

# Rx Ipsa Loquitur

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## President's Message

*Kimberly Burns  
ASPL President*

ASPL will be holding its 21<sup>st</sup> Annual Developments in Pharmacy Law Seminar from November 18-21, 2010 at the beautiful La Quinta Resort and Club in La Quinta, California. Following the success of last year's program, the seminar will again be in conjunction with the National Alliance of State Pharmacy Associations (NASPA).

ASPL's Education and Scholarship Committee is currently hard at work scheduling valuable and timely educational programs that offer pharmacy and law continuing education credits. We will once again offer our popular Legislative and Regulatory Update and Case Law Reviews. At last year's meeting, ASPL provided the opportunity to receive ethics CLE, which resulted in many positive comments to the Board. Therefore, the plan again this year is to again offer ethics CLE. Other tentative educational programs include a DEA update, a REMS update, and state board of pharmacy issues.

With the fall meeting in sight – less than 6 months away – it is time to put out that very important invitation for sponsorship. Sponsors are crucial for the success of ASPL and our fall conference – because ASPL is a charitable organization, we rely on contributions from people and companies interested in supporting our educational efforts. Sponsorship of the 20th Annual Seminar allowed ASPL to put on an amazingly successful event. The success experienced was only possible with our sponsors, and we hope to achieve as high a level of quality programming and attendee satisfaction this year as well. To do this, we need the continued support of our past sponsors, and the support of new sponsors. For those that have already

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## Featured Case



### *Does the CSA Apply to Non-Registrants?*

***U.S. v. Birbragher, No. 08-4004 (8th Cir. Apr. 26, 2010)***

*By Joseph Hanes, JD, and Roger Morris, BSP Pharm, JD\**

In April, the 8th Circuit Court of Appeals rejected a criminal defendant's motion to set aside his indictment under the federal Controlled Substances Act ("CSA"), claiming that the CSA was unconstitutionally vague as applied to him. The court also rejected the defendant's appeal of his sentence.

The defendant, Orlando Birbragher, was co-owner and operator of Pharmacom International Corporation ("Pharmacom"), an online distributor of prescription drugs, including Schedule III and IV controlled substances. Customers visiting Pharmacom's website to place orders for prescription drugs were required to complete a short health history questionnaire and provide credit card information. Pharmacom did not verify customer identities or require them to submit any medical records. Doctors who had contracted with Pharmacom would then review the prescription orders, and issue a prescription. These doctors approved the orders without an in-person examination, and typically without viewing any medical records. Pharmacom contracted with pharmacies to fill the physician-approved prescription orders. These pharmacies would download the orders, fill them, and ship them throughout the country, typically without proper permits or registration.

In November, 2007, Birbragher was indicted and charged with two counts of conspiracy. Count I alleged conspiracy to violate the CSA, and Count II alleged conspiracy to launder funds from the drug conspiracy. Each of the four objects of the drug conspiracy count under the CSA alleged that Birbragher dispensed and distributed Schedule III and Schedule IV controlled substances "outside of the usual course of practice." After unsuccessfully challenging the indictment in front of the district court, Birbragher entered into a plea agreement in exchange for his assistance in the prosecution of his codefendants. Pursuant to federal sentencing guidelines, the court reduced his mandatory sentence range by roughly 24% in exchange for his cooperation. The court ultimately sentenced Birbragher to 35 months in prison. Birbragher subsequently appealed this sentence, as well as the district court's denial of his motion to dismiss the indictment.

