NICOLAS HANSEN

DTC UNBOUND

DTC pharma advertising works—ask anyone. But over the years, its effectiveness has been blunted by FDA requirements that, marketers claim, befog rather than clarify. **Larry Dobrow** surveys the DTC landscape in the wake of the FDA's new—and some say revolutionary—guidance for communicating risk information in print ads

It's an irony of the highest order: The industry that serves up millions of prescriptions has an issue with the governmental body that regulates it for not being sufficiently prescriptive.

Or at least it traditionally did in the realm of direct-to-consumer marketing. Ever since the US became the second country to allow DTC ads, in 1997—New Zealand, in 1981, was the first—the pharmaceutical business has alternately basked in the freedom (and elevated sales) DTC has fostered, and chafed at the absence of solid etched-in-concrete rules. Broadly speaking, industry marketers weren't entirely content with the FDA's sporadically issued, long-in-coming guidance about what they could or couldn't do within the context of DTC communiqués. They appreciated the tips and hints and suggestions but wanted more. They were thankful to be handed a flashlight before venturing into a darkened house, so to speak, but it sure would've been keen if someone had told them about the loose floorboards and leaky sinks.

"When you don't know what exactly the rules are, you end up overloading and overcompensating for unforeseen liabilities. You end up clouding the true benefits of a product to the patient who isn't thinking about these things every day," says Ken Begasse, CEO of Concentric.

So in February, when the FDA released the snappily titled draft guidance "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drug Products," pharma marketers were enthused but skeptical. The guidance updated a similarly titled one issued 11 years ago, which had the effect of scaring would-be print advertisers into submission. Lest they step over an unmarked line and not include enough information about health risks in their ads, drugmakers either included the entirety of the risk-related portions of product package inserts or a goodly chunk of them.

Ultimately, this solution satisfied no one, except perhaps the most-buttoned-up members of pharma companies' legal teams. Marketers worried that artfully crafted messages would lose their appeal once they were appended with preemptive cautions about, say, oily discharge. Much more disturbingly, the heavy-handed conveyance of voluminous risk information served to intimidate the people who needed it most: suffering patients.

To fit it all into the space, marketers generally printed the information in a nigh-microscopic font ("basically mouse type," jokes Heartbeat Ideas CEO Bill Drummy). This, combined with the medically charged verbiage, rendered the risk-relaying parts of the ads borderline unreadable to anyone without some degree of scientific knowledge.

"More is not more," Mike Rutstein, founder and CEO of Strikeforce Communications, states flatly. "The brief summaries have always been crafted for someone who has a Ph.D.—as opposed to someone who has a GED, which is the population for many of these products." Adds Begasse: "The last thing any of us wanted to do was list so many unimportant things or remote possibilities that it overly impacted a patient's decision of whether to go into therapy. But that was exactly what we were doing." Mary Brown, SVP, managing director for wellness marketing at Ogilvy CommonHealth, puts it even more succinctly: "Our copy has landed outside the average person's ability to understand it."

> "The brief summaries have always been crafted for someone who has a Ph.D.—as opposed to someone who has a GED, which is the population for many of these products."
> —*Mike Rutstein, Strikeforce Communications*

A NEW DAY?

Despite the hand-wringing, pharma has strongly backed the medium. Advertisers spent $4.5 billion in consumer promotion last year, figures from Nielsen show (see p. 36).

With the new print guidelines, though, the FDA has come out in favor of coherence and customer service. "FDA believes that the brief summary should focus on the most important risk information rather than an exhaustive list of risks and that the information should be presented in a way most likely to be understood by consumers. Thus, FDA strongly recommends against the use of the traditional approach to fulfill the brief summary requirement in consumer-directed advertisements, an approach in which risk-related sections of the PI are presented verbatim, often in small font," the guidance reads in its "policy overview" section. Later, it adds, "The risk information in the PI sometimes includes lengthy lists of all possible adverse events. In general, FDA believes that exhaustive lists that include even minor risks detract from, and make it difficult for, consumers to comprehend and retain information about the more important risks."

In other words, the FDA has reversed course. "What they're saying here is that companies shouldn't present the risk information/PI verbatim," explains Andy McAfee, creative director at AbelsonTaylor. "So they've been telling people to do this for a decade and now they're telling people not to do this: 'Believe it or not, nobody is reading this information.' Well, duh." But McAfee's secondary response coincides with one shared by many of his peers: Namely, the revised FDA guidance is kind of a big deal, as much for its freeing effect on print ad creative as for what it potentially signals about the FDA's approach going forward.

