercise results with Patient Medication Information	Missed key information (e.g., interactions, side effects) during medication information review	Concerns confirmed during the exercise

*Rating scale 1-5; 5 = full understanding
Source: Focus Groups (patients n = 21; providers n = 10)

DOSING INSTRUCTIONS: PRESENTED MORE QUESTIONS THAN ANSWERS

Patients were most confident about their understanding of dosing as illustrated in Table 1. Fifty-five percent of poll respondents indicated that dosing instructions in medication information sheets were clear, but qualitative feedback from both patients and healthcare providers presented a more complicated picture.

Providers offered an alternative view regarding dosing information, believing that patients often didn't have a clear understanding of dosing instructions. The more complex the instructions, the greater likelihood of confusion. This was illustrated by a healthcare provider who prescribed pain medication to be titrated according to pain level. It was difficult for family members as well as the patient to assign a dose based on gauging mild, moderate, or severe pain.

In listening sessions, providers noted that practical, real-world questions arose once patients began a new medication regimen, such as what time of day to take the medication, how to handle missed doses, and how to interpret subjective instructions such as "as needed" or those based on pain level. Patients strongly believed that visual cues would be helpful in indicating if medications should be taken with food or at certain times of day (e.g., moon or sun icons that indicated whether medication should be taken in the morning or at night). Qualitative patient feedback also indicated challenges integrating new medications into existing care routines.

DRUG INTERACTIONS: A CRITICAL INFORMATION CHALLENGE

> *"They need to also know how to dose it properly, what to do if a dose is missed and what to be on the lookout for [as well as] benefits of the medication."*
>
> – healthcare provider (listening session)
>
> *"I often have clients asking me what time of day would be best for them to take their medications."*
>
> – healthcare provider (listening session)

Regarding medication information on drug interactions, only 36% of poll respondents reported that they found the information clear; slightly more (41%) had an easier time with information on food interactions. Patients in focus group exercises struggled to wade through medication information sheets with dense text. They commented that information on food interactions was often missing or unclear, and that they wanted to easily locate the information that was relevant to them. During the exercise, one focus group participant learned that a food she had been eating while taking her medication was actually listed as one to avoid due to a possible interaction.

Providers noted that interactions are one of the most difficult topics to explain, and that it is unrealistic to expect patients to understand interactions from current medication information sheets alone. Both patients and providers agreed that pictures or other visual depictions could improve risk awareness.

DRUG SIDE EFFECTS: A SOURCE OF PATIENT CONCERN AND MEDICATION NON-ADHERENCE

Side effects were a major concern for patients, and failure to prioritize them or put them in perspective can lead to nonadherence.

Side effects were the biggest issue identified in focus groups and listening sessions and raised in polling by both patients and healthcare providers. Over half of poll respondents also reported that side effects were not presented in a way they could easily understand.

Patients worried about how side effects may affect their daily life (e.g., ability to focus, drive, sleep) and expressed some confusion about how to differentiate a drug side effect from a drug interaction—both of which could be harmful to patients. In focus group exercises, most patients could eventually locate information on side effects but felt it took too long to find. They commented that the information was not always on the bottle or in the summary provided by the pharmacy and voiced a desire for a standardized layout.

They preferred to see icons that provide at-a-glance information, often referring to supplemental labels sometimes added to medication bottles at a pharmacy, such as those that might signal drowsiness with a nightcap, dizziness with a spinning figure, or general danger with a skull and crossbones.

Providers in listening sessions said medication information sheets overwhelm patients by listing too many side effects, some of which are not meaningful, and can create more fear and anxiety than clarity. Patients who experience angst and confusion relating to possible side effects may forego needed treatment by not taking the medication from the start or prematurely discontinuing the medication without consulting their healthcare provider. For others, when side effects do arise, patients are unsure of the next steps they should take. For these reasons, providers expressed a desire to focus on common, actionable risks.