Birbragher alleges that the CSA is unconstitutionally vague as applied to him. In consideration of this claim, the Court of Appeals began by recognizing that to defeat a vagueness challenge a statute must pass a two part test. First, the statute must provide adequate notice of the prescribed conduct; second, it must not lend itself to arbitrary enforcement. Birbragher claimed he lacked the notice required by the first prong because at the time of his conduct, it was not clear that the CSA applied to nonregistrants like Birbragher,

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# State Prescription Drug Monitoring Programs

William E. Fassett, PhD, RPh, Editor

A state prescription drug monitoring program (PDMP) is a “statewide electronic database which collects designated data on substances dispensed in the state. The PDMP is housed by a specific statewide regulatory, administrative or law enforcement agency. The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession.”<sup>1</sup> The National Alliance for Model State Drug Laws (NAMSDL), reports that 42 U.S. states have enacted legislation to enable a PDMP.<sup>2</sup> States without enabling legislation include AK, DC, GA, MD, MO, MT, and NE. Legislation is pending in DE and NH. 32 states have operational PDMPs; states with legislation but no operating program include AK, FL, KS, MN, NJ, OR, SD, WA (whose program is suspended due to fiscal issues), and WI.<sup>2</sup> The DEA’s website reported in January 2010 that Guam is the only territory with legislation (but not yet an operational program). The DEA also reported that legislation was under consideration in GA, MO, and MT.<sup>1</sup>

Several national organizations have particular interest in PDMPs. In 2003, the DEA and the Bureau of Justice Assistance designated NAMSDL the technical assistance provider for the Harold Rogers Prescription Drug Monitoring Program, which provides grants to states to assist in developing PDMPs, and to providers who deliver technical assistance and training to the states. The program was created by the Department of Justice Appropriations Act of 2002.<sup>3</sup> NAMSDL continues to provide information on PDMPs. The National Association of State Controlled Substance Authorities (NASCSA) joined with the Alliance of States with Prescription Monitoring Programs (the Alliance) to adopt a Prescription Monitoring Program Model Act in 2002.<sup>4</sup> NAMSDL refers individuals seeking programmatic and operating assistance to the Alliance. The Alliance website contains links to national meetings as well as PDMP contacts, as well as current and archived issues of *The Alliance MonitorRx*, its bimonthly newsletter.<sup>5</sup>

A 2006 review characterized PDMPs as either *reactive*, in which the program generates reports only in response to an inquiry by a prescriber, dispenser, or other authorized party, or *proactive*, in which the program identify and investigate cases of possible abuse. Programs may also differ in their scope: some programs

track only Schedule II drugs, while others include drugs in Schedule II-V<sup>6</sup> and/or non-controlled substances. Programs in PA and MA are restricted to C-II monitoring only and programs in WI and RI extend to C-II and C-III substances only. The remaining states can monitor C-II through C-IV drugs. 21 states may also monitor C-V drugs, and 10 states have authority to monitor non-controlled drugs.<sup>7</sup> NAMSDL also categorizes programs along other lines: (1) whether the program must use an advisory group;<sup>8</sup> and (2) whether the program explicitly imposes no burden on practitioners to access information in the database.<sup>9</sup>

There is sparse jurisprudence regarding the operation of PDMPs. In *US v. Phung*<sup>10</sup> the Court relied on Oklahoma law to determine that the Oklahoma Bureau of Narcotics and Dangerous Drug Control did not have authority to release records for 10 patients from the Oklahoma PMP in response to a *subpoena duces tecum* from the criminal defendant. The constitutionality of the Kentucky monitoring program was challenged, and upheld by the Kentucky Court of Appeals, in *Whisman v. Commonwealth of Kentucky*,<sup>11</sup> which held that the “system, with its substantial safeguards against inappropriate disclosure, reasonably advances” a state interest in regulating and tracking the use of drugs (citing its 2002 decision in *Thacker v. Commonwealth of Kentucky*).<sup>12</sup>

