Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

State Enforcement and Prosecution of Pharmaceutical Law and Regulation

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Introduction

State Attorneys General serve as the chief law enforcement officer for the citizens of their states, with powers and duties arising from state constitutions and statutes and the common law. The Attorneys General also act as *parens patriae* on behalf of the citizens of their states, taking action, as necessary, to safeguard consumers from misleading, deceptive and other unlawful practices.

Changes in the pharmaceutical marketplace, including direct-to-consumer advertising and the Internet marketing and sale of prescription medication have created new challenges for both the industry and state enforcement authorities. The following provides an overview of actions by the states to enforce consumer protection, antitrust, and other laws in the area of pharmaceuticals.

Average Wholesale Price Manipulation

The drug pricing practices of pharmaceutical companies in establishing the Average Wholesale Price or "AWP" for the drugs they produce have recently come under scrutiny by state authorities. The calculation of AWP, sometimes referred to as the list or suggested retail price, is not defined by law. Instead, AWPs are set and periodically reported by manufacturers, and are used as the basis for calculating wholesale acquisition cost and estimated acquisition cost.

At least 10 states[1] have individually filed suit against pharmaceutical companies accusing them of defrauding the states and individual citizens out of millions of dollars by falsely inflating the AWP of their drugs. Because AWP is used by Medicare and many state programs as a basis for pharmaceutical reimbursement rates, the states maintain that the manufacturers' alleged practice of setting artificially high prices results in higher costs to health programs, those who use health programs and those purchasing the drugs. States have used traditional consumer protection and antitrust theories to pursue these claims, in addition to Medicaid Fraud and other causes of action.

Representative examples are set forth below:

a) ***State of California ex rel. Ven-A-Care v. Abbott Lab., Inc.,*** No. BC 287198A (Cal.Super., filed Jan. 7, 2003; originally filed under seal on July 28, 1998) – California Attorney General Bill Lockyer alleged that the defendants inflated reimbursements by reporting false, excessive prices to the price reporting service used by California's Medicaid Program, known as Medi-Cal, the state's healthcare program for poor, old and disabled Californians. The Attorney General maintained that by artificially inflating prices, the defendants presented

[1] CA, CT, KY, MA, MN, MT, NY, NV, OR and TX.

false claims to the state, in violation of California's False Claims Act, and made or used false records or statements in order to secure payment/approval by the state. This action is pending.

b) ***Commonwealth of Mass. v. Mylan Lab.,*** No. 1:03-CV-11865 PBS (Mass., filed Sept. 25, 2003). - Massachusetts Attorney General Tom Reilly filed suit against 13 pharmaceutical companies alleging the companies participated in price fixing and marketing schemes involving prescription medication. The suit, which is pending, was the result of an ongoing investigation by the Massachusetts Attorney General's Medicaid Fraud Unit.

c) ***People of the State of New York v. GlaxoSmithKline,*** No. 905-03 (N.Y., filed Feb. 13, 2003) – On February 13, 2003, the Consumer Protection Division of New York Attorney General Eliot Spitzer's office filed a lawsuit against pharmaceutical companies alleging that the defendants: (i) made fraudulent representations of the average wholesale prices of the drugs, which deceived Medicaid beneficiaries and others into believing that they were paying the legally permitted price for those drugs; (ii) made false statements and misrepresentations concerning the wholesale acquisition costs of their Medicaid-covered drugs; and, (iii) fraudulently engaged in marketing the spread on these drugs, resulting in the overpayment of public funds for the medications. This action is pending.

d) In the past year, at least five states[2] have brought actions against the makers of prescription drug treatments for asthma, bronchitis, emphysema and other diseases, alleging that the companies unlawfully inflated drug prices, sometimes charging eight hundred percent (800%) more than the actual cost of the drugs. These state actions are ongoing, however one action brought by the Texas Attorney General's office against several parties recently resulted in an $18.5 million settlement with one of the defendants.[3]

