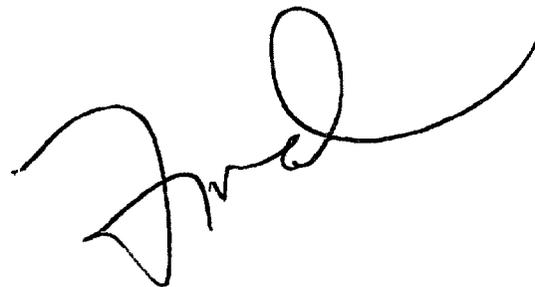


VIA ELECTRONIC SUBMISSION
8-10-04

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852



Docket No. 2004D-0042

Dear Sir or Madam:

Eli Lilly and Company (Lilly) respectfully submits the following comments regarding FDA Draft Guidance *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements*.

Executive Summary

Lilly believes the communication of risk information for pharmaceutical products is an important public health tool that should be designed to encourage the appropriate use of prescription drugs and to protect and advance the public health. While there has been much attention placed on the appropriate method for communication of risk, we believe a discussion of risk presentation should never occur in isolation; it is the appropriate balance of benefit and risk information that is necessary to allow consumers to make informed decisions about their health.

While pursuit of more consumer-friendly advertisements is important, consumers are not and should not be in a position to make prescription medicine decisions on their own. This basic premise must guide all attempts to enhance or improve communication of drug information to consumers. Health professionals receive extensive training over many years on medicines and pharmacology and are licensed to prescribe medication based on this training. An advertisement should lead to a meaningful discussion with a health professional but must not take the place of the learned intermediary.

Currently available research results suggest that the current format for communicating risk information in consumer-directed print advertisements is less than optimal. Research conducted by FDA suggests that an increasing number of consumers read little or none of the brief summary in its current format.¹ Furthermore, additional research by Slaughter et al suggests that almost half of consumers did not recall the brief summary.² These results emphasize the need for focused efforts to improve the format for communicating risks to consumers.

¹ See K. Aiken, "The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient Relationship," Presentation at FDA public meeting on direct-to-consumer promotion, Washington, D.C., 22-23 September 2003, slide 5, www.fda.gov/cder/ddmac/aiken/sld005.htm (15 April 2004). To the question, "How much of the brief summary do you read? 56 percent responded a little/none in 1999, and 73 percent responded a little/none in 2002.

² See E. Slaughter, "Consumer Reaction to DTC Advertising of Prescription Medicines, 1997 to 2002," Presentation at FDA public meeting, Washington, D.C., 22-23 September 2003, www.fda.gov/cder/ddmac/Plslaughter/index.htm (13 April 2004). In that study, 46 percent of respondents were not aware of or did not recall a brief summary.

2004D-0042

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The Food and Drug Administration (FDA) introduced the concept of "less is more" in this draft guidance document. Lilly believes that a "less is more" approach to the communication of important risk information may increase retention and comprehension in consumer-directed print advertisements. However, we believe that only well-designed consumer research can fully articulate the appropriate content and format that would provide the most useful information to consumers, and we encourage the FDA to withhold final guidance unless and until adequate research is available to support evidence-based policy.

Evidence-based policy is essential to minimize subjectivity and decrease differences in interpretation that often result from unclear guidance. Furthermore, evidence-based policy would facilitate consistency across all parts of FDA including various review divisions and DDMAC. Toward that end, we believe the best way to communicate risk information can only be ascertained through rigorous research methods which analyze both traditional and non-traditional methods of risk communication. Results of such research should support evidence-based policy and guidance which clearly outline regulatory requirements in order to minimize the potential for subjective interpretation. Lilly conducted consumer research for print ads in an effort to obtain useful information and support the development of evidence-based policy. Furthermore, the data from this study may be able to be extrapolated to television ads, especially on how the amount of risk information disclosed affects consumer comprehension and recall.

Specific Comments

1. Need clear, objective guidelines

The current draft guidance lacks clear, objective guidelines. For example, the guidance states, "FDA believes that exhaustive lists of minor risks distract from and make it difficult to comprehend and retain information on the more important risks." While Lilly generally agrees with this position and believes that focusing only on the most important risk information related to a product would likely result in improved consumer understanding and comprehension, we are concerned that without clear, objective guidelines, the reality of this "less is more" approach will not be realized. The draft guidance stresses the importance of including "all" contraindications, "all" warnings, and "major" precautions related to the drug. The requirement to include "major precautions" is not definitive and requires a subjective assessment of what actually constitutes a "major" precaution. Lilly believes this ambiguity may result in differences among therapeutic categories based on the FDA reviewers responsible for interpreting this guidance. This lack of clarity may also result in differences of opinion between the FDA and sponsors. Strong consideration should be given to not including precautions in consumer-directed print advertisements if consumer research demonstrates that a "less is more" approach is essential to obtaining adequate comprehension and retention of risk information. Although, if included, Lilly believes that a more clear definition of "major" should be included in the final guidance document, and that the precautions should be limited to drug-specific risks that consumers need to know before talking to their doctor about the medication.

This same rationale for requiring only "major" precautions, and defining what "major" is, should be considered for warnings as well. Such an approach may be most appropriate if

research demonstrates that "less is more" for risk communications.³ FDA may be able to justify this policy in light of current regulations by taking an approach similar to that used by the agency for television advertising. In this case, reference to full prescribing information in the ad combined with the fair balance risk content is deemed to be an adequate provision of risk as required by FDA's regulations. The problem companies currently confront is how to select which precautions (and warnings) should be included in print ads. Without clear guidance in this regard, the company cannot know whether it will be deemed to be in compliance with FDA advertising regulations and such an approach by FDA creates product liability implications. This issue is not limited to precautions and warnings.

Lilly also recommends clearer guidance regarding the inclusion of side effects. The guidance recommends including "the 3-5 most common non-serious adverse reactions most likely to affect the patient's quality of life or compliance with drug therapy." These are ambiguous, subjective criteria. Research is needed to outline an objective way to define which side effects to include in ads. The appropriate criteria for inclusion of adverse events should be supported by consumer research to fully elucidate what is the most useful information for consumers. Lilly conducted consumer research in this area and encourages FDA to use consumer research to develop evidence-based policy regarding this issue. Ultimately, the final guidance should clearly delineate the standards for selecting side effects to be included in print ads. Presently, it is impossible to know which events to select without seeking advisory comments from the DDMAC.

