

# Exhibit 74

## Analysis of Terms Comprising Potential Names for a Recall Notification Campaign

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Recall notices are vital in promulgating warnings about defective products to consumers. The present study examined potential names/titles of recall notifications that might be used in campaigns requesting the return of defective items such as foods, drugs, medical devices, etc. Sixty-one potential names were evaluated showing that some combinations of particular words forming potential names produced higher ratings, such as the terms *Recall* and *Urgent*. The term *Recall* is viewed as appropriate for campaigns involving many kinds of products, however, participants indicated that a different term should be used when the defective product is a surgically implanted medical device. Further analyses indicated that inclusion of *FDA* in the name produces higher ratings of appropriateness than a generic company name. Also, evaluations of individual words comprising the names showed similar patterns when combined with other words. Implications of these results are discussed.

### INTRODUCTION

Each year, numerous products are discovered to have defects after leaving the manufacturer that pose risks to consumers' safety. When safety problems (or suspected safety problems) are discovered following the distribution or sale of the product, the product is sometimes recalled for credit, repair or replacement. The intention of a recall campaign is to alert the public to actual or potential product hazards or defects. Gibson (1998) points out that in the U.S. in 1996 there were over 1,885 recalls, or 5.16 per day. In theory, defective products are supposed to be recalled by the manufacturer. A manufacturer-based recall is frequently called a "voluntary" recall. When a manufacturer fails to perform a satisfactory voluntary recall, the government may step in to strongly recommend or require a recall to protect public safety and health.

How to effectively notify consumers in recall campaigns has not received much attention in research. However, there has been considerable research on the broad topic of warnings (e.g., Wogalter, 2006). Warnings and recall notices are both safety communications. Warnings generally accompany the product when purchased such as labels, inserts and manuals. However, recall notices are produced after the product has already left the manufacturer. Thus, with recall notices there is a temporal and spatial separation from the product that is larger than for most kinds of product warnings. For certain products, manufacturers have information on where to send the recall notices (e.g., registration or invoice information) but in many cases, a list of specific owners does not exist (Heiden, 2003). Therefore, in order to get the recall message publicized, press releases and other mass media methods are often used; and now more frequently, recalls are

disseminated via the web. However, people may not see or hear about these press releases or have any awareness that they should search the web for recalls. Furthermore, in reaching target product users, consideration needs to be given to different literacy rates, social classes, native languages and age groups.

A potential way to benefit or facilitate the recall process is to title the notification so that it effectively alerts people to recognize that the communication concerns a defective product. The title or name of the recall notification might, in fact, use the term "recall" as it is highly descriptive of the purpose of the communication. Whatever name is chosen should probably serve to alert and convey a sense of urgency so as to provide some impetus to read (or listen to) the notification and to encourage people to return, repair or replace the product. Thus, the name ought to be both informative and motivating.

Research on components of warning messages has taken a similar tact of examining specific terminology to perform similar functions as desired for a recall campaign name. Warnings research has shown that there are differences in the way signal words (e.g., DANGER, CAUTION) differ in hazard connotation, attitudes/beliefs, and motivation (e.g., Edworthy & Hellier, 2006). Other descriptive terms in warnings can affect hazard judgments and compliance intentions (e.g., Kreifeldt, 1993; Lehto, House, & Papastavrou, 2000). Another important example of terminology in warnings is explicitness, in which specific messages (not general ones) increase measures of warning effectiveness (Laughery & Paige-Smith, 2006). Recently, Kim, Cowley and Wogalter (2007) examined the effects of textual semantics within warning instructional statements on intent-to-comply judgments. Kim et al.

(2007) examined the effect of adding certain terms (e.g., critical, important, extremely) to warning directives to determine whether they increase compliance intentions. In general, the results indicated that some terms added emphasis to root or core instructional statements. Similar methodology is used in the present study to examine various names for recall notices.

The source of the message may also be important for credibility and urgency of the message. Research by Wogalter, Kalsher, and Rashid (1999) indicates that including relevant names of professional/scientific organizations or U.S. government agencies in warnings increases its rated credibility and people's compliance intent judgments. Wogalter et al.'s (1999) findings suggest the possibility that including the name of a U.S. government agency as part of the name of the recall notice might add value compared to the use of a non-government entity such as a product manufacturer. This issue is examined in the present research.

