

For several **WEB EXTRAS** about the drug facts box, including a video interview with Drs. Schwartz and Woloshin, see [dartmed.dartmouth.edu/su09/we04](http://dartmed.dartmouth.edu/su09/we04).

## Drug info boxes contain “just the facts, ma’am”

Just one and heartburn’s done” boasts an ad for a prescription heartburn drug. “It’s time for a Maxtor summer” advocates another. Both drugs sound promising, but how is a patient to know which one is better?

Proponents of direct-to-consumer (DTC) pharmaceutical ads say the ads educate the public about symptoms and diseases. But the problem with such ads, argue three DMS researchers—Lisa Schwartz, M.D.; Steven Woloshin, M.D.; and H. Gilbert Welch, M.D.—is that they give no data about how well the drugs work.

**Data:** To tackle this problem, the DMS team has created a “drug facts box,” a tabular summary—like the nutrition facts box on packaged foods—of a drug’s benefits and side effects, according to clinical trial data. The box shows outcomes for trial subjects who did and did not take the drug, plus the most frequent side effects. Earlier studies showed that people understood and valued the facts box, but they were done on relatively limited samples (for details about these studies, see [dartmed.dartmouth.edu/sp08/d01](http://dartmed.dartmouth.edu/sp08/d01)). “One of the comments we got,” says Woloshin, “was how do we really know that people will be able to use this information?”

So, with funding from the National Cancer Institute, the researchers conducted two randomized controlled national studies: one of a drug to control symptoms and one of a drug to prevent disease. In the symptom study, 109 people were shown two ads for heartburn medications plus the related drug facts boxes; one of the two drugs, a proton-pump inhibitor (Maxtor—all the drug names were made up, though the drug data was real), clearly outperformed the other, a histamine-2 blocker (Amcid). The control group (122 people) saw ads for the two drugs plus the standard listing of risks and side effects. The goal was to see if the boxes helped people choose the superior drug.

The results were very favorable: 70% of

the drug box group versus 8% of the control group correctly identified Maxtor as “a lot more effective” than Amcid.

**Risk:** The prevention study involved two cardiovascular drugs, a statin (Concor) and a blood-thinner (Pridclo). The objective was to see if people could pinpoint how well the drugs reduced the risk of heart-attack and death. Again, the drug box group showed a much better understanding of the drugs’ benefits: 72% of the drug box group and just 9% of the control group correctly identified how much Concor reduced heart-attack risk. In the control group, 65% of the subjects overestimated the benefits of Concor “by a factor of 10 or more,” wrote the researchers in the *Annals of Internal Medicine*.

They concluded that the drug box groups showed a much better understanding of the benefits of the drugs, as well as of the likelihood and magnitude of their side effects.

Schwartz and Woloshin have been working for some time with the Food and Drug Administration (FDA) to develop the drug facts box concept. Recently, an FDA advisory committee unanimously recommended that the FDA require the use of the facts box in both print ads and drug package inserts.

**Box:** There is still a lot of work ahead, notes Woloshin, as any change in FDA policy requires, literally, an act of Congress. But the DMS team is hopeful. “The real value of the drug box is a way of summarizing what the FDA knows at the time of approval and making that clearer,” says Schwartz.

Even the drug industry may be coming around to seeing the value of the drug facts box concept. Robert Ehrlich, the CEO of DTC Perspectives, a company that publishes about and consults with pharmaceutical firms, wrote of the Dartmouth study: “I support anything that gives consumers clear and numerical information on how a drug may help or hurt them.” MATTHEW C. WIENCKE

**The DMS team has been working with the FDA on the concept.**

Prescription Drug Facts: MAXTOR (moprasozole)		
What is this drug for?	To relieve heartburn	
Who might consider taking it?	Men and women bothered by heartburn or acid reflux disease	
Who should NOT take it?	Women who are pregnant or breastfeeding	
Recommended testing	None	
Other things to consider doing	Eat frequent, small meals; avoid fatty foods (and others which trigger your symptoms); excessive alcohol and eating close to bedtime; don't smoke; look into other medications.	
MAXTOR STUDY FINDINGS BOX		
500 people with bothersome heartburn were given MAXTOR or a sugar pill for 2 weeks. Here's what happened:		
What difference did MAXTOR make?	People given a sugar pill	People given MAXTOR (20 mg x day)
Did MAXTOR help? Fewer people taking MAXTOR had heartburn (72% fewer)	81% 816 in 1000	11% 110 in 1000
Did MAXTOR have side effects? Life threatening side effects (No difference between AMIC D and a sugar pill)	None observed	
Symptom side effects		
No difference in abdominal pain	About 5% in both groups 50 in 1000	
No difference in diarrhea	About 4% in both groups 40 in 1000	
No difference in headache	About 3% in both groups 30 in 1000	
How long has the drug been in use? Maxtor was approved by FDA in 1997. Studies show that most serious side effects or recalls of new drugs happen during their first 2 years of approval.		

**It's time for a Maxtor summer.**

You already know that the medicine of prescription PPIs like Maxtor are the experts in acid reflux disease. And that Maxtor isn't just another heartburn pill. Now you can tell your friends and your doctor. Frequent and persistent heartburn about 14.8 times a day.

Remember to take your PPIs every day for 24 hours of complete heartburn relief that's possible with Maxtor.

**AdvaPharmaz** **Maxtor (moprasozole) 20mg/2000**

MAXTOR (moprasozole) Delayed-Release Capsules		AMICID (famotidine) Delayed-Release Tablets	
Heartburn	81%	11%	11%
Abdominal pain	5%	5%	5%
Diarrhea	4%	4%	4%
Headache	3%	3%	3%
Other side effects	None	None	None

**Patients in a national study who saw “drug facts boxes” like the one at top showed much better understanding of two drugs’ respective benefits than did patients who saw only standard drug ads—like the one in the middle for Maxtor (the drug names were made up, but all the data was real)—plus the standard so-called “brief summary” like the one above.**