2. Need consistency across all parts of the FDA

Because the FDA review divisions play a central role in the development of labeling documents and the Division of Drug Marketing Advertising and Communications (DDMAC) plays a central role in applying the labeling documents to promotional advertising, Lilly encourages alignment between review divisions and DDMAC. It is imperative that the review divisions fully understand the impact of labeling documents on the communication of risk information in promotional labeling. To that end, the development of the patient labeling (i.e., Patient Package Insert) should focus primarily on the most important risk information associated with the product and be aligned with the "less is more" approach to communicating risk information consistent with findings of research in this area.

3. Need clarification of risk communication when product has multiple indications

Many products have multiple indications. Such products may have different risk profiles based on the indicated use of the drug. In such instances, Lilly believes that the risk information associated with the specific indication mentioned in the advertisement should be highlighted. For the common side effects, the risks communicated should be limited to those relevant to the advertised indication, assuming only one indication is being addressed. The most serious risk information for each molecule should be communicated to the consumer regardless of the indication advertised. The current draft guidance is

³ Some medications have many pages of precautions and warnings in their full package insert. Furthermore, some of these precautions and warnings are not relevant to how patients use the product. For example, a precaution for clinically significant "transaminase elevations" would be too complicated for consumers to understand.

silent on this issue. Lilly encourages the Agency to include these as standards in the final guidance document.

4. Need to clarify that standards adopted in final guidance comply with applicable laws.

While a "less is more" approach to disclosing product risk information would likely benefit patients, there is concern that such an approach could present product liability issues for sponsors. The FDA draft guidance states, "In the circumstances described [in section III of the guidance], FDA does not intend to object to consumer-directed print advertisement for a prescription drug on the ground that it does not present risk information *in compliance with* the brief summary requirement." (emphasis added). This language may suggest that, while FDA does not believe the options outlined in the guidance fully comply with the Code of Federal Regulations, the agency will use its enforcement discretion in this area. Lilly believes that the approaches contained in the FDA draft guidance and that Lilly recommends herein fulfill the requirements outlined in 21 CFR 202.1(e)(1). Therefore, we recommend that the final document communicate the consistency of this guidance with regulatory requirements. If, however, the FDA does not believe the outlined approaches fulfill the regulatory requirements, the Agency should amend the applicable regulations.

5. Need research to evaluate impact of varying format and content of risk information

The current guidelines require the inclusion of risk information in the body of the advertisement as well as an additional page outlining risks associated with the product. Research is needed to understand the impact of repetition of information in multiple places in print ads on consumer comprehension and retention. Less-detailed risk information may be included in the body of the ad with more details on the back page in a consumer-friendly format. It also may be possible to adequately disclose all necessary risk information in the body of the advertisement, thus eliminating the need for an additional page of information. This observation has been noted in research and was outlined in the following comments from the Federal Trade Commission:

"The current brief summary requirement for print ads also imposes unnecessary costs on drug manufacturers who desire to advertise their products. These costs are significant because advertisers must often pay for an additional page in a print publication to meet the brief summary requirement. The additional costs imposed on print ads may have several negative effects. The extra expense may lead advertisers to advertise less overall than they would have otherwise, depriving consumers of the information that they would otherwise have received from print ads."⁴

Lilly is conducting consumer research to assess the appropriateness of different approaches.

⁴ Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission in the Matter of Request for Comments on Consumer-Directed Promotion, Docket No. 2003N-0344 (2003); Requiring additional information to qualify a claim or identify possible drawbacks of a product increases the cost of advertising.... If a significant fraction of each communication must be devoted to required disclosures, sellers may disseminate information about product advantages less widely." J. Howard Beales, III, *Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 Seton Hall L. Rev. 1370, 1381 (1994);

Lilly Research Protocol

Background

The FDA has requested feedback on ways in which to effectively incorporate appropriate risk information in consumer-directed print advertisements. Lilly has conducted a quantitative study with consumers that provide specific, actionable data on consumer comprehension and retention of risk information. The primary objective of the research was to evaluate a range of prototype magazine ads to determine which ad best communicates the risk information of interest to consumers before they talk to their doctors about prescription medications. A summary of the preliminary results from the primary objective and recommendation process is contained in this document. Further analyses of these and other collected data are ongoing and will be shared at a future date. Lilly plans to submit to the docket an updated version of these comments based on further analysis. In addition, Lilly will submit to the docket for public evaluation the study protocol, analytical plan, questionnaire, and the complete data collected. Finally, the results are being summarized for publication in an appropriate peer-reviewed journal.

A large number of studies have provided *attitudinal* data on how the public perceives DTC advertising and risk information in general, which is important to monitor but not specific enough with which to make policy decisions. The recommended ads are not simply what people *say* they want, it is what they have demonstrated as effectively providing the right amount of information in a format that can be understood and recalled. The difference in attitude and behavior is a common occurrence in social science, and one that poses challenges when thought and action differ.

The significance of this new research is that the data are based on a monadic evaluation of a wide range of ads that vary both the back and front page of the ad in a tightly controlled environment. Lilly designed five different front and three different back pages varying only the amount and layout of the risk information presented in each. The safety information on both the front and back page was based on the approved label for a marketed compound. Each respondent evaluated one ad pair (front and back) only and responded to specific questions that measured comprehension, effectiveness, amount of risk information, layout, clarity and recall of side effects.

A specific question posed in the FDA guidance document was about the optimal number of side effects to list in the ad, suggesting 3-5 under the 'less is more' hypothesis. To address this issue, a supplemental experiment was included which consisted of three ads that differed only in the number of side effects. The control ad had 4 side effects on the front page, the second had 8, and the third had 12. All had the PPI back page. While the number of side effects is important, the criteria upon which to select the side effects are equally important, but a much tougher question. Questions were included to assess the importance of different categories of side effects that could be used to determine which side effects to include in ads.

