## Feature Article

# Print DTC: How Does It Measure Up?

*A Quantitative Analysis of Risk vs. Benefit Information*

By **John Mack**

FDA's draft guidance "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" encourages manufacturers to use clearer, less cluttered formats for presenting risk information in direct-to-consumer (DTC) print ads. FDA suggests that drug advertisers focus their risk disclosures on the most important and the most common risks and to do so in language easily understood by the average consumer. This is often referred to as the "less is more" approach (see "FDA Draft Guidance for Print DTCA: Less than Feared").

The brief summary is the part of DTC ads that conveys detailed risk information. Typically, this information appears on the back side of the print ad and is written in small type.

"FDA believes that exhaustive lists of minor risks detract from and make it difficult to comprehend and retain information on the more important risks."

**Is Less or More Better?**

Despite the allure of "less is more" doublespeak, most drug companies still prefer the "more is better" approach and opt to use the FDA-approved professional labeling (aka, package insert or PI) to fulfill the brief summary requirement for print ads.

In addition to the brief summary required in print ads, the FDA requires "fair balance" in the creative area of the ad itself. According to the Federal Food, Drug, and Cosmetic Act, fair balance is "[T]he presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness or safety."

**Some Like it Less**

While FDA and the drug industry are looking for ways to strike the right balance between benefit and risk information in print DTC ads, some organizations, including the Coalition for Healthcare Communication (CHC), a coalition of major advertising, marketing and PR organizations, and the conservative Washington Legal Foundation (WLF), seem to want to eliminate the risk information altogether or to allocate the task of communicating risk completely to the "brief summary."

CHC and WLF contend that the creative section of print DTC ads includes too much risk information or information that already appears in the brief summary. This, they contend, either confuses the consumer or takes away from the benefits of DTC ads.

For more on the CHC proposal regarding risk communication in DTC ads, see "DTC without the Risk." For a critique of the WLF's case, see "WLF: A No-Risk Ad is a Good Ad."

**A Quantitative Approach**

The "less is more" argument and the criticisms of CHC and WLF shout out for a quantitative analysis of risk vs. benefit information in print DTC ads.

Such a quantitative analysis would be useful to establish at least a baseline for further discussion about whether or not the creative sections of print DTC ads for prescription drugs carry too much risk information. A purely "mechanistic approach" to interpreting and applying the fair balance requirement, however, would not be practical or fair from a regulatory standpoint.

To perform the analysis, I collected over 60 drug ads that appeared in several major consumer magazines and measured the space allocated to images, benefit statements, risk information, and the brief summary (see FIGURE 1, next page). This article summarizes my findings.

**Methodology**

Sixty-one (61) Rx and seven (7) over-the-counter (OTC), non-prescription print ads were included in this study (see Tables 1 and 2 in the "Print Ad Data Pack"). The square inches allotted to the following elements of each ad were measured:

1. Image
2. Benefit statements
3. Risk statements; ie, "fair balance" [applies to Rx ads only]
4. Brand logo
5. BRC (if included)
6. "Brief Summary" [applies to Rx ads only]

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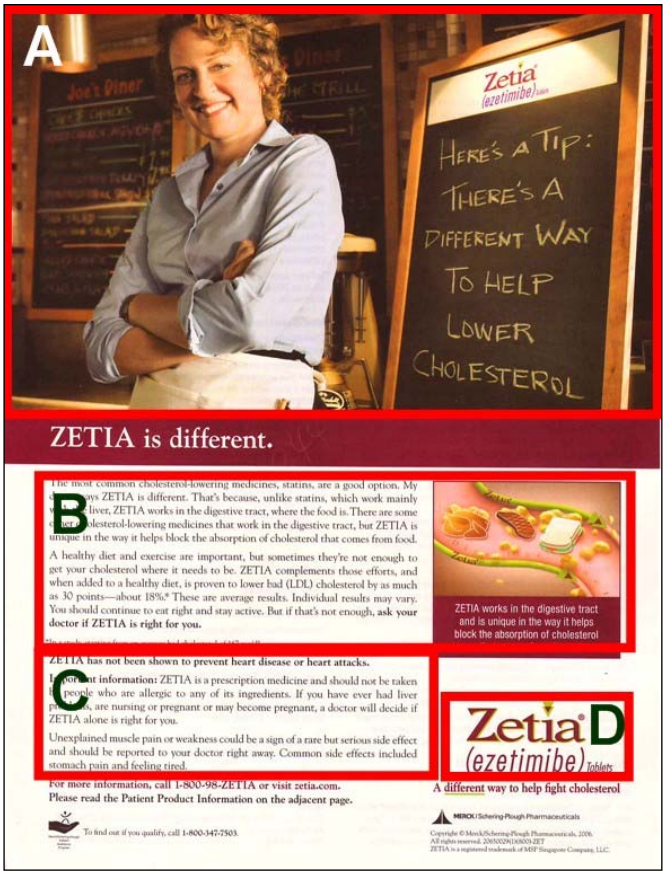