"What it does is open up the conversation," says Brown. "The FDA has given us entrée to communicate [risk information] in a way that's reader-friendly. People might actually be able to understand it now." Begasse goes even further: "It's a sign to the marketplace that the FDA finally gets it. I know it's limited [to print ads], but what the FDA is saying here is that what really matters is that patients have the ability to make good decisions based on good information communicated in a way they can understand. You can see the steps forward from here."

David Kopp, EVP and general manager, media, at online healthcare information resource Healthline, concurs, but for a different reason. "I mostly deal with the social side of all this, but I keep going back to outcomes," he explains. "Think about cancer: There are so many people and pieces involved with the therapy, the only constant is the patient. If the patient isn't more involved, we're not going to improve healthcare—and if the patient can't understand what we're talking about, the patient isn't going to be as involved as he might otherwise be."

Coupled with the FDA's long-awaited social-media

Ten Best DTC Ads of 2014

"To be honest, it was tough to come up with 10." That's how **Mary Skoyles**, president and director of media at Medical Media Services Inc. (MMSI), summarized the challenge of looking back over the last year of DTC ad campaigns and identifying her 10 best. Nonetheless, Skoyles—who's been planning media for the pharma business for more than 35 years, for entities like Lowe McAdams and Forest Laboratories—was up to the task. Here she weighs in on the great, the good and everything in between.

BREO ELLIPTA

GlaxoSmithKline

The ad does a very effective job at connecting the brand name to the disease state: "Hello, my name is Katie. I have COPD. I use Breo." They're all four-letter words and they all sound right together; the rhythm is right on target. I love the simplicity, but at the same time I remembered the name of the product after I saw the ad just once. That doesn't happen too often, in pharma or outside it.

TAMIFLU

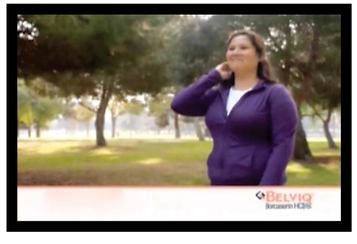
Genentech

This one's unique in that it does a wonderful job of conveying the gravity of catching the flu. It gets across the urgency of seeing a doctor right away, but it also frames the need in terms of a relatable image. The person's head is so swollen that she can't fit into the doctor's office. Don't you feel that way when you get the flu? I do.

ABILIFY

Otsuka

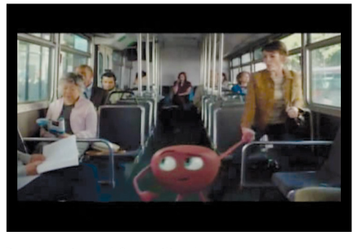
It delivers a very calming message in a pleasant way. It also feels more positive than what we see in the antidepressant space; it doesn't dwell on the negativity and it doesn't overpromise. It makes a good case for adding Abilify to your current antidepressant and seeing results in one or two weeks. The prospect of success in short order for such a debilitating illness? That's a good message.



BELVIQ

Eisai

The ad offers a realistic solution to handling hunger and fighting obesity. Usually you get "all the weight will just drop off and you'll fit back into that little black dress," but here the messaging is much more grounded. It speaks about the risks of being overweight but doesn't beat that point to death. It doesn't make any big promises. It just says, "This may help." Patients want to be treated in that kind of straightforward way.



MYRBETRIQ

Astellas

I love this. You have this lady on the bus with this overactive bladder that's depicted as kind of a little monster, which forces her off the bus. Then she's on a line—maybe for the movies?—and the same thing happens. The animated monster character really drives the messaging. It's clever and it gets the point across in a really smart way.

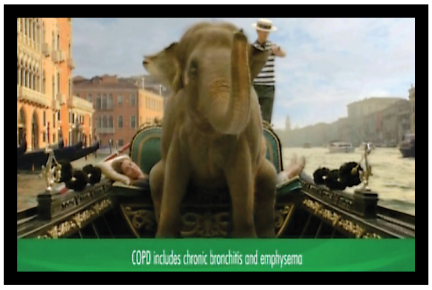
Reels courtesy of Competitrack

Continued

CELEBREX

Pfizer

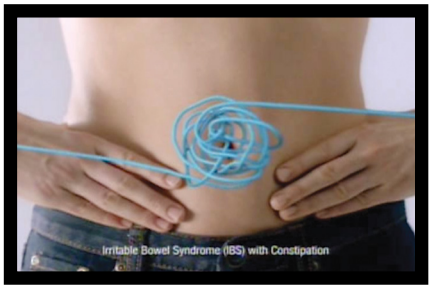
There are a few reasons why I noticed this ad. It's simplistic and elegant in its nature—the visual of the older couple dancing. But it's interesting how the ad mentions the cardiovascular risks right up front. Maybe they have to, given the history, but that's still a bold choice. I'm not sure I agree. My guess is that if you're on Celebrex or you're thinking about going on it, you've done your googling and you know the score.