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[2] *See generally*, ***State of Connecticut v. Dey, Inc.,*** No. CV03-0824416S (Conn., filed March 12, 2003); ***State of Connecticut v. GlaxoSmithKline,*** No. CV03-0824414S (Conn., filed March 12, 2003); ***State of Connecticut v. Pharmacia Corp.,*** No. CV03-0824413S (Conn., filed March 12, 2003); ***State of Connecticut v. Aventis Pharm., Inc.,*** No. CV03-0824415S (Conn., filed March 12, 2003); ***Commonwealth of Kentucky v. Abbott Lab., Inc.***, No. 03-CI-D1134 (Franklin Circuit Court, filed September 15, 2003); ***Commonwealth of Kentucky ex rel. Chandler v. Warrick Pharm. Corp.,*** No. 03-CI-01135 (Franklin Circuit Court, filed Sept. 15, 2003); ***State of Minnesota v. Pharmacia***, No. 02-CV-1779 (Hennepin County District Court, filed June 18, 2002); ***State of Minnesota v. Warrick Pharm. Corp.,*** No. 03-MC-14691 (Hennepin County District Court, filed August 27, 2003);***State of Montana ex rel. Mike McGrath v. Abbott Lab., Inc.***, No. 6:02CV00009 (Mont., filed Feb., 2003); and ***State of Nevada v. Abbott Lab., Inc.***, No. CV-N-02-0080 (Nev., filed Jan. 17, 2002).

[3] ***State of Texas ex rel. Ven-A-Care v. Dey, Inc.,*** No. GV022327 (Tex. Dist. Ct., filed Sept. 14, 2000).

Importation

With American seniors and some municipalities purchasing prescription medications outside the United States, the issue of imported pharmaceuticals has raised a public debate on drug safety and affordability. The FDA maintains that the practice of sending prescriptions outside the country to be filled by drug wholesalers for delivery to American consumers is unlawful. Several Attorneys General have taken action under state law, as have state Pharmacy Boards.

a) **Kansas Attorney General Phill Kline** ordered Rx Depot, a storefront operation which sends prescriptions for individual consumers to Canada, to shut down its operations and cease any further commercial advertising in the media in September of 2003. The Attorney General contended that Rx Depot was unlawfully exhibiting the "Rx" symbol, which he said could only be used by a legally licensed pharmacy that employed a full-time pharmacist. *See* Theresa Agovino, *Rx Depot Ordered to Close Stores*, KANSAS CITY STAR, September 10, 2003.

b) ***United States v. Rx Depot,*** No. 03-CV-616EAM (N.D. Okla., filed Sept. 11, 2003) – In September 2003, the FDA filed a petition, supported by the Office of Oklahoma Attorney General W. A. Drew Edmondson and the Oklahoma State Board of Pharmacy, seeking a nationwide injunction to stop Tulsa-based Rx Depot from operating in the United States. Witnesses for both sides presented testimony in October and the case is ongoing.

c) **Colorado Attorney General Ken Salazar** recommended legislative changes to address these issues. They included making the operation of an unlicensed pharmacy which imports drugs from unregistered foreign pharmacies, a felony. He also suggested making it illegal to operate a website that charges consumers a fee to be connected with such pharmacies. *See* Letter from Colorado Attorney General Ken Salazar, *Canadian Meds USA, Inc.*, to K.C. Owen, *RxPlus Pharmacies, Inc.* (Sept. 15, 2003).

d) **The Arkansas State Board of Pharmacy** sent a letter to Rx Depot on March 21, 2003, advising it to cease operations, which were considered to be violations of state law. The Board alleged that Rx Depot was dispensing prescription drugs within Arkansas without being licensed by the Arkansas State Board of Pharmacy, which violated Arkansas law. The Board also alleged that using the word "drug" on its outdoor signage without an Arkansas pharmacy permit was prohibited. *See* Letter from Charles S. Campbell, Arkansas State Pharmacy Board Executive Director, to Harry Jones, *Rx Depot* (March 21, 2003).

Marketing

Traditional consumer protection theories, such as deceptive, confusing or misleading advertising and marketing representations, have been used by the states to pursue the questionable marketing practices of several pharmaceutical manufacturers and sellers. Other cases have relied on antitrust causes of action. These include:

a) ***In the Matter of Pfizer, Inc.***, No. 6 M.D. 2003 (Pa. Commw. Ct., settled January 6, 2003) – In January 2003, 19 states[4] announced a multi-state settlement to resolve state claims relating to defendant's allegedly aggressive promotional efforts to sell the prescription-only antibiotic drug azithromycin under its trade name, Zithromax. In an Assurance of Voluntary Compliance, the company agreed to pay $4 million to the states in costs, attorney fees, and/or public protection monies (Pennsylvania received $127,273). Defendant also agreed to change its marketing practices and to provide $2 million in funding for public service announcements (PSAs) and other educational materials for circulation during the next three cold seasons between January 2003 and March 2005.

