Advocating for the Inclusion of Allergen Statements on Medication Labeling

Bailey Arman

Submitted under the supervision of Dr. Molly Kessler to the University Honors Program at the University of Minnesota-Twin Cities in partial fulfillment of the requirements for the degree of Bachelor of Science, *summa cum laude* in Technical Writing & Communication.

May 10, 2020

Acknowledgments

At this point in my life, I have not had a child, but I imagine the proverb “it takes a village to raise a child” applies to theses and dissertations, too. Although I had the germ of the idea and the motivation to write it into fruition, this thesis would not be the robust document it is today without the help of a wide, diverse support system. This includes, but is not limited to:

- My thesis supervisor, Dr. Molly Kessler, who counseled me at each step of my thesis, advising me on everything from the overarching structure and topic to tiny things like a citation or wordy sentence. As a technical communicator specializing in healthcare, she is the perfect advisor for this project, and I am grateful to have had her guidance.
- My secondary readers, Dr. Daniel Card and Dr. Anna Milone, who graciously donated their expertise in technical writing and pharmacy, respectively. Their questions and suggestions provided valuable feedback and insight when I was too close to the project to see the big picture.
- The many scientists and immunological advocates that came before me, conducting the experiments and surveys whose data contributed to my analysis.
- My roommate Nirvi Ajmera, who listened to me gripe about the difficulty of finding gluten-free medications and consoled me when I questioned whether my research was even worth publishing.
- My friends, like Nina Vang, who encouraged me with pithy sayings and cute animal gifs when I was tired of working or overwhelmed with information.
- My parents and other family members, who go out of their way to buy me gluten-free treats, even though they are wildly more expensive and no one else will eat them but me. They allow me to enjoy the good things in life when it seems like I will be condemned to a life of chronic unhealthiness.
- Myself, for pushing through and writing this thesis, even when I was confused, embarrassed, dejected, or angry. I’m very proud of myself.
- Finally, I acknowledge that I completed this work for anyone with a food sensitivity. Those without food sensitivities may not realize how draining it can be, having to worry about what to eat three times a day, every day, without break. If my work in any way contributes to the FDA requiring allergen statements on pharmaceuticals, and thus lessening that daily stress for food-sensitive individuals, I will be happy.

To everyone who has contributed to my thesis journey, thank you. Truly, thank you. Your work was not in vain.

Abstract

As defined by the Society for Technical Communication (n.d.), the job of a technical communicator is to: “communicate about technical or specialized topics; communicate by using technology; and/or provide instructions about how to do something.” Though technical communication is frequently associated with software and engineering, it has important applications for other disciplines, including the medical field. In this thesis, allergen statements on a medical document are critiqued from a technical communication, and further usability, viewpoint.

Allergen statements are primarily associated with food products and are rarely found on pharmaceutical labeling. However, pharmaceuticals, although they include medication (the API), they also include “filler” materials made from food products, including incendiary foods like lactose, wheat, and soy. The lack of an allergen statement on pharmaceuticals may endanger food sensitive individuals, like those with food allergies, celiac, or food intolerances.

The following thesis provides a brief review of research done on allergen statements and incendiary foods in pharmaceuticals; results from a usability test conducted based on principles of technical communication, like comprehension and readability; an analysis and discussion of those results; and recommendations for the FDA and pharmaceutical manufacturers. Based on a literature review and the results from this usability test, it is highly recommended that the FDA require pharmaceutical companies to include an allergen statement somewhere on their product. This statement should include brief details on where cross-contamination could occur and be accessible to consumers, not just healthcare professionals.

Table of Contents

Introduction 5
Incendiary Foods in Medications 6
Disclosing Incendiary Foods in Medication 8
Improving Allergen Statements 11
Methods 13
Ethics 13
Recruitment 13
Usability Test & Data Collection 14
Data Recording and Tools 15
Evaluation Metrics 15
Results and Analysis 18
Background Questionnaire 18
Usability Metrics 18
Debriefing, Quantitative 19
Debriefing, Qualitative 21
Readability 24
Summary 24
Limitations 25
Recommendations 25
Conclusion 27
Bibliography 28
Appendices 31
Glossary 31
Usability Test Plan 33
Consent Form 33
Script 33
Background Questionnaire 33
Debriefing Questionnaire 33
Label 1 34
Label 2 35
Label 3 36

Introduction

As many technical writers recognize, the practice and development of technical communication, including discussions, research, and content produced by technical communicators, primarily take place in the field of information technology. This is likely because information technology is the field that technical communication and, later, usability and UX design, emerged from. In fact, usability was developed when employees of IBM and at Digital Equipment Corporation first analyzed products with an eye for "usability engineering" in the late 1980s (Redish, 2010). However, many other fields can benefit from the application of technical communication, and have been of increasing interest to the technical communication community, one such field being healthcare and pharmacy. The research presented in this senior thesis will contribute to the existing sphere of technical communication of healthcare content. Though all areas of healthcare are rich with complex communication, this particular study focuses on one part of a medication label—the allergen statement, or lack thereof. It is important to note that "labeling" in the context of this project refers to a package insert labeling document not on a pill bottle. Hereafter, any mention of labeling, labels, pharmaceutical labeling, medication labeling, or any other form of this phrase refers to the aforementioned specification.

Unfortunately, pharmaceutical products are not required to include an allergen statement anywhere on their product, although pharmaceuticals often contain incendiary foods like lactose, wheat, and soy. By placing existing allergen statements in pharmaceutical documents and allowing participants to complete a task using that document, the usability test conducted for this project reveals how these statements can be improved and that the average consumer does support disclosing allergen information. In discussing this topic, the ideal result is not just FDA-level mandating of allergen statements on pharmaceuticals, but also to improve the safety of those with food sensitivities. Secondary goals include increasing consciousness of the responsibility BigPharma has to create patient-friendly materials and of the responsibility technical communicators have to apply their unique skillset to fields outside of software and engineering.

To be explicitly clear, this research will not analyze the overall design of the label, nor the location of the allergen statement, but rather solely the allergen (or incendiary food) statement. The allergen statements in question are not novel, but rather allergen statements that appear frequently on food packaging.

Before diving into the research review, please note that this topic requires knowledge of certain medical and technical communication terms, ranging from “allergy” or “readability” to “excipient” and “refractory celiac.” For definitions of these terms and more, a glossary of terms can be found in the appendices.

Incendiary Foods in Medications

For some, it is a shock to realize that medications contain incendiary foods and can cause a food-sensitive individual to react. Some are aware of penicillin allergies or of eggs in vaccines, but few are aware of how common incendiary foods are in medications, prescribed or over-the-counter (OTC). Recent research has found that "almost all oral solids (92.8%) contain at least one potential allergen" (Reker, et. al., 2019, p. 3), with the most commonly found allergen being lactose or milk, “found in 45% of oral solids" (Reker, et. al., 2019, p.3).

There are, though, a wide variety of medications that accomplish the same thing. Think of a fever reducer, which could refer to common medications like paracetamol, ibuprofen, naproxen, or aspirin. Each of these individual medications, known as active pharmaceutical ingredients (API), may be sold by dozens of different brands. Aspirin, for example, can be found in Alka-Seltzer, Bayer, Excedrin, CVS, or up&up brands, among many others. Though these various brands of pharmaceuticals contain the same API, they all contain different excipients. Excipients, also known as “fillers”, are the non-active part of the medication that can make up the majority of the medication tablet, capsule, or pill; it has been estimated that pharmaceuticals are, on average, 90% excipients (Haywood & Glass, 2011, p. 112). Excipients can be starches, gelatins, or any number of organic materials. In short, there are many different brands and formulas for one single medication. According to recent research, “on average, 82.5 alternative formulations are available per API for the 18 most frequently prescribed oral medications in the United States” (Reker, et. al., 2019, p. 3). So anyone with a food sensitivity

could probably find a medication that is safe for them to take, right? Unfortunately, this may not be the case, as “only 28% of active ingredients have at least one available formulation that avoids all of these potential allergens, and only 12% of APIs are free of inactive ingredients that have been reported to cause allergic reactions" (Reker, et. al., 2019, p. 3).

Although this may be disheartening, perhaps the scariest thing for consumers is that manufacturers too often cannot back up their claims of being allergen-safe. In the case of gluten (found in wheat, barley, and rye), a survey conducted on behalf of the University of Kansas Drug Information Center found that although 69% of manufacturers claimed their products were gluten-free, only 17% of manufacturers had tested their products for gluten content and could provide documentation (King, 2013). In a different survey on gluten content in nonprescription medication, pharmaceutical researchers found that 13 out of 15 products that claimed to be gluten free were not tested for gluten content, and that four of six websites reviewed reported information on gluten content that was different from information reported over the phone with the same manufacturer. (Mangione, Patel, Shin, & Fiebert, 2011, p. 734).

It’s important to note that some do not believe incendiary foods in pharmaceuticals pose a risk to folks with food sensitivities and that “zero risk of cross contamination is not a realistic expectation” (Zurzolo, Mathai, Koplin, & Allen, 2012, p. 292). Perhaps many food sensitive individuals *can* tolerate trace amounts of that allergen in their pharmaceuticals, but the fact remains that there are those that suffer from ingesting trace amounts of incendiary foods. Take, for example, someone with asymptomatic celiac. Though they may experience no outward symptoms upon ingesting something with trace amounts of gluten, such as an OTC medication, their immune system will begin to destroy their intestines. For someone with celiac, exposure to as low as 1.5 mg of gluten daily can damage the intestines (Chartrand, Russo, Duhame, & Seidman, 1997, p. 616). This is a very real situation, as many pills weigh between 25 mg and 600 mg. Some pharmaceutical and gastroenterological research indicates that medication, not food, may lead to the primary intake of gluten for those with celiac (Maltin, Charabaty, & Mangione, 2009). Almost half of Americans take one prescription drug daily, and almost 25% take three or more (CDC, 2017). If a patient is taking multiple medications daily, this only increases the potential intake of gluten for a celiac patient, or of an

incendiary food for a food sensitive individual. It is possible that some food-sensitive individuals do not experience symptoms when ingesting trace amounts of their incendiary food, but this is not the case for everyone, whether or not they recognize or have symptoms.