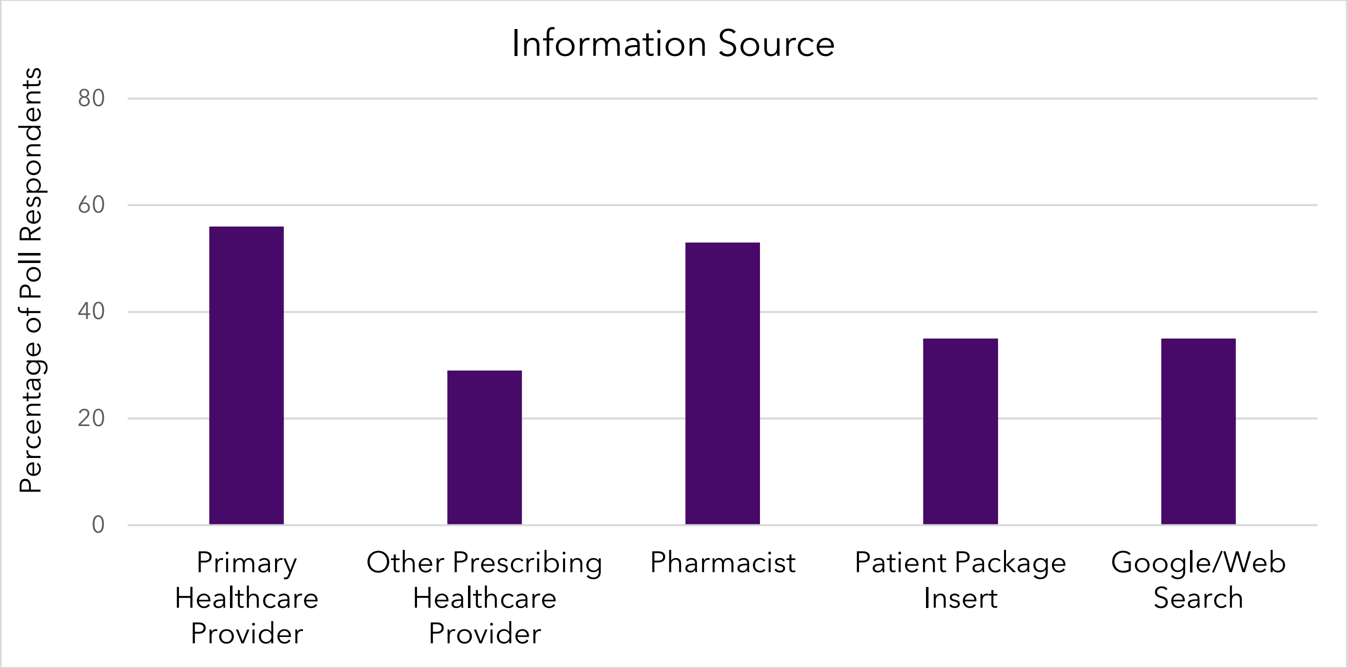
> *"It [side effects] was listed, but it took me a while to find it."*
>
> – patient (focus group)
>
> *"The biggest thing …for me was side effects. That's really important. That's probably the very first thing that I focus on, because I want to know how much is this going to really impact me during my day or my sleep."*
>
> – patient (listening session)
>
> *"Patients often read the label, and they read the side effects, and they don't know if they're going to go away or if these are forever, and they start to panic and want to stop taking their medication without talking to their provider."*
>
> – healthcare provider (listening session)

Information Resources

Resources Used by Patients

While patients prioritized trusted healthcare providers for information, they also reported turning to other sources. A strong majority of consumers polled (79%), felt they had all or most of the information they needed when leaving their provider's office with a prescription for a new medication. They reported seeking answers from trusted healthcare providers as well as web searches and patient medication information sheets (see Figure 1).

Figure 1. Patient Sources for Answers to their Medication Questions
Patients with questions rely on trusted healthcare providers and, to a lesser extent, online searches and patient package inserts.



