Judgment and Decision Making, Vol. 5, No. 6, October 2010, pp. 428–436

To give or not to give: Parental experience and adherence to the Food and Drug Administration warning about over-the-counter cough and cold medicine usage

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Abstract

The Food and Drug Administration (FDA) warned against administering over-the-counter cough and cold medicines to children under 2. This study evaluated whether experienced parents show poorer adherence to the FDA warning, as safe experiences are predicted to reduce the impact of warnings, and how adherence can be improved. Participants included 218 American parents (mean age: 29.98 (SD = 6.16), 82.9% female) with children age $\leq$ 2 who were aware of the FDA warning. We compared adherence among experienced (N=142; with other children > age 2) and inexperienced parents (N=76; only children $\leq$2). We also evaluated potential moderating variables (amount of warning-related information received, prevalence of side effects, trust in the FDA, frequency of coughs and colds, trust in drug packaging) and quantified the impact of amount of information. Logistic regression assessed the ability of experience alone, and experience combined with amount of information, to predict adherence. 53.3% of inexperienced but 28.4% of experienced parents were adherent (p = 0.0003). The groups did not differ on potential moderating variables. Adherence was 39.5% among experienced parents receiving "a lot of information", but 15.4% for those receiving less (p = 0.002); amount of information did not affect adherence in inexperienced parents (p = 0.22) but uniquely predicted adherence compared to a model with experience alone (p = 0.0005). Experienced parents were also less likely to mistrust drug packaging (p = 0.03). Targeting FDA information to experienced parents, particularly via drug packaging, may improve their adherence.

Keywords: OTC-CCM, adherence, experience, parent, decision-making, risk assessment, FDA warning, compliance, young children.

1 Introduction

In October 2007, following an expert review regarding the safety of over-the-counter cough and cold medication (OTC-CCM), the Food and Drug Administration (FDA) recommended that "these drugs not be used to treat infants and children under 2 years of age because serious and potentially life-threatening side effects can occur." (United States Food and Drug Administration [FDA], 2008). Since earlier studies have shown that people ascribe little risk or harm to OTC medications (Glasziou, 2002; Roumie & Griffin, 2004), it is important to evaluate adherence to the FDA warning. Indeed, despite wide publicity, a recent nationally representative survey found that only 16% of parents with children under 2 (or 19% of parents who were aware of the FDA warning) intended to comply with the FDA warning (National Public Radio/Kaiser Family Foundation/Harvard School of Public Health [NPR/KFF/HSPH], 2007).

The decision-making literature suggests people are ill-equipped to incorporate information about rare side effects into their decisions (Barron & Erev, 2003; Erev & Barron, 2005; Fox & Hadar, 2006; Hertwig, Barron, Weber, & Erev, 2004; Kahneman & Tversky, 1979; Li, Rakow, & Newell, 2009). When information about a rare event comes externally from a description, as from a warning, people tend to overweigh the rare event in their decisions (Barron & Erev, 2003; Li, Rakow, & Newell,

*We would like to thank the Center for Health and Wellbeing, Princeton University, for providing financial support, the members of the health psychology group at University of Plymouth for comments on an earlier version of the survey, and Eric Brass, Max Bazerman and Michael Norton for comments on an earlier version of the manuscript. The work described in this paper was done when Talya Miron-Shatz was at the Center for Health and Wellbeing, Princeton University and Greg Barron was at the Harvard Business School, Harvard University. Address: Talya Miron-Shatz, Ono Academic College, 104 Zahal St. Kiryat Ono, Israel; telephone: +972 2 56 333 04; fax: +1 609 258 5974. Email: talyam@wharton.upenn.edu.

