Communicating Risk: Let the Dialog Begin
By John Mack

On March 30, 2006, John Kamp, Executive Director of the Coalition for Healthcare Communication (CHC) and frequent Pharma Marketing Roundtable participant, was kind enough to send me a copy of a Citizen Petition his organization was to file with the FDA at 9 AM on the following day (March 31, 2006). This was the first time I heard of this petition and when I opened the pdf file and read it, I immediately took away the message that the CHC—comprised of major advertising, marketing and PR organizations, including the American Association of Advertising Agencies, the Association of National Advertisers, and the Public Relations Society of America—was proposing the elimination of specific risk information in direct-to-consumer (DTC) TV, print, and Internet ads. The next day (7:35 AM, March 31, 2006) I published my reaction entitled “DTC Without Risk” in the Pharma Marketing Blog (see excerpts below; read the full text).

At the same time, I sought opinions from readers and visitors to Pharma Marketing Network by launching an online survey that asked two simple questions: (1) In your opinion does this proposal have merit? and (2) How likely is it that the FDA will adopt the recommended amendment to its DTC regulations? The results to date from this survey are presented in this article.

Surprisingly, there wasn’t any response from my friends at the CHC, a couple of whom, it turns out, were out of the country. Therefore, I reached out to Harry Sweeney, CHC’s Executive Committee Chair, Pharma Marketing Roundtable member, and Pharma Marketing News Advisory Board member, and suggested to him that a PM Roundtable conference call would be a good forum for CHC to clarify its proposal. He agreed. This article presents a lightly edited transcript of that call plus excerpts from news stories about the CHC petition, results of the survey and a collection of comments from survey respondents and bloggers.

Pharma Marketing Roundtable Discussion
The participants in the April 13, 2006 Pharma Marketing Roundtable conference call were (for contact information, please see “Experts Consulted and/or Cited In Articles,” pg. 18):

- Jack Angel, representing CHC
- Jack Barrette, Yahoo!
- Neil Gray, Healthcare Trends & Strategies
- John Mack, Pharma Marketing News
- Harry Sweeney, representing CHC

John Mack: As you know, the Coalition’s recent Citizen’s Petition to the FDA seeks new prescription drug advertising rules and specifically calls for simplifying the communication of risk information in broadcast, print, and Internet DTC ads. My initial interpretation of the petition after a careful reading was that the CHC proposed the elimination of specific risk information in DTC ads and I wrote a critical blog based on that interpretation. Excerpts from this posting are reproduced here.

“DTC without the Risk”
(Posted to Pharma Marketing Blog, March 31, 2006. See http://www.pharma-mkting.com/blog/blogpost149.htm.)

The Coalition for Healthcare Communication (CHC)... proposal calls for the elimination of specific risk information in print and broadcast DTC (direct to consumer) advertising. You know, things like erections lasting 4 hours or longer and sleep binge eating; great material for comedians but a royal pain in the ass for advertisers.

Instead of eliminating DTC or grappling with how to communicate risk, the CHC simply wishes to do away completely with the necessity to communicate risk in DTC -- including print and Internet DTC! And they call themselves communicators!

CHC's argument goes something like this:

1. Consumers are too dumb to weigh all the risks vs. benefits [CHC doesn't use that derogatory term. Their petition uses the more PC phrase "consumers with different educational and economic backgrounds"]
2. Only prescribers -- "learned intermediaries" -- can do this
3. DTC ads are effective at getting consumers to visit their doctors and ask about treatment and not effective as an educational tool
4. DTC ads, therefore, should not mention specific risks, just say that there are risks and direct consumers to discuss these risks with their physicians.

QED.

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Here’s what the CHC envisions the risk statement in a DTC ad to look like:

“Like all drugs, [drug name] has both benefits and risks. [Drug name] is only available by prescription, and your doctor can explain how [drug name] is likely to affect you. Be sure to tell your doctor about all of your medical conditions, and about any other medications you are taking, because this information could affect whether you should take [drug name]. Remember, only your doctor can decide if [drug name] is best for you.”

According to the CHC, "the patient is the decision-maker only with respect to whether a practitioner should be approached." How atavistic can you get?

