Risky Business:
Prioritizing Risk Information in FDA Documents

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Clear communication is at the core of the FDA's Mission

"We recognize that effective communication is the foundation for successfully implementing [the FDA's guiding] principles."

FDA Strategic Priorities (2011-2015), Section 1.3: Guiding Principles. http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm245959.htm#1_1

Consider Objective 3.3 of FDA's 2014-2018 Strategic Plan

Improve Safety and Health Information Provided to the Public

From FDA Strategic Priorities (2014-2018), p. 24.

http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM416602.pdf

And from HHS's Strategic Plan

"Engage individuals and families as partners in their care by incorporating patient and caregiver preferences; using clear and productive communication strategies; improving the experience of care for patients, caregivers, and families; integrating health literacy principles; and promoting patient self-management."

From Strategic Goal 1: Strengthen Health Care

http://www.hhs.gov/strategic-plan/goal1.html

To provide a strategy for the RCAC to help achieve these communication goals

Let's consider REMS

REMS = Risk Evaluation & Mitigation Strategy

When are REMS used?

- When the FDA determines that "additional safety measures are needed beyond the professional labeling to ensure that a drug's benefits outweigh its risks."

- **Note:** one of the main points of a REMS is to communicate risk to patients & providers.

Consider the mindset of those creating REMS

- Goal is to get the food, drug, cosmetic approved.
- Their lawyer's main goal is to protect the organization.
- Patients & consumers are secondary.

PATIENT AGREEMENT

The maker of ZYPREXA RELPREVV, Eli Lilly and Company and their delegates run the ZYPREXA RELPREVV Patient Care Program.

Your doctor will send your name, date of birth, and other information that directly identifies you to the ZYPREXA RELPREVV Patient Care Program. Ask your doctor if you have questions about the information that will be collected.

The ZYPREXA RELPREVV Patient Care Program will collect and use your information in the following ways:

- Your doctor will provide dose, date and time of each injection, and medical information to the ZYPREXA RELPREVV Patient Care Program.
- Your information will be stored in the ZYPREXA RELPREVV Patient C gram computer system.
- The information will be used to help Lilly learn more about the safety of Z REXA RELPREVV.
- Information from all patients in the ZYPREXA RELPREVV Patient Care Program will be reviewed and may be combined with information from clinical studies.
- This combined information will not be able to identify you or any other patient. This combined information may be shared with:
  - regulatory agencies,
  - doctors at other institutions,
  - the committee overseeing the ZYPREXA RELPREVV Patient Care Program, and/or
  - publications or as part of scientific discussions.

Also, by signing this form you agree to the following:

- I understand that I must enroll in the ZYPREXA RELPREVV Patient Care Program registry to get ZYPREXA RELPREVV.
- I agree to have my information entered in the ZYPREXA RELPREVV Patient Care Program registry.
- My doctor has explained the risks and benefits of treatment with ZYPREXA RELPREVV.
- I have received a copy of the Medication Guide.
- I understand that I will be observed at the clinic for 3 hours after each injection.
- Someone must go with me to my destination when I leave the clinic.
- I understand that I can not drive or use heavy machinery for the rest of the day on which I get an injection.
- I agree to seek medical care right away if I have a reaction such as excessive sleepiness, dizziness, confusion, difficulty talking, difficulty walking, muscle stiffness or shaking, weakness, irritability, aggression anxiety, increase in blood pressure or convulsions.
- I agree to contact my doctor if I have a reaction to ZYPREXA REL .
- I may be asked to complete occasional surveys about my und g of the risks and benefits of treatment with ZYPREXA RELPREVV.
- I or my caregiver have discussed any questions or concerns a ny treatment with ZYPREXA RELPREVV with my doctor.

Risk info

You may stop participating in the ZYPREXA RELPREVV Patient Care Program at any time by telling your doctor. If you stop participating, you will no longer be able to receive the drug. Your doctor will no longer provide any of your information to the ZYPREXA RELPREVV Patient Care Program except to answer safety questions. The ZYPREXA RELPREVV Patient Care Program will still use information that was collected before you stopped participating. You will be provided a copy of this form.

Signature

Date: ☐☐ – ☐☐ – ☐☐☐☐
month day year

Let's take a closer look...

Do we need more of the info disclosure?

