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COMMENTARY

Commentary in Response To Paulozzi *et al.*: prescription drug abuse and safe pain management

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Response to ''Increasing deaths from opioid analgesics in the United States''. Leonard J. Paulozzi, Daniel S. Budnitz and Yongli Xi. Pharmacoepidemiology and Drug Safety 2006;15: (in press). DOI: 10.1002/pds.1276.

The study by Paulozzi, Budnitz, and Xi highlights the alarming problem of prescription drug abuse in America. These data have profound and disturbing ramifications. But if we are to have responsible and effective responses to prescription drug abuse, the problem must be considered in its full context. Solutions must factor in the full complexity of drug abuse, addiction and all of the related social and medical disorders, to avoid penalizing those with legitimate needs. In particular, we must be careful with implications that these data inadvertently suggest that prescription drug abuse is mostly related to prescribers and their patients, implying that limiting medically appropriate use will have any affect on reversing this disturbing trend. Just as in this report, many government statements and policies have simplistically assumed that the growing prescription drug abuse problem must rest largely with prescribers.[1] As detailed in the accompanying commentary by Joranson and Gilson, this may be faulty logic based on inadequate data.

Like prescription drug abuse, under-treated pain is also a public health crisis. A recent ABC News/USA Today/Stanford University poll estimated that approximately one of two Americans suffers from pain at any time and one in four has chronic pain.[2] Although increasing attention has been focused on solutions to the problem of under-treated pain, it may not be obvious that attempts to control drug abuse may negatively impact pain care.[3] Several recent events have sent intimidating messages to caring physicians who prescribe opioids appropriately for chronic pain. While it stands to reason that most physicians would agree that finding and prosecuting physicians who fraudulently prescribe dangerous drugs is important for the protection of society, high profile criminal prosecutions of physicians who prescribe large amounts of opioids for chronic pain coupled with shifts in Drug Enforcement Administration (DEA) policies on controlled substance prescribing, raise concerns among law abiding physicians that they may get into trouble even for appropriate prescribing.[3]

Recognition of prescription drug abuse has evoked many regulatory and legislative responses in an attempt to find solutions. There have recently been several regulatory shifts where healthcare policy is increasingly influenced by law enforcement agencies. By their nature, law enforcement agencies will naturally focus on the abuse side of the opioid prescribing equation, without always considering the detrimental effect on medically appropriate use of the same medications. Only through open and honest debate about the advantages and disadvantages of such regulatory policies can the rights of patients who deserve adequate pain control be balanced against the need to protect the public against the rise in prescription opioid abuse.

An example of a legislative reaction to the prescription drug abuse problem came in 2004 when the US Congress quietly gave the DEA-increased authority for reviewing new drugs within the Food and Drug Administration (FDA).[4] The new authority was

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granted within the congressional appropriations committee. Through an almost secret process known as legislation through appropriation, the DEA received 50 million dollars to fund the effort without benefit of the normal process of making law. The process occurred with no public review or commentary. The new authority was vague and exactly how it could impact patients was not clear. It was clear, however, that a real line had been crossed since approving new drugs had been the sole function of the FDA. Through this legislative shell game, the FDA's oversight for new medications became shared with a law enforcement agency focused on drug abuse (DEA). In light of the effects that this change could have on advancing new analgesics, members of the pain care community raised concerns, attracted media attention, and recruited political support. On 4th November 2005, Congress reversed itself and removed the new authority as well as the 50 million dollars it had granted to the DEA just 1 year earlier.[4]

Another major legislative response to prescription drug abuse came when Congress recently passed the National All Schedules Prescription Electronic Reporting Act (NASPER), an attempt to deal with monitoring abusible drugs. This new law institutes a program intended to offer individual states funding for establishing prescription monitoring programs (PMPs) that could help detect individuals who ''doctor shop'' to obtain controlled substances. It is well known that such programs can offer helpful tools for enhancing safe prescribing, but can also impede appropriate prescribing. NASPER was hailed as a major tool for clinicians but it did not insure that the collected information would be directly available to physicians at the time that they treat their patients despite its availability to law enforcement. NASPER also failed to mandate that the authority to monitor prescribing would come under state agencies responsible for health rather than law enforcement. Such transparent shortcomings lead some to wonder if NASPER is less intended as a clinical tool than as a physician mousetrap.

