

A Clinician's Perspective on OTC Cough and Cold Products

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Case Study

- A concerned mother calls me regarding her 18 month old who has been coughing for almost a week.
- Over the past 3 days, Molly has developed worsening cough. She is fussing and has not been sleeping well.
- Molly's mother has seen an advertisement for a cold medication in a parenting magazine.



No one worries about her cold like you do.
 No one takes the worry out of how to treat it,
 like Little Remedies®.

No alcohol · No artificial flavors or dyes · No saccharin · No gluten · No aspirin · No harmful preservatives



What medicine to give them? Will it be safe and gentle? Little Remedies relieves Moms of these worries with a line of cough and cold products made just for babies. With everything babies need to make them feel better. And nothing they don't. Because like all Little Remedies products, they were created by a pharmacist for his own children. So you know you're treating your baby right. Ask your pediatrician about Little Remedies.

Little Remedies
 Products



We make it all better.

www.littleremedies.com

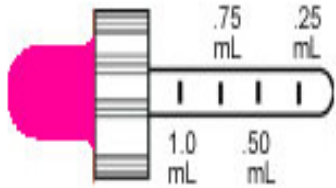
- She tells me that she bought the medication she saw in the ad, and used it for three days before calling.
- The box states that this medicine is “Pediatrician Recommended”
- Now she is calling to check if she is using the right dose of medication
- At my office, the child is found to have asthma



What Do I Recommend?

Dosage:

See Little Dose Chart: The Little Dose trademark means this product has been specially formulated to provide small concentrated doses for easier administration. For accurate dosing, only use the enclosed dropper and follow all dosing instructions.



Age (yr)	Dose
Under 2	Consult Physician
2 to under 6	1 Dropperful (1 ml)

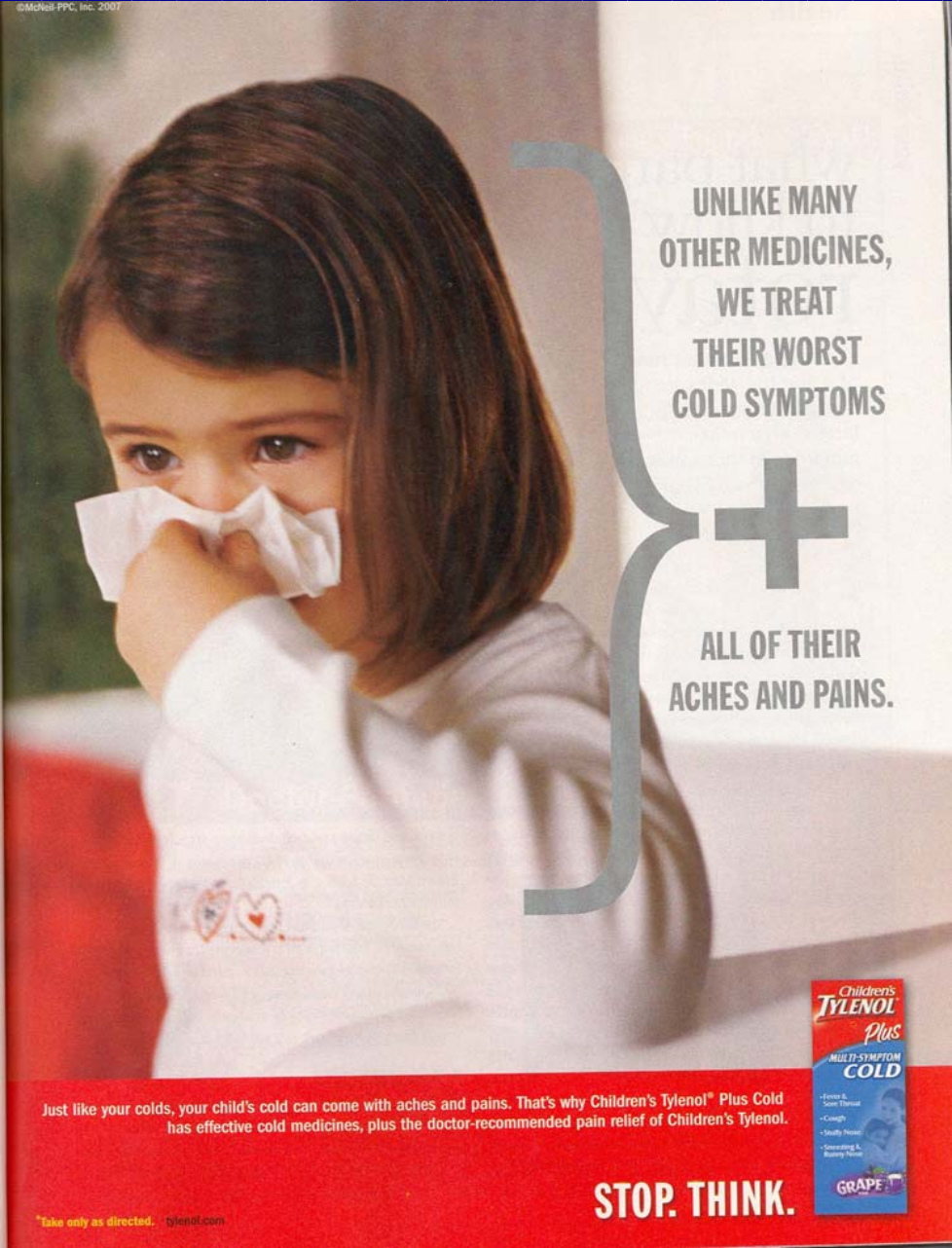
All doses should be taken by mouth only and may be repeated every 4 hours. Not to exceed 6 doses in a 24 hour period.

● “Consult physician” labeling creates an expectation that physicians have access to evidence-based dosing information

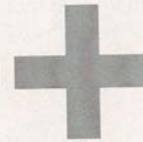
● No such evidence exists

Case Study #2

- A mother has brought her three year old to my office for fever and cough of a week's duration. She has treated the symptoms with cough medicine on her own for four days.
- Exam discloses a very ill-appearing child with findings suggestive of bacterial pneumonia.
- Laboratory and x-ray findings confirm the diagnosis. The child is admitted to the hospital



UNLIKE MANY
OTHER MEDICINES,
WE TREAT
THEIR WORST
COLD SYMPTOMS



ALL OF THEIR
ACHES AND PAINS.

Just like your colds, your child's cold can come with aches and pains. That's why Children's Tylenol® Plus Cold has effective cold medicines, plus the doctor-recommended pain relief of Children's Tylenol.



*Take only as directed. tylenol.com

STOP. THINK.

What do I recommend?

- Doses are extrapolated from adult studies without justification
- No evidence that cough and cold medicines are more effective than placebo in children.
- Parents may give OTC medications at home when the condition may be more serious, such as pneumonia or asthma

FDA Action Needed

- To make clear to the public that the use of OTC cough and cold medications for children under age 6 is not supported by evidence
- To reduce conflict between state of marketing and the state of the science
- To protect children from harm
- To avoid delayed care that can have serious consequences