b) ***State of West Virginia ex rel. Attorney General v. Purdue Pharma, L.P.***, No. 01-C-137-S (W.Va., filed June, 2001) – In June 2001, West Virginia Attorney General Darrell V. McGraw, Jr. filed a lawsuit against the manufacturers and promoters of the prescription drug OxyContin, alleging the companies violated West Virginia's Consumer Protection and Antitrust Acts and created a public nuisance by promoting and marketing OxyContin as appropriate for the treatment and management of mild pain. The state maintained that because of the defendants' highly aggressive marketing practices, OxyContin was over-prescribed in inappropriate circumstances, thereby misleading the public and unnecessarily exposing consumers to potential addiction.

The lawsuit sought to stop the defendants' allegedly aggressive and deceptive marketing in the state; damages in an amount sufficient to repay the state for medical costs incurred in unnecessary prescriptions of OxyContin and for the cost of treatment for those who suffer from addiction and side-effects caused by misuse of OxyContin. The lawsuit also sought the establishment of a medical monitoring fund to aid in recording, preventing, and halting OxyContin abuse. This action is pending.

[4] AR, AZ, CA, CT, FL, KS, MA, MD, NM, NV, NY, NC, OH, OR, PA, TN, TX, VT and WI.

c) ***State of Tennessee v. Knoll Pharm. Co.***, No. 97C6017, MDL No. 1182 (Tenn., settled in 1999) – In 1999, the State of Tennessee reached a settlement with the defendant drug manufacturers, which agreed to a payment of $41.8 million to 37 states[5] to resolve concerns over the marketing of the thyroid hormone replacement drug Synthroid. The states alleged that the companies misrepresented the efficacy of the product by: (i) attempting to prevent the publication of a study which showed that Synthroid and some less expensive generic products were bioequivalent; (ii) making deceptive claims that Synthroid was a "reference product" or the standard for levothyroxine sodium products; and, (iii) making deceptive claims that no other competing brand was equivalent to or useful in place of Synthroid. Pennsylvania filed a separate lawsuit alleging that the pharmaceutical company suppressed information about the effectiveness of the thyroid drug, thereby driving up health costs. This action was settled in 2001 through the payment of $7 million to the Commonwealth. ***Commonwealth of Pennsylvania, v. BASF Corp.,*** No. 003127 (C.P. Phila. County, filed May 12, 2000).

d) ***State of Connecticut, et al. v. Mylan Lab., Inc., et al.***, M.D.L. 1290, Misc. No. 990276 (TFH/JMF); consolidated with multi-state and FTC action at Civ. No. 1:98-CV-3115 (U.S. District Ct., Dist. Of Columbia, filed Dec. 1998) – In December 1998, the FTC and 10 states filed suit against the maker of two anti-anxiety drugs and four other defendants in the United States District Court for the District of Columbia.[6] The FTC and the states alleged that the firm monopolized the market for lorazepam and clorazepate (both generic drugs), through anticompetitive supplier agreements; and, specifically, that it prevented other generics from obtaining the active pharmaceutical ingredients to make lorazepam and clorazepate. The firm then raised the prices for lorazepam and clorazepate significantly — over 2000%. For a 500 count bottle, lorazepam prices rose from $7.30 to $191.50 and clorazepate prices rose from $11.36 to $377.00. The parties agreed to settle the case in February 2001. The firm paid $100 million to the states to reimburse state agencies and consumers and $8 million in fees and costs. The settlement also included injunctive relief addressing the illegal conduct.

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[5] AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, MD, MA, MI, MO, NE, NV, NJ, NM, NY, NC, OH, OK, OR, RI, SC, TN, TX, VT, VA, WA, WV and WI.

