Northwestern University Feinberg School of Medicine

A Consumer-Led Process for Improving FDA Medication Guides

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Funded by an unrestricted research grant from Abbott Laboratories

Background – Medication Guides

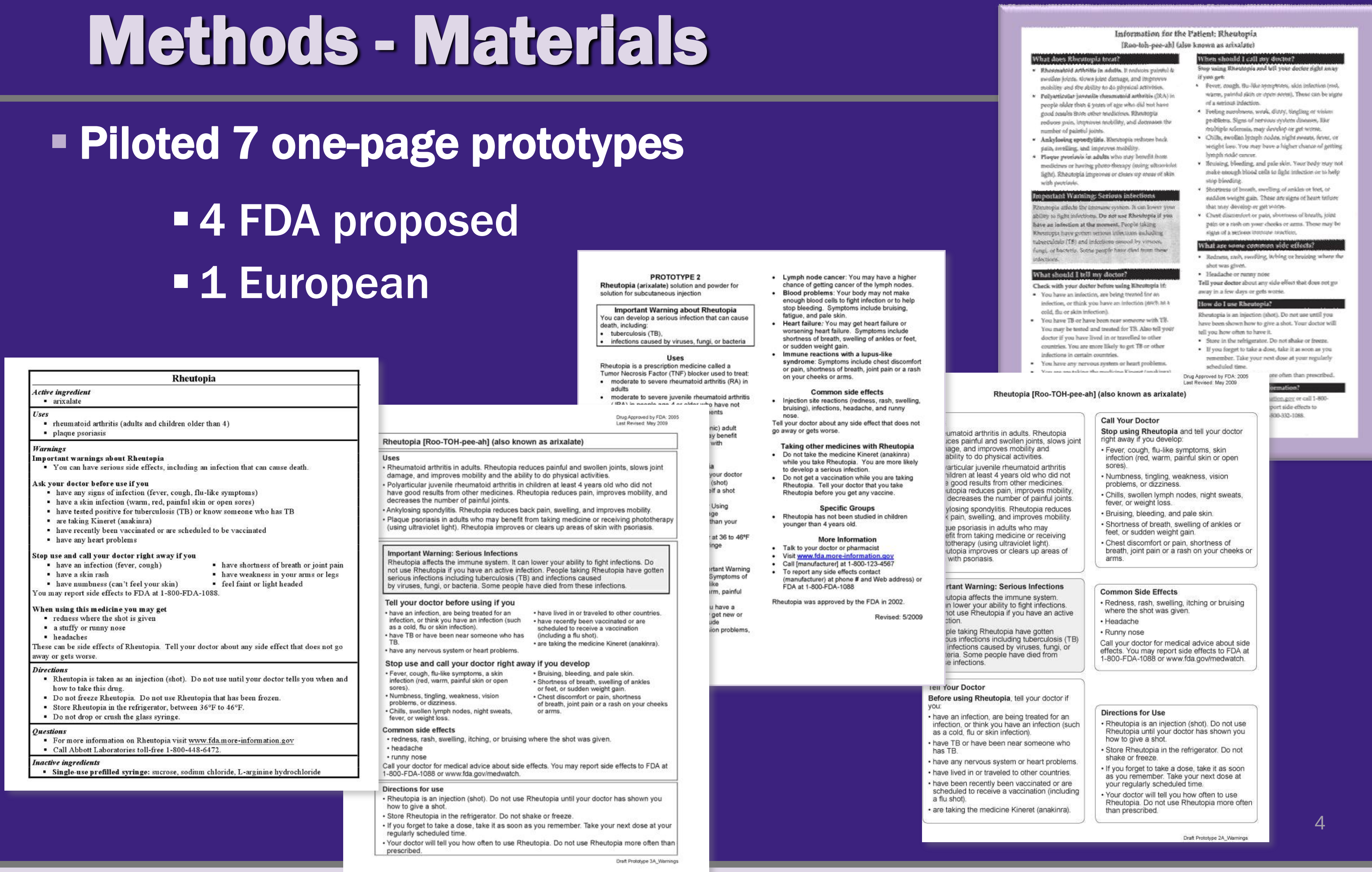
- FDA required; issued to consumers for prescription medications that possess "serious and significant public health concerns"
- Industry-developed; no standard format
- Wolf et al.
  - **2006 study** - Too complex and written at too high a reading grade level
  - **2010 study** - 53% correct in an open book, untimed assessment
- FDA and Brookings Institution actively working to create improved, more readable documents

Objective

Obtain consumer feedback and refinement on proposed, one-page Med Guide prototypes, which will then be incorporated in developing and field-testing an improved, patient-centered Med Guide.