It is generally desired that research uncover principles that are applicable beyond the specific circumstances of the research. Thus it would be desirable to come up names of recall campaigns that are applicable to all products. However, there may be appropriate exceptions to the general "rules" for naming recall campaigns. Consider a special type of product, such as a surgically-implanted medical device (e.g., pacemakers). Indeed, 21% of all medical device recalls involve cardiac medical devices (Wallace & Kuhn, 2001). Moreover, medical device recalls have been increasing in number (Maisel, Sweeney, Stevenson, Ellison, & Epstein, 2001). The problem is that surgically-implanted medical devices cannot be "recalled" like other products. Return to the manufacturer cannot be easily accomplished if the device is already implanted. Moreover, the promulgation of a surgically implanted device recall may cause heightened anxiety and fear in affected persons. These negative emotions may not be justified, as the device might not actually be defective (e.g., it simply needs to be monitored more closely). In addition, these emotions might negatively influence whether some people will use this form of treatment in the future. Given that surgically implanted medical devices are different than most other products with respect to return or disposal, should it have the same or different name than other defective product recall campaigns? It is possible that consumers believe that *all* defective product notifications should have the same consistent name or do they believe an exception should be made exclusively for surgically-implanted devices? These questions are among those addressed in the present research.

## METHOD

### Participants

Data was collected from two different groups of participants. For the first group, data was collected ( $n = 94$ ,  $M_{age} = 37.8$ ,  $SD_{age} = 13.9$ ) from undergraduates at two U.S. universities ( $n = 31$ ,  $M_{age} = 24.5$ ,  $SD_{age} = 6.0$ ) and from a sample of non-student adults ( $n = 63$ ,  $M_{age} = 44.4$ ,  $SD_{age} = 11.7$ ) in the Raleigh-Durham area of North Carolina. The university student group was composed of 22.6% males and 77.4% females, and they reported themselves to be in the following race/ethnic categories: 38.7% Hispanics and Latinos, 32.3% Caucasians, 12.9% African Americans, and 9.7% Asian and 6.4% other ethnicities. The nonstudent adult group was composed of 69.8% males and 30.2% females with self-reported race/ethnic classifications of 79.4% Caucasian, 17.5% African American and 3.1% Hispanic or Latino.

For the second group of participants collected ( $n = 143$ ), the mean age was 25.7 years ( $SD_{age} = 11.4$ ). There were 71 males and 72 females and the self-reported ethnic classifications were 69.9% Caucasian, 15.4% African American, 3.5% Asian and 11.2% other.

### Materials and Procedure

Each participant completed a consent form followed by a demographics form and then were given the main study questionnaire with 3 parts.

In **Part 1**, participants were given a page of background information to read explaining the processes of recalls involving private companies and the FDA.

*Imagine you are in charge of notifying the public about a potentially hazardous product, which after having left the manufacturer, is discovered to be potentially unsafe. Assume it could be a food product, a medicine, or a medical device, such as contaminated canned meat, substandard antibiotics, or a defective blood-sugar meter.*

The participants were then asked to examine the provided list of 61 potential names/titles of recall notices, and then asked to rate the appropriateness of each using a 9-point scale with the following numerical anchors and associated text: (0) *not at all appropriate*, (2) *somewhat appropriate*, (4) *appropriate*, (6) *very appropriate* and (8) *extremely appropriate*.

**Part 2** began with a printed description of how a recalled surgically implanted medical device might or might not be a problem if the term *recall* was used in the name. Specifically stated was the following:

*Some medical devices are surgically implanted inside a human body, such as heart pacemakers. Sometimes after surgery, it is discovered that some of the implanted devices may have defects and they*

*need to be recalled. These situations are different from most other kinds of recalls of defective products because the people who have these devices may need to visit a physician, and may need to have another surgery to remove the device. However, "recalled" implanted devices are not always defective and may not need to be removed, but rather monitored more frequently by the physician. Thus there is some concern that people with the recalled device may panic unnecessarily. Here is the issue: Because users cannot simply "return" their surgically implanted device and may become anxious, do you think the word 'recall' should be used in these notices?*

After reading the above paragraph, participants were asked to rate their agreement for the three items listed in Table 3 on a 9-point scale using the following numerical textual anchors: (0) *do not agree at all*, (2) *somewhat agree*, (4) *agree*, (6) *very much agree* and (8) *completely agree*.

**Part 3** asked participants to rate, using the same rating scale as in Part 1, a set of 14 individual terms that were components of phrases used in Part 1. The list of terms can be seen in Table 2.

## RESULTS

Table 1 shows the mean ratings and standard deviations of the 61 names/titles of recall notices. The list is ordered from the highest to lowest means. Certain components in the names tended to appear in the higher rated items. These included the words *Urgent*, *Recall*, *Alert*, *Danger*, and *FDA*. Of these, names with *Urgent* tended to be rated consistently the highest. Also, *Danger* was present in only a few names which were also highly rated.

