

FORENSIC PAIN MEDICINE SECTION

The Challenge of Prescription Drug Misuse: A Review and Commentary

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Introduction

This article presents an analysis of the patterns of illicit use of prescription pain relievers, of the likely structure of the illicit market, and of the complexity of pain management. It suggests that a federal enforcement policy focused on physicians is unlikely to reduce the overall use of illicit drugs, but that it is likely to have an adverse impact on the ethical structure of medical care and to compromise the effectiveness of pain treatment.

Pain medications, such as OxyContin, Vicodin, and Methadone, have received increased government and media attention over the last 2 or 3 years, as the growth of their application in the treatment of patients with acute and chronic pain has been accompanied by an increase in reported drug abuse and dependence, adverse medical events, and pharmacy robberies. In response, the federal government announced a new initiative to control prescription drug abuse.¹ Various proposed measures, including heightened scrutiny of physicians' practices, increased prosecution of physicians, increased restrictions on a number of pain medications, drug monitoring programs to catch "doctor shoppers," and encouragement of more rigorous patient screening, will, it is claimed,

limit the diversion of prescription medications from medical channels.

In its 2002 review of OxyContin diversion, the Drug Enforcement Administration (DEA) stated "Illegal acts by physicians and pharmacists are the primary sources of diverted pharmaceuticals available on the illicit market."² The DEA report goes on to identify other sources of diversion, including doctor shopping, robberies, burglaries, thefts, illicit internet distribution, drug gang distribution, and foreign diversion. In view of the multiplicity of sources and the lack of quantitative information regarding the contribution of each source to the illicit market, it is not clear on what basis the DEA claimed that physicians and pharmacists are the primary sources. However, the recently proposed measures to control diversion and abuse appear to be predicated on the assumption that medications diverted to illicit use come primarily from prescriptions issued by criminal or inadequately vigilant doctors to inappropriate patients, who abuse or divert prescribed medications.

It would follow from this assumption that removal of the "bad apples" among doctors and that greater precision by well-intentioned doctors in directing prescriptions to appropriate patients would reduce the quantities available for misuse. It is further assumed that restricting the supply of

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¹Office of National Drug Control Policy Press Release, U.S. Drug Prevention, Treatment, Enforcement Agencies Take on "Doctor Shoppers," "Pill Mills," March 1, 2004.

²Drug Intelligence Brief, Oxycontin: Pharmaceutical Diversion March 2002. Available at <http://www.usdoj.gov/dea/pubs/intel/02017/02017p.html> (Note: All websites in the footnotes were accessed in June, 2004).

Table 1 Illicit drug and illicit pain reliever use in the past year

	Numbers and Percent of Population of Users			
	12 or Older	12–17	18–25	26 or Older
U.S. population	235,143,000	24,753,000	31,024,000	179,366,000
Percent of population	100%	10.5%	13.2%	76.3%
Any illicit use	35,132,000	5,495,166	11,013,520	18,654,064
Percent of all users	100%	16%	31%	53%
Illicit pain reliever use	10,992,000	1,881,228	3,536,736	5,560,346
Percent of all users	100%	17%	32%	51%

Data recompiled from Tables H.1 through H.5 referenced in footnote 3.

medications available for diversion from medical practice will restrict the access of would-be illicit users to prescription medications, and that restricted access will lower the overall burden of substance abuse. Whether the new enforcement policy will limit diversion or reduce substance abuse remains to be seen.

Who Misuses Prescription Drugs?

The 2002 National Survey of Drug Use and Health (NSDUH) provides basic epidemiological data on the scope and correlates of illicit drug use.³ The NSDUH distinguishes between drug use and abuse or dependence according to DSM-IV⁴ definitions and indicates the time frame within which respondents had engaged in illicit use. DSM-IV characterizes substance abuse and dependence as follows.

Substance Abuse

A pattern of substance use leading to significant impairment in functioning. One of the following must be present within a 12-month period: 1) recurrent use resulting in a failure to fulfill major obligations at work, school, or home; 2) recurrent use in situations which are physically hazardous (e.g., driving while intoxicated); 3) legal problems resulting from recurrent use; or 4) continued use despite significant social or interpersonal prob-

lems caused by the substance use. The symptoms do not meet the criteria for substance dependence as abuse is a part of this disorder.