Source: Poll; respondents were able to reference more than one source
Primary Healthcare Care Provider = general practitioner/regular physician
Other Prescribing Healthcare Provider = issues medications but is not the patient's regular, primary care physician (e.g., hospitalist, urgent care provider, specialist)

In focus groups, patients referenced turning to patient portals, artificial intelligence tools, printed after-visit summaries, peer support groups, and caregivers for medication information. In listening sessions, they reported looking to social media and online communities (e.g., Facebook, Reddit) to engage with others who had the same medical conditions to share information about their experiences with medications. One third of poll respondents reported that they have scanned QR codes on medications and 67% stated they would likely scan a QR code for more information about their medication.

> *"I found [information about an interaction] it on ChatGPT... my doctor said, 'I should have mentioned that.'"*
> – patient (focus group)
>
> *"I would just Google it... by the time I'd find it on here [the patient label], I wouldn't want something to happen."*
> – patient (focus group)

Providers in focus groups voiced concerns about some of the information sources patients consulted (see table 2).

> *"We communicate well in-clinic. It's the info they get elsewhere that causes problems."*
> – healthcare provider (focus group)
>
> *"The pharmacy isn't going to know the true reason behind why the physician or provider prescribed that as an off-label use."*
> – healthcare provider (focus group)

Table 2. Patient Sources for Medication Information: Patients Use vs. Healthcare Providers

Some of the sources patients use raise concerns for providers.

Information Source	Patients' Actual Use & Perception	Provider Preferences & Perceptions
Patient Portals	Used to contact provider, but slow response times can be a barrier	Strongly encouraged; seen as a primary resource
Pharmacists	Viewed as more accessible for urgent needs	May cause patient confusion if not aligned with a provider's medication guidance
Doctors/Providers	Trusted, but often contacted after other sources	Want patients to contact them first
WebMD/Google	Used when other sources were unavailable, some skepticism	Not recommended; may lead to inaccurate conclusions
AI tools (e.g., ChatGPT)	Occasionally used by tech-savvy patients for extra insight	Not mentioned or endorsed
Printed after-visit summaries	Sometimes referenced, especially for dosing instructions	Used to reinforce key information given verbally
Family Members	Especially important for elderly patients	Seen as important stakeholders, but may be a source of confusion if information is not similarly heard by the patient and the family member

Source: Focus Groups

Resources Used by Providers

Healthcare providers currently do not use FDA resources for prescribing information, instead turning to other sources which often draw from FDA news feeds, alerts, and information. Providers relied on available resources such as *drugs.com* and other systems that offer a consistent, faster mechanism for accessing drug and prescribing information.

In listening sessions, providers said FDA communications about approvals and new medications were extremely valuable, as the FDA is a trusted organization. However, in recent years, few providers (3 of 10) could recall receiving FDA communications other than those related to the COVID-19 pandemic. Like patients, providers experienced information overload and preferred access to materials designed to be grasped "at-a-glance." Providers described information from the FDA as too broad and found it difficult to identify information that pertained to their patients. They also described the Agency's communication delivery as something that needed to be modernized, for example, by the use of digital tools.

Table 3 shows the range of external information sources providers told us they use, including academic journals, respected institution websites, and other software.

Table 3. Drug Information Resources Used by Healthcare Providers

	Academic Journals/ Papers	**Clinics** (Cleveland Clinic, Mayo Clinic)	**Drugs.com**	**Epocrates**	**EMR Software**	**Medscape**	**UpToDate**
Nurse				✓			✓
Medical Doctor	✓	✓	✓	✓	✓	✓	✓
Pharmacist		✓	✓		✓		✓
Physician's Assistant	✓		✓			✓	
Therapist/ Psychologist					✓		

Opportunities to Enhance Patient and Provider Engagement

While the research identified significant shortcomings in disseminating medication information, it also revealed actionable opportunities for the FDA to enhance patient and provider communication about medications. Participants from all groups expressed a strong desire for more effective communication.

The FDA has an opportunity to enhance engagement in medication information with both patients and providers. For patients, the Agency could modernize patient package inserts to make the information more accessible. Reimagined in a user-friendly format, the streamlined medication information could serve as an essential resource for patients. For providers, the FDA could leverage digital tools to enhance the relevance and delivery of communications. Providing an option that could tailor content by specialty and disseminate updates through timely, targeted electronic channels (e.g., QR codes, email, and social media) could improve awareness and practical application in clinical settings.