**Table 1.** Mean Appropriateness Ratings (and SD) for Names/Titles of Recall Notices Ordered from Highest to Lowest (n=94)

Name	Mean	SD
FDA Urgent Recall Notice	5.72	2.00
FDA Public Safety Warning	5.70	1.98
Urgent Product Recall Bulletin	5.57	2.14
Product Danger Alert	5.54	2.16
FDA Urgent Recall	5.51	2.18
Public Safety Warning	5.49	2.12
Urgent Recall Notice	5.46	2.08
Urgent Recall	5.46	2.32
Product Danger Notice	5.36	2.25
Urgent Product Recall	5.31	2.13
FDA Recall Warning	5.23	2.01
Unsafe Product Notice	5.22	2.12
FDA Safety Warning	5.18	1.92
Product Warning Alert	5.17	2.24
FDA Unsafe Product Notice	5.13	2.35
Urgent Recall Bulletin	5.12	2.18

FDA Health and Safety Alert	5.05	2.22
FDA Alert	5.04	2.20
FDA Unsafe Product Advisory	5.03	2.27
FDA Health and Safety Bulletin	5.03	1.98
Company-X Urgent Recall	5.02	2.36
Product Warning	5.00	2.16
Company-X Urgent Recall Notice	4.99	2.34
FDA Warning	4.95	2.16
FDA Recall	4.90	2.25
Recall Notice	4.82	2.44
Public Safety Notice	4.79	2.20
FDA Safety Alert	4.74	2.13
Safety Warning	4.72	2.15
Product Recall Notice	4.70	2.22
Unsafe Product Advisory	4.69	2.21
Public Safety Alert	4.66	1.99
Urgent Notice	4.63	2.34
Recall Warning	4.62	2.15
Health and Safety Alert	4.60	2.39
Product Alert	4.57	2.33
Product Recall Warning	4.56	2.22
Company-X Warning	4.47	2.30
Company-X Recall Notice	4.40	2.40
Health and Safety Bulletin	4.39	2.40
Product Warning Notice	4.39	1.99
Safety Notice	4.36	2.21
Company-X Recall	4.31	2.33
Safety Alert	4.30	2.37
Product Recall Bulletin	4.28	2.26
FDA Notice	4.28	2.30
Public Safety Bulletin	4.21	2.36
Recall Bulletin	4.18	2.52
Safety Advisory	4.12	2.18
Safety Alert Bulletin	4.10	2.15
Safety Bulletin	4.06	2.40
Safety Recall Bulletin	3.99	2.12
FDA Bulletin	3.99	2.38
FDA Advisory	3.95	2.32
Product Advisory	3.94	2.40
FDA Safety Bulletin	3.85	2.26
Company-X Advisory	3.26	2.35
Product Notice	3.14	2.36
Company-X Notice	2.98	2.49
Company-X Bulletin	2.60	2.31

Mean ratings and standard deviations for the individual words evaluated in Part 3 are shown in Table 2. Note that the highest rated single terms in Table 2 were components of the highest rated names given in Table 1.

Phrases extracted from Part 1 containing the source entity *FDA* or *Company-X*, were analyzed to determine whether they were rated differently. Both entities were paired with the root words (*Bulletin*, *Warning*, *Recall*, *Advisory*, and *Notice*) and the means are displayed in Figure 1 and Table 1. The standard deviations were fairly homogeneous ranging from 2.16 to 2.89. A 2 (Source entity: *FDA* vs. *Company-X*) X 5 (Paired root words: *Bulletin*, *Warning*, *Recall*, *Advisory*, *Notice*) repeated measures analysis of variance (ANOVA) showed a significant main effect for both entities,  $F(1, 93) = 42.27$ ,  $p < .0001$ , and root words,  $F(4, 372) = 22.88$ ,  $p < .0001$ .

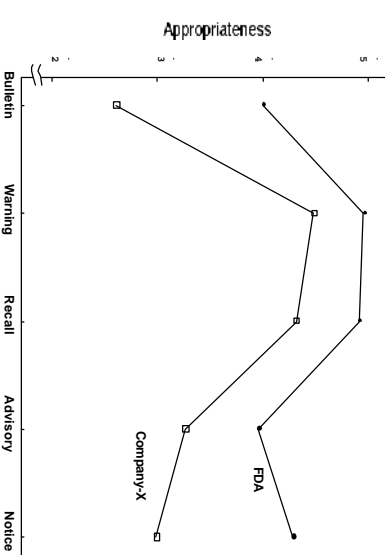
*FDA* received significantly higher ratings than *Company-X*. The terms *Warning* and *Recall* were given the highest mean ratings among the root words. The ANOVA also showed a significant interaction between root words and entities,  $F(4, 372) = 4.25, p < .01$ . The interaction means are displayed in Figure 1. The graph shows a pattern of means reflecting the main effects described above with the exception that the difference between the two entities was larger for *Bulletin* and *Notice* than for other root words.