Substance Dependence

Substance use history which includes the following: 1) substance abuse (see below); 2) continuation of use despite related problems; 3) increase in tolerance (more of the drug is needed to achieve the same effect); and 4) withdrawal symptoms.⁵

Table 1 summarizes illicit drug use, in general, and illicit pain reliever use in the year prior to the survey for the U.S. population aged 12 and older. It is estimated that almost 11 million people engaged in the nonmedical use of prescription pain relievers. It is evident from Table 1 that illicit drug use disproportionately affects the young. While those aged 12–17 are only 10.5% of the population aged 12 or older, they account for 16% of those who use illicit drugs and 17% of illicit users of pain relievers. Similarly, those aged 18–25 are only 13.2% of the population; however, they account for 31% of illicit drug users and 32% of illicit pain reliever users.

The increased prevalence of illicit drug use among younger users is not unique, but corresponds to the age distribution of use of alcohol and cigarettes, as Figure 1⁶ illustrates. The percent of individuals who use illicit drugs rapidly rises through adolescence and remains at a peak of approximately 40% from age 18 to 22, after which it gradually declines (Figure 1).

The preceding data presented a picture of the American population at one point in time, not a longitudinal study of the same people passing through different stages of life. It is possible that the higher rates of use among the younger age

³The National Survey of Drug Use and Health (NSDUH) is available online at <http://www.oas.samhsa.gov/nhsda/2k2nsduh/html/toc.htm>. The drug use prevalence data in this article are extracted from Tables 1.1B, 1.2B, 1.3B, 1.4B, 1.19B, 1.26B, 5.25B, 5.27B, and 8.2N accessible through the referenced website or from Tables H.1 through H.6, H.16, H.22, and H.44 from SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2002 at <http://www.oas.samhsa.gov/nhsda/2k2nsduh/Results/appH.htm>.

⁴Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition (DSM-IV), published by the American Psychiatric Association, Washington, DC, 1994.

⁵Available at <http://allpsych.com/disorders/substance/index.html>.

⁶Table H.16, Alcohol Use, Percentages, 2002, Table H.22, Cigarette Use, Percentages, 2002, and Table H.6, Any Illicit Drug Use, Percentages, 2002 referenced earlier.

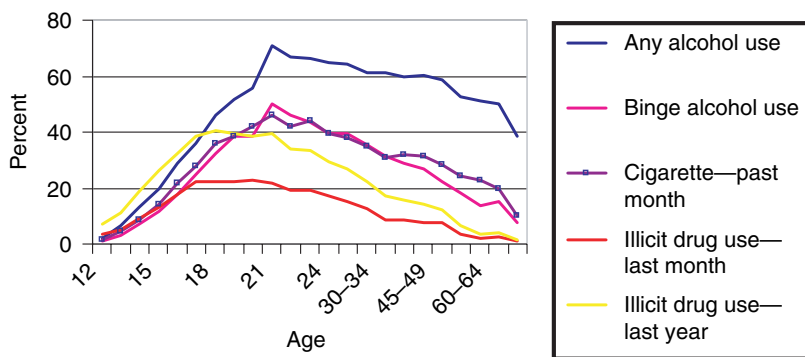


Figure 1 Alcohol, cigarette, and illicit drug use by age.

groups now will be reflected in higher rates among older groups in the future, as these individuals age. But it is equally plausible that the pattern of drug use is age specific, reflecting changes in life circumstances.

This notion of age- and circumstance-specific determinants of drug use is supported by a study of drug use among Vietnam veterans. The study revealed that “before arrival, hard drug use was largely casual, and less than 1% had ever been addicted to narcotics. In Vietnam, almost half of the general sample tried narcotics and 20% reported opiate addiction. After return, usage and addiction essentially decreased to pre-Vietnam levels.” [1]

Part of what has prompted the government initiative is a recent rapid growth in illicit prescription drug use and related adverse medical events. One index of that growth is the change in drug-related emergency department visits reported through the Drug Abuse Warning Network (DAWN). DAWN collects information on drug abuse-related emergency department visits, and specifies, when possible, the drug or drugs involved in the drug-abuse related visit.⁷ Table 2 records the change from 1997 to 2002.

⁷These data are extracted from the DAWN data available at <http://dawninfo.samhsa.gov>.