[6] CT, FL, IL, MN, NY, NC, OH, WV, WI and PA. On February 8, 1999 twenty-one other states and the District of Columbia joined the action in an amended complaint. The twenty-one other states were AL, AR, CA, CO, ID, IA, KY, LA, ME, MI, MO, NM, OK, OR, SC, SD, TN, TX, UT, VT and WA.

e) ***State of Ohio v. Bristol-Myers Squibb Co***., Civ. No. 1:02-CV-01080 (Ohio, filed June 2002) – In June 2002, 29 states[7] along with the District of Columbia, Puerto Rico and the Virgin Islands filed suit against the maker of an anti-cancer drug in the United States District Court for the District of Columbia. The states alleged that the firm monopolized the market for paclitaxel based anti-cancer drugs and unlawfully maintained that monopoly. The alleged unlawful conduct included: (i) fraudulent procurement of patents for the methods of use of Taxol; (ii) knowingly listing fraudulent patents in the FDA's Orange Book; (iii) conspiracy to list invalid patents in the FDA's Orange Book; and, (iv) the acquisition and use of patent claims and exclusive licenses to maintain its monopoly. This case settled in April 2003 for $62.5 million with $37 million going to state agencies, $12.5 million to consumers, $5 million for the publication of consumer notice and costs and $6.7 million in free Taxol to states to use in the treatment of lower income cancer patients. The firm was also enjoined for a 10 year period from engaging in anti-competitive conduct that would result in delaying generic versions of its drugs from entering the marketplace.

f) ***State of Alabama v. Bristol-Myers Squibb Co.***, Civ. No. 01-CV-11401, MDL No. 1413 (Ala., filed Dec. 2001) – In December 2001, twenty-nine states[8] and Puerto Rico filed suit against the maker of Buspar in the United States District Court for the Southern District of New York. The states alleged that the firm intentionally made false statements regarding the scope of Buspar's patent to the FDA which resulted in an improper listing in the FDA's Orange Book. This enabled the firm to foreclose generic competition for Buspar. The price difference between brand name and generic Buspar is over $70.00 per month. In January 2002, the states amended their Complaint to add two additional defendants. The states alleged that in December 1994, the firm entered into an anti-competitive agreement with these companies which resulted in preventing generic buspirone from being introduced in the mid-1990's. This case settled in March 2003 for $100 million with $50 million going to state agencies, $40 million to consumers and $10 million for the publication of consumers notices and costs. The firm was also enjoined for a ten year period from engaging in anti-competitive conduct that would result in delaying generic versions of its drugs from entering the marketplace.

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[7] AL, AK, AZ, AR, CA, CT, DE, FL, ID, IL, KS, KY, LA, MD, MS, MI, NY, NC, OH, OK, OR, PA, RI, SC, TX, UT, VT, WA and WI.

[8] AL, AK, AZ, AR, CO, CT, DE, FL, ID, IL, KY, LA, ME, MD, MA, MI, MS, NM, NY, NC, OH, OR, PA, RI, SC, TX, VT, WV and WI.

g) ***State of New York v. Aventis S.A.***, 99-MDL-1278 (U.S. Dist. Ct., E.D. Mich., filed May 14, 2001) – In May 2001, 27 states,[9] the District of Columbia and Puerto Rico filed suit against the maker of a heart medication in the United States District Court for the Eastern District of Michigan. The states alleged that the firm paid another company $89 million not to produce the generic equivalent drug of Cardizem CD. As a result, consumers paid nearly double the price for Cardizem CD, one of the most effective heart medications on the market. For a month's dose, the brand name drug cost $73.00 and the generic form cost $32.00. In January 2003, the parties settled this case for $80 million in damages.[10] The $80 million payment from the companies will compensate consumers, state agencies and insurance companies that overpaid for Cardizem CD and its generic equivalents from 1998 through January 2003.

Online Sales

With the increasing popularity of the Internet, businesses are providing consumers with access to every product and service imaginable: prescription drugs are no exception. With the availability of these products over the Internet, often from unlicensed doctors and pharmacies, state Attorneys General have taken action to safeguard consumers from misleading and deceptive practices related to the marketing and sale of pharmaceutical products through this medium.

a) ***State of Missouri ex rel. Attorney General v. S&H Drug Mart, Inc.,*** MD, 99CV212429 (Circuit Ct. Jackson County, filed Dec. 1999) – In December 1999, Missouri Attorney General Jeremiah W. Nixon obtained an injunction to prevent S&H Drug Mart (d/b/a www.ThePillBox.com) from illegally selling prescription drugs online to Missourians. The suit was based in part on sales of prescription drugs to Missouri consumers by individuals or entities not licensed in the state. The injunction required the defendants to provide refunds to Missouri consumers who purchased drugs from the site; pay a $15,000 fine to the state; and, prominently display on their website that products and services are not available to residents of Missouri.

b) ***State of Arizona v. T.A.C.E., LLC***, No. CV00-3531 (Ariz. Sup. Ct., consent decree filed Nov. 16, 2000) – In November, 2000, then Arizona Attorney General Janet Napolitano reached a settlement in a consumer fraud lawsuit filed earlier in the year against an Arizona-

[9] AK, AZ, AR, CA, CT, HI, ID, IN, IA, KS, ME, MI, MN, NV, NM, NY, NC, ND, OK, RI, SC, UT, VT, WA, WV, WI and WY.