FIGURE 1: Typical Rx DTC print ad. This is the "creative area" of a Zetia print ad, which appeared in the July 2006 issue of *Arthritis Today*. Shown are the different sections of the ad that were measured in this study: A=image area, B=benefit statement area, C=fair balance area, and D=brand logo. Not shown is the "brief statement," which is on the back side of the ad.

To do the measurements, a simple ruler was used to measure the width and height of each element. Area was calculated and the results as percentages of the total "creative ad space" were recorded in an Excel spreadsheet (see Tables 3, 4, and 5 in the "Print Ad Data Pack").

It was sometimes difficult to compartmentalize information into one area or another, especially when trying to distinguish what to include as part of the benefit statement. For example, the statement "Zetia is different" in the ad shown in FIGURE 1 is clearly a benefit statement, but it is not included in the benefit area; instead the illustrative graphic showing food moving through the intestine was included as part of the benefit statement.

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Also, image areas are often overwritten with or contain embedded benefit text statements (eg., the blackboard in the Zetia ad). These statements were not included in the benefit measurement unless the text overwhelmed the image underlying it or was not integrated into the image (see FIGURE 2). Since image areas hardly ever contain risk test, if anything, the methodology employed in this study tends to under represent the amount of ad space devoted to benefit statements.

Ads were also characterized as to whether or not they included the following specific items:

- PAP (Patient Assistance Program) or PPA notice (Partnership for Prescription Assistance)
- "Ask Your Doctor" callout
- Life style message
- Consumer-friendly, question-and-answer organized, large-type formatted "brief summary"

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FIGURE 2: The Nasonex ad image (left), which occupies 71% of ad space, contains text threaded through it that is clearly a benefit statement. However, this text wasn't included in the benefit area (2.9% of the ad space) because it was such an integral part of the image. On the other hand, the text over the image in the Abilify ad (right) clearly must be included as part of the benefit and risk statements and not part of the image. In this ad, therefore, only the image of the woman, which occupies 15.4% of the ad space, is considered the image area whereas the benefit and fair balance occupy 44.2% and 21.5%, respectively.

The vast majority of Rx and OTC ads in this study appeared in consumer publications between June and September, 2006.

For a list of the drug ads in this study, plus all the data, please download the "Print Ad Data Pack" (pdf file).

**Space Allocated to Image**

As expected, a large portion of OTC and Rx print ads are devoted to imagery (64.1% and 46.0%, respectively; see FIGURE 3, right). Images are most often photographs of people enjoying life or the benefits of treatment by the advertised drug. The image in the Nasonex ad shown in FIGURE 2, for example, clearly demonstrates the benefit of enjoying pets, carpet cleaning, and flowers without suffering allergy symptoms. It's unclear, however, what message the angry-looking bee coveys.