The results of this study will provide important input on content and format of print ads as well as guidance on the number and selection criteria for side effects.

Ad Concepts

In the test, there were 5 different front pages and 3 different back pages, as well as a 'no back page' option for a monadic/factorial design. In total, there were 14 ad combinations tested (relevant combinations of front and back pages were tested). For example, the brief summary was only tested with the traditional ad, because there are existing data that indicate this format is not effective in communicating risk information. Also, it made no sense to test Concept E (with all risk information on the back page) with the 'no back page' option. See protocol for full design description.

A: Traditional ad				N = 300
Brief Summary on back, full page N = 100	Patient Package Insert on back, full page (Q&A format) N = 100	Consumer Friendly Prescriber Risks Highlights on back N = 100		
B. Ad with fair balance in risk window (like food label) (CI/Warning/4SE)				N = 300
	Patient Package Insert on back, full page (Q&A format) N = 100	Consumer Friendly Prescriber Risks Highlights on back N = 100		N = 100
C. Ad with fair balance in risk window (like food label) (4SE)				N = 300
	Patient Package Insert on back, full page (Q&A format) N = 100	Consumer Friendly Prescriber Risks Highlights on back N = 100		N = 100
D. Ad with "learned intermediary" language as fair balance				N = 300
	Patient Package Insert on back, full page (Q&A format) N = 100	Consumer Friendly Prescriber Risks Highlights on back N = 100		N = 100
E. Ad with all risk information on back page				N = 300
	Patient Package Insert on back, full page (Q&A format) N = 150	Consumer Friendly Prescriber Risks Highlights on back N = 150		
F. Ad with all risk information on back page				N = 200
	Patient Package Insert on back, full page (Q&A format) N = 550	Consumer Friendly Prescriber Risks Highlights on back N = 550		N = 1700
Supplemental Cell BP Variations*				
		N = 100		
		N = 100		

* Supplemental analyses will be conducted only in this cell.

The concepts are described as follows:

Front Page:

- Concept A: Traditional ad with fair balance copy in body of ad
- Concept B: Ad with fair balance in risk window (like food label) containing contraindications, warnings, and four side effects
- Concept C: Ad with fair balance in risk window (like food label) containing 4 side effects
- Concept D: Ad with "learned intermediary" language as fair balance
- Cell E: Ad with all risk information on back page

Back Page:

- Concept S: Traditional Brief Summary
- Concept P: Patient Package Insert (full page, Q & A format)
- Concept H: Consumer-friendly Prescriber Risk "Highlights"
- Concept a: No back page

Decision Criteria

As stated in the protocol document, a 'funnel' approach to data reduction was used to determine the ad combinations that best communicated risk information, based on the primary and secondary composite scores as well as the recall of side effects score.

Preliminary Results

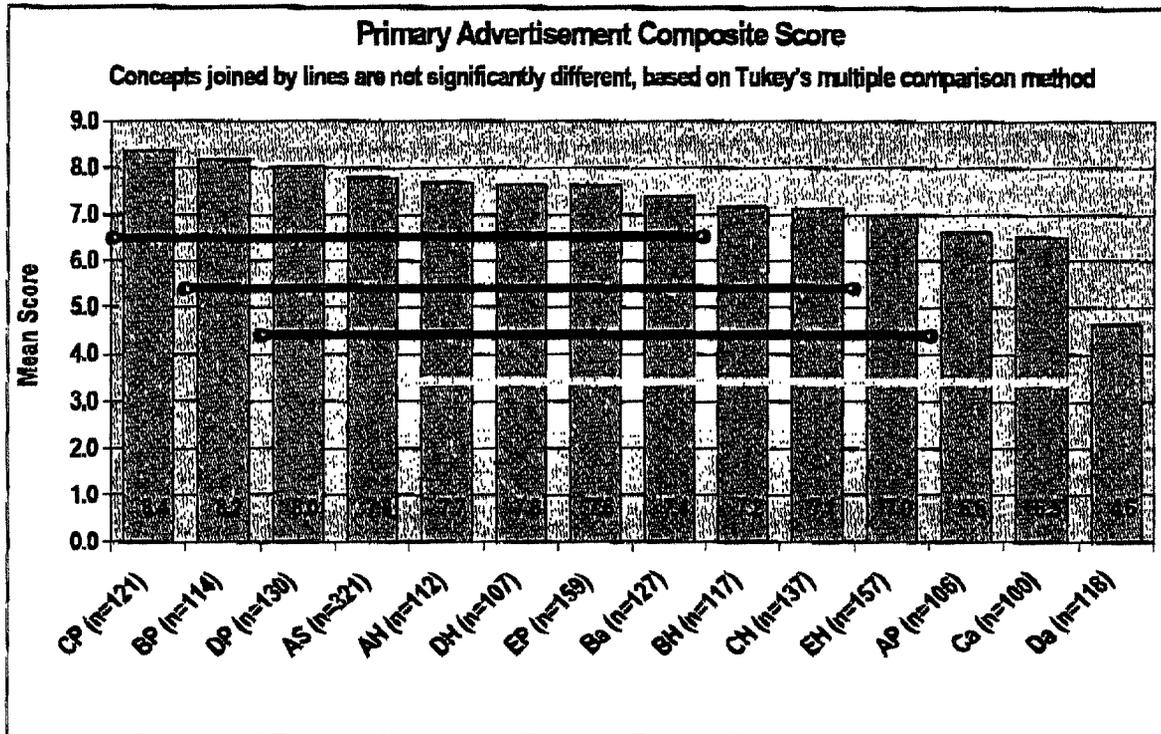
Primary Advertisement Composite Score

1. The primary advertisement composite score evaluated the ads on the following dimensions:

- Comprehension
- Effectiveness of communication
- Amount of risk information

These components were considered primary since, at a minimum, consumers must rate the ad as effective at providing them with the information they need to talk to their doctor, must rate the ad as containing enough risk information, and must demonstrate that they are able to comprehend the information provided in the ad.

In the primary analysis, there were 6 concepts that were statistically inferior to the best scoring ad. Therefore these 6 (BH, CH, EH, AP, Ca, Da) did not move forward for further analyses. However, there were 7 ads that were not statistically different from the best scoring ad. These 7 (BP, DP, AS, AH, DH, EP Ba), plus the best scoring ad (CP)) were taken to the second step in the recommendation process.