Table 2 DAWN emergency department mentions for selected prescription medications 1997–2002

DAWN	1997	2002	% Change
Hydrocodone	11,570	25,197	117.8
Oxycodone	5,012	22,397	346.9
Methadone	3,832	11,709	205.6
Morphine	1,300	2,775	113.5

The percentage increase in DAWN mentions for prescription pain relievers has been greater than the increase for marijuana, cocaine, and heroin. It has been exceeded only by the percentage increase in Ecstasy mentions. Table 3 records change in DAWN mentions for these nonprescription drugs over the same interval.

It should also be noted that the number of DAWN mentions for the selected illicit drugs (with the exception of Ecstasy) is 5–10 times higher than for prescription drugs in 2002. However, NSDUH data for 2002 reflect a greater prevalence of use and of dependence on or abuse of pain relievers than of heroin, as illustrated in Table 4. This disproportionate representation of DAWN mentions for heroin as compared with prescription pain relievers confirms that heroin is much riskier. One measure of the relative risk of these substances is the ratio of the rates of DAWN mentions to the prevalence of use or abuse. For users in the past year, heroin users were 21.3 times more likely than pain reliever users to generate DAWN mentions, and heroin abusers were 5.5 times more likely than pain reliever abusers to generate DAWN mentions (Table 4).

The growth in nonprescription illicit drug reports suggests that prescription drug abuse is part of a more general trend in drug abuse. Data from the NSDUH indicate both the dimension of illicit drug use and commonalities in the patterns

Table 3 DAWN emergency department mentions for selected nonprescription medications 1997–2002

DAWN	1997	2002	% Change
Marijuana	64,720	119,472	84.6
Cocaine	171,894	207,395	20.7
Heroin	70,712	93,519	32.3
MDMA (Ecstasy)	637	4,026	532.0

Table 4 Prevalence data of past year use and dependence or abuse versus DAWN mentions for pain relievers and heroin in 2002

	Past Year Use	Dependence/ Abuse	DAWN	DAWN Mentions per Hundred Users with Past Year Use	DAWN Mentions per Hundred Users with Dependence/Abuse
Pain relievers	10,992,000	1,509,000	119,185	1.08	7.9
Heroin	404,000	214,000	93,519	23.2	43.7

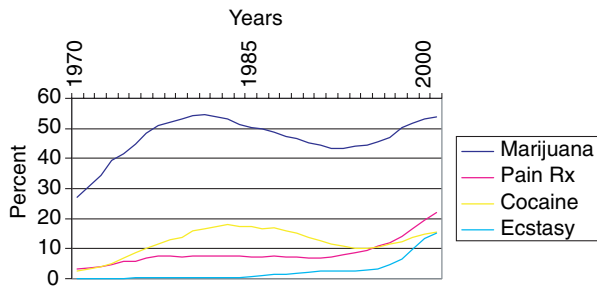


Figure 2 Lifetime use 18- to 25-year-olds—selected drugs 1970–2002.

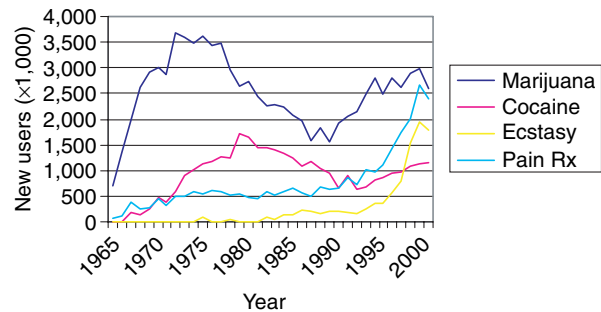


Figure 3 Initiates of selected drugs—all ages.

of use that illicit use of prescription drugs share with other illicit drugs, alcohol, and tobacco. Figure 2⁸ below traces the proportion each year of 18- to 25-year-olds reporting prior use of marijuana, cocaine, Ecstasy, and the nonmedical use of prescription pain relievers from 1970 to 2002.

As illustrated in Figure 2 and Figure 3,⁹ tracking new users of selected drugs, there has been a general increase in illicit drug use since the early 1990s. The parallel paths for marijuana and

cocaine suggest common epidemiological determinants of the fluctuation in use of these established drugs. The rapid rise from relatively low levels of pain reliever and Ecstasy use may indicate a common pattern for new fad drugs.

For all classes of drug, the proportion reporting abuse or dependence is dramatically lower than those reporting use alone. Table 5 presents these data for pain relievers.