[10] Pennsylvania joined in this settlement.

based company, T.A.C.E., LLC; a Virginia pharmacy; and, an Ohio physician, which together prescribed and sold medications online through *http://www.Rxleader.com*. The settlement prohibited the advertising, marketing, selling, shipping, or accepting orders for prescription medication without a pharmacy license to Arizona consumers through the Internet.

That same year, the Arizona Attorney General filed another consumer fraud lawsuit against A Fresh Life Inc., citing the company's practice of prescribing medications, including Viagra, to patients without a medical examination. ***State of Arizona v. A Fresh Life Inc.,*** No. C20003252 (Ariz., filed June 21, 2000). *See also*, *Internet Company Charged with Illegally Selling Viagra Prescriptions*, 16 Pharmaceutical Litigation Reporter 6 (2000).

c) ***Commonwealth of Pennsylvania v. 4 Health Drugs, LLC,*** 231 M.D. 2002 (Pa. Commw. Ct., filed May 3, 2000), ***Commonwealth of Pennsylvania v. Cyber Health Services, Inc. et al.,*** 230 M.D. 2002 (Pa. Commw. Ct., filed May 3, 2000), and ***Commonwealth of Pennsylvania v. Kwikmed, Inc. et al.,*** 229 M.D. 2002 (Pa. Commw. Ct., filed May 3, 2000) – On May 3, 2000, Pennsylvania Attorney General Mike Fisher filed three separate lawsuits against Internet companies, doctors and pharmacies for alleged violations of Pennsylvania's Consumer Protection Law, Pharmacy Act and Medical Practices Act. These entities sold prescription drugs to Pennsylvania consumers without obtaining a medical license or pharmacy permit in the Commonwealth of Pennsylvania.

Under Pennsylvania law, doctors and pharmacies must be licensed in the Commonwealth to prescribe or dispense prescription medicines. Nevertheless, Office of Attorney General agents found several unlicensed businesses and individuals selling prescription drugs to Pennsylvania residents without a valid prescription or doctor's visit. In one undercover investigation, the fifteen-year old daughter of a staff member posed as a consumer and obtained a prescription for the weight loss drug Xenical simply by answering a few questions and making arrangements for payment. In the same investigation, agents easily obtained various prescription "lifestyle drugs" such as Propecia and Viagra without the appropriate safeguards.

These lawsuits resulted in Consent Decrees providing for the payment of civil penalties and investigative costs; injunctive relief, including a permanent bar on advertising, selling, delivering, or dispensing prescription drugs to consumers located in Pennsylvania; and, refunds to consumers who made purchases on these websites.

d) ***Commonwealth of Pennsylvania, ex rel. Attorney General v. Toxicology Associates, Inc.,*** 270 M.D. 2002 (Pa. Commw. Ct., filed May 1, 2002) – Following a number of anthrax-related deaths in late 2001, the states, both collectively and individually, began investigating the online sale of Cipro and supposed bioterrorism-related goods such as "anthrax detectors" and other products claiming to treat anthrax infections. Numerous cases were filed, including this action by Pennsylvania Attorney General Mike Fisher against Toxicology Associates, Inc., relating to its practices in selling anthrax test kits over the Internet. The Ohio-based company was subsequently ordered to issue full refunds; pay civil penalties and investigation costs; and, to permanently cease advertising and offering for sale the test kits to Pennsylvania residents.