Tip from Patients: Modernize the package insert to make medication information more accessible.

Insights from patients highlighted barriers to understanding medication information and potential improvements (see Table 4); these insights were reinforced by healthcare provider perspectives. The results converged on a set of core principles for reimagining package inserts as an essential patient resource:

Patient-friendly language: Provide medication information in plain language that is easy to understand and free from medical jargon—or that clearly defines any necessary medical terms.

Concise summary: Create a one-page, accessible, plain-language summary that highlights the most critical information on dosing, side effects, and interactions.

Intuitive, consistent design: Develop a standardized structure and patient-friendly formatting that optimizes typography (e.g., larger font, bold headings) and iconography to help patients easily find and comprehend information.

Supplemental digital options: Include ways to access additional information and alternative formats through digital channels. Options could include QR codes that link to websites, explainer videos, or audio summaries that cater to different learning styles and preferences for consuming information.

Table 4. Insights From Patients on Barriers and Potential Improvements to Medication Information*

Patients articulated both concerns and potential solutions.

Top Barriers	Top Improvements
Too long, dense jargon	One-page summary of dosage, side effects, and interactions
Tiny fonts	Larger font size
Poor formatting with minimal use of bold, headings, or symbols	Bold headings Standardized presentation

Source (barriers): Focus groups

Source (improvements): Poll

*refers to any provided medication information

Tip from Healthcare Providers: Use digital tools to make medication information more relevant to their practice and provide timely updates.

Healthcare providers indicated that while they value the FDA as a trusted information source, they look elsewhere for prescribing information. They suggested strategies the Agency could use to enhance provider outreach by adopting digital tools that facilitate timely, targeted dissemination:

Notifications within existing workflows: Provide crucial alerts through electronic medical record (EMR) software.

Tailored information: Allow providers to opt in to receive information specific to their medical specialty, making the content more relevant and less likely to be ignored.

Digital communication platforms: Increase the use of e-newsletters and social media to disseminate important medication information and safety updates in a concise, accessible format.

Takeaways

These findings align with FDA-conducted research that supported the need for plain language and effective design to facilitate patient comprehension of medication information. Current patient medication information sheets can be more effective. The content and format create barriers to understanding, leading to concerning gaps in knowledge about dosing, interactions, and side effects. These gaps put patients at risk for poor health outcomes, particularly those with challenges such as low literacy, age-related cognitive decline, and complicated health issues or caregiving arrangements.

Patients, healthcare providers, and the FDA have a strong shared interest in modernizing patient medication information. By creating more user-friendly medication information sheets and supplementing them with digital tools, the FDA has a clear opportunity to promote patient safety and medication adherence, reduce medication errors, and empower patients to become more informed about their own care. Potential next steps, such as adding messaging customized to a patient health profiles, would provide even more support. These changes have the potential to help lower costs through reduced treatment and hospitalization.

Effective implementation is key to realizing these benefits. To support medication manufacturers in adopting the proposed changes, the FDA could provide practical guidance, templates, and training. The Agency could also encourage user testing and evaluation of outcomes such as patient safety, adherence, comprehension, and satisfaction.

Finally, our findings suggest that the FDA's communication with healthcare providers about medications also could be enhanced. In our current healthcare system and larger information ecosystem, providers are deluged with content and stretched thin. They lack the time and resources to sift through materials to find what is urgent or relevant to them and their patients. Digital tools offer the ability to deliver the information they need when they need it. The FDA could evaluate how to best use such tools to strengthen its partnership with providers on behalf of patients.

Appendix A: Methodology

This report presents the results of a mixed-methods sequential study that collected qualitative data followed by quantitative data. This approach allowed for comprehensive, nuanced understanding and cross-validation to corroborate the findings and increase their reliability. The methods included listening sessions, focus groups, and a national consumer poll.

