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# BLACK BEAUTIES, GORILLA PILLS, FOOTBALLS, AND HILLBILLY HEROIN: SOME REFLECTIONS ON PRESCRIPTION DRUG ABUSE AND DIVERSION RESEARCH OVER THE PAST 40 YEARS

JAMES A. INCIARDI, THEODORE J. CICERO

*Although the problem of prescription drug abuse has endured for well over two centuries, research into the abuse and diversion of these drugs has been relatively recent. The first general population survey to document the abuse of prescription medications occurred in 1970, and subsequent studies demonstrated that the abuse and diversion of amphetamines, opioids, and sedatives has continued to be widespread. During the 1980s and much of the 1990s, prescription drug abuse took a back seat to other more pressing concerns: "freebase" and powder cocaine, the cocaine wars, crack and sex-for-crack exchanges, rising rates of drug-related street crime, and HIV/AIDS among injection and non-injection drug users. However, recent surveys suggest that the current outbreak of prescription drug abuse began during the early to mid-1990s. Although the abuse and diversion of prescription drugs was clearly an evolving problem, what seemed to galvanize the attention of the media, the government, and the public at large was OxyContin®. Currently, there is no question that the problems of prescription drug abuse and diversion continue to grow. Why this is so, however, is open to speculation. Perhaps the reason lies in the increasing numbers of prescription drugs that are being legally marketed. Or perhaps the popularity of prescription drugs is rooted in the beliefs that they are more acceptable, less dangerous, and less subject to legal consequences than are illicit drugs.*

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**INTRODUCTION**

If anything has been learned about the drug problem in the United States, it is that patterns of drug-taking and drug-seeking are continually shifting and changing. Fads and fashions in the drugs of abuse seem to come and go. Drugs of choice emerge and then disappear from the American drug scene. Still others are rediscovered, reinvented, revitalized, repackaged, recycled, and become permanent parts of the landscape. As new drugs of abuse become visible, concomitant media and political feeding frenzies call for a strengthening of the “war on drugs.” There was heroin in the 1950s; marijuana, amphetamines (black beauties), and LSD in the 1960s; Quaaludes<sup>®</sup>, barbiturates (gorilla pills), and PCP in the 1970s; and crack and other forms of cocaine in the 1980s and 1990s. And then came Vicodin<sup>®</sup>, OxyContin<sup>®</sup> (hillbilly heroin), and Xanax<sup>®</sup> (footballs), which gained attention during the latter 1990s and the opening years of the twenty-first century. But where did it all begin?

With the prescription drugs, perhaps it goes back to the early part of the 18th century with Thomas Dover, a student of British physician Thomas Sydenham, considered the “father” of clinical medicine, and strong advocate of the use of opium for the treatment of disease. Following in the path of his mentor, Dover developed a form of medicinal opium. Known as Dover’s Powder, it contained one ounce each of opium, ipecac (the dried roots of a tropical creeping plant), and licorice, combined with saltpeter, tartar, and wine. Dover’s Powder was introduced in 1709 and soon made its way to America, where it remained one of the most widely used opium preparations for almost two centuries (Inciardi, 2008; Souhami, 2001; Terry & Pellens 1928 ).

Although opium had been a popular narcotic for thousands of years, the attraction of Dover’s Powder was in the euphoric and anesthetic properties of opium. The introduction of Dover’s Powder apparently started a trend. By the latter part of the eighteenth century, similar patent medicines containing opium were readily available throughout urban and rural America. They were sold in pharmacies, grocery and general stores, at traveling medicine shows, and through the mail (Terry & Pellens, 1928). This patent medicine industry eventually provided the backdrop for the abuse of prescription drugs and other pharmaceuticals (Inciardi, 2008).

**THE EARLY DAYS**

Our introduction to the study of prescription drug abuse and diversion emerged during the late 1960s and early 1970s, with much of it coming from the work of the late Carl D. Chambers, who at the time was Director of Research for the New York State Narcotic Addiction Control Commission. Although few members of the newer generations of drug abuse researchers are likely to know him, or even

be familiar with his contributions, in many ways he was a pioneer—a trailblazer—and innovator in the field of substance abuse research. Years before the first National Household Survey on Drug Abuse was launched, for example, Chambers designed and fielded the first general population survey of drug abuse. It was done in New York, and it paved the way for National Institute on Drug Abuse's (NIDA) National Household and Monitoring the Future studies. Chambers' New York general population survey was the first to empirically document that prescription drug abuse and diversion were problems that needed to be addressed (Chambers, 1971).

