Dangers lurk in off-label drugs

Even if the Obama administration falls short on health care reform, a recent landmark plea agreement and settlement could make 2009 the year of health care enforcement.

Among the thousands of federal crimes on the books, few observers would guess the one responsible for the highest criminal fines in our history would be the Food, Drug and Cosmetic Act. On Sept. 2, the Department of Justice announced a historic settlement between the federal government and pharmaceutical giant Pfizer Inc. (along with its subsidiaries Pharmacia and Upjohn Co. Inc.), over a pattern of fraudulent marketing of drugs.

Pfizer’s payment of $2.3 billion (that’s with a “b”) arose from a global settlement that included civil and criminal components. More specifically, Pfizer’s criminal fine and forfeiture of $1.3 billion was part of its guilty plea to a felony violation of the Food, Drug and Cosmetic Act for misbranding the anti-inflammatory drug, with the intent to defraud or mislead. Under the act, a company is required to specify the intended uses of a product in its application to the FDA. If the drug is approved, it cannot be marketed or promoted for any “off-label” or unapproved use.

On the civil side, Pfizer will pay $1 billion to settle allegations under the civil False Claims Act. The company’s alleged promotion of four drugs caused false claims (or requests for payments) to be sent into state and federal health care programs for uses that were not medically approved and not covered.

The civil settlement also resolves allegations Pfizer paid kickbacks to doctors to encourage them to prescribe the drugs.

Another element of the settlement was a corporate-integrity agreement, which outlines procedures and audits to prevent and detect similar violations. But what if everyone else is doing it? Apparently, promoting off-label drug use to physicians is a common practice. Unfortunately, this fact is no defense. No matter how common or widespread the practices may be within an industry, this is a disaster waiting to happen, and it will eventually give rise to an aggressive enforcement campaign.

As Pfizer now knows, it’s far better to prevent and detect than simply to react, respond and pay.

There’s a unique aspect to the Pfizer plea. Unlike many recent federal criminal-enforcement initiatives, this case involved no criminal charges against executives. Despite the record-setting criminal fine, Justice did not force anyone to take the fall and go to jail time.

The proper prescription for avoiding Pfizer’s heartburn is to make a priority of compliance.

This includes setting up a compliance plan with standards and procedures and possibly a hotline; designating a high-level executive to serve as the compliance officer; conducting background checks for employees; engaging in regular training, monitoring and audits; and altering management’s audits of improper conduct and continually improving the program; and enforcing standards consistently.

That’s how a proactive company can spell relief.

Pete Anderson is a former federal prosecutor and is co-founder of Anderson Terpening in Charlotte, which defends individuals and businesses on criminal, regulatory and litigation matters.

Should North Carolina refuse stimulus funds?

The Civitas Institute, a conservative think tank in Raleigh, recently released a study on the economic impact of the federal stimulus package on the North Carolina economy. The study’s main result was striking. Whereas the Obama administration expects the stimulus to create or save more than 100,000 jobs in North Carolina, the Civitas study claims that it will cost the state nearly 70,000 jobs.

That’s a 170,000-job difference of opinion, which is roughly the difference between an 8 percent and a 12 percent unemployment rate.

Should North Carolina really refuse stimulus money? Mainstream economists are clearly bullish on the benefits. Fortunately or unfortunately (depending on your politics), this study doesn’t come close to making the case for a negative impact.

The study’s conclusions are less surprising when one looks at its byline. It was produced by the consulting firm founded by Arthur Laffer, the economist best known for his Reagan-era support of “supply-side economics,” and more recently for his apparent belief that Medicare and Medicaid are not government programs.

The direction taken by the Laffer study is made clear early on. It claims that “increasing federal spending does not stimulate the economy.” Really? Not under any circumstances? Not even in the midst of the worst recession since the 1930s? Many economists have studied when and how types of federal spending stimulate the economy. A few aren’t. Ignoring the exceptions may lead to a consistent belief system, but it’s bad economics.

A more serious problem with the crowding-out claim is that it only makes sense if the private sector is ready to spend but is prevented by the intrusion of government money. But in a deep recession, there is very little private spending to crowd out. That’s the whole problem right now! Did Laffer and his associates not notice this?

After making a few more questionable assumptions and misapplying an overly simple statistical model, the Laffer study eventually pops out its prediction of nearly 70,000 lost jobs. All in all, it’s a pretty dubious piece of work.

But the blanket statements don’t stop there. In promoting the Laffer study, a Civitas analyst has said that “government does not create wealth.” Clearly, the analyst has never driven on a government-built highway or visited a government-funded school.

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