
ONE

SAN DIEGO

Interview Recorded March 10, 2015, Between Roneet Lev, MD, and Nathan Painter, PharmD

NOTE: The opinions expressed in this interview do not necessarily represent the opinions of the San Diego County Medical Society (SDCMS).

INTRODUCTION

Lev: The Prescription Drug Abuse Medical Task Force hopes to bring together our entire medical community to a "One San Diego" message for safe prescribing of controlled medications. This was the theme of our March 11 symposium. One San Diego means a unified approach for all medical specialties with five principles:

1. One physician and one pharmacy for all controlled medications;
2. Appropriately using the CURES system;
3. Using medical agreements for patients who need three or more months of controlled medication;
4. Avoiding opioid and benzodiazepine combinations; and
5. Adhering to the emergency and urgent care safe prescribing principles.

We often practice in silos — primary care, emergency, orthopedic, psychiatry, urology, dentists, pharmacy — each one of us doing a great job within our own profession but not always working and coordinating optimally as a team. In this interview we hope to help prescribers and dispensers understand each other better so we can provide better coordinated care.

Nathan, thank you so much for joining us today. Let's start with some background about yourself.

Painter: Thank you for inviting me. I am a pharmacist and full-time faculty at UC San Diego Skaggs School of Pharmacy and Pharmaceutical Science. I have a clinical practice site at the family medicine clinics at UCSD, where I mainly do medication management for diabetes, hypertension, anticoagulation, and other chronic conditions. One of my areas of focus has been to educate physicians and students about prescription drug abuse, using CURES, and trying to tackle the issue from different fronts.

I have been a part of the San Diego and Imperial County Prescription Drug Abuse Medical Task Force for the last three and a half years. This task force has been the inspiration for the recently created Pharmacy Committee, which brings together representatives of different pharmacies throughout San Diego County, as well as representatives from the medical community, DEA, and County. I am very much looking forward to the interaction between the Task Force and the Pharmacy Committee. We work together very well, but we each have our own specific issues. Together, I am sure we will work to improve safe prescribing in San Diego.

PHONE CALLS

Lev: As physicians, our interaction with pharmacists is, unfortunately, often seen as an interruption of our day. We're busy seeing patients, juggling different tasks, and the phone rings. A pharmacist on the phone, really? Can't you read my handwriting? Can't you just fill the prescription? Nathan, can you tell us how often you really need to call physicians, and what are some of the red flags that make a pharmacist call a physician?

Painter: I know as pharmacists we understand the interruptions physicians experience, and we want to change the perception that we are just calling to validate prescriptions. We hope to convey that it's sometimes a very necessary interruption.

Roneet Lev, MD

Nathan Painter, PharmD

Pharmacists certainly are on the phone a lot more than physicians, dealing with insurance companies, dealing with patients calling in refills, and all those sorts of issues, so the phone is almost second-nature to pharmacists, whereas we definitely understand that it's not on the priority list for physicians when they're seeing patients.

It really depends on the pharmacy, the volume of the pharmacy, and even the individual pharmacist on how often they're calling physicians. Probably, a typical pharmacy calls on a dozen prescriptions a day, and that's a store that's filling about three or four hundred prescriptions.

Some of the main reasons that we call would be for missing data on the prescription, such as strength, quantity, or refills. Some prescriptions are illegible or not on a proper controlled prescription pad. Sometime there is a suspicion of a fraudulent prescription. But certainly physicians shouldn't be called more than once a day for a patient of their own.

In dealing with controlled substances, some pharmacies require a diagnosis on a controlled substance.

Lev: Do we really have to write a diagnosis on a prescription? It hasn't been my practice. Some diagnoses are confidential … you really want to say gonorrhea on a script?

Painter: Having a diagnosis on a prescription is not required by law; however, when dealing with controlled medications, it can become part of a verification process to make sure the prescription is appropriate. Also some insurances require a diagnosis if the prescription is written for a non-covered medication or if a prior authorization is required. The decision to call is probably related to quantity and multiple red flags, which we'll talk about in a minute. If your prescriptions look valid, the quantity looks appropriate coming out of the emergency department, name is consistent, and everything kind of checks out, then you shouldn't get a phone call. But if you're writing for higher-dose opioids, long-term opioids, or more than one controlled substance, then you're going to add red flags to the prescription that might warrant a phone call.

But, absolutely, if you're writing an antibiotic for a sensitive diagnosis, then I think it's completely appropriate, especially if it's an acute medication, not a chronic medicine, to not put the diagnosis on a prescription.