Considerable interest was generated in 2009 by *Sanchez v. Wal-Mart*, in which the plaintiffs alleged negligence on the part of 8 pharmacies for failing to use information from Nevada’s PDMP to prevent the continued abuse of narcotics by a patient who caused the injuries to plaintiffs. The Nevada Supreme Court held, in part, that nothing in the enabling legislation “requires pharmacies to take action to protect the general public after receiving a Task Force letter ... it is evident that the Legislature did not intend to create a policy that requires pharmacies to protect third parties from a pharmacy customer’s actions.”<sup>13</sup> As recognized by McGuire and Seiwert, the fact that many – but not all – states explicitly do not require prescribers or pharmacists to access or use the PDMP data does not mean that these or other states specifically immunize practitioners against civil suits for failure to use the information available to them. Further, some states, including Nevada, may require prescribers to assess the program data when determining the necessity of a prescription.<sup>14</sup> McGuire DR, Seiwert A. Rx & the Law: Impact of state prescription drug monitoring program.

Pharmacists and the attorneys who advise them should be alert to the specific requirements and protections in their own jurisdiction and establish appropriate practice policies for dealing with the growing impact of prescription drug monitoring programs.

(Endnotes - Note: all links shown in these references were validated on 2010 June 9.)

<sup>1</sup> USDOJ – DEA, Questions & Answers – State Prescription Drug Monitoring Programs, 2010 January; [http://www.deadiversion.usdoj.gov/faq/rx\\_monitor.htm](http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm).

<sup>2</sup> NAMSDL, Status of State Prescription Drug Monitoring Programs, 2010 June 1; <http://www.namsdl.org/documents/StatusofStatesJune12010.pdf>.

<sup>3</sup> Pub. L. 107-77.

<sup>4</sup> ASPMP/NASCSA, Prescription Monitoring Program Model Act, 2002 October; <http://www.nascsa.org/PDF/PMPmodelact02.pdf>.

<sup>5</sup> Alliance of States with Prescription Monitoring Programs, <http://www.pmpalliance.org>.

<sup>6</sup> Simeone R, Holland L. An evaluation of prescription drug monitoring programs: executive summary. <http://www.namsdl.org/resources/PDMP%20Study%20Executive%20Summary.pdf>.

<sup>7</sup> NAMSDL. Drugs monitored under state PMP programs – Maps (June 2010); <http://www.namsdl.org/presdrug.htm>.

<sup>8</sup> NAMSDL. States that mandate the use of an advisory committee, council, task force or working group. 2010 June 1; <http://www.namsdl.org/documents/StatesThatMandateTheUseofanAdvisoryCommitteeCouncilTaskForceorWorkingGroup-1Rev.pdf>.

<sup>9</sup> NAMSDL. States that explicitly impose no burden on practitioners to access PMP information, 2010 June 1; <http://www.namsdl.org/documents/StatesThatExplicitlyImposeNoBurdenonPractitionersToAccessPMPInformationRev.pdf>.

<sup>10</sup> U.S. v. Phung, No. CR-08-131-M, W.D. Okla., 2008 U.S. Dist. LEXIS 98799, December 8, 2008.

<sup>11</sup> Whisman v. Commonwealth of Kentucky, No. 2003-CA-002051-MR, Ky. App., 2006 Ky. App. LEXIS 131, May 5, 2006, Cert. denied, 2006 Ky. LEXIS 308 (Ky., Nov. 15, 2006).

<sup>12</sup> Thacker v. Commonwealth of Kentucky, 80 S.W.3d 451, Ky. App., 2002.

<sup>13</sup> Sanchez et al. v. Wal-Mart et al., 221 P.3d 1276, Nev. Supr. Ct., December 24, 2009.

<sup>14</sup> Pharmacy Marketing Group, Inc., 2007; [www.pmgrx.com/ImpactofStatePrescriptionDrugMonitoringProgram.asp](http://www.pmgrx.com/ImpactofStatePrescriptionDrugMonitoringProgram.asp).