Table 6 presents the percentage of individuals who had discontinued pain reliever use after some exposure, as well as those whose use is designated abuse or dependence, calculated from the data in Table 5. Contrary to commonly held beliefs, mere exposure to pain relievers among those using the medicine for nonmedical purposes does not lead

⁸Table H.27 (Marijuana), H.28 (Cocaine), H.30 (Ecstasy), and H.31 (Pain Reliever) at <http://www.oas.samhsa.gov/nhsda/2k2nsduh/Results/appH.htm>.

⁹Table H.35 (Marijuana), H.36 (Cocaine), H.38 (Ecstasy), and H.39 (Pain Reliever) at <http://www.oas.samhsa.gov/nhsda/2k2nsduh/Results/appH.htm>.

Table 5 Illicit use of and abuse/dependence on pain relievers

	Numbers (×1000) and Percent of Each Age Cohort							
	12 or Older	%	12–17	%	18–25	%	26 or Older	%
U.S. population	235,143		24,753		31,024		179,366	
Illicit pain reliever use (lifetime)	29,611	12.6	2,772	11.2	6,856	22.1	19,910	11.1
Illicit pain reliever use (past year)	10,992	4.7	1,881	7.6	3,537	11.4	5,560	3.1
Illicit pain reliever use (past month)	4,377	1.9	792	3.2	1,272	4.1	2,332	1.3
Pain reliever abuse/Dependence-past year	1,509	0.6	237	1.0	419	1.4	853	0.5

The data were extracted and recompiled from the tables summarizing NSDUH data as follows:
 Table H.1 (1.1B) Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2002
 Table H.2 (1.2B) Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Percentages, 2002
 Table H.3 (1.3B) Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12–17: Percentages, 2002
 Table H.4 (1.4B) Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 18–25
 Table H.5 (1.19B) Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 26 or Older: Percentages, 2002
 Table H.43 (5.25B) Substance Dependence or Abuse for Specific Substances in the Past Year, by Age Group: Numbers in Thousands, 2002
 Table H.44 (5.27B) Substance Dependence or Abuse for Specific Substances in the Past Year, by Age Group: Percentages, 2002
 Table G2 Numbers (in Thousands) of Persons Aged 12 or Older, by Gender and Detailed Age Categories: 2002.

Table 6 Percent who discontinue pain relievers and percent of abuse/dependence among users in past year and among those who had ever used

	12 or Older	12–17	18–25	26 or Older
Percent of users who discontinue	62.9%	32.1%	48.4%	72.1%
Percent abuse/dependence among users in past year	13.7%	12.6%	11.8%	15.3%
Percent abuse/dependence among those who had ever used	5.1%	8.5%	6.1%	4.3%

The percent who discontinue pain relievers is calculated by subtracting the number of past year users from those who had ever used and dividing the result by the number who had ever used for each age cohort (users in lifetime – past year users)/(users in lifetime). The percentages of abuse/dependence among past year users and among users in lifetime are calculated directly from the data entered in the designated categories in Table 5.

Table 7 Frequency of pain reliever use among 18–25 years olds—percent using for the specified number of days or fewer in prior year (2002)

Days	1	2	3	5	10	15	30	60	90
Percent	12.9	24.1	32.3	42.4	52.4	60.7	71.3	85.2	86.7

These data were generated by online analysis available at <http://www.oas.samhsa.gov/samhda.htm> (accessed in June 2004).

to abuse or dependence in the majority of those exposed. In each age category, discontinuation of use after some period of exposure is a common outcome, and the proportion of those discontinuing use increases with age, from a low of 32.1% in the 12–17 age group to 72.1% among those 26 and older. Even among those who have used in the past year, the rate of abuse/dependence is 15.3% or less.

Most individuals who engage in illicit use of pain relievers do so infrequently. NSDUH asked respondents to estimate the number of days in the prior year that they had used pain relievers. As noted in Table 7, slightly fewer than one quarter of those reporting use in the prior year used on only 1 or 2 days. The majority (52.4%) had used these medications on 10 days or fewer in the prior year. The predominance of low frequency use further supports the proposition that mere exposure does not inevitably lead to abuse and dependence. It also suggests the informal and opportunistic, rather than deliberately planned, pattern of most youthful drug use (Table 7).

