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Unexpected Infant Deaths Associated With the Use of Cough and Cold Medications

To the Editor.—

Thank you for publishing the article “Unexpected Infant Deaths Associated With Use of Cough and Cold Medications” by Rimsza and Newberry.¹ There is growing evidence that the number of deaths and other adverse events associated with cough and cold medications in children are vastly underrecognized, and this research adds to the evidence. When a child comes into a doctor’s office or emergency department with upper respiratory infection symptoms, tachycardia, nausea, vomiting, and fussiness, maybe we should start placing “over-the-counter cough and cold medication overdose” near the top of our differential.

As a dad and a doctor, I find this a very scary topic. If you extrapolate the 10 infant deaths associated with cough and cold medications from Arizona’s population of 6 million, to the combined US and Canadian population of 337 million, the estimated deaths associated with cough and cold medications are >500 per year!

In October of 2007, members of the children’s cough and cold drug industry promised the US Food and Drug Administration (FDA) and the nation that they would place on their dosing instructions “do not use” for children younger than 2 years of age. Last night I was at a national grocery/pharmacy, and of all the children’s cold and cough medications that were on the shelf (and there were several), only 1 brand had “do not use” for children younger than 2 years of age printed on the label; the rest have not adopted wording this yet.

In October 2007 the FDA reviewed safety and effectiveness data on these medications, and a majority of its expert panel voted that on the basis of the current data, cough and cold medications should “not be used now in children under the age of 2,” and they should “not be used for the common cold right now for children between the ages of 2 and less than 6.” (www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4323m1-Final.pdf [see page 6]).

It is time that we stood up to the drug companies and tell our elected officials and the FDA that these medications need to be pulled from the shelves. This needs to come from the top down; the drug companies have already proven that they will not keep their promises. When a medication has been shown to be dangerous and has never demonstrated good evidence of efficacy, then we should not be giving it to children.

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REFERENCE

1. Rimsza ME, Newberry S. Unexpected infant deaths associated with use of cough and cold medications. *Pediatrics*. 2008;122(2). Available at: www.pediatrics.org/cgi/content/full/122/2/e318

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In Reply.—

We share Dr Chamberlain’s concern that further efforts are needed to educate parents on the potential dangers associated with the use of cough and cold medications for infants and young children. As noted in our article, parents may not seek medical advice before using these drugs and, thus, are likely to rely on the information included on the product. Thus, it is critical that these products have appropriate warnings. As a result of our study, we have suggested that our state Medicaid program initiate a public education campaign regarding the risks associated with use of over-the-counter cough and cold medicines because poor, publicly insured families may be more likely to give these products to their infants. We have also recommended that this information be provided in both English and Spanish, because non-English-speaking families may be more likely to use these products.

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Effects of the Accreditation Council for Graduate Medical Education Duty-Hour Limits on Sleep, Work Hours, and Safety

To the Editor.—

After introduction of the Accreditation Council for Graduate Medical Education resident duty-hour restrictions in 2003, many voiced concerns about an increased number of handoffs, during which patient care responsibility is transferred from 1 resident who is leaving the hospital to another resident who will be staying and covering other residents’ patients.^{1,2} In a survey of accredited US internal medicine residency programs, handoffs did, in fact, increase significantly after duty-hour restrictions, and a member of the primary health care team was present in the hospital for less than half of a patient’s hospitalization.³ This highlights the importance of addressing handoffs in conjunction with restricted duty hours.

In a recent *Pediatrics* article by Landrigan et al,⁴ there was no significant change found in the total hours of work or sleep before and after duty-hour restrictions were implemented. Although there was no change in overall medication error rates, there was a significant increase in errors that the authors classified as having little potential for harm and a trend toward an increase in physician ordering errors. As the authors suggested, this may have been a result of the increased handoffs without a corresponding increase in handoff education and improvement.

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