Talking with June L. Dahl, PhD: The Impact of Legislative and Regulatory Policy on the Practice of Pain Management in the United States

An Interview with June L. Dahl, PhD

BY LENNIE DUENSING

THIS INTERVIEW WITH JUNE L. DAHL, PHD, *is based on her presentation at the Academy's 16th Annual Meeting. Dr. Dahl is Professor of Pharmacology at the University of Wisconsin School of Medicine and Public Health. She received a PhD in Physical Chemistry and spent many years in basic research before turning her attention about twenty years ago to efforts to bring improvements in pain management. Her focus on pain began when she was serving as Chair of Wisconsin's Controlled Substances Board and cofounded the Wisconsin Cancer Pain Initiative with David Joranson. She currently serves as advisor to the Alliance of State Pain Initiatives and remains involved in work directed at the knowledge, regulatory, and system barriers responsible for the undertreatment of pain.*

Q. At the Academy's Annual Meeting, you indicated that certain laws and regulations might serve as barriers to effective pain control in this country. What evidence do we have that this is so?

DR. DAHL. First, it's important to be clear about the laws and regulations that are the focus of our discussion. These are the ones that govern the production and distribution of controlled substances. Most of these drugs, especially the opioids, have important medical uses. We are particularly concerned about opioid analgesics, which are essential to control of moderate to severe pain. The purpose of these laws and regulations is to prevent the diversion of controlled substances to the illicit market—and therefore to protect the public from the adverse effects that are associated with the abuse of these drugs.

Many people in pain management feel that these laws and regulations have a negative effect on pain management, and data support that concern. Surveys conducted over the last decade have documented that physicians alter the way they prescribe these medicines because of their concerns about regulatory scrutiny. They may prescribe lower doses, or they may prescribe them for a shorter period of time. Even more shocking are reports that physicians may even be reluctant to prescribe adequate doses for patients who are dying and in severe pain.

Probably most frustrating are reports that some physicians are so paranoid about laws and regulations that they won't prescribe these drugs at all, particularly for those with chronic non-cancer pain problems. Adding to the challenges are the results of surveys that show that physicians don't know what they [the laws and regulations] are. It's not surprising that laws and regulations have a chilling effect on pain management.

The problem is further compounded by the increase in diversion and abuse of prescription medications. The abuse is a real thing. Some people have

described it as an epidemic—we've all seen the media reports. I'm not sure if it is an epidemic, but it is a significant problem and there are tragic reports of deaths of teenagers who have gotten hold of these medicines and have overdosed on them. So there are increased concerns among physicians that they might be duped by people who are not really pain patients, but substance abusers who want these medicines for illicit purposes.

The challenge we face is to get the data needed to demonstrate conclusively that fears about prescribing, and changes in prescribing practices, affect patient care. We assume they do, but we don't have the kinds of studies that are needed in order to support that conclusion. If you go about the business of changing the regulations—removing these barriers—then you need baseline data to demonstrate the effect on patient care.

cannot call in prescriptions for Schedule II drugs, and they cannot write for refills. For these reasons, it is more challenging to get those medications. The drugs in the schedules that have the higher numbers are less restrictive in that physicians can write for refills (they can have five refills within a six-month period), and they can call in the prescriptions. This allowance probably contributes to the fact that hydrocodone with acetaminophen is the most prescribed drug in the United States. It's a great analgesic; however, you can't give a lot of it because of the toxicity of the acetaminophen in it.

It's important to know that the federal laws govern the drugs themselves and their distribution through the system—from the supplier to the end user at a health care facility or a pharmacy.

The challenge we face is to get the data needed to demonstrate conclusively that fears about prescribing, and changes in prescribing practices, affect patient care.

Q. Are there federal laws that are particularly problematic?

DR. DAHL. The answer is, 'No!' In fact, there is nothing in federal law that prevents the appropriate use of opioid analgesics for pain control. Federal law recognizes that these drugs are essential for the public health, and guarantees that they will be available to patients who need them. And federal law has not placed any restrictions on the amount of drug or the length of time that such a drug can be prescribed. I think there is a misunderstanding and an assumption that federal laws are in the way, when indeed they are not. Recent actions by the Drug Enforcement Administration (DEA) have certainly contributed to that assumption.

