THE PENCAK REPORT

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Website Update

I am launching a refresh of my website, www.pharmacylawpro.com by the end of the year. The website has information regarding the practice areas of my firm. It also has enhanced navigation, allowing you to access my blog, newsletter or contact me. Please contact me if you have any questions or comments regarding my newly-launched website.

You may of course access it now. You can find links to cases, articles and other items in my newsletter.

Controlled Substance Self-Protection

As a prescriber or pharmacist, you know the importance of pain management as part of the healing process. Healing occurs faster and further injury is limited. Therefore, your patients have a legitimate need for acute and chronic pain relief. And you have an ethical and professional obligation to alleviate needless suffering.

The DEA and State Boards **say** their intention is not to deter doctors and pharmacists from treating pain. Yet, we all know health professionals who have been punished for "overprescribing" or "over dispensing" controlled substances. Today, it is not enough that your motivation is pure and your patients are legitimate. I know many ethical prescribers and pharmacists who have been falsely accused of improprieties.

Pharmacists are especially burdened by balancing the need to provide adequate pain relief while serving as a screener for fake, forged or altered prescriptions, often without access to medical records. How can pharmacists objectively prove compliance with 21 CFR 1306.04(a) and still properly treat their patients?

How do you comply with these immense responsibilities? Government agencies are not helpful. I can help you because I have successfully helped many before you. A measure of my success is **not** reading in the newspaper about an indictment of a pharmacy or clinic that I represent. I can best help **before** there is trouble.

DEA Crackdown

You need to read a recent *Washington Post* article entitled, "DEA Crackdown Hurts Nursing Home Residents Who Need Pain Drugs", October 29, 2009. The article highlights the suffering of nursing home residents and Hospice patients due to a DEA crackdown on prescription drugs. The DEA put stricter enforcement in effect in **Michigan**, Ohio, Wisconsin and Virginia this year. A coalition of pharmacists, geriatric experts and Senate Democrats asked Attorney General Eric Holder to revise DEA regulations. Currently, pharmacies are intimidated because they can be fined tens of thousands of dollars if they deviate from strict procedures requiring doctors to sign paper prescriptions and fax them to the pharmacy before a nurse can administer them in a nursing home.

The "war on drug philosophy" has failed. Widespread unemployment exacerbates drug diversion. I don't believe hospices, nursing homes and pharmacies should be a "battleground" in the war on drugs.

The link can be found in my blog.

Where are the Pharmacists?

The debate over health care reform is missing an **informed** voice—pharmacists. Who is more authoritative on prescription health insurance, **you** or media pundits *in the pay of* health insurance companies?

The role that pharmacists can play in educating and crafting legislation has been undervalued. Patients justifiably trust their pharmacists to navigate them (free of charge) through complex insurance coverage issues.

Why should pharmacists take an active role? Pharmacists could be among the top beneficiaries of insurance reform.

Imagine being able to concentrate on counseling patients, medication therapy management and dispensing without the irritating and expensive hassle of multiple rules for dispensing or authoritarian and predatory auditors. Imagine owning a pharmacy and being able to compete on an even playing field with all.

Imagine an America with universal health care that cuts out the enormously expensive overhead costs of private, monopolistic health insurers. As you may know, top executives are being compensated at the **b**illion-dollar level!

To explain this to a patient, I like a simple, arithmetic example. To pay for *just one*, low level, 10 **m**illion dollar a year insurance executive, either 10,000 must pay $1000 per year in insurance premiums or 100,000 people must pay $100! Small wonder insurance is so expensive and insurance companies will spare no expense to preserve their astronomical profits. I don't have enough zeroes to calculate what the billion dollar man costs.

Presently, health insurance companies are **not** regulated. If reform means **state** regulation, then the insurers will domicile in the state with the most favorable or no regulation, the same way credit card companies do.

Only a true government option, such as extending Medicare to all citizens, would provide meaningful competition to the presently omnipotent insurers.

Another false argument made by the insurance companies is that "government can't run anything". Enron and AIG could? If insurance companies really believed that, why do they **fear** competition from government?

You may also inform people that today, significant advances in pharmacology come at public expense through National Institute of Health (NIH) funded research.

Big Pharma all too often "innovates" repackaged versions of drugs about to go off-patent. These "new" patented drugs are often of questionable value but are always more expensive.

I wonder whether the "new" version of Auralgan Otic is reasonably priced at about $150 wholesale and presents any therapeutic advantages over the older or generic versions, (antipyrine or benzocaine). I am certain you have similar questions of your own.

Get off the bench and into the game. Your knowledge is needed.

Pharmacy Liability

The *Wall Street Journal* carried an article about a case pending before the Nevada Supreme Court regarding pharmacy liability for patients abusing drugs. In this case, a woman, Patricia Copening, was abusing prescription drugs and, while driving, struck and killed one man and injured another. The victim and families filed a suit against Wal-Mart, which dispensed a prescription to Copening. State officials had sent letters to pharmacies in the area; warning them that Copening might have been abusing drugs. With this information, what legal responsibility do pharmacies have?

The link can be found in my blog.