There has been no detailed analysis of the sources of supply to this predominantly young market for prescription pain relievers. Data from an earlier household survey of drug use, presented

in Table 8 [2], reported that the majority of users of illicit nonprescription drugs obtained their drug from friends, frequently, as a gift. From information gathered in the course of investigation the Department of Justice has concluded that “young people rarely obtain prescription drugs using methods commonly associated with pharmaceutical diversion such as pharmacy theft, prescription fraud, or doctor shopping—visiting numerous doctors to obtain multiple prescriptions. Instead, adolescents typically obtain prescription drugs from peers, friends, or family members.”¹⁰

Taken together, data presented in this section suggest that the illicit demand for prescription pain relievers is part of a broader upward trend in the demand for illicit drugs. This increase is a component of larger cultural trends in drug misuse, which wax and wane over time. That the use of prescription medications for nonmedical purposes is merely one component of the more general phenomenon of illicit drug use is confirmed by commonalities in the historical trends and age distribution of illicit prescription and other illicit drug use and by the coincident use of multiple nonprescription illicit drugs by illicit prescription drug users.¹¹ Drug misuse typically includes licit

Table 8 How past-month users obtained their drug [2]

Drug Source	Marijuana	Cocaine	Crack
None avowed	7.2%	7.8%	8.8%
Bought from dealer	18.0%	32.8%	45.4%
Bought from friends but not from dealer	31.9%	22.7%	18.9%
Gifts, did not buy	41.7%	34.6%	24.4%
Other	1.2%	2.1%	2.6%

¹⁰Information Brief: Prescription Drug Abuse and Youth, National Drug Intelligence Center, Document ID: 2002-L0424-004, August 2002.

¹¹“On average, 2 drugs were mentioned in each ED visit involving narcotic analgesics, and more than 1 drug was involved in 72% of the visits . . . Cocaine taken with unspecified narcotic analgesics was the most frequently reported combination in 2001.” *The Dawn Report*, January 2003. Available at http://dawninfo.samhsa.gov/pubs_94_02/shortreports/files/DAWN%20Report%20NA_10.pdf.

Table 9 Adverse actions against DEA registrants [4]

	1999	2000	2001	2002	2003
Registrants	879,011	897,953	923,829	939,763	963,385
Actions	765	783	698	568	441
Percent	0.09	0.09	0.08	0.06	0.05

and illicit drugs, is initiated at a young age, and declines with age. Most users do not satisfy medical criteria for dependence or abuse, but engage in haphazard and incidental use. If the pattern of drug distribution observed among illicit drug users is applicable to illicit prescription drug users, the majority obtain their medications from nonphysician intermediaries (who may or may not obtain medications from physicians).

The Relationship Between Medical Prescription and Diversion

Unlike other illicit substances, prescription medications are subject to federal government-monitored production and distribution from designated manufacturers through licensed wholesalers, to licensed pharmacies or healthcare facilities for final distribution to patients via valid prescriptions from licensed practitioners. This system of federal drug control implicitly recognizes that there is a risk of diversion at every level of the chain of distribution. At each stage in the distribution process, there are opportunities for diversion by theft or fraud.

An assessment of the contribution of nonphysician sources is critical to the success of drug control policy. As reported in the *Wall Street Journal*, the General Accounting Office (GAO) has found that massive quantities of pharmaceuticals enter the U.S. daily. “John F. Kennedy Airport in New York receives a whopping 40,000 drug packages each day, while some 30,000 pharmaceutical shipments land in Miami and Chicago receives at least 4,300 packages containing drug products every day” [3]. The article goes on to report that nearly 30% of the packages contained controlled substances, and that the GAO was able to purchase controlled substances without a prescription and without visiting a doctor.

The limitations of a strategy focused on physician prescribing have been implicit in proposals to suppress internet sales of prescription medications directly to consumers. But even this focus may have little impact on illicit access to prescription medications if diversion from higher levels in the distribution chain contributes substantially to black market supplies, allowing dealers and users simply to obtain supplies from alternative sources.

It is unlikely that prescriptions written by dishonest doctors or those easily duped constitute a significant black market supply. This is so, because the size of the illicit market, approximately 11 million illicit users of prescription painkillers in 2002,¹² is simply too large to be supplied by a small group of doctors. If, for example, there were 1,000 active criminal or highly negligent doctors, on average they would have to issue enough bogus or excessive prescriptions yearly to provide for distribution to 1,100 individuals each. While DEA enforcement policy may fail to detect physicians who issue small numbers of prescriptions destined for illicit use, one would expect that those who issue large prescriptions or large numbers of small prescriptions destined for the illicit market would be highly visible and targeted for investigation. As evident from Table 9 [4], the rate of adverse actions against physician registrants over the interval 1999 through the third quarter of 2003 has been low and declining during a period of significant increase in prescription drug abuse. It is theoretically possible that large numbers of high volume prescribers are ignored by regulatory authorities and criminal prosecutors, but it is far more likely that intentional distribution by doctors represents a very small proportion of those in practice—too few to furnish a significant fraction of the illicit market. There are simply not enough “bad” doctors to account for distribution to 11 million people.