Accordingly, research has demonstrated that incendiary foods in medications are a problem for food-sensitive individuals (Reker, et. al., 2019, Johnson, Skaff, & Senesac, 2014, and Maltin, Charabaty, & Mangione, 2009). Unfortunately, consumers, and often their pharmacists, too, do not have access to consistent or regulated allergen statements for pharmaceutical products. For Americans with food sensitivities, this may be changing soon.[1]

Disclosing Incendiary Foods in Medication

In the absence of the formal law, some pharmaceutical companies have responded to consumer concerns by voluntarily labeling their products with an allergen statement, such as Target brand up&up OTC medications. However, in general, there continues to be a severe lack of both labeling on pharmaceuticals and the availability of information regarding incendiary foods in medications. Concerned patients can ask their pharmacists or doctors about the possibility of incendiary foods in their medications, or can call the manufacturer themselves, though this has its own problems, as one survey of 41 pharmaceutical manufacturers found that only six of those manufacturers that included gluten data on their websites, and that "four of six websites indicated gluten status that was different from the information provided via the telephone call with the manufacturer" (Mangione, Patel, Shin, & Fiebert, 2011, p. 734). What's a consumer to believe when they receive conflicting information from the same manufacturer?

Incendiary foods in non-food items are, as mentioned, not yet required by law to be disclosed, but in April 2019, Representative Tim Ryan [D-OH] introduced H.R. 2074, the Gluten in Medicine Disclosure Act of 2019, to the US House of Representatives, which progressed to the Senate floor on December 11, 2019 (Gluten in Medicine Disclosure Act of 2019, 2019). This

[1] It is imperative to recognize that the societal context of this research is focused within the United States of America. The labels analyzed, many of the statistics, and laws discussed exist in the United States of America, and may or may not apply to other countries. Ideally, there would be a global standard of allergen disclosure and food sensitivity testing, but this is not yet a reality. For the specifics of your country's labeling guidelines, please refer to your national health organization.

bill dictates that pharmaceutical manufacturers must disclose gluten content in pharmaceuticals according to the labeling guidelines that the Food Allergen Labeling and Consumer Protection Act (FALCPA) established for food items in the United States in 2004. While a fantastic and entirely necessary step forward (and hopefully an encouragement to pass similar laws for all other incendiary foods), the existing FALCPA guidelines do not effectively protect consumers because they are confusing and inconsistent, and thus require revision.

In the United States of America, the US Food and Drug Administration (FDA) determines and maintains laws regarding food labels, including ingredients and allergen information. Under the FDA, FALCPA rules that packaged foods sold in the US, even those imported from a foreign country, must be clearly marked in plain language as containing the eight main food allergens (FDA, FALCPA questions and answers, 2018). In addition to conventional food, FALCPA also applies to vitamins and dietary supplements, infant formula and foods, and medical foods. FALCPA does not apply to raw foods (like fruits and vegetables), products regulated by the U.S. Department of Agriculture (like meat, poultry, and egg products), products regulated by the Alcohol and Tobacco Tax and Trade Bureau (alcoholic drinks, spirits, beer and tobacco products), cosmetics (like mouthwash or toothpaste), or, notably, drugs, prescription or nonprescription.

For products that do require labels, manufacturers use a wide variety of voluntary allergen statements on their products (in addition to the standard disclosure of “contains: [incendiary food]”), including:

- may contain [incendiary food(s)]
- may contain traces of [incendiary food(s)]
- produced in a facility that also processes [incendiary food(s)]
- produced in a factory which handles [incendiary food(s)]
- produced on shared equipment which also processes [incendiary food(s)]
- made in a production area that also uses [incendiary food(s)]
- made in a factory that also produces [incendiary food(s)]
- packed in an environment where [incendiary food(s)] may be present
- due to the methods used in the manufacture of this product, it may occasionally contain [incendiary food(s)]
- not suitable for [food sensitivity]

- (no allergen statement, but **bolding** allergens in the ingredients list)[2]

Those with wheat allergies, celiac, and wheat or gluten sensitivities have the added stress of wading through even more labels, in addition to all the ones previously mentioned. Additional warnings for this group include: naturally gluten-free; no gluten; free of gluten; without gluten (FDA, Gluten and food labeling, 2018). Many products include a combination of two or three of the statements listed above, which can, occasionally, introduce conflicting logic. For example, does a package that say "free of gluten" and "not suitable for celiacs" mean it is safe for wheat allergic individuals? And if it is truly free of gluten, then why is it not suitable for someone with celiac? This is just one situation someone with a food sensitivity may have to deal with.

There is overwhelming evidence to suggest a general confusion on consumer's parts as to what these labels mean in relation to one another, which inevitably leads to risky behavior. In particular, the 'may contain' label is not well-respected or taken seriously. A group of medical researchers in the UK found "the majority of teenagers [interviewed] reported eating foods labelled as 'may contain' an allergen as they perceive that they are actually very unlikely to contain an allergen" (Monks, et al., 2010, p. 1533). Similar research on adults in the United Kingdom also found that "only a third of respondents always avoided products with 'may contain' labels" (Cochrane, Gowland, Sheffield, & Crevel, 2013, p. 1). Monks et. al suggest that the "may contains" statement, therefore, leads to "risk-taking behaviour in the management of their food allergies" (Monks, et al., 2010, p. 1533). Some research by immunologists attribute exposure to incendiary foods to consumers "incorrectly assuming that statements such as 'shared facility' and 'may contain' indicate different levels of risk" (Zurzolo, Mathai, Koplin, & Allen, 2012, p. 293). However, when immunologists asked consumers themselves were asked to pinpoint the cause of an accidental exposure, "47.0% attributed the event to inappropriate labeling, 28.6% to failure to read a food label, and 8.3% to ignoring a precautionary statement" (Sheth et al., 2010, p. 60). It appears that there are discrepancies in how consumers interpret accuracy of and the danger indicated by existing allergen statements.

[2] List content provided in part by Turner, Kemp, & Campbell, 2011, p. 2.

Some may protest getting rid of voluntary statements, as they assume that this variety of labeling allows for a greater level of nuance in labeling practices. This is not the reality. As immunologists Turner, Kemp, and Campbell write, "Advisory labels are helpful if they provide reliable information on the allergen content. However, manufacturers widely use them as a 'safety net' to convey an unspecified risk of possible contamination" (Turner, Kemp, & Campbell, 2011, p. 1).

Overall, it is clear that there is a mismatch between how consumers understand the severity indicated by labels and the way that manufacturers use them. Based only on a research review, evidence suggests the FDA should explicate on the level of danger implied by each allergen statement and the likelihood that the product does actually contain the allergen.

Improving Allergen Statements

From a usability perspective, it's clear that the phrasing of allergen statements do not in any way meet Nielsen's heuristic of consistency and standards[3] (Nielsen, 1994). Consistency in word use is key in ensuring that a consumer has consistent information and can therefore make informed decisions. If terms are used inconsistently or multiple terms (or phrases) are used to indicate the same thing, users may be unable to draw the intended conclusion from the information or may confuse meanings for each other. Based on usability principles, to improve the user experience and user outcomes, existing allergen statements must be whittled down to only a few allowed phrases, or all current allergen statements must be ranked hierarchy with indications about risk of contamination, so the consumer understands clearly each statements relation to their own health.

Once these phrases are determined, the FDA must require pharmaceutical manufacturers to include them on their products standardize the allergen statements on both food and pharmaceutical labeling. This action would likely result in increased consumer trust in products; increased consumer adherence to allergen statements; and decreased negative health outcomes for food-sensitive individuals. Following these actions, consumers must be

[3] Nielsen's heuristics are a set of 10 general principles for creating software (and later applied to non-software products) that is user-facing and has high usability. These heuristics are well-known and respected in the technical communication sphere, and most frequently employed in UX (user experience) design.

educated to begin looking for these statements and to understand the level of risk implied with various phrases, if multiple phrases continue to be in use. The recent introduction of the Gluten in Medication Disclosure Act of 2019 provides the perfect opportunity to reevaluate the existing allergen statements with a critical eye for technical communication principles, like usability.

Usability can function both a noun and an adjective. As an adjective, it describes products that, at the most simple definition, allow users to do what they need to without many problems. More precisely, usability is "the extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" (International Organization for Standardization, 1998, section 3.1.1). As a noun, usability testing "focuses on observing and learning from your users who are working with your product to perform tasks that are real and meaningful to them" (Barnum, 2010, p. 53). This test relies on both definitions to offer improvements to allergen statements.

The problem of allergen statements on medication labels is complex: medications are not required to include allergen statements, but even if they were, current allergen statements are confusing, interpreted differently by different individuals and corporations, and unintentionally promote risk-taking behavior. This study aims to take three common allergen statements and determine which one participants interpret to be the safest; whether or not determining that safety is difficult; and what changes participants recommend to make that decision easier.

It has been 15 years since the FALCPA and the first regulated allergen statements were introduced in The United States of America. While FALCPA was an entirely necessary step forward, the allergen statements it regulates can be improved by the application of technical communication principles and usability testing. This research should be done prior to or in tandem with the passing of the Gluten in Medication Disclosure Act of 2019 and any other related acts pertaining to incendiary foods and pharmaceuticals. The usability testing done for this thesis provides initial insights into that data.

Methods

The usability test conducted for this project attempted to determine the consumer preference of phrasing of allergen statements on medication labeling. To discover this preference, participants were given a scenario in which they have an allergy to wheat, read three pharmaceutical labels, and were asked to decide which medication was safest for them to take. Allergen statements were evaluated based on comprehensibility, readability, and legibility. Data on efficiency and user satisfaction was also collected. The full test plan can be found in the appendices, but this section will include a broad overview of how the usability test was created, conducted, and altered.

Ethics

In addition to following the IRB standards and the principles outlined in the Belmont Report, all persons involved with the usability test were required to adhere to the following ethical guidelines:

- The performance of any test participant could not be individually attributable. Individual participant names were not used in reference outside the testing session.
- A description of the participant's performance was not reported with any identifying information.
- Recordings of the participant testing did not leave the possession of Bailey Arman, and were stored in a safe, secure, and password-protected location. These recordings will not be distributed at any point, unless requested by a higher authority, e.g. the police or the participant of whom the recording is of.

