EDITORIAL

Actos, Slings, Finasteride, and the Vaccine Compensation Solution

A "bad drug" commercial recently caught my attention. It featured a lawyer stating that if you had taken Actos and developed bladder cancer you could be eligible for cash compensation. Seconds later a flashing screen heralded a commercial showing an image of a bony pelvis with a mesh sling overlay. The theme again was if you were treated with a mesh sling and had problems, you could be eligible for cash. Strange, I thought. Two urology related pleas for launching a lawsuit. But moments later yet another law firm announced if you had taken finasteride and developed prostate cancer you should call now, once again dangling the cash carrot. These three ads comprised the rarely seen urology related litigation triple play on late night TV.

This "bad drug" TV advertising is certainly not limited to urology drugs or devices. No specialty, drug or medical device seems to be immune. What is somewhat concerning, particularly for the two drugs highlighted here, is taking new post approval FDA label warnings and commercializing them as if they were some type of willful and callous injustice against patients. In the case of finasteride, the approval was in 1992 and the prostate cancer risk label change did not come until 2011, almost 20 years later. Diabetics have an overall increased risk of bladder cancer. The Actos issue is still highly controversial. How can a bladder cancer in an individual patient be definitively related to the drug? If this post approval "bad drug" trend continues, the consequences are clear. Increasing costs for bringing useful drugs to market which have been vetted by the FDA for safety will continue as the litigation costs increase for any harms noted after approval. This will contribute to the ever rising costs of health care in the United States.

Any practitioner is fully aware that the reason prescription drugs require authorization is due to the potential for adverse effects. The vast majority are known at the time of approval, but some may only be discovered after the drug is widely used. Patients should know that a drug risk-benefit is in favor of the latter. As the crisis in rising health care costs continues, the need to protect patients should be balanced by the need to bring effective and lifesaving drugs to market. But is there a proven solution to this problem?

Let's examine the National Vaccine Injury Compensation Program (VICP), managed by the US Department of Health and Human Services as the model of a potential solution. A public health disaster was looming in the 1980s as many immunization manufactures were pulling out of the market. This was due to increasing lawsuits claiming immunization harms to children in particular. To avoid the calamity of insufficient vaccines, the government established the VICP to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by vaccination. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to individuals found to be injured by the medications. The US Court of Federal Claims decides who will be paid. The concept was brilliant and saved our country from losing access to immunizations while preserving the right of individuals to seek legal relief. It is funded by a manufacturer excise tax for those in this specific product area. If a patient or their parents believe that there was harm done it is the fund that is engaged in the courtroom and not the manufacturer. The plaintiff attorneys' significant bounties in these cases were contained and the program promoted reasonable legal fees. Suddenly the plaintiffs attorneys "jackpot" mentality of going after large cash awards was eliminated while protecting patient's rights.

Time has come to consider a similar restitution plan more globally for all prescription medications and medical devices. This would keep lawsuit abuse in check while respecting the ability of patients to seek relief if there is convincing evidence that damage occurred by an approved product. The potential saving to the health care system in terms of reduced litigation costs could be enormous. Another bonus: removing the "bad drug" commercial genre from our late night TV viewing.

Leonard G. Gomella, MD
Thomas Jefferson University
Philadelphia, PA