Obviously, I could go on all day about this. I prefer, however, to open this up to your comments…

John: It turns out that I was not alone in how I interpreted the petition. The Associated Press, for example, reported on April 1 – a day after my blog post appeared – that the CHC “wants to strip most of the warnings from prescription drug ads aimed at consumers.” After doing a search on Google for other stories and blogs related to this petition, and after surveying readers of Pharma Marketing News, I found that the general reaction has not been very positive. Harry, I don’t know if you’ve seen all this criticism, but maybe you can give us your perspective.

Harry Sweeney: When I saw your blog I was quite taken aback; the very first highlighted statement says the proposal calls for the elimination of specific risk information (“The proposal calls for the elimination of specific risk information in print and broadcast DTC…”). This is simply wrong! I was really crestfallen at how that came to pass, because the CHC for 10 to 12 years has stood for more communication, more information, not less. So how that got misinterpreted was confounding to me.

There is nothing in the CHC press release (see “Coalition for Healthcare Communication Seeks New Prescription Drug Advertising Rules”) about eliminating specific risk information; there is certainly nothing in the submission to the FDA (see the full text of the petition) that suggests that. What it does suggest is that there has been a failure to recognize the differences in the amount of information that can be communicated effectively per medium, and also that the kind of information that should be provided needs to be tailored, depending on the audience. We have never wavered from supporting the “learned intermediary” doctrine, which recognizes that prescription drugs have serious as well as not-so-serious risks, but there is a balance of risks and benefits and that’s why they require a licensed professional to prescribe them.

John: But in support of its proposal, in a section of the petition with the heading “Statutory Support for the Proposed Revision,” the CHC points out that the current FDA side effect disclosure requirements "does not require comprehensive side effect disclosure or even specific side effect disclosure…” This leads me to believe that the CHC is proposing, when all is said and done, that specific risks need not be included.

The petition also suggests specific language to use in DTC ads and this language does not suggest that any specific side effects be mentioned. (The petition offers this example of language in a footnote: “Like all drugs, [drug name] has both benefits and risks. [Drug name] is only available by prescription, and your doctor can explain how [drug name] is likely to affect you. Be sure to tell your doctor about all of your medical conditions, and about any other medications you are taking, because this information could affect whether you should take [drug name]. Remember, only your doctor can decide if [drug name] is best for you.”)

Harry: The language suggested is exemplary, rather than mandatory. The Petition was purposely silent about what specific risk information should be provided for which drug, because that’s got to be decided on a case by case basis. What’s the objective here? The objective is to alert consumers generally that prescription drugs are not trivial and depending on the audience. We have never wavered from supporting the “learned intermediary” doctrine, which recognizes that prescription drugs have serious as well as not-so-serious risks, but there is a balance of risks and benefits and that’s why they require a licensed professional to prescribe them.

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The underlying problem is that the “body politic” is busy drafting restrictive DTC legislation, largely without the benefit of the information generated at the three FDA hearings on DTC and risk communications. One of our objectives was to stimulate the kind of dialog we’re having here today. No where do we suggest that information should be quashed or eliminated.

**Jack Barrette:** I’m reading the April 1, 2006, AP story (“Coalition wants most warnings banished from consumer drug ads”) – what they picked up from the press release. The story’s opening line is “Saying ‘less is more,’ a coalition of advertising and public relations groups wants to strip most of the warnings from prescription drug ads aimed at consumers.” Can you help us clarify the line between “eliminate it all,” which is clearly not exactly what you meant, and what you do mean?

**Harry:** For years there’s been a back and forth, yin-yang conversation going on about how to straighten out the brief summary, which is neither brief nor a summary. If you are a company lawyer, you want to have the kitchen sink in there so that the plaintiffs’ bar doesn’t come after you. If you are on the communications side of the fence, you throw your hands up and say: “This is having the opposite effect of what we’re trying to accomplish.” There’s plenty of anecdotal evidence (and maybe a few actual studies) which suggest that patients are reading this stuff and getting frightened, and either ignoring their doctors’ instructions, or not complying.