Participants received a consent form that included an overview of their rights prior to the testing session, including that they were allowed to end testing at any point, for any reason, without having to explain why. Participants had access to this form near them throughout the entire test and verbally consented to testing and to being recorded prior to testing.

Recruitment

Eligible participants were restricted to those able to comfortably read without assistance from text-to-speech devices and to native English speakers, as assistive tools or interpreters were not

able to be acquired. Age could range from 18 to 60, and people of all genders, races, sexuality, and occupations were able to participate. Participants were expected to have some understanding of what an allergy or food sensitivity is.

Participants were recruited in person and verbally. They received consent forms and potential testing times in-person or via email. The intended number of participants was 10, but due to the COVID-19 outbreak and social distancing protocols, there were only 5 participants.

Usability Test & Data Collection

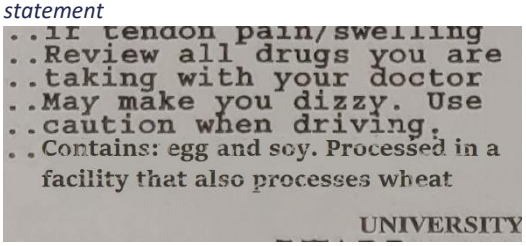
Participant activities included providing background information in a background questionnaire, completing the task scenario, and providing post-test feedback on the task and allergen statements. The usability test itself required participants to complete only one task and one scenario. This was to better reflect the real situation of a food-sensitive individual selecting a medication to take and also to better appeal to busy participants, who may not have been able to dedicate an hour of time to testing but could manage to give 20 minutes.

All participants received the same scenario and task. The scenario and task, choosing to take a medication based on three different allergen statements, are representative of the typical decisions a food-sensitive individual must make. The medication label document itself, although fictional, is representative of a typical package-insert label. All three labels had a "contains: [allergens]" statement, while two had additional statements, one a "may contain traces of [allergens]" and one a "processed in the same facility as [allergens]". These labels can be found in the appendices. These allergen statements (table 1) that were introduced to the label were based on allergen statements found on food products, not pharmaceuticals, as there are no standardized allergen statements for pharmaceutical labels.

Table 1. List of allergen statements used in testing

Label	Allergen Statement
1	Contains: egg and soy. Processed in a facility that also processes wheat
2	Contains: egg, soy, wheat
3	Contains: egg, soy. May contain traces of wheat.

Figure 1. A close-up of label 1 featuring the allergen statement



The allergen statements all include egg, soy, and wheat, but the phrase involving wheat changed across labels. These allergens were chosen because they can be found in pharmaceuticals more commonly than, say, shellfish (Reker, et. al., 2019, p. 5). The scenario assigned an allergy and not some other food sensitivity because most participants would understand what a wheat allergy is, but fewer may have understood what an intolerance or celiac are. A wheat allergy specifically was assigned because the phrases involving wheat are the ones that change across the labels, and the different phrases are what the participants were intended to pay attention to.

> ***Scenario****: You have had an allergy to wheat your entire life. After coming down with the flu recently, your doctor wants to prescribe you a fever-reducer. You must review the allergen statements on three different medication labels and decide which medication is safest for you to take.* (remember to say done when you are finished!)

The task was completed when the participant indicated that the scenario's goal had been accomplished or the participant requested and received sufficient guidance as to warrant scoring the scenario as a critical error. The time to complete a scenario, referred to as "time on task," was collected in minutes and seconds. It was measured from the time the person began the scenario to the time they signaled completion.

Data Recording and Tools

Data was recorded in a password-protected Excel spreadsheet. Data collected included subjective opinions, time on task, task completion, error rates, and subjective comparison of labels. Feedback and background information (collected voluntarily) was collected verbally and then input in the Excel spreadsheet. Demographic data was collected primarily to identify potential lack of diversity in participants. The testing sessions, in addition to initial, audible consent, were recorded with audio only, and are currently password-protected.

Evaluation Metrics

The usability test aimed to capture both quantitative and qualitative data. Quantitative data are represented by scenario completion rates, time on task, and error rates (of both critical and non-critical errors), and were measured against predetermined metric goals.

Qualitative data are represented by subjective evaluations about specific labels, comprehension, ease or difficulty of task, and overall satisfaction. Qualitative data were not measured against goals, but rather compared from participant to participant to discover the somewhat intangible aspect of user satisfaction and experience. These subjective evaluations were collected via questionnaires prior to and just after testing. The questionnaires utilized open-ended questions and free-form responses.

This usability test evaluated all errors as either critical or non-critical. Critical errors prevent a user from accomplishing their task. Choosing the least safe label ("contains wheat"), not finding the allergen statements, not making a decision, or otherwise reporting total confusion are all examples of critical errors. Participants may or may not have been aware that the task goal was incorrect or incomplete.

Non-critical errors are errors do not result in failure to accomplish the task. However, they are generally frustrating to the participant. These errors may be procedural, in which the participant does not complete a scenario in the most optimal means (e.g., takes excessive time to find the allergen statement compared to other participants), errors of mild confusion, or general difficulty in using the product (e.g., the text is small and hard to read without reading glasses). Exploratory behavior, such as reading a different section while searching for the allergen statement, was not scored as an error.

Error Severity

In addition to classifying errors as critical or non-critical, a method of problem severity classification was used in the analysis of the data to prioritize recommendations. This approach treated problem severity as a combination of two factors: the criticalness of the problem and the frequency of the problem. Frequency is the percentage of participants who experience the problem when working on a task. Frequency was initially defined as:

- High: 30% or more of the participants experience the problem
- Moderate: 11% - 29% of participants experience the problem
- Low: 10% or fewer of the participants experience the problem

However, given the impact COVID-19 had on participant recruitment, frequency was adjusted to accurately reflect participant pool size. Frequency is now defined as the following:

- High: 41% or more of the participants experience the problem
- Moderate: 21% - 40% of participants experience the problem
- Low: 20% or fewer of the participants experience the problem

Problem severity was assigned based on the combination of problem frequency and level of criticalness. The identified severity for each problem includes a general reward for resolving it and a general risk for not addressing it.

Severity 1. Non-critical errors that occur at low frequency. There is low risk to not resolving these problems. Reward for resolution is typically exhibited in increased user satisfaction.

Severity 2. Non-critical errors that occur at moderate to high frequency. These are minor annoyance problems faced by many participants. Reward for resolution is typically exhibited in reduced time on task.

Severity 3. Critical errors that prevent a user from correctly completing a task. They occur in varying frequency and may be representative of calls to the manufacturer or pharmacy or taking a medication that is unsafe for the consumer. Reward for resolution is typically exhibited in fewer calls and reduced negative health impacts.

Results and Analysis

The background questionnaire and debriefing interview questions can be found in full in the appendices.

Background Questionnaire

Table 2. Background Questionnaire Data

Question / Participant	P1	P2	P3	P4	P5
Gender	f	f	m	f	f
Age	20-29	20-29	50-59	50-59	20-29
Do you have a food sensitivity or care for someone with one?	No	Yes	Yes	Yes	Yes
What is that sensitivity?	n/a	Friend has celiac	Child has celiac	Child has celiac	Has an allergy to raw apples and peaches
How often do you check medication for allergen statements?	Rarely	Less than half the time (for religious dietary restriction of egg)	Never	More than half the time	Never
How comfortable are you with deciding if it's safe to take OTC medication? (1 is very uncomfortable, 5 is very comfortable)	4	4	2	5	3.5

Participants were primarily female and ranged from 20 to 59. Due to the COVID-19 pandemic, there was a lack of diversity in the demographic data of participants and overall size of participant group. All participants knew someone with a food sensitivity, but only one participant had a food sensitivity themself. Most participants reported checking medications for allergen statements less than half the time, but, with an average score of 3.7, felt comfortable deciding if OTC meds were safe for themselves to take.

Usability Metrics

As outlined in the usability plan and methods section of this document, this test had a series of usability metrics and goals. The goals and the actual results are as follows:

Table 3. Usability Metrics Results

Metrics / Data	Definition	Goal	Result
Completion rate	Percentage of participants who successfully complete the task without critical errors.	rate of 100%	Rate of 80%
Error-free rate	Percentage of participants who complete the task without any errors (critical **or** non-critical errors).	Rate of 70%	Rate of 0%
Frequency	Percentage of participants who experience the problem.	n/a	**Severity 1** problems occurred at moderate frequency **Severity 2** problems occurred at high frequency **Severity 3** problems occurred at low frequency
Problem Severity	The identified severity for each problem includes a general reward for resolving it and a general risk for not addressing it.		

Below, specific problems are sorted by severity.

- **Severity 1:** Participants in the age range of 50-59 needed glasses to read, indicating that the allergen statement may have poor legibility for older consumers; Multiple participants stated they would have preferred a callout, title, or another format to make it easier to locate the allergen statement.
- **Severity 2:** Participants struggled to distinguish the difference of danger indicated by allergen statements. This led to decreased confidence in the safety in the medication.
- **Severity 3:** One participant declined to complete the task, saying they did not feel comfortable stating that any label would be safe for a food sensitive individual.

Debriefing, Quantitative

Table 4. Usability Test Results

Question/ Participant	P1	P2	P3	P4	P5
Difficulty of task (1 is very easy and 5 is very difficult)	3	3	3	1	5
Which label did you choose to take?	1	1	1	1	No decision initially, later 1
Which is safest?	1	1	1	1	No decision initially, later 1
Which is least safe?	2	2	2	2	2

Which info do you feel is necessary to make these decisions?	All	Ingredient, contains, and processed	Contains and may contain	All	All
Time on task (min:sec)	2:20	3:30	4:30	2:50	n/a, did not finish task

The participant with the least amount of experience with allergen labels had the shortest time on task (TOT), but those with more experience varied in how long they took. The participant who had the second-lowest TOT found the task the easiest. The average TOT was 3:08 and the average and median difficulty of the task was a 3, neither difficult nor easy, though the range of responses fully spanned from very easy to very difficult.

It is also important to note that participants in the 50-59 age range wore reading glasses during the task. When asked "do you have any questions for me before beginning the task?" these participants asked if it was okay to wear reading glasses, implying that the font size of the allergen statement could be too small for some populations to read.