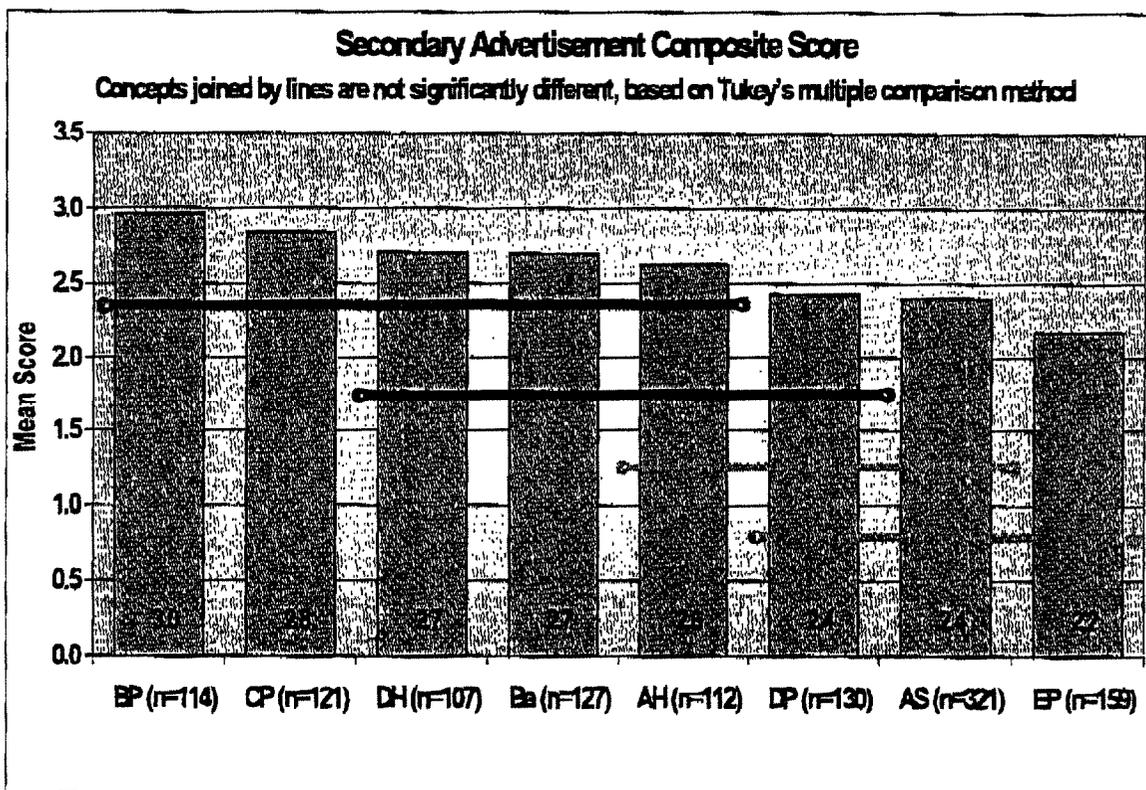
Secondary Advertisement Composite Score

2. The secondary advertisement composite score evaluated the ads on the following dimensions:

- Format/layout
- Clarity of communication

Also important in the evaluation of the ads was the perception by consumers of the format of the ad (ease in finding risk information) and the clarity of the ad (use of consumer-friendly language). Given that an ad is effective, comprehensible, and contains adequate risk information, format and clarity were selected as most important for the secondary advertisement composite score. Formats that appeal to the consumer with clear language should be preferred to more cumbersome ads.

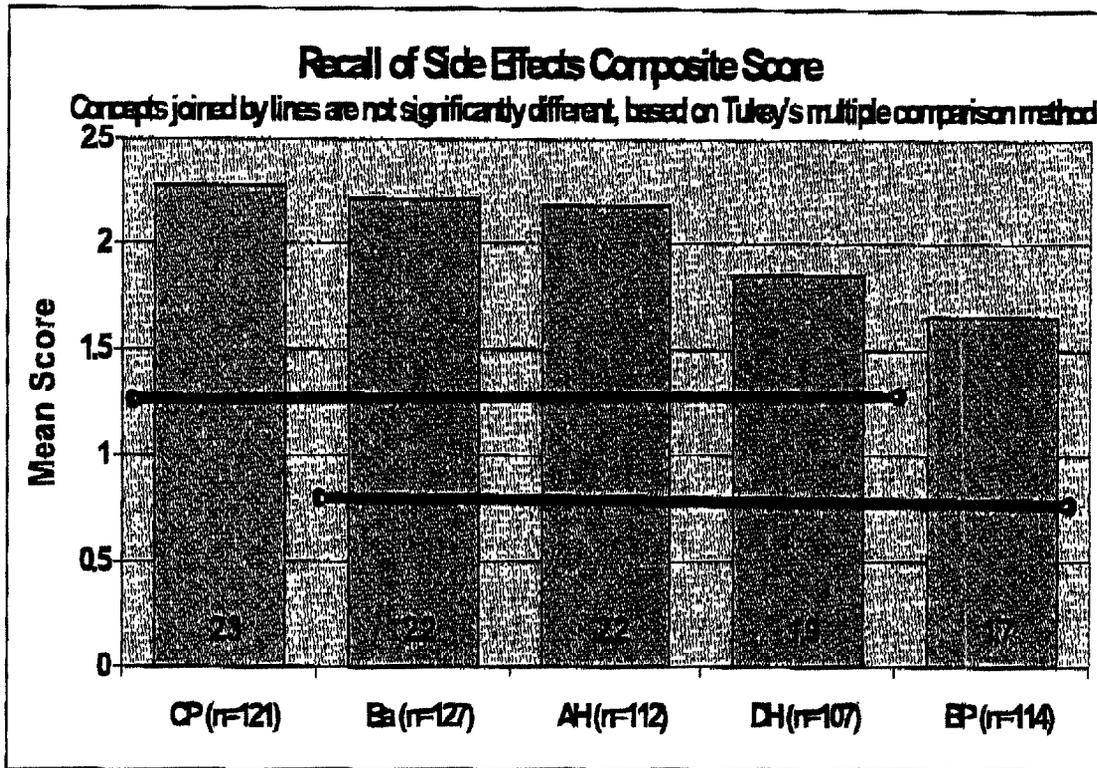
In the secondary analysis, there were 3 concepts that were statistically inferior to the best scoring ad. Therefore these 3 (DP, AS, EP) did not move forward for further analyses. However, there were 4 ads that were not statistically different from the best scoring ad. These 4 concepts (CP, DH, Ba, AH), plus the best scoring ad (BP), were taken to the final step in the recommendation process.