Lev: So the bottom line is that it's not obligatory to include the diagnosis on a prescription, but it's helpful for controlled medications with a chronic condition.

Painter: Correct.

RED FLAGS

Lev: Physicians have red flags for questioning controlled medications. What are some of the pharmacy red flags?

Painter: One of the red flags is when a prescription looks fraudulent, such as irregularities on the face of the prescription, different colored inks, or numbers that just look off because of potential tamper. Certain patient behaviors are red flags, such as nervousness or a young patient with chronic pain. Other red flags include patients with multiple addresses, multiple prescribers, wanting to pay cash, not using insurance, and requesting early refills. In addition, pharmacists are on alert when they see prescriptions written for an unusually large quantity of pills or high doses of medications.

Medication therapy that does not make sense is another red flag. For example, duplicative drug therapy such as two fast-acting opioids or two long-acting opioids could be a red flag. An initial prescription for a high-dose medication or a long distance from the patient to the pharmacy or the physician are other examples. Irregularities in the prescriber's qualifications may also be an alert, such as a pediatrician writing for a large quantity of opioids, or a dentist writing for stimulants. A prescription that has no logical connection to an illness or condition is a red flag, which is where a known diagnosis is useful.

Lev: Do pharmacists have a specific checklist on what is a red flag and when to call?

Painter: They have a general checklist but nothing specifically spelled out. Each pharmacy may publish its own warning list as well as encourage pharmacists to be on alert for suspicious prescriptions. It is not like one red flag they call or three red flags they call. It is always left up to the judgment of the pharmacist, and it will almost always come down to their familiarity with the patient and the physician and any potential mismatches that are found.

Lev: I have received pharmacy calls that ask, "Hey, this prescription is four months old, do you still want me to fill it?" Is there a rule or guideline about when prescriptions are too old to fill?

Painter: A C2, schedule II controlled substance, is only valid for six months. All other prescriptions are valid for two years, although insurance typically only pays for a prescription that is less than one year old. However, it depends on the prescription. If you're writing for acute pain, and the patient comes to the pharmacy three months later, or even one week later, then that is a mismatch and warrants a confirmation phone call. However, a chronic medication that presents with a delay in refilling a prescription would be acceptable. The pharmacist should be checking the refill history and making sure the dispensing is consistent.

Lev: As we move on to the next question, I hope physicians will see pharmacy phone calls as an opportunity to make a correction rather than a nuisance. It is similar to when a nurse comes to you and asks, "Did you really mean to write IM instead of IV or did you want Tramadol or Trazodone?" These types of questions are an opportunity to think and take a second look at a potential error.

Painter: There's a survey that demonstrates that pharmacists realize that communication with physicians is very important but are reticent to call physicians because they worry these phone calls and communications can be annoying, disruptive, and interfere with a positive relationship. I think at the end of the day we should understand that both physicians and pharmacists are trying to provide the best care for our patients.

CORRESPONDING RESPONSIBILITIES

Lev: Physicians are often caught in a balance of providing pain relief, keeping people safe, and keeping our patient satisfaction scores up. And yet, our legal environment is that we're sued if we prescribe, sued if we don't prescribe, and people complain for too many prescriptions or too few prescriptions. The bottom line is that we just have to do the right thing regardless. What are the legal responsibilities for pharmacists?

Painter: That's a good point. Obviously, pharmacists and physicians have a role when it comes to making sure that prescriptions are appropriate, and it's the pharmacist's responsibility to make sure that a prescription is valid and appropriate.

In 2013 the California Board of Pharmacy made a precedential decision regarding corresponding responsibility in the distribution of all controlled substances, but this particular case involved opioids (www.pharmacy.ca.gov/enforcement/fy1011/ac103802.pdf). The physician and pharmacist were disciplined in this case. The Pharmacy Board has established a standard that requires a pharmacist to inquire whenever they believe that a prescription may not have been written for a legitimate medical purpose. So here we see the issue of diagnosis again. Pharmacists are required to make sure that a prescription is written for a legitimate medical purpose, but we don't know if that's the case unless we know the diagnosis. Furthermore, the pharmacist must not fill a prescription when the results of a reasonable inquiry indicate that a prescription is not written for a legitimate medical purpose. A pharmacist must do their due diligence by calling the prescriber, checking CURES, or doing whatever else they feel is necessary before filling a questionable controlled prescription. And the bottom line is that they must refuse to fill the prescription if they suspect it is not appropriate.