In general, the first minute was spent skimming the document to find the allergen statements. Once the participant found the allergen statement on one label, they assumed (and were correct) that the allergen statements on the other two labels would be in the same place. This suggests participants look for consistency in the location and format of the allergen statement. After having read all three allergen statements, all participants immediately ruled out label 2 ("contains"). The rest of the time was spent weighing whether label 1 ("processed") was more or less safe that label 3 ("may contains"). Almost all participants chose to take label one ("processed") and felt that it was the safest for a wheat-allergic individual. All participants chose label 2 ("contains") as the most unsafe.

One participant experienced a critical error and did not choose a label, explaining that they didn't feel comfortable making that decision. This implies that the participant did not feel comfortable potentially endangering a wheat-allergic individual, and thus that none of the medications were perceived as entirely safe. After going through the debriefing questions, this participant requested the chance to re-review the labels, and then retroactively chose to take label 1, citing it as the safest for a wheat-allergic individual.

Responses were divided as to what information is necessary in an allergen statement to allow the consumer to make an informed decision, but the most popular response was "all of the above," referring to including: medication ingredients; a "contains: [allergens]" statement; a "may contains: [allergens]" statement; and a "processed in a facility that also processes: [allergens]" statement. This suggests that consumers prefer to have as many details about cross-contamination and allergen content as possible.

Debriefing, Qualitative

When asked what was most frustrating, participants responded with statements like:

- "I spent time trying to read all the fine print when really I only needed that one sentence." (p1)
- "The level of uncertainty. It's not a particularly life-threatening situation for me, so I'm not as personally invested in it to the same level. But just by taking the perspective of someone who does have a wheat allergy, there's so much uncertainty in whether or not [the medication] contains wheat. So that's what I appreciated about [label] 2, is that it straight-up said 'yo, I've got wheat.'" (p2)
- "Trying to understand the initial differences between the statements" (p3)
- "Well, I don't think the experience in and of itself was frustrating, it might be just frustrating trying to figure out if one would [sic] even be able to be safely taken" (p4)
- "I don't like how undetailed and unspecific the [statements] are." (p5)

When asked what participants would change about the statement itself (not the label), participants responded with the following recommendations:

- "Based on that little sentence [the allergen statement] on each of them […] I have a feeling that they're all, like, exactly the same but just stated differently […] so it's confusing because […] they all probably have wheat in them, they just say it in a different way. So why don't they just process it in a place without wheat?" (p1)
- "I would add a line so [the allergen statement is] somewhat separated from [the rest of the text], so that it stands out. Maybe put a box around it so that it's more eye-catching. Even just labeling it 'allergen information' would help." (p2)

- [Regarding label 1] “In addition to saying ‘created in a facility that processes wheat’ you could go further and say ‘it may contain’ wheat.” (p3)
- [in regard to label 3] “Instead of saying it ‘may contain traces of wheat,’ I would say it *does* contain wheat. Because aren’t you risking it, you have a 50/50 chance, right? If it contains wheat or does not, so I would take out wheat and say it does contain traces of wheat.” (p4)
- “I like how the first two [labels] are specific in their wording, and that they say more specifically about how wheat is a part of this medicine. If it just says ‘wheat,’ I don’t know if wheat is actually in the medicine, or processed in a facility, so I would make the label more detailed.” (p5)

Participants seem to assume that the “may contains” indicates a lack of safety but were confused about to what degree the product is not safe. They wanted more details on where and why the contamination is occurring. P4 even requested that any amount of potential contamination should automatically be marked as “contains wheat,” whether or not the product does actually contain the incendiary food. This seems to be in line with how researchers have suggested that manufacturers use allergen statements, as “a ‘safety net’ to convey an unspecified risk of possible contamination” (Turner, Kemp, & Campbell, 2011, p. 1). Though p4 was possibly using it as a figure of speech, they also assumed that using a “may contains” statement indicates that there is a “50/50 chance” that the product contains that incendiary food, but this is not the case; the “may contains” statement does not indicate any specific level of safety or danger.

All participants expressed a need for more specificity. In particular, they found “may contains” to be overly vague. On the flipside, participants liked how explicit label 2 (“contains”) was. For participants, there was no question that label 2 was unsafe, so it was the first label ruled out. Participants expressed a level of uncertainty about if label 1 (“processed”) or label 3 (“may contains”) was more unsafe. In the end all participants ruled label 3 as more unsafe than label 1. One participant explained that they made this decision because “at least” label 1 discloses where the contamination is occurring—label 3 does not disclose where or why potential contamination is occurring.

Although all participants ranked the allergen statements in the same order of safety, the confusion, frustration, and uncertainty they felt about their decisions speaks to a lack of comprehension. Comprehension, or, in usability terms, "whether a user can understand the intended meaning of a text and can draw the correct conclusions from the text" (Nielsen, 2015), exists at only the most basic level. Consumers need more details and indications of safety, not just indications of danger, to feel comfortable making decisions, and making those decisions more quickly. Consumers should not have to spend two minutes comparing which of the two options are safer. It should be as simple as reading the allergen statements and taking one or the other. Further, consumers should also have access to knowing whether a pharmaceutical is *free* of allergens, not just access to information about the confirmed allergens.

Two options seemed to emerge from the results of this usability test: either manufacturers label all pharmaceuticals that potentially have contact with an incendiary food as "contains [incendiary food]" or manufacturers list specific details about where and how the potential contamination is happening. Another option, listing a product as "allergen free," would be the most ideal, as it indicates safety rather than potential danger. An "allergen free" statement would be the ideal epitome of safety in the hierarchy of allergen statements, but as this standard does not yet apply to even food products, it may be unfair to expect it of pharmaceutical companies just yet.

When asked for final comments, concerns, suggestions, etc., participants responded with:

- "That is outrageous [that allergen statements aren't required on medication]! Put that [allergen statement] on there, outrageous!" (p2)
- "Participating in this has given me new insight into the fact that I should be checking labels of medications." (p3)

While these final statements may be more personal than a statement of fact, they do provide insight to the average user's (and, in the case of these quotes, a non-food sensitive individual's) impression of having allergen statements on medication documents. In short, consumers want allergen statements on pharmaceutical documents.

Readability

Readability "measures the complexity of the words and sentence structure in a piece of content. The assumption behind this metric is that complex sentences are harder to parse and read than simpler ones" (Nielsen, 2015, section "Readability"). General guidelines for writing readable content are to use plain language (avoid jargon and unique words); write shorter sentences; and aim for an 8th grade reading level (Nielsen, 2015, section "Readability"). The allergen statements were evaluated by two measures of readability, the Gunning fog index and the Flesch Kincaid grade level. Both estimate the level of formal education someone would need to understand the text (based on the US education system). A 12 indicates 12 years of education, or a typical senior in the US (17-18 years old). It is important to note, though, that both tests work best with longer amounts of text, and the input text of the allergen statements are very short in comparison. Therefore, the estimates are meant to be exactly that, estimates, not a precise and absolutely accurate representation of the education necessary to read the statements.

Table 5. Readability of Allergen Statements

Label	Allergen Statement	Gunning Fog index	Flesch Kincaid Grade Level
1	Contains: egg and soy. Processed in a facility that also processes wheat	5.73	8.38
2	Contains: egg, soy, wheat	1.6	3.67
3	Contains: egg, soy. May contain traces of wheat.	1.6	5.14

Given that writing at a level at or below 8th grade is the recommended style of writing, all the allergen statements have high readability levels. Therefore, any problems with understanding the text are not likely to be caused by complex sentences or a lack of plain language. Instead, the allergen statements may have poor comprehensibility or legibility, which the results from the usability test support.

Summary

In summary, the allergen statements, although they have an accessible readability level, have low legibility and low comprehension. Participants found it easy to identify danger, but hard to identify safety, and felt that they were picking the least dangerous medication rather than the

most safe medication. All participants in this study expressed a confusion of the hierarchy of danger associated with allergen statements. They all identified the “contains” as the most dangerous, but had trouble distinguishing whether “may contains” indicated a level of potential contamination that is higher or lower than a “processed in a facility” statement. Participants know what is unhealthy, but not what is safe. However, all participants ultimately decided that “processed in a facility” was a safer risk than a “may contains” product, because, as p4 put it, “[the manufacturers with processed statement] are at least telling you ***where*** the contamination could be happening. The ‘may contains’ doesn’t have that information” (emphasis added). Most participants thought in terms of “do as little harm as possible” instead of “do what is most safe.” When they knew where the cross-contamination is occurring, they felt more comfortable making a decision about the risk involved in consuming that product.

Limitations

Due to the COVID-19 outbreak, participant recruitment was severely affected. The recruited participant pool was half of the intended amount and that participant pool was overwhelmingly female. A repetition of this test should include a larger sample size that is more equally divided among genders. A potentially information-wealthy repetition of this test could be done by comparing individuals who have no experience reading allergen statements with food-sensitive individuals and/or their caregivers. Additional research to confirm or further nuance the findings of this study is necessary, but these initial results point to need for improved consistency of allergen statements, additional regulation of allergen statements, and the necessity of allergen statement inclusion in pharmaceutical documents.

Recommendations

Based on the results of this study and a review of relevant literature, the FDA should implement the following recommendations:

- **Severity 3**
    - Require allergen statements on pharmaceuticals. Although the presence of allergen statements caused one participant to not feel comfortable taking any of the medications, the presence of allergen statements also allowed this

participant to make an informed decision about what was going in their body. For their health, food-sensitive individuals should have access to the knowledge about what ingredients and allergens are in pharmaceuticals to make a fully informed decision (in conversation with their pharmacist and physician) about whether or not they will consume the medication.

- **Severity 2**
    - Explicate the level of danger associated with each allergen statement and create an easy-to-understand hierarchy of allergen statements. Eliminate voluntary allergen statements to ensure consistency in allergen statements across products. Eliminate vague allergen statements to improve comprehensibility. Reward for resolution will likely be fewer help center calls, reduced time on task, and reduced negative health impacts for food-sensitive individuals.
- **Severity 1**
    - Enlarge the font of the allergen statement or distinguish it from other text with a box or header. This will improve legibility. Regardless of how this is done, it should be consistent across all statements in keeping with Nielsen's heuristic of consistency. Reward for resolution will likely be increased user satisfaction and reduced time on task.