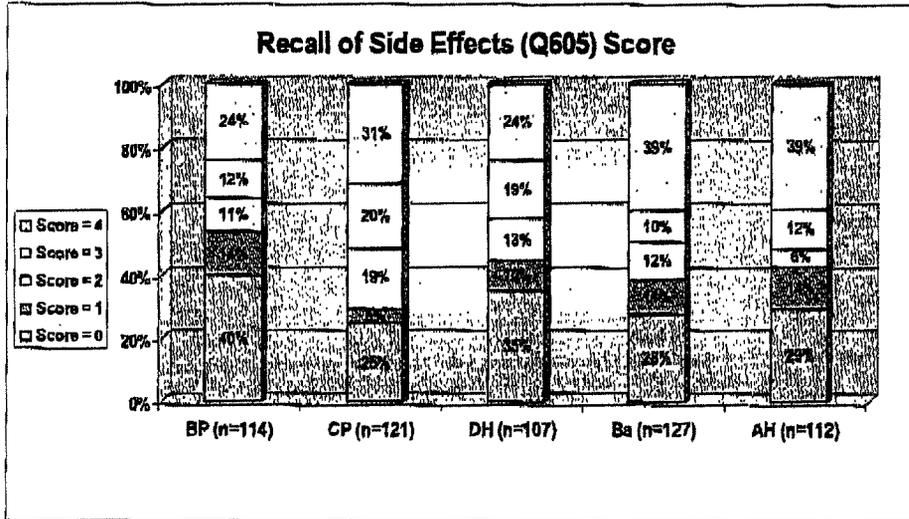
Recall of Side Effects Score

3. The final step in the recommendation process was evaluation of the recall of side effects score. The ads were evaluated based on the respondents' number of correct responses to an eight-item yes/no question. For ads that are effective, comprehensible, contain adequate risk information, have an easy to read format, and use clear language, recall of side effects is a further distinguishing criterion. The question asked respondents to recall the 4 common side effects communicated in the ads.

Of the five ads included in this step of the recommendation process, four ads (CP, Ba, AH, DH) scored significantly higher on the recall of side effects measure than the fifth ad (BP).



The data in the table below show a further breakdown of the percentage of respondents who correctly recalled the side effects listed in each ad. These data show that at least 25% of respondents viewing each of the five ads scored no better than could have been obtained through random guessing.



Respondents who correctly answered 0 to 4 of the 8-part question were included in the Score=0 group since random guessing would be expected to yield 4 correct answers. Correct answers of 5, 6, 7, and 8 were included as a Score of 1, 2, 3, and 4, respectively.

Analysis of Primary Objective

There are 4 different front pages and 3 different back pages in the final ad pairs, suggesting that the combined effect of front and back page is important. The front page that was eliminated contained no specific risk information, and all of the risk information on the various back pages that were tested (Concept E). Clearly, consumers have said that they want and expect to have some safety information on the front page of the ad, which may be general or specific depending on the back page that is utilized. The back page that was eliminated was the traditional Brief Summary, which contains the most risk information. Consistent with the FDA's hypothesis, the brief summary is not an effective way to communicate risk information.

Based on our preliminary analysis of the results, the data indicate that concise windows, either on the front or back page of print ads, are required to effectively communicate risk information to consumers. Like a food label, it makes sense to set apart risk information in a consistent and predictable manner so consumers know where to look and what to expect.

In addition, the results show no clear indication that repetition of safety information yields better recall. Concept Ba, with no back page and all safety information on the front page, and DH, where all drug specific risk information was on the back page, were statistically indistinguishable throughout the funnel of analyses from CP and AH, where risk information is listed on *both* the front and back. Furthermore, this study suggests that a single page can suffice if it contains all the appropriate risk information consumers need before they talk to their doctor, even for a complex compound with a similar amount of risk information as was included in this test.

Overall, the study results demonstrate that ads are read as a whole. The data show that as you decrease risk information on the back page, more risk information needs to be provided on the front page in order to optimize risk communication to consumers. The converse is also true—as you decrease the information on the front page, the more you need on the back.

Additionally, the study shows that contraindications and warnings are essential elements of print ads; however these risks need to be conveyed through use of *concise* windows on either the front or back page of the ad. Other data suggest that consumers cannot accurately recall an exhaustive list of risk information. (See analysis section of supplemental cell results). What is important is the combination of a risk window with a summary of risk information. Windows cannot effectively communicate exhaustive lists of risks to consumers.

The four ads that best communicate risk information consist of varying templates. These variations are statistically indistinguishable, and provide flexible options for print ads.

Analyses are ongoing in order to further understand how these four ad pairs compare on other dimensions.

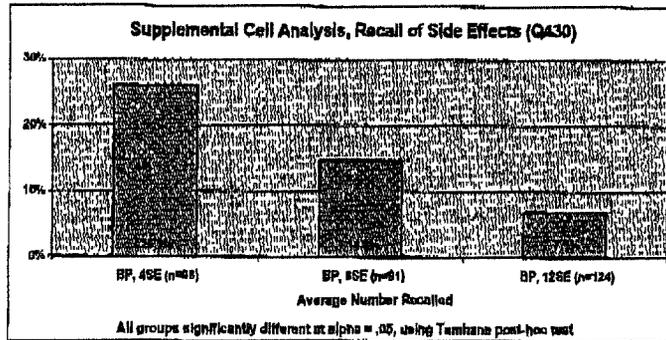
Supplemental cell analysis – Number of side effects

Two supplemental cells of respondents were included to investigate the impact of increasing the number of common side effects on the consumer’s ability to recall the side effects. A large body of literature already exists supporting the concept that recall is better when fewer items are presented^{4, 5, 6, 7}; however, no research has been conducted in this specific setting (i.e., prescription drug print advertisements). There is a tremendous amount of information in the ad that both FDA and industry want consumers to retain. For these reasons, the ability of consumers to recall the side effects in the context of a full print advertisement was studied.