**John:** When I was reading the petition, I was focused on where 70% of the DTC budget is spent; ie, on TV ads where there is no brief summary. Under the CHC proposal would you say that Viagra or Cialis ads, for example, should still mention specific side effects like the four hour erection?

**Harry:** I would say that, depending on the class of drugs, there are some side effects that should be mentioned, but it would be in a simple “such as” statement. The objective here is to recognize that consumers should not be making ultimate decisions without consultation with professionals. Almost every conceivable way of getting information to consumers is available: package inserts, 1-800 numbers, etc. The old adage applies: “There are none so blind as those who will not see and none so deaf as those who will not hear.” Our objective is to assure that the kind of communications that we are creating are not part of the problem, but are part of the solution.

**Blog Comment: A Train Wreck**

The CHC’s argument is absurd on its face. The logic behind it could equally be used to argue that we should also eliminate the FDA-approved label, except for physicians. The army of pharmaceutical salespeople gives the lie to the notion of a dispassionate and independent learned intermediary. With the debacles of the past two years -- Vioxx, Celebrex, Paxil, and on and on, how can anyone be arguing for less disclosure to patients? If this is the position of the industry, then they are virtually inviting Congress to legislate limits on DTCA. Given Congress’ recent inquiries into much at the FDA -- the refusal to approve OTC Plan B, the questions re: the VNS device approval -- you’d think the industry would be trying to mollify them (e.g. PhRMA DTC "guidelines") rather than inflame them.

It’s like watching a train wreck...

**Neil Gray:** A couple of observations. First, anything that promotes clear and good education and communication between providers and patients – there’s going to be very few people who think that is not a good thing to do. I’m all for clarity over obfuscation. Being clear is always helpful in the education process.

The second point, however, is the quality of the relationship between the provider and the patient. Perhaps we are reaching the super-saturation point for DTC on television. I’m in the business, but I can’t watch any more consumer ads on TV. I simply have had my fill.

The petition has some very good merits if you read it from the vantage point of clarifying and simplifying, although leaving the dialog to the provider and the patient is not, on some level, reflecting where the public is today with access to information. When you’re thirsty, you want a drink of water but you don’t necessarily want to drink from a fire hose.

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Survey Results
Merit of CHC Petition to FDA

Pharma Marketing Network is hosting an online survey asking respondents' opinions regarding the CHC petition. The following are preliminary results from that survey. The survey will continue through May 30, 2006. Give us your opinion online at http://www.surveymonkey.com/s.asp?u=584891966082.

Merit vs Likelihood of Adoption
When asked “In your opinion, does this proposal have merit?,” 50% of respondents said “Yes” and 50% said “No.” However, when asked “How likely or unlikely, in your opinion, is it that the FDA will adopt such an amendment to its regulation of DTC advertising?”, none said it was “very likely”, only 7% said it was “somewhat likely” whereas 14% said it was “somewhat unlikely” and 71% said it was “very unlikely” (see FIG. 1).

Some Comments from Survey Respondents
“Eliminating risk information from advertising will make the public trust pharma less, not more. While there are certainly problems with current risk provision, audiences feel that advertising without risk information is unbalanced. This proposal runs counter to the current trend in DTC advertising with pharmaceutical companies providing more informative advertising.”

“It is absurd to require specific DTC disclosure for products that are available only through an informed intermediary. To insist that risks be disclosed directly to potential patients, is an abject lack of respect for prescribing professionals and the healthcare system.”

“I hope the FDA does not yield to industry pressure to remove these warnings. Doctors do not have the time nor inclination to warn patients. Patients are being led by the nose into believing that drugs are completely safe. This proposal would make it even easier to have patients continue in their delusion. It’s dishonest, unethical, and meant only to manipulate patients into demanding specific drugs from their doctors.”

“Irrational thinking in today’s world of moving toward patient/consumer-directed health care; if anything, health information needs are heightened to weigh risk/benefit in making informed decisions on health care matters. Balanced information applies to not only decisions about drugs -- it extends to devices, procedures, plan benefits, etc.”

“They already feel that there needs to be more effective declaration of issues. Smoking warnings have only grown in presence, yet everyone knows they are worthless.”