Also as expected, images in OTC ads occupy a much larger portion of the ad area than images in Rx ads. Relatively speaking, OTC ad images take up 39% more of the total ad space than images in

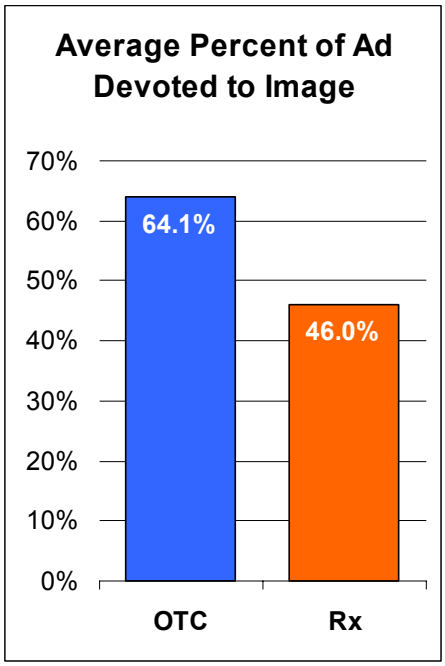


FIGURE 3: Percent of Ad Devoted to Image

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Rx ads. The absolute difference (64.1% minus 46.3%) is 17.8%. This "extra" space in Rx ads is used to present relatively more benefit and fair balance information in text format than is available in OTC ads (see below).

**Image Area by Indication**

There was quite a range in the percent allocated to images in Rx ads—from 4.3% (Astelin) to 81.4% (Rozerem). Generally, insomnia drug ads (Rozerem and Lunesta) dedicated a much greater portion of the ad to images than did ads for drugs with other indications (see FIGURE 4).

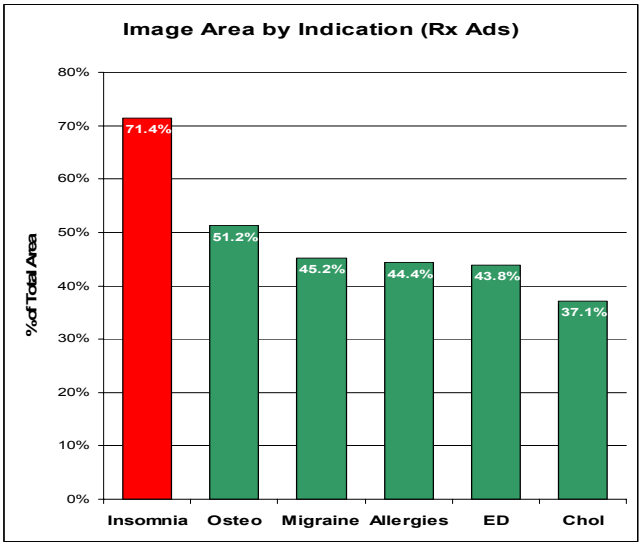


FIGURE 4: Percent of Ad Devoted to Image in Rx Ads, by Indication

**Space Allotted to Benefit Statements**

In OTC ads, benefit statements comprise 13.8% of the ad space, whereas in Rx ads, these statements take up 19.3% of the ad space.

On the Rx side, there was quite a range in the percent that ads dedicated to benefit statements: 0.0% to 61.1%. The Botox Cosmetic ad contained absolutely no explicit benefit information—it is a "reminder ad," which does not make any representation (in words) about the drug's indication, benefits or, unfortunately, risks. The image, however, conveys a positive feeling that some might interpret as a benefit statement (see FIGURE 6, next page).

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## Not All Ads Require Risk Disclosure

There are two types of DTC ads that mention the drug name, product-claim ads and reminder ads. The differences between these types of ads are listed below. Only product-claim ads require inclusion of risk information (ie, fair balance and brief summary). While new PhRMA voluntary DTC guidelines call for the elimination of reminder ads on TV, same pharmaceutical companies have not signed on or still run reminder ads (see, for example, "Sepracor Sneaks In Lunesta Reminder Ad").

### Product-claim ads:

- mention a drug by name
- make representations about the drug, such as its safety and effectiveness
- must have fair balance of information about effectiveness and risks
- are required to disclose risks in a "brief summary" of benefits and risks (for print ads)
- are required to give a "major statement" of risks and "adequate provision" for finding out more, such as a toll-free number (for broadcast ads).