The control for this evaluation was ad BP that contains four side effects on the front page. Two additional cells of approximately 100 respondents each looked at the same ad containing eight and 12 common side effects, respectively. In these ads, the only content that varied was the number of side effects presented. The question was open ended, and respondents were asked to list all of the side effects they remembered from any part of the advertisement, both front and back page.

Percentage Recalled

The *percentages* of side effects recalled for each ad were all significantly different (p=0.05). Ad BP with 4 side effects had the highest percentage correct recall.



⁴ Miller, G.A. (1956). The magical number seven, plus or minus two: Some limits on our capacity for processing information. *Psychological Review*, 63, 81-97.

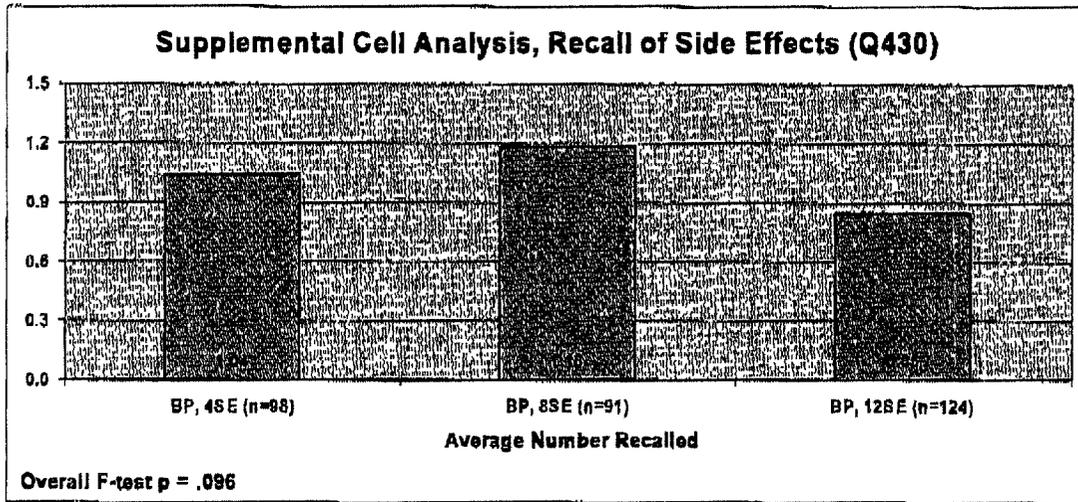
⁵ Cowan, N. (2001). The magical number 4 in short term memory: A reconsideration of mental storage capacity. *Behavioral and Brain Sciences*, 24, 87-187.

⁶ Just, M.A., & Carpenter, P.A. (1992). A capacity theory of comprehension: Individual differences in working memory. *Psychological Review*, 99, 122-149.

⁷ Shiffrin, R.M., & Nosofsky, R.M. (1994). Seven plus or minus two: A commentary on capacity limitations. *Psychological Review*, 101, 357-361.

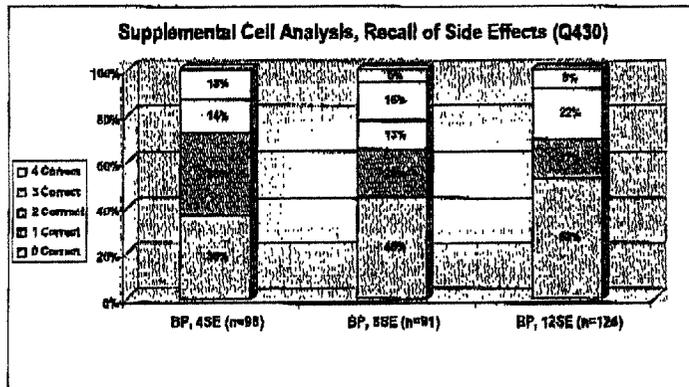
Number of side effects recalled

The average *number* of side effects recalled for each ad was not statistically different ($p=0.096$). The average number of side effects recalled for ads BP, B8P, and B12P were 1.04, 1.18, and 0.85, respectively. Respondents remembered, on average, only one side effect regardless of how many were included in the ad.



Impact of increasing numbers of side effects

The percentage of respondents who recalled zero, one, two, three, or four side effects for each ad was also calculated. The percentage of respondents who remembered none of the side effects in the ad increased as the number of side effects increased. Thirty-six percent, 45%, and 53% remembered zero side effects correctly, respectively. Conversely, the percentage of respondents who remembered one or more side effects correctly decreased as the number of side effects in the ad increased. Sixty-three percent, 55%, and 47% remembered one or more side effects, respectively.



Recall of four most common side effects

These data show that increasing the number of side effects has a negative impact on recall. In the 8 and 12 side effect cells, the majority of respondents could not accurately recall even one of the 4 most common side effects. Furthermore, these data suggest that the recall of each of the 4 most common side effects decreases as the number of side effects listed increases.

% of respondents recalling top four side effects (upset stomach, drowsiness, decreased appetite, shakes) in open-ended question			
	BP (n=98)	B8 (n=91)	B12 (n=124)
0 mentioned	35.7%	54.9%	52.4%
1 mentioned	35.7%	20.9%	16.9%
2 mentioned	14.3%	13.2%	21.8%
3 mentioned	14.3%	11.0%	8.9%
4 mentioned	0.0%	0.0%	0.0%
Total	100.0%	100.0%	100.0%
Individual responses (multiple responses allowed) to listed side effects			
Unaided Recall		%	%
upset Stomach	34	27	18
drowsiness	26	13	21
decreased appetite	9	7	9
shakes	38	8	18
Subtotal	107	55	66
headache		19	10
difficulty sleeping		12	11
anxiety		5	4
nervousness		2	8
Subtotal		38	33
weakness			0
dry mouth			8
sweating			1
yawning			4
Subtotal			13
Total	107	93	112

Inclusion of 4 side effects resulted in more accurate recall than inclusion of 8 or 12. Respondents remembered, on average, only one side effect regardless of the number included in the ad. Additional analyses showed that the recall of the 4 most common side effects decreased as the total number of side effects increased, thereby diluting the respondent's ability to recall, arguably, the most important events in the list of side effects. Further study is needed to determine the optimal number of side effects, however these data suggest that recall is disappointing with only 4.

