

ATTORNEY GENERAL JANET MILLS
REMARKS TO THE MAINE MEDICAL ASSOCIATION
PRACTICE EDUCATION SEMINAR
WEDNESDAY, JUNE 3, 2009

Thank you for inviting me to speak to you today. I am no stranger to the medical world and the community of physicians in this state. I live in Farmington, just a block away from Franklin Memorial Hospital, home to the award-winning Franklin Health Network and the groundbreaking Healthy Community Coalition.

My sister is a physician who later earned her MPH at Harvard and now serves as the Director of the Maine CDC—as I call her, the “Queen of Health.”

I want to say a few words about how the Office of the Attorney General interacts with the medical community and then entertain any questions you may have.

Although medical practitioners sometimes see lawyers as antagonists and troublemakers, I see our offices working in concert, for the most part, in order to solve a broad array of medical-legal issues in today’s society, including some of the most dangerous phenomena to hit our state in decades.

1. Medical professionals as witnesses:

There is a longstanding—and somewhat justifiable—fear by doctors of being called to testify in court. I say “justifiable” because we all know that being subpoenaed is a disruptive, time-consuming and annoying event. It is financially costly and costly to the health of patients who await your attention.

In recent years several things have been accomplished to address some of these concerns:

SAFE Program: The Attorney General’s Office continues to provide training for dozens of nurses and investigators annually in the forensic examination and collection of evidence in sexual assault cases. The intent of this training and uniform protocol is to obtain effective evidence, increase the number of guilty pleas without the victim’s testimony, achieve convictions and sentences that are just *and* avoid involving ER doctors, OB-GYNs and primary care doctors in courtroom proceedings.

MTLA – MMA protocol: With Gordon Smith’s help, and the Bar Ass’n and the Trial Attorneys, efforts are underway to update the doctor-lawyer protocol and to circulate it to all lawyers, not just those who do trial work regularly. It deals with trial discovery issues, the timely provision of medical records, fees and scheduling of depositions and court hearings when absolutely necessary.

The records exception to the Hearsay Rule and 16 MRSA 357 allow certified records of hospitals and other medical facilities into evidence, including copies of these records, if they are certified by the custodian of the record as being accurate. These rules & statutes allow medical records to come into evidence without the testimony of the physician. Records can also be offered if they are relied upon by another physician, an expert who has reviewed them in forming an expert opinion.

AG/DAs’ access to medical records, 5 MRSA §200-E:

“In any criminal proceeding or investigation, where medical examination or treatment has been provided to a victim, upon written request of the Attorney General,...or the district attorney...an entity which has rendered the examination or

treatment shall immediately provide the authorized person with all medical records pertaining to the medical examination or treatment...”

The records remain confidential except as to the prosecutor and investigating officer, subject to further court order.

This law does not obviate the need for live testimony, but it shortens what might otherwise be a fishing expedition in an important investigation.

2. FTC Red Flag Rule – This new rule has been postponed twice; the effective date now 8/1/09. The rule will require basically all creditors to ‘red flag’ accounts of people who might be victims of identity thefts, and it identifies 26 red flags. You will be hearing more about this later in the day.

3. Data Mining law – This is a state law enacted in 2007 which allows physicians to check a box when they re-register with the Board of Licensure to prevent data about their prescribing practices from being used for marketing purposes. The purpose of the law is to restrict the marketing of individual prescribing practices by so-called “prescription drug information intermediaries.”

IMS Health Corp. brought a lawsuit to enjoin this law in federal court before it could take effect. In January 2008 the federal court in Bangor issued a partial temporary restraining order. That case is on appeal in the First Circuit law, pending a review of certiorari by the US Supreme Court of a similar case out of New Hampshire. The law is partially on hold, *but* doctors can still sign up for their prescription data will not to be used for marketing if the law is allowed to go forward.

4. Licensing Boards

As you know, my office performs a dual role—as counselor to the licensing boards and as sometime prosecutor of licensing violations.

