Regulation

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REGULATION was first published in July 1977 "because the extension of regulation is piecemeal, the sources and targets diverse, the language complex and often opaque, and the volume overwhelming." REGULATION is devoted to analyzing the implications of government regulatory policy and its effects on our public and private endeavors.

On Acetaminophen

I must disagree with Jeremy Lott's criticism ("Worse than the Cure," Fall 2009) of a set of regulatory proposals formulated last summer by a Food and Drug Administration advisory panel considering the risks posed by overdosage with acetaminophen (the key ingredient in Tylenol and an ingredient in many pain relievers and cold medicines). Experience and sound cost-benefit analysis support many of the panel's principal recommendations.

The three dozen physicians, pharmacists, and researchers brought together on the panel suggested a range of regulatory options — including withdrawal from the market of widely prescribed pain relievers Vicodin and Percocet, which combine an opiate and acetaminophen — in order to reduce the incidence of liver damage associated with overdoses from acetaminophen. Such overdoses account for more than 56,000 emergency hospital visits, 2,600 hospital admissions, and about 450 deaths each year.

Overdosage is most often caused by patients not realizing that acetaminophen is found in a wide range of products with different names and uses. The drug, which was first approved in 1951, is contained in some 600 prescription and over-the-counter products.

I endorse the withdrawal of the combination medicines Vicodin and Percocet. I dislike combination products unless the various ingredients must be combined for efficacy, which is rare. (There are some combination products, such as the asthma drugs Advair and Symbicort, which make sense because there is genuine synergy between the ingredients.) Otherwise, it is preferable to prescribe the individual ingredients so that they can be titrated, or adjusted, for maximum effectiveness and the fewest side effects.

Thus, for example, rather than prescribing a patient Vicodin, which is a mixture of the narcotic hydrocodone and acetaminophen, it makes more sense to prescribe separately a small dose of an opiate as well as a sufficient amount of an over-the-counter analgesic (such as naproxen, acetaminophen, ibuprofen, or celecoxib) to control pain.

The advantage is that one can exploit the various characteristics of the individual products. For example, naproxen, ibuprofen, and celecoxib have anti-inflammatory properties (opiates do not), and celecoxib is easier on the gastrointestinal tract than naproxen or ibuprofen. Many patients dislike the "foggy" feeling they get from opiates.

Let me emphasize that no patient would be denied adequate pain relief if Vicodin and Percocet were no longer available, because their individual components would still be freely available.

Some physicians would argue that because they are more convenient, combination pills such as Caduet (which contains a statin drug to lower cholesterol and another compound to lower blood pressure) encourage patient compliance. But a combination pill locks in the relative dosages, and this can be problematic for conditions such as lipid disorders and high blood pressure in which patients' responses to treatment are often hard to predict. In such situations, arguably the flexibility and the ability to fine-tune the individual medicines should trump convenience.

The FDA advisory panel made various other recommendations, including limiting the maximum single dose of acetaminophen to 650 milligrams, down from the 1,000-milligram dose found in two tablets of Extra Strength Tylenol. They also endorsed lowering the current maximum daily dose of over-the-counter acetaminophen from 4 grams, but they did not specify a recommended dosage.

At the price of a small amount of patients' convenience, the panel's recommendations should help to make those who take acetaminophen-containing drugs more aware of how much of the substance they are ingesting. With vigilance and better communication among patients, doctors, and pharmacists, overdoses should be reduced. That is a cost-benefit balance that we can all live with.

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