2009). In other words, people behave as if the rare event is more likely to occur than its objective probability. Conversely, when people learn from their own experiences, they tend to underweigh rare events, behaving as if the event is less likely to occur than its objective probability (Barron & Erev, 2003; Erev & Barron, 2005; Fox & Hadar, 2006; Hertwig et al., 2004; Li et al., 2009).[1]

The two tendencies imply that different decisions can result from the same information, depending upon how one learns about the potential consequences of the choices and their probabilities. A recent literature has focused on the mechanisms underlying this apparent "gap" between description- and experience-based decisions and their relative importance (Barron & Yechiam, 2009; Camilleri & Newell, 2009; Fox & Hadar, 2006; Fox & Hadar, 2009; Hertwig et al., 2004). The mechanisms include 1) recency — when rare events happen in the distant past and memory is constrained, decisions will rely on a small set of past outcomes, 2) statistical sample bias — as rare events are underrepresented more often than overrepresented (due to the skewness of the binomial distribution), and 3) judgment bias — as people incorrectly estimate an event's likelihood even in an unbiased sample.

In practice, people gain information from *both* external descriptions and personal experience. In deciding whether to adhere to a given warning, people who have previously used the risk-causing agent are subject to potentially conflicting influences from the warning and past experience. Others, possessing little or no experience with the risk-causing agent, are presumably more reliant upon the warning. Research has shown that inertia tends to guide the risk-taking behavior of people who have had safe experiences with the risk-causing agent, such that they continue their exposure to the agent despite new information about associated dangers (Barron, Leider, & Stack, 2008). The FDA warning created an opportunity to examine this behavior as applied to a risk-causing agent that affects millions of parents and children, with clear implications for health policy. By measuring adherence in parents with older children, who presumably have more experience with colds and use of OTC-CCM in children under 2, and those without older children, we were able to test the following hypothesis: behavioral inertia due to safe experience with OTC-CCM would reduce adherence to the FDA warning.

Even if a warning with the appropriate content reaches and is understood by its target audience, recipients may still not know what to believe if communicators are perceived to have a vested interest (Morgan, Fischhoff, Bostrom, & Atman, 2002). In the United Kingdom, for example, parents' decisions not to vaccinate against measles, mumps, and rubella (MMR) — despite assurances and campaigns by the UK government — stemmed largely from lack of trust in messages about the safety of these vaccines (Cassidy, 2006; Cassidy, Cresswell, Wilson, & Panter-Brick, 2006; Hobson-West, 2007). Thus, in order to isolate the effect of experience on adherence, we also measured parents' stated trust in the FDA as a source of information.

We conducted a survey to explore the hypothesis that experienced parents would exhibit poorer adherence, as well as to examine other factors potentially affecting adherence: amount of relevant information received, prevalence of side effects, trust in the FDA, and frequency of child's coughs and colds. To our knowledge, this is the first study to evaluate the effect of parental experience on adherence to the FDA warning. On the basis of our findings, we propose a tentative strategy for increasing adherence.