In summary, the FDA must explicate the hierarchy of potential contamination associated with each label and should restrict vague allergen statements. If the "may contains" statement continues to be used, it must be accompanied with details about how and where that contamination is happening. Allergen statements on pharmaceuticals should include: ingredients; a contains statement; and a may contains statement with a brief explanation on areas of potential contamination, such as "processed in a facility". This allergen statement should be called out or formatted in a way that makes it easy to find and legible to most consumers.

Conclusion

No one can force a consumer to read allergen statements, but manufacturers should at least provide them with the correct, most updated information on ingredients and cross-contamination to allow consumers the opportunity to make a fully-informed decision about taking the pharmaceutical. As such, the FDA must require pharmaceutical manufacturers to include this information on medical documentation. Part of increasing consumer adherence to allergen statements is by explaining the meaning and danger implied by those labels. Once new allergen statements are developed, consumers, doctors, and pharmacists must be educated on the levels of safety indicated by the new allergen statements. Doctors and pharmacists should be the first line of defense and inquire as to whether the consumer has food-sensitivities, cross-checking them against medication ingredients, but community organizations such as the Asthma and Allergy Foundation of America, the American Academy of Allergy Asthma & Immunology, and the Celiac Disease Foundation can be partners in increasing awareness about this information.

The usability test conducted for this senior thesis represents an analysis only of those allergen statements that already exist. Ultimately, the lack of consistent or comprehendible allergen statements can be solved with a joint effort from technical communicators, healthcare professionals, and government officials. The government is already making an effort by introducing the Gluten In Medication Disclosure Act to Congress, so it is time for technical communicators and healthcare professionals to commit to developing better allergen statements. The average consumer needs the information that healthcare professionals have, but it must be designed with the consumer in mind, not just their doctor or pharmacist. Future work on allergen statements should employ technical communicators, UX designers, and expert physicians and pharmacists in designing new phrasings of allergen statements; conducting usability testing of those allergen statements; and refining and honing them to ensure more comprehensible and consistent allergen statements for all food-sensitive consumers.

For the safety of millions of Americans, the FDA must overhaul the allergen statement labeling system under the guidance of technical communicators and require pharmaceuticals to

include an allergen statement on their product. It is necessary to have facts about a product, but the information is only helpful if it is accurately communicated to consumers in a way that easily comprehensible to them. Technical communicators are capable of easing this tension only so long as technical communicators are actively involved. Let us all, technical communicator, healthcare official, government official, or the average, food-sensitive individual, contribute our unique skillset and knowledge to collaboratively and collectively improve the health of all Americans.

Bibliography

Barnum, C. (2010). *Usability testing essentials: Ready, set…test!* Burlington, MA: Morgan Kaufmann Publishers

Center for Disease Control. (2017). Therapeutic drug use. *Center for Disease Control*. Retrieved from URL. Accessed 27 April 2020.

Celiac Disease Center. (2006). Celiac disease facts and figures. *The University of Chicago Medicine*. Retrieved from URL.

Chartrand, L., Russo, P., Duhame, A., & Seidman, E. (1997). Wheat starch intolerance in patients with celiac disease. *Journal of the American Dietetic Association, 97*(6), 612–618. Retrieved from URL.

Cochrane, S., Gowland, H., Sbeffield, D., & Crevel, R. (2013). Characteristics and purchasing behaviours of food-allergic consumers and those who buy food for them in Great Britain. *Clinical and Translation Allergy, 3*. Retrieved from URL.

Crowe, J., & Falini, N. (2001). Gluten in pharmaceutical products. *American Journal of Health-System Pharmacy, 58*, 396-401. Retrieved from URL.

Cruz, J. et al. (2015). Gluten content of medications. *American Journal of Health-System Pharmacy 72*(1), 54-60. Retrieved from URL.

FDA. (2014). Allergy inspection guide (4/01). *FDA*. Retrieved from URL.

FDA. (2018). Food allergen labeling and consumer protection act of 2004 questions and answers. *FDA*. Retrieved from URL.

FDA. (2017). Frequently asked questions about food allergies. *FDA.* Retrieved from URL.

FDA. (2018). Gluten and food labeling. *FDA.* Retrieved from URL.

FDA. (2018). Guidance for industry: Questions and answers regarding food allergens (edition 4). FDA. Retrieved from URL.

FDA. (2018). Questions and answers on the gluten-free food labeling final rule. *FDA.* Retrieved from URL.

FDA. (2018). What you need to know about food allergies. *FDA.* Retrieved from URL.

Food Allergen Labeling and Consumer Protection Act of 2004. 21 USC 301 note. Section 201-210. Retrieved from URL.

Gluten in Medicine Disclosure Act of 2019, H.R. 2074, 116 Cong. (2019).

Gupta, R., Warren, C., Smith. B., et al. (2019). Prevalence and severity of food allergies among US adults. *JAMA Network Open, 2*(1). Retrieved from URL.

Haywood, A., & Glass, B. (2011). Pharmaceutical excipients – where do we begin? *Australian Prescriber, 34*(4), 112-114. Retrieved from URL.

Hlywiak, K. (2008). Hidden sources of gluten. *Practical Gastroenterology*. Retrieved from URL.

International Organization for Standardization. (1998). Part 11: Usability: Definitions and concepts. *ISO 9241: Ergonomics of human-system interaction.* Retrieved from URL. Accessed 26 April 2020.

Johnson, A., Skaff, A., & Senesac, L. (2014). Medication and supplement use in celiac disease. *US Pharm, 39(*12), 44-48.

Kelso, J. (2014). Potential food allergens in medications. *Journal of Allergy and Clinical Immunology, 133*(6), 1509-1518. Retrieved from URL.

King, A. (2013). Gluten content of the top 200 medications: Follow-up to the influence of gluten on a patient's medication choices. *Hospital Pharmacy, 48*(9), 736-743. Retrieved from URL.

Maltin, V., Charabaty, A., & Mangione, R. (2009). Medications: A hidden source of gluten. *Practical Gastroenterology, 33*(8), 32-36+38. Retrieved from URL.

Mangione, R., Patel, P., Shin, E., & Fiebert, J. (2011). Determining the gluten content of nonprescription drugs: Information for patients with celiac disease. *Journal of the American pharmacists Association, 51*(6), 734-737. Retrieved from URL.

Mayo Clinic staff. (2019). Celiac disease. *Mayo clinic*. Retrieved from URL.

Mayo Clinic staff. (2014). Gluten may not be culprit in nonresponsive celiac disease. *Mayo clinic*. Retrieved from URL.

Merriam-Webster Dictionary. (n.d.). Excipient. *Dictionary by Merriam-Webster Dictionary.* Retrieved from URL. (Accessed 19 April 2020).

Monks, H., et al. (2010). How do teenagers manage their food allergies? *Clinical & Experimental Allergy, 40*(10), 1533-1540. Retrieved from URL.

Moore, A. (2019). Expanding vigilance for food allergies. *American Academy of Allergy Asthma & Immunology*. Retrieved from URL.

Nielsen, J. (1994). 10 usability heuristics for user interface design. *Nielsen Norman Group*. Retrieved from URL. Accessed 20 March 2020.

Nielsen, J. (2015). Legibility, readability, and comprehension: Making users read your words. *Nielsen Norman Group*. Retrieved from URL. Accessed 26 April 2020.

Puglisi, G., & Frieri, M. (2007). Update on hidden food allergens and food labeling. *Allergy and Asthma Proceedings, 28*(6). Retrieved from URL.

Redish, J. (2010). Technical communication and usability: Intertwined strands and mutual influences commentary. *IEEE Transaction on Profession Communication, 53*(3), 191-201. Retrieved from URL.

Reker, D., et al. (2019). "Inactive" ingredients in oral medications. *Science Translational Medicine, 11,* 483. Retrieved from URL.

Rojas-Hijazo, B. et al. (2006). Unsuspected lupin allergens hidden in food. *International Archives of Allergy and Immunology,* (141), 47-50. Retrieved from URL.

Schäfer, T., et al. (2001). Epidemiology of food allergy/food intolerance in adults: Associations with other manifestations of atopy. *Allergy, 56,* 1172-1179. Retrieved from URL.

Sheth, S., et al. (2010). Role of food labels in accidental exposures in food-allergic individuals in Canada. *Annals of Allergy, Asthma & Immunology 104*(1), 60-65. Retrieved from URL.

Society for Technical Communication. (n.d). Defining Technical Communication. *Society for Technical Communication.* Retrieved from URL. Accessed 25 April 2020.

Trivedi, H., Trivedi, A., Hannan, M. (2014). Readability and comprehensibility of over-the-counter medication labels. *Renal Failure, 36*(3), 473-477. Retrieved from URL.

Turner, P., Kemp, A., Campbell, D. (2011). Advisory food labels: Consumers with allergies need more than "traces" of information. *The BMJ, 343*. Retrieved from URL.

Warren, C., et al. (2019). Prevalence and severity of sesame allergy in the united states. *JAMA Network Open, 2*(8). Retrieved from URL.

Wood, R., et al. (2014). Anaphylaxis in America: The prevalence and characteristics of anaphylaxis in the United States. *The Journal of Allergy and Clinical Immunology 133*(2). Retrieved from URL.

Zurzolo, G., Mathai, M., Koplin, J., & Allen, K. (2012). Hidden allergens in foods and implications for labeling and clinical care of food allergic patients. *Current Allergy and Asthma Reports, 12*(4), 292-296. Retrieved from URL.

Appendices

Glossary

Active pharmaceutical ingredient (API): the ingredient in a medication that brings relief. Examples include paracetamol, aspirin, naproxen, or ibuprofen. They generally make up a very small part of the actual pill, tablet, or capsule itself.

Allergen statement: a brief sentence found primarily on food packaging that discloses any of the top eight allergens that are or could be found in the product. Allergens must be listed in plain language, and either bolded within the main ingredient list, or in the same font and size but outside of the main ingredient list (FDA, Food allergen labeling and consumer protection act of 2004 questions and answers, 2018).

Allergy: a medical condition wherein a person's immune system overreacts to a specific food. A microscopic amount of this food can cause symptoms such as hives, swollen airways, nausea, vomiting, and diarrhea. In the most severe cases, a patient can enter anaphylactic shock and die if not treated soon enough (FDA, What you need to know about food allergies, 2018). According to the most recent data, 11% of Americans have at least one food allergy (Gupta, Warren, Smith, & et al., 2019).