One approach to assessing the contribution of diversion from medical practice to illicit use is to compare the change in the retail distribution of medications to emergency department visits

¹²Table H.1, NSDUH, 2002.

Table 10 DAWN mentions and retail sales of opioid medications (grams of medication) 1997–2002

	DAWN 1997	DAWN 2002	DAWN % change	RETAIL 1997	RETAIL 2002	RETAIL % change
Hydrocodone	11,570	25,197	117.8	8,669,311	18,822,618	117.1
Oxycodone	5,012	22,397	346.9	4,449,562	22,376,891	402.9
Methadone	3,832	11,709	205.6	518,737	2,649,559	410.8
Morphine	1,300	2,775	113.5	5,922,872	10,264,264	73.3

related to drug use through the DAWN. A study applying this approach over the interval 1990 through 1996 concluded that “The trend of increasing medical use of opioid analgesics to treat pain does not appear to contribute to increases in the health consequences of opioid analgesic abuse” [5].

As Table 10 illustrates, over the following 6 years (1997–2002), as retail sales increased, so did DAWN mentions. Changes in Hydrocodone mentions correlate almost exactly with changes in retail distribution, each rising 117%, while the dramatic increases in Oxycodone and Methadone retail distribution were accompanied by significant, although somewhat smaller increases in DAWN mentions. A recently published study covering the interval from 1997 to 2001 reports data consistent with Table 10 [6].

The correlation of change in DAWN mentions and the amount distributed to retail outlets does not prove that prescribed medications are the source of the medications that led to emergency room visits. Medications diverted to the illicit market could have been diverted by theft or fraud from a higher level in the distribution chain, or obtained through foreign purchase.

There are no studies on the pattern of diversion of prescription medications from medical practice in the United States. However, a recent British study of the illicit market for prescription methadone in London may shed light on the pattern of diversion from medical practice.

The size of the market is substantial and appears to involve a large number of individuals, each diverting small amounts of their own prescribed drugs. Major motives for selling prescribed drugs are to raise funds to buy other, preferred, drugs and/or to pay for a private prescription. Buyers in treatment appear to be motivated by a desire to supplement their own prescriptions because they are dissatisfied with the particular drug prescribed, dosage and formulation. Drug users in treatment can exploit the variations in prescribing practice—such as how much “take-home” medication they are allowed and whether tests are conducted to ascertain if they are using it themselves—and divert their prescribed drugs. [7]

The office-based treatment of heroin addiction in the UK has some elements in common with the office-based treatment of pain in the U.S.—patient control over medication and limitations in the ability to detect diversion. If the American pattern follows the market structure outlined above, it is most likely that the largest proportion of prescription-based illicit supply comes from patients who receive prescriptions in the course of routine medical care by well-intentioned doctors,

and that these patients, in turn, sell or share some of their medications.

Patient Selection and the Risk of Diversion

The current policy emphasis on “appropriate” patient selection seems to suggest that patients may be divided into two discrete groups, the first, with pain, honest, and reliable, the second, without pain and dishonest, who divert and/or abuse their medication. Law enforcement and medical lore suggest that some individuals are able to feign medical conditions to obtain medications. If such individuals formed a substantial part of the illicit market, the prescription-monitoring programs to catch “doctor shoppers” and heightened care by physicians in selecting patients might hold some promise in reducing diversion. Sooner or later, such “patients” would be detected.

The clinical reality presents a more complex picture. Having a painful condition is no guarantee of honesty or reliability in the control of prescribed medications. Nor does a history of addiction or criminality prevent the emergence of painful conditions or mandate noncompliance with medical instructions. The fact that there is a substantial subset of patients with painful conditions who may be unreliable raises both practical and ethical dilemmas for a strategy of diversion control predicated on accurate patient selection. Should such patient characteristics as prior drug abuse, prior criminal record, or uncertain financial resources to obtain medications, which might be assumed to be associated with a heightened risk of criminal activity, justify excluding patients from access to treatment of severe pain? The application of these screening criteria probably entails a risk of erroneously excluding a patient who would not divert medications. Should patients with these characteristics be forever denied effective pain treatment? Are there practical measures to minimize the risk of diversion even in a high risk patient population?