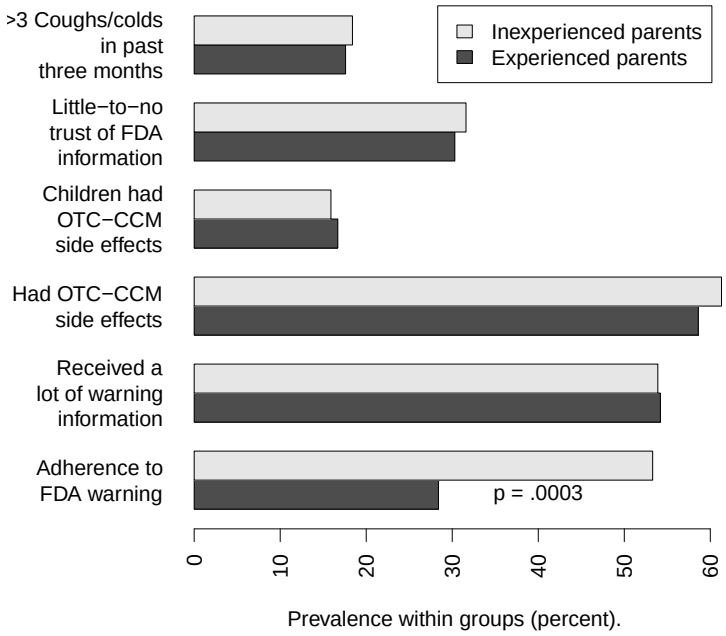
2 Methods

Participants (N=218) were parents (mean age [SD]: 29.98 [6.16] years) of children age 2 and younger who indicated in an online survey that they had heard of the FDA warning against using OTC-CCM in young children; parents who reported not having heard of the FDA warning (N=32) were excluded from analysis. Most participants were female (82.9%), and most had completed college (63.1%). Participants were recruited online between January and April 2008 via paid advertisements on Google and Facebook and completed an online survey regarding their use and perception of OTC-CCM. All participants were from the United States, and representation by region (Northeast: 24.4%; Midwest: 27.2%; South: 30.4%; West: 18.0%) was similar to that as measured by the 2000 US census (United States Census Bureau, 2001). Upon completion of the survey, participants were entered into a raffle to win one $50 gift certificate for a major Internet retailer.

The primary study outcome was *adherence* to the FDA warning, as measured by participants' reported intention to stop administering OTC-CCM (Table 1). To quantify the effect of parenting experience upon adherence, participants were divided into two groups: *experienced* parents

[1]Given the widespread use of OTC-CCM, serious adverse events from them are relatively rare: while an estimated 95 million packages are sold each year (Brown, 2008), approximately 1,500–1,600 children under 2 were admitted to emergency rooms for OTC-CCM-related issues between 2004 and 2005 (Centers for Disease Control and Prevention [CDC], 2007; Schaefer, Shehab, Cohen, & Budnitz, 2008). In 2007, the FDA completed a review indicating that between 1969 and the fall of 2006 there were a total of 54 reported child deaths from decongestants and 69 from antihistamines, most involving children under 2 (Akhavan-Toyserkani, Chang, & Ahmad, 2007). Based on these safety data and the paucity of studies demonstrating efficacy in children under 2, the FDA advisory committee recommended OTC-CCM not be used in children under 2 (FDA, 2008).

Figure 1: Prevalence of adherence to the FDA warning against use of OTC-CCM in young children, separately for experienced (older children in addition to a child age 2 or younger) and inexperienced (only a child age 2 or younger) parents. Inexperienced parents were significantly more likely to adhere. However, the groups were similar in reported amount of warning information received, prevalence of side-effects in the parents and their children, trust of FDA information, and number of coughs or colds in the preceding three months. Differences are non-significant unless indicated.



(*N*=142; mean age [SD]: 31.09 [5.64] years; 88.6% female; 60.7% completed college), who reported having older children (in addition to a child or children aged 2 or younger); and *inexperienced* parents (*N*=76; mean age [SD]: 27.93 [6.59] years; 72.4% female; 67.6% completed college), who reported having only a child aged 2 or younger (Table 1). Experienced parents were older ($p<0.001$) but similar to inexperienced parents in educational level ($p=0.12$). Other variables of interest included subjective amount of information received about the FDA warning, prevalence of OTC-CCM-related side effects experienced by participants and their children, level of trust in the FDA and drug packages to provide accurate information on the safety and effectiveness of OTC-CCM, and occurrence of coughs or colds in the previous three months (Table 1). These variables were recoded as dichotomous (Table 1) for consistency with study hypotheses and in consideration of the small sample size for several response options (Table 2), as well as to simplify interpretation of their correspondence with the binary adherence and experience variables. Frequency of response for each original response option is shown in Table 2, separately for experienced and inexperienced parents.

The χ^2 statistic was used to compare adherence between experienced and inexperienced parents and to contrast the groups on other potential moderating variables. The χ^2 statistic was also computed to evaluate the effect of amount of information received upon each experience group. Logistic regression analysis was used to evaluate the ability of parental experience alone and combined with each potential moderating variable to predict adherence; an interaction term was included to control for moderating effects on experience. The χ^2 statistic was used to assess the unique contribution of information received.