The Controlled Substances Act (CSA), which was passed by Congress in 1970, is designed to assure the availability and control of drugs that have the potential to be abused. It is administered by the Drug Enforcement Administration (DEA), which is in the Department of Justice. The CSA places drugs, which have the potential to be abused, into five schedules. These are designated by Roman numerals I-V.

Those in Schedule I are drugs such as marijuana, heroin, and LSD—drugs that are not approved for medical use in the United States. Very important drugs for pain control, such as morphine, fentanyl, and oxycodone, are in Schedule II. Drugs in Schedule III are those that have less potential to be abused, such as hydrocodone and codeine in combination with acetaminophen. In Schedule IV, you find drugs such as propoxyphene, which is a very ineffective analgesic. In all states, except New York, benzodiazepines are in Schedule IV. Schedule V includes drugs such as anti-diarrheals and cough medicines. In most states, you don't even need a prescription for these drugs.

Now, what difference does it make for the clinician and for the patient if a drug is in Schedule II as compared to being in Schedule III, IV, or V? A major distinction is that clinicians

Q. What laws and regulations exist on the state level? Which ones are particularly problematic?

DR. DAHL. All states have laws regarding controlled substances that resemble those on the federal level, but states have also promulgated their own. These are the ones that are particularly problematic. We have to bear in mind that the federal laws and regulations deal with the drugs, whereas the state laws and regulations govern professional practice. So, in every state, we have licensing boards for physicians, nurses, and pharmacists. These boards are not only responsible for licensing clinicians, but also for investigating complaints about the practices of these healthcare professionals.

Getting back to these laws and regulations, many of the states (26 of them at last count) have implemented prescription-monitoring programs (PMPs). These began many years ago in a few states such as New York, Texas, and California. Initially, these were programs in which physicians purchased special prescription forms (triplicate forms) to write prescriptions for Schedule II substances. A barrier was clearly created by that requirement.

Several years ago I wrote to the controlled substances authorities in the states with "triplicate" programs to find out how many physicians purchased the forms, and how many physicians had used them to prescribe Schedule II drugs. I was surprised to find out that in the State of California, for example, only about half had actually purchased the forms. This told me right away that these PMPs had created a barrier.

In the early '90s, when pharmacies were computerized (because they were transmitting data to third-party payers), the states switched to electronic data-transfer systems (EDT programs). Then the programs became more sophisticated. In August 2005, President Bush signed the National All Schedules Prescription Reporting Act (NASPER) into law. It was to provide sixty million dollars through 2010, to enable states to

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establish prescriptionmonitoring programs, or to upgrade their existing programs. The Alliance of State Pain Initiatives recommends that all medications in Schedules II – IV be monitored to avoid the potential for a PMP to reduce the appropriate use of Schedule II drugs. Indeed, most states do monitor Schedule II to IV drugs; only three track just Schedule II drugs. It is also recommended that PMP programs be administered by a state agency responsible for health matters; however, in a few states, reports are made to law enforcement agencies.

Q. What value do PMPs have?

DR. DAHL. One of the values PMPs could have is to allow physicians to get ready access to data. So, if a patient exhibits aberrant behavior, the physician could call up information from the database about the patient and either be reassured that everything was fine, or have his or her suspicions confirmed. Unfortunately, the turnaround time is slow. The folks in Texas who run the PMP (which is old and only tracks Schedule II drugs) told me that some rural pharmacies don't have computers to transmit data, so the turnaround time is very long—which means that physicians can't access the data quickly. And in some states there's isn't a provision in the law for physicians to access the database. And these programs can be very expensive.

So I think that it's important that when states implement PMPs, they make sure that certain features are in place—that the PMPs cover all controlled substances, not just Schedule II drugs; that the states report data to health agencies, not law enforcement agencies; and that the data are readily accessible so that there is a rapid turnaround and also that confidentiality is protected.

Q. What happens on the local level? How do *attitudes* about opioids influence patients and physicians?

DR. DAHL. There is such a stigma associated with treatment with opioids that many people don't want others to know—even if they have a severe pain problem for which opioids are appropriate and without which they would have no quality of life. I don't know how we are going to get rid of that stigma. You can get rid of all the impediments in laws and regulations and still not remove that lack of security or comfort.