### Reminder ads:

- provide the name of the medication
- may provide other minimal information, such as cost and dosage form
- do not make a representation about the drug, such as the drug's use, effectiveness, or safety

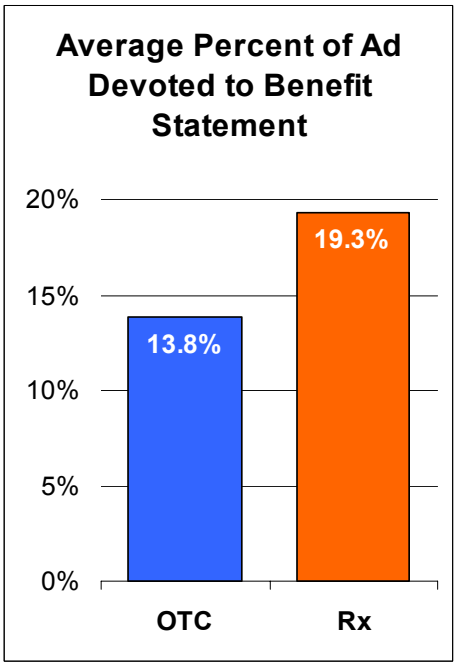


FIGURE 5: Percent of Ad Devoted to Benefit

**Reminder Print Ads**
The Botox ad (FIGURE 6, left panel) by Allergan is a rare example of a "reminder" print ad. Allergan, which also runs reminder TV DTC ads for Botox, is not a signatory to the PhRMA's Guiding Principles for DTC Advertising, which does not apply to print ads.

Compare the Botox ad to a Claritin ad (FIGURE 6, right panel). The Claritin ad is representative of an OTC ad. These two ads are similar with regard to the space they allocate to images (66% and 76%, respectively) as well as fair balance information (0% for both). The Claritin ad, of course, can mention benefits, yet only devotes 8.3% of the ad space to that purpose. It's a good example of what an Rx ad might look like if the FDA adopted the suggestions of the WLF, which advocates relying entirely on the brief summary to communicate risk information.


FIGURE 6: Reminder Print Ads Resemble OTC Print Ads. Botox Rx (Reminder) Ad, left; Claritin OTC Ad, right.

The five drug ads with the *smallest relative area dedicated to describing* ***benefits*** are:

| Brand | Indication | % of Ad |
|---|---|---|
| Botox Cosmetic | Winkles | 0.0% |
| Nasonex | Allergies | 2.9% |
| Rozerem | Insomnia | 5.1% |
| WellbutrinXL | Depression | 6.3% |
| Avandia | Diabetes | 7.0% |

The five drug ads with the *largest relative area dedicated to describing* ***benefits*** are:

| Brand | Indication | % of Ad |
|---|---|---|
| Coreg | Congestive Heart Failure | 61.1% |
| Restasis | Chronic Dry Eye | 47.6% |
| Abilify | Bipolar Disorder | 44.2% |
| Levitra | Erectile Dysfunction | 43.8% |
| Imitrex | Migraine | 37.2% |

**Space Allotted to Fair Balance Statements**
Only 11.8% of Rx ad space is devoted to fair balance statements (vs. 19.4% devoted to benefit statements). There is quite a range, however. Botox print ads have no benefit statements at all. Coreg had the most space devoted to benefits (61.1% vs. 13.3% devoted to fair balance).

The five drug ads with the *smallest relative area devoted to* ***fair balance*** are:

| Brand | Indication | % of Ad |
|---|---|---|
| Botox Cosmetic | Winkles | 0.0% |
| Nexium | Erosive Esophagitis | 2.0%* |
| Nasonex | Allergies | 3.6% |
| Aloxi | Chemo-induced Nausea | 3.7% |
| Astelin | Allergies | 4.1% |

* Ad in Prevention Magazine devotes 0% to fair balance.

The five drug ads with the *largest relative area devoted to* ***fair balance*** are:

| Brand | Indication | % of Ad |
|---|---|---|
| Humira | Rheumatoid Arthritis | 40.7% |
| Viagra | Erectile Dysfunction | 28.6% |
| Celebrex | Pain | 23.7% |
| Remicade | Rheumatoid Arthritis | 22.9% |
| Daytrana | ADHD | 21.7% |

**Benefit vs Risk**
If the space allocated to fair balance information in print ads was equal to the space allocated to benefit statements, all the points in the scatterplot