“One advertising network chairman said this was done to because ‘great advertising’ required clear messages...well, the message here is loud and clear: ad agencies involved in this are trying to re-shape the PhRMA DTC guidelines to their benefit, where the real point is to shape them to the benefit of the patient and consumer. It also is absurd to think a doctor has time to go over all the information a patient needs in their time-squeezed environment.”

“Thin-slicing the petition leads me to the (albeit cynical) view that this is a transparently veiled tactic to protect the massive earnings that could potentially be lost if FDA regulation on DTC is tightened/becomes more restrictive. Why not simplify the entire proposal to an old bit of Latin: caveat emptor.”

FIGURE 1: How likely or unlikely, in your opinion, is it that the FDA will adopt such an amendment to its regulation of DTC advertising?
The whole milieu has swung to potentially minimalizing what the risks really are with certain products. As an individual, I am kind of on the fence on this issue. I can see both sides’ perspectives. Ultimately, we end up best when we write and communicate in the language of the listener and when we sell in the language of the buyer. I am not sure drug companies effectively do that with DTC.

**Jack Angel:** Let’s look at the context in which this proposal was made. There is a lot of negative information and criticism about the DTC advertising process and as we have all experienced in the past, all too often things reach a crisis quickly and decisions are made by lawyers and/or the government and then people run around trying to react. Generally, that is not a very satisfactory approach. The Coalition is trying to open the dialog *in advance of that* and provide some basic principles, which I thought were pretty sound. If anybody cared to read the press release, “Our goal is simpler, clearer messages that communicate both the risks and benefits of prescription medicines.” It also states “The three core messages that would have to appear in every consumer ad relate to drug risks, the need for a professional consultation and prescription, and the patient’s role in those consultations.”

Other media came away with the same conclusion as John in his blog, to the effect that we were advocating the elimination of risk information. How, I cannot understand. Our view is that, rather than stand around and wait for a bomb to drop, we better get a dialog started. There are not enough knowledgeable communications people out there talking about these issues, which currently are bottled up in lawyers’ offices and the FDA. If we don’t stimulate open discussion now, we could be too late, later, to have any significant impact on what legislative or regulatory proposals finally come forward. We are trying to get some of these issues out on the table now, to make sure that any outcomes are not ill-considered or onerous.

**John:** Please refer to page 11 of the petition. The proposal puts up a straw man to knock down by implying that DTC ads are required now to fully warn patients of all possible risks (“The Coalition urges that the FDA expressly disavow any reliance on DTC to fully warn patients of all possible risks and side effects.”). Ads—especially TV ads and even print ads—today certainly don’t fully warn patients of all possible risks and side effects. So, why should the FDA disavow that goal?

**Harry:** In conversations and discussions about the “Major Statement” of side effects, I have heard suggestions that DTC advertising should contain all of the known risks and side effects (see, for example, “DTC Pros and Cons Presented at FDA Hearing”; PMN Reprint #410-01). If opponents could burden DTC advertising by forcing sponsors to run the full disclosure, they would. And they would do it under the guise of providing necessary information. What they really want to do is grind the advertising to a halt.

**John:** What you are saying then is that this petition is a “pre-emptive” strike against that?

**Neil:** That’s what I am hearing as well.

**John:** Because currently, DTC is not encumbered the way you suggest.

**Harry:** DTC is encumbered by working with a 40-year old regulatory scheme that has not been updated since. This is a petition to amend the regulations governing prescription drug advertising to consumers. If that’s a pre-emptive strike, then it’s a pre-emptive strike. We didn’t use that language.

**John:** Then I would have to say that this petition does not communicate very well what the goals of the Coalition really are.

**Harry:** It wasn’t meant to communicate the goals of the Coalition. It was meant to suggest that it is time to examine these issues in a due process fashion and begin to address them. And to that degree I think it’s been
very successful. It’s brought the negative views out of the woodwork very quickly. We haven’t begun to hear other views.

Neil: Some DTC ads right now offer a marriage with the Internet as a means of accessing additional or more in-depth information. Am I right or wrong in assuming that that capacity to get more information could really address the whole issue of risk or is the Internet not universal enough to be accessible to everybody? It seems to me that as long as the advertisers are providing access to that information and combine that with more provider education the expansion of one will drive increased need for the other.