First, listening sessions with patients and healthcare providers gathered data on the perspectives, knowledge, and behaviors of patients. Next, focus groups with patients and providers probed topics that were explored during the listening sessions. In addition, exercises with patients during the focus groups tested their ability to find and understand information in real time about their own prescriptions, using medication information they were asked to bring to the session. This medication information may have included pharmacy sheets, prescription labels, or patient/provider prescription inserts.

Finally, a national poll was conducted to quantify consumer attitudes and behaviors. The poll posed a series of questions about whether and how patients use product labels, what information they look for, how they understand specific types of information, and what actions they take based on label information.

About Qualitative Research: Listening Sessions and Focus Groups*

- One listening session (January 2025) and one focus group with healthcare providers (July 2025)
- One listening session (December 2024) and two focus groups (June-July 2025) with patients who have chronic illnesses
- At the moderator's discretion, the order of questions and activities may be adjusted to account for topics that are raised organically or earlier than planned

**Exclusive Focus Group Exercise (patients and healthcare providers): identify information in written patient medication information.*

About National Polling

The survey was fielded online from August 30 to September 1, 2025, in English among a sample of 2,063 adults nationwide using non-probability sampling. Data quality measures included the use of an attentiveness check where respondents were directed to select a particular response, a consistency check between a respondents' age and birth year range, measures to prevent duplicate responses, and terminating respondents who selected "Yes" on three or four of the four questions about receiving government benefits since adults who receive three or four represent only 0.1% of the U.S. adult population. Respondents who answered more than one-third of the questions in less than one-third of the median response time per question were removed from the data file. The sample was weighted to population benchmarks for adults in the United States from the U.S. Census

Bureau’s American Community Survey on gender, age, race/ethnicity, and education, as well as on the following interactions: region by metro/non-metro area, gender by education, age by education, and race/ethnicity by education. The sample was also weighted to population benchmarks from the U.S. Census Bureau’s Current Population Survey/Housing and Vacancy Survey on homeownership. Calculated the way it would be for a random sample and adjusted to incorporate the effect of weighting, the margin of sampling error is ± 2.2 percentage points. This estimate of precision does not account for other potential sources of error that can occur in online surveys with non-probability samples, such as non-coverage due to the survey being conducted online.

The following tables provide characteristics about the participants in the qualitative groups and the poll respondents.

Table A1. Listening Session #1 Participants: Patients (December 2024)

Metric	**Details**
Number of participants	9
Age range	23-71
Reported Sex	4 male, 5 female
Education range	High school or less to post-graduate
Conditions (some with co-morbidity)	Arrythmia Breast/ovarian cancer Diabetes Epilepsy High blood pressure HIV IBD Organ transplant

Table A2. Listening Session #2 Participants: Healthcare Providers (January 2025)

Metric	**Details**
Number of participants	10
Age range	18-45+
Sex	4 male, 6 female
Profession	Medical doctor, Medical technologist, Nurse, Pharmacist, Physician's assistant, Psychologist/therapist

Table A3. Focus Group Participants (June-July 2025)

Metric	Details	
Healthcare providers	10 (one group) Age range: 30-52 Sex: 5 male, 5 female Profession: Nurses and Medical doctors	
Patients	21 (two groups) Group 1 = 11 participants Age range: 37-69 Sex: 6 male, 5 female	Group 2 = 10 participants Age range: 30-68 Sex: 4 male, 6 female

Table A4. National Consumer Poll Respondents (August 2025)

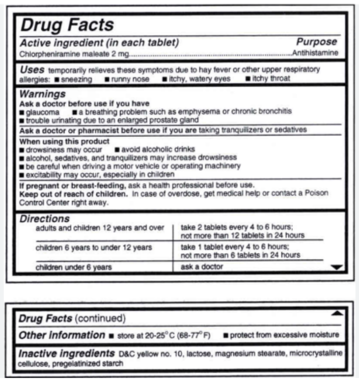
Metric	Details
Number of respondents	2,063
Age range	28-80
Sex	Roughly even split between male and female
Urbanicity	Rural, urban, suburban
Education	Non-college (66%), College (34%)
Chronic illness	56% report a chronic illness or condition, most commonly– Depression (27%) Hypertension (24%) Diabetes (14%) Obesity (14%)