Supplemental cell analysis – Categories and frequency of side effects

The difficult policy choice is how to select which 1-4 side effects to include in the ad. This study shows that 2 out of 3 consumers rate three categories of side effects as extremely important: side effects caused by the drug; side effects resulting in discontinuation from clinical trials; and side effects lasting as long as the medication is taken. The types of side effects considered less important were those that were temporary, and those naturally occurring in people with the disorder.

	% Rating Extremely Important
<i>Q: How important is it to provide this information in magazine ads? (n=228)</i>	
Side effects that are caused by the use of the medicine	67%
Side effects that caused people to stop taking the medication or drop out of the clinical trial	63%
Side effects that last as long as you take the medicine	63%
Side effects that are temporary, and last for a short time when you first take the medicine	37%
Side effects that naturally occur in people with the disorder	31%

The persistency factor of side effects (those that last as long as you take the medication) is not currently part of prescription drug labels; and therefore, it would be difficult to establish a rule to guide the selection of side effects to be included in ads. Future evaluation is needed to understand how to categorize this type of information considering the high consumer interest. The remaining two categories, side effects that are caused by use of the medicine and those that cause clinical trial discontinuation, could be the basis upon which to select the side effects to include in pharmaceutical print ads.

The second part of this analysis was to determine at what frequency consumers want to know about side effects. For the 'most important' side effect categories, almost half of respondents said they wanted to know about all levels, no matter how infrequently the side effect occurs.

	All levels, no matter how small
<i>At what level is it important to mention in a magazine ad? (n=228)</i>	
Side effects that are caused by the use of the medicine	48%
Side effects that caused people to stop taking the medication or drop out of the clinical trial	45%
Side effects that last as long as you take the medicine	45%
Side effects that are temporary, and last for a short time when you first take the medicine	34%
Side effects that naturally occur in people with the disorder	35%

This interest level demonstrates the importance consumers place on information about side effects. Unfortunately, their desire for information and their ability to recall a long list of side effects is contradictory. These data show that there is an important distinction between what consumers want to know and what they can practically assimilate. As seen earlier, consumers cannot, on average, recall more than one side effect. Furthermore, this study shows that consumers consider the primary purpose of magazine ads to inform them about illnesses and available medicines, and to encourage them to talk to their doctors. The purpose is *not* to decide if the medicine is right for them (self-diagnosis) or to give them as much information as possible about the medicine, as shown on the following table.

Q: Which of the following statements best reflects your feeling about the primary purpose of magazine ads for prescription medicines? (N=192S)

	% Answering
The primary purpose of magazine ads for prescription medicines is to make me aware of illnesses and medicines to treat them.	29%
The primary purpose of magazine ads for prescription medicines is to help me decide if a medicine is right for me or someone in my family.	18%
The primary purpose of magazine ads for prescription medicines is to give me as much information as possible about the risks and benefits of the medicine.	16%
The primary purpose of magazine ads for prescription medicines is to encourage me to talk to my doctor.	37%
	100%

Implications of Study Results for Policy Development

1. Need guidance on appropriate format and content for print advertisements

This study shows that consumers do not fall into extreme categories but instead take a practical approach to reading and comprehending consumer-directed print advertisements. This has produced a kind of “Goldilocks effect” in that the ads recommended are neither of the extremes, not too much risk information, not too little is required for effective communication. One of the most significant finding from this study is that windows are the most effective way to communicate risk information when presented in summary form. The rules that are developed should include as templates the four ad variations recommended by this study.

When contraindications and warnings are placed on the front page, the data show that this information does not have to be on the back page. If only side effect information or a learned intermediary statement is included on the front page, then the contraindications and warnings should be on the back page.

2. Need guidance on criteria for side effect selection

One of the most significant conclusions of the study was that four side effects are probably too many for effective communication of risk. This suggests a need for criteria on how to select these four side effects given that exhaustive lists are not appropriate. According to the study, the most important types of side effects are side effects causes by the drug or cause patients to drop out of clinical trials. Policymakers can either base the selection of side effects on the frequency of occurrence caused by the drug, or choose the four based on the two most frequently caused by the medicine and the two that resulted in the greatest incidence of discontinuation. However, in the latter case, the side effect discussion would increase in complexity because the consumer would need to be advised of two different criteria for side effect selection and, in order to be balanced in the presentation, the low percentage of discontinuation rate would probably need to be identified, thereby making it necessary to reflect the frequency percentages in the most prevalent effects disclosed. All these additional statements could result in a complexity that reduces the likelihood of getting the best side effect comprehension from the consumer—especially when consumers on average only accurately recall 1 side effect. It is important in this context to remember that the consumers report wanting to know more

than they show they can retain, so perhaps limiting the side effect disclosure to the 4 most frequently caused adverse events would lead to the best policy position.

A guidance document on risk communication in consumer-directed print advertisements should be prepared in an expedient manner. Lilly will work with the FDA to clarify any questions the Agency may have about these data and to assist in preparing standards that are evidence-based. Lilly is committed to providing to the public docket the data collected in this study. This submission will occur when all of the data become available and analyses have been completed. This is expected to occur in the next thirty days.