Unfair Competition by PBMs

Prescription benefit managers ("PBMs") administer the prescription drug benefit for employers, unions, health plans and public agencies under contractual agreements. Under these agreements, PBMs have the authority to select formularies and contract with drug manufacturers and retail pharmacies. State enforcement activity has recently extended to the business practices of various PBMs in managing these benefits for consumers. One state has filed a legal action on this issue and unions and consumer groups have brought their own civil suits.

a) ***State of West Virginia ex rel. Attorney General v. Medco Health Solutions, Inc.,*** Civ. Action No. 02-C-2944 (Circuit Court of Kanawha County, filed Nov. 2002) – West Virginia Attorney General Darrell V. McGraw, Jr. filed a lawsuit against Medco Health Solutions (the former drug benefit administrator for West Virginia state employees) and others alleging that the defendants increased costs for the West Virginia Public Employees Insurance Agency by switching employees/consumers to higher cost drugs without full disclosure and by failing to pass along rebates earned by defendants.

b) ***Am. Fed'n. of State, County and Municipal Employees v. AdvancePCS,*** No. BC 292227 (Super. Ct. Los Angeles, amended complaint filed April 4, 2003) – In March 2003, the American Federation of State, County and Municipal Employees ("AFSCME") and a consumer group called the Prescription Access Litigation Project filed a lawsuit in California against four pharmacy benefit managers alleging that the companies were inflating prescription drug prices. The lawsuit was filed under California's unfair competition law and alleged, among other things, that: (i) the PBMs had "secret dealings" with drug companies to force health plans and consumers to pay

inflated prescription drug prices; (ii) the companies "reaped billions of dollars in illegal profits by steering health insurers and health care consumers into reliance on more costly drugs"; and, (iii) the companies negotiated rebates from drug makers and discounts from retail pharmacies, boosting profits while refusing to pass the savings on to health plans and consumers. The action seeks an end to alleged "illegal pricing practices" and immediate restitution from the pharmacy benefit manager.

Miscellaneous

a) **Counterfeit Drugs** - On October 2, 2003, the FDA issued an interim report outlining ways the government and drug industry can combat prescription drug counterfeiting. This action followed a case in which Florida investigators discovered that labels for Procrit, a clear liquid drug used in the treatment of anemia, were being placed on vials of water and that weaker dosages of the drug were being substituted for more concentrated, expensive ones. Officials from the North Carolina Attorney General Roy Cooper's office recently opened a separate investigation into drug wholesalers in that state. *See* Sabine Vollmer, *Poison Pills: How N.C. Wants to Avoid Counterfeit Drugs Flooding Market*, Triangle Business Journal, Feb. 3, 2003.

b) **Privacy** – On July 25, 2002, eight Attorneys General[11] announced a settlement with Eli Lilly & Co. to resolve allegations that the manufacturer of Prozac and other psychotropic medications failed to protect consumers' privacy in administering a site where a consumer could enroll and receive periodic information called "prozac.com." The states alleged that in June, 2001, Eli Lilly sent an electronic message to site users containing the e-mail addresses of approximately 670 service subscribers.

The exposure of consumers' confidential information was investigated by the states and settled through an agreement requiring Eli Lilly to strengthen its internal standards on privacy protection and training and monitoring; and, to institute automated checks of its software that accesses consumer information databases. Eli Lilly also agreed to pay $160,000 to the states in addition to undergoing annual compliance

[11] CA, CT, ID, IA, MA, NJ, NY and VT. ***See e.g., In the Matter of Eli Lilly and Company***, FTC Docket No. C-4047. The settlement with the states expanded upon the administrative order issued by the Federal Trade Commission on January 18, 2002. The FTC determined that Lilly had failed to provide appropriate training and oversight for its employees regarding consumer privacy and information security, and neglected "appropriate" checks and controls on the process.

reviews over the next five years and, to report the findings of those reviews to the states.

Criminal Enforcement

According to well known authorities, prescription drug abuse accounts for almost 30% of the overall drug problem in the United States, representing a close challenge to cocaine addiction. Pharmaceutical diversion reaps large profits for the traffickers, and devastation for the abusers. This eventually affects their friends, families, and their workplace.

The diversion of pharmaceutical drugs means that prescription drugs were illegally obtained by a variety of methods and a variety of offenders. This may have been accomplished by deception, or an outright theft of the drugs.

Health care professionals face the prescription drug abuser on a daily basis. These drug seekers prey on physicians, pharmacists, dentists, and their staff, in a relentless attempt to obtain pharmaceuticals. Valuable time is taken away from legitimate patients while health care professionals deal with drug seekers in the clinic, office, and hospital emergency rooms across the United States. These drug seekers see a multitude of health care professionals to obtain more and more of the prescription drugs they need to satisfy their addiction, and/or to sell at high profits on the street.