Harry: Access to that kind of in-depth information doesn’t mean comprehension. Writing this information in consumer-friendly language is still in the very early stages and only a few companies are doing it. This is a work in progress. Consumer access to prescription drug information has been pretty well taken care of. It’s the content and comprehension issues that the petition suggests need to be addressed, taking into account the particular media and the particular audiences being communicated with.

Neil: I would agree with that point but I think that the really smart manufacturers are going to increasingly recognize that they need to help healthcare professionals become better patient educators. You don’t see in the marketplace, despite the growth of DTC, very many examples of where there’s a concurrent effort to help physicians better communicate with patients. That, to me, is the part that would round out the whole DTC piece. What I see is lots of DTC to better tell and better sell patients about products, but not a concurrent level of activity with physicians about how to talk to patients so they really understand and comprehend the benefits and risks associated with our products.

Jack B: There are two important issues here. One, the Coalition’s petition and subsequent press release seems to have been widely misinterpreted by the media and, I must admit, by me as well, in suggesting that the current method of delivering risk be eliminated. The CHC desire was, in fact, to call into question the ability of consumers to understand what they are being told. This, I believe, is an interesting and key point for us to look at.

Next is the fact, at least for me, that DTC is a good thing and helps to get consumers to visit their physicians to discuss medical conditions they may not have even known they had. That’s not in question. What the Coalition has done and what groups like PhRMA should be doing more of is putting out examples of solutions that would really help consumers. It’s bound to have its detractors, but by putting that anchor out there it forces us to think about what makes sense and starts a dialog that otherwise would focus solely on how to change the “mouse type” and whether to use 4-point or 5-point size type. We now have for consideration the continuum from virtually eliminating the so-called “brief summary” information at one extreme to keeping it exactly as it is on the other end of the spectrum.

John: I have a question about how the CHC’s proposal extends to the Internet. In the petition, you say in a footnote (see Petition, pg. 12), “The new DTC risk disclosure requirements will apply [to] print and broadcast ads, as well as Internet communications that promote specific drug products but are not aimed at patients who have already obtained prescriptions – that is, Internet communications that do not provide directions for use.”

Jack B: The Internet is a good example of the problem we have been talking about. Various manufacturers’ compliance departments have interpreted the non-existent Internet regulations from DDMAC and some have said that they have to put the same fair balance information in Internet banner ads as they do in print or TV ads. We know that this is creatively virtually impossible. Others have said “Let’s be realistic about this and recognize that this information is literally one click away for the consumer to get access to a very understandable and potentially interactive explanation of the risks.”

John: I understand that in a TV ad you can only get one message across to the consumer and I agree that the most important message is “see your physician if you think you have the condition that this product treats.” In a 60-second TV ad, you don’t really have the ability to get into educating the consumer about risks. That’s why I am critical of industry leaders who categorize DTC ads as “direct-to-consumer education” (see, for example, “Is DTC Educational or Motivational?”). On the Internet—banner ads aside—there are many creative ways to advertise a product that is information rich and beyond what can be done on TV or even in print (see, for example, “cDetailing: Addressing the Consumer Education Gap”). That being the case, why would the CHC propose the

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same regulations for these types of Internet ads as they proposed for print and TV ads?

**Harry:** My reading of the petition is that if it’s a banner ad or something of that nature that it should be treated appropriately with the appropriate level of information required and that the ad should provide a clickthrough to as much of the information—or all the information—required. Let’s face it, the Internet is ideal for communicating everything that is known about a drug. I’ve been waiting for someone to take a package insert and rewrite it at 3 or 4 different educational levels and present the information to the consumer based on the level the consumer specifies.

**Neil:** I think that is ultimately where this has got to go. Risk-wise, we can’t be all things to all people although I think there is benevolent intent behind trying to get as much risk information in front of people as possible. I am conscious of the fact that economically not everyone has access to the Internet. Nevertheless, the marriage between TV and Internet is a perfect venue to start off on a broadcast level and then to delve into a narrowcast information stream.