Respectfully submitted,

ELI LILLY AND COMPANY

David R. McAvoy, JD, MSES
Director, Scientific and Regulatory Policy

Mary W. Elsner
Manager, Consumer Marketing

Matthew D. Rotelli, PhD
Head, Statistics – U.S Commercial Information Sciences

Stacy M. Holdsworth, PharmD
Manager, U.S. Regulatory Affairs

Name	Role	Status
Mary W Elsner	Owner	Accepted
William Maxey	Required	Accepted
Veronica Chase	Required	Accepted
Richard Bush	Required	Accepted
Michele Dow	Required	Accepted
Michael C Knapp	Required	Accepted
Lisa E Kirk	Required	Accepted
Kelly A Butler	Required	Accepted
Juan F Diez	Required	Accepted
Jill Crimm	Required	Accepted
Jeffrey S Ball	Required	Accepted
Jana B Klopp	Required	Accepted
James P Kremidas	Required	Accepted
J Brad Booze	Required	Accepted
Holly M Sullivan	Required	Accepted
Floyd Pruitt	Required	Accepted
Douglas W Wilson	Required	Accepted
Diana T Caldwell	Required	Accepted
Catherine Stiver	Required	Accepted
Brian F Smith	Required	Accepted
Benjamin L Basil	Required	Accepted
Anne L Myers	Required	Accepted
Uma Kannappan	Required	Tentative
Todd A Seifferlein	Required	Tentative
John E McMahan	Required	Tentative
Janice H Adewuyi	Required	Tentative
Amanda Fontenot	Required	Tentative
Stacy E Miller	Required	Declined
Sharon F Laukhuff	Required	Declined
Paula Garrett	Required	Declined
Monideepa Chand	Required	Declined
Maura O Kahn	Required	Declined
Marie C Sparks	Required	Declined
Laura A Downey	Required	Declined
John F Lucas	Required	Declined
Joachim B Osther	Required	Declined
Emily Frische	Required	Declined
Dennis A Wimer	Required	Declined
Bethany Meder Thomson	Required	Declined
Ann M Cunningham	Required	Declined
Nathaniel M Osborne	Required	Delegated
Thomas Batdorf	Required	No response
Stephen Reed	Required	No response
Ryan P Dullea	Required	No response
Richard A Meyer	Required	No response
Paul M Berman	Required	No response
Michael J Halpin	Required	No response
Joseph R Holman	Required	No response
Charles P Southall	Required	No response
Nicole Hebert	Delegat	No response

Delegation History:

Nathaniel M Osborne -> Nicole Hebert

Print

Close

Calendar Entry:

Meeting

Subject: Strategy & Capabilities Consumer Intern Presentation - Brian Smith Location: 145-3-G

Begins: Wed 08/11/2004 09:30 AM Entry type: Meeting

Ends: 12:00 PM

Sent by: Floyd Pruitt/AM/LLY

~~Invitations already sent~~

To: Amanda Fontenot/AM/LLY@Lilly, Ann M Cunningham/AM/LLY@Lilly, Anne L Myers/AM/LLY@Lilly, Benjamin L Bethany Meder Thomson/AM/LLY@Lilly, Brian F Smith/AM/LLY@Lilly, Catherine Stiver/AM/LLY@Lilly, Charles Dennis A Wimer/AM/LLY@Lilly, Diana T Caldwell/AM/LLY@Lilly, Douglas W Wilson/AM/LLY@Lilly, Emily Frisc Pruitt/AM/LLY@Lilly, Holly M Sullivan/AM/LLY@Lilly, J Brad Booze/AM/LLY@Lilly, James P Kremidas/AM/LLY@Lilly, Janice H Adewuyi/AM/LLY@Lilly, Jeffrey S Ball/AM/LLY@Lilly, Jill Crimm/AM/LLY@Lilly, Osther/AM/LLY@Lilly, John E McMahan/AM/LLY@Lilly, John F Lucas/AM/LLY@Lilly, Joseph R Holman/AM/LLY@Lilly, Kelly A Butler/AM/LLY@Lilly, Laura A Downey/AM/LLY@Lilly, Lisa E Kirk/AM/LLY@Lilly, M Sparks/AM/LLY@Lilly, Maura O Kahn/AM/LLY@Lilly, Michael C Knapp/AM/LLY@Lilly, Michael J Halpin/AM/LLY@Lilly, Monideepa Chand/AM/LLY@Lilly, Nathaniel M Osborne/AM/LLY@Lilly, Paul M Berman/AM/LLY@Lilly, Richard A Meyer/AM/LLY@Lilly, Richard Bush/AM/LLY@Lilly, Ryan P Dullea/AM/LLY@Lilly, Stacy E Miller/AM/LLY@Lilly, Stephen Reed/AM/LLY@Lilly, Thomas Batdorf/AM/LLY@Lilly, Veronica Chase/AM/LLY@Lilly, William Maxey/AM/LLY@Lilly

cc:

bcc:

 Pencil In Mark Private Notify me

Categorize:

Time will appear free to others.

Others cannot see any details about this event.

Have Notes notify you before the event.

Description:

Presentation Summary:

The first portion of the presentation examines shared-learnings and best practices along the Consumer Marketing Planning Process. The project deliverable includes a reference library cataloging lessons from various Lilly consumer-marketing experiences. Information such as cost-ranges, timing, key partners, resources, and road maps will be highlighted across the Consumer Marketing Planning Process.

The second portion of the presentation examines the increasing importance of Consumer Relationship Marketing (CRM) in the pharmaceutical industry. In the presence of downward pressure on prices and the saturation of traditional sales and marketing channels, marketing strategists are beginning to look to tactics that address the bottom half of the Health Care

Transaction Model (HCTM). The objective is to give you Lilly's perspective and to provide a framework to evaluate if CRM tactics can help extend the lifetime of increasingly costly Rx acquisitions. Topics covered include: Defining CRM, Leakage along the HCTM, Cost of Acquisition, ROI per Rx, Patient Lifetime, Relationship Value Propositions, Driving Patient Outcomes, Health Management, Non-Sales Physician Resources, Disease Management, Compliance, External Industry Insights into CRM, and the culture and tools necessary to build an effective CRM infrastructure.

Participants that declined:

John Lucas declined. I have to teach an all day class this date. I would appreciate hearing from you on how Brian did in his assignment.

Maura Kahn must decline due to calendar conflict.

Sharon Laukhuff declined. would love to attend, but am in training that day. I met w/ Brian this morning and did a "test run". He did a great job.

Stacy Miller declined. My apologies, I will be in training all day