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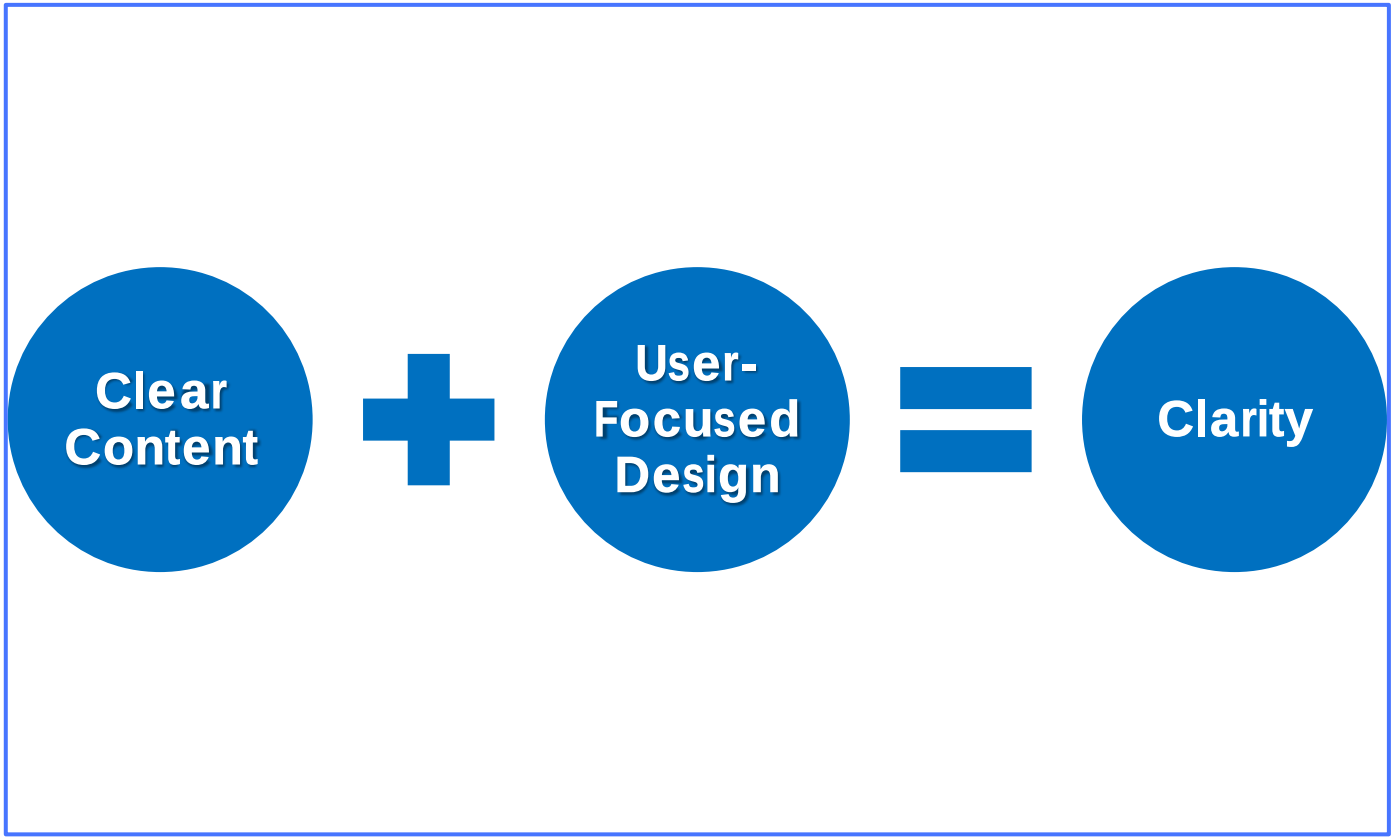
Why would you order the information in this way?

1. Because you just don't understand what is important to patients; or
2. Because you are more worried about complaints over information disclosure than you are about the risks of the treatment; or
3. Because you needed to get this done quickly to comply with FDA regulations and meet company objectives.

Because of these competing interests, the FDA should further guide the way risk information is communicated.

A general formula for clarity



Document design is critical

and so is the way the info is organized within the doc

Prioritizing risk info by creating functional risk hierarchies

What is that? A functional risk hierarchy is simply a guide for prioritizing and ordering the information based on the needs of the document's intended audience.

For patient-focused documents, this means prioritizing what is important to patients first, and then including whatever else you feel needs to be included to protect your org.