**Harry:** I couldn’t agree more.

**John:** What also caught my attention in the petition was some of the language used. It sounded anti-patient or at least out of touch with the current trend towards patient empowerment, one example of which is consumer-driven healthcare. I cited in my Blog, for example, the phrase in the petition "the patient is the decision-maker only with respect to whether a practitioner should be approached” (see **Petition**, pg. 28). The concepts presented in the petition, in my view, were not well articulated. This might have been OK if the petition was a private, internal document, but it was made publicly available by the Coalition. As a public document, I would say that it wasn’t “politically correct.” Did anyone else get that impression?

**Neil:** I took that to mean that they are encouraging a dialog between the patient and the healthcare provider. As a pathway to that, the CHC proposes to abbreviate some of the other messages that have traditionally been part and parcel of the DTC environment. I did feel, however, that this was written by lawyers. If we are trying to craft a patient-centric model, I’d make sure that the documents we prepare to advance our point of view adhere to that model as well. I might have piloted this with some different groups before I released it.

**Harry:** I think those are fair criticisms. Fortunately or unfortunately, there is a legal language of art required to file these petitions. This petition was written that way. Clearly there have been some misinterpretations. What we are trying to do here is say: “Take a look at the Petition itself,” and clarify what our intent is. As already pointed out, this is the opening salvo in an attempt to create a dialog in which these issues can be addressed by reasonable people, who might even develop some reasonable solutions.

**John:** Just for the record, my blog post was written and posted a full day before the AP article was published and I came to same conclusion independently. Other people have also come to these conclusions. That this happened must be the fault of how the petition was written. While the document had to be written in legalese for the FDA, it was also made public by the CHC.

**Harry:** I think you are reading too much between the lines.

**John:** I base a lot of my comments on language in the petition that’s in the lines and not between them. When you say that the intent was not to eliminate risk information in DTC ads, you have to balance that against the example provided, albeit in a footnote, which not everyone reads. I, however, did read the entire Petition, including footnotes, very carefully. The specific language the CHC suggests does not mention specific risks. If you are going to be honest about it, if this is the language the CHC is suggesting, then the Coalition is suggesting that the specific risk information we are used to seeing in DTC ads should not be there. The petition says that too much information in ads deter from the real message that should be communicated (“it [detailed risk information in DTC ads] is confusing…and thus detracts from the achievable and critical messages that DTC can convey.” See Petition, pg. 12). Now here’s where I may be reading between the lines; namely, that, according the CHC, specific risk information detracts from the benefit message—“the achievable and critical message”—of the ad.

I agree that risk communication in DTC needs fixing, but I think there are more creative ways to do it—especially in print and Internet-based DTC ads—that do not involve eliminating specific risk information. Pfizer, for example, has begun using a consumer-friendly and tested brief summary in its print DTC ads for Lipitor (see pg 11). TV ads pose a unique challenge and what I would recommend...
is that the CHC proposal should be limited to TV advertising. Internet and print ads perhaps require a different approach.

**Harry:** The proposal does not say that advertisers cannot go beyond the language suggested and add specific risks.

**John:** Correct. The proposal does state that it should be up to the advertiser how to describe risks or how much further they want to go than the example statement provided in the petition. However, I can imagine, for example, Pfizer mentioning priapism (aka the four hour erection) in its Viagra ads and complaining to the FDA that Lilly did not also mention this side effect in its Cialis ads. Under the CHC regulatory scheme, the FDA would not be able to address that in order to level the playing field at least. Consequently, no drug company advertiser would be motivated to mention specific risks. That’s just an illustration of the problem I see with leaving it up to the advertiser—there just won’t be any specific risks listed at all.

**Harry:** I don’t think that’s the way of the world. I think the FDA would be in consultation with both manufacturers about what they think would be needed to be put into the risk statement.

**John:** Then we would be in exactly the same situation we are now. That’s what the FDA does now.

**Harry:** But they do it without portfolio.

**John:** Let’s move on to the other proposal made in the petition—for the FDA to establish a “standing Communications Advisory Committee to ensure that the agency’s rules and policies are based on the best available social scientific and professional knowledge of consumer behavior and effective consumer communications.” Can you say something about that?