Chambers' subsequent work focused on the abuse and diversion of prescription drugs: pentazocine (Talwin®), propoxyphene (Darvon®), amphetamines, barbiturate-sedatives, and methadone. Not surprisingly, he made a few enemies along the way. First there were the pharmaceutical companies whose drugs he was writing about (Chambers, Inciardi, Petersen, Siegal, & White, 1987). Then, at the Third National Conference on Methadone Treatment in New York City in 1970, a number of the methadone maintenance matriarchs and patriarchs devoted an entire two-hour session to Chambers' work, endlessly castigating him for having introduced such terms as "supplementation," "cheating," and "diversion" into the methadone literature. Supplementation referred to increasing the maintenance dose of methadone to get high; cheating referred to abusing cocaine during maintenance therapy; diversion referred to a patient's participation in more than one methadone program and selling the excess on the street (Chambers & Brill, 1973; Chambers, Taylor, & Moffett, 1972).

Chambers also mentored a number of researchers who, to some extent, would follow in his footsteps: Jim Inciardi, Dave Petersen, Dick Stephens, and the late Harvey Siegal. The near-epidemic abuse of methaqualone and the amphetamines in the 1970s led to increased focus on the prescription drug problem, and a significant body of scientific literature began to develop, yet it was Chambers who really got it all going.

During the 1980s and much of the 1990s, however, prescription drug abuse took a back seat to other more pressing concerns. "Freebase" and powder cocaine were major concerns, with the attendant cocaine wars in Florida, Latin America, and the Caribbean instigated by Colombia's Medellín and Cali cartels. In inner-city crack houses across the nation, crack and the sex-for-crack exchanges appeared (Ratner, 1993). Rates of drug-related street crime rose as did the violence associated with drug gang wars over control of emerging crack markets. The occurrence of HIV/AIDS among injection drug and crack users became a concern and was followed by early attempts to understand the phenomenon and develop effective science-based

interventions. During those years, little attention could be focused on prescription drug abuse.

#### RECENT TRENDS AND ACCOMPLISHMENTS

In 1994, with little fanfare and for the most part unknown to researchers in the drug field, Ortho-McNeil Pharmaceutical funded what turned out to be the longest and most expensive drug abuse research study to date (excluding, of course, the annual National Household and Monitoring the Future surveys). The focus was Ultram<sup>®</sup> (tramadol HCl), an opioid-like analgesic, which had just been approved by the Food and Drug Administration (FDA) as a nonscheduled drug under the Controlled Substances Act. The nonscheduled status was contingent on the development and implementation of a comprehensive postmarketing surveillance program by an Independent Steering Committee external to Ortho-McNeil, charged with monitoring abuse and recommending scheduling if necessary. The program was composed of a variety of studies, including: (a) a nationwide network of some 400 key informants in the drug field who participated in a quarterly survey, reporting their observations of any abuse of Ultram<sup>®</sup>; (b) a quarterly survey of diversion investigators recruited from police departments and regulatory agencies in all 50 states; (c) an in-depth study of impaired health professionals in four states; and (d) a follow-up study of almost 90,000 interviews with over 11,000 pain patients who had been prescribed Ultram<sup>®</sup> for noncancer pain. In addition, in locales where the abuse of Ultram<sup>®</sup> was suspected, citywide and statewide physician education programs and other interventions were developed. For more than 10 years, the Independent Steering Committee met monthly to review the data and to make recommendations to Ortho-McNeil and the FDA. Ultimately, the postmarketing surveillance effort documented that although there was indeed abuse and diversion of Ultram<sup>®</sup>, both occurred at a relatively low rate (Adams et al., 2006; Cicero et al., 1999; Inciardi et al., 2006).

Not long after the postmarketing surveillance study of Ultram<sup>®</sup> had been implemented, researchers, clinicians, and government observers began noticing that prescription drugs were being more widely prescribed and abused (Compton & Volkow, 2006; Zacny et al., 2003). A study conducted by the National Center on Addiction and Substance Abuse at Columbia University, for example, found that from 1992 to 2002, opioid prescriptions increased by 222%, codeine prescriptions increased by 12%, fentanyl by 1,106%, hydrocodone by 376%, meperidine by 66%, hydromorphone by 107%, methadone by 1,597%, morphine by 279%, and oxycodone by 380% (The National Center on Addiction and Substance Abuse at Columbia University, 2005). For the period 1995 through 1997, the Drug Enforcement Administration's Automation of Reports and Consolidated Orders

System (ARCOS), which measures the retail distribution of pain medications in grams, found substantial increases in the medicinal use of morphine (up 59%), fentanyl (1,168%), oxycodone (23%), and hydromorphone (19%). Subsequently, the period of 1997 to 2001 demonstrated increases in the retail distribution of oxycodone (up 348%), morphine (49%), and fentanyl (151%) (Joranson, D.E., Ryan, K.M., & Gilson, A.M. et al., 2000; Novak, S., Nemeth, W.C., Lawson, K.A., 2004). One could argue that these increases served as a catalyst for the increasing abuse, dependence, and diversion of prescription opioids.