SPIRIVA

Boehringer Ingelheim

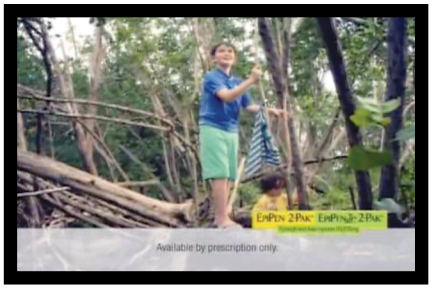
Everybody remembers this one: "Oh, it's the elephant on the person's chest." That's a lasting visual image of what COPD patients live with, that feeling of having this constant weight to bear. I like the creative use of the elephant prop. I like that they show the elephant following the patient around after she's been treated—it's a reminder that COPD isn't something that leaves you overnight.



LINZESS

Forest/Ironwood

Full disclosure: A few years ago I worked on the professional campaign for Linzess. One of the things I like in consumer campaigns is when they have some kind of link to the professional one. Here, there's a simple visual: that blue line that is knotted up. That's similar enough to what was in the professional campaign that a person who can't remember the product name can describe what he saw and the doctor should be able to piece it together.



EPIPEN AND EPIPEN JR.

Mylan

The ad itself is okay, but what makes it work is the way it speaks to the importance of visiting the website and understanding how to use the product—when to get rid of it, etc. The how-to on the site is very high level. That's the real revelation and point of differentiation here.

NAMENDA

Forest

What a great tagline. "I am …" their advocate, their voice, their caregiver. For Alzheimer's, nobody has really figured out how to speak to the caretakers in a way that's sensitive and acknowledges their burden. There's a consistency and continuity here, in terms of tone and image, that's striking.

Reels courtesy of Competitrack

guidance from last summer, the new print advisory suggests that the agency might be embracing selective abbreviation in the communication of risk information. Of course, it's just a guidance, not a hard-and-fast rule, so the fun will lie in how drugmakers interpret it. And while the FDA has softly suggested a handful of more consumer-friendly formats—Q&As versus chunky blocks of copy—marketers must also muddle their way through this aspect of the risk-conveyance exercise.

But let's say that the optimists are proved right. Let's say that the slightly slackened FDA rules for risk information in print ads lead to similar relaxations of the rules in other mediums, placing a premium on clear, effective communication for and with consumers. Could it be that such a shift would usher in a new era of engaging promotion? Could laxer guidelines unleash agency creativity?

There's some evidence that they might. Take some of the quick-hit tactics employed by underdog brands in the wake of the release of the social-media guidelines, like photo Tweets that help skirt the character-count challenge. In pharma marketing as elsewhere, motivated parties will find a clever way around loosely enforced or defined rules.

But ultimately, agency experts don't expect a flood of boundary-pushing work soon. The main reason? Owing to regulatory and legal worries—some overstated, many not—pharma companies have never been the first to dive into the deep end of the risk pool. Rather, they've made a point of waiting to see how the first guy emerged from his aquatic immersion. Only then did they tiptoe into the shallow end, recoiling if the temperature wasn't just so.

It's a tortured metaphor but apt. "My main problem with some of the guidance is that they encourage [companies] to be conservative, which isn't the outcome that's best for public safety. It shouldn't be 'you can do this if you want.' It should be 'you have to,'" argues Drummy. "The FDA's slowness and timidity in granting guidance isn't helping anyone."

Rutstein, who characterizes the new print guidance as "a positive, more or less," counters that what may appear to some as timidity could be interpreted by others as prudence. "I think it's better to have a little bit of flexibility right now," he says. "I'm not sure the FDA itself knows what the right answer is. They're using this as a kind of an incubator to find the right way to communicate this information, to find the right balance."