Celiac: a medical condition involving a non-fatal but still detrimental reaction to eating gluten, which is a protein found in wheat, barley, and rye. An allergy is an immune response, but with celiac the response is autoimmune, because the immune system begins to attack the intestines, where the gluten is located. Symptoms include diarrhea, fatigue, flatulence, and joint pain. There is no cure. Failure to maintain a gluten-free diet can lead further health complications like anemia, diabetes, and osteoporosis. Long-term exposure to gluten leads to malabsorption, malnutrition, permanent damage to the intestines and, as a result, premature death (Mayo Clinic staff, 2019). Up to 1% of the US population has celiac—that's about three million people (Celiac Disease Center, 2006).

Comprehension: “whether a user can understand the intended meaning of a text and can draw the correct conclusions from the text. In the case of instructional or action-oriented content, we also want users to be able to perform the intended actions after reading the text” (Nielsen, 2015, section “Comprehension”).

Excipient: a “filler” ingredient that makes up the bulk of a pill or medication. The official definition in Merriam-Webster dictionary is “a usually inert substance (such as gum Arabic or starch) that forms a vehicle (for a drug).” It usually serves as a vehicle or carrier of the active

ingredient, or the ingredient or chemical that medicates the body. Excipients can be gelatin, cellulose, starches, lactose, sucrose, or any other food, artificial or otherwise.

Food sensitivity: for the purpose of this paper, I have defined a "food sensitivity" as an allergy to any of the top eight food allergens or sesame, an intolerance to the top eight food allergens or sesame, or celiac. In this way, all these medical conditions can be referred to collectively. Any food that elicits these reactions will be referred to as an "incendiary food".

Glutening: a noun or verb, this term refers to an instance when someone with celiac inadvertently ingests gluten. Example: "Yeah, I won't be in to work today, I was glutened by the food at the party" or "I had a glutening when I went to the local bar last time, so I'll skip it this time."

Incendiary foods: this group includes the top eight allergens, which are, as listed by the FDA, milk, eggs, peanuts, tree nuts (almonds, cashews, walnuts, etc.), fish, shellfish, soy, and wheat. The top eight allergens account for 90% of all food allergies (FDA, What you need to know about allergens, 2018). Incendiary foods also include the gluten-containing grains barley and rye, and sesame, the ninth most common allergy (Warren, et al., 2019).

Intolerance: any number of non-damaging medical conditions in the digestive system leading to difficulty digesting the food, usually attributed to a lack of a specific enzyme. Symptoms include intestinal gas, abdominal pain, and diarrhea. It is estimated that up to 20% of a population has a food intolerance (Schäfer, et al., 2001).

Legibility: "whether people are able to see, distinguish, and recognize the characters and words in your text. Legibility is thus mainly determined by visual design, specifically typography" (Nielsen, 2015, section "Legibility").

OTC: OTC stands for "over the counter," and refers to medications that can be purchased without a prescription.

Readability: "measures the complexity of the words and sentence structure in a piece of content. The assumption behind this metric is that complex sentences are harder to parse and read than simpler ones. It's usually reported as the reading level (stated as years of formal education) needed to easily read the text. For example, a 12th grade reading level means that somebody with a good high-school diploma will be able to read the text without difficulty" (Nielsen, 2015, section "Readability"). General guidelines for writing readable content is using plain language (avoid jargon and unique words), write shorter sentences, and aim for an 8th grade reading level (Nielsen, 2015, section "Readability"). Note that making content readable is *not* "dumbing it down," but rather opening it up to everyone.

Refractory celiac: a rare form of celiac wherein the body does not heal even after strictly adhering to a gluten-free diet (Mayo Clinic staff, 2019). About 1% of those with celiac have refractory celiac (Mayo clinic staff, 2014).

Technical communication: "To communicate about technical or specialized topics; communicate by using technology; or to provide instructions about how to do something" (Society for Technical Communication, n.d.).

Usability: As an adjective, usability is “the extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use” (International Organization for Standardization, 1998, section 3.1.1). As a noun, usability testing “focuses on observing and learning from your users who are working with your product to perform tasks that are real and meaningful to them” (Barnum, 2010, p. 53).

Usability Test Plan

test_plan.pdf

Consent Form

Consent_form.pdf

Script

script.pdf

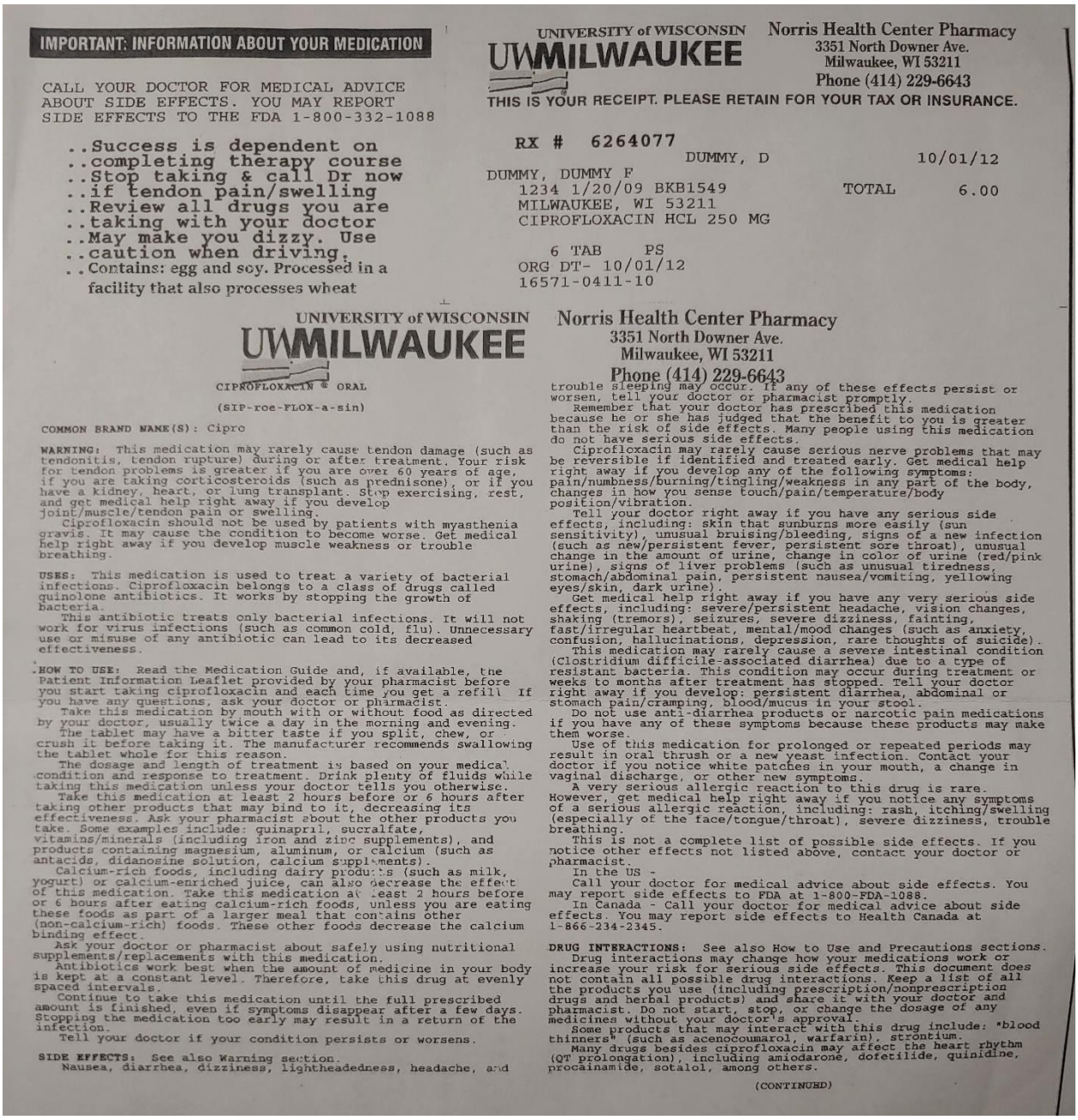
Background Questionnaire

Demographics_questionnaire.pdf

Debriefing Questionnaire

Debriefing_interview_questions.pdf

Label 1



IMPORTANT: INFORMATION ABOUT YOUR MEDICATION

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA 1-800-332-1088

..Success is dependent on
..completing therapy course
..Stop taking & call Dr now
..if tendon pain/swelling
..Review all drugs you are
..taking with your doctor
..May make you dizzy. Use
..caution when driving,
..Contains: egg and soy. Processed in a facility that also processes wheat

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Norris Health Center Pharmacy
3351 North Downer Ave.
Milwaukee, WI 53211
Phone (414) 229-6643

THIS IS YOUR RECEIPT. PLEASE RETAIN FOR YOUR TAX OR INSURANCE.

RX # 6264077 DUMMY, D 10/01/12

DUMMY, DUMMY F
1234 1/20/09 BKB1549 TOTAL 6.00
MILWAUKEE, WI 53211
CIPROFLOXACIN HCL 250 MG

6 TAB PS
ORG DT- 10/01/12
16571-0411-10

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Norris Health Center Pharmacy
3351 North Downer Ave.
Milwaukee, WI 53211
Phone (414) 229-6643

CIPROFLOXACIN ® ORAL

(SIP-roe-FLOX-a-sin)

COMMON BRAND NAME(S): Cipro

WARNING: This medication may rarely cause tendon damage (such as tendonitis, tendon rupture) during or after treatment. Your risk for tendon problems is greater if you are over 60 years of age, if you are taking corticosteroids (such as prednisone), or if you have a kidney, heart, or lung transplant. Stop exercising, rest, and get medical help right away if you develop joint/muscle/tendon pain or swelling.

Ciprofloxacin should not be used by patients with myasthenia gravis. It may cause the condition to become worse. Get medical help right away if you develop muscle weakness or trouble breathing.

USES: This medication is used to treat a variety of bacterial infections. Ciprofloxacin belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria.

This antibiotic treats only bacterial infections. It will not work for virus infections (such as common cold, flu). Unnecessary use or misuse of any antibiotic can lead to its decreased effectiveness.