At the same time, national data suggested that the abuse of many different prescription drugs had been escalating since the early to mid-1990s. The National Survey of Drug Use and Health found that the numbers of new nonmedical users of prescription opioids (primarily products containing codeine, hydrocodone, and oxycodone) increased from 600,000 in 1990 to over 2.4 million in 2004, marking it as the drug category with the largest number of new users in 2004 (Substance Abuse and Mental Health Services Administration, 2005). In addition, reports from the Drug Abuse Warning Network indicated that abuse-related emergency department (ED) visits involving narcotic analgesics increased by 153% from 1995 through 2002, and during the same period, abuse-related ED visits involving benzodiazepines increased by 41% (Substance Abuse and Mental Health Services Administration, & Office of Applied Studies, 2004a, 2004b). Similar increases were reflected in data on drug abuse treatment admissions.

Although the abuse and diversion of prescription drugs was clearly an evolving problem, OxyContin<sup>®</sup> galvanized the attention of the media, the government, and the public at large. When the drug was first introduced in 1996, it was hailed as a breakthrough in pain management. The medication is unique in that its time-release formula allows patients to enjoy continuous, long-term relief from moderate to severe pain, but the honeymoon period for the drug turned out to be quite brief. Abuse of OxyContin<sup>®</sup> first surfaced in rural Maine, soon spreading along the east coast and Ohio Valley, and then into rural Appalachia. Communities in western Virginia, eastern Kentucky, West Virginia, and southern Ohio were especially hard hit, and a number of factors characteristic of these areas seemed to correlate with the apparent high rates of abuse (Inciardi & Goode, 2003). Aspects of the culture in northern Maine and rural Appalachia are markedly different from those in other parts of the country. Many of the communities are quite small and isolated, often situated in the mountains and “hollers” (small crevice-like mountain dens and valleys), a considerable distance from major towns and highways. As a result, many of the usual street drugs are simply not available. Instead, locals make due with resources already on hand, like prescription drugs. Isolation limits options for amenities and entertainment, a major contrast to the distractions of metropolitan

areas. Many substance abuse treatment patients in these rural areas have told their counselors that they started using drugs because of boredom. Many start abusing drugs quite young, as well.

In addition, many adults in these rural areas tend to suffer from chronic illnesses and pain syndromes, born out of hard lives of manual labor in perilous professions: coal mining, logging, fishing, and other blue-collar industries that often result in debilitating injuries. As a result, a disproportionately high segment of the population lives on strong painkillers. Use of pain pills evolves into a kind of coping mechanism, and the practice of self-medication becomes a way of life for many. As such, the use of narcotic analgesics has become normalized and integrated into the local culture (Inciardi & Goode, 2003).

Media outlets in Maine began reporting on OxyContin® abuse in early 2000. The Bangor Daily News ran several features, which included information not only about the properties of the drug, but also about: (a) how to compromise its time-release mechanism, (b) the tactics of diversion that people were using to obtain the drug (including Medicaid fraud), and (c) the concerns of the medical profession about the potential for abusing the drug. In addition, numerous examples of alleged OxyContin®-related crimes were described in detail. A smattering of news articles followed in other parts of the nation, and in May, 2000, the Boston Globe became the first major daily to focus on OxyContin® (Meier, 2003). After that, OxyContin® became a national media event, and the escalating rates of prescription drug abuse and diversion were more fully recognized.

#### **FOIBLES, ODDITIES, ECCENTRICITIES, AND MISCONCEPTIONS: SOME REFLECTIONS ON THE PAST, PRESENT, AND FUTURE**

For the most powerful nation in the world, we are continuously amazed by the many frivolous, flaky, foolish, and downright absurd approaches to drug policy that have been put forward, from not only our political leaders, but from a few of our colleagues and peers as well. There are far too many examples, but perhaps a few will get the point across. A good place to start might be the “Just Say No” media campaign from the 1980’s “war on drugs.” Championed by First Lady Nancy Reagan, the idea was to discourage children from recreational drug use (and violence and drinking and premarital sex) by offering a variety of ways of saying “No!” In theory, it was a laudable goal. The campaign made its way into popular American culture as several television sitcoms of the period, including Punky Brewster and Diff’rent Strokes, produced episodes centered around the campaign. Then in 1987 La Toya Jackson became the spokesperson for “Just Say No.” She even recorded a song entitled “Just Say No.” In the end, however, the campaign became the subject of satire and ridicule (Elliott, 1993). Moreover, it

was ineffective, but did anyone really think that the solution to the youth drug abuse could be reduced to a snappy catch phrase? But it gets worse.