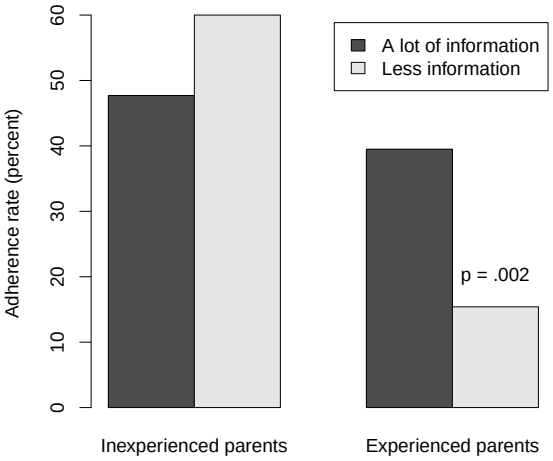
3 Results

More than half (53.3%) of inexperienced parents adhered to the FDA warning, compared with just over a quarter (28.4%) of experienced parents ($\chi^2(1) = 13.08$, $p = 0.0003$; Figure 1). Parenting experience was a significant predictor of adherence ($B = 1.06$, $Wald(1) = 12.70$,

p = 0.0004), such that inexperienced parents were 2.89 times more likely to be adherent. The effect of experience could not be attributed to the experienced group receiving less information, as similar proportions of both groups reported receiving "a lot of information" (experienced: 54.2%; inexperienced: 53.9%; $\chi^2(1)$ = 0.002, p = 0.97; Figure 1), and experience remained a significant predictor even when amount of information received and its interaction with experience were included in the model (B = 1.53, *Wald*(1) = 10.07, p = 0.002). Similarly, the effect could not be attributed to a higher prevalence of OTC-CCM-related side effects encountered by inexperienced parents (experienced: 58.6%; inexperienced: 61.3%; $\chi^2(1)$ = 0.155, p = 0.69) or their children (experienced: 16.7%; inexperienced: 15.9%; $\chi^2(1)$ = 0.018, p = 0.89; Figure 1) as experience continued to predict adherence even after inclusion of each potential moderator and its interaction with experience in the model (parents: B = 1.00, *Wald*(1) = 4.01, p = 0.045; children: B = 1.10, *Wald*(1) = 10.56, p = 0.001). The experience effect could not be accounted for by greater mistrust in the FDA in the experienced group, as the proportion of parents expressing little to no trust in FDA information was comparable among the groups (experienced: 30.3%; inexperienced: 31.6%; $\chi^2(1)$ = 0.039, p = 0.84; Figure 1), and experience again remained a significant predictor even after trust of FDA and its interaction with experience were included in the model (B = 1.61, *Wald*(1) = 8.08, p = 0.004). Finally, poorer adherence in the experienced group did not appear to be explained by more coughs or colds, as the frequency of parents reporting "more than several" coughs or colds in the months prior to the survey was similar between the groups (experienced: 17.6%; inexperienced: 18.4%; $\chi^2(1)$ = 0.022, p = 0.88; Figure 1). Experience was no longer a significant predictor of adherence after inclusion of this potential moderator and its interaction with experience in the logistic regression model (B = 0.52, *Wald*(1) = 0.28, p = 0.59), but it remained significant after inclusion as a covariate in a parametric analysis without an interaction term (F(1,177)=13.65, p=0.0003; see below).

Parametric analyses run on the original variables (i.e., using all the response options shown in Table 1, prior to recoding) were highly consistent with the above, yielding an experience effect on adherence (F(1,178)=13.15, p=0.0004) and no differences among the experience groups on potential moderators (information: F(1,216)=0.30, p=0.58; side effects in parents: F(1,213)=0.47, p=0.50; side effects in children: F(1,205)=0.03, p=0.86; trust of FDA: F(1,216)=1.01, p=0.32; coughs and colds: F(1,216)=0.59, p=0.44). Moreover, the significant experience effect was preserved (p<0.003) even after covarying for each of the potential moderators. None of the potential moderating variables was significantly correlated with both adherence and experience. Results were comparable irrespective of whether the "I am not sure what I will do" adherence response was included.

Figure 2: Adherence rate among parents who reported receiving a lot of information about the FDA warning as compared with those who reported receiving less information, separately for experienced and inexperienced parents. Receipt of more information significantly improved adherence rate in experienced parents, but not in inexperienced parents. Differences are non-significant unless indicated.



