



# What is Clarity for a FDA Patient Information Sheet?

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# Two Issues on the Adderall Patient Information Sheet

- What is clarity?
- How do you know?



# What Is Clarity?

- Consumers can find the answers to their questions easily.
- Consumers can understand the answers.



# Consumers Can Find the Answers Easily

- How do we do this?
  - Know the questions that consumers want to know.



# Survey Results

Question	Responses (n = 10)
Are there any side effects?	9
Will the drug react with other medications or vitamins I'm taking?	5
How long has this drug been on the market?	3
What do I do if I turn out to be allergic to this drug?	3
Where can I find information about how or whether this drug was tested?	3



# How'd We Do?

- Clarity for the consumer will be answering these questions.
- What's on the information sheet?
  - Usual FDA information
  - FDA Alerts
  - Warning about abuse
  - Q&As
    - What is Adderall XR?
    - Who should not take Adderall?
    - What are the risks?
    - Are there any interactions?
    - How do I take Adderall?



# Consumers Can Understand the Answers

- Let's look at the language of the Adderall alert.



# Original Alert Statement

Health Canada has suspended marketing of Adderall XR products from the Canadian market due to concern about reports of sudden unexplained death (SUD) in children taking Adderall and Adderall XR. SUD has been associated with amphetamine abuse and reported in children with underlying cardiac abnormalities taking recommended doses of amphetamines, including Adderall and Adderall XR. In addition, a very small number of cases of SUD have been reported in children without cardiac abnormalities taking Adderall. At this time, FDA cannot conclude that recommended doses of Adderall can cause SUD, but is continuing to carefully evaluate these data.



# Consumers Can Understand the Answer

- Flesch-Kincaid shows a reading grade level of 16.7
- Take out the word Adderall, and it's the same level.



# Consumers Can Understand the Answer

- Readability is a function of so much more than words and sentence lengths.



# Consumers Can Understand the Answer

- Consider the following rewrite. It reduces the reading grade level to 13.3.
- But is it easier to read?



# Sample Rewrite

## **Status**

Health Canada no longer allows marketing in Canada of Adderall XR products.

## **Reason**

Some children taking Adderall XR have died suddenly and without apparent cause.

A sudden unexplained death (SUD) has occurred with three types of medical conditions:

1. in children with an abuse of amphetamines
2. in children with underlying cardiac abnormalities and who are taking recommended doses of Adderall and Adderall XR, and
3. in a very small number of children without underlying cardiac abnormalities

## **The Future**

FDA is looking at these data, but cannot conclude that recommended doses of Adderall can cause SUD. FDA will update this information when we learn more.



# What Did We Do?

- Set up a predictable structure
- Categorized information according to consumer questions
- Simplified words
- Broke up long sentences
- Defined unknown words
- Broke out the three key pieces of information with numbers
- Added information that explicitly states that FDA will provide more information



# What is Clarity?

- Clarity is not a simple quest.
  - Know the consumers' questions.
  - Write so consumers can understand the answers.



# How do you know?

- Test! Test! Test!
- The ultimate judge of a document's success is the consumer.
- Ask about
  - The consumer's questions
  - The structure
  - The language



# What Is Clarity?

“Out of clutter, find  
simplicity.”

—*Frank Lloyd Wright*