

Worse Than the Cure

BY JEREMY LOTT

Hey FDA, you can pry that bottle of extra-strength over-the-counter Tylenol from my cold, dead fingers!” read one over-the-top message posted to a popular social networking site in early July. The intemperate author — that would be me — was responding to reports that the Food and Drug Administration might crack down on that dread menace acetaminophen, popularly known as Tylenol.

In fairness to the FDA, there is a real risk of liver failure and death if a person consumes too much acetaminophen. About 400 people die each year from overdosing on the drug, and more than 40,000 are hospitalized. Those numbers prompted an FDA science advisory board to recommend (by a narrow vote) that the agency recall several strong drugs that contain acetaminophen, including Vicodin and Percocet. The panel further urged that several over-the-counter medicines be more stringently regulated. Dosages should be cut back generally, the panel said, with higher doses available only on a doctor’s say-so. The variety of acetaminophen-containing drugs marketed for children should be drastically reduced. Product warnings should be more explicit, so that people know to avoid doubling up with medications that include the drug.

However, short of adding a skull and crossbones with a “Pay attention: This could kill you!” warning, it’s hard to see how the current labeling could be much better. The bottle of Tylenol 8-Hour pills on my desk bills itself as an “acetaminophen extended-release pain reliever.” It says in all-caps over the Tylenol logo “DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN,” and repeats that warning in smaller print elsewhere.

The label tells readers twice that the bottle’s contents “may cause liver damage,” especially if they don’t take the pills correctly. It gives advice for how much and when to take the medicine. It says to consult a doctor if there are any questions whatsoever and gives the 800 number for the Poison Control Center for emergencies. It contains the obligatory warning “Keep out of reach of children,” and the bottle cap is designed to frustrate young, prying hands. And yet, Reuters reported that FDA officials “are concerned that current warnings are not heeded by consumers” and are thus casting about for “new ways to reduce



the number of overdoses.”

The Obama FDA is likely to act on this. After all, this is the agency that threatened to regulate Cheerios as a drug because General Mills advertised its cereal’s health benefits, flipped out because Google searches of some drug makers’ websites do not always bring up dire warnings about their products’ side effects, and is rumored to have its eye on curtailing the “off label” prescription of drugs. In the case of acetaminophen, “agency officials” told Reuters that “many of the recommendations could be implemented voluntarily by drug companies.”

“Voluntary regulation” sounds great — unless a regulator is calling for it. The FDA is saying that if Johnson & Johnson

wants to avoid explicit regulation, it should “voluntarily” reduce the amount of acetaminophen in my Tylenol 8-Hour pills from 650 mg to, say, 500 mg, and dial back the number and frequency of pills it recommends I should take when my head starts pounding like a jackhammer in the D.C. summer heat.

What’s really worrisome is that no one seems to realize that people will likely compensate for the lower-dosage pills by simply taking more of them — instead of one 650 mg tablet, they’ll get a 1,000 mg dose from two pills. If so, expect more poisonings and calls for further regulation from experts who will wonder why the previous measures didn’t take.

Of course, the FDA could really crack down. Pain sufferers could get the same treatment that frequent cold sufferers now get every time they go into a pharmacy: they have to produce identification to prove that they’re not meth dealers (because, I guess, meth dealers don’t carry ID). Or the regulators could demand a doctor’s note every time you want to deal with a headache. Make no mistake: that would almost certainly cut down on accidental self-inflicted liver damage by pain sufferers. But don’t forget to read the footnote.

It says that an advisory committee of doctors and scientists probably doesn’t look very closely at the “cost” part of the cost-benefit calculations. Fewer overdoses undoubtedly would be a good thing. But can an advisory panel of doctors and scientists, carefully eyeing one current cost, correctly determine by a simple vote how all the different costs and benefits and all the different unintended consequences will play out from their recommendation?

Just thinking through all that is enough to make me reach for my Tylenol. **R**

Jeremy Lott is an editor at Capital Research Center and author of *The Warm Bucket Brigade: The Story of the American Vice Presidency*.