The Pennsylvania Office of Attorney General has a Diversion Investigation Unit called the Bureau of Narcotics Investigation. The Diversion Investigation Unit is responsible for conducting investigations of the diversion of legally manufactured drugs into illegal channels. In Pennsylvania, there are over 300,000 individuals licensed to either prescribe, dispense, or administer controlled substances. In addition, there are almost 3,000 retail pharmacies and 400 hospital pharmacies. Any one of these licensees or licensed establishments could become a point of diversion, along with the thousands of forged prescriptions passed each year.

There are approximately 1.5 billion prescriptions written in the United States each year. It is estimated that several hundred million dosage units are diverted each year. The diversion of legitimate drug products to the illicit market and the abuse of prescription medication, particularly controlled substances, are of great concern to the law enforcement community.

The physician must be aware of the various methods and activities employed to divert controlled substances. There are those activities for which the physician is entirely responsible through criminal intent in the pursuit of profit. The primary source of this criminal activity is Ascript writing≅. This method of diverting licit drug products can be extremely profitable. Theft of controlled substances from a physician=s office and theft of prescription blanks are other methods for diverting controlled substances.

Willful and intentional diversion by a physician is another source of diverted controlled substances.

Mis-prescribing, over-prescribing, and inappropriate prescribing are practices which may lead to drug abuse. Prescribing excessive quantities or issuing prescriptions for longer periods than necessary may create the events necessary to initiate drug abuse or dependence or cause the medication to be diverted to other persons for abuse or for illicit purposes. Moreover, the physician who has not kept current with medication therapy may cause medication to be available to those who may not require it.

It is estimated that between 80% and 90% of all pharmaceutical drug diversion occurs in doctors= offices, at pharmacy counters or in hospitals. Doctor and pharmacy "shoppers" constitute the greatest portion of prescription drug diversion. Many acquire to self-medicate; other for resale. Although health care professionals have little control over medication after the point of sale, the American Medical Association has adopted a "4-D" physician classification to explain why physicians might mis-prescribe or over-prescribe. The four (4) categories are: duped, dated, disabled and dishonest.

a) **Duped or deceived –** Here, the physician is most vulnerable and the greatest amount of diversion occurs. The physician, failing to detect deception, is manipulated into prescribing drugs for a dishonest patient. It is the patient who has failed to meet his or her responsibility in the doctor-patient relationship. The scams used by the diverting patient range from the simple to elaborate. Given the right circumstances, any physician could be deceived for a period of time.

b) **Dated –** The dated doctor fails to keep current with prescribing practices or knowledge about current drug abuse patterns. A physician might mis-prescribe psychoactive drugs because the data on which the prescription is based is obsolete. A number of doctors acknowledge that many medical schools do not adequately teach how to prescribe controlled substances. For many years, the view that drug and alcohol abuse were moral problems has resulted in the omission of these subjects from medical school curriculums. Other physicians claim that too many of their colleagues are unprepared to diagnose and treat addiction.

c) **Dishonest –** According to sources in both the law enforcement and regulatory communities, only 1% or 6,000 of the nation=s doctors fall into the Adishonest≅ category. These physicians, or so-called Ascript docs≅ are those who use their medical licenses to deal drugs. Even though the overall numbers may be small, this group has the potential to prescribe or dispense large quantities of drugs. In Tennessee, for example, one DEA survey showed that of the 10,000 health care professionals eligible to order narcotics, 38 had ordered half of all shipped to that state and three had ordered 22% of the state=s narcotics.

d) **Disabled –** The disabled physician mis-prescribes or over-prescribes because of his or her own impairment - mental illness or misuse of self-prescribed psycho tropic medications. Several studies show that health professionals have a higher prevalence of substance abuse than the general population. This trend is due, in part, to physician=s access to controlled substances. Narcotics rank second as the chemical substances misused by health professionals.

Some states are considering electronic prescription monitoring systems to deal with the problem of pharmaceutical diversion. Electronic monitoring is often referred to as Electronic Data Transfer or Electronic Point-of-Sale System. To date, only a few states have adopted such a system to monitor the dispensing of controlled substances. Pennsylvania does have such an initiative and now electronically monitors all Schedule II controlled substances. Among the advantages of such a system are the following:

- It targets diversion activities at patient, prescriber and dispenser level.
- It is not burdensome to prescriber.
- It includes all population groups in a state.
- Electronic entry speeds report generation.