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Perspective

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Abusive Prescribing of Controlled Substances — A Pharmacy View

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Public health advocates are increasingly focused on illness and deaths caused by inappropriate use of controlled substances — in particular, opioid analgesics. Opioid prescriptions have increased dramatically, by more than 300% between 1999 and 2010.[1] This increase has led to substantial iatrogenic disease. Most strikingly, the number of deaths due to overdose in the United States increased from 4000 in 1999 to 16,600 in 2010.[2] Indeed, overdose is now the second-leading cause of accidental death in this country, where more than 2.4 million people were considered opioid abusers in 2010.[3]

The causes of increases in prescriptions and the prevalence of abuse are manifold. In the mid-1990s, advocates for treatment of chronic pain began arguing that pain was largely undertreated and appropriately exhorted clinicians to be more liberal in their treatment. In addition, a number of new formulations of opioid agents became available, with purported advantages in analgesia.

But perhaps just as important, inappropriate prescribing has grown. The worst form of such prescribing occurs in so-called pill mills, wherein fully licensed physicians with valid Drug Enforcement Administration (DEA) numbers write prescriptions that provide large quantities of powerful analgesics to individual patients. Such bogus pain clinics cater to younger patients, operate on a cash basis, and draw clients from a broad geographic area. States and the DEA have attempted to curb pill-mill activities — the best example being Florida's closure of 254 "pain clinics" — but the efficacy of such regulation is unclear.[4]

Pharmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular. Under the Controlled Substances Act, pharmacists must evaluate patients to ensure the appropriateness of any controlled-substance prescription. In addition, state boards of pharmacy regulate the distribution of opioid analgesics and other controlled substances through the discretion of pharmacists. Yet in the majority of cases of potential abuse, pharmacists face a patient who has a legal prescription from a licensed physician, and they have access to very little other background information. That makes it difficult for individual pharma-

Prescribing Habits of Outlier Prescribers.

Specialty or Type of Clinician	Average Monthly Doses of High-Risk Drugs Prescribed		No. of Outlier Prescribers
	42 Outlier Prescribers	Nonoutlier Prescribers	
Internal medicine	11,314	422	12
Physical medicine	5,599	916	1
Family practice	12,903	575	8
General practice	24,502	462	2
Psychiatry	18,757	213	3
Nurse practitioner	10,715	160	2
Obstetrics and gynecology	11,096	110	3
Physician assistant	5,211	116	1
Pain medicine	8,811	3813	1
Sports medicine	7,025	387	1
Pediatrics	5,524	31	2
Anesthesiology	8,128	1749	1
Geriatric medicine	15,544	493	1
Endocrinology	6,142	116	1
Emergency medicine	7,935	203	2
Preventive medicine	44,397	662	1

cists to use their own partially informed judgment to identify prescriptions that have come from a pill-mill doctor.

Chain pharmacies, however, have the advantage of aggregated information on all prescriptions filled at the chain. At CVS, we recently instituted a program of analysis and actions to limit inappropriate prescribing. Our program was intended to identify and take action against physicians and other prescribers who exhibited extreme patterns of use of "high-risk drugs" relative to other prescribers. We aimed to minimize the potential for falsely identifying legitimate prescribers (false positives), accepting that doing so might result in a failure to identify some suspicious prescribers.

We identified high-risk prescribers by benchmarking them against others on several parameters. We used data from submitted prescriptions from March 2010 through January 2012 for hydrocodone, oxycodone, alprazolam, methadone, and carisoprodol. Prescribers were compared with others in the same geographic region who had the same listed specialty. The first parameters were the volume of prescriptions for high-risk drugs and the proportion of the prescriber's prescriptions that were for such drugs, as compared with the volume and proportion for others in the same specialty and region; the thresholds for suspicion were set at the 98th percentile for volume and the 95th percentile for proportion. Next, prescribers were evaluated with regard to the number of their patients who paid cash for high-risk–drug prescriptions and the percentage of their patients receiving high-risk drugs who were 18 to 35 years of age. In both cases, the thresholds for suspicion were set at the 90th percentile among clinicians in the same region and specialty. Finally, we compared the prescriptions for noncontrolled substances with the prescriptions for controlled substances within the prescriber's practice on the same parameters. To minimize the possibility that we would suspend dispensing privileges for clinicians who were appropriately treating patients, we attempted to interview physicians whom we'd identified as outliers to ascertain the nature of their practice and their use of controlled substances.