Bd. of Registration in Medicine

We have been involved in app. 25-30 disciplinary actions against medical doctors in the last couple of years. They are based on a variety of grounds. Importantly, *none* of them were based on allegations of *under* prescribing of drugs.

32 MRSA sec.3282-A(2) – grounds for discipline: fraud or deceit in obtaining a license or in the delivery of health care, habitual substance abuse, a diagnosis of a mental or physical condition that may endanger patients, aiding and abetting unlicensed practice, incompetence, unprofessional conduct, conviction of a felony or crime of dishonesty or a crime related to medicine; false or misleading advertising, “*prescribing narcotic or hypnotic or other drugs listed as controlled substances by the DEA for other than accepted therapeutic purposes*”; and revocation or suspension of licensure by another state.

Similar language for the Bd. of Osteopathic Medicine and the Bd. of Nursing whom we also counsel in licensing proceedings and the like.

Nursing Board:

Our office has been involved in app. 200 licensing cases a year involving nurses (out of 24,000 licensed nursing professionals in Maine), a substantial number of them involving substance abuse allegations and drug diversion. The legislature, in response, just this year enacted a law establishing a nurse health program for impaired nurses. The

law also requires nurses who the board determines are suffering from a mental illness or the use of intoxicants or drugs to submit to a mental or physical examination as a condition of their license.

5. HIPAA enforcement

This is a new role for our office, and frankly we haven't yet thought through the details.

The federal stimulus funding package, the "American Recovery and Reinvestment Act of 2009," makes certain changes to HIPAA. In the case of a breach of protected health information, the covered entity that discovers the breach must notify the individual that their records have been disclosed within 60 days of the breach. Notice is primarily by first-class mail.

In the case of a massive breach—involving more than 500 residents—the entity must also notify the media and the Sec. of the US HHS immediately. In breaches involving fewer than 500 people, the entity may maintain a log and provide this log to the Sec. of HHS annually.

This legislation also authorizes the *state* Attorneys General to enforce HIPAA. It allows the AGs to bring civil actions (not criminal) to enjoin violations and to obtain damages on behalf of residents of between \$100 and \$25,000. In successful actions the Attorney General may also be awarded attorneys fees.

The United States Attorneys, however, retain authority to prosecute criminal or *intentional* violations of this law on behalf of the Secretary of Health & Human Services. It is unclear where the line will be drawn and exactly how we will enforce it. Once there is a new U.S. Attorney appointed for the State of Maine, I will sit down to discuss this matter with him or her.

For the most part, our office will not be out beating the bushes looking for HIPAA violations; but we will act upon any complaints received (there have been two that I am aware of) and will determine if our office or the U.S. Attorney's office should handle the particular matter.

The law also requires the Secretary of HHS to designate an individual in each regional HHS office within the next few months to give guidance and education to both the public and to covered entities regarding HIPAA requirements.

Former Assistant Attorney General Ken Lehman will be talking to you more about HIPAA later today.

6. Healthcare Crimes Unit

This has been existence since 1979. It consists of two lawyers, four investigators, one auditor, a paralegal and a secretary.

The Healthcare Crimes Unit within the Attorney General's Office (which is the Medicaid Fraud Control Unit for the State of Maine) investigates fraud or abuse by a health care provider or its employees or abuse or neglect or exploitation of a resident of a health care facility or by a provider, including home health care services, that is funded by MaineCare or Medicare. Reports of such incidents to our HealthCare Crimes Unit are an *exception to HIPAA*. They are not only encouraged, they are required by state and federal regulations and good faith reports are provided with immunity.

22 MRSA sec. 1711-C(6) gives examples of when a practitioner may disclose information without authorization—including when one is reporting in order to protect the public health and welfare when authorized or required by law, or when reporting a suspected crime against the practitioner or facility and when authorized by law. This law works in tandem with the federal and state laws, which are exceptions to HIPAA.

The Healthcare Crimes Unit can receive detailed information regarding patient care and abuse, though they cannot redisclose it further without a court order.

