Prescription of a black box warning medication leads to a lawsuit...

Volume 2, Issue 5 **July, 2016**

Thinking Outside the (Black) Box

Background

A 67-year-old male has been treated by his primary care physician for many years for multiple diagnoses including BPH, anxiety and GERD. For the GERD the patient has been on a long course of Nexium and is also being followed by a gastroenterologist.

In December 2012 the patient presents to his primary care physician with complaints of recalcitrant heartburn and bloating. The PCP noted a prescription for Nexium 40 mg bid and added a prescription for Reglan (metoclopramide) 5 mg bid for a course of six months. There was no discussion documented by the PCP about potential side effects from the Reglan. Nor was there any documentation reflecting the physician's thought process about the length of time the prescription was written for (6 months).

The patient followed-up with the gastroenterologist the following month. The gastroenterologist noted that the patient was taking Reglan as well as Nexium. He also documented alternative treatment options for the patient's GERD. Finally, the gastroenterologist included a detailed note recording a "long discussion" with the patient and his wife about the potential adverse neurologic side effects of Reglan.

Six months later the patient followed up with his PCP. There is no documentation from this visit of the PCP asking about any potential side effects of the Reglan. The PCP wrote another prescription for a 90-day supply of Reglan which authorized two refills.

In November 2013 the patient was transported to his local emergency department with a chief complaint of tremors and dystonia. He was admitted to the hospital. He was seen in consultation by a neurologist who diagnosed tardive dyskinesia secondary to prolonged Reglan use. The offending medication was stopped but the patient's symptoms did not resolve. His tardive dyskinesia has been refractory to all treatments attempted.

The patient sued his PCP for negligent prescribing of the Reglan. Of note, the gastroenterologist was not named in the suit. The case eventually settled for an amount in excess of $1 million.

Discussion

In 2009 the FDA issued a “black box” warning on metoclopramide. The warning specifically mentioned the risk of movement disorders, such as tardive dyskinesia, associated with either long-term or high-dose use of metoclopramide. Prior to 2009 metoclopramide labeling already contained a warning about the risk of developing tardive dyskinesia with chronic use.

Many medications that are viewed as efficacious and safe can have detrimental effects if prescribed for chronic use. Examples of this include proton pump inhibitors and Pyridium, both of which have been implicated in the development of renal failure with long-term use.

In the case above it may have been entirely appropriate to prescribe the Reglan on a long-term basis (even with the existence of the “black box” warning). Doing so, however, requires the prescriber to document the discussion with the patient about the risks and benefits of such a long-term prescription. Alternate treatment modalities should also be considered and recorded in the medical record.

Subsequent encounters with the patient should address specific side effects caused by the medication in question. Organ-system specific history and physical exam findings, neurologic in this case, should be meticulously documented.

Why wasn't the gastroenterologist named in this suit? We may never know for sure but we can surmise from the medical records that the discussion the gastroenterologist had with the patient (and his wife) influenced the decision not to name him as a defendant. Numerous studies have demonstrated that when patients initiate lawsuits it frequently has more to do with communication skills than the quality of care rendered.

Action Points

Black Box Warnings - these medications are not forbidden to be written; they just require heightened vigilance. Additional patient education, research into alternate therapies and increased documentation will be required.

Chronic medication prescriptions - while these may be perfectly appropriate, they all require periodic review. Certain medications, like Reglan, may only be appropriate for chronic use if they are shown to be efficacious and there is no reasonable alternative.

Talk it out - the two action points above, Black Box warnings and chronic medication prescriptions, should be discussed with your patients. Education of the risks and benefits of the medications should be discussed, questions answered and documentation of the discussion should be recorded in the patient’s chart. The primary point of this is to

educate the patient, a secondary, but substantial benefit, is strengthening the bond between the patient and the doctor.

When side effects happen - we cannot usually predict which patients will have side effects to medications and which won't. A certain percentage will develop unwanted, and perhaps untreatable, side effects. The development of side effects is not, in and of itself, evidence of a poor prescribing decision. When side effects do develop, however, documentation of the risks and benefits of the medication as explained to the patient prior to initiating treatment will go a long way toward defending the doctor who writes the initial prescription.

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