Preserving Your Health

We know intellectually about the necessity of exercise in preserving our bodies, particularly after age 35. Yet, most of us do not take our own advice. Being a health care professional is stressful, including standing on hard surfaces for long hours and irregular meals with no respite from pressure.

I believe many busy health professionals are too discouraged to exercise themselves because they believe exercise myths that you really aren't exercising unless you run five kilometers a day or lift weights for an hour every other day

I highly recommend *Body by Science*, by Little and McDuff MD. Dr. McDuff presents a persuasive argument, backed by citations to medical studies, that you can gain the health benefits

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of exercise by strength training only once, every seven days. Make no mistake; this one strength training session **must** be **very** intense but brief. In a nutshell, you obtain all the health benefits of exercise without wearing out or damaging your joints and causing arthritis as you are more likely to do with repetitive high impact exercise, like long distance running.

The "triathlon/marathon/running" industry has done a wonderful job of persuading the masses that it is the **only** way, despite evidence that it damages knees, kidneys, hearts and actually decreases longevity. As I write this, although the pathology reports are not complete, three "physically fit" runners died in the half-marathon portion of the annual *Detroit Free Press*/Flagstar Marathon.

Therapeutic Interchange

Therapeutic interchange is dispensing one drug, which differs from the prescribed drug chemically, but is expected to have the same or similar effects. The main benefit is cost savings. Therapeutic interchange is common in closed systems, such as hospitals and the VA but it is possible to do at your pharmacy too, if you proceed properly.

I can advise you on how to follow the rules on therapeutic interchange and work with physicians and patients to ensure a safe, legal program. If you want to enter into this professionally satisfying practice, I would love to draft the documents for you and your prescribers.

Be Ready to Compound

There are concerns about Tamiflu shortages because a bad flu season is expected. Already pharmacies are dispensing higher amounts than previous years and some pharmacies are running low. Many pharmacies are resorting to compounding Tamiflu liquid doses, especially for children. Get ready to compound by securing supplies and equipment now. I personally enjoy compounding and always did.

Negligence versus Malpractice

In a recent case, a Michigan appeals court ruled a dispensing error was ordinary negligence, not medical negligence. In the case, Prograf 5 mg was dispensed instead of the prescribed Prograf 0.5 mg. The court ruled that the 10-fold error was like a clerical error, not a professional error.

The Michigan Supreme Court reasoning regarding negligence versus medical error is, "[i]f the reasonableness of the health care professionals' action can be evaluated by lay jurors, on the basis of their common knowledge and experience, it is ordinary negligence. If, on the other hand, the reasonableness of the action can be evaluated by a jury only after having been presented the standards of care pertaining to the medical issue before the jury explained by experts, the claim sounds in medical malpractice."

So what does this mean? A three-year statute of limitations instead of two years and much less procedural protection and substantive protection. I believe that the defense should have argued that it would take a pharmacist's knowledge to **recognize** an overdose of a medication.

Pharmacist Pay Discrimination

The Massachusetts Supreme Judicial Court unanimously upheld a $2 million award to female pharmacist Cynthia Haddad. She worked over 10 years for Wal-Mart before being fired. Haddad claimed in the discrimination lawsuit that she was fired for complaining that she earned less money than her male colleagues. Justice Judith Cowin wrote in the decision, "There was evidence that Wal-Mart paid the plaintiff substantially less than less-experienced male pharmacists, refused to pay the plaintiff the pharmacy manager salary differential that it paid to male pharmacists, and terminated the plaintiff purportedly for a single policy violation but did not terminate male pharmacists for that or for more serious infractions involving violations of State and Federal law." I wonder whether this is happening in Michigan?

Bilingual Pharmacy Services?

Some people have proposed that all pharmacies should offer bilingual services in English and Spanish. Bilingual services can be a smart business practice and reach more members of the community. However, it should not be mandated but rather be an individual's business decision. In some areas of the country, Spanish is almost essential, but in Michigan, it is not as prevalent. Rather, services offered in Arabic, for example, would be more useful in some parts of the state.

While it is the prerogative of individual businesses to make the decision, in my own experience, I know the importance of recognizing and adapting to working with all members of the community. It is also more interesting because I learn new things from my clients.

DME Accreditation Delay

A bill delaying Medicare durable medical equipment (DME) accreditation deadlines passed in the House and Senate. It was signed by the President on October 13. The previous deadline was September 30, 2009. It will be extended to December 31, 2009.

Georgia Pharmacy Audit Bill of Rights

In 2006, Georgia passed "The Pharmacy Audit Bill of Rights". This law set guidelines auditors must follow when auditing pharmacies. Some of the important guidelines include:

- Notice of at least one week prior to conducting on-site audits
- A pharmacy has at least 30 days following receipt of the preliminary audit report to produce documentation addressing discrepancies
- Audits cannot be initiated or scheduled during the first seven calendar days of a month due to high pharmacy workload during that time

This Audit Bill of Rights is an important first step in guaranteeing fair and equal treatment of pharmacists by auditors. Pharmacists in Michigan should continue to contact their State Representatives to enact an Audit Bill of Rights here.

For the complete text of Georgia's Audit Bill of Rights, please visit my blog.