Statistics: Last year the Healthcare Crimes Unit obtained ten criminal convictions—three cases of fraud and seven cases of patient abuse/neglect/exploitation. The Unit also recovered \$3.7 million for the State from civil cases and settlements against pharmaceutical companies, for instance, for deceptive marketing practices. Currently we have 65 open investigations. We are working with the US Attorney’s Office and other federal agencies, with state licensing boards, with law enforcement at all levels and with enforcement agencies in other states to ensure that state and federal Medicaid and Medicare funds are spent wisely and in the public interest.

The HCU Hotline Number is: 626-8870

And the HCU email is: ag.hcu@maine.gov

7. Prescription Drug diversion

Finally, and most importantly, I want to talk to you about prescription drug diversion.

Here’s a problem in which we can all share the solution—and in which we all *must* share in the solution, for it is urgent.

A. The Problem:

Statistics/Consequences—

Surveys show that 10-20% of all adults have chronic pain (non-cancerous) for which they’re taking some medications.

In 2005 more than 10 million Americans were abusing prescription drugs—more than the combined number of people abusing cocaine, heroin, hallucinogens and inhalants.

Washington County reportedly has the highest incidence of prescription drug abuse in the state; and Maine is one of the highest in the nation for Oxycodone and OxyContin abuse.

The CDC tells us that prescription opioids are associated with more drug overdose deaths than are cocaine and heroin combined.

In 1998 the MDEA, working with the Attorney General’s drug prosecutors, reported only 50 arrests for prescription drug offenses, 7% of all drug arrests that year. In 2008, however, there were 259 arrests for prescription drug offenses, and they accounted for 39% of all drug arrests.

Keeping in mind that *arrests* are just the tip of the iceberg, and that MDEA is just *one* law enforcement agency that makes arrests and seizes evidence in drug cases, MDEA’s arrests alone resulted in the seizure of 10,889 pills in 2008, nearly double the amount seized in 2005. Over the past ten years, MDEA has seized approximately 87,000

prescription pills in drug trafficking arrests.

Diversion of prescription drugs has now outpaced cocaine for the first time, according to the Director of the MDEA, Roy McKinney.

This is a public health issue, an economic issue, a public safety issue.

The number of drug induced deaths from prescription drugs between 2000 and 2008 more than doubled. Just last week, reading the summaries of twelve unattended deaths in Maine, I noted that six of them—one half—appear to be related to prescription drugs.

There were 154 deaths involving prescription drugs in 2007, 164 in 2008. four times the number in 1997. As Dr. Marcella Sorg has noted, the number of persons dying from drug overdose now rivals the number who die each year from motor vehicle accidents.

The percentage of these deaths which were caused by at least one pharmaceutical has increased to greater than 90%, *the highest percent ever*. Our tax dollars are paying for the drugs (MaineCare, Medicare) and our tax dollars are then paying for the treatment for addiction and dependency. Doctor shopping has become commonplace, very expensive and difficult to control.

More importantly, 343 drug-affected babies were born in Maine last year. And most of these babies were born in the rural areas of Maine, Lewiston north. This is *not* simply a big city problem.

Just last week there were 3 overdoses in New Hampshire—a 20-year old who accidentally overdosed on methadone, klonopin and alcohol; her 22-year old roommate; and a 19-year old boy who died of an accidental overdose of the painkiller fentanyl.

Elderly people are being abused and exploited for their prescriptions. A woman in her 70's said she allowed her grandson to take her pills and use them himself and sell them on the street, leaving her with only small insufficient doses, because she was afraid he would leave and she would have no one to take care of her if she didn't.

The newly published US Dept. of Justice report, "National Prescription Drug Threat Assessment," concludes that the diversion and abuse of prescription drugs has cost public and private insurers \$72.5 *billion* a year and that it has resulted in a 114 percent increase in overdose deaths.

Our office prosecutes all murders in Maine. Last year there were 31 homicides—the highest in 30 years. We count at least five in the last two years that were related to prescription drugs. People are killing each other over these pills.

Then there are the robberies, thefts, burglaries, home invasions and assaults of all kinds.