Creating a functional risk hierarchy

- Consider your intended users and learn about their needs. (Focus groups? User testing afterwards?)
- Write down the information that your intended users would want to know.
- Rank that information from most important to least important.
- Then write down any other information you must disclose by law (or that your org wants to discuss).
- Add those into the bottom of the list (only move it up if the law requires it, for example).

What do we know about users of health documents?

1. People decide for themselves how much attention to pay to a document
   - We cannot assume people will work their way through a document because we think it is important!
2. These documents are tools that are meant to be used for a purpose.
   - They are not novels meant to be read from cover to cover.

For more, read – Redish, J.C. (1993). Understanding Readers, Chapter 1. In Barnum, C.M and Carliner, S. (Eds.) Techniques for Technical Communicators. New York: Macmillan.

3. People actively interpret as they read – they don't wait until the end and then assess the big picture.
   - So what we put up front matters greatly.
   - And so does the way we draw a user's attention – e.g. text walls won't work.

4. Users interpret documents based on their own knowledge and expectations.
   - User-testing high-stakes documents can help to ensure the document's message is reaching the intended audience.

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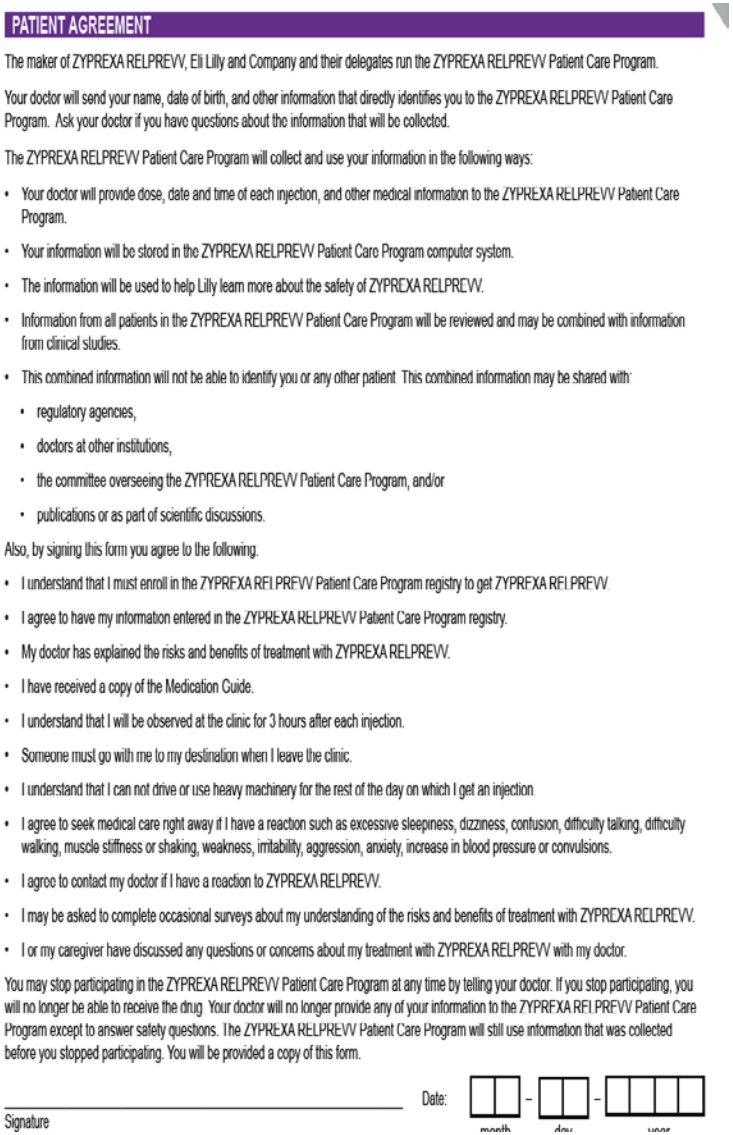
How was the info ordered?

- Operators of the patient care program.
- 1/3 of the page on information disclosure for the program.
- A reminder that the Pt. must enroll in the program to get drug.
- Then risks and benefits acknowledgement.
- Post-injection recovery statements.
- Allergic reaction statements.
- Acknowledgement that Pt. asked all questions.
- Finally, the right to stop taking drug, which terminates info disclosure.



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- I have received a copy of the Medication Guide.
- I understand that I will be observed at the clinic for 3 hours after each injection.
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Signature _____ Date: ☐☐ - ☐☐ - ☐☐☐☐

month day year

A better REMS risk hierarchy

PATIENT AGREEMENT

By signing this form, I acknowledge that:

- I have received, read, and understand *What You Need to Know About LEMTRADA Treatment: A Patient Guide* that my doctor has given to me.
- My doctor has reviewed with me the benefits and risks of treatment with LEMTRADA.
- I am aware that LEMTRADA is associated with serious risks, including autoimmune conditions, infusion reactions, and malignancies, and that these complications can be identified through periodic monitoring and awareness of the initial signs and symptoms.
- I understand the need to have blood and urine tests within 30 days prior to my first LEMTRADA treatment, then each month for 4 years following my last treatment with LEMTRADA.
- I understand the need to have thyroid testing within 30 days prior to my first LEMTRADA treatment, then every 3 months for 4 years following my last treatment with LEMTRADA.
- I understand the need to have yearly skin exams prior to my first LEMTRADA treatment, and continuing for 4 years following my last treatment with LEMTRADA.
- I will tell my doctor if I have any reactions or symptoms after receiving LEMTRADA.
- I understand that I must tell all of my doctors that I have received LEMTRADA.
- I understand that in order to receive LEMTRADA, I am required to enroll in the LEMTRADA REMS Program and my information will be stored in a secure and confidential database of all patients who receive LEMTRADA in the United States. After enrolling, my doctor will provide me with a signed copy of the enrollment form.
- My doctor has counseled and provided me with a LEMTRADA Patient Safety Information Card, which I should carry with me at all times in case of an emergency.
- I understand that I must tell Genzyme if I change my doctor.
- I understand that I must tell Genzyme if my contact information changes.
- I give permission to Genzyme and its agents to use and share my personal health information for the purposes of enrolling me into the LEMTRADA REMS Program, coordinating the dispensing of receiving LEMTRADA, administering the LEMTRADA REMS Program, and releasing my personal health information to the Food and Drug Administration (FDA) as necessary.
- By completing the information below, I understand Genzyme and its agents will contact me via phone, mail, or email to support administration of the LEMTRADA REMS Program.

I prefer to be contacted:

☐ By mail ☐ By phone

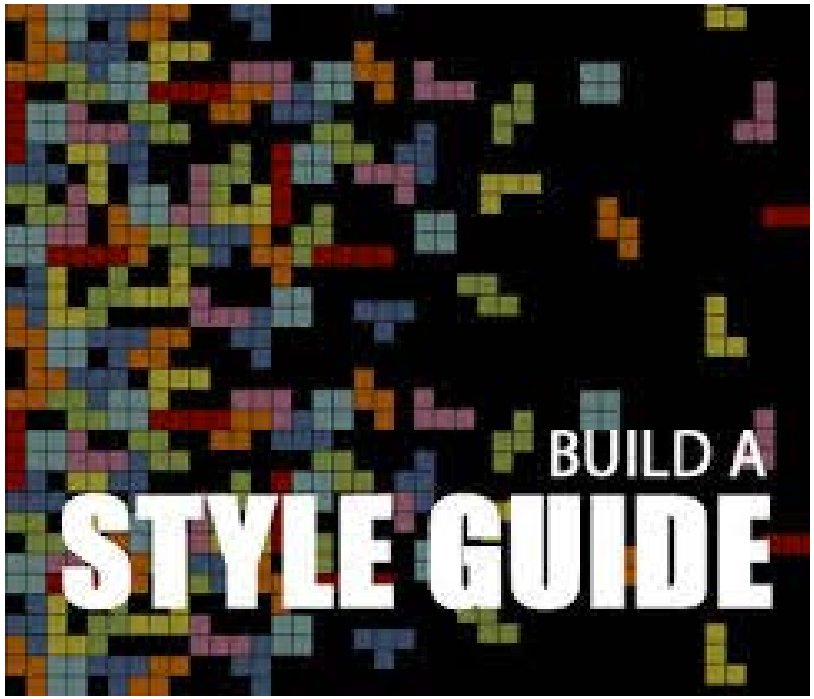
☐ By email (please provide email address)

_____

What can the FDA do to fix this for REMS?

FDA should commission usability studies to create an evidence base to better determine the order that patients prefer to receive risk information.

- This can be doe for providers too – since they receive their own REMS documents
  - We expect that provider preferences differ from patient preferences, but evidence would help further define this.



The FDA can then create a REMS style guide that uses this evidence to suggest the preferred order of information delivery in a particular REMS document.

- This guide can also address other topics like using plain language, doc design principles, using statistics, etc.

Thank you!