HOW TO USE: Read the Medication Guide and, if available, the Patient Information Leaflet provided by your pharmacist before you start taking ciprofloxacin and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth with or without food as directed by your doctor, usually twice a day in the morning and evening.

The tablet may have a bitter taste if you split, chew, or crush it before taking it. The manufacturer recommends swallowing the tablet whole for this reason.

The dosage and length of treatment is based on your medical condition and response to treatment. Drink plenty of fluids while taking this medication unless your doctor tells you otherwise.

Take this medication at least 2 hours before or 6 hours after taking other products that may bind to it, decreasing its effectiveness. Ask your pharmacist about the other products you take. Some examples include: quinapril, sucralfate, vitamins/minerals (including iron and zinc supplements), and products containing magnesium, aluminum, or calcium (such as antacids, didanosine solution, calcium supplements).

Calcium-rich foods, including dairy products (such as milk, yogurt) or calcium-enriched juice, can also decrease the effect of this medication. Take this medication at least 2 hours before or 6 hours after eating calcium-rich foods, unless you are eating these foods as part of a larger meal that contains other (non-calcium-rich) foods. These other foods decrease the calcium binding effect.

Ask your doctor or pharmacist about safely using nutritional supplements/replacements with this medication.

Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals.

Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may result in a return of the infection.

Tell your doctor if your condition persists or worsens.

SIDE EFFECTS: See also Warning section.

Nausea, diarrhea, dizziness, lightheadedness, headache, and trouble sleeping may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Ciprofloxacin may rarely cause serious nerve problems that may be reversible if identified and treated early. Get medical help right away if you develop any of the following symptoms: pain/numbness/burning/tingling/weakness in any part of the body, changes in how you sense touch/pain/temperature/body position/vibration.

Tell your doctor right away if you have any serious side effects, including: skin that sunburns more easily (sun sensitivity), unusual bruising/bleeding, signs of a new infection (such as new/persistent fever, persistent sore throat), unusual change in the amount of urine, change in color of urine (red/pink urine), signs of liver problems (such as unusual tiredness, stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes/skin, dark urine).

Get medical help right away if you have any very serious side effects, including: severe/persistent headache, vision changes, shaking (tremors), seizures, severe dizziness, fainting, fast/irregular heartbeat, mental/mood changes (such as anxiety, confusion, hallucinations, depression, rare thoughts of suicide).

This medication may rarely cause a severe intestinal condition (Clostridium difficile-associated diarrhea) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Tell your doctor right away if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool.

Do not use anti-diarrhea products or narcotic pain medications if you have any of these symptoms because these products may make them worse.

Use of this medication for prolonged or repeated periods may result in oral thrush or a new yeast infection. Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge, or other new symptoms.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

DRUG INTERACTIONS: See also How to Use and Precautions sections.

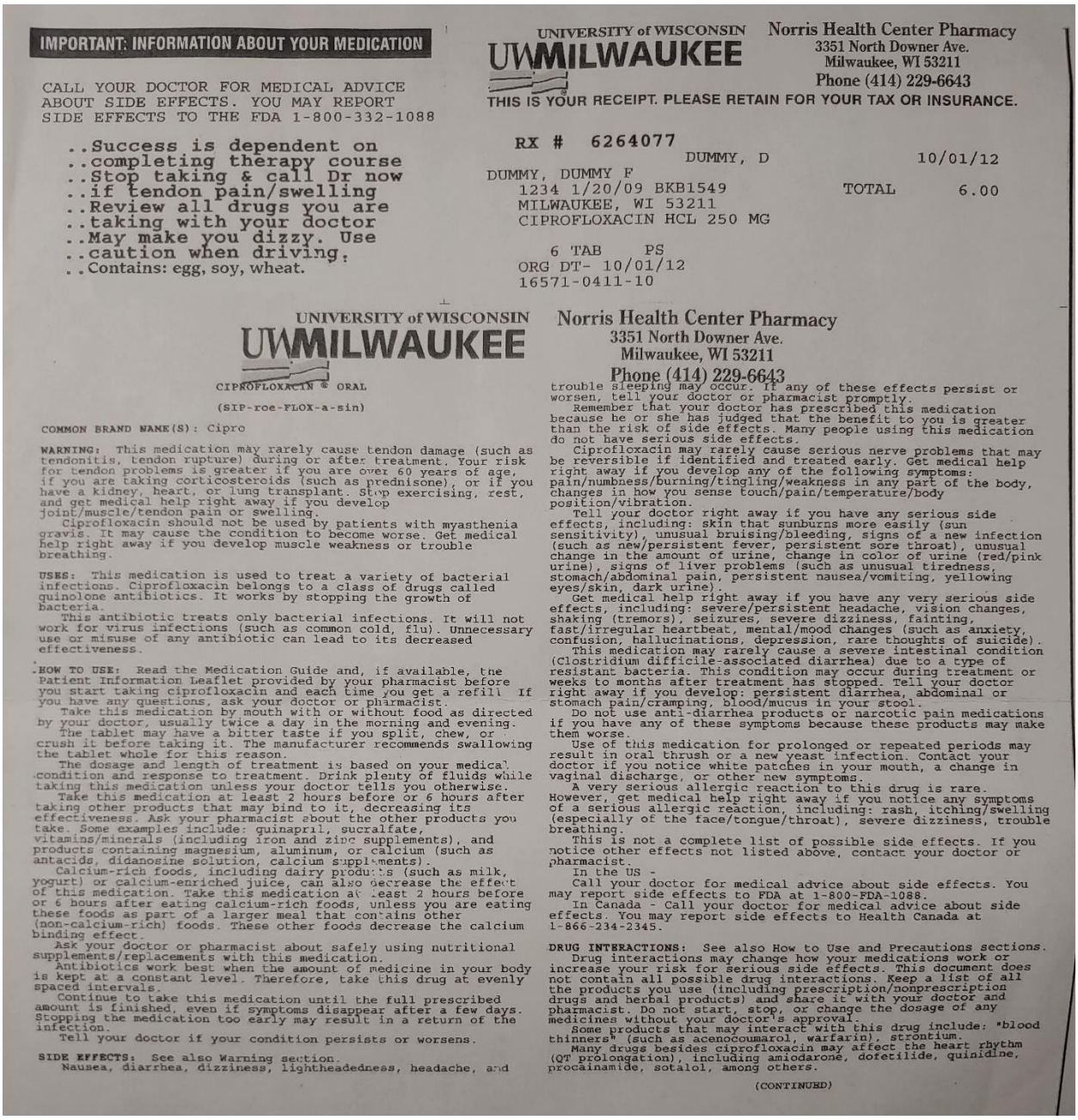
Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: *blood thinners* (such as acenocoumarol, warfarin), strontium.

Many drugs besides ciprofloxacin may affect the heart rhythm (QT prolongation), including amiodarone, dofetilide, quinidine, procainamide, sotalol, among others.

(CONTINUED)

Label 2



IMPORTANT: INFORMATION ABOUT YOUR MEDICATION

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA 1-800-332-1088

..Success is dependent on
..completing therapy course
..Stop taking & call Dr now
..if tendon pain/swelling
..Review all drugs you are
..taking with your doctor
..May make you dizzy. Use
..caution when driving.
..Contains: egg, soy, wheat.

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Norris Health Center Pharmacy
3351 North Downer Ave.
Milwaukee, WI 53211
Phone (414) 229-6643

THIS IS YOUR RECEIPT. PLEASE RETAIN FOR YOUR TAX OR INSURANCE.

RX # 6264077 DUMMY, D 10/01/12

DUMMY, DUMMY F
1234 1/20/09 BKB1549 TOTAL 6.00
MILWAUKEE, WI 53211
CIPROFLOXACIN HCL 250 MG

6 TAB PS
ORG DT- 10/01/12
16571-0411-10

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Norris Health Center Pharmacy
3351 North Downer Ave.
Milwaukee, WI 53211
Phone (414) 229-6643

CIPROFLOXACIN ® ORAL

(SIP-roe-FLOX-a-sin)

COMMON BRAND NAME(S): Cipro

WARNING: This medication may rarely cause tendon damage (such as tendonitis, tendon rupture) during or after treatment. Your risk for tendon problems is greater if you are over 60 years of age, if you are taking corticosteroids (such as prednisone), or if you have a kidney, heart, or lung transplant. Stop exercising, rest, and get medical help right away if you develop joint/muscle/tendon pain or swelling.

Ciprofloxacin should not be used by patients with myasthenia gravis. It may cause the condition to become worse. Get medical help right away if you develop muscle weakness or trouble breathing.

USES: This medication is used to treat a variety of bacterial infections. Ciprofloxacin belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria.

This antibiotic treats only bacterial infections. It will not work for virus infections (such as common cold, flu). Unnecessary use or misuse of any antibiotic can lead to its decreased effectiveness.

HOW TO USE: Read the Medication Guide and, if available, the Patient Information Leaflet provided by your pharmacist before you start taking ciprofloxacin and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth with or without food as directed by your doctor, usually twice a day in the morning and evening.

The tablet may have a bitter taste if you split, chew, or crush it before taking it. The manufacturer recommends swallowing the tablet whole for this reason.

The dosage and length of treatment is based on your medical condition and response to treatment. Drink plenty of fluids while taking this medication unless your doctor tells you otherwise.

Take this medication at least 2 hours before or 6 hours after taking other products that may bind to it, decreasing its effectiveness. Ask your pharmacist about the other products you take. Some examples include: quinapril, sucralfate, vitamins/minerals (including iron and zinc supplements), and products containing magnesium, aluminum, or calcium (such as antacids, didanosine solution, calcium supplements).

Calcium-rich foods, including dairy products (such as milk, yogurt) or calcium-enriched juice, can also decrease the effect of this medication. Take this medication at least 2 hours before or 6 hours after eating calcium-rich foods, unless you are eating these foods as part of a larger meal that contains other (non-calcium-rich) foods. These other foods decrease the calcium binding effect.

Ask your doctor or pharmacist about safely using nutritional supplements/replacements with this medication.

Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals.

Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may result in a return of the infection.

Tell your doctor if your condition persists or worsens.

SIDE EFFECTS: See also Warning section.

Nausea, diarrhea, dizziness, lightheadedness, headache, and trouble sleeping may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Ciprofloxacin may rarely cause serious nerve problems that may be reversible if identified and treated early. Get medical help right away if you develop any of the following symptoms: pain/numbness/burning/tingling/weakness in any part of the body, changes in how you sense touch/pain/temperature/body position/vibration.