The comorbidity of pain and addiction poses a significant challenge for a policy of diversion control based on exclusion of high-diversion-risk patients. Studies of heroin addicts in methadone treatment report that the incidence of chronic pain in this population is substantial. A study of patients in methadone maintenance in Massachusetts revealed that 61.3% suffered chronic pain [8]. A more recent study of patients in methadone

maintenance programs in New York revealed that 37% experienced chronic severe pain [9]. Although there is an unofficial bias against treating addicts with opioid medications, professional organizations support the concurrent treatment of both conditions in a setting of heightened monitoring and control.¹³ There are no reports on the success of these strategies, either with respect to clinical outcomes, such as pain control and functionality, or with respect to the risk of diversion.

There have been studies, however, of heroin addicts treated in an office-based settings in an attempt to minimize the stigma and inconvenience of conventional methadone clinics. One study reviewed the experience of 158 addicts referred for office management from 1983 to 1998 [10]. Of this group, 83.5% were compliant with the program, while 16.5% were not. A more recent study monitoring 73 “highly stable” patients selected for office-based methadone treatment over a 6-month period found a 1% “dirty” urine rate, very low rates of medication misuse, and no evidence of diversion [11]. These patients were subject to two random urine screens monthly and a “medication recall procedure.” Those who failed were referred for “intensified treatment.”

Whether care of pain patients could achieve the high level of patient performance reported in the later study is uncertain. The study implemented a level of monitoring and control not typical of the approach taken in most medical practices, and the patients were carefully screened for reliability prior to acceptance into the study protocol. The treatment of pain typically requires more dosing flexibility than usually afforded patients on methadone maintenance and therefore provides more opportunity for patient dishonesty and diversion.

One strategy that attempts to mitigate the risk that pain patients will misuse or divert their medication is the imposition of treatment contracts authorizing physicians to monitor for abuse and diversion. Such contracts typically contain provisions that patients found to have violated the contract may be subjected to heightened scrutiny, referred for supplemental treatment of addiction,

¹³Public Policy Statement on the Rights and Responsibilities of Healthcare Professionals in the Use of Opioids for the Treatment of Pain, adopted by American Society of Addiction Medicine, April 1997; revised April 2004, Adopted by American Academy of Pain Medicine, March 2004, adopted by American Pain Society, March 2004, available at <http://asam.org/ppol/opioids.htm>.

or discharged from care.¹⁴ However, this assertion of professional power transforms the physician from a benign healer into an intrusive policeman. Such procedures as monitored provision of urine specimens for drug testing are often perceived as demeaning by patients.

The attitudes and procedures suitable for pain management are in tension with those suitable for the management of addiction and the prevention of diversion. Those attitudes and procedures useful to monitor for addiction and diversion infuse the doctor–patient relationship with mutual suspicion and distrust. Those physician qualities that promote the trust and candor required for effective pain treatment make the physician vulnerable to deception and exploitation.

In an age that gives ethical blessing and legal force to respect for patient autonomy, the assertion of professional paternalism to control addiction and diversion in the context of pain medicine is difficult to reconcile with the contemporary ethical commitments of professional practice. It is an issue that needs discussion and dialogue between and within both the medical and regulatory communities.

The Ethics of Medical Policing

Medical practice is grounded in ethical principles designed to afford patients competent, compassionate care that respects their dignity. At its core, the treatment of pain is the expression of medical compassion, a sentiment rooted in its most idealistic conception, in the recognition of a common humanity between doctor and patient—a common humanity that transcends the differences and distinctions that commonly give rise to prejudicial treatment in the course of social interactions.

In the provision of routine medical care, doctors frequently come into contact with patients who deviate from society’s or the particular physician’s conception of virtue. Sexual promiscuity,

¹⁴If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities including: 1) urine/serum medication levels screening when requested; 2) number and frequency of all prescription refills; and 3) reasons for which drug therapy may be discontinued (i.e., violation of agreement). Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, the Federation of State Medical Boards of the United States, Inc. (adopted May 2, 1998).

infidelity, or homosexual orientation, excessive consumption of alcohol or food, and use of tobacco or illicit drugs are among the most commonly disapproved behaviors. Patients' candor regarding their behavior may well be critical to the provision of effective medical care and the protection of third parties. A judgmental or punitive response to patient disclosure of disapproved behavior would inhibit candor and frustrate treatment.