DECONSTRUCTING DTC

Which doesn't mean that anybody expects pharma to quickly and spiritedly attempt to help draw the new DTC

By the numbers: 2014 DTC ad spend

TOP 20 COMPANIES BY DTC SPENDING

Rank 2014	Rank 2013	Company	US DTC media $ (millions)	% Change vs. prior year
1	1	Pfizer	$1,095.8	28.8%
2	3	AbbVie	$363.0	-8.9%
3	4	AstraZeneca	$340.7	18.5%
4	2	Eli Lilly	$332.0	-25.3%
5	12	Johnson & Johnson	$257.8	123.2%
6	6	Allergan	$246.0	26.6%
7	8	Bristol-Myers Squibb	$222.0	42.1%
8	5	Merck	$205.5	-24.3%
9	19	Sumitomo	$190.1	634.0%
10	7	Amgen	$135.7	-28.8%
11	13	Boehringer Ingelheim	$124.7	68.7%
12	9	GlaxoSmithKline	$110.6	-28.5%
13	11	Otsuka	$108.1	-11.0%
14	-	Ironwood	$102.5	N/A
15	15	Roche	$80.4	49.4%
16	-	Eisai	$78.8	N/A
17	-	Shionogi	$70.8	N/A
18	10	Novo Nordisk	$60.9	-50.8%
19	-	Gilead Sciences	$54.8	N/A
20	16	Mylan	$48.6	39.7%

Total spend comprises broadcast, print, outdoor and B2B, but not digital

TOP 20 BRANDS BY DTC SPENDING

Rank	Brand	Company	US DTC media $ (millions)	% Change vs. prior year
1	Cialis	Eli Lilly	$248.7	15.2%
2	Eliquis	Bristol-Myers Squibb/Pfizer	$219.0	89.9%
3	Viagra	Pfizer	$211.2	32.0%
4	Latuda	Sunovion	$179.2	N/A
5	Xeljanz	Pfizer	$160.7	69.3%
6	Lyrica*	Pfizer	$123.1	63.7%
7	Humira**	AbbVie	$119.9	-9.4%
8	Celebrex	Pfizer	$118.9	-21.0%
9	Abilify	BMS	$107.9	-10.8%
10	Lyrica***	Pfizer	$105.7	11.6%
11	Chantix	Pfizer	$103.1	29.7%
12	Linzess	Forest	$102.5	N/A
13	Breo Ellipta	GlaxoSmithKline	$98.1	N/A
14	Symbicort	AstraZeneca	$92.4	37.1%
15	Humira****	AbbVie	$83.3	-8.3%
16	Xarelto	Janssen	$81.3	-12.1%
17	Belviq	Eisai	$78.8	N/A
18	Invokana	Janssen	$73.8	N/A
19	Tamiflu	Genentech	$72.9	N/A
20	Osphena	Shionogi	$70.8	N/A

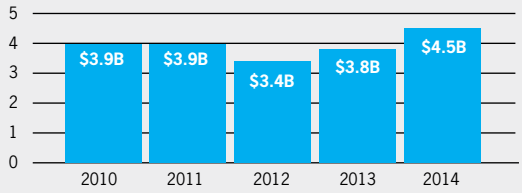
*for fibromyalgia; **for arthritis; ***for diabetes; ****for psoriasis
Total spend comprises broadcast, print, outdoor and B2B, but not digital

DTC AD SPEND BY MEDIA TYPE

Rank	Media	US DTC media $ (millions)	% Change vs. prior year
1	Television	$3,157.7	26%
2	Magazine	$1,226.4	13%
3	Newspaper	$127.0	-15%
4	Radio	$25.8	6%
5	Outdoor	$3.7	-1%

Source: Nielsen

DTC AD SPEND ACROSS ALL MEDIA (excluding web)



boundaries. Like Rutstein and other agency peers, Drummy believes that it's the natural tendency of pharma to focus on the downside risk, whether in the form of lawsuits or antagonizing regulators.

"You get a lot of, 'I don't want to do anything to annoy the FDA. I've got a big product and I don't want a delay in the process. I don't want to have to pull back my ads and redo them,'" he continues. "Well, do you want misinformation or unclear information out there? That's the alternative. Given the reputation of our industry, doing more rather than doing nothing at all would help to build trust and [the industry's] terrible reputation has costs of its own … There's a tort bar out there, lawyers looking for this kind of [inaction] all the time. If you don't find any problems you have and get them out there, they will. In terms of liability, shouldn't [pharma companies] want to be able to say that they were on top of it from the outset? Juries come back with, 'How could you not have known? You should've known.'"