We initially identified 42 outliers (see table) from our database of nearly 1 million prescribers; 17 of the 42 failed to respond to our three letters requesting an interview, despite our indication in the second and third letters that we would stop filling the clinician's controlled-substance prescriptions if he or she would not speak with us. Eight prescribers sent a written response, and one response was sufficiently detailed to convince us that the prescribing was appropriate. The other seven responses were inadequate, and the prescribers refused to engage in a telephone discussion. Two prescribers retained an attorney, and future conversation occurred through legal channels. We considered these 26 clinicians nonresponsive.

The remaining 15 were contacted by phone, and 5 gave us legitimate reasons why their practice had the identified characteristics — in particular, that each was the only practitioner in a given geographic area caring for patients with chronic pain. The remaining 10 either maintained that their approach was legitimate

but that they didn't have to explain why or averred that they planned to curb their prescribing of narcotics. For all 10 of these clinicians, we decided not to fill their controlled-substance prescriptions through our pharmacy. The same approach was taken for the 26 nonresponsive clinicians. Surprisingly, now 9 months after we stopped filling controlled-substance prescriptions for these clinicians' patients, we've had contact from only 3 of them requesting reinstatement in our pharmacy chain. The table provides details on the 42 outliers' practices, as compared with those of the average prescriber in our database. There was no clear regional concentration of outliers.

Our program is certainly not a comprehensive solution, but it provides some sense of the kind of inappropriate prescribing that is going on in our health care system. We believe that some of these clinicians may be part of pill mills, doing cursory examinations in high volumes of patients, all of whom then receive opioid analgesics. People seeking to abuse these medications will travel long distances to obtain them and often deal in cash only. These patients are generally younger than the average patient with chronic disease. A comprehensive solution would involve the use of a national prescription-drug–monitoring database that would be used by clinicians at the point of prescribing and by all pharmacies at the point of dispensing. This enhanced view of a patient's controlled-substance history and behaviors would support both prescribers and pharmacists in applying their professional judgment regarding the appropriateness of dispensing a controlled substance.

As we noted, pharmacists have an ethical duty, backed by both federal and state law, to ensure that a prescription for a controlled substance is appropriate. A young person traveling a good distance to fill a prescription and paying cash should raise some concerns for a pharmacist. If the prescription is valid, the pharmacist might have limited grounds on which to deny medication to someone who might be in pain. Yet the DEA has now identified both pharmaceutical distributors and chain pharmacies as part of the problem,[5] encouraging our industry to develop new programs to reduce inappropriate use.

Our findings provide a lens into the problem we face as a country. Programs providing greater transparency regarding controlled-substance prescribing, such as mandatory use of e-prescribing for all controlled substances and a national, uniform program of prescription-drug monitoring, would help pharmacists and clinicians target interventions more accurately to help patients who are abusing medications. Some state solutions, such as the Massachusetts database that allows clinicians to look up their own patients' prescriptions, also have merit. Analyses of aggregated data like ours can also target patterns of abuse by both prescribers and patients. Given the growing use of controlled substances and the resulting illness and deaths, more innovative use of transparent data is only prudent.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From CVS Caremark, Woonsocket, RI.

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Transforming Academic Health Centers for an Uncertain Future

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Academic health centers (AHCs) have long led the advancement of science and medicine by pursuing missions of clinical care, research, and education. AHCs have been places where important fundamental and translational research is performed and medical innovations are created and tested. Given the dramatic changes ahead in health care and deteriorating research funding, can this record of achievement continue, or do AHCs in the United States face a growing risk of extinction?[1]