The President's National Drug Abuse Policy of 2004 described PMPs as one of the major solutions to the prescription drug abuse problem. The report states: *"The effectiveness of PMPs can be seen in a simple statistic: In 2000, the five states with the lowest number of OxyContin prescriptions per capita all had PMPs . . . According to DEA, the five states with the highest number of prescriptions per capita all lacked them."*[1] This may seem straightforward, but it is counterintuitive reasoning when you factor in the other real public health crisis of under treated pain. Why should low rates of Oxycontin prescribing automatically serve as evidence of less abuse or even successful prescription monitoring? Theoretically, in a state that has improved its ability to offer effective and appropriate pain management, decreasing barriers to prescribing opioids for legitimate patients with chronic pain might result in overall increased opioid prescribing. On the other hand, a state with a PMP that serves as a barrier to appropriate opioid prescribing might have low opioid prescribing rates through reduced access for legitimate patients in pain without substantially reducing prescription abuse rates.

The recent experience of the state of California is an example. California had the oldest PMP system in the US, utilizing serialized triplicate prescriptions solely for Schedule II drugs. On several occasions, pain care advocates tried to convince the California legislature to rescind the triplicate program as it was widely believed to be a barrier to adequate pain management. On each occasion, representatives of law enforcement referred to the same statistics that were referenced in the 2004 National Drug Abuse Policy arguing that if California removed its triplicate based PMP, then it would change into a state with high Oxycontin prescribing and abuse. The assumption was that maintaining low levels of Schedule II drug prescribing was protecting citizens from drug abuse. The triplicate PMP was ultimately removed when it became clear that, although the triplicate PMP clearly resulted in low rates of Schedule II prescribing including low Oxycontin prescribing, California had a disproportionately high rate of Schedule III opioid prescribing, particularly hydrocodone (Vicodin). This was alarming, since, as Paulozzi *et al*. note, hydrocodone ranked higher than oxycodone in the specific opioids reported in 2002 Drug Abuse Warning Network (DAWN) emergency room visits. The California experience should have been predicted. It is well established that when physicians are faced with barriers to prescribing a certain type of medication they will often prescribe around that barrier, turning to drugs that are perceived to be less scrutinized, even if they are less efficacious and/or more harmful.[5–9] This pattern is known as the substitution effect.[10]

Implementation of some PMPs have been demonstrated to decrease the prescribing of Schedule II controlled substances and to stimulate reactionary aberrant prescribing patterns.[11–13] After initiation of such a program, Schedule II prescribing decreased by 50% in Idaho, 54% in New York, 57% in Rhode Island, and 64% in Texas.[14] In 1989, states with multiple copy PMPs had 1.8% of all prescriptions written for Schedule II controlled substances, while in states without such programs this percentage was 4.7%.[15] In

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contrast, Schedule III controlled substances in states with multiple copy PMPs were 19.6% of all prescriptions, while in states without such programs they were only 14.4%.[15] After benzodiazepines were added to drugs that require a triplicate prescription in 1989, New York's benzodiazepine prescription rates decreased, but increases were seen in alternative drugs that were often therapeutically less optimal, held a greater chance of toxicity, and carried equal or greater abuse potential.[7,8,16–18] Prescriptions for meprobamate declined by 9% nationally but jumped 125% in New York.[7,9] Likewise, methyprylon prescriptions decreased by 15% nationally but grew by 84% in New York.[13,18] Prescribing of butabarbital was also down 15% nationally but increased by 31% in New York.[7,9] Use of chloral hydrate dropped off by 0.4% nationally but inflated by 136% in New York.[7,9] Although the total number of benzodiazepine overdoses slightly decreased, from 1294 in 1988 to 1265 in 1989 (a 2.2% decrease), there was a 29.7% increase in non-benzodiazepine sedative-hypnotic overdoses.[19] On another front, alcohol consumption had declined in the years immediately preceding the 1989 benzodiazepine triplicate regulation in New York but began to rise again when the new regulation took effect.[20]