Prescription drug diversion is an *epidemic* in our state, in our nation today... We need to cry out, "*All Hands on Deck!*"

B. What has been done?

Mailback program – This is a pilot program funded by an EPA grant – The state has gotten back several thousand envelopes so far, containing app. two hundred thousand pills which have been returned for proper disposal to the MDEA; 86% of those pills were controlled substances, and nearly half of the total were medicines that were out of date.

New prescription forms have reduced the number of thefts of scrips.

Internet trafficking has been a major source of prescription drugs. In 2006, 34 rogue Internet pharmacies dispensed nearly a hundred million dosage units of hydrocodone combination products.

The Ryan Haight Act of 2008 gives new enforcement tools to the federal government to prosecute these rogue pharmacies and rogue doctors.

The FDA is imposing new limits on prescription of schedule II narcotics (Feb. 2009 NYTimes). I believe you will see more action at the federal level to combat prescription drug abuse.

Prescription Monitoring Program:

38 states have enacted PMP legislation. I can't stress enough the importance of doctors & doctors' offices accessing, checking the PMP before prescribing or re-prescribing a drug, particularly one that is often abused or sold. Pending legislation in other states would *require* doctors to check the PMP; we have not proposed that here in Maine.

Legislation did just pass in Maine to allow the state's MaineCare administrators to have put in data and access the PMP.

The PMP could also be equipped to cross check names and data and report apparent misdeeds to primary care docs so the doc can have patient in and refer them for services, discontinue a prescription.

Insurance companies and CMS have utilization data. They could clamp down, warn doctors of apparent abuse through prescriptions (though not in their bailiwick if patient pays with cash for one or more px's).

I want to also go over the provisions of the Criminal Code relating to "Acquiring Drugs by Deception" which should be of interest to you, because these provisions have been tightened in recent years.

Note first that drug offenses are not simply furnishing or possessing or selling; they include possessing a drug not in the prescribed container; and they include using a drug in a manner not prescribed.

17-A MRSA sec 1108, copies provided here, makes it illegal for a person to obtain or exercise control over a prescription for a scheduled drug as a result of deception. "Deception" includes:

"Failure by a person, after having been asked by a prescribing health care provider or a person acting under the direction or supervision of a prescribing health care provider, to disclose the particulars of every narcotic drug or prescription for a narcotic drug issued to that person by a different health care provider within the preceding 30 days; or

Furnishing a false name or address to a prescribing health care provider or a person acting under the direction or supervision of a prescribing health care provider."

This criminal statute also abrogates the privilege for communications made to a health care provider in an effort to obtain drugs by deception. And the statute allows a

health care provider to report a suspected violation to a law enforcement agency, with immunity for good faith reporting.

C. What more can be done?

We have a problem with people traveling out of state to get prescriptions filled, oftentimes easier than here in Maine. So, we must work to tighten controls among the states.

We are told there is sometimes a problem with coordination between primary care doc and specialists, that a specialist is prescribing a controlled drug without the knowledge of the primary doctor.

We can expand the use of the PMP to prevent this from happening.

Less than a quarter of all prescribers in Maine—dentists, doctors, nurse practitioners, osteopaths, podiatrists and physician assistants—are currently registered in the PMP. Only 10% of pharmacists in Maine are registered with the PMP. And the major ones—Rite Aid and CVS—are putting data in but do not check the PMP before filling a prescription.

The data for the PMP also needs to be updated more quickly.

Marketing/Pharma companies continue to promote painkilling drugs, in stark contrast to the lethal reality. Note in particular Purdue Pharma's admission in 2007 that it falsely and intensely marketed OxyContin to doctors over a five-year period, selling this drug as being less subject to abuse or withdrawal symptoms and less addictive than other painkillers. The criminal convictions and massive monetary settlements that resulted from this misconduct will *never* undo the deception inflicted on thousands of physicians and the great harm that was done to millions of consumers and their families.

We can clarify the standard of medical care—

LD 1193 is a Resolve for the Board of Licensure in Medicine to convene nursing, dental, Office of Substance Abuse, podiatrists, osteopaths, medical and veterinary professionals to develop a common protocol for the use and administration of controlled substances. There is no good reason not to have a uniform standard or policy across all of the professions which prescribe controlled substances.

