Disclaimer: This lecture is not intended to be a comprehensive review or discussion on all issues of medical/pharmaceutical liability. It is meant to be a primer on general liability issues and practical suggestions related to the healthcare provider’s prescribing of medication to patients.
Public Perception/Understanding of prescription drug side effect warnings - Video 1

Public Perception/Understanding of prescription drug side effect warnings - Video 2
The Good

Benefits of DMT to the MS patient:

– slow disease progression
– relieve symptoms/reduces relapses
– improve quality of life
– potential for long term use

The Bad

Risks/Side Effects of DMT

– Infection
– PML (Progressive Multifocal Leukoencephalopathy)
– Headache, fatigue
– Melanoma
– Flushing
– GI symptoms
– Elevated liver enzymes
THE UGLY

• RECENT CASES

The Duty

“Standard of Care” = ordinary care = REASONABLENESS

“Ordinary Care” – that degree of care that a physician of ordinary prudence would use under the same or similar circumstances

“Negligence” – Means failure to use ordinary care, that is, failing to do that which a physician of ordinary prudence would have done under the same or similar circumstances or doing that which a physician of ordinary prudence would not have done under similar circumstances.

Texas Pattern Jury Charges
The Duty

- Duty + Breach of Duty (Negligence) + Causation = Liability
- Duty + Breach of Duty + Causation + No Damages = No Case
- Duty + Breach of Duty + No Causation + Damages = No Case

Learned Intermediary Doctrine

Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchases of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a “learned intermediary” between manufacturer and consumer.

Centocor, Inc. vs. Hamilton, 372 S.W.3d 140 (Tex. 2012)*

*Other states have overwhelmingly adopted the learned intermediary doctrine.

*Exception to Learned Intermediary Doctrine
— DTC (Direct to Consumer) Advertising—
Informed Consent

In a suit against a physician or health care provider... that is based on the failure to disclose or adequately disclose the risks and hazards involved in the medical care..., the only theory on which recovery may be obtained is that of negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.

—Texas Civil Practices and Remedies Code §74.101

“Reasonable Person” Rule v. Locality Rule

The reasonable person rule focuses on the disclosures which would influence a reasonable person in deciding whether to consent to (the treatment) rather than the disclosures the doctors in a certain community deem material.

Peterson v. Shields, 652 S.W.2d 929, 931 (Tex. 1983)

Proof required

1. The medical condition (side effect) is a risk inherent in the medical (treatment) performed;
2. The risk is material in the sense that it could influence a reasonable person’s decision to consent.
The Takeaway

Education
- stay informed of updated/recent drug information (FDA Manufacturer)
- review practice literature regarding use of prescription drugs
- attend lectures/conferences (CME)
- confer with colleagues

The Takeaway

Communication
- provide warnings/side effect information (Government, Manufacturer, Personal Experience)
- cover major issues (verbal)
- provide written information (package inserts, website information, office info sheets, Medication Guides/Consumer Info Sheets)
- invite patient to ask questions
- talk to patient with your eyes
- the more serious the side effect – the more serious the warning
The Takeaway

Documentation

– document in chart that patient was provided warning/side effect information (verbal and written material)

– document that patient was provided opportunity to ask questions

– document that patient indicated understanding of side effects, etc.

– document time spent with patient

– consider written consent form

– monitor patient/follow-up