Appendix B: Sources of Patient Medication Information

Information Type	Overview
Patient Package Inserts	A Patient Package Insert (PPI), also known as "Patient Information" is patient labeling that can be part of the FDA-approved prescription drug labeling. Certain PPIs are developed by the manufacturer and approved by the FDA.
Medication Guides	A Medication Guide is patient labeling that is part of the FDA-approved prescription drug labeling for certain prescription drugs when the FDA determines that: • Patient labeling could help prevent serious adverse reactions • The drug has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product, or • Patient adherence to directions for use is crucial to the drug's effectiveness.
Instructions for Use (IFU)	The Instructions for Use is developed by applicants for patients (or their caregivers) who use prescription drugs that have complicated or detailed patient-use instructions. The IFU provides detailed, action-oriented, step-by-step written and visual instructions for the patient on how to use the drug including instructions on preparation, administration, handling, storage, and disposal.

FDA Patient Package Insert

Drug Package Label



Drug Facts

Active ingredient (in each tablet) — *Purpose*
Chlorpheniramine maleate 2 mg........Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings
Ask a doctor before use if you have
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product
■ drowsiness may occur ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Drug Facts (continued)

Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

FDA Prescribing Package Insert

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PROPRIETARY NAME safely and effectively. See full prescribing information for PROPRIETARY NAME.

PROPRIETARY NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol
Initial U.S. Approval: YYYY

WARNING: TITLE OF WARNING
See full prescribing information for complete boxed warning.
- Text (4)
- Text (5.x)

RECENT MAJOR CHANGES
Section Title, Subsection Title (x.x) M/YYYY
Section Title, Subsection Title (x.x) M/YYYY

INDICATIONS AND USAGE
PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for .... (1)

Limitations of Use
Text (1)

DOSAGE AND ADMINISTRATION

DOSAGE FORMS AND STRENGTHS
Dosage form(s): strength(s) (3)

CONTRAINDICATIONS
- Text (4)
- Text (4)

WARNINGS AND PRECAUTIONS
- Text (5.x)
- Text (5.x)

ADVERSE REACTIONS
Most common adverse reactions (incidence > x%) are text (6.x)

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
- Text (7.x)
- Text (7.x)

USE IN SPECIFIC POPULATIONS
- Text (8.x)
- Text (8.x)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling OR and Medication Guide.

Revised: M/YYYY

Patient Labeling Resources: For Industry. U.S. Food and Drug Administration. (2024, August 19.) U.S. Department of Health and Human Services. https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources

Appendix C: Question Categories for Listening Sessions, Focus Groups and Polling

Topics for Discussion: Patients

- Understanding written information about your prescription medication
- Getting answers to questions about your prescription medications
- Searching online for information about a medication you've been prescribed
- Likeliness of asking follow-up questions to the prescribing provider or pharmacist
- Barriers to understanding written medication information
- Concerns about their prescription