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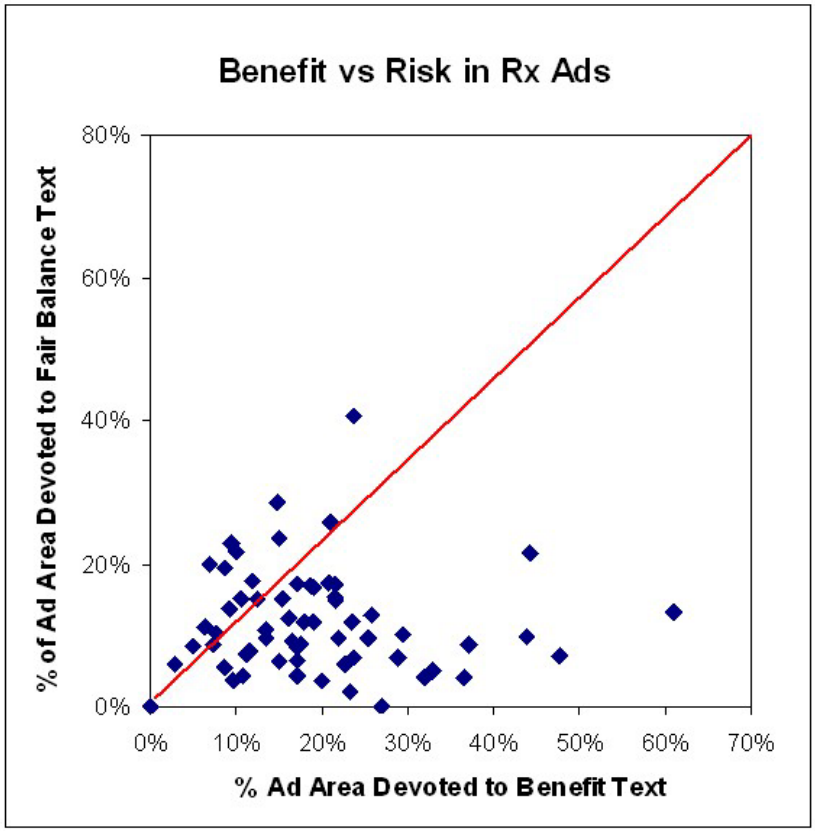


FIGURE 7: Benefit vs. Risk Scatter Plot (Rx print ads)

in FIGURE 7 would lie on the red diagonal line. In fact, in a large majority (69%) of Rx print ads, more space is allocated to benefit information than to fair balance (ie, points lie BELOW the red line in FIGURE 7). While 39% of Rx print ads allocate 20% or more of ad space to benefit statements, only 11% allocate more than 20% to fair balance information.

Overall, the space allocated to fair balance is 84% of the space allocated to benefit statements. That is, for every square inch of benefit information, there is only 0.84 square inch of fair balance information.

Critics contend that the current level of risk information in DTC ads overwhelms the benefit message and consumers would be "more" educated when confronted with "less" risk information in ads. Leaving aside the "brief summary," which most people do not read, the results of this quantitative analysis do not support the idea that risk information in the creative area of print ads overwhelms the benefit information.

Of course, OTC ads do not include any fair balance (risk) information at all. Yet, *even less space is devoted to benefit statements in OTC ads than in Rx ads* (13.8% vs. 19.3%; see FIGURE 5). This suggests that Rx drug advertisers have compensated for the required risk statement by allocating more space to benefit statements.

If drug advertisers were allowed to eliminate the fair balance portion of print ads—that is, if Rx ads were more like OTC ads except for the "brief summary" on the reverse side of the ad—the OTC evidence in this study suggests that the extra ad space would be allocated to images rather than to more benefit information. Given the ambiguous messages conveyed by many images in print ads (eg, Rozerem; FIGURE 8), this would hardly result in Rx ads that conveyed better benefit information overall.

**Images and Fair Balance**

Diana Zuckerman of the National Research Center for Women & Families, in testimony at a public hearing hosted by the FDA on DTC advertising, suggested that the power of DTC is in the images, not the words. Images, most often used in DTC to illustrate benefits, are so powerful, she contended, that they defeat any attempt at fair balance.

If the image area of an ad is considered part of the benefit statement, then the ratio of fair balance to benefit falls to just 19% on average for all print ads examined.