## Resources to Comply with Federal Rules for Patients with Limited English Proficiency

Any pharmacy that serves Medicaid or Medicare patients must have in place a compliance plan for patients with Limited English Proficiency (LEP). The National Health Law Program, in conjunction with the American Association of Colleges of Pharmacy and the National Alliance of State Pharmacy Associations has prepared two guides to assist pharmacies in complying with requirements to serve LEP patients:

- Language Services Resource Guide – February 2010 – available at <http://www.naspa.us/documents/lep/Pharmacy%20Resource%20Guide%202010.pdf>
- Analysis of State Pharmacy Laws: Impact of Pharmacy Laws on the Provision of Language Services – available at <http://www.naspa.us/documents/lep/PharmacyLawBooklet.pdf>
- The Department of Health and Human Services also has guidance for providers on its LEP website: <http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/index.html>.

## President's Message...

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committed to sponsoring this year's seminar, thank you very much! For others interested in learning more about being an ASPL sponsor, please contact me at (814)866-8461 and request sponsor information.

I would again like to thank everyone for their support of ASPL – and for the hard work and commitment of the Board of Directors, ASPL committees, our Executive Director, and of course, all our members!

## Mark Your Calendars

### 2010 Developments in Pharmacy Law XXI

Join us at the LaQuinta Resort and Club for ASPL's annual seminar - November 18-21, 2010 in LaQuinta, California. ASPL will again be holding the seminar in conjunction with the National Alliance of State Pharmacy Associations.

*Some of the proposed topics include:*

- Fraud and Abuse Traps under the New Health Reform Laws
- Defending Pharmacists in the Face of Federal Criminal Charges
- Policy and Legal Trends with Medical Marijuana
- Sizzling Issues for Boards of Pharmacy
- Privacy Law and the Effect of HITECH Amendments to HIPAA
- What's In Store for Pharmacists under New FDA Risk Evaluation and Mitigation Strategies (REMS)
- DEA Update on Regulations and Enforcement
- Latest News on Legislative and Regulatory Issues
- Annual Case Law Reviews
- Legal Ethics: Applying Lawyers Codes of Conduct to Pharmacy Cases

Earn up to 15 continuing legal and pharmacy education credits!

Look for a more detailed list of sessions and their descriptions in the near future.

## Does the CSA Apply to Non-Registrants?

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nor was it clear that the manner in which Pharmacom distributed controlled substances was prohibited by the CSA. The court, however, disagreed. Section 841 of the CSA broadly prohibits the distribution of controlled substances unless one of the stated exceptions applies. The plain language of the statute does not limit its application only to registrants, and courts have repeatedly held that nonregistrants can be convicted of participating in conspiracies to distribute controlled substances in violation of the CSA. The court likewise disagreed with Birbragher's claim that the CSA was impermissibly vague because it was not clear that it applied to the distribution of controlled substances over the Internet. As the court stated, "Birbragher was not indicted because his business, Pharmacom, utilized the Internet to distribute controlled substances. Rather, he was prosecuted for conspiring with doctors and pharmacists" to violate the CSA.

The court next considered the second prong of the test, which requires that a statute not be so vague that it permits "policemen, prosecutors, and juries to pursue their personal predilections." (quoting *Kolender v. Lawson*, 461 U.S. 352, 358 (1983)). In finding that the CSA is sufficiently clear to pass this prong of the test, the court noted that the term "usual scope of professional practice," which is essential to section 841, has an objective meaning that prevents arbitrary prosecution and conviction. Because the CSA passed both prongs of the vagueness test, the court found that the statute was not unconstitutionally vague as applied to Birbragher's ownership and operation of Pharmacom. Consequently, the court rejected his appeal of the indictment. For reasons not addressed in this summary, the court also rejected Birbragher's appeal of his sentence.

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## Mark Your Calendar:

November 18-21, 2010

### Developments in Pharmacy Law Seminar XXI

*In Conjunction with National Alliance of State Pharmacy Associations  
LaQuinta Resort & Club - LaQuinta, California*



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Watch for information at [www.aspl.org](http://www.aspl.org).*