The prescription drug abuse problem has also stimulated reactions in other branches of government. For instance, the DEA has recently had to deal with a messy public relations debacle over its handling of a frequently asked question (FAQ) document that the DEA and a group of pain experts created to clarify the confusion over the appropriate use and abuse of prescription pain medication.[21] Many months after heralding the release of the FAQ through a press conference that received international media attention, the DEA suddenly pulled the FAQ from their website and rescinded their support. They later announced interim policy statements and clarifications that have led to confusion and concern among physicians. Regardless of their real motives, these changing policies and unclear directives catch fire with the media and have the unintended effect of intimidating some doctors who fear legal, regulatory, or administrative sanctions.

A particularly disturbing trend has been the rare but highly publicized cases of physicians who are charged with criminal offenses that occurred within their practice of medicine. The concern here is not to protect physicians who cross the line into criminal activities but rather to enforce the necessary separation of substandard medical practice from criminal activities. This line was blurred in the recent case of Dr. William Hurwitz, a Virginia Physician, who was recently found guilty in a federal court of 50 counts including racketeering and drug trafficking and sentenced to 25 years in federal prison.[22] Controversy peaked when a letter was sent to the court from past presidents of the American Pain Society (APS) repudiating the testimony of the prosecutions expert witness, who was also a former APS president.[23] Another intriguing aspect of this case was the role of the DEA, who abruptly withdrew the FAQ described above, directly after the FAQ was admitted into evidence in the Federal trial of Dr. Hurwitz. Although the DEA stated that the FAQ was withdrawn solely due to inaccuracies, the temporal connection to the Hurwitz case has led many to suspect otherwise.

Irrespective of the virtues or deficiencies of Dr. Hurwitz's patient care, this case has raised serious questions about whether Dr. Hurwitz was inappropriately prosecuted in the criminal justice system when his offenses may have been within the scope of professional medical practice and therefore should have been dealt with through civil and administrative processes. The case has recently been heard by the 4th District Federal Court of Appeals and several groups have filed amicus briefs that highlight the flaws in how the court may have mishandled the precedent setting jury instructions that undermined the jury's ability to distinguish the extreme or substandard practice of medicine from drug dealing.

How did physicians get caught in the drug abuse crossfire? Several medical, social, and political trends have converged to create controversy and confusion.[24] In response to increasing prescription drug abuse, law enforcement has worked to limit these medications in the hopes of reducing their diversion. Unfortunately, targeting prescribers and hoping that they will prescribe less abusable drugs is unlikely to curb drug abuse, since street abuse will likely shift back to illicit drugs while those with legitimate need will have reduced access.

This clash of pain and the law will continue to influence the climate of pain care in America. For instance, all prescribing clinicians should be aware that the DEA has admonished prescribers to increase vigilance in prescribing abusable drugs, particularly in patients with known or suspected risk of abuse. However, statements by the DEA and by the Office of National Drug Control Policy imply that they may unrealistically believe physicians currently have the means to accurately assess all patients for abuse risk. Real solutions require much more than strategies based on oversimplified views of the complex problems of drug abuse or pain management. Effective solutions must address the current state of inadequate

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education for clinicians on safe and effective prescribing of controlled substances, and must advance research into improved assessment of pain and effective pain management as well as screening for drug abuse potential.

As such, care is required in interpreting data such as presented in the report by Paulozzi *et al*., particularly when such interpretations are integrated into future strategies for reducing drug abuse. Drug abuse and under treated pain are both public health crises, but the solution to one need not undermine the other. While it is critically important to respond aggressively and appropriately to the prescription drug abuse crisis, substantial harm to millions of patients can occur when we draw conclusions from an inadequate quantum of evidence, impose solutions that are insensitive to their collateral damages, and displace the regulation of medicine from government agencies responsible for health to those focusing on law enforcement. Healthcare decisions, including those involving legitimate use of strong analgesics, must remain in the hands of healthcare professionals. Drug abuse solutions must not undermine patients in pain and all involved should be clear that policies that achieve this balance are in the best interest of society. The least we can do is make sure that the casualties of the war on drugs are not suffering patients who legitimately deserve relief.

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