

Testimony of the Coalition for Healthcare Communication

Food and Drug Administration

Direct to Consumer Advertising Hearings

November 1, 2005

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C O A L I T I O N F O R

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On behalf of the Coalition for Healthcare Communication, thank you for the opportunity to present our views this morning. Though it has been only ten years since we first had this conversation in an open FDA Hearing, the FDA, drug companies and the communications industries have learned much that can help improve and advance the patient and professional communication enabled by DTC. To maximize our time, we seek only to emphasize a few points, then ask a significant question on how best to pursue our common goal of effective consumer communication of drug information.

First, we want to note that for all its advantages and perceived disadvantages, DTC advertising is here to stay. DTC has taken a prominent place in the tool bag of consumer communication tools. Careful research demonstrates that DTC helps patients become aware of drug options, stimulates conversations with doctors, leads to better prescribing decisions, and encourages patient compliance with drug regimes.

We need not repeat the findings of significant public policy research in our testimony today because it is well known to the FDA. Indeed, you and others have compiled leading edge research. We're also pleased that several witnesses today and tomorrow, including Dr. Kleit on this panel, will be talking about new research further demonstrating its value.

We note however that some of the most important issues of consumer communication -- namely the best ways to improve literacy, increase patient compliance, and to communicate safety information -- are still not well understood. Until much more data are available, we must proceed carefully with any new regulation.

We've learned much in the past 10 years from the research by the FDA and others. Most important: DTC advertising works. For the FDA, for the industry, and for the public health. Our current scheme of DTC advertising fundamentally is not broken, so let's be careful as we move to improve it to avoid "fixes" that break it.

Some proposed "fixes" would do exactly that.

Here's one: Because drugs are not completely safe and some might have hidden safety issues, DTC must be banned.

First, it's a non-sequitur. Cars, like drugs, are often recalled for safety reasons. Cars, like drugs, can kill if not used as directed. And even when used as directed, can have latent, unknown deadly safety risks. It makes no more sense to ban drug advertising in response to drug recalls than it would to ban car advertising in response to brake recalls.

Also, let's not fall for the seemingly sensible calls for a rigid one, two or even three year "moratorium" on DTC for new drugs, especially those that propose it as a type of Phase IV clinical trial period where small populations might "test" safety or effectiveness. Such schemes undermine the very integrity of the FDA drug approval process, and need to be rejected outright.

Meanwhile, we applaud drug companies and PhRMA for putting in place programs to delay launch of their DTC programs to insure that professionals are informed first.. These flexible programs enable companies to tailor the timing of DTC to the specific safety profile of the drug and balance the needs of doctors and consumers while insuring that innovative new drugs are quickly available to patients who need them.

But, a rigid rule here might well inhibit the public health. As we all contemplate the possible horror from an Avian Flu pandemic, neither the FDA nor a company should face a well-meaning moratorium prohibiting consumer information on the availability of use of a new vaccine urgently needed throughout the population.

Moving on, advertising professionals are heartened by the increasing understanding of FDA reviewing staff in the nuances of consumer behavior and consumer reaction to advertising messages. Then Commissioner

McClellan stated it most succinctly last year when announcing proposed revisions of the brief summary rules: “We have learned that often ‘less is more’ in consumer advertising.”

Consumers can only take away one or two ideas from a given ad, at most three. We must not allow the search for perfection to overwhelm the practical limits of advertising as a drug safety information vehicle.

Although not seriously broken, it is time for the FDA to do a systematic review of its consumer advertising policies. DTC advertising is the most regulated form of advertising in the United States. Indeed, drug ads often include a seemingly endless list of dangers and contra-indications that serve to confuse more than enlighten.

Wayne Pines, a well respected former FDA staffer who counsels many on marketing issues, may have said it best in a recent edition of the *FDLI Update*: “The time has come for FDA to recognize--and incorporate into its regulatory approach--the view that DTC advertising is not just a derivative form of physician advertising. Simply put, what a physician needs to know (in deciding whether to prescribe a drug and how to advise a patient when a product is prescribed) is different from what a consumer needs to learn from a DTC advertisement.” “A New Approach to Risk Disclosure in DTC Advertising”, *FDLI Update*, November/December 2004

We recognize and praise the FDA for recent strides that enable companies to make the “brief summary” and risk information more consumer friendly. Similarly, the FDA should eliminate the immense subjectivity of FDA advertising policy. For as Pines said, “There is no way that any company or advertising agency can anticipate all the issues that a collective DDMAC review will identify.”