Tell your doctor right away if you have any serious side effects, including: skin that sunburns more easily (sun sensitivity), unusual bruising/bleeding, signs of a new infection (such as new/persistent fever, persistent sore throat), unusual change in the amount of urine, change in color of urine (red/pink urine), signs of liver problems (such as unusual tiredness, stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes/skin, dark urine).

Get medical help right away if you have any very serious side effects, including: severe/persistent headache, vision changes, shaking (tremors), seizures, severe dizziness, fainting, fast/irregular heartbeat, mental/mood changes (such as anxiety, confusion, hallucinations, depression, rare thoughts of suicide).

This medication may rarely cause a severe intestinal condition (Clostridium difficile-associated diarrhea) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Tell your doctor right away if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool.

Do not use anti-diarrhea products or narcotic pain medications if you have any of these symptoms because these products may make them worse.

Use of this medication for prolonged or repeated periods may result in oral thrush or a new yeast infection. Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge, or other new symptoms.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

DRUG INTERACTIONS: See also How to Use and Precautions sections.

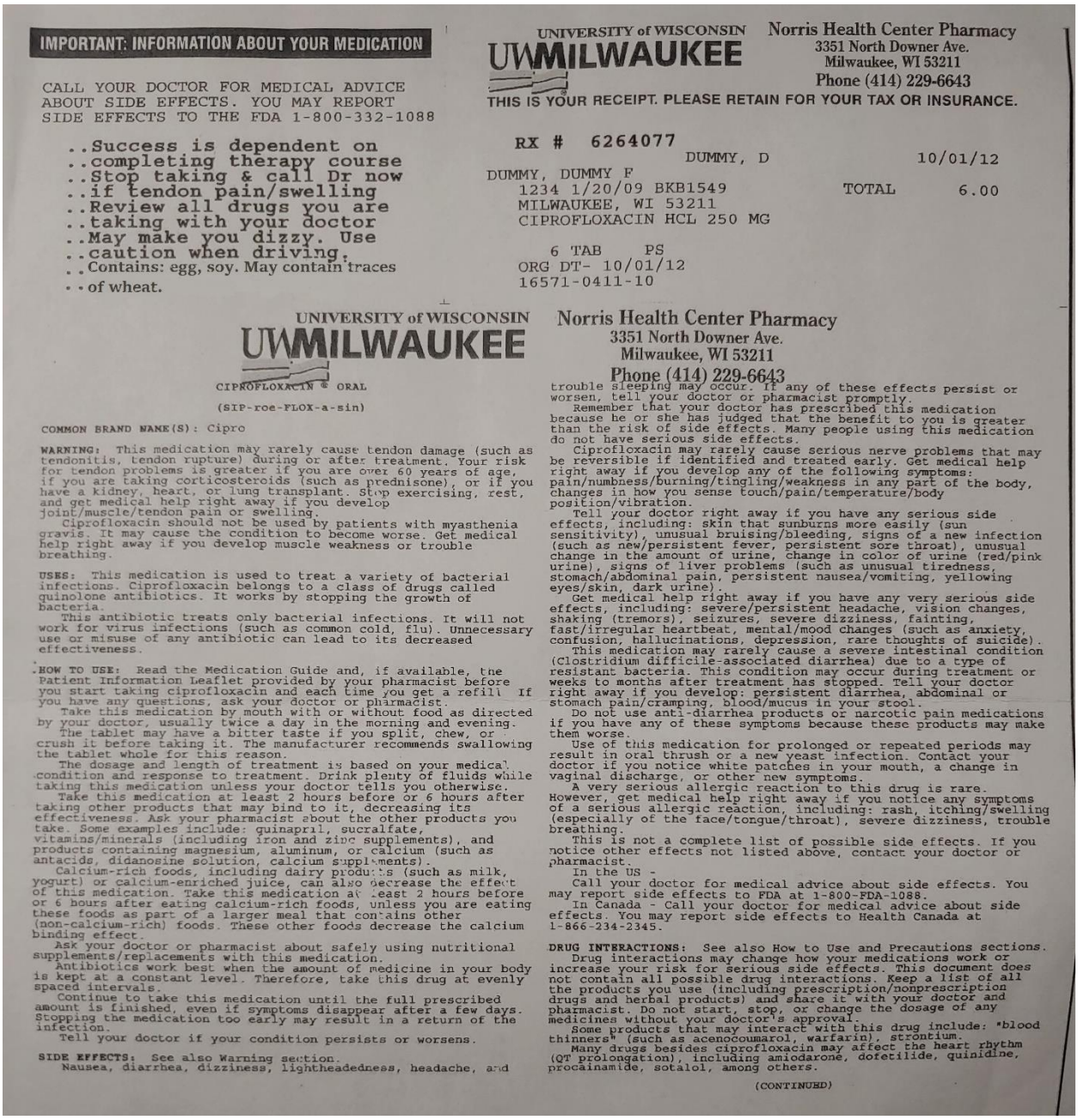
Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: *blood thinners* (such as acenocoumarol, warfarin), strontium.

Many drugs besides ciprofloxacin may affect the heart rhythm (QT prolongation), including amiodarone, dofetilide, quinidine, procainamide, sotalol, among others.

(CONTINUED)

Label 3



IMPORTANT: INFORMATION ABOUT YOUR MEDICATION

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA 1-800-332-1088

..Success is dependent on
..completing therapy course
..Stop taking & call Dr now
..if tendon pain/swelling
..Review all drugs you are
..taking with your doctor
..May make you dizzy. Use
..caution when driving.
..Contains: egg, soy. May contain traces
..of wheat.

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Norris Health Center Pharmacy
3351 North Downer Ave.
Milwaukee, WI 53211
Phone (414) 229-6643

THIS IS YOUR RECEIPT. PLEASE RETAIN FOR YOUR TAX OR INSURANCE.

RX # 6264077 DUMMY, D 10/01/12

DUMMY, DUMMY F
1234 1/20/09 BKB1549 TOTAL 6.00
MILWAUKEE, WI 53211
CIPROFLOXACIN HCL 250 MG

6 TAB PS
ORG DT- 10/01/12
16571-0411-10

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Norris Health Center Pharmacy
3351 North Downer Ave.
Milwaukee, WI 53211
Phone (414) 229-6643

CIPROFLOXACIN ® ORAL

(SIP-roe-FLOX-a-sin)

COMMON BRAND NAME(S): Cipro

WARNING: This medication may rarely cause tendon damage (such as tendonitis, tendon rupture) during or after treatment. Your risk for tendon problems is greater if you are over 60 years of age, if you are taking corticosteroids (such as prednisone), or if you have a kidney, heart, or lung transplant. Stop exercising, rest, and get medical help right away if you develop joint/muscle/tendon pain or swelling.

Ciprofloxacin should not be used by patients with myasthenia gravis. It may cause the condition to become worse. Get medical help right away if you develop muscle weakness or trouble breathing.

USES: This medication is used to treat a variety of bacterial infections. Ciprofloxacin belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria.

This antibiotic treats only bacterial infections. It will not work for virus infections (such as common cold, flu). Unnecessary use or misuse of any antibiotic can lead to its decreased effectiveness.

HOW TO USE: Read the Medication Guide and, if available, the Patient Information Leaflet provided by your pharmacist before you start taking ciprofloxacin and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth with or without food as directed by your doctor, usually twice a day in the morning and evening.

The tablet may have a bitter taste if you split, chew, or crush it before taking it. The manufacturer recommends swallowing the tablet whole for this reason.

The dosage and length of treatment is based on your medical condition and response to treatment. Drink plenty of fluids while taking this medication unless your doctor tells you otherwise.

Take this medication at least 2 hours before or 6 hours after taking other products that may bind to it, decreasing its effectiveness. Ask your pharmacist about the other products you take. Some examples include: quinapril, sucralfate, vitamins/minerals (including iron and zinc supplements), and products containing magnesium, aluminum, or calcium (such as antacids, didanosine solution, calcium supplements).

Calcium-rich foods, including dairy products (such as milk, yogurt) or calcium-enriched juice, can also decrease the effect of this medication. Take this medication at least 2 hours before or 6 hours after eating calcium-rich foods, unless you are eating these foods as part of a larger meal that contains other (non-calcium-rich) foods. These other foods decrease the calcium binding effect.

Ask your doctor or pharmacist about safely using nutritional supplements/replacements with this medication.

Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals.

Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may result in a return of the infection.

Tell your doctor if your condition persists or worsens.

SIDE EFFECTS: See also Warning section.

Nausea, diarrhea, dizziness, lightheadedness, headache, and trouble sleeping may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Ciprofloxacin may rarely cause serious nerve problems that may be reversible if identified and treated early. Get medical help right away if you develop any of the following symptoms: pain/numbness/burning/tingling/weakness in any part of the body, changes in how you sense touch/pain/temperature/body position/vibration.

Tell your doctor right away if you have any serious side effects, including: skin that sunburns more easily (sun sensitivity), unusual bruising/bleeding, signs of a new infection (such as new/persistent fever, persistent sore throat), unusual change in the amount of urine, change in color of urine (red/pink urine), signs of liver problems (such as unusual tiredness, stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes/skin, dark urine).

Get medical help right away if you have any very serious side effects, including: severe/persistent headache, vision changes, shaking (tremors), seizures, severe dizziness, fainting, fast/irregular heartbeat, mental/mood changes (such as anxiety, confusion, hallucinations, depression, rare thoughts of suicide).

This medication may rarely cause a severe intestinal condition (Clostridium difficile-associated diarrhea) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Tell your doctor right away if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool.

Do not use anti-diarrhea products or narcotic pain medications if you have any of these symptoms because these products may make them worse.

Use of this medication for prolonged or repeated periods may result in oral thrush or a new yeast infection. Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge, or other new symptoms.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

DRUG INTERACTIONS: See also How to Use and Precautions sections.

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: *blood thinners* (such as acenocoumarol, warfarin), strontium.

Many drugs besides ciprofloxacin may affect the heart rhythm (QT prolongation), including amiodarone, dofetilide, quinidine, procainamide, sotalol, among others.

(CONTINUED)