To explore whether adherence by experienced parents might be improved through increased awareness of the FDA warning, the effect on adherence of amount of information received was examined in each group. Indeed the adherence rate (39.5%) in experienced parents who reported receiving "a lot of information" was more than twice the rate (15.4%) in those who reported receiving less information ($\chi^2(1)$ = 10.01, p = 0.002; Figure 2). By comparison, amount of information did not affect adherence rate in the inexperienced group (a lot: 45.7%; less: 60.0%; $\chi^2(1)$ = 1.53, p = 0.22; Figure 2).[2] Moreover, in a logistic regression model including an interaction term, both amount of information (B = 1.28, *Wald*(1) = 9.41, p = 0.002) and experience (B = 1.53, *Wald*(1) = 10.07, p = 0.002) predicted adherence, such that parents who reported receiving "a lot of information" were 3.59 times more likely to be adherent than their counterparts who received less information, and inexperienced parents were 4.63 times more likely to adhere than experienced par-

[2]Parametric analyses of the original variables (i.e., prior to recoding) yielded similar results (experienced parents: F[2,113]=3.03, p=0.05; inexperienced parents: F[2,61]=0.46, p=0.63).

Table 1: Study variables, associated survey questions and responses, and coding scheme for statistical analysis.

Variable(s)	Survey question	Survey responses	Coding
Adherence	In view of the FDA recommendation, what do you intend to do when your child has a cough or cold in the future?	a) I intend to keep giving my children the cough and cold medicine we have at home and buy more when we run out. b) I intend to keep giving my children the cough and cold medicine we have at home, but to reconsider using them when we run out. c) I intend to keep giving my children the cough and cold medicine we have at home, but I will not buy more when we run out. d) I intend to stop giving my children cough and cold medicine e) I am not sure what I will do	adherent: response d) non-adherent: all other responses
Experience	Please list the ages of ALL of your children. (Leave the extra boxes blank if you have fewer than 8 children; if you have more than 8 children, please list the ages of the 8 YOUNGEST.)	age of: YOUNGEST child: __ 2^{nd} youngest child: __ 3^{rd} youngest child: __ ... 8^{th} youngest child: __	experienced: older children in addition to the one child ≤ 2 inexperienced: only one child ≤ 2
Amount of information received about FDA warning	Have you heard that a panel of expert advisers for the FDA reported that most over-the-counter cough and cold medicines do not work for children under 6, and may also be dangerous if taken in quantities that are too large, as a result of which their use cannot be recommended?	a) I have not heard about this report at all* b) I have not heard much about this report c) I have heard something about this report d) I have heard a lot about this report	a lot: response d) not a lot: responses b) and c)
Prevalence of Side Effects in Participants	How often have YOU experienced side effects after taking an over-the-counter cough and cold medicine?	a) never b) rarely c) sometimes d) often e) always	yes: responses b) through e) no: response a)
Prevalence of side effects in children	Think of the over-the-counter cough and cold medicines that you gave your child when he/she had a cough or a cold during the past three months. How often has your child experienced side effects after taking any of these medications?	a) never b) rarely c) sometimes d) often e) always	yes: responses b) through e) no: response a)
Trust of FDA; Trust of medicine packages	How much do you trust each of the following sources to provide you with accurate information about the safety and effectiveness of over-the-counter medicines for your children: the Food and Drug Administration (FDA), the information included in the over-the-counter medicine packages?	a) not at all b) a little c) somewhat d) a lot	little-to-none: responses a) and b) somewhat-to-a-lot: responses c) and d)
Number of coughs or colds in previous three months	Think of the last three months. Can you tell us how many times your child had a cough or a cold during this period?	a) 0 times b) 1–3 times c) 4–6 times d) 6–10 times e) more than 10 times	0–3 times: responses a) and b) >3 times: responses c) through e)

* Respondents who had not heard about the FDA report at all were excluded from this study.

Table 2: Frequency of responses to study variables for experienced (N=142) and inexperienced (N=76) parents.