**Jack A:** When we provided formal comments to FDA about DTC advertising regulations about two years ago, it was clear that lawyers were dominating the process, and that experts who understand the science of communication were not sufficiently involved in the deliberations. Our concern was— and is— that we could end up with regulations that make it exceedingly difficult for message senders to send and/or receivers to receive clear communications.

**John:** The CHC proposes to populate the committee with experts and I anticipate that not all of them will be on your side.

**Harry:** We don’t expect everyone to—as you put it, John— “be on our side.” The issue is that we feel that there is not enough input to the regulatory development process from the commercial sectors that deal with communications every day of the week.

**Neil:** I think the committee is a terrific idea. When you blend the experts from different backgrounds you will get better output and regulations.

**Jack A:** John, you make a good point, suggesting that we have not done a good enough job educating people about our intent. But it hasn’t been without a major effort on John Kamp’s part who has tried very diligently to engage as many people as he can. He’s worked with PhRMA and many other trade associations in Washington prior to the filing of the Petition. I think that he’s done an admirable job engaging people, and beginning to open up the dialog.

**John:** I also appreciate the fact that John Kamp went out of his way to send me a copy of the petition a few hours before it was made public at the March 31 press conference. I hope he doesn’t regret doing that! But I am happy that it has led to this discussion and opportunity for the Coalition to clarify its position. The dialog is joined! What’s the next step vis-à-vis the FDA response?

**Harry:** The FDA has 180 days to respond. One of the interesting comments we’ve had is from Ralph Nader’s Public Citizen group, who said that we could be sure that if there was any dialog on these issues that they would be part of the dialog.

**John:** Well, the CHC should marshall its forces because I believe Nader will have something to say at an upcoming DTC conference in Washington, DC.

**Harry:** Yes, he and John Kamp, are on a panel together.

**John:** With that, I thank you all for participating in this conversation and let’s continue to keep the dialog open.

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**Are You Convinced?**

Now that you’ve heard both sides of the issue, what’s your opinion? Take the online **Survey About CHC’s Petition to FDA on DTC and Risk Communication**
**Case Study**

**Pfizer’s Way of Communicating Risk in DTC**

Pfizer recently announced and adopted improvements to communicating risk and benefit information in consumer advertising for prescription drugs. The following is reproduced from its news release (see [http://www.pfizer.com/pfizer/are/news_releases/2005pr/mn_2005_0811.jsp](http://www.pfizer.com/pfizer/are/news_releases/2005pr/mn_2005_0811.jsp)).

“To help consumers better understand the risks and benefits of prescription medicines, Pfizer will fundamentally change its approach to communicating risk and benefit information to improve educational value while continuing to motivate people to overcome barriers to healthy behavior.

“Pfizer has submitted to the FDA for review a new consumer-friendly and consumer-tested print brief summary, the part of the print ad that extensively lists the risks of a medicine [see below for an example]. Should the FDA approve this new version, Pfizer will use this new format in all its print advertising and on all of its product Web sites.

“[Pfizer] will provide use, risk and benefit information in all product TV and print prescription medicine advertisements. This means Pfizer will no longer create ‘Go ask your doctor about a medicine’ TV and print advertisements that do not include the benefits and risks associated with the advertised medicine. In cases where a product is mentioned as part of a sponsorship package, such as ‘This event is brought to you by Brand X,’ risk and benefit information will not be included because these communications are about support for the sponsored entity, not the Pfizer product.”

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**WHO IS LIPTITOR FOR?**

**BEFORE YOU START LIPTITOR**

**NEED MORE INFORMATION?**

**AN EXAMPLE OF PFIZER’S NEW CONSUMER-FRIENDLY BRIEF SUMMARY**

An example of Pfizer’s new consumer-friendly brief summary (which is really brief and a summary!)
Experts Consulted and/or Cited In Articles

The following experts were mentioned or consulted in the preparation of articles for this issue.

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Resource List

The following resources were consulted in the preparation of this issue or are cited within this issue.

- Full text of petition: http://www.cohealthcom.org/content/FinalCHCCitizenPetition.pdf

Pharma Marketing News

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