I had a call from a patient in northern Wisconsin who told me that the pharmacist dispensing her medicine (she was on chronic opioids) reported her to the sheriff and asserted that she was probably a drug abuser. This patient sent me an X-Ray of her cervical spine, and you could actually see the lesions! So it's not just the medical board or the laws and regulations per se, but sometimes it's the attitudes of law enforcement at the local level that creates the problems. In these cases, the local sheriff or district attorney can make a decision about whether it is appropriate or not for someone to be taking a controlled substance. And the same thing is true for physicians. One physician in a practice may be willing to prescribe a controlled substance, while others in the same practice may not. And that physician is also stigmatized. So it's not just the laws and regulations.

Q. What's being done to eliminate the documented barriers to effective pain management?

DR. DAHL. There's an enormous amount being done by individuals and organizations. For example, the Pain & Policy Studies Group (PPSG) has analyzed all the state laws and regulations. And they have used a set of criteria to identify what factors may enhance or diminish effective pain management. And knowledge of those good and bad regulations is critically important to designing approaches to making change. You have to know what the facts are before you can address this problem in a significant way.

Of course, changing the laws and regulations doesn't guarantee that there's going to be a change in the quality of pain management. One has to go beyond that. Physicians need to be made aware that improvements have been made, and then they need to become comfortable with prescribing when it's appropriate.

Q. Tell us about the work of the Federation of State Medical Boards.

DR. DAHL. Early in the 1990s, through the PPSG, there were a number of workshops for medical board members. In the context of those workshops, PPSG surveyed medical board members to get their sense of what they thought was legal and medically appropriate in terms of the use of controlled substances. It was shocking to find that only 75% of the members thought it was legal and medically appropriate to prescribe opioid analgesics for patients with chronic cancer pain. It should be no surprise that the numbers were much smaller for patients with chronic non-cancer pain.

This work [of PPSG] and these kinds of data stimulated the Federation of State Medical Boards, the umbrella organization of all the medical licensing boards in the states, to develop a model guideline for the use of controlled substances for the treatment of pain. The guideline outlined the importance of good pain control, as well as the adverse consequences of unrelieved pain. Additionally, it provided a basic process for

physicians to use when they determined that controlled substances, such as opioids, were essential to treat a pain problem.

In 2004, the Federation revised its model guideline and published it as a model policy called "Model Policy for the Use of Controlled Substances for the Treatment of Pain." This has been an important development because it stimulated medical boards in many states to adopt their own policies regarding the use of opioids for pain control. In some states, pharmacy and nursing boards have also issued position statements. This says to prescribers that it is indeed appropriate to use these drugs for pain control, and describes the commonsense approaches they need to use. It says to physicians that what they have to do to avoid getting into trouble is to document the reasons why they have chosen to use opioids, assess the response, and document that as well. Even if a state board adopts such a policy, the challenge is to make sure the licensees know.

Q. And whose role is it to get the word out to them?

DR. DAHL. Here in Wisconsin, where we're just getting our medical board to issue a position statement (our nursing board is thinking about it and the pharmacy board adopted a position statement last year), it would be a good idea to create a Frequently Asked Questions (FAQ) page on their Web site so that licensees can ask questions and get answers online. Also, we're developing a process to increase awareness, but you've touched on a significant problem. And that is, that even if you change the laws and regulations and issue positive policy statements, they will do no good if they're issued into a vacuum. It's a problem that we at the Alliance of State Pain Initiatives are working on.

Q. The challenge is to find the 'magic' words to reach the most people—and learn what's going to change physicians' prescribing behaviors.

DR. DAHL. That's the million-dollar question. But first you need to change the laws and regulations and work to develop a positive regulatory climate. One thing we did in this state in 2003—and it was expensive—was to hold five regional workshops where we brought together members of the medical and pharmacy boards and clinicians. We talked about the laws and regulations and let clinicians ask questions. The exchanges were wonderful. For instance, there was an opportunity for physicians and pharmacists to talk and express their frustrations. I'd love to see that happen in every state. We have to find ways to be innovative, and do what you just said—change behaviors.

There has been an unprecedented activity in the states. Matt [Matt Bromley] and I went to our medical board [Wisconsin] because they had been reluctant to talk about these issues and now they are enthusiastic. They wanted to know why they hadn't done it before and wanted to get the message out.