It's not obligatory to include the diagnosis on a prescription, but it's helpful for controlled medications with a chronic condition.

San Diego and Imperial County Prescription Drug Abuse Medical Task Force

The San Diego and Imperial County Prescription Drug Abuse Medical Task Force is a coalition of medical leaders who have joined efforts to reduce deaths and addiction due to prescription drugs. The number-one cause of unintentional deaths in San Diego County is from unintentional drugs deaths. Almost one person a day in our county dies from this preventable cause.

The Task Force includes pain specialists, internal medicine physicians, emergency physicians, psychiatrists, dentists, pharmacists, hospital administrators, health department administrators, and our local DEA. The Task Force also includes broad health partners, including Kaiser Permanente, Scripps Health, Sharp HealthCare, UC San Diego Health System, Palomar Health, and the Community Clinics.

The Task Force encourages all medical practitioners to use the materials provided to improve patient care. Visit www.SanDiego-SafePrescribing.org for further information.

To get involved in the Task Force or the Pharmacy Committee, contact Angela Goldberg at angelagoldberg@sbcglobal.net.

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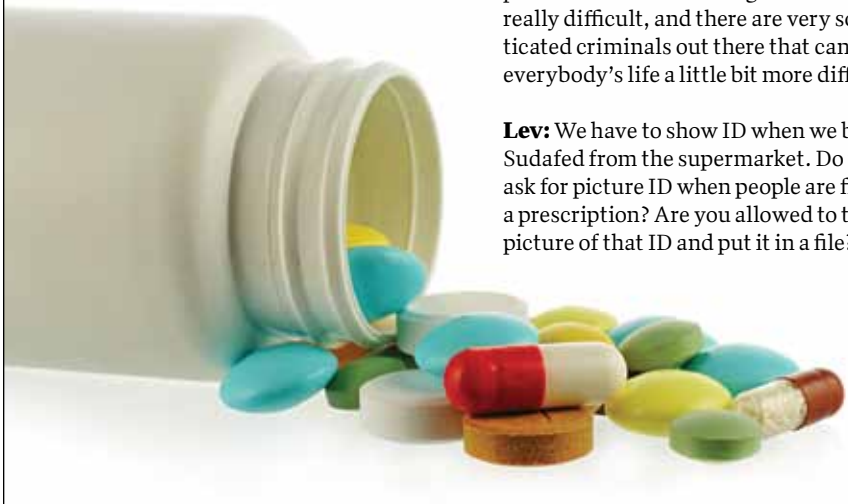

Lev: This is what's called corresponding responsibility?

Painter: Yes, and, as you see, pharmacists are placed in a difficult position between dispensing and confirming legitimacy of the prescription.

Lev: Do you know what was the price tag of that lawsuit?

Painter: In that particular case, the pharmacy was fined $39,666 by the Board of Pharmacy. There are also cases in other states, and in July 2013 Walgreens paid $80 million for civil penalties for retail stores in Florida, Michigan, Colorado, New York, and investigations nationwide. The stores received three times the state average for prescriptions such as oxycodone. They also filled prescriptions that they knew or should have known were not for legitimate medical uses. In April 2013 CVS paid out $11 million to settle civil penalty claims to the Controlled Substances Act. In 2012 $500,000 was paid by an Internet pharmacy case from DEA diversion investigation.

Lev: Do you have a story or an example of a red flag prescription? I see you brought examples of some.

Painter: Essentially, changing the quantity, changing the strength, or adding a different medication onto the prescription face itself are big red flags. Some of the other examples that I've heard patients doing are printing up their own controlled substance forms or stealing prescription pads from the physician's office, but — I don't know how they do this — they'll put their own cell phone on the prescription so that when the pharmacist does call to verify it actually goes to the patient's cell phone. These are all things that can be really difficult, and there are very sophisticated criminals out there that can make everybody's life a little bit more difficult.

Lev: We have to show ID when we buy Sudafed from the supermarket. Do you ask for picture ID when people are filling a prescription? Are you allowed to take a picture of that ID and put it in a file?

Painter: There is no law requiring picture ID; however, many pharmacies developed their own protocols of asking for ID and taking pictures of ID. Many pharmacies note operational problems such as no good location to store a picture or a time delay of getting this information as a line forms when picking up prescriptions. Some solutions have been to ask for ID when people drop off the prescription and to write the driver's license number on the back of the prescription. At this point many pharmacies are not checking IDs.