Zuckerman's suggestion left the FDA wondering how it would regulate images to achieve fair balance—how could they measure the effect of images? Clearly, not every image in an Rx ad can be characterized as conveying a pure benefit statement. Zuckerman was unfazed, however, and offered this solution: the only way to guarantee fair balance is to do away with images in ads.

**Ad Images Can Confuse**

Most images in print and TV DTC ads are pretty straightforward and show people enjoying the benefits of taking the advertised drug. It could be Dorothy Hamil ice skating or a woman blissfully sleeping.

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Some ads, however, use images that are confusing even to marketing professionals. A case in point is the ad campaign for the sleep aid drug Rozerem.

This ad was discussed in a post to Pharma Marketing Blog (see "Rozerem Ads Dis Lincoln, Show Beaver"). Many commenters were confused about what message the image of Lincoln and the beaver were supposed to convey.

Most experts suggested the goal of the imagery was to create "buzz" and because it generated so much discussion, the goal was achieved.

**Consumer-Friendly "Brief Summary"**

"There has been a great deal of discussion about the brief summary that accompanies DTC print ads," says an article in FDA Consumer Magazine ("Truth in Advertising: Rx Drug Ads Come of Age"; FDA; July/August 2004). "The typical brief summary is not brief and uses technical language. This is because it reprints all of the risk information from the physician labeling. People have complained that the brief summary cannot be understood by consumers. Kathryn J. Aikin, Ph.D., a social scientist in DDMAC says, 'Patients do not typically read the brief summary in DTC print ads unless they're interested in the product.' Even then, she says, much information is likely glanced at, rather than fully read."

Recently, Pfizer submitted to the FDA for review a new consumer-friendly and consumer-tested print brief summary. This consumer-friendly version is written in a question-and-answer format in a large, easy-to-read typeface. Pfizer says it will use this new format in all its print advertising and on all of its product Web sites if the FDA approved the new version (see "Pfizer Announces Improvements to Consumer Advertising for Prescription Medicines," August 11. 2005).

Print Rx ads have a long way to go in improving the brief summary. Only 57% of the Rx print ads in this study used a question-and-answer format for the brief summary. Not all of these were in the new Pfizer format and not all used a large font typeface. Surprisingly, Pfizer's new print ad for Caduet, a dual action cardiovascular pill that combines Norvasac and Lipitor, uses an old-fashioned, mouse type format presented in 2 full pages!

**Pharma Marketing News**

## Industry Expert Calls for FDA-Mandated Patient Friendly Brief Summary

*The following is excerpted in its entirety from the September 15, 2006, DTC in Perspective eNewseletter. The title of the original piece was "The Progress on Brief Summaries." It is reproduced here with permission from the author.*

I have been a strong advocate that all DTC print ads contain an understandable brief summary. My philosophy is simple. Any ad meant for a consumer should contain information that is readable and understandable for a basic reading level. If the drug industry wants a consumer friendly reputation it cannot continue to view risk and side effect information in the brief summary as merely a legal requirement.

To date most brands have switched to a patient friendly summary. There are still a number of leading brands, however, that have failed to make this move. I am told it is because legal and regulatory still prefer the full medical brief summary to cover all risks in the approved labeling. This has the practical effect of making the summary useless for consumers.

What is more disturbing than older brands failure to produce a consumer brief summary are the new brands launched recently with the old medical style. These brands have had plenty of time pre-launch to develop the consumer language needed. I am sure the brand managers would tell me that they are developing a replacement summary and that it was not a priority at launch for them or FDA. New brands, however, have a special obligation to tell consumers the full story in understandable terms because of the lack of real world use. I will not name names here, but some well known drug companies are involved.

I think that PhRMA should have made understandable brief summaries part of their DTC guidelines. The fact that some companies can do it for all their drugs makes the legal argument of the others hard to believe. At this point I have to blame senior management for not stepping in and making a policy decision to overrule legal.

My suggestion to the FDA is that they should mandate patient friendly brief summaries as part of any DTC overhaul. After more than ten years of heavy DTC print ad use, the drug industry has run out of acceptable reasons not to make their ads fully understandable.

**Bob Ehrlich**, Chairman
DTC Perspectives, Inc.