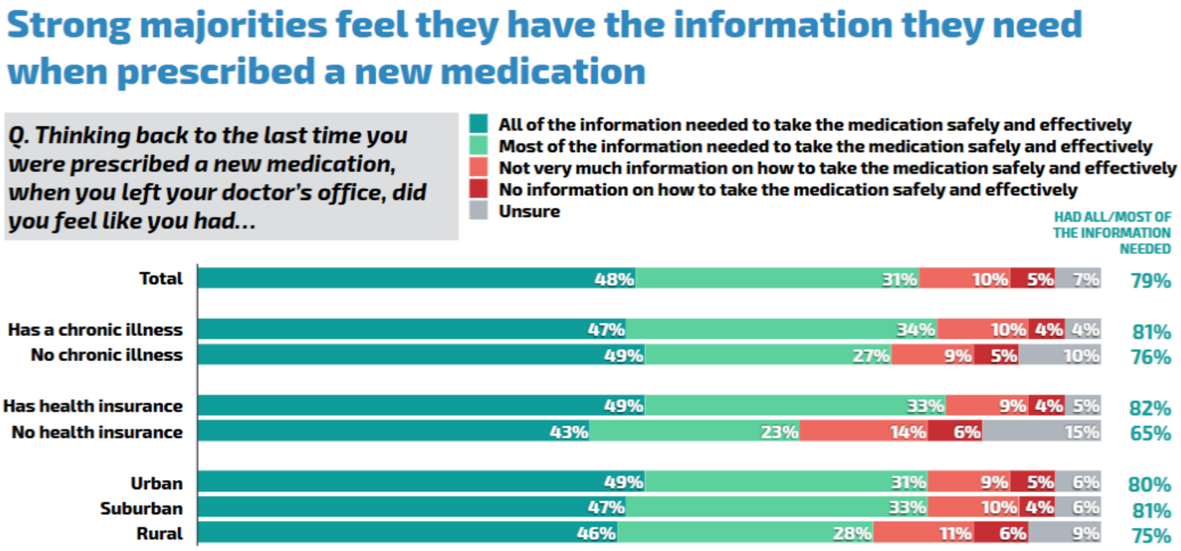
Topics for Discussion: Healthcare Providers

- Questions that patients ask healthcare providers
- Perspective on patient understanding of written medication information
- Concerns about medication compliance
- Resources for prescribing information

Exclusive Focus Group Exercise (patients and healthcare providers): identify information in written patient medication information.

National Poll Questions and Answers

The following data represents questions and participant answers.

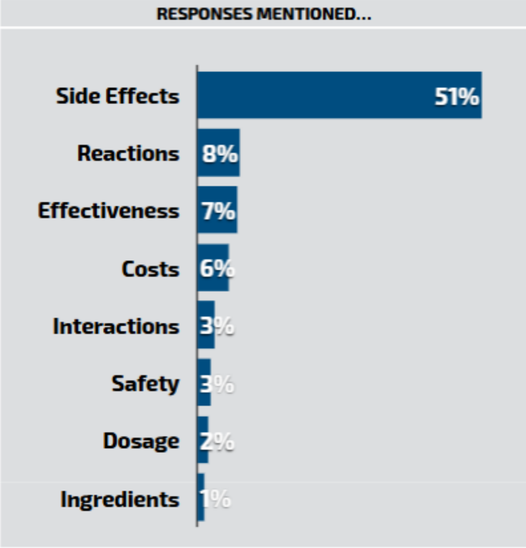


Strong majorities feel they have the information they need when prescribed a new medication

Q. Thinking back to the last time you were prescribed a new medication, when you left your doctor's office, did you feel like you had...

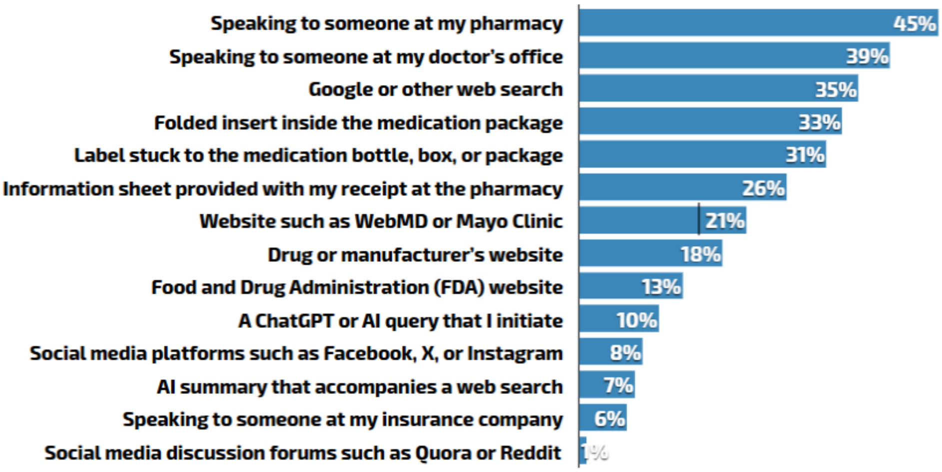
The majority of patients are concerned about side effects when starting a new medication

When you start a new medication, what are typically one or two of your biggest concerns?