Enter Bob Dole, the Republican Senator from Kansas. History tells us that he was a war hero, an effective politician, and in later years a capable and believable television commercial protagonist for both Viagra® and Dunkin' Donuts. But in the drug policy realm, something was missing. During his campaign for the presidency against incumbent Bill Clinton in 1996, Senator Dole searched around for a nifty catch phrase of his own. Cognizant of the attention garnered by Nancy Reagan's "Just Say No" crusade and the commercial success of Nike's "Just Do It" ad blitz, Dole came up with "Just Don't Do It" as his message to American youth about recreational drug use. Most everyone realized that it was rather unconvincing. Clinton won the election with an Electoral College landslide (379 to 159), and Dole moved on to Viagra®, Dunkin' Donuts, and Saturday Night Live.

At about the same time, researchers at the University of Miami School of Medicine received seed funding from NIDA to develop a concept called MODUS (Model of Drug Use Spread). The purpose of MODUS was to determine from existing data and policies what factors contributed to the drug abuse problem, particularly in Latin American nations. Science-based solutions for reducing drug abuse would be developed from these data. In theory, it was a good idea, but after more than a year's effort, the resulting solutions were amateurish and simplistic. For example, some of the suggested remedies for solving the drug problem included: (a) arrest drug traffickers; (b) keep drugs away from youth; (c) make treatment available to drug abusers; (d) strengthen anti-drug legislation; and (e) offer economic alternatives to poppy and coca cultivation (Health Services Research Center, 1996). In 2006, it would appear that the Maryland Attorney General had modeled his solutions to the prescription drug problem after MODUS when he made similar recommendations: (a) strengthen laws relating to the distribution of prescription drugs; (b) increase coordination among law enforcement agencies; and (c) regulate the online pharmaceutical industry (Kunkle, 2005).

Shifting to more serious considerations, there is no question that the problems of prescription drug abuse and diversion continue to grow. The most recent National Survey on Drug Use and Health documented that U.S. household residents are more likely to report the nonmedical use of prescription opioids than any illicit drug, other than marijuana. The 2006 Monitoring the Future survey reached the same conclusion. Moreover, ED visits involving the abuse or misuse of prescription drugs increased by 21% from 2004 to 2005 (Substance Abuse and Mental Health Services Administration, 2008; Johnston, L. D., O'Malley, P. M., Bachman, J. G., & Schulenberg, J. E., 2007). There were about 600,000 cases in 2005—almost as

many as for heroin and cocaine combined (Substance Abuse and Mental Health Services Administration, & Office of Applied Studies, 2005).

Although the reasons behind this are open to speculation, two things are indeed apparent. First, the number and variety of prescription drugs have increased significantly in recent years, which is a positive trend for patients in legitimate need of care. At the same time, however, it has been repeatedly documented that availability seems to invariably create demand for drugs with a high potential for abuse. Second, prescription drugs are popular among abusers because they are considered to be more acceptable, less dangerous, easier to rationalize, and less subject to legal consequences than are illicit drugs. These phenomena tend to support the contention that fads and fashions in both the preferences in, and patterns of, drug abuse appear to be continually shifting and changing. The current trend would appear to be prescription drugs.

One of the big mysteries about the prescription drug problem appears to be where the drugs are coming from, that is, "diversion." Specifically, diversion involves the unlawful channeling of regulated pharmaceuticals from legal sources to the illicit marketplace, and this can occur along all points in the drug delivery process: from the original manufacturing site, the wholesale distributor, the physician's office, the retail pharmacy, or the patient. Diversion, however, has been the focus of only minimal study, and ideas on the sources of illegal supplies of prescription drugs vary. Federal agencies maintain that diverted drugs enter the illegal market primarily through "doctor shoppers," inappropriate prescribing practices by physicians, and improper dispensing by pharmacists. Given this belief, the major solution suggested has been the creation of prescription monitoring programs, which enable pharmacists and drug control agencies to detect "script docs" who write prescriptions for a fee, as well as "doctor shoppers" who go from physician to physician and from pharmacy to pharmacy to obtain multiple supplies of prescription drugs. Federal authorities have also identified Internet sales as a major source of diversion. Correspondingly, in 2005 the authors surveyed diversion investigators in 300 police and regulatory agencies across the nation as to their perceptions of the primary sources of diversion. Interestingly, almost three-fourths of the survey participants considered drug abusers posing as patients to be the major source of diversion through doctor shopping and prescription theft and forgery (Inciardi et al., 2007). At the same time, only 3% considered the Internet to be a significant source of prescription drugs. By contrast, the 2005 National Survey on Drug Use and Health found that among individuals ages 12 and older who reported abusing prescription opioids in the last year, 72.3% had obtained the drugs from friends or relatives, 18.5% had obtained them from a physician, and less than 1% reported that they were getting the drugs from the Internet (Substance