At the same time, it's worth noting that it wasn't a plucky renegade that took the first definitive steps toward evolving the communication of risk information in its print ads. Rather, it was a moderately well-known concern named Pfizer, which changed the formatting of DTC risk information within its print ads a few years ago for numerous brands. "Somebody over there clearly said, 'You know what? We can do better. We can present [risk information] in a way that readers might actually understand it,'" says Brown. Some execs believe, in fact, that Pfizer's move toward consumer-comprehensible formats spurred the FDA to reexamine the issue in the first place.

Not surprisingly, others are eager to cast the FDA in its traditional role of default bogeyman. While most pundits believe the agency's heart and head are in the right place—Kopp stresses that "pharma has issues that are far bigger than the FDA"—others wonder if the FDA is equipped to react quickly and decisively to changes in the DTC marketing landscape.

"When are they going to get real about the new channels?" Drummy asks. "It's nice that we have this print guidance, but print ads are becoming less and less important in the overall media landscape. You wonder if the next step is a guidance on the use of papyrus scrolls."

Drummy's critique stings as the best one-liners do, but he has a point: The FDA may not be structured in a way that allows it to keep up with the pace of change in communications forums. The social-media guidance, for instance, arrived half a decade after the FDA's first bleats that it planned to examine that particular channel. "They don't have the staffing to move at the speed these things require," Drummy shrugs. "We'd all like to see something for DTC and mobile, right? But we'll probably have devices embedded in our skin before they get around to that."

And there's the whole "is DTC worth it?" component of the debate. Nobody doubts that DTC marketing spurs sales. If patients specifically ask their doctors for a product, more often than not they walk out of the office with a script. Still, even in light of their pending semi-emancipation from the chore of conveying pages worth of risk information, many drugmakers have started to get all philosophical-like about the DTC process.

"For a lot of [companies], it's about understanding whether or not you have a DTC product," Begasse explains. "No matter how great your product works, if the risk information is going to leave patients with the impression that the product is even a little bit dangerous—rather than making them think, 'maybe I should talk to my doctor about this'—you should not be doing DTC advertising." Asked to identify a prime candidate for stepped-up DTC consideration, Begasse points to Valeant's topical toenail fungus treatment Jublia. "It's a fairly benign drug for a condition that's fairly prevalent and not systemic. The risk/benefit ratio is way higher on the benefit side of it."

Much of this sounds grim—and, frankly, a little extraneous to any conversation with the potential for a DTC creative revolution as its launching point. So it's worth stating once again, with feeling: Nobody views the new DTC print guidelines as irrelevant, unnecessary or without promise. Some of its potential benefits, in fact, seem to have been understated—like the money its adoption could eventually free up. Less mandatory information in a print ad, in theory, means a more modest media buy.

"When clients have to purchase two full pages for a brief summary, that makes [print] a tougher sell," McAfee says. Brown, on the other hand, deadpans, "Being able to do more with our budgets? There's a thought."

> "We'd all like to see something for DTC and mobile, right? But we'll probably have devices embedded in our skin before they get around to that."
>
> *—Bill Drummy, Heartbeat Ideas*

UP NEXT: CHANGE, OR NONE WHATSOEVER

As for the possibility of immediate changes in the print-ad landscape, each of the agency execs says that his or her clients are thrilled by the prospects of having to include less risk information and reformatting whatever's left in a manner that's more consumer-friendly … but that legal and regulatory haven't yet rendered their own verdicts. In other words, check back in a month or 14. "It won't be the first time we've heard, 'I really want to push the boundaries and do something innovative, but show me where it's been done before,'" Begasse says.

If nothing else, the new print guidelines could help put to rest the calls to ban DTC pharma advertising altogether. Critics of these ads count as an argument linchpin that consumers don't understand the risks associated with a given medication, even after pharma companies are done explaining them in breathtaking detail. Altering print-ad requirements to make them leaner and more comprehensible would appear to defuse that particular line of reasoning.

"[The guidelines] will help the industry's cause," Rutstein says. "It'll be a little harder to make the case that anybody is trying to pull the wool over consumers' eyes."

And again, even the most cynical pharma marketers see longer-term promise in the FDA's print-ad pronouncement. "There are going to be more changes and I think they'll be meaningful," McAfee says. "It's like how on TV we say, 'See our ad in *Redbook* for all the details,' at a time when magazine readership is declining. A while from now we'll look back on a lot of this and think, 'That was ridiculous.'" ■