SAMPLE RESPONSES
When starting a new medication, one or two of the biggest concerns are usually possible side effects and whether it will actually be effective.
If it will have a reaction to medications I'm already taking and to make sure I'm not allergic to it
My biggest concerns are possible side effects and whether the medication will actually be effective for my condition.
How much is it going to cost.
How will my body react- side effects, and will it interact with my other medications
My major concerns are safety, and side effects
If I can swallow it, and how far apart do I take each dose.
The ingredients that's in it and the side effects that it may cause

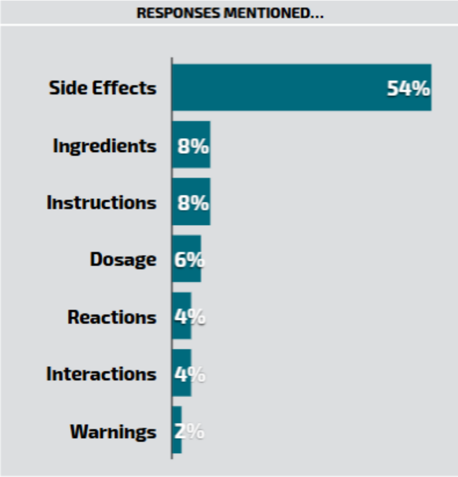
While patients generally rely on doctors and pharmacists for follow up questions, digital tools are also popular



Q. When you have questions about dosing, side effects, or interactions with other medications or foods when you start a new medication, which of the following, which of the following do you use for information? Select all that apply.

Side effects were by far the most frequently named piece of information patients look for in package inserts

When you read the insert, typically folded, that comes with your medication, what type of information are you primarily looking for?



SAMPLE RESPONSES

I'm looking for any ingredients or side effects

I'm looking for the ingredients, dosage and expiration date

Instructions on use and any side effects that may occur

Dosage frequency and possible side effects

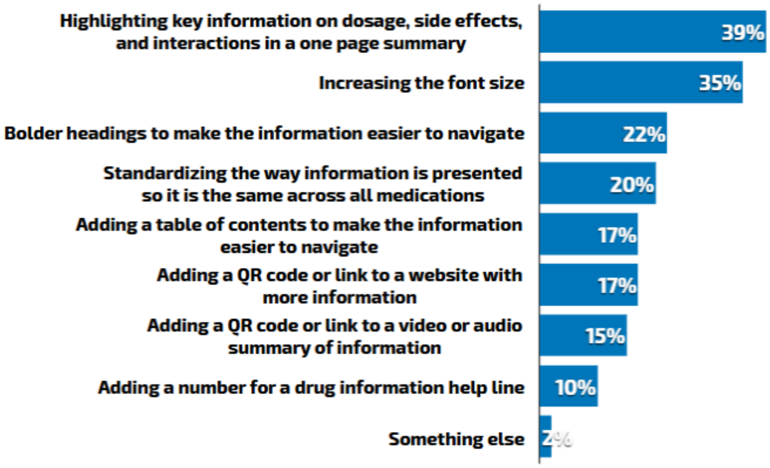
Any reactions the medication can cause

Possible interactions to other medicines

Warnings of any kind and recommended dosage.

Patients are receptive to the idea of a one page summary and would like information to be larger and bolder

Like we heard across our focus groups, patients feel that package inserts are too lengthy and would like to see a one-pager that highlights the key information associated with their medications.



Q. What are the top one or two things you would change to make it easier to find or understand important information on the insert that comes with prescription medication?

6-in-10 or more say they would be likely to scan a QR code for medications or medical devices

How likely would you be to scan a QR code on the packaging of each of the following types of products in order to find more information?