Lev: What are the best practices as far as checking IDs?

Painter: My recommendation is that the ID should be checked for all new controlled prescriptions or new patients. This is important just like checking CURES and verifying that the prescription is going to the right person.

Lev: At the Pharmacy Committee, we heard stories from other pharmacies that when they encounter something suspicious, they simply say, "Can I see your ID, please?" and then people bolt right out of the store.

Painter: That is true, and it's a good deterrent question that should be utilized. Our Pharmacy Committee will be working on best practices and flow solutions such as this.

SAFE PRESCRIBING INITIATIVE

Lev: The Prescription Drug Abuse Medical Task Force has a robust safe prescribing initiative that includes guidelines for emergency departments, urgent cares, medication agreements, and prescribing guidelines (www.SanDiegoSafePrescribing.org). Do you think that most pharmacies are aware of these guidelines?

Painter: At this time, most pharmacists are not aware of the guidelines. Our newly formed Pharmacy Committee will develop pharmacy education that will include the safe prescribing initiative and the One San Diego mission. This is important for emergency department prescriptions, chronic prescriptions, and all other parts of the guidelines. Pharmacists do not have to ask patients if they have a medication agreement. Pharmacists should understand that most patients on

controlled medications for three months or more should have an agreement, and that means using one pharmacy and one physician. It would be a red flag if we find a discrepancy.

Lev: I would like to remind our physician community that we have a long and short version of medication agreements on our website at www.SanDiegoSafePrescribing.org. The agreements are available in English at a fifth-grade reading level and in Spanish. We recommend using them not just for opioids but for benzodiazepines and stimulants as well. One thing we have noticed is that some physicians and patients use medication agreements as "free tickets" to get medication refills. Please don't turn your brain off when using these agreements; you still have to verify each time a patient needs to continue the medication or can start a weaning process. Our CURES ZIP code study has shown that East County San Diego prescribed more opioids, benzodiazepines, and stimulants per capita than any other area of our county.

DRUG INTERACTIONS

Lev: Let's talk about drug interaction. One of the more useful pharmacy queries is alerting a physician about drug allergies or potential drug interactions. One of my patients that I won't ever forget as an emergency physician was a nice elderly gentleman who was diagnosed with gout by his physician and placed on Cipro the day before. He was on Coumadin and presented with vomiting blood. Despite my best effort to reverse his coagulopathy, he bled to death in front of me. Do pharmacists routinely check medication interactions such as Cipro and Coumadin or other interactions? How do you handle medication interactions?

Painter: Every pharmacy I know of utilizes drug interaction checkers that are automated. This means that any time a medication is entered, a screen will pop up that will say which medications have an interaction, what the general severity of the interaction is, and what the overall impact of that interaction may be. Unfortunately, the Cipro and Warfarin is a good example of the pharmacist not always acting on the warning. A pharmacist may not immediately say the patient needs to go back to their doctor to get their INR checked and be monitored because sometimes Cipro may actually be the most appropriate drug for that patient at that time. But the important point is that pharmacists should be providing some education to the patient, and if possible calling the physician to get that medication changed. But drug interactions are being run all the time.

Lev: Every pharmacy has automatic drug interaction checkers; however, they won't work when medications are filled at different pharmacies such as Costco, CVS, or Walgreens.

Painter: That is correct. Medication interactions can be checked only when using the same pharmacy or when the patient gives their current medication list to the pharmacist.

Lev: Do pharmacists ask, "What other medications are you taking?"

The Pharmacy Board has established a standard that requires a pharmacist to inquire whenever they believe that a prescription may not have been written for a legitimate medical purpose.

Painter: Most pharmacists will ask about other medications taken.

Lev: How often do you see drug interactions and act upon them?

Painter: Unfortunately, pharmacists can suffer from "warning fatigue," similar to physicians who get many alerts from the electronic medical records.

Lev: What about benzodiazepines and opioids? Or the "holy trinity": opioids, benzodiazepines, and Soma? We know from our study using San Diego medical examiner deaths in 2013 that over 50% of the people who have died have CURES reports that included opioid and benzodiazepine combinations, and 22% of deaths included the two medications. What do you do when you see that combination?

Painter: Opioid and benzodiazepines are a common and pervasive issue. We receive many alerts for this combination; often it is the same physician prescribing both medications, and currently we do not act upon this combination.