It is a generally accepted ideal that the quality of medical care and attention should not be determined by the social or moral status of the patient, but by the clinical characteristics of his or her illness. The disposition to limit the impact of adverse moral judgment on medical care and to refrain from exploitation of professional status and power in the service of nonclinical objectives serves patient interests by providing a supportive social relation that encourages patient candor and confidence and that is free of physician motive ulterior to the patient's clinical interest. This principle applies, for example, to prisoners and to wounded enemy soldiers. To encourage clinically egalitarian medical care for prisoners, prison doctors are routinely kept in the dark regarding the crimes of which their inmate patients have been convicted. It is considered a violation of internationally recognized medical ethical norms to breach the confidentiality of enemy combatants through the disclosure of medical information to their interrogators [12].

Physicians are not free to exploit their professional power to impose their conceptions of morality. The professional approach to the monitoring of pain treatment is in tension with the more customary nonjudgmental, nonmoralizing mode of medical care. As noted above, physicians are advised to define boundaries of acceptable patient behavior, transgression of which will lead to heightened monitoring and control or discharge from care. Patients are monitored for the use of illicit drugs, the misuse of prescribed drugs, and criminal activity. When such behavior is detected, steps are taken to control it which involve heightened monitoring and other possible sanctions. Such boundaries are often included in pain treatment contracts and are designed to induce patients to comply with the laws governing controlled substances.

Whether such constraints under the threat of possible discharge from pain care are effective is unknown. Although cast in therapeutic terms, the imposition of sanctions to discipline patient

behavior constitutes a dramatic departure from the advisory role respectful of patient autonomy that physicians typically undertake in routine medical care. When the approach used to monitor addicts is applied in the treatment of pain, the doctor-patient relationship is transformed into one of professional control based on the power to inflict pain by terminating pain treatment.

Pain care may need to be premised on the explicit requirement that patients subject themselves to heightened monitoring and possible termination of treatment for deviation from approved behavior to prevent diversion and abuse. However, such policing, enforced by subjecting patients to involuntary withdrawal, is in conflict with the contemporary ethical framework of an advisory physician role in a consensual doctor-patient relationship.

Conclusion and Implications

Definitive data on the structure of the market for illicit drugs are not available. There is sufficient information, however, to suggest that criminal acts by doctors cannot account for a substantial proportion of the medications diverted to the illicit market. The lack of clear differentiation between patients with pain and those prone to addiction or diversion suggests that there is no simple technical solution to the problem of patient selection.

Whether the proposed strategies focusing on physician performance are likely to be effective in reducing prescription drug abuse is unknown. Given the apparent capacity of the illicit market to respond to demand for abusable drugs, it is at least conceivable that any curtailing of supply through medical channels is likely to be offset by increased nonmedical distribution of the restricted medications or an increase in the use of alternative illicit medications. It is likely, however, that heightened scrutiny of physicians and harsh sanctions for inappropriate prescribing will have an adverse effect on patient care, as normally cautious physicians employ measures to minimize their risks, such as accepting fewer patients for pain treatment and imposing tighter restrictions on those who qualify.

There is little to guide physicians or policy makers in establishing rational criteria for patient selection or in the determination of the best trade-off between access to pain treatment and control of diversion and abuse. There are no published epidemiological data on the risk of diversion by patients, or how the risk might vary as a function

of patient characteristics. At a more global level, while the NSDUH and DAWN surveys attempt to provide routine systematic information on the prevalence and burden of illicit drug use, there is no comparable routine systematic evaluation of the prevalence and burden of untreated or inadequately treated pain. Without such data, there is no way to assess whether the application of current or proposed screening and monitoring approaches, or regulatory policy as a whole, impose disproportionate costs on deserving patients in relation to the benefits of diversion control. How can there be a balanced policy without a scale to measure all the relevant outcomes?

Imposition on doctors of the duty to treat pain and to avoid diversion imposes inconsistent requirements that cannot achieve both objectives with the resources and organizational characteristics of conventional medical practice. In this author's opinion, the emphasis on control of diversion from medical practice entails a transformation of the practice of medicine that is incompatible with the traditional ethical commitments to the primacy of the individual patient, the voluntary and consensual basis of the doctor-patient relationship, and the sanctuary for privacy, confidentiality, and acceptance based on common humanity afforded by civilized societies in the structure of medical care.

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