Variable	Survey responses	% Participants (n) Experienced	Inexperienced
Adherence	I intend to keep giving my children the cough and cold medicine we have at home and buy more when we run out	39.4 (56)	19.7 (15)
	I intend to keep giving my children the cough and cold medicine we have at home, but to reconsider using them when we run out	11.3 (16)	11.8 (9)
	I intend to keep giving my children the cough and cold medicine we have at home, but I will not buy more when we run out	2.8 (4)	1.3 (1)
	I intend to stop giving my children cough and cold medicine	28.2 (40)	51.3 (39)
	I am not sure what I will do	17.6 (25)	14.5 (11)
	(no response)	0.7 (1)	1.3 (1)
Amount of information received about FDA warning	I have not heard about this report at all[1]	-	-
	I have not heard much about this report*	9.2 (13)	3.9 (3)
	I have heard something about this report	36.6 (52)	42.1 (32)
	I have heard a lot about this report	54.2 (77)	53.9 (41)
Prevalence of side effects in participants	never	40.8 (58)	38.2 (29)
	rarely	33.1 (47)	35.5 (27)
	sometimes	21.1 (30)	15.8 (12)
	often	3.5 (5)	9.2 (7)
	always	0 (0)	0 (0)
	(no response)	1.4 (2)	1.3 (1)
Prevalence of side effects in children	never	81.0 (115)	76.3 (58)
	rarely	11.3 (16)	9.2 (7)
	sometimes	4.9 (7)	3.9 (3)
	often	0 (0)	1.3 (1)
	always	0 (0)	0 (0)
	(no response)	2.8 (4)	9.2 (7)
Trust of FDA	not at all	8.5 (12)	6.6 (5)
	a little	21.8 (31)	25.0 (19)
	somewhat	50.0 (71)	36.8 (28)
	a lot	19.7 (28)	31.6 (24)
Trust of medicine packages	not at all	7.7 (11)	18.4 (14)
	a little	32.4 (46)	36.8 (28)
	somewhat	46.5 (66)	39.5 (30)
	a lot	13.4 (19)	5.3 (4)
Number of coughs or colds in previous three months	0 times	4.9 (7)	7.9 (6)
	1–3 times	77.5 (110)	73.7 (56)
	4–6 times	15.5 (22)	10.5 (8)
	6–10 times	0.7 (1)	2.6 (2)
	more than 10 times	1.4 (2)	5.3 (4)

* Respondents who had not heard about the FDA report at all were excluded from this study.

ents. The interaction term did not reach significance (B = -0.70, $Wald(1)$ = 1.25, p = 0.26), possibly due to insufficient sample size.[3] Amount of information (and its interaction with experience) contributed uniquely relative to experience alone ($\chi^2(1) = 11.94$, $p = 0.0005$), suggesting that increasing the amount of information may boost adherence irrespective of the experience effect.

Finally, to give an indication of the efficacy of using drug packaging to increase awareness of the FDA warning in experienced parents, trust in drug packaging information was compared across groups. In fact, mistrust of medicine packaging information was significantly more prevalent among inexperienced (55.3%) than experienced (40.1%) parents ($\chi^2(1) = 4.57$, $p = 0.03$), suggesting that experienced parents might indeed be receptive to additional information provided via packaging.[4]

4 Discussion

The current findings suggest that experienced parents exhibit reduced adherence to the FDA warning against giving OTC-CCM to children under 2. Furthermore, reduced adherence in experienced parents does not appear attributable to receiving less information, fewer side effects, greater mistrust in FDA, or fewer coughs and colds. Thus the effect seems consistent with the experienced parents' behavioral inertia (Barron et al., 2008), motivated by a history of safe experiences with OTC-CCM. Despite poorer adherence overall, experienced parents who received "a lot of information" about the warning were more adherent than those who did not, and amount of information uniquely predicted adherence. Thus, experienced parents' behavioral inertia may be counteracted by providing them with additional information. Finally, the data suggest that drug packaging rather than public announcements may be a particularly effective medium for increasing adherence in experienced parents.