The "holy trinity" is another matter. Many pharmacists will call and request an explanation of why the patient requires this combination of medication that is generally known to be problematic.

Lev: I see this combination often on the medication list of my emergency patients. I tell them that they have a medication interaction that they need to discuss with their doctor, and at the very least they should not take the two medications at the same time. The CURES 2.0 system will include this combination in their alert system.

The VA system has stopped allowing the opioid/benzodiazepine combination, to the chagrin of psychiatrists. The Indian health clinics have stopped carrying Soma in their pharmacies. The medical community needs to do more about education, and the insurance industry can do more about paying for problematic medications. Given your explanation, I don't think we can expect pharmacists to act upon all potential medication interactions.

PRESCRIPTION PADS

Lev: We get a lot of phone calls about issues with prescription pads, especially if you use an institutional pad with lots of different physicians. One of the phone calls we received is about not having an NPI number on the prescription. However, with 20+ names and DEA numbers on a pad, the NPI number does not fit. Do we really have to have an NPI number on a prescription?

Painter: The tamper-resistant prescription forms must have the following security features:

- Void protection to prevent duplication or chemical washing to alter prescriptions;
- Watermark on the backside of the prescription with the text "California Security Prescription";
- Thermo-chromic ink that changes color when exposed to heat;
- A description of the security features printed on each prescription form;
- Quantity check-off boxes; and
- The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.

NPI is not required to fill a controlled substance, but insurance often requires it for billing purposes.

Lev: It does appear that the new physicians get the phone calls.

Painter: Exactly, because the pharmacy doesn't have the new physician in the system, and they will need the NPI number for billing.

Lev: Is there a computer system where they can get the NPI number without calling the hospital?

Painter: NPI numbers are available on the Internet (https://nppes.cms.hhs.gov/NPPESRegistry/NPIRegistryHome.do); however, there are a few pharmacies where the Internet is blocked, so they may not be able to do the search.

Lev: Another prescription pad issue we have seen is using a blank prescription form where the physician name and DEA is handwritten or stamped on the top. We have some pharmacies refuse these prescriptions. Is that appropriate?

Painter: A handwritten prescription on a controlled substance pad is allowed. In some large institutions, such as a hospital, the physician's name can be handwritten, but the address must be pre-printed.

Lev: I have heard of some groups that print their own prescriptions on special paper? How does that work?

Painter: You can actually purchase special security paper that fits in an approved printer. This is often used in conjunction with an EMR system. At UCSD we have such a system, and the computer system recognizes that a controlled prescription is being written, and defaults to a controlled substance printer. The printer is located in an office that is normally locked unless someone is in the office. This is used at our family medicine clinics and a few other places. Kaiser also uses this system.

Lev: Can a solo practitioner use this in their office? Is it cost-effective or is it cheaper to buy prescription pads?

Painter: The cost of the paper ranges from $15 to $20 for 1,000 sheets. This does not include the cost of the printer, which has some additional security features, such as the ability to lock the paper drawer.

DOCTOR-SHOPPING

Lev: Now we'll change gears and talk about doctor-shoppers. The definition of a doctor-shopper is problematic. For research purposes I have used "4-4-12" or four pharmacies and four physicians in 12 months. I know the DEA uses a different definition for prosecution. However, we have seen patients who simply "double dip" — two doctors and two pharmacies each month — and they don't meet the research definition of doctor-shopping. It is better to discuss safety of prescriptions rather than accuse people of doctor shopping. We therefore like our "One San Diego" statement of one pharmacy and one physician for all controlled medications. We understand that patients see different specialists, primary care, psychiatry, orthopedics. But one physician needs to be overseeing all the different prescriptions.

What do pharmacists do when they encounter doctor-shoppers, and how do you define doctor shopping?

Painter: Pharmacies do not have a specific definition of doctor-shopping. We will run a CURES report, and if a patient is using different pharmacies, but with the appropriate 30-day refill interval, this will not send a red flag. However, if there are multiple physicians or filling prescriptions before the 30-day expected timeframe, there will be a red flag. Multiple physicians within a month will be a red flag.

Lev: Will pharmacists say, "I'm sorry, I'm not filling this," without even calling the doctor?

Painter: Yes, absolutely. It does not happen often, but it does happen.

Lev: When you call a physician and ask, "Is this the right prescription?" or "Did you write this amount?" and the physician replies that the prescription is fraudulent, what do you do? Sometimes the doctor will say, "Call the police," but we know that that is not the correct solution.