**Table 2.** Single Word Mean Appropriateness Ratings in Recall Campaign Names ( $n=143$ )

Single Words	Mean	SD
Urgent	6.37	1.61
Recall	6.26	1.83
FDA	6.00	2.13
Danger	5.97	2.06
Warning	5.87	1.68
Unsafe	5.80	1.93
Alert	5.71	1.77
Safety	5.34	2.09
Health	5.33	2.02
Product	4.71	2.35
Advisory	4.62	2.00
Notice	4.05	2.20
Public	3.99	2.28
Bulletin	2.87	2.06

In Part 2, participants were asked to rate three items pertaining to the use of the term *Recall* in the name of a product-defect notification involving a surgically-implanted medical device. The means and standard deviations are displayed in Table 3.

**Figure 1.** Mean ratings of appropriateness for word pairs involving entities and root words



**Table 3.** Means and Standard Deviations for Items Concerning the Use of the Term "Recall" with Respect to Medical Devices ( $n=94$ )

Mean	SD	Item
(a) 3.50	2.9	The word 'recall' should be used for <i>all</i> defective and potentially hazardous food, medicines and implanted medical devices.
(b) 5.09	2.7	A <i>different</i> word other than 'recall' should be used as part of the name for notices specifically concerning surgically implanted devices. The word 'recall' should only be used for all other instances of potentially hazardous food, medicines, and (non-implanted) medical devices.
(c) 2.55	2.8	The word 'recall' should <i>not</i> be used at all as part of the name of notices for potentially hazardous food, medicine and medical devices. Rather, another name should be used to fit <i>all</i> kinds of defective products (including surgically implanted ones).

A one-way repeated measures ANOVA applied to the data in Table 3 was significant,  $F(2, 186) = 17.84, p < .0001$ . Comparisons among the means using Tukey's HSD test ( $\alpha = .05$ ) showed that participants indicated the highest agreement to the second statement (Table 3, Item b), i.e., that the term *Recall* is appropriate for non-surgically implanted products but a different term other than *Recall* should be used for surgically implanted medical devices. The other two statements in Table 3 (Items a and c) were significantly lower and did not differ between themselves.

**DISCUSSION**

Although there has been research on terms used in warnings, this study provides insight into a somewhat different kind of safety communication: product-defect recall notifications. The results showed that in two separate assessments (one evaluating names of recall campaigns and the other evaluating individual component words), certain individual terms consistently produced high ratings of appropriateness for product-defect recall notification names. The top eight individual words from an independent group of participants were often components of the highly rated names: *Urgent*, *Recall*, *FDA*, *Danger*, *Warning*, *Unsafe*, *Alert*, and *Safety*. Similarly, the six highest rated names were: *FDA Urgent Recall Notice*, *FDA Public Safety Warning*, *Urgent Product Recall Bulletin*, *Product Danger Alert*,

*Public Safety Warning, and FDA Urgent Recall.* Given these results, consideration should be made to the use of the highest rated names and components of titles of actual product-defect notifications.

While the highest rated names tended to be 3 to 4 words, if greater brevity was desired then there were several 2-word phrases (e.g., *Urgent Recall*) that were rated nearly as high as longer names. Interestingly, both in this study on recall names and in Kim et al.' (2007) study with warning instruction statements, the word *Urgent* produced some of the highest ratings.

The results also showed that the inclusion of the source entity, *FDA*, produced higher ratings than a name with *Company-X*. This hierarchy was maintained across several root word pairings. Nevertheless, given the methodology employed, it is unclear whether the findings would generalize to an actual company name or to a different government agency (e.g., the U.S. Consumer Product Safety Commission). However, the direction of the findings is consistent with past research showing that the inclusion of the name of a government entity enhances warning credibility and compliance intent (Wogalter et al., 1999).

This research provides some insight with respect to consistent terminology for recalls and/or warnings. A common design strategy is to use standardized terminology and formats. However, the results of the present study suggest something somewhat different. The results showed that people believed it permissible not to use the term *Recall* for surgically-implanted medical devices, despite the fact that they believed that the term *Recall* should be used in other product defect campaigns. Thus, the "rules" should allow the use of different terminology for unique situations. This last finding further suggests that additional research is needed to determine the specific, appropriate wording for names of surgically implanted medical device "recall" campaigns as well as wording for other unique situations.

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