Q. Are they working along with the Wisconsin State Pain Initiative?

DR. DAHL. The State Pain Initiative engaged them.

Q. So that's what made the difference. It shows that that kind of work has a positive effect.

DR. DAHL. Oh yes, it does! We also have to be grateful to the advocacy people in the American Cancer Society, and to individual clinicians who have been fed up with things and are working to make change. They are working in collaboration with the State Pain Initiatives—but this is not easy. Everything is about the work of individuals—people who are willing to commit their time and effort.

Again, these medical board guidelines are important, and more recent PPSG surveys show that attitudes, knowledge, and beliefs among medical board members have changed, but the boards now have to make sure that their licensees change.

Q. How concerned should we be with the recent actions of the DEA? What should the relationship be between the DEA and the pain community?

DR. DAHL. What you need is communication and collaboration. You need to be on the same page. Under the DEA administration of Asa Hutchinson, there was a good rapport. In 2001, the DEA joined with 21 healthcare and pain organizations in issuing a statement that called for a balanced policy to assure that opioids were available to persons who needed them for pain control. This was a major achievement. I was in the room with Asa Hutchinson when he signed that. It was two days before 9/11. It was a striking achievement because this consensus statement represented the first time that the DEA had made a public commitment to the principle of balance.

This dialogue between the DEA and pain community, however, came to an abrupt halt a couple of years ago. The pain community and the DEA developed a document called Frequently Asked Questions (FAQ) that addressed questions commonly asked by both healthcare professionals and law enforcement people. Two months later, the DEA precipitously withdrew the FAQ. Then they issued an interim policy statement on November 16, 2004. The document had a harsh tenor and in it the DEA seemed to draw back from its previous statement that physicians would not be investigated solely on the basis of the quantity of controlled substances they prescribed and reversed its previous position on the writing of multiple prescriptions on the same day with orders that the scripts not be filled until a later date.

Q. What happened behind the scenes that precipitated that?

DR. DAHL. I wish I knew. It's likely the philosophy of the Justice Department changed with the Bush administration. Probably, the people from the DEA who were involved in helping to

craft these questions and answers didn't jump through the right hoops. Maybe a new legal staff had a whole different perspective on things. One of the things that may have led to the withdrawal of the FAQ, was the criminal prosecution of Dr. William Hurwitz. With the withdrawal of the FAQ, meaningful dialogue between the pain community and the DEA came to a halt. I think things are changing and there is a new proposal about the writing of multiple scripts for Schedule II drugs. Perhaps trust can once again be established between the pain community and the DEA.

Q. What about the work of the National Association of Attorneys General. What has their role has been?

DR. DAHL. When Drew Edmondson was elected President of the National Association of Attorney Generals (he is the Attorney General from the State of Oklahoma), he determined that his presidency would focus on end-of-life care. His wife, Linda Edmondson, is a social worker and very committed to this issue, and I think she was important in helping him make that decision. What he did was to hold three listening sessions in different parts of the United States to present the problem of unrelieved pain in persons at the end of life. He talked about symptom control generally and made a sincere effort to look at how laws and regulations may adversely affect the quality of care for patients at that critical time in their life. And these sessions resulted in a beautiful summary report that summarized their findings.

And then Drew Edmondson formed a committee, which is continuing to look into these issues. The committee was, for example, very concerned about the withdrawal of the FAQ, and Attorney General Edmondson began a dialogue with the Federal Department of Justice in order to restore some kind of dialog. He and his work group continue to be looking into this arena.

Q. What do you see for the future?

DR. DAHL. Obviously, it is critical to continue to focus on the development of a balanced drug policy. And of course there has to be enhanced communication between policy makers and healthcare professionals. We need to do a better job of educating law enforcement. At the same time, we must recognize that there is often uncertainty and confusion about use of opioids for pain control. There is consensus about their critical role in the management of acute and cancer pain. But there is not unanimity within the medical community about what constitutes "appropriate" use for patients with persistent, non-cancer pain. And there are few data from clinical trials to provide evidence to guide.

...it's best that these prescription-monitoring programs track all controlled substances. It would be ideal if all of the programs reported data to the state health authorities; however, in a few states, reports are made to law enforcement agencies.