Painter: Pharmacists do not routinely call the police. I wish that there were a better and easier way to report these incidents. Unfortunately, many such prescriptions go unreported, and there's no real follow-up. This is an issue that our committee could be addressing.

Lev: When the medical community met with the DEA, we also didn't want to make a phone call that could be time-consuming, so we worked out an email solution. If we think a patient is doctor-shopping and should be investigated, or may benefit from court-mandated drug rehab, we can email the DEA with the patient's name, birthdate, the location of the occurrence, and a description of the suspicion at deatips-sandiego@usdoj.gov. The DEA does not need any medical information, and such information does not affect HIPAA. This tip line is available to both physicians and pharmacists.

One San Diego for Safe Prescribing

—1—
One physician and one pharmacy for all controlled medications.

—2—
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—5—
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NALOXONE

Lev: A new California ruling allows pharmacists to prescribe naloxone — this in response to the increase in heroin-related deaths from approximately 5,000 per year to 8,000 a year nationwide, and a desire by families of lost loved ones to see an increase in access to this reversal agent. Our website has some information for prescribers. Can you comment on how you see pharmacists prescribing naloxone?

Pharmacists should understand that most patients on controlled medications for three months or more should have an agreement, and that means using one pharmacy and one physician.

Painter: Increasing naloxone availability is important, and the pharmacy community is happy to play their part in this mission. The concept of prescribing rather than dispensing by pharmacists is new and will require an educational process at each pharmacy. The mechanism and documentation of giving the prescription will need to be established, but in general if a patient requests naloxone, they will be able to purchase it from behind the counter. It is available in injection form and nasal atomizer. Currently, the most readily available form is from a manufacturer called Evzio and is an auto-injector that gives audible directions and costs $600 for a package of two.

LIFE OF A PHARMACIST

Lev: Tell us about your regular day as a pharmacist, what happens when you refuse to fill a script, what's the hardest part of your job, and do you ever feel in danger?

Painter: I've had pharmacists express the element of fear and danger if they refuse a prescription, especially if a patient is already agitated or very adamant about something. Being alone behind the pharmacy window can also make people feel vulnerable. One pharmacist will say, "I'm sorry, we're out of stock of this medication," and simply give the prescription back to the patient. This is unfortunate, and is passing the buck for someone else to deal with. A better way would be to copy the prescription before returning it and then contact the DEA. Another solution would be to ask for a driver's license — just like the request for ID can send some customers out of the store without further inquiry. There are cases of murder and assault against pharmacists for drugs, and so there is a real reason to be fearful.

Lev: One of the things that is common to physicians and pharmacists is checking the CURES system. Pharmacists and physicians will not write a prescription without checking for allergies. Similarly, the gold standard would be not to refill controlled medications without checking CURES. CURES registration will be mandatory for physicians by 2016, and our San Diego public health office has been deputized to process the registration paperwork with notary.

IF YOU HAD ONE REQUEST TO PRESCRIBERS ...

Lev: If you had one request to prescribers from the pharmacy community, what would that be?

Painter: I think we all need to have patience with each other, and try to understand a little bit about everybody else's perspective. Pharmacists don't necessarily assume that all physicians are prescribing improperly, just like I don't think all prescribers assume that pharmacists are just pill pushers. Physicians should understand that pharmacists have a legal corresponding responsibility and, just like physicians, are liable for inappropriate prescriptions.

SUMMARY

Lev: Thank you very much for joining us today. Physicians and pharmacists have much in common in helping patients and preventing harm. We want to promote teamwork and our One San Diego message for dealing with the epidemic of prescription drug abuse for all our specialties, including pharmacies.

Painter: Thank you for this opportunity to speak and promote our collaboration in our professional work that is so important for the care of our patients. **SDP**

Roneet Lev, MD, 22-year member of SDCMS-CMA, is a full-time emergency physician practicing at Scripps Mercy Hospital and serves as the director of operations for the emergency department. She chairs the San Diego and Imperial County Prescription Drug Abuse Medical Task Force. The Safe Prescribing program in the emergency departments won the 2014 National Association of Counties Award. Nathan Painter, PharmD, is an associate clinical professor and clinical pharmacist at UC San Diego Family Medicine Clinics. An active member of the San Diego and Imperial County Prescription Drug Abuse Medical Task Force, he received the 2015 Cardinal Health Generations Rx Champions Award from the American Pharmacist Association.