The FDA advisory committee's public announcement of the OTC-CCM warning (FDA, 2008) was effective, since the majority of both experienced and inexperienced parents reported receiving "a lot of" warning-related information (Figure 1). Despite similar intake of information between the groups, adherence was much poorer in the experienced parents (Figure 1). Thus it would seem that even more information and/or more effective dissemination of it must be used to combat the behavioral inertia in experienced parents. Fortunately, experienced parents do show better adherence when given additional information (Figure 2) and generally trust the FDA (as do inexperienced parents; Figure 1). Moreover, experienced parents tend to trust drug packaging, suggesting that this medium may be employed to boost adherence. Indeed our data suggest that levels of trust in drug packaging and in the FDA are comparable. These findings, coupled with the immediacy and efficiency associated with drug package warnings may make them a viable alternative to public announcements.

Inexperienced and experienced parents reported similar prevalence of OTC-CCM side effects in themselves and their children, though with higher prevalence in the parents than in the children (Figure 1). Notably, this observation may not reflect reduced likelihood of OTC-CCM side effects in children relative to adults for a given OTC-CCM administration. Rather, this difference may be explained by parents being older and hence having had more opportunities to experience side effects.

Several limitations of the present study should be considered. First of all, collection of data by self-report rather than by objective observation may have artificially increased some ratings (i.e., adherence, amount of information) and lowered others (i.e., mistrust of FDA and packaging), given considerations of social desirability (Schwarz, 2007). However, such influences would be expected to affect all participants equally, irrespective of parenting experience. Second, other variables that may moderate adherence were not examined (e.g. physician's advice, media influence). Third, improved adherence with greater information in experienced (but not inexperienced) parents may be an artifact of greater impact of information at lower levels of adherence. Further studies should examine the effect of provision of additional information over the range of adherence values. To describe and track effects of behavioral inertia over time, longitudinal studies are ultimately required. Finally, the survey's online format may raise concerns about selection issues. Though the web has been identified as an excellent tool for generating large, heterogeneous samples (Birnbaum, 2004), participants in the present study were slightly younger and more highly educated than the general US population (see 2000 US Census; United States Census Bureau, 2001), highlighting the need for larger, more representative studies.

Our results have clear public health implications, as continued use of OTC-CCM may increase the risk of serious side effects. Understanding the antecedents of parents' adherence to FDA warnings, such as a history of safe experiences with the risk-causing agent and adequate knowledge of the FDA warning, is important to determine how to enhance adherence in the least compliant population segment via communication. The present findings indicate that such communication efforts should target households with many young children (and hence experienced parents). Currently, the FDA issues warnings

[3]The interaction also failed to reach significance if tested by parametric analysis: F(2,174)=0.40, p=0.67.

[4]Parametric analyses of the original variable (i.e., prior to recoding) yielded a similar result (F[1,216]=8.51, p=0.004).

on its Medwatch system, which does not target specific populations (FDA Division of Drug Information, Center for Drug Evaluation and Research, personal communication, August 13, 2008). Our data argue for a different approach: The FDA may benefit from issuing such a general warning regarding OTC-CCM, but it may benefit further by issuing a warning targeting the parent group least likely to follow its recommendation, namely, experienced parents. Moreover, it may help to disseminate the warning via packaging information rather than public announcement. Also, to counteract the underweighing of rare events in experienced parents, it may be effective for the FDA to exploit the affect heuristic (Slovic et al., 2002) and target the experiential rather than the rational system (Epstein et al., 1994; Lowewenstein et al., 2001; Slovic et al., 2004). For example, descriptions of vivid case studies illustrating the detrimental effects of OTC-CCM may be more effective in promoting adherence than disseminating statistical information on prevalence of such effects.

Other potential solutions are regulatory in nature. In the US, the FDA decides whether a medicine is OTC, behind the counter or by prescription only. Having medications behind the pharmacy counter (e.g., Pseudoephedrine) or by prescription only reduces the risk of counterindicated use at the cost of availability. As the FDA makes this decision by weighing a medication's risks and benefits, our results suggest an additional risk regarding OTC-CCM-poorer adherence to the warning among experienced parents. While the benefits of making these medications widely available may still outweigh the risk of lower adherence, a careful analysis seems warranted. Follow-up studies should identify the ideal quantity of information and mode of communication to optimize adherence.

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