Abuse and Mental Health Services Administration, & Office of Applied Studies, 2006). One of the questions that these findings suggest is: Where are the friends and relatives getting the drugs? Are they sharing their legitimate supplies, or are they giving away pills that should have been discarded? Are the friends or relatives the doctor shoppers who are visiting multiple physicians, or forging prescriptions? Are they getting the drugs from street dealers, and if so, where are the dealers obtaining their supplies? Moreover, our research suggests that dealers are a major source of prescription drugs (Inciardi, Surratt, Kurtz, & Cicero, 2007). There seems to be a “black box” that warrants some investigation.

One might begin by looking at losses of prescription drugs from pharmacies, distributors, hospitals and clinics, treatment programs, or any other business or organization where controlled substances are stored. When losses occur through robberies, burglaries, shoplifting, or employee theft, the Drug Enforcement Administration (DEA) requires that its Form 106 (Report of Theft or Loss of Controlled Substances) be filed. Although the Form 106 data are not routinely tabulated and published, what has been released suggests the potential magnitude of losses. From 2001 to 2003, some 563,677 “standard dosage units” of methadone (1 methadone dosage unit in DEA terminology = 10 mg) were reported as lost or stolen, and almost all were through illegal means. From January 2000 to June 2003, the DEA reported that almost 1.4 million tablets of OxyContin® were lost or stolen through 2,494 separate incidents (U.S. Drug Enforcement Administration, 2005). Moreover, a request by the University of Wisconsin under the Freedom of Information Act found a total of 12,894 theft and loss incidents reported to DEA from 2000 to 2003 in 22 Eastern states, involving some 28 million dosage units of controlled substances (Joranson & Gilson, 2005). These data suggest that massive quantities of prescription opioids are being stolen prior to being prescribed.

Residential burglary also should be studied. Millions of residential burglaries occur in the United States each year, and evidence suggests that prescription drugs are a major target in a significant portion of these crimes (Inciardi et al., 2007). In scores of focus groups and in-depth interviews conducted with hundreds of drug-involved offenders, active street drug users, and recovering addicts over the past decade, participants agreed that the four items typically sought in residential burglaries are cash, jewelry, guns, and prescription drugs. Studies conducted by the Department of Justice and by independent researchers as well as newspaper reports support this contention (Inciardi et al., 2007).

Are residential burglaries and pharmacy losses the major sources of supply for street dealers? Perhaps, but our research with prescription drug abusers also points to script doctors, illegal sales in small pharmacies, acquaintances who sell their personal prescriptions, sex workers’ clients, disability patients, Medicaid recipients,

and personal prescriptions intended for the treatment for drug dependence or mental illness. All of this suggests that focused research is needed targeting the “black box” of diversion. This also suggests that prescription monitoring programs are likely intercepting only a segment of those individuals diverting prescription drugs.

As a final point, a number of other approaches may help us to better understand and address the problems of prescription drug abuse and diversion:

1. The data on prescription drug losses sent to the DEA on Form 106 are not readily available. Data for Form 106 can be obtained under the Freedom of Information Act, but what is typically received is incomplete. To garner a better idea of the extent and geographical distribution of losses of controlled substances, funding should be allocated to the DEA for better archiving and analysis of Form 106 data.
2. The Federal Bureau of Investigation’s (FBI) Uniform Crime Reporting System has been collecting and publishing nationwide data on crime for generations. However, in the areas of larceny/theft and burglary, no data are collected on what is actually stolen. The FBI’s crime reporting system should be revised to collect more relevant information on burglaries and other thefts.
3. For a number of years, segments of the pharmaceutical industry, at the request of the FDA, have been supporting postmarketing and risk management programs to determine the nature and extent of the abuse and diversion of specific controlled substances (Cicero et al., 2007; Katz et al., 2007). The FDA’s requirement for postmarketing surveillance should be expanded to include all controlled substances with a potential for abuse—both new and old—and both branded and generic varieties. In addition, when a continuing problem of abuse becomes apparent with a given drug in a specific locale, the FDA and industry should share the burden of determining the exact nature of the problem and provide interventions, where appropriate.

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