The proposed updated version of Chapter 11, circulated to the six professional boards as a model, recommends a detailed controlled substances contract for patients taking scheduled drugs and it reiterates the obligation to deal with illegal acts perpetrated by patients, including reporting these acts to law enforcement.

Implications for medical professionals:

The Model Policy becomes the standard of care—plus or minus, for over prescribing or for under prescribing.

Dr. Scott Fishman points out in his book, Responsible Opioid Prescribing, “The collision between the War on Pain and the War on Drugs has created a ‘perfect storm’ of controversy. And, for better or for worse, physicians are being enlisted to fight on both fronts: combating pain while simultaneously reducing the risk of diversion and abuse of, as well as addiction to, pain medications.”

Fishman's book, commissioned by the Federation of State Medical Boards, is recommended reading for all primary care doctors and pain specialists. And I understand it has been distributed, with the help of this Association and the Board of Licensure, to all licensed medical doctors in the State of Maine.

As a non-physician reading that book, what I found most cogent was the emphasis on measuring progress through documented improvements in life *functions*, if and when prescription opioids are required for treatment of a serious and chronic condition. Documentation of concrete progress in specific areas such as work, sleep and social interaction will improve the patient's life, minimize the risk of addiction and keep your practice within the professional standard of care.

Secondly, Dr. Fishman recommends a contract for care, or physician-patient agreement especially when opioids are involved in treatment. These documents should include a one-doctor, one-pharmacy agreement and perhaps a random drug testing agreement, among other things.

I would take this one step further and ask the patient to disclose any federal or state convictions or pending proceedings or probation conditions involving the alleged use or furnishing of any scheduled drug.

The medical professional needs more information beyond that which the patient is willing to give. A patient may be on probation for drug trafficking, or may be out on bail for drug abuse, or may have just been convicted and be on his or her way to prison. It's indelicate, to say the least, for the doctor or nurse to solicit this information. And it's too much to expect for the medical professional to read the arrest log and the court news in the local paper in order to check up on a patient's status.

I would ask that all of you develop a relationship with your local law enforcement agencies so that they may notify you of arrests and convictions involving drug related offenses. It's all public information. It's just a matter of having it and using it.

We can't legislate our way out of this problem.

We can't prosecute our way out of this problem.

We have *got* to be aware at all times and at all costs of what is being prescribed, how much is being prescribed, to whom it is being prescribed and for what it is being prescribed.

Prescription drug diversion is a major cause of death in our state.

It is the number one excuse for crime in this state.

And together *we* have got to stop it.

I believe you in the medical field *must* err on the side of caution and not give out these drugs except as a very last resort. Prescribing opioids is supplying an underground economy of death and violence, abuse and exploitation. The consequences are devastating.

When you give a drug trafficker or an addict a prescription for opioids, you are giving them a prescription for a profit, a prescription for a problem.

Consider that your son or daughter, your neighbor's child, your children's schoolmates, will be the ultimate consumer of these drugs; that these drugs will be mixed with other narcotics and with alcohol in a fatal cocktail for someone's child.

Because this is today's reality.

Do not prescribe large quantities of opioids. Do not authorize refills of opioids and other scheduled drugs based on call ins by patients or common excuses akin to "the dog ate my term paper"... (cf. DEA guidelines)

I hope that medical professionals will adopt more than a proactive approach to this problem. I hope that you will adopt a *zero tolerance* for illegal behaviors and deceptive drug-seeking activities.

We cannot afford more drug addicted babies, more drug overdoses, suicides, homicides, robberies and assaults of all kinds.

A much more *cautious* and *circumspect* policy towards pain management is called for. The health and sanity of our state is at stake.

Again, my office is pledged to work *with* you, not against you, to rid our state of this epidemic, to allow the terminally ill, the elderly and patients in real need to receive the palliative care they need, while keeping scheduled drugs out of the hands of traffickers and abusers who feed these pills to our children and to themselves.

Thank you.