That’s a problem for the FDA and the industry, and it will magnify under the PhRMA Principles as more ads are submitted for preapproval. Advertisers and their agencies must be able to fully understand the rules and confidently develop ads that meet them, well before those ads are submitted to the FDA for review.

Just ten days ago, Ron Pantello, CEO of EURO RSCG Life Worldwide and Chairman of the Advertising Agency Committee of the American Association of Advertising Agencies, noted that this subjectivity ultimately

gets in the way of good consumer understanding: “Because it’s impossible to predict how the FDA staff will react to certain creative executions -- even those that are only slight variations of previously approved ads -- our drug company clients respond by becoming increasingly conservative. As a result it is nearly impossible to create compelling advertising messages that consumers can fully understand.”

The FDA itself needs to rethink its approach for another reason. It’s no secret that FDA’s reputation and jurisdiction is under attack from many quarters. ‘Wannabe’ drug advertising regulators are seeking to whittle away the FDA’s primacy in this area through a plethora of federal and state consumer protection and “false claims” actions. State legislators are crafting laws that sometimes are contrary to FDA policies.

Moreover, private class action lawyers are using marketing theories in high profile product liability and ‘failure to warn’ law suits that stem from allegedly inadequate disclosures. FDA must continue to pre-empt these actions when necessary. Moreover, it must develop clearer, more effective policies that demonstrate leadership and demand legislative and judicial deference. FDA must lead the way.

Doing so will enable FDA to regain its position as the pre-eminent regulator of drug marketing, and to begin to sweep away the encroachments on its jurisdiction by the HHS-IG, state legislators, and plaintiff’s attorneys. American citizens don’t need multiple sets of drug marketing regulations. They need one set that makes sense, works and can be vigorously enforced.

Our final point today is to express concern about so-called “voluntary” constraints on DTC and other marketing that are increasingly part of the drug approval process. Especially noteworthy is the FDA’s approval of the drug Symlin from Amylin earlier this year. Similar, but less extensive limits, have been imposed on other approvals, and more are expected.

Our question: How do the Coalition and the public appropriately participate in the FDA decision-making process on these issues?

We have asked to participate in the December hearings on communicating drug safety, but worry that the most important of these decisions will continue to be made outside the public view.

We recognize that these limits are only nominally “voluntary,” much like when I “volunteered” to go to Viet Nam when my draft papers were in the mail.

Decisions to ban DTC, to ban professional advertising for two years and to ban marketing to only a limited number of clinicians are not private matters. They are profound public policy and health education matters subject to judicial review under both the Administrative Procedures Act and the Constitution.

As you well know, FDA must adhere explicitly to the First Amendment mandates required of all government agencies when developing commercial speech limits. Though rigorous, the Supreme Court’s rules are quite straightforward. In short, ad restrictions must be effective, must be as limited as possible, and must be avoided if non-speech restrictions would suffice. These mandates require good evidence, public transparency, critical reasoning, tough but objective standards, and common sense. The burden of proof on all of these points is strictly on the FDA.

Limits on Symlin marketing may or may not be appropriate and necessary. There is no way for the public to tell. There is no public record of their need, that they work, that they are as limited as possible and that other less speech restrictive limits were rejected as inadequate.

On a personal note, I am diabetic and a possible candidate for this new drug, reportedly the most important breakthrough treatment of diabetes since the development of insulin early in the last century. I am startled that the FDA accepted as a condition of approval the idea that the company must hide information about the drug from both my primary care physician and me. Somehow the safety issues are deemed so important that both my primary physician and me are better served by ignorance than by information. My doctor does not agree.

Indeed, without a clear public record, these restrictions reflect of a kind of paternalism unsuited to our culture and contrary to the basic idea that educated physicians and educated consumers lead to better healthcare decisions. So, again, our closing question is how should the Coalition and the public participate at the FDA in these vital decisions about consumer and professional communications?