Methods - Materials

- Piloted 7 one-page prototypes
  - 4 FDA proposed
  - 1 European



Methods – Materials, cont.

- 2 Northwestern proposed

SOME IMPORTANT THINGS TO KNOW ABOUT YOUR MEDICATION

Generic name	Arixalate
Brand name	Rheutopia
Purpose	This medicine helps treat rheumatoid arthritis (RA), ankylosing spondylitis (AS), ongoing (chronic) adult plaque psoriasis, and Crohn's Disease.
Benefit	Rheutopia is a tumor necrosis factor (TNF) blocker. Rheutopia helps to prevent the negative side effects of RA, AS, and Crohn's Disease.
How to take	• Take Rheutopia as prescribed by your doctor • Rheutopia is taken as an injection (shot) • Store Rheutopia in the refrigerator, between 36 to 46°F • Do not drop or crush the glass syringe
For how long	Your doctor will tell you how long you should be on this medication. Refill this medicine until your doctor tells you to stop.
Important!	Ask your doctor before use if you: • have any signs of infection (fever, cough, flu-like symptoms) • have a skin infection (warm, red, painful skin or open sores) • have tested positive for tuberculosis (TB) or know someone who has TB • are taking Kineret (anakinra) • have recently been vaccinated or are scheduled to be vaccinated • have any heart problems
Stop taking and call us	Stop taking this medicine and call your doctor right away if you: • have an infection (fever, cough, flu-like symptoms) • have a skin rash • have numbness (can't feel your skin) or tingling skin • have shortness of breath or joint pain • have weakness in your arms or legs • feel faint or light headed
Call us	Call us if these side effects are severe, last longer than one week, or if you feel concerned: • redness where the shot was given • a stuffy or runny nose • headaches
Remember	Talk to your doctor about any questions or concerns you may have regarding this medicine. • Follow up is important to see how well the medicine is working. • Remember the date of your next appointment.

You will get more detailed information from your pharmacy. You may find the following website useful: www.nlm.nih.gov/medlineplus

RHEUTOPIA® (ARIXALATE)

Purpose
This medication helps treat rheumatoid arthritis (RA), ankylosing spondylitis (AS), ongoing (chronic) adult plaque psoriasis, and Crohn's Disease.

Benefit
People with these diseases have too much of a protein called tumor necrosis factor (TNF) in their body. This medicine can block pain and other bad effects of TNF.

Length of Treatment
You may need to be on this medication for the rest of your life.

Instructions
Rheutopia is taken as an injection (shot). Take Rheutopia as prescribed by your doctor and store it in the refrigerator at 36 to 46°F. Do not drop or crush the glass syringe.

Safe Use
To avoid unwanted interactions, it is very important that you tell us:
- About all your medications (especially Kineret), vitamins, herbal products, and supplements.
- If you are allergic to medications or foods.

To use this medicine safely, tell us if you:
- Have any signs of infection, or a problem with your heart.
- Have tested positive or been around someone with tuberculosis (TB).
- Have gone outside the country.
- Have recently been vaccinated or are scheduled to be vaccinated.

Side Effects
Some patients have redness where the shot was given, headaches, or a stuffy or runny nose when using this medicine. Call us if these last longer than one week or get worse (312-695-8630).

Risks and Warnings
All medicines have risks. This medicine affects your immune system and can lower the ability of your immune system to fight infections. Signs of infection include fever, cough, flu-like symptoms skin problems (red, warm, painful skin), or open sores. If any of these happen, stop taking this medicine and call us right away (312-695-8630).

For women of child bearing age: Talk to your doctor before use if you are pregnant, think you are pregnant, or breastfeeding.

Discussion Points
Be sure to review your ability to take the medication, to pay for it, and any concerns or questions.

Follow Up
You should follow up with your doctor to see how Rheutopia is working for you.

This sheet provides brief information to help you and your doctor make a decision about the medication. You will get more detailed information from your pharmacy.

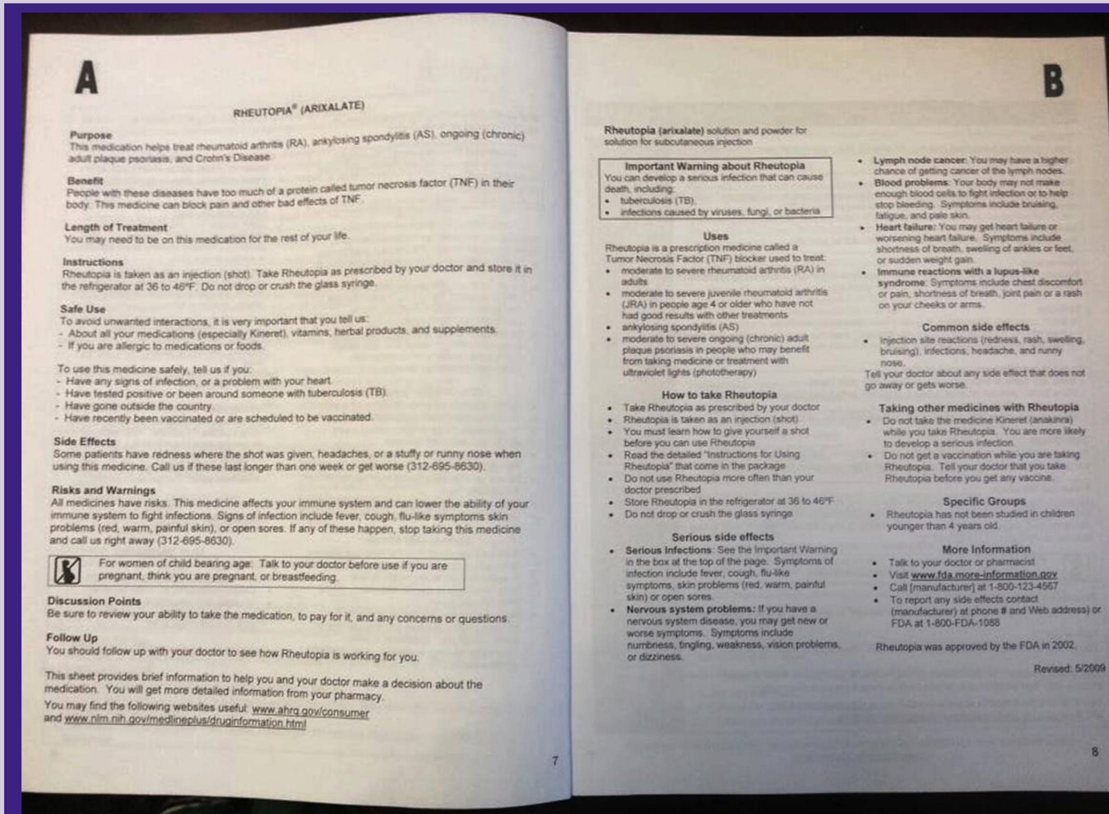
You may find the following websites useful: www.ahrq.gov/consumer
and www.nlm.nih.gov/medlineplus/druginformation.html

Study – Methods

- 6 in-person focus groups; 47 English-speaking adults
- Recruited from 2 primary care clinics and 1 adult basic education center
- **Individual Interview**
  - Demographic and socioeconomic information
  - Prescription use and behaviors
  - Health literacy assessment - Newest Vital Sign (NVS)

Study – Methods

- **Group Discussion**
  - Brief overview
  - Pairwise comparison
  - Group discussion



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- If you are allergic to medications or foods.

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Rheutopia (arixalate) solution and powder for solution for subcutaneous injection

Important Warning about Rheutopia
You can develop a serious infection that can cause death, including:
- tuberculosis (TB).
- infections caused by viruses, fungi, or bacteria

Uses
Rheutopia is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker used to treat:
- moderate to severe rheumatoid arthritis (RA) in adults
- moderate to severe juvenile rheumatoid arthritis (JRA) in people age 4 or older who have not had good results with other treatments
- ankylosing spondylitis (AS)
- moderate to severe ongoing (chronic) adult plaque psoriasis in people who may benefit from taking medicine or treatment with ultraviolet lights (phototherapy)

How to take Rheutopia
- Take Rheutopia as prescribed by your doctor
- Rheutopia is taken as an injection (shot)
- You must learn how to give yourself a shot before you can use Rheutopia
- Read the detailed "Instructions for Using Rheutopia" that come in the package
- Do not use Rheutopia more often than your doctor prescribed
- Store Rheutopia in the refrigerator at 36 to 46°F
- Do not drop or crush the glass syringe

Serious side effects
- **Serious Infections**: See the Important Warning in the box at the top of the page. Symptoms of infection include fever, cough, flu-like symptoms, skin problems (red, warm, painful skin) or open sores.
- **Nervous system problems:** If you have a nervous system disease, you may get new or worse symptoms. Symptoms include numbness, tingling, weakness, vision problems, or dizziness.
- **Lymph node cancer**: You may have a higher chance of getting cancer of the lymph nodes.
- **Blood problems**: Your body may not make enough blood cells to fight infection or to help stop bleeding. Symptoms include bruising, fatigue, and pale skin.
- **Heart failure**: You may get heart failure or worsening heart failure. Symptoms include shortness of breath, swelling of ankles or feet, or sudden weight gain.
- **Immune reactions with a lupus-like syndrome**: Symptoms include chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common side effects
- Injection site reactions (redness, rash, swelling, bruising), infections, headache, and runny nose.

Tell your doctor about any side effect that does not go away or gets worse.

Taking other medicines with Rheutopia
- Do not take the medicine Kineret (anakinra) while you take Rheutopia. You are more likely to develop a serious infection.
- Do not get a vaccination while you are taking Rheutopia. Tell your doctor that you take Rheutopia before you get any vaccine.

Specific Groups
- Rheutopia has not been studied in children younger than 4 years old.

More Information
- Talk to your doctor or pharmacist
- Visit www.fda.more-information.gov
- Call [manufacturer] at 1-800-123-4567
- To report any side effects contact (manufacturer) at phone # and Web address) or FDA at 1-800-FDA-1088

Rheutopia was approved by the FDA in 2002.

Revised: 5/2009

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Results – Sample Characteristics (N=47)

- Age - 54% between 18-45 years old
- Female - 60%
- 69% NH-Black, 69% ≤ High School, and 64% ≤ $20,000

Health Literacy, %			Read Info	New Rx, %	Refill, %
Limited	49		Always/often	58	33
Marginal	24		Sometimes	18	24
Adequate	27		Rarely/never	24	42

Results – Pairwise Comparison

Winners:

Rheutopia
Active ingredient ▪ arixalate
Uses ▪ rheumatoid arthritis (adults and children older than 4) ▪ plaque psoriasis
Warnings **Important warnings about Rheutopia** ▪ You can have serious side effects, including an infection that can cause death.   **Ask your doctor before use if you** ▪ have any signs of infection (fever, cough, flu-like symptoms) ▪ have a skin infection (warm, red, painful skin or open sores) ▪ have tested positive for tuberculosis (TB) or know someone who has TB ▪ are taking Kineret (anakinra) ▪ have recently been vaccinated or are scheduled to be vaccinated ▪ have any heart problems   **Stop use and call your doctor right away if you** ▪ have an infection (fever, cough) ▪ have a skin rash ▪ have numbness (can't feel your skin) ▪ have shortness of breath or joint pain ▪ have weakness in your arms or legs ▪ feel faint or light headed You may report side effects to FDA at 1-800-FDA-1088.   **When using this medicine you may get** ▪ redness where the shot is given ▪ a stuffy or runny nose ▪ headaches These can be side effects of Rheutopia. Tell your doctor about any side effect that does not go away or gets worse.
Directions ▪ Rheutopia is taken as an injection (shot). Do not use until your doctor tells you when and how to take this drug. ▪ Do not freeze Rheutopia. Do not use Rheutopia that has been frozen. ▪ Store Rheutopia in the refrigerator, between 36°F to 46°F. ▪ Do not drop or crush the glass syringe.
Questions ▪ For more information on Rheutopia visit www.fda.more-information.gov ▪ Call Abbott Laboratories toll-free 1-800-448-6472.
Inactive ingredients ▪ **Single-use prefilled syringe:** sucrose, sodium chloride, L-arginine hydrochloride

Chosen 54.5% (138/235)

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Chosen 54.0% (127/235)

Results - Formatting

- **Break up text, white space**
  - “It’s too hectic; the words are too back-to-back.”
  - “It looks like a textbook, or a homework assignment I’d throw in my bag and never take out again.”
- **Headings**
  - “I can find the information based on the heading. It helps me to decide what information I want to read.”
- **Bolding, bullets, and boxes**
  - “I like that the warning is shaded because side effects are important to me and the box means that is important information.”

Results – Sequence and More Information

- **Sequence of topic areas**
  - "I want the directions at the top – I won't have adverse reactions to the medicine if I take it correctly."
  - "The information in the box seems a little bit more important, but everything is important on here."
- **Icons**
  - "I like the symbol of a pregnant woman because it makes me read the information very closely."
- **More Information**
  - "If I can't read this paper or don't understand something, I want a phone number up at the top, real big, for me to call and talk to someone."

Limitations

- Small sample size (N=47)
- Hypothetical situation
- Pharmacy limitations of color

Conclusion and Next Steps

- Patient-centered approach can confirm viable improvements to current Med Guide formats and support the need for a standardized template
- Found very popular to have a one page, ‘top hits’, document
- Merge findings with evidence-based guidelines for content
- Next steps to finalize optimal final format(s), confirm via clinical trial
- Recognize there may be multiple ‘winners’